SiGMA® Knee Replacement System

THE EVIDENCE: SUMMARIES OF CLINICAL PAPERS AND ABSTRACTS

References Grouped by Level of Evidence
The SIGMA® Total Knee Replacement System is one of the most widely implanted total knee arthroplasty (TKA) designs, with over 380,000 documented SIGMA implantations in registries, and is supported by a large body of clinical performance and safety evidence since its introduction in 1996. A systematic review identified 96 separate scientific articles reporting the results of the SIGMA knee system in primary TKA.¹

This document contains a summary of each of these articles. The summaries are grouped by level of evidence, I, II, III and IV. Articles are then listed in the order they appear in the reference list of the Systematic Review. This is generally in alphabetical order, except for three articles which are cited in the introduction of the review.

This document contains a summary of each article included in the systematic review. Full versions of each article can be found online or via the relevant journal. Each study publication has its own scope and limitations, for further detail, including the full identity of the authors and any conflicts of interest statements, please review the full study paper. The publication summaries refer to statistically significant as p<0.05, unless otherwise set out in an individual summary. Each summary conclusion relates only to the study in question and is not intended to make wider observations.

**Ratings based on Knee Society (KS) Knee and Function Scores**³
- KS Knee (90-100) + KS Function (90-100) = Excellent
- KS Knee (90-100) + KS Function (80-89) = Excellent/Good
- KS Knee (80-89) + KS Function (90-100) = Excellent/Good
- KS Knee (80-89) and KS Function (80-89) = Good
- KS Knee < 80 or KS Function < 80 = Satisfactory

**Ratings based on Oxford Knee Scores (OKS)**⁴
- OKS (42 to 48) excellent
- OKS (34 to 41) good
- OKS (27 to 33) fair
- OKS (< 27) poor

**Ratings based on Hospital for Special Surgery Scores (HSS)**⁵
- (85-100) excellent
- (70-84) good
- (60-69) fair
- (< 60) poor

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¹. Published Registry Data review conducted October 2015, Data on file DePuy Synthes.


## Level I Studies: Randomised Controlled Trials

1. **Munro 2010** Loss of Tibial Bone Density in Patients with Rotating or Fixed Platform Total Knee Arthroplasty
2. **Blyth 2012** Comparison of Cruciate Sacrificing and Cruciate Retaining P.F.C. SIGMA Total Knee Replacement: 683 Knees Minimum Two Year Follow Up
3. **Choi 2010** Comparison Between Standard and High Flexion Posterior Stabilised Rotating Platform Mobile Bearing Total Knee Arthroplasties
4. **Fu Pei-Liang 2008** Comparison of Midvastus and Standard Medial Parapatellar Approaches in Total Knee Arthroplasty
5. **Gioe 2009** Mobile and Fixed Bearing (All-Polyethylene Tibial Component) Total Knee Arthroplasty Designs: A Prospective Randomised Trial
6. **Hamilton 2011** Prospective Randomised Comparison of High Flex and Standard Rotating Platform Total Knee Arthroplasty
7. **Hanusch 2010** Functional Outcome of SIGMA Fixed and Rotating Platform Total Knee Arthroplasty: A Prospective Randomised Controlled Trial
8. **Harrington 2009** Fixed vs. Mobile Bearing Total Knee Arthroplasty: Does It Make a Difference? A Prospective Randomised Study
9. **Hasegwa 2009** Staged Bilateral Mobile Bearing and Fixed bearing Total Knee Arthroplasty in the Same Patients: A Prospective Comparison of a Posterior Stabilised Prosthesis
10. **Higuchi 2009** Relationship between Joint Gap Difference and Range of Motion in Total Knee Arthroplasty: A Prospective Randomised Study between Different Platforms
11. **Hossain 2011** Knee Arthroplasty with a Medially Conforming Ball and Socket Tibiofemoral Articulation Provides Better Function
12. **James 2012** Patello Femoral Tracking in Fixed and Mobile Bearing Knee Designs
13. **Jawed 2012** A Comparative Analysis between Fixed Bearing P.F.C. SIGMA Total Knee Arthroplasty and Rotating Platform P.F.C. SIGMA Total Knee Arthroplasty with Minimum Three Year Follow Up
14. **Juosponis 2009** Functional and Radiological Outcome after Total Knee Replacement Performed with Mini-Midvastus or Conventional Arthrotomy: Controlled Randomised Trial
15. **Kalisaavart 2012** Randomised Clinical Trial of Rotating Platform and Fixed Bearing Total Knee Arthroplasty: No Clinically Detectable Differences at Five Years
16. **Kim 2007** Alignment and Orientation of the Components in Total Knee Replacement with and without Navigation Support
17. **Kim 2009** Early Outcome of Total Knee Arthroplasty with a Medial Pivot Fixed Bearing Prosthesis is Worse than with a P.F.C. SIGMA Mobile Bearing Prosthesis
18. **Kim 2007** Simultaneous Mobile and Fixed Bearing Total Knee Replacement in the same Patients
19. **Kim 2011** Comparison of the Low Contact Stress and P.F.C. Rotating Platform Mobile Bearing Prostheses in Total Knee Arthroplasty
20. **Ladermann 2008** Fixed Bearing vs. Mobile Bearing Total Knee Arthroplasty: A Prospective Randomised, Clinical and Radiological Study with Midterm Results at Seven Years
21. **Maruyama 2004** Functional Comparison of Posterior Cruciate Retaining vs. Posterior Stabilised Total Knee Arthroplasty
22. **Muller 2006** Should We Reconsider All-Polyethylene Tibial Implants in Total Knee Replacement
23. **Pagnano 2004** Rotating Platform Knees did not Improve Patellar Tracking: A Prospective, Randomised Study of 240 Primary Total Knee Arthroplasties
25. **Shemshaki 2012** Fixed vs. Mobile Weight Bearing Prosthesis in Total Knee Arthroplasty
### Level II Studies: Prospective Non-Randomised Controlled Trials

26. **Keenan 2012** Ten Year Survival of Cemented Total Knee Replacement in Patients Aged Less than Fifty Five Years

27. **Baker 2012** The Effect of Surgical Factors on Early Patient Reported Outcome Measures (PROMS) Following Total Knee Replacement


29. **Casino 2009** Knee Stability before and after Total and Unicondylar Knee Replacement: In Vivo Kinematic Evaluation Utilising Navigation

30. **Dalury 2009** Analysis of the Outcome in Male and Female Patients using a Unisex Total Knee Replacement System

31. **Hall 2008** Extensor Mechanism Function in Single Radius vs. Multiradius Femoral Components for Total Knee Arthroplasty

32. **Jung 2010** Comparison of Clinical Outcomes after Total Knee Arthroplasty with P.F.C. SIGMA RPF and LCS

33. **Lundblad 2008** Prediction of Persistent Pain after Total Knee Replacement for Osteoarthritis

34. **Martin-Hernandez 2009** Comparison of High Flex and Conventional Implants for Bilateral Total Knee Arthroplasty

35. **Ploegmakers 2010** Physical Examination and in Vivo Kinematics in Two Posterior Cruciate Ligament Retaining Total Knee Arthroplasty Designs

36. **Sancheti 2011** Comparative Analysis of the Clinical and Functional Outcome of High Flex Indus Knee and Conventional Posteriorly Stabilised Total Knee Prosthesis: Results of a Prospective Study

37. **Sawaguchi 2010** Mobile Bearing Total Knee Arthroplasty Improves Patellar Tracking and Patello-Femoral Contact Stress

38. **Shetty 2010** Simultaneous Bilateral vs. Unilateral Computer Assisted Total Knee Arthroplasty: A Prospective Comparison of Early Post-Operative Pain and Functional Recovery

### Level III Studies: Retrospective Non-Randomised Controlled Trials

39. **Asif 2005** Midterm Results of Cemented P.F.C. SIGMA Total Knee Arthroplasty System

40. **Boese 2011** Range of Motion and Patient Satisfaction with Traditional and High Flexion Rotating Platform Knees

41. **Dennis 2010** Gap Balancing vs. Measured Resection Technique for Total Knee Arthroplasty

42. **Dennis 2011** The John Insall Award: Control-Matched Evaluation of Painful Patellar Crepitus after Total Knee Arthroplasty

43. **Devers 2011** Does Greater Knee Flexion Increase Patient Function and Satisfaction after Total Knee Arthroplasty

44. **Ek 2008** Comparison of Functional and Radiological Outcomes after Computer-Assisted vs. Conventional Total Knee Arthroplasty: A Matched-Control Retrospective Study

45. **Evans 2006** Comparative Flexion after Rotating Platform vs. Fixed Bearing Total Knee Arthroplasty

46. **Fisher 2011** Rotating Platform Spinouts with Cruciate Retaining Mobile Bearing Knees

47. **Frye 2012** Effect of Femoral Component Design on Patello Femoral Crepitance and Patella Clunk Syndrome after Posterior Stabilised Total Knee Arthroplasty

48. **Geiger 2008** Comparison of a New Mobile Bearing Total Knee Prosthesis with a Fixed Bearing Prosthesis: A Matched Pair Analysis

49. **Griffin 2007** The Mark Coventry Award: Sterilisation and Wear Related Failure in First and Second Generation P.F.C. Total Knee Arthroplasty

50. **Gupta 2006** The P.F.C. SIGMA RPF Total Knee Arthroplasty Designed for Improved Performance: A Matched Pair Study

51. **Ishida 2011** Midterm Outcomes of Computer-Assisted Total Knee Arthroplasty
52. Suh 2008 The Total Knee Arthroplasty with P.F.C. SIGMA RPF: Two Year Short-Term Results

53. Kim 2010 Osteolysis in Well Functioning Fixed and Mobile Bearing Total Knee Arthroplasties in Younger Patients

54. Lang 2008 Results of Contralateral Total Knee Arthroplasty in Patients with a History of Stiff Total Knee Arthroplasty

55. Luring 2009 Two Year Follow Up Comparing Computer-Assisted vs. Freehand Total Knee Replacement on Joint Stability, Muscular Function and Patient’s Satisfaction

56. Luring 2006 Two Year Follow Up on Joint Stability and Muscular Function Comparing Rotating vs. %Fixed% Bearing Total Knee Replacement

57. Luring 2012 A Five to Seven Year Follow Up Comparing Computer-Assisted vs. Freehand Total Knee Replacement with Regard to Clinical Parameters

58. Massin 2010 Does Hyperflex Total Knee Design Improve Post-Operative Active Flexion

59. Matsumoto 2006 Clinical Values in Computer-Assisted Total Knee Arthroplasty

60. Minoda 2010 A Cemented Mobile Bearing Total Knee Replacement Prevents Periprosthetic Loss of Bone Mineral Density Around the Femoral Component


62. Nam 2012 A Comparison of the Clinical and Radiographic Results of P.F.C. Rotating Platform High Flexion and Low Contact Stress Mobile Bearing Prosthesis in Total Knee Arthroplasty: Short-Term Results

63. Ranawat 2004 Comparison of the P.F.C. SIGMA Fixed Bearing and Rotating Platform Total Knee Arthroplasty in the same Patient

64. Ranawat 2006 Patellar Crepitation in the P.F.C. SIGMA Total Knee System

65. Reay 2009 Premature Failure of KINEMAX PLUS Total Knee Replacements

66. Sharma 2008 Does Patellar Eversion in Total Knee Arthroplasty cause Patella Baja

67. Spencer 2010 Secondary Resurfacing of the Patella in Total Knee Arthroplasty

68. Wasielewski 2008 Lack of Axial Rotation in Mobile Bearing Knee Designs

69. Yang 2008 Lateral Retinacular Release Rates in Mobile vs. Fixed Bearing Total Knee Arthroplasty

Level IV Studies: Case Series

70. Clayton 2006 Five Year Results of the SIGMA Total Knee Arthroplasty

71. Arif 2005 Early Results of Rotating Platform Total Knee Replacement

72. Bauman 2012 Can a High Flexion Total Knee Arthroplasty Relieve Pain and Restore Function without Premature Failure

73. Bhatt 2012 Primary Total Knee Arthroplasty using the P.F.C. SIGMA Rotating Platform Cruciate Retaining Endoprosthesis: A Six Year Follow Up

74. Casino 2009 Intra-Operative Evaluation of Total Knee Replacement: Kinematic Assessment with a Navigation System

75. Cook 2008 A Comprehensive Joint Replacement Program for Total Knee Arthroplasty: A Descriptive Study

76. Cossetto 2011 Uncemented Tibial Fixation in Total Knee Arthroplasty

77. Dalury 2008 Midterm Results with the P.F.C. SIGMA Total Knee Arthroplasty System


79. Dalury 2012 All-polyethylene Tibial Components in Obese Patients are Associated with Low Failure at Midterm Follow Up

80. Futai 2011 In Vivo Kinematics of Mobile Bearing Total Knee Arthroplasty during Deep Knee Bending Under Weight Bearing Conditions

81. Futai 2008 In Vivo Kinematics of Mobile Bearing Total Knee Arthroplasty including Polyethylene Insert
82. Goldstein 2006 Optimising Range of Motion in Cruciate Retaining Mobile Bearing Total Knee Arthroplasty: Experience with 2000 Cases
83. Hepinstall 2010 High Flexion Total Knee Replacement: Functional Outcome at One Year
84. Hunter 2009 P.F.C. SIGMA Total Knee Arthroplasty: Seven to Nine Years Results
86. Maniar 2011 Five to Eight Year Results of a Prospective Study in 118 Arthroplasties using Posterior Stabilised Rotating Platform Knee Implants
87. Maniar 2012 High Flex Rotating Platform Knee Implants Two to Six Year Results of a Prospective Study
88. Meftah 2012 Safety and Efficacy of a Rotating Platform, High Flexion Knee Design: Three to Five Year Follow Up
89. Meftah 2012 The Effect of Patellar Replacement Technique on Patello Femoral Complications and Anterior Knee Pain
90. Meftah 2012 Ten Year Follow Up of a Rotating Platform, Posterior Stabilised Total Knee Arthroplasty
92. Pomeroy 2000 Results of All-Polyethylene Tibial Components as a Cost Saving Technique
93. Ranawat 2005 Experience with an All-Polyethylene Total Knee Arthroplasty in Younger, Active Patients with Follow Up From Two to Eleven Years
94. Signorelli 2011 Uncemented Total Knee Arthroplasty: Two Year Follow Up of 100 Knees with a Rotating Platform, Cruciate Retaining Design
95. von Schewelov 2009 A Clinical and Radiostereometric Study of the Cemented P.F.C. SIGMA Prosthesis
96. Zaki 2007 Medium Term Results with the P.F.C. SIGMA Knee Prosthesis: The Wrightington Experience
LEVEL I STUDIES: RANDOMISED CONTROLLED TRIALS
1. LOSS OF TIBIAL BONE DENSITY IN PATIENTS WITH ROTATING OR FIXED PLATFORM TOTAL KNEE ARTHROPLASTY

Munro J, Pandit S, Walker C, Clatworthy M, Pitto R.
Clinical Orthopaedics and Related Research 2010;468:775–81

Objective
To compare tibial bone density changes in cemented components with different bearing designs.

Treatment
SIGMA Rotating Platform (RP) cemented knee

Comparator
SIGMA Fixed Bearing (FB) cemented knee

Outcomes
Bone Mineral Density (BMD), Range of Motion (ROM), Oxford Knee Score (OKS), Knee Society Score (KSS), WOMAC, SF-12, Complications

Study Design
Randomised Controlled Trial

A group of 54 cemented knees in 46 patients were randomised to two designs:
- 28 received a SIGMA RP knee
- 26 received a SIGMA FB knee

Patients were eligible if they met the inclusion criteria of 45 to 85 years old, without severe deformity. The surgery was performed at one of two institutions by MC or RP. All implants were cemented, and the patellas were resurfaced as the surgeon saw necessary. Patients were followed for two years.

Results
Patient demographics and pre-operative status were similar in both groups. Mean patient age was 67.2 and 67.7 in the RP and FB groups respectively.

In both groups, at 1 and 2 years, there was significant BMD loss when compared with the baseline BMD (p<0.001). However, comparing between year 1 and year 2 showed no difference in BMD (p = 0.117). BMD loss at 1 year ranged from 5.2 to 9.5% and at 2 years ranged from 5.7% to 10.5%.

At two years, cancellous bone loss was estimated at 12.6% and cortical bone loss at 3.6%, indicating that the loss of BMD in cancellous bone was significantly larger (p<0.001).

At 1 and 2 years, between the two implant types, there was no difference in clinical or radiographic outcomes, and also no difference between the BMD change (p=0.854).

There was no statistical difference between the rotating and fixed bearing for post-operative ROM (114° vs. 117°, p=0.1), OKS (18 vs. 17, p=0.23), KS score (88 vs. 89, p=0.1), KS functional score (81 vs. 79, p=0.48) and WOMAC score (96 vs. 97, p=0.4). There was also no difference in mental or physical SF-12 scores (p=0.3 and 0.41 respectively).

There were no major complications, no revisions and no loose implants according to the criteria of the KSS in either group. There was no significant loss of BMD in the non-operated knees for cancellous or cortical bone (p=0.385 and p=0.765 respectively).

Study Conclusion
These findings show tibial cancellous BMD loss is more pronounced than cortical BMD loss, a phenomenon that may not be apparent on conventional radiographic imaging.

There was no difference in tibial BMD change, or clinical outcomes between the RP and FB total knee arthroplasty platforms.
Objective
This large study compares clinical outcomes in groups having Posterior Stabilised (PS) and Cruciate Retaining (CR) Total Knee Replacement (TKR) and reports the results at 1 and 2 years post-operatively.

Treatment
SIGMA Fixed Bearing (FB) and Rotating Platform (RP), Cruciate Retaining (CR) knee

Comparator
SIGMA Fixed Bearing (FB) and Rotating Platform (RP) Posterior Stabilised (PS) knee

Outcomes
Knee Society Score (KSS), Oxford Knee Score (OKS), Patellar Score, Range of Motion (ROM)

Study Design
Randomised Controlled Trial

A group of 683 primary TKR patients were enrolled into this prospective multi-centre study.

In the first arm, patients receiving a PS component were randomised to receive either a mobile bearing (176 patients) or a fixed bearing (176 patients).

In the second arm, patients receiving a CR component were randomised to either receive a mobile bearing (161 patients) or a fixed bearing (170 patients).

Neither the use of cement or treatment of the patella were stated. All patients were assessed pre-operatively and at one and two years post-operatively. The results compared the PS fixed and mobile bearing knee group with the CR fixed and mobile bearing knee group and patients did not appear to be randomly allocated to PS or CR knees.

Results
There was a greater improvement in the pain component of the Knee Society Score (KSS) in patients with a PS knee at 1 (p=0.0003) and 2 years (p=0.0085).

There was also a greater improvement in KS Knee Score in patients with a PS knee at 1 (p=0.0001) and 2 years (p=0.001).

The improvement in ROM was greater in the PS group, at 1 (p=0.0001) and 2 years (p=0.0170).

PS knees also achieved better outcomes in these variables in both mobile and fixed subgroups, but no comparisons between fixed and mobile bearings were made.

There were no significant differences in the scores between the two groups with any other measures at any time point.

Study Conclusion
There was a greater improvement in the pain and knee components of the KSS score and ROM at both 1 and 2 years follow up in patients with PS knees. Although this difference was statistically significant, the absolute differences were small.
3. COMPARISON BETWEEN STANDARD AND HIGH FLEXION POSTERIOR STABILISED ROTATING PLATFORM MOBILE BEARING TOTAL KNEE ARTHROPLASTIES: A RANDOMIZED CONTROLLED STUDY

Choi W, Lee S, Seong S, Jung J, Lee M.  

**Objective**  
To prospectively compare the SIGMA Rotating Platform (RP) knee and SIGMA Rotating Platform Flex (RPF) knee in terms of clinical and radiographic outcomes after a minimum duration of two years follow up.

**Treatment**  
SIGMA Rotating Platform (RP), Posterior Stabilised (PS) cemented knee

**Comparator**  
SIGMA Rotating Platform Flex (RPF), Posterior Stabilised (PS) cemented knee

**Outcomes**  
Knee Society Score (KSS), Range of Motion (ROM), Hospital for Special Surgery (HSS), WOMAC, Patient Activities, Satisfaction, Radiographic Analysis, Knee Alignment.

**Study Design**  
Randomised Controlled Trial

A group of 170 knees (128 patients) were enrolled into the study. Only patients with a diagnosis, Osteoarthritis (OA) were included. Patients were randomly allocated into groups of 85 SIGMA RP knees and 85 SIGMA RPF knees by block randomisation allocation. All prostheses were posterior stabilised and cemented, with the patellas resurfaced in most cases. Mean follow up was 28 months. Intention to treat and per protocol analysis was performed.

**Results**  
There were no differences in the pre-operative patient demographics or clinical status.

There was no significant difference in the post-operative mean flexion contracture (p = 0.705) or active maximal flexion angle (p = 0.281) between the RP group (2° and 130°) and the RPF group (2° and 128°) on average.

Mean post-operative KS knee score (RP: 95, RPF: 94) and KS function score (RP: 92, RPF: 91) were both similar (p= 0.358 and p=0.597 respectively). There was also no significant difference in mean post-operative HSS scores (93 vs. 92) or WOMAC scores for pain (2 vs. 2) stiffness (1 vs. 1) and function (9 vs. 9) for the RP and RPF groups respectively.

In the RP and RPF groups respectively, there were no significant differences between the groups in the percentage of patients able to kneel (74% vs. 70%), squat (65% vs. 67%), sit cross legged (78% vs. 72%), rise after sitting on floor (82% vs. 87%).

All outcome scores were comparable between the groups. There was also no difference between number of patients satisfied with outcomes (RP: 89% RPF: 90%, p= 0.871).

Tibio-Femoral angles (5° valgus vs. 5° valgus), tibial slope (5° vs. 5°) and change in femoral condylar (1mm vs. 1mm) were all very similar for the RP and RPF groups respectively (p= 0.774, p=0.855 and p=0.79).

No obvious radiolucent line around prostheses or any sign of osteolysis was observed.

**Study Conclusion**  
The ability to perform activities that required weight-bearing knee flexion, such as kneeling, squatting, and rising after sitting on the floor, were similar in patients receiving SIGMA RP and RPF knees.
4. COMPARISON OF MIDVASTUS AND STANDARD MEDIAL PARAPATELLAR APPROACHES IN TOTAL KNEE ARTHROPLASTY

Fu PL, Li XH, Wu YL, Xie QY, Sun JY, Wu HS.

Objective
To evaluate the early functional outcome and the related parameters of the midvastus approach compared with the standard medial parapatellar approach in total knee arthroplasty (TKA) by a prospective, randomised, double-blind trial.

Treatment
SIGMA knee implanted by the Midvastus Surgical Approach, fixed with cement

Comparator
SIGMA knee implanted by the Medial Parapatellar Surgical Approach, fixed with cement

Outcomes
Surgical Parameters, Range of Motion (ROM), Visual Analogue Scale (VAS) Pain, Patient Recovery Time, Complications.

Study Design
Randomised Controlled Trial

A group of 34 patients from March 2004 to March 2006 having simultaneous bilateral TKA with SIGMA knees were randomly allocated to have a different surgical approach in each knee, the midvastus and medial para-patellar approach. There were 24 cases with osteoarthritis, and 10 cases with rheumatoid arthritis. No patellas were resurfaced and all knees were cemented. Bearing type or cruciate ligament treatment was not reported. Patients were followed up to 3 months post-operatively.

Results
The midvastus approach had significantly less blood loss (286ml vs. 368ml, p<0.05), and also required lateral release less often (4 vs. 7), however the latter was not statistically significantly different.

In the midvastus group, VAS scores of pain at rest, and in motion, were significantly less (better) at days 1, 3 and 7 post-operatively, compared to the medial parapatellar group (p<0.05). However, there was no difference between the groups at 15 days.

The number of days to straight leg raise was also significantly lower in the midvastus group (1.8 vs. 4.5, p<0.01), and so were the number of days to 90° active flexion (3.2 vs. 7.1, p<0.01).

Mean ROM was significantly higher in the midvastus group at 7, 30 and 45 days follow up (all p<0.05), but there was no difference at 90 days follow up (also no difference pre-operatively).

There was only one complication and it occurred in the medial parapatellar group. No poor healing, infection or DVT occurred in any patients.

Study Conclusion
In the early rehabilitation period following TKA, the midvastus approach is better than the standard medial parapatellar approach in relieving pain and improving ROM and is associated with a shorter time to straight leg raise and 90° flexion.
5. MOBILE AND FIXED BEARING (ALL-POLYETHYLENE TIBIAL COMPONENT) TOTAL KNEE ARTHROPLASTY DESIGNS: A PROSPECTIVE RANDOMISED TRIAL

Gioe T, Glynn J, Sembrano J, Suthers K, Santos E, Singh J.

Objective
To assess whether a rotating platform design offers advantages over an all-polyethylene design for a variety of radiographic and clinical outcomes.

Treatment
SIGMA Rotating Platform (RP), Posterior Stabilised (PS) cemented knee

Comparator
SIGMA Fixed Bearing (FB), PS (with an all-polyethylene tibial component) cemented knee

Outcomes
Knee Society Score (KSS), WOMAC, Short Form 36 (SF-36) Score, Range of Motion (ROM), Knee Alignment, Complications.

Study Design
Randomised Controlled Trial

A group of 136 patients were randomly allocated to receive an all-polyethylene tibial component, and 176 to receive a rotating platform tibial component. All implants were posterior stabilised (cruciate sacrificing), all patients received a polyethylene patella and all components were cemented.

The pre-operative diagnosis was osteoarthritis in 97.1% (303 knees), inflammatory arthritis in 1.3% (four knees), and posttraumatic arthritis in 1.6% (five knees). Mean follow up was 42 months (minimum 24 months).

Results
There were no differences in the pre-operative patient demographics or clinical status. Mean patient age was 72.62 and 71.79 in the FB and RP group respectively.

There were no differences between the all-polyethylene and the RP groups for KS knee score (90.4 vs. 88.2, p=0.168), KS function score (55 vs. 63.1, p=0.088) or KS pain score (44.9 vs. 43.1, p=0.108).

None of the three WOMAC sub-scores (pain, physical function and stiffness) showed any significant differences between the groups.

SF-36 also showed no significant differences between the groups for physical function (p=0.908), role physical (p=0.773), bodily pain (p=0.536) and general health (p=0.851).

Mean flexion was 111.9° and 110.4° (p=0.21) and mean extension was 1.0° and 1.3° (p=0.257) for the all-polyethylene and RP groups respectively.

Radiographic findings were similar between the two groups for axial, femoral and tibial alignment (p>0.05 for all).

There were 10 revisions: 7 infections, 1 patellar fracture, 1 due to instability, and 1 due to aseptic loosening. 7 revisions were in the RP group and 3 were in the all-polyethylene group (no p value).

Study Conclusion
The two designs functioned equally well at the time of early follow up in this low-moderate demand patient group. The rotating platform design had no significant clinical advantage over the design with the all-polyethylene tibial component.
Objective
To assess any improvement on flexion or clinical outcomes with the rotating platform high flex design compared with the standard Rotating Platform (RP) total knee.

Treatment
SIGMA Rotating Platform Flex (RPF) Posterior Stabilised (PS) cemented knee

Comparator
SIGMA Rotating Platform (RP) Posterior Stabilised (PS) cemented knee

Outcomes
Oxford Knee Score (OKS), Knee Society Score (KSS), Radiographic Analysis, Range of Motion (ROM), Flexion, Complications

Study Design
Randomised Controlled Trial

Between August 2007 – April 2009, 142 patients between the ages of 40-70 with osteoarthritis of the knee and BMI <40 kg/m2 were enrolled into the study. On the day of surgery patients were randomly allocated to receive either the SIGMA RP or the RPF knee with 71 patients in each group. The patella was resurfaced in all patients and all knees were cemented. The mean follow up time was 1 year (range 0.8-1.8) and occurred at 4 weeks, 4-6 months and 1 year.

Results
There were no differences in patient demographics, or pre-operative clinical status, except that there were more females in the RP group than in the RPF group. There was also no difference in clinical or radiographic flexion between the two groups before surgery or post-operatively.

At 1 year, there was no difference in mean clinical flexion. This was 124.0° for the RP group and 124.2° for the RPF group (p=0.949). X-ray flexion gave lower results, with 117.9° for the RP group and 117.6° for the RPF group (p=0.985).

Between groups, there was no difference in satisfaction scores, which were 88.7% for the RP group and 81.8% for the RPF group. Also there were no differences between the groups in the mean post-operative OKS and KS knee and function scores. These were all better at 1 year than pre-operatively.

The mean difference in pre and post-operative flexion decreased with increasing pre-operative flexion. Patients with pre-operative flexion >120° had a negative mean flexion difference, meaning that they had lower ROM post-operatively. The mean radiographic flexion difference for the group with higher pre-operative flexion was – 9.5° for the RP group, and – 5.1° for the RPF group (p=0.144)

Complications included; the withdrawal of 2 patients from the study due to infection and subsequent polyethylene liner exchange; 4 patients who suffered stiffness; 1 patella fracture; 1 extensor mechanism reconstruction; 13 patients diagnosed with patellar crepitus; 3 symptomatic patellar crepitus patients requiring arthroscopic nodule debridement; 2 patients from the RP group who complained of pain. Of the 13 patients with patellar crepitus, 11 were in the RPF group.

Study Conclusion
There was no clear benefit to the RPF design compared with the RP design and instead a higher incidence of patellar crepitus was found in the high flexion group. The potential beneficial or harmful outcomes will need to be monitored under long-term surveillance. Otherwise patients with both the SIGMA RP and RPF knees obtained excellent post-operative outcomes and flexion.
7. FUNCTIONAL OUTCOME OF SIGMA FIXED AND ROTATING PLATFORM TOTAL KNEE ARTHROPLASTY: A PROSPECTIVE RANDOMISED CONTROLLED TRIAL

Hanusch B, Lou T, Warriner G, Hui A, Gregg P.
International Orthopaedics (SICOT) 2010;34:349–54

Objective
To determine whether there is a difference in functional outcomes between the Fixed Bearing (FB) and Rotating Platform (RP) versions of the SIGMA total knee replacement system.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee

Comparator
SIGMA Rotating Platform (RP) Cruciate Retaining (CR) cemented knee

Outcomes
Knee Society Score (KSS), Oxford Knee Score (OKS), Range of Motion (ROM), Complications.

Study Design
Randomised Controlled Trial

All patients with osteoarthritis implanted by two senior authors (BH and TNL) over 4 years were eligible for inclusion. In total, 55 patients were randomly allocated to receive a SIGMA FB knee and 50 to receive a SIGMA RP knee. All knees were cruciate retaining, no patellas were resurfaced, and all components were cemented. Patients were followed for a mean of 13.4 months.

Results
Pre-operative demographics and clinical status were similar except that there were more males in the RP group and the extension was higher in the FB group.

There were no statistical differences between the two groups for any of the KSS, OKS or Range of Motion values reported.

Mean KS knee scores were 36.7 pre-operatively and 84.5 post-operatively in the FB group, and 42.9 pre-operatively and 84.3 post-operatively in the RP group.

Mean KS function scores were 43.5 pre-operatively and 76.7 post-operatively in the FB group, and 44.5 pre-operatively and 76.4 post-operatively in the RP group.

Mean KS pain scores were 7.3 pre-operatively and 41.7 post-operatively in the FB group, and 6.9 pre-operatively and 42.6 post-operatively in the RP group.

The mean OKS total score was 40.4 pre-operatively and 21.4 post-operatively in the FB group and 40.2 pre-operatively and 21 post-operatively in the RP group. A lower OKS score is better.

There was no statistical difference in mean ROM between the two groups (FB: 100.8° vs. RP: 101°, p=0.91).

There was no post-operative increase in mean flexion in either group, but mean extension improved significantly in both groups. The improvement in extension was significantly higher for the FB group compared to the RP group (6.5° vs. 4.5°, p=0.041) but this was not clinically important. Five patients in each group had a persisting fixed flexion deformity (mean 6.6°). There was no radiographic loosening or osteolysis in either group.

There were 7 post-operative complications for the RP group and 2 for the FB group. There were no revisions at 1 year for infection, loosening or bearing dislocation.

Study Conclusion
This study showed no statistically significant difference in functional outcomes and survivorship between the fixed bearing and mobile bearing design of the P.F.C. SIGMA knee replacement system in the short-term.
Objective
To compare the clinical outcomes of Total Knee Arthroplasty (TKA) using fixed and mobile bearings in a randomised controlled trial.

Treatment
SIGMA Rotating Platform (RP), Cruciate Retaining (CR) and Posterior Stabilised (PS) knees

Comparator
SIGMA Fixed Bearing (FB), (CR and PS) knees

Outcomes
Surgical Details, Range of Motion (ROM), Knee Society Score (KSS), WOMAC, SF-36, Knee Alignment, Complications.

Study Design
Randomised Controlled Trial

All candidates eligible for primary Total Knee Replacement (TKR) were eligible for inclusion and 72 knees were treated with a SIGMA FB knee and 68 knees were treated with a SIGMA RP knee, all of which were enrolled in the study.

The primary diagnosis was osteoarthritis in 88% of the FB group and 85% of the RP group. The decision to cement the prosthesis was not mentioned. The treatment of the cruciate ligament was decided at time of surgery, and all patellas were resurfaced. Patients were followed up for a minimum of 2 years (at 6 weeks, and 3, 6, 12, and 24 months).

Results
Pre-operative demographics and clinical status were similar in both groups.

There were no statistical differences noted between the 2 groups in terms of surgical outcomes (operation time, tourniquet time, estimated blood loss).

Mean ROM was higher in the RP group at every post-operative follow up, but this was only statistically significant at 6 weeks and 12 months (p= 0.039 and 0.032 respectively).

There were no statistical differences in KSS, WOMAC or SF-36 scores at any follow up time for any score. These all demonstrated improvements throughout the study for both groups.

At 2 years the mean KS knee score was 93.2 and 91.4 for the FB and RP groups respectively (p=0.287).

Mean alignment was 4.0° valgus for the RP group and 3.2° for the FB group (p=0.27). There was no difference in patella tilt between the two groups (FB: 5.5° vs. RP: 4.2°, p=0.142).

In each group 1 patient had an infection and 1 patient had a pulmonary embolism. There was one revision in the FB group for persistent pain and 1 knee in the FB group was also radiographically loose. There were no revisions, loosening or spin out in the RP group.

Study Conclusion
There were few significant differences between the SIGMA RP and FB knees out to 2 years, with both demonstrating improvements in outcomes throughout the study. Although ROM was higher at some points with the RP knee, there was no difference at 2 years.
9. STAGED BILATERAL MOBILE BEARING AND FIXED BEARING TOTAL KNEE ARTHROPLASTY IN THE SAME PATIENTS: A PROSPECTIVE COMPARISON OF A POSTERIOR STABILISED PROSTHESIS

Hasegawa M, Sudo A, Uchida A.
Knee Surgery, Sports Traumatology, Arthroscopy 2009;17:237–43

Objective
To compare the results of Mobile Bearing (MB) and Fixed Bearing (FB) total knee arthroplasties (TKAs) (with the same femoral component) in the same patients.

Treatment
SIGMA Rotating Platform (RP), Posterior Stabilised (PS) cemented knee

Comparator
SIGMA FB, Posterior Stabilised (PS) cemented knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Radiographic Analysis, Complications.

Study Design
Randomised Controlled Trial

Between April 2003 and July 2006, 25 consecutive bilateral knees with osteoarthritis were randomly allocated to receive a posterior stabilised SIGMA FB (Metal Backed Tibial Component) and a posterior stabilised SIGMA RP prosthesis in each knee. All components were fixed with cement and patellas were routinely resurfaced with a polyethylene button.

Patients were blinded to their prostheses. Mean patient age was 73 and mean follow up was at 40 months.

Results
There was no difference in post-operative mean KS knee (p=0.86) or mean KS function (p=0.72) scores.

Mean KS knee scores were 24 pre-operatively and 98 post-operatively for the FB group, and 26 pre-operatively and 97 post-operatively for the RP group.

Mean KS function scores were 46 pre-operatively and 84 post-operatively in the FB group, and 42 pre-operatively and 83 post-operatively in the RP group.

There was no difference in the mean flexion or flexion contracture between the FB and RP groups at final follow up (p= 0.69 and 0.24 respectively).

There were no significant differences in the radiographic results for the two groups after measuring component alignment. There was no osteolysis, loosening, infection or revisions in any patient.

Only one complication occurred, a dislocation of the rotating bearing. However this patient had spontaneous reduction and the dislocation did not recur.

Study Conclusion
There were no significant differences in the early clinical or radiographic findings between fixed bearing and rotating platform posterior stabilised TKAs using the same femoral component. The early results with both designs were satisfactory, but it is difficult to draw definitive conclusions as the study is small and long term results are required.
10. RELATIONSHIP BETWEEN JOINT GAP DIFFERENCE AND RANGE OF MOTION IN TOTAL KNEE ARTHROPLASTY: A PROSPECTIVE RANDOMISED STUDY BETWEEN DIFFERENT PLATFORMS

International Orthopaedics (SICOT) 2009;33:997–1000

Objective
To investigate Range of Motion (ROM) in Mobile Bearing (MB) and Fixed Bearing (FB) Total Knee Arthroplasty (TKA) and to evaluate whether there was a difference in ligament balance between the two when measured intra-operatively.

Treatment
SIGMA Rotating Platform (RP), Cruciate Retaining (CR) knee

Comparator
SIGMA Fixed Bearing (FB), Cruciate Retaining (CR) knee

Outcomes
Range of Motion (ROM), Medial and Lateral Joint Gap (GAP), Knee Ligament Balance.

Study Design
Randomised Controlled Trial

A series of 76 knees in 68 patients with osteoarthritis were included in this study. Of these 31 were randomly allocated to have a SIGMA RP CR knee and 45 a SIGMA FB CR knee. The use of cement and whether the patella was resurfaced were not reported.

Mean follow up was 4 years, but outcomes reported are at 1 year post-operatively (unless stated). Intra-operatively the joint gap with the patella reversed was measured with the knee in extension of 0° and flexion of 90° using a knee balancer (DePuy). The correlation between the scale of medial and lateral joint gap and post-operative change in flexion was determined by calculating Pearson’s correlation coefficients.

Results
There was an improvement in Range of Motion (ROM) in extension after Total Knee Arthroplasty (TKA) in both groups.

In the RP group, mean extension improved from – 11.7° pre-operatively to a post-operative mean of 0.3°. In the FB group, mean extension improved from – 10.8° pre-operatively to a post-operative mean of – 1.6°. The extension range was particularly notable in group RP and was significantly greater than in group FB.

In the RP group, mean flexion was 113.5° pre-operatively and 115.8° post-operatively. In the FB group, mean flexion was 109.6° pre-operatively and 110.8° post-operatively.

In the RP group, there was no correlation between medial gap and change in flexion angle or lateral gap and change in flexion angle.

In the FB group, there was a 0.51 positive correlation between medial gap and change in flexion angle, indicating that a larger medial gap was associated with a larger post-operative increase in flexion. Also, there was a 0.54 positive correlation between lateral gap and change in flexion, indicating a larger lateral gap was associated with a larger post-operative increase in flexion.

At four years post-operatively there was also a correlation between gap difference and flexion range for the FB group but not the RP group.

Study Conclusion
After TKA with both the SIGMA RP CR and FB CR knee, the post-operative knee extension angle was significantly improved. In SIGMA RP TKA there was no association between the intra-operative gap difference and the post-operative change in flexion. However, with the SIGMA FB CR knee, there was an association between the intra-operative gap difference and the post-operative change in flexion.
Objective
To compare a new medially conforming ball and socket design knee to a fixed bearing posterior stabilised knee, and assess the Range of Motion (ROM), Knee Society Score (KSS) and other clinical scores.

Treatment
Medial Rotation Knee™ (MRK™) (MatOrtho)

Comparator
SIGMA Fixed Bearing (FB) Posterior Stabilising (PS) cemented knee

Outcomes
Range of Motion (ROM), Knee Society Score (KSS), WOMAC, SF-36, Oxford Knee Score (OKS), Total Knee Function Questionnaire (TKFQ), Radiographic Analysis, Radiographic Analysis, Complications.

Study Design
Randomised Controlled Trial

This study is from a single centre study comparing 82 patients, of which 2 were lost to follow up. Of these, 40 patients were randomly allocated to have a SIGMA FB CR knee and 40 to have Medial Rotation Knee (MRK). Initial diagnosis of patients included osteoarthritis and traumatic or rheumatoid arthritis but the numbers were not stated.

All patellas were resurfaced and all knees were cemented. Patients were followed up at 1 and 2 years post-operatively.

Results
The MRK group had a higher proportion of females. Otherwise, demographic and pre-operative clinical status were similar in both groups. Mean patient age was 69 and 73 in the SIGMA and MRK groups respectively.

At 1 and 2 years mean post-operative ROM was significantly better (p<0.0001) for the MRK. For the MRK it was 114.9° compared to the 100.1 for the SIGMA knee at 2 years.

At 1 and 2 years, the mean KS knee score was higher on average for the MRK group, (76.3 vs. 68.6, p=0.06 at 2 years), but this was not statistically significant. There were no differences in KS function scores between the two (MRK: 71.4 vs. SIGMA: 68, p=0.47 at 2 years).

There were no statistically significant differences between the two groups in the post-operative stiffness, disability and total WOMAC scores. However, at 1 and 2 years the WOMAC pain score was significantly lower in the MRK group (2.7 vs. 5.4, p=0.003 at 2 years).

Considering SF-36 scores, the physical component was significantly better for the MRK at both 1 and 2 years (p=.008 and p=.02 respectively) The mental component was also significantly better at 1 year but not at 2 years (p<.0001 and p=.27 at 1 and 2 years). The mean OKS was comparable, with no statistical difference between the two.

There was no difference in radiographic alignment between the two implant groups at two years. No progressive bone-cement or cement-implant interface lucencies were observed. There were two cases of DVT, one in each group, and one patient with an MRK had a painful haematoma which required surgical evacuation. There were no revisions in either group.

Study Conclusion
Both implant designs improved function, which were consistent with other single implant reports for both. The medially conforming ball did provide increased range of motion and increased function scores with some, but not all, measures.
12. PATELLO-FEMORAL TRACKING IN FIXED AND MOBILE BEARING KNEE DESIGNS

Journal of Bone and Joint Surgery (Br) 2012; 94-B(SUPP III): 151

Objective
To assess the impact of mobile bearing knee (MB) and the use of a patella button on the lateral release rates with an identical femoral component.

Treatment
SIGMA Rotating Platform (RP), Posterior stabilised (PS) knee with Patella Resurfacing

Comparator
• SIGMA RP PS knee without Patella Resurfacing
• SIGMA Fixed Bearing (FB) (PS) knee with Patella Resurfacing
• SIGMA FB PS knee without Patella Resurfacing

Outcomes
Lateral Release Rates

Study Design
Randomised Controlled Trial

A group of 347 patients were randomly allocated to receive a mobile bearing (171 knees) or fixed bearing (176 knees) version of the posterior stabilised SIGMA prosthesis.

The fixed and mobile bearing group were sub randomised into patella resurfacing or retention groups. The “no thumbs technique” was used to determine the need for lateral patella release.

Results
There was no difference in the lateral release rate between the fixed and mobile bearing groups. These were 9.65% for the FB group and 9.94% for the MB group (p=0.963).

Lateral release rates were lower for the patella resurfacing group compared to the patella retention group (5.8% vs. 13.8%; p=0.0131).

The difference was greatest in the mobile bearing group, with significantly lower lateral release in the patella resurfacing group compared to the patella retention group (3.5% v 16.3%; p=0.005).

Study Conclusion
There was no difference in the lateral release rate between fixed bearing and rotating platform tibial components. Patella resurfacing seems to be the more important factor, and the combination of a mobile bearing design and patella resurfacing appears to give the lowest lateral release rate in a posterior stabilised SIGMA knee design. These findings are similar to those reported by Pagnano et al, Clin Orthop Relat Res 2004;(428):221-7.

Jawed A, Kumar V, Malhotra R, Yadav C, Bhan S.
Archives of Orthopaedic and Trauma Surgery 2012;132(6):875-81

Objective
To compare the results of the fixed bearing (FB) and rotating platform (RP) SIGMA knee in patients undergoing bilateral total knee arthroplasty (TKA) with regards to clinical and radiologic outcomes and complication rates, with special emphasis on instability and patello-femoral complications.

Treatment
SIGMA RP (PS) cemented knee

Comparator
SIGMA FB (PS) cemented knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Pain Scores, Radiographic Analysis, Complications.

Study Design
Randomised Controlled Trial

A group of 50 patients having bilateral TKA had their knees randomised to fixed bearing or rotating platform tibial implants in otherwise identical designs of a posterior stabilised SIGMA knee. Tibial and femoral components were cemented, but no patellas were replaced. The original diagnosis was osteoarthritis in 44 patients and rheumatoid arthritis in 6.

Patients were followed for a mean of 40 months, with all patients followed up at 3, 12 and 36 months.

Results
The bilateral knees had similar deformity and ROM pre-operatively.

For the FB group, mean ROM was 100° pre-operatively and 110° at 3 years post-operatively. For the RP group, mean ROM was 102° pre-operatively and 112° at 3 years post-operatively. The difference in the improvement in each group was not significant (p>0.05).

For the FB group, mean KS knee scores were 55.72 pre-operatively and 86.94 at 3 years. For the RP group, mean KS knee scores were 56.4 pre-operatively and 87.6 at 3 years. The difference in the improvement in KS knee score between each group was not significant (p > 0.05).

Mean pain scores were similar (p>0.05) for the two groups, with the FB group improving from 11.4 pre-operatively to 25.4 (out of 30) post-operatively, and the RP group improving from 11.7 pre-operatively to 26.1 post-operatively.

Radiographic analysis at 1 year post-operatively showed minimal differences between the two groups for patella height and Insall Salvati ratio.

There were a similar number of complications for wound necrosis (2 vs. 4), anterior knee pain (6 vs. 7) and radiolucent lines (2 vs. 2) for the FB and RP groups respectively. No patient in either group had a dislocation or osteolysis. There were no revisions for either prosthesis.

Study Conclusion
The theoretical advantages of the SIGMA rotating platform knee over the SIGMA fixed bearing knee could not be demonstrated in this study. However outcomes for both groups of knees were good. A longer follow up would be necessary to compare the performance of the two designs.
Objective
To compare the Mini Midvastus (MMV) approach against the Medial Parapatellar (MPP) approach for component alignment and knee function at 3 months.

Treatment
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) cemented knee implanted via the Medial Parapatellar surgical approach.

Comparator
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) cemented knee implanted via the Mini Midvastus surgical approach.

Outcomes
Surgical Details, Knee Society Score (KSS), Range of Motion (ROM), Radiographic Analysis

Study Design
Randomised Controlled Trial

A group of 70 patients admitted with osteoarthritis, a BMI <35, valgus deformation < 10° and varus deformation < 20° between October 2005 to March 2007 were included. Of these, 35 were randomised to the mini-midvastus (MMV) surgical approach and 35 to the medial parapatellar (MPP) surgical approach.

All patients had a cemented, posterior stabilised, fixed bearing SIGMA knee, and no patellas were resurfaced. Patients were assessed at 3 months follow up.

Results
Patient demographic and pre-operative clinical status were similar in each group, and the mean patient age was 72 and 71.4 in the MMV and MPP groups respectively.

The mean length of incision favoured the MMV approach (10.6cm vs. 17.1cm, p<0.001) over the MPP approach.

The length of surgery was significantly longer for the MMV than MPP approach (93 mins vs. 86 mins, p<0.001).

At 6 weeks, the MMV group had a better mean KS knee score (84.5 vs. 64.5), mean KS function score (75.6 vs. 58.6) and mean ROM (119.8° vs. 110.4°) compared to the MPP group, all of which were statistically significantly different (p<0.001).

At 12 weeks there were no significant differences in the results, although the MMV approach was still slightly favoured for all of the outcomes; mean KS knee score (91.2 vs. 89.2; p=0.055); mean KS function score (89.5 vs. 89.1; p= 0.77) and mean ROM (124.7° vs. 123.3°; p= 0.075).

There was no difference between the two approaches in the radiological analysis of component positioning post-operatively.

Flexion was significantly better in the MMV group from days 2 to 6 post-operatively (p<0.001). However, extension was significantly better for the MPP group from days 2-5 (p<0.005), but not at day 6 (p=0.11).

Study Conclusion
The mini midvastus approach is associated with faster recovery and reproduces the same accuracy in component positioning as the medial para-patellar approach. There was minimal difference between the groups for ROM.
CLINICAL PAPER

15. RANDOMISED CLINICAL TRIAL OF ROTATING PLATFORM AND FIXED BEARING TOTAL KNEE ARTHROPLASTY: NO CLINICALLY DETECTABLE DIFFERENCES AT FIVE YEARS

Kalisvaart M, Pagnano M, Trousdale R, Stuart M, Hanssen A.
Journal of Bone and Joint Surgery (Am) 2012;94:481-9

Objective
To assess whether the posterior stabilised SIGMA Rotating Platform (RP) knee provided better maximum flexion, better function or better durability at five years of follow up compared with a fixed bearing version of the same design.

Treatment
SIGMA RP Posterior Stabilised (PS) cemented knee

Comparator
SIGMA Fixed Bearing (FB) PS cemented knee with all-polyethylene tibial component.

Outcomes
Knee Society Score (KSS), Range of motion (ROM), Patient Activities, Stair Climbing Score, Survivorship, Complications.

Study Design
Randomised Controlled Trial

Between March 2001 and March 2003, 240 patients were randomised to all-polyethylene, metal backed and rotating platform tibial components, in an otherwise identical version of a cemented (tricomponent) SIGMA knee. There were 80 knees in each group. All patients had a diagnosis of osteoarthritis. Mean follow up was 5.3 years (Range: 4 to 7.7 years). One year results are reported by Pagnano et al. Clin Orthop Relat Res 2004;(428):221-7.

Results
Pre-operative patient demographics and clinical status were similar, in all 3 groups.

For the all-polyethylene, metal backed and rotating platform cohorts, the mean pre-operative knee flexion was 112°, 109° and 107°.

At two years, the respective values were 111°, 111° and 110°.

At five years, the respective values were 110°, 109° and 109°.

For the three groups respectively, the mean KS function score pre-operatively was 53, 54 and 51, and the mean KS pain score was 61, 61, and 63. None of these differences were significant.

At 5 years there was no difference in these scores. In the FB all-polyethylene group, the modular metal backed group and the RP groups respectively, the mean KS function scores were 69.7, 77.4 and 69.2 (p=0.06). The mean KS pain scores were 88.3, 88.7 and 87.8 (p=0.87).

Stair climbing improved significantly in all groups, but at 5 years there was no significant difference between them, with values of 37.3, 39.9 and 35.6 for the three groups respectively (score out of 50) (p=0.08).

At 5 years, there was no difference in survivorship with revisions for any reason as the endpoint. This was 98.7% for the all-polyethylene group, 97.4% for the metal backed group and 98.7% for the rotating platform group (p>0.05). There were 3 cases of aseptic loosening that required revision surgery, 1 in the FB all-polyethylene group and 2 in the metal backed group.

Study Conclusion
The rotating platform version of the SIGMA knee was reliable and durable but didn’t provide increased maximum knee flexion or any improvements in function compared to the fixed bearing versions including the all-polyethylene tibia, which also performed well. Longer follow up is required to see if the rotating platform confers longer-term benefits in terms of fixation and wear.
Kim Y, Kim J, Yoon S.  
Journal of Bone and Joint Surgery (Br) 2007;89:471-6

Objective  
To evaluate the accuracy of the orientation of components and post-operative limb alignment in CT-free computer-assisted navigated Total Knee Replacement (TKR) and to compare this with the results of conventional TKR in patients who were undergoing bilateral sequential TKR.

Treatment  
SIGMA Rotating Platform (RP) Cruciate Retaining (CR) cemented knee implanted with Computer Aided Surgery (CAS)

Comparator  
SIGMA RP cemented knee (CR) implanted conventionally

Outcomes  
Surgical Details, Range of Motion (ROM), Knee Society Score (KSS), Hospital for Special Surgery (HSS), Pain Scores, Knee Alignment, Radiographic Analysis, Complications.

Study Design  
Randomised Controlled Trial

A group of 100 consecutive patients with bilateral TKRs treated with cruciate retaining SIGMA RP knees who met inclusion criteria participated in the study. All patients had an original diagnosis of osteoarthritis and < 20° varus deformity. In each patient, one knee was randomly allocated to implantation with CAS (Vector Vision) and the other to implantation with conventional instruments. All components were cemented.

Mean follow up was 2.3 years (2-3 years).

Results  
Pre-operative clinical status was the same in both groups and mean patient age was 67.6 (57 - 83) years. Operation time was significantly longer in the CAS group (97 vs. 82 min, p <0.001) the mean tourniquet time was significantly longer in the CAS group as well (59 vs. 44 min. p<0.001), but these were the only significant surgical differences between the groups.

Pre and post-operative mean KSS scores were not significantly different between the groups, p=0.288 and p=0.456 respectively. Pre and post-operative mean HSS scores were also not significantly different, p=0.760 and p=0.433 respectively.

Mean KS knee scores were 29 pre-operatively and 93 post-operatively for the CAS group, and 28 pre-operatively and 94 post-operatively for the conventional group.

Mean KS function scores were 25 pre-operatively and 85 post-operatively in the CAS group, and 26 pre-operatively and 84 post-operatively in the conventional group.

Mean KS pain scores were 0 pre-operatively and 44 post-operatively in the CAS group, and 0 pre-operatively and 46 post-operatively in the conventional group (a higher score meaning less pain).

Mean post-operative ROM was 127° for the CAS group and 126° for the conventional group.

There were no significant differences between the two groups in terms of alignment, position of femoral or tibial components in the coronal and sagittal planes, patella angles, tibial surface area covered, and orientation of pre – and post-operative joint lines.

There were no revisions and no patella problems in either group. There were 7 complications in the CAS group and 1 in the conventional group. In the CAS group, there were six cases of anterior femoral notching and one excessive resection that required a 14mm tibial insert. The conventional group had one case of anterior femoral notching.

Study Conclusion  
In this series total knee replacement with CAS did not result in more accurate orientation and alignment of the components than that achieved by conventional total knee replacement.
17. EARLY OUTCOME OF TOTAL KNEE ARTHROPLASTY WITH A MEDIAL PIVOT FIXED BEARING PROSTHESIS IS WORSE THAN WITH A P.F.C. SIGMA MOBILE BEARING PROSTHESIS

Kim Y, Yoon S, Kim J.
Clinical Orthopaedics and Related Research 2009;467:493–503

Objective
To provide a comparison of clinical and radiographic outcomes, Range of Motion (ROM), patient satisfaction and complications between knees with a Medial Pivot fixed bearing and a SIGMA mobile bearing prosthesis.

Treatment
ADVANCE® Medial Pivot Fixed Bearing (FB), Cruciate retaining (CR) cemented knee (Wright Medical)

Comparator
SIGMA Rotating Platform (RP), Cruciate retaining cemented knee

Outcomes
Knee Society Score (KSS), Hospital for Special Surgery (HSS), Range of Motion (ROM), Radiographic Analysis, Complications, Patient Satisfaction.

Study Design
Randomised Controlled Trial

A group of 92 bilateral patients from a consecutive series of 98 bilateral patients met the inclusion criteria which included an original diagnosis of osteoarthritis. One knee had a Medial Pivot fixed bearing prosthesis (Wright Medical) and the other knee was a SIGMA RP knee. All implants were cemented and of cruciate retaining design. All patellas in both groups were resurfaced with a polyethylene prosthesis.

Patients were followed for a mean of 2.6 years (2-3 years).

Results
Pre-operative clinical status was the same for both groups and mean patient age was 69.5.

Mean KS knee score was significantly better for the SIGMA knee than the Medial Pivot knee at 3 months (86 vs. 79; p<0.05), 1 year (94 vs. 87; p<0.05) and 2.6 years (94 vs. 87; p<0.05).

There was also a non significant trend for higher (better) KS function scores for the SIGMA knee compared to the Medial Pivot knee at 3 months (67 vs. 67; p=0.806), 1 year (85 vs. 80; p=0.103) and 2.6 years (86 vs. 80; p=0.065).

HSS total knee score was also better for the SIGMA knee compared to the Medial Pivot at 3 months (85 vs. 80; p<0.05), 1 year (93 vs. 86; p<0.05) and 2.6 years (93 vs. 87; p<0.05), all of which were statistically significant.

ROM was significantly better for the SIGMA knee compared to the Medial Pivot at 3 months (126° vs. 98°; p<0.05), 1 year (110° vs. 128°; p<0.05) and 2.6 years (115° vs. 127°; p<0.05). Pre-operative ROM was 124° for both groups.

Radiographic results were similar between the two for alignment (p= 0.2), radiolucencies (p= 0.388), and for sagittal or anteroposterior planes of tibial or femoral components (p >0.05 in all). No knee was revised in either group. There were fewer complications with the SIGMA knee compared to the Medial Pivot knee (2 vs 13; p=0.001).

Patients had significantly more pain with the Medial Pivot knee compared to the SIGMA knee for KSS and HSS scores (p = 0.043 and p = 0.04). The mean satisfaction of the Medial 6.5 for the Pivot knee and 7.9 for the SIGMA knee (no p value).

Study Conclusion
Although the Medial Pivot fixed bearing prosthesis is in theory designed to improve kinematics compared with those of previous TKAs using fixed bearing prostheses, in this study there were worse early clinical outcomes, lower ROM, less patient satisfaction, and a higher complication rate with it compared to the SIGMA RP knee.
18. SIMULTANEOUS MOBILE AND FIXED BEARING TOTAL KNEE REPLACEMENT IN THE SAME PATIENTS

Kim Y, Kim D, Kim J.
Journal of Bone and Joint Surgery (Br) 2007;89:904-10

Objective
To compare the clinical and radiological results of mobile and fixed bearing total knee replacements (TKRs) with a similar type and design.

Treatment
SIGMA Rotating Platform (RP) Cruciate Retaining (CR) cemented knee

Comparator
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee

Outcomes
Knee Society Score (KSS), Hospital for Special Surgery (HSS), Pain Scores, Range of Motion (ROM), Patient Satisfaction, Radiographic Analysis, Complications, Patella Crepitus, Survivorship.

Study Design
Randomised Controlled Trial

From a consecutive series of 194 patients between June 2000 and May 2001, 174 bilateral patients received one SIGMA FB knee and one SIGMA RP knee randomly allocated to each knee. The original diagnosis was osteoarthritis in 173 patients (346 knees) and rheumatoid arthritis in 1 patient (2 knees). All knees were a cruciate retaining design and all components were cemented. All patellas were resurfaced with an all-polyethylene component. Mean follow up was 5.6 years.

Results
Pre-operative clinical status was similar in both groups and mean patient age was 67 years.

There were no differences between the two groups in the mean post-operative KSS (p=0.789), HSS score (p=0.49), or pain, using both knee scoring systems, (p=0.949). There was no difference in mean ROM, both before (p=0.875) and after surgery (p=0.807).

The mean KS knee score was 28.1 pre-operatively and 90 post-operatively with the RP knee and was 28.7 pre-operatively and 91 post-operatively with the FB knee.

The mean KS function score was 25 pre-operatively and 83 post-operatively with the RP knee and was 24 pre-operatively and 86 post-operatively with the FB knee.

The mean KS pain score was 0.3 pre-operatively and 48 post-operatively with the RP knee and was 0.2 pre-operatively and 49 post-operatively with the FB knee (a higher score meaning less pain).

Radiolucent lines were found in 21 RP knees and 30 FB knees (p= 0.131), but no osteolysis was seen in either group. Of these, 17/21 RP knees and 24/30 FB knees only had radiolucent lines of <1mm in zone 1 of the tibial plateau.

There were two revisions in the RP group (two infections) and none in the FB group.

Other complications included one nerve palsy in each group. Patellar crepitus occurred in 44 RP knees and 52 FB knees (1 FB knee also had patellar clunk associated with pain). Two knees in each group had skin edge necrosis.

Best case survivorship was 99% and 100% for RP and FB respectively at 5 years.

Study Conclusion
Excellent clinical and radiological results were achieved with both SIGMA mobile and fixed bearing cruciate retaining total knee designs at a mean follow up of 5.6 years. However, there was no significant clinical advantage for a mobile bearing over a fixed bearing TKR.
Objective
To determine whether the knee and function scores, range of motion and the radiographic results for the knees with a posterior stabilised SIGMA RP prosthesis would be better than those with a LCS® RP prosthesis.

Treatment
SIGMA Rotating Platform (RP) Posterior stabilising (PS) cemented knee

Comparator
LCS Rotating Platform (RP) Cruciate Sacrificing (CS) cemented knee

Outcomes
Knee Society Score (KSS), Hospital for Special Surgery Score (HSS), Pain Scores, Range of Motion (ROM), Radiographic Analysis, Knee Alignment, Osteolysis, Survivorship, Complications.

Study Design
Randomised Controlled Trial

A group of 107 females undergoing bilateral Total Knee Arthroplasty (TKA) performed by YHK were entered into the study. All patients had bilateral osteoarthritis and mean patient age was 66.8. In each patient each knee was randomly allocated a cruciate sacrificing LCS RP knees and a posterior stabilised SIGMA RP knees, 107 of each. All knees were cemented, and all patellas were resurfaced with a polyethylene implant. Twenty-three knees had valgus alignment of 8° to 12°, and the remaining 191 knees had varus alignment of 8° to 20°. Patients were followed for a mean of 7.4 years.

Results
There was no significant difference between the groups in post-operative KSS (p = 0.167) and HSS scores (p = 0.087). For the LCS RP group, the mean post-operative KS knee score was 96 and HSS score was 93. For the SIGMA RP group, the mean post-operative KS knee score was 97 and HSS score was 94.

In the LCS RP group, the following were reported by patients: No pain in 90 (84%), Mild pain in 16 (15%) and moderate pain in one (1%). In the SIGMA RP knees the following were reported by patients: No pain in 88 (82%), Mild pain in 18 (17%) and moderate pain in one (1%).

There was a statistically significant difference in the mean post-operative ROM between the LCS RP knee and the SIGMA RP knee (127.7° vs 132.4°; p<0.0001). This was not clinically important as the margin for error in measurement was 5°.

There was no difference between the two groups for alignment of the knee, position of femoral and tibial components, patella angle and a number of other radiographic outcomes. There was also no difference in the presence of radiolucent lines (12 knees vs. 10 knees), or prevalence of osteolysis (2 knees vs. 3 knees), for LCS RP knees and P.F.C. SIGMA RP knees respectively.

At 7 years, with revision for any reason as the endpoint, survivorship was 97.2% (3 revisions) for the LCS RP knee and 98.1% (2 revisions) for the SIGMA RP knee. All revisions were due to deep infection. However, 1 LCS knee required open reduction and internal fixation for a fracture, and 2 knees in the SIGMA RP group had patella clunk. However they had good results after arthroscopic debridement.

Study Conclusion
There were no significant differences between the two prostheses after 7 years. In the present study, both the LCS RP and SIGMA RP knees performed well. The posterior stabilised construct referred to in this paper describes the surgical philosophy of posterior stabilisation. The SIGMA femoral component used in the study was actually the SIGMA Cruciate Substituting (CS) implant.
Objective
To compare the clinical and radiographic midterm results of two identical knee prostheses, where the only difference was the presence or absence of a mobile bearing tibial insert.

Treatment
SIGMA Rotating Platform (RP) Posterior Stabilised (PS) cemented knee

Comparator
SIGMA Fixed Bearing (FB) PS cemented knee

Outcomes
Knee Society Score (KSS), Pain Scores, Visual Analogue Score (VAS), SF-12, Range of Motion (ROM), Radiographic Analysis, Patella Tilt, Complications.

Study Design
Randomised Controlled Trial

All patients with tri-compartmental osteoarthritis implanted from December 1999 to May 2001 were eligible to participate. A group of 104 knees were enrolled into the study with 52 knees randomly allocated to receive a SIGMA FB knee and 52 to receive a SIGMA RP knee. All implants were cemented, posterior stabilised and the patellas were routinely resurfaced. Mean follow up was 7.1 years for both groups (5.8 - 7.8 years).

Results
There were no differences in the pre-operative demographic and clinical status of patients in each group. Mean patient age was 70 and 72 in the FB and RP groups respectively.

There was no difference between the FB and RP groups for mean post-operative KS knee score (92.2 vs. 92.3; p= 0.959), KS function score (78 vs. 80.6; p= 0.542), and KS pain score (44.7 vs. 45.5; p= 0.677).

There were also no significant differences in the mean post-operative VAS scores (p= 0.848), anterior knee pain (p= 0.320), flexion angle (p=0.301), SF-12 physical score (p= 0.959), and SF-12 mental score (p= 0.719).

Radiolucent lines could be seen in 10% of the FB group and 7% of the RP group. One young active patient with an RP prosthesis had radiolucent lines of more than 10mm (in zones 1, 3 and 4), and clear signs of loosening of the tibial component. Patella tilt occurred in 2 patients in the FB group and 1 patient in the RP group but was never associated with anterior knee pain.

The number of complications in each group was comparable, and there were no intra-operative complications. In the FB group there was one pulmonary embolism. In the RP group 2 patients underwent a second operation, one for septic loosening and one for a stiff joint with limited motion.

Study Conclusion
No clear advantage was observed with respect to function, pain, range of motion, general health, and radiological signs of loosening with the fixed bearing or rotating platform versions of the SIGMA knee at a mean follow up of 7.1 years.
21. FUNCTIONAL COMPARISON OF POSTERIOR CRUCIATE RETAINING VS. POSTERIOR STABILISED TOTAL KNEE ARTHROPLASTY

Maruyama S, Yoshiya S, Matsui N, Kuroda R, Kurosaka M.

Objective
To compare the cruciate retaining (CR) implant with the posterior stabilised (PS) implant in patients with bilateral osteoarthritis. Short term clinical evaluations were then done to compare the two implants randomised to each knee.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee

Comparator
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) cemented knee

Outcomes
Knee Society Score (KSS), Patient Satisfaction, Range Of Motion (ROM), Mean Joint Line.

Study Design
Randomised Controlled Trial

Between January 1998 and July 2000, 20 patients underwent bilateral Total Knee Arthroplasty (TKA) with each knee being randomised to each prosthesis. Patients received one CR and one PS version of the SIGMA FB knee.

All surgeries were performed by the same surgeon with standardised instrumentation, and all components were cemented. The diagnosis was osteoarthritis in all patients and mean follow up was 31.7 months (Min 24 months).

Results
There were no significant differences between the pre-operative or post-operative KS scores (p<0.05).

Satisfactory clinical outcomes were achieved in 95% of CR and 90% of PS knees.

Mean KS scores were 42.8 pre-operatively and 89.8 post-operatively in the CR group, and 43.6 pre-operatively and 89.5 post-operatively in the PS group.

Mean KS knee function scores for both groups were 55.3 pre-operatively and 83.3 post-operatively, with no difference between the groups (p<0.05).

Extension improved from -7.2° to -0.3° in the CR group and -7.5° to -0.9° in the PS group.

Flexion improvement was significantly higher (p<0.05) for the PS knee, with improvement from 119.7° to 122.3° for the CR knee and from 120.3° to 131.3° for the PS knee.

There was no significant difference between the mean joint line (23.6 vs. 24.3) for CR and PS designs respectively (p>0.05).

Study Conclusion
The comparison of cruciate retaining and posterior stabilised knees showed a superior range of motion in the posterior stabilised design. Tension of the posterior cruciate ligament causing abnormal knee kinematics in flexion is a factor that is thought to be associated with flexion limitation in the cruciate retaining knee. A longer term follow up study and three dimensional fluoroscopic analysis of knee motion in the same group will further clarify the differences.
22. SHOULD WE RECONSIDER ALL-POLYETHYLENE TIBIAL IMPLANTS IN TOTAL KNEE REPLACEMENT

Muller S, Deehan D, Holland J, Outterside S, Kirk L, Gregg P, McCaskie A.
Journal of Bone and Joint Surgery (Br) 2006;88:1596-602

Objective
To evaluate and compare the performance of the cruciate retaining SIGMA all-polyethylene and metal-backed tibial components of identical design, using radiostereometric analysis.

Treatment
SIGMA Fixed Bearing (FB), Cruciate Retaining (CR) cemented knee (all-polyethylene tibial component)

Comparator
SIGMA Fixed Bearing (FB), Cruciate Retaining (CR) cemented knee (metal backed tibial component)

Outcomes
Radiostereometric Analysis (RSA), SF-12, Oxford Knee Score (OKS), Range of Motion (ROM), Knee Alignment.

Study Design
Randomised Controlled Trial

Primary TKR patients over 65 years with osteoarthritis (OA) or rheumatoid arthritis (RA) were eligible for randomisation. Of the patients included in the study, 21 received an all-polyethylene tibial component and 20 received a metal backed tibial component. All patients received a cemented, cruciate retaining SIGMA knee and were followed for 2 years.

Results
There were no differences in patient demographics and pre-operative clinical status.

There was no significant difference in the translation in the x (medial), y (proximal) and z (posterior) planes at 24 months between the two groups (p= 0.98, 0.49 and 0.47 respectively), and also no difference in rotational displacement.

SF-12 and Oxford knee score (OKS) both increased after the operation, but there was no significant difference between the all-polyethylene group or the metal-backed group for the pre-operative, 6, 12, or 24 month assessments.

Median OKS was 13.5 pre-operatively and 34 post-operatively in the all-polyethylene tibia group and 17 pre-operatively and 32.5 post-operatively in the metal-backed group.

The median active range of movement was also not significantly different between the two groups, with a mean change in active flexion from 104° to 101° for all patients at 6 months.

At two years one metal-backed implant showed migration of more than 1 mm, but no polyethylene implant reached this level.

The median varus-valgus tibial alignment assessed on anteroposterior weight-bearing radiographs measured 88°. No significant difference was found between the two groups at 24 months (p= 0.99).

Study Conclusion
There was no statistical difference in migration between the all-polyethylene SIGMA FB tibial prosthesis and the metal-backed counterpart. There was no difference in the clinical results assessed using the SF-12, the Oxford knee score, alignment, or range of movement at 24 months, although the study was not powered to measure differences with these assessment measures.
Objective
To compare the cruciate retaining (CR) implant with the posterior stabilised (PS) implant in patients with bilateral osteoarthritis. Short term clinical evaluations were then done to compare the two implants randomised to each knee.

Treatment
SIGMA Rotating Platform (RP) Posterior Stabilised (PS) cemented knee

Comparator
SIGMA Fixed Bearing (FB), Posterior Stabilised (PS) cemented knee (all-polyethylene tibial Component)

Outcomes
Lateral Release, Patella Tilt, Patello-femoral Complications, Range of motion (ROM), Knee Society Score (KSS), Patient Activities.

Study Design
Randomised Controlled Trial

A posterior stabilised SIGMA knee was used in 240 patients enrolled in this study. All patients had an original diagnosis of osteoarthritis. Three groups of 80 patients were randomised to: an all-polyethylene fixed bearing tibial component, a modular metal backed fixed bearing tibial component, or a rotating platform tibial component. All were tri-compartmental cemented total knee arthroplasties (TKA), all with identical femoral and patella components. Patella resurfacing occurred in all patients. Patients were followed up regularly out to 5 years.

Results
Patient demographic and pre-operative clinical status was similar in each group.

3 patients in each group required lateral retinacular release. One of the three patients in the RP group went on the develop patella tilt (measured 9°).

Patellar tilt (>5°) occurred in 4 of the all-polyethylene FB group, 6 of the metal backed FB group and 9 of the RP group (not significant). Mean tilt angle was 8.5° (5-15°).

There was no difference in knee flexion between the groups, which were 110°, 111° and 112° for the all-polyethylene FB, metal-backed FB, and RP groups, respectively (p>0.05).

Stair climbing significantly improved at 3 months (p <0.05) for the all-polyethylene FB group (32 to 38) and for the metal backed FB group (34 to 41) but not for the RP group (32 to 35). However all three groups had statistically better results at 1 year compared to pre-operatively (p<0.01).

KS knee, KS function and KS pain scores all improved but there was no difference in any of these scores between any of the three groups (p>0.05). At one year the mean KS knee score in all groups was 92 and the mean KS function score was 89.

Complications occurred in 5 of the all-polyethylene FB group, 8 of the metal backed FB group and 5 in the RP group. No patient had a patella dislocation.

Study Conclusion
There was no difference in the prevalence of lateral retinacular release, prevalence of patellar tilt/subluxation, knee flexion, knee society scores and improvement in stair climbing ability between the RP and the posterior stabilised metal backed FB and all-polyethylene FB knee at 3 months and at 1 year post-operatively.
**Objective**
To identify possible differences in the clinical outcome after total knee arthroplasty (TKA) in patients with fixed bearing (FB) and rotating platform (RP) designs of the SIGMA knee system. To also compare the post-operative range of motion (ROM), radiographic appearance, and patient satisfaction with each design at a minimum of 2 years after the surgery.

**Treatment**
SIGMA Rotating Platform (RP), Posterior Stabilising (PS) cemented knee

**Comparator**
SIGMA Fixed Platform (FB), Posterior Stabilising (PS) cemented knee

**Outcomes**
WOMAC, SF-12, Oxford-12, Patient Satisfaction, UCLA activity level (UCLA), Range of motion (ROM), Radiographic Analysis, Knee Alignment, Complications.

**Study Design**
**Randomised Controlled Trial**
A group of 52 patients with 54 knees were block randomised to receive either a SIGMA FB or RP cemented posterior stabilised knee. The original diagnosis was osteoarthritis (OA) in 100% of RP knees and 85% of the FB knees with 15% of FB knees diagnosed with rheumatoid arthritis (RA). The patella was resurfaced in 58% of the RP and 89% of the FB knees. Of the patients enrolled 27 knees receiving an FB knee were followed for 40 months, and 24 knees receiving an RP knee were followed for 43 months.

**Results**
Baseline demographics and clinical status were similar in both groups except that there was a higher proportion of patients with RA in the FB group. Both groups had significant improvements in all parameters of functional outcome post-operatively.

At final follow up there was no significant difference between the FB and RP knees for WOMAC, SF-12, Oxford-12, and patient satisfaction.

Mean global WOMAC scores were 49.1 pre-operatively and 83.6 post-operatively in the RP group. These were 45.6 and 79.5 in the FB group.

Mean OKS (normalised out of 100) were 38.6 pre-operatively and 83.3 post-operatively in the RP group, and 40.7 and 77.4 in the FB group.

The UCLA activity level was significantly better in the RP group than the FB group (6.1 vs. 4.9, P = 0.04).

Range of flexion and flexion contracture improved for both groups but there was no difference between the groups (p= 0.92 and 0.907 respectively). There was also no difference between the groups for tibio-femoral alignment (p= 0.94).

Radiolucent lines were found in four knees in each group (17% RP, 15% FB), but there was no evidence of component migration or loosening in either group.

Each group also had three complications. The number of patella resurfaced in each group was statistically different, with 58% and 89% of RP and FB patellas resurfaced respectively.

**Study Conclusion**
Although the midterm results of the RP knee were encouraging, there was no convincing evidence to prove the superiority of the RP compared to the FB design of SIGMA total knee designs. However, subtle differences may be revealed in further investigations. Patient activity level was higher in the RP group, but this may be a result of the inclusion of RA patients in the FB group.
25. FIXED VS. MOBILE WEIGHT-BEARING PROSTHESIS IN TOTAL KNEE ARTHROPLASTY

Shemshaki H, Dehghani M, Eshaghi MA, Esfahani M.  

**Objective**  
To compare the clinical, radiological, and general health outcomes of mobile and fixed weight-bearing devices that are used in total knee arthroplasty (TKA) and follow them up for 5 years.

**Treatment**  
SIGMA Rotating Platform (RP), Posterior Stabilised (PS) cemented knee

**Comparator**  
SIGMA Fixed Bearing (FB), Posterior Stabilised (PS) cemented knee

**Outcomes**  
Knee Society Score (KSS), Range of Motion (ROM), Pain, Radiographic Analysis, Complications.

**Study Design**  
Randomised Controlled Trial

A series of primary 300 knees were randomised to receive either FB or RP versions of the cemented, posterior stabilised SIGMA knee. In total, 150 knees were randomised to each group. The original diagnosis in the patients was not stated but patients with mediolateral instability, infective arthritis, and severe deformity > 20° were excluded. All patellas were resurfaced. Patients were followed out to 5 years.

**Results**  
Patient demographics and clinical status pre-operatively were similar in both groups. Mean patient age was 68 and 70 in the FB and RP groups respectively.

At 5 years follow up there was no difference in mean KS knee and function scores in the FB and RP groups (p>0.05).

Mean KS knee scores were 41 pre-operatively and 92 post-operatively in the FB group and 40 pre-operatively and 93 post-operatively in the RP group.

Mean KS function scores were 47 pre-operatively and 85 post-operatively in the FB group and 45 pre-operatively and 86 post-operatively in the RP group.

There was no difference in ROM in each group. In the FB group ROM was 3-101° pre-operatively and 0-113° post-operatively. In the RP group ROM was 4-98° pre-operatively and 0-116° post-operatively, no p value given. SF-36 scores increased for both groups but there was no difference between the two groups at final follow up, 62 and 64 in the FB and RP groups respectively (p>0.05).

In the FB and RP groups, 80% and 88% of patients respectively were pain free, and the improvement in the ability to walk was similar in both groups.

Multivariate regression analysis showed gender, age and prosthesis had no impact on the KSS score.

There were no statistical differences between the groups for tibial or femoral component positioning.

There were no intra-operative complications, no osteolysis and no revisions in either of the two groups.

**Study Conclusion**  
There was no difference in clinical and safety outcomes between mobile and fixed weight-bearing implants with midterm follow up. In both groups, post-operative outcomes were greatly improved compared to pre-operative outcomes. Gender, age, and type of prosthesis had no impact on the total KSS score at 5 year follow up. Longer follow up beyond 10 years may demonstrate a survivorship difference.
LEVEL II STUDIES: PROSPECTIVE NON-RANDOMISED CONTROLLED TRIALS
26. TEN YEAR SURVIVAL OF CEMENTED TOTAL KNEE REPLACEMENT IN PATIENTS AGED LESS THAN FIFTY FIVE YEARS

Journal of Bone and Joint Surgery (Br) 2012; 94-B:928–31

Objective
To report the ten year survival of a cemented total knee arthroplasty (TKA) in patients aged < 55 years at the time of surgery, and compare the functional outcome with that of patients aged > 55 years.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee or cemented CR P.F.C. knee in patients below the age of 55.

Comparator
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee or cemented CR P.F.C. in patients above the age of 55.

Outcomes
Oxford Knee Score (OKS), American Society of Anesthesiologists Score (ASA), Knee Society Score (KSS), Radiological Outcomes.

Study Design
Prospective Controlled Study

Patients undergoing primary TKA since 1995 were followed and data was collected on them at 18 months, 3, 5 and then 10 years post-operatively. All patients had an original diagnosis of osteoarthritis or inflammatory arthritis. Patients were treated with either a SIGMA FB CR cemented knee, 1998 onwards, or a P.F.C. CR cemented knee (1995-1997).

The outcome of 203 patients (255 TKRs) aged <55 years, mean age 50, were compared with the outcome of 2216 patients (2397 TKRs) aged >55 years, mean age 70.8. In the younger group, the diagnosis was osteoarthritis in 171 patients. The operations were performed by ten different consultant surgeons, or under their direct supervision. The patellas were not routinely resurfaced.

Results
The overall mean post-operative KSS were similar in patients aged < 55 years and those aged > 55 years (p=0.16). Mean post-operative OKS was similar at five years (36.44 vs. 35.11, p = 0.089) and ten years (35.54 vs. 33.44, p = 0.071) post-operatively.

In patients below 55 years, there was a decline in the number of patients with an excellent result during the study period between 5 and 10 years with a larger proportion having a good or fair result at 10 years.

At 5 years 32% of patients had an excellent OKS outcome, rated 42-48, and 36% had a good OKS outcome, rated 34-41. At 10 years 10% of patients had an excellent OKS outcome, and 39% had a good OKS outcome.

There were 4 revisions in this group, 1 for deep infection (at 28 months) and 3 for change of polyethylene only. Assuming that those patients who were lost to follow up did not require revision (4 knees), the best case scenario gave a ten year survivorship of 98.2%. The worst case scenario, assuming that those lost were failures, gave a ten year survival of 89.5%.

Study Conclusion
Overall, the data supports the view that good results can be expected at ten years post-operatively in patients aged < 55 years who undergo a cemented TKR.
Objective
To analyse the impact of patient factors, surgical technique, and design characteristics of knee prostheses on patient reported outcomes measures (PROMS) following total knee arthroplasty (TKA) using PROMS data linked to the national joint registry (NJR) of England and Wales.

Treatment
Sigma knee.

Comparator
NexGen® (Zimmer), Genesis® II (Smith & Nephew), AGC (Biomet), Triathlon® (Stryker), other.

Outcomes
Oxford Knee Score (OKS), EuroQol 5 Dimension (EQ-5D)

Study Design
Prospective Controlled Study

PROMS data linked to NJR records on 22,691 patients undergoing primary TKA between August 2008 and 2011 were included in the study. There were 6 knee implant brands reported: SIGMA (n=8287), NexGen (n=3283), Genesis II (n=1818), AGC (n=2398), Triathlon (n=1896) and other (n=5009). Only patients diagnosed with osteoarthritis who had completed pre-operative questionnaires and post-operative questionnaires between 6 and 12 months post surgery were included.

Univariable analysis of pre and post-operative PROMS by prosthesis brand was performed. Multiple regression of post-operative improvements in PROMS was also performed. Covariates included prosthesis brand, hospital type, pre-operative PROMS, general patient health, patient age, patient anxiety, patient depression.

Results
In unadjusted analyses the mean post-operative increases in OKS and EQ-5D were significantly higher for the NexGen knee compared with all other implant types (p<0.001).

Mean unadjusted OKS was 18.7 pre-operatively and 33.9 post-operatively for the SIGMA knee, and 18.9 pre-operatively and 35.1 post-operatively for the NexGen knee.

Mean unadjusted EQ-5D was 0.396 pre-operatively and 0.708 post-operatively for the SIGMA knee and 0.409 pre-operatively and 0.730 post-operatively for the NexGen knee.

In the multiple regression, the most important factors influencing post-operative change in PROMS were pre-operative PROMS, patient ratings of general health, and the presence of anxiety and depression. Surgical factors, such as prosthesis brand and hospital type, had a small influence that was statistically significant. The effect of hospital type was related to differences between NHS hospitals (20,288 cases) and independent hospitals (1491 cases) and independent sector treatment centres (ISTCs) (912 cases), with greater improvements seen in the latter two institutions.

Study Conclusion
In this study, the factors demonstrating the greatest influence on PROMS related mainly to patients. For example, every 1 point increase in pre-operative OKS lead to -0.66 point decrease in the improvement in post-operative OKS. The effect of prosthesis brand was small in comparison. There was a statistically significant difference in the change in OKS between the NexGen and SIGMA knee, but the difference was not clinically important.

Ballantyne A, McKinley J, Brenkel I.
Knee 2003;10(2):193-8

Objective
To analyse the results of the SIGMA knee at one institution and compare them to the Original P.F.C. knee, to assess the impact of the changes on early clinical results, in particular the difference in lateral release rates.

Treatment
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) and Cruciate Retaining (CR) cemented knee

Comparator
Original P.F.C. Fixed Bearing (FB) Cruciate Substituting (CS) and Cruciate Retaining (CR) (CS) cemented knee

Outcomes
Lateral Release, Knee Society Score (KSS), Surgical Details, Range of Motion (ROM) Complications.

Study Design
Prospective Controlled Trial

A group of 543 primary Original P.F.C. knees, consecutively implanted Jan 1995 to Dec 1997, were compared to 423 primary SIGMA FB knees, consecutively implanted Oct 1998 to Dec 2000.

9.4% of the Original P.F.C. knees and 6.7% of the SIGMA knees were cruciate sacrificing, with the rest cruciate retaining. Patellas were not routinely resurfaced and all were cemented.

Patients were followed up at 6 months post-operatively.

Results
Significantly fewer patients had lateral release with the SIGMA knee than with the Original P.F.C. knee (15.1% v 28.9%; p<0.001). Length of hospital stay was also significantly shorter for SIGMA knee patients than for Original P.F.C. knee patients (9.3 v 11.4 days; p<0.001).

There was no significant difference in pre-operative or post-operative ROM between the two groups, and this applied to both cruciate retaining and sacrificing prostheses.

For all patients there was no significant difference in pre-operative and post-operative ROM, with the Original P.F.C. knee ROM was 96° and 90° respectively and with the SIGMA knee ROM was 98° and 91° respectively.

There was also no difference in KSS between the two groups (no p values).

At 6 months, the mean KS knee score was 80.6 with the Original P.F.C. knee and 83.6 with the SIGMA knee.

The deep infection rate was higher in the SIGMA group (0.6% vs. 1.2%), but this was not statistically significant. Mortality for both groups was comparable, being 1.5% in the Original P.F.C. group and 1.1% in the SIGMA group at 6 months.

The only revision required at 6 months was for an infection.

Study Conclusion
The changes in the trochlear groove on the femoral component appear to have improved patellar tracking. This has resulted in a reduction in the incidence of lateral release with the SIGMA knee compared to the Original P.F.C. knee. Short-term outcomes show that the knee scores are unchanged following the introduction of the SIGMA knee.
Objective
To define an effective intra-operative protocol for a computer aided kinematic evaluation of knee stability before and after total and unicompartmental knee replacement.

Treatment
SIGMA Rotating Platform Flex (RPF), Posterior Stabilised (PS) knee implanted using Computer Aided Surgery (CAS).

Comparator
PRESERVATION™ Uni-Compartmental knee (DePuy Synthes), implanted using CAS.

Outcomes
Operative Details, Varus/ Valgus (VV) Laxity, Anterior/ Posterior (AP) Displacement, Complications.

Study Design
Prospective Controlled Study

Group of 20 consecutively selected patients from September 2006 to February 2007 were treated surgically using CAS (KIN-Nav), all performed by one surgeon. 10 patients had multicompartamental osteoarthritis and were treated with a SIGMA RPF posterior stabilised total knee arthroplasty (TKA). The remaining 10 had unicompartamental knee arthroplasties (UKA) with the Preservation Uni-Compartmental knee system (DePuy) prosthesis. Use of cement and treatment of the patella were not stated.

Results
The added operative time for kinematic testing was 12.7 min, and no complications occurred due to CAS.

For the TKA group, VV laxity at extension was significantly reduced from 7.9° to 5.6° (p<0.01). At 30° of flexion VV laxity of the replaced knee was similar to that of the OA knee (6.7 to 7.7°).

For the UKA group, VV laxity at extension was significantly reduced from 7.7° to 4.0° (p<0.01). At 30° the difference between pre- and post-operative laxity was not significant (7.3 to 6.0°).

Analysis of the anteroposterior displacement of the knee compartments confirmed that UKA produces small changes in AP behaviour. The two prostheses did not produce medial pivoting, but a similar behavior of the two compartments and a range of AP displacements less than those obtained for UKA patients.

Study Conclusion
Intra-operative kinematic evaluations with CAS provided new information on the functional outcome of the reconstruction, which is useful in the restoration of knee kinematics during surgery. The study concluded that use of CAS is preferable for both component alignment and kinematic evaluation during surgery.
30. ANALYSIS OF THE OUTCOME IN MALE AND FEMALE PATIENTS USING A UNISEX TOTAL KNEE REPLACEMENT SYSTEM

Dalury D, Mason J, Murphy J, Adams M.
Journal of Bone and Joint Surgery (Br) 2009;91:357-60

Objective
To determine if the outcome of Total Knee Arthroplasty (TKA) using a modern unisex knee replacements system is different for male and female patients.

Treatment
SIGMA Fixed Bearing (FB) cemented knee in males

 Comparator
SIGMA Fixed Bearing (FB) cemented knee in females

Outcomes
Knee Society Score (KSS), Radiographic Analysis, Osteolysis, Complications, Range of Motion (ROM), Survivorship.

Study Design
Prospective Controlled Study

The results of 1316 cemented SIGMA Fixed Bearing knees are reported here, and have also previously been reported as a prospective consecutive case series by the same author.

Original diagnosis of the patients was osteoarthritis in 1269 (96.4%), rheumatoid arthritis in 24 (1.8%), post-traumatic arthritis in 14 (1.1%), and osteonecrosis in 9 (0.7%).

All implants were cemented, and 81.2% were cruciate retaining designs. The patella was resurfaced in 94.5% of patients.

This is a comparison of 602 women and 384 men with a mean age of 68.6 years and with 7.3 years mean follow up (min 5 years).

Results
There was no difference in pre-operative demographic characteristics and BMI, other than gender. However, pre-operative KS function, flexion and pain scores were significantly lower in women.

Men had significantly higher post-operative improvements in KSS (35.95 vs. 31.06, p=0.003) but also had more osteolysis (3.8% vs. 1.1%, p<0.001) and more radiolucencies (4.69% vs. 1.99% p=0.001).

There were no significant differences between male and female patients; in complications (Men: 2.68%, Women: 2.02%); post-operative improvements in KS function (women: 23.26, men: 22.49, p=1.0); improvements in KS pain score (Men: 34.21, Women:33.82, p=0.968); change in flexion and extension (p>0.05). There were also no significant differences in the stress shielding or radiologic loosening between the two groups.

Mean KS knee scores were 53.93 pre-operatively and 86.5 post-operatively for females and 51.48 pre-operatively 88.61 post-operatively for males.

Mean KS function scores were 43.68 pre-operatively and 67.22 post-operatively for females and 51.59 pre-operatively and 76.12 post-operatively for males.

Mean KS pain scores were 7.27 pre-operatively and 41.34 post-operatively for females and 8.66 pre-operatively and 43.18 post-operatively for males.

The estimated ten year survivorship was 97% in women and 98% in men (p=0.96).

Study Conclusion
Men had significantly better KS knee scores but also had more osteolysis.

Despite these findings, there was little difference between the genders treated with this unisex design. Implant survivorship was also very similar between the two groups.
31. EXTENSOR MECHANISM FUNCTION IN SINGLE RADIUS VS. MULTIRADIUS FEMORAL COMPONENTS FOR TOTAL KNEE ARTHROPLASTY

Hall J, Copp S, Adelson W, D’Lima D, Colwell C.
Journal of Arthroplasty 2008;23(2):216-9

Objective
To compare a contemporary single sagittal radius design of cruciate retaining total knee arthroplasty with a contemporary multiradius design.

Treatment
SIGMA Fixed Bearing (FB), Cruciate Retaining (CR) cemented knee – Multiradius Design

Comparator
SCORPIO® (CR) cemented knee (Stryker®) – Single Radius Design

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Anterior Knee Pain.

Study Design
Prospective Controlled Study

A group of 100 knees were prospectively allocated to each prosthesis type. There were 50 knees that received a single radius SCORPIO prosthesis, and 50 knees that received a multi radius SIGMA prosthesis.

The initial diagnosis and inclusion criteria were that patients had osteoarthritis, posttraumatic arthritis, or osteonecrosis. Both devices were cruciate retaining, all patellas were routinely resurfaced and all components were cemented. All patients were followed up at 4-6 weeks, 3 months and 1 year.

Results
There were no differences in the pre-operative patient demographics or clinical status. Mean age was 69.5 and 72.6 for the SCORPIO and SIGMA groups respectively.

Flexion values and KSS showed no significant differences between the two prostheses at any time points (P>0.05).

Mean KS knee scores were 43 pre-operatively and 83.4 post-operatively for the SIGMA group and 45 pre-operatively and 85.7 post-operatively for the SCORPIO group.

Mean KS function score was 55.3 pre-operatively and 67.8 post-operatively in the SIGMA group and 52.4 pre-operatively and 67.1 post-operatively for the SCORPIO group.

Mean flexion values showed no significant differences between the groups at any time point. At final follow up (1 year) the mean flexion was 111.7° for the SIGMA group and 109.5° for the SCORPIO group and (p<0.05).

Extension improved in both groups over the 1 year period. A difference in extension favoured the SIGMA knee at 4-6 weeks (SIGMA: -2.7°, SCORPIO: -4.3°, p =0.01), but this was not clinically important and resolved at 1 year (SIGMA: 0.8°, SCORPIO: 0.7°, p =0.9).

The ability to rise from a chair without assistance increased from 42% at 4-6 weeks post-operatively to 82% at 1 year post-operatively with the SIGMA knee. The increase was from 38% to 88% with the SCORPIO knee without significant differences between groups at any time point.

Incidence of anterior knee pain whilst rising from a chair decreased from 28% to 11% with the SIGMA knee and 32% to 15% in patients with the SCORPIO knee, at 4 to 6 weeks and 1 year without any significant differences at any time.

Study Conclusion
Knee extensor mechanism function after total knee arthroplasty (TKA) with either the SIGMA CR multi radius or SCORPIO single radius implant was comparable in contemporary posterior cruciate ligament retaining TKA and early outcomes were similar. Long-term follow up of these two implant types will determine which is more effective.
Objective
The aims of this study were to assess the clinical outcomes particularly range of motion (ROM) after total knee arthroplasty (TKA) with the SIGMA Rotating Platform Flex (RPF) knee, vs. the LCS Rotating Platform (RP) knee.

Treatment
SIGMA Rotating Platform Flex (RPF) knee

Comparator
LCS Rotating Platform (RP) knee

Outcomes
Range of Motion (ROM), Knee Society Score (KSS)

Study Design
Prospective Controlled Study

A group of 110 knees underwent TKA with the LCS RP knee, and were prospectively compared to 59 knees with SIGMA RPF knees.

Clinical outcomes were compared at 1 year follow up. The LCS AP glide was excluded.

Results
There was no difference in the mean post-operative active non weight bearing ROM, which was 127° with the SIGMA RPF knee and 124° with the LCS RP knee (p= 0.55).

There were no significant differences in the mean post-operative KS knee scores, (94.12 LCS RP vs 93.54 RPF ; p=0.50), or the mean post-operative KS function scores (62.58 LCS RP vs 65.14 RPF; p=0.91), or the mean post-operative HSS scores (87.73 LCS RP vs 87.85 RPF; p=0.50).

Study Conclusion
There were no significant differences between the groups for any of the clinical scores.
33. PREDICTION OF PERSISTENT PAIN AFTER TOTAL KNEE REPLACEMENT FOR OSTEOARTHRITIS

Lundblad H, Kreicbergs A, Jansson KÅ.

Objective
To test whether separate pre-operative assessments of pain at rest and on movement could be of value in predicting the effect of total knee arthroplasty (TKA) on pain in patients with osteoarthritis (OA). Also, to establish the usefulness of the Pain Matcher as a tool for measuring different aspects of pain in OA, and its value in predicting pain relief.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) knee

Study Design
Prospective Controlled Study

A group of 69 prospective patients scheduled for TKA, with knee pain with a mean duration of 8.5 years, formed the study group. All patients in the study group received a posterior retaining SIGMA (FB) knee for an original diagnosis of osteoarthritis. The use of cement was not mentioned and the patella was not resurfaced in all cases. A group of 24 non-TKA patients, who had no pain and were healthy, acted as a control group and were tested for the same thresholds.

Pre-operatively a Pain Matcher device gave an electrical stimulus which matches the intensity but not necessarily the nature of the actual pain, and was used to provide five scores:

Sensation Threshold: the first notable sensation.

Pain Threshold: When the perceived signal was painful.

Matched Pain: device started again, patient's state when their pain is of the same level as pain from their knee at movement.

Pre-operative Pain at Rest: Measured using the Pain Matcher and a Visual Analogue Scale (VAS).

Pre-operative Pain with movement: Measured using the Pain Matcher and VAS.

Post-operatively patients rated pain at rest and pain with movement using VAS, measured at 18 months.

Multivariate regression analyses were conducted to measure the predictive power of pre-operative status, such as pain and pain threshold using VAS and the Pain Matcher.

Results
Pre-operatively 23% of patients had no pain at rest. Pain at rest was significantly less than pain with movement (p<0.001). All patients, except four, rated their pain with movement as almost three times higher (2.9) than pain at rest on VAS.

The patient group had a significantly higher sensation threshold than the control group (7.1 vs. 4.5 p <0.001) and a significantly lower pain threshold (16.4 v. 21.1, p= 0.012). Women had significantly lower sensation thresholds than men (6.4 vs. 7.8, p=0.017) and lower pain threshold (13.5 vs. 19.4, p=0.004) than men.

At 18 months post-operatively, 34% had no pain and rest or movement. 24% had pain at rest. 66% had pain during movement.

Only two variables, pain at rest and pain threshold, were found to be predictive of post-operative pain in the regression analysis. Greater pain at rest and a lower threshold for pain were associated with a worse post-operative outcome in terms of pain.

Study Conclusion
The relationship between pain before and after surgery is a complex interaction of the type of pain and the sensory threshold of individuals. Numerical pain scores should be applied separately to different aspects of pain, pain at rest and pain with movement.

Patients with a high VAS scores for pain at rest and low pain thresholds should not be precluded from TKR, but they should be made aware of the higher risk of persistent pain post-operatively.
Objective
The aim of this study was to compare the early clinical outcomes and radiological results after bilateral total knee replacement (TKR) first using a conventional posterior stabilised implant and later using a high flexion total knee arthroplasty (TKA) in the contralateral side.

Treatment
SIGMA Rotating Platform Flex (RPF), Posterior Stabilised (PS) cemented knee

Comparator
SIGMA Fixed Bearing (FB), Posterior Stabilised (PS) cemented knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Radiographic Analysis, Tibial Slope.

Study Design
Prospective Controlled Study

In 2007, 20 patients eligible to receive staged bilateral TKR first received a SIGMA PS Knee, and then 6 to 8 months later, on the contralateral knee, received a SIGMA RPF Knee. All patients in the study had been diagnosed with bilateral degenerative arthritis.

Tibial and femoral components were all cemented. Patients were followed up for 1 year. The patellas were always resurfaced and cemented.

Results
Pre-operative clinical status was similar in each group.

There was no difference in KS knee scores (p= 0.3) but the SIGMA RPF group had a significantly better KS function score (p= 0.004).

Mean KS knee scores were 41 pre-operatively and 86 post-operatively in the SIGMA PS group, and 40 pre-operatively and 88 post-operatively in the SIGMA RPF group.

Mean KS function scores were 44 pre-operatively and 81 post-operatively in the SIGMA PS group, and 43 pre-operatively and 91 post-operatively in the SIGMA RPF group.

Mean maximal flexion was significantly higher in the RPF group in comparison to the PS group (119° vs. 97°, p= 0.0007).

There was no difference in the other radiological findings, including: tibial slope (p= 0.5) femoral flexion (p= 0.3) tibial anterior (p=0.15) and femoral anterior (p=0.2).

Study Conclusion
The high flexion design, SIGMA RPF, is associated with a higher range of motion of the knee, resulting in better functional outcomes. The mean KS function score was also significantly higher for the RPF implant, although there was no difference in the mean KS knee score.
Objective
To investigate the differences in clinical performance between the two designs and the functional knee kinematics during weight bearing KB and DKB activities. Focus was specifically placed on knee AP instability.

Treatment
P.F.C. SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee

Comparator
Continuum® Knee System (CKS) (Zimmer®)

Outcomes
WOMAC, Visual Analogue Scale (VAS), Knee Society Score (KSS)

Study Design
Prospective Controlled Study

This study compares the results of TKA over two periods of time, during the first period of time all patients were implanted with the P.F.C. SIGMA design and then in the second period of time (due to a change in hospital protocol) all patients were implanted with the CKS design. During the follow up, surgeons believed that the CKS design was showing less favourable results and the use of this design was stopped.

Patients were randomly selected from a large CKS group by an independent researcher, these patients were then matched with patients from the P.F.C. SIGMA FB CR group by diagnosis and age.

In the analysis there were 19 P.F.C. SIGMA FB CR knees and 14 CKS knees. The indication for surgery was rheumatoid arthritis in 3 of the 19 P.F.C. SIGMA knees and 2 of the 14 CKS knees. Otherwise, the diagnosis was osteoarthritis. The median age was 69 years in the P.F.C. SIGMA group and 69 years in the CKS group. The median follow up was 40 months in the P.F.C. SIGMA group and 32 months in the CKS group. Patients were assessed by clinical outcomes measures and fluoroscopic investigations.

Results
The WOMAC joint stiffness total score was 87.5% for the P.F.C. SIGMA group and 75% for the CKS group which was significantly different (p=0.05). This indicates that the P.F.C. SIGMA patients exhibited less joint stiffness.

Median post-operative KS knee scores with both the P.F.C. SIGMA FB CR and CKS knees were 93.

Median post-operative KS functions scores were 80 and 68 for the P.F.C. SIGMA FB CR and CKS knee respectively. However, this difference was not statistically significant.

There were no statistically significant differences in the total WOMAC score, VAS pain, VAS satisfaction, total KSS score, ROM, stability, and limitations.

During knee bending (KB) and deep knee bending (DKB) activities, the CKS tibia was more internally rotated (p<0.05, ANOVA). From maximum extension to maximum flexion during DKB activities, the CKS design showed a significantly lower range of tibial rotation than the P.F.C. SIGMA design (p<0.05).

Condylar translation from 0° to 30° was not significantly different for the two designs, but from 30° to 100° flexion the medial contact locations were significantly more anterior in the CKS knees (p<0.05). The lateral contact location at 70° to 80° flexion was significantly different (p<0.05) during knee bending activity, with the CKS knee translating more anteriorly.

Study Conclusion
In conclusion, in this study the clinical scores and kinematic analyses revealed differences between the P.F.C. SIGMA and CKS knees. Kinematic analyses demonstrated that the CKS design has larger AP translations. Additionally, there was significantly more joint stiffness with the CKS knee than the P.F.C. SIGMA knee. However, it remains unclear whether this can be ascribed to PCL deficiency, or whether it is a combination of implant design factors and post-operative ligament laxity.
Objective
To compare the clinical, functional and radiological outcomes following total knee arthroplasty (TKA) done with the high flex INDUS Knee and a conventional posteriorly stabilised prosthesis.

Treatment
SIGMA Fixed Bearing (FB), Posterior Stabilised (PS) cemented knee

Comparator
INDUS High Flexion, Posterior Stabilised (PS) cemented knee (BioRad Medisys)

Outcomes
Visual Analogue Scale (VAS) Pain Score, Range of Motion (ROM), Knee Alignment, and Knee Society Score (KSS).

Study Design
Prospective Controlled Study

Between Jan 2007 to April 2008 in India, 50 patients received a posterior stabilised SIGMA FB knee, and were compared to 50 patients receiving the INDUS High Flexion knee. All knees were cemented, with a cemented all-polyethylene patella, and all patients were diagnosed with osteoarthritis.

Patients with a minimum of 1 year follow up were reviewed.

Results
Patient demographics were similar in both groups, but pre-operative clinical status was not reported. Mean patient age was 63.5 and 65.2 in the INDUS and SIGMA group respectively.

There was no difference in mean post-operative VAS pain score between the groups. The mean score was lower on average in the INDUS group, but this was not statistically significant (43.75 vs. 45.25, p=0.5).

At 1 year follow up, the mean range of motion for the INDUS group was significantly higher 128° compared to 107.5° for the SIGMA group (p< 0.001).

There was no difference in post-operative flexion deformity, which was 2.8° and 3.95° for the SIGMA group and the INDUS group respectively (p=0.26).

There was no difference in the mean post-operative KS knee score, which was 86.9 for the SIGMA group and 89.7 for the INDUS group (p=0.35).

Mean post-operative KS function score was 85.25 for the P.F.C. SIGMA group and 89.75 for the INDUS group, statistically better for the INDUS group (p<0.01).

Study Conclusion
In this study, post-operatively the INDUS group had better ROM and KS function score compared to the SIGMA FB PS group. The improvement in other outcomes was comparable, including pain score, flexion deformity and KS knee score.
37. MOBILE BEARING TOTAL KNEE ARTHROPLASTY IMPROVES PATELLAR TRACKING AND PATELLO-FEMORAL CONTACT STRESS

Sawaguchi N, Majima T, Ishigaki T, Mori N, Terashima T, Minami A.

Objective
To evaluate the effect of rotating platform knee replacement on patellar tracking, patello-femoral force and tibial rotation, through an intra-operative comparison of mobile and fixed bearing tibial components in the same knee using computer aided surgery.

Treatment
SIGMA Rotating Platform Flex (RPF) knee, tibial component evaluated intra-operatively

Comparator
SIGMA Fixed Bearing (FB) posterior stabilised (PS) knee, tibial component evaluated intra-operatively

Outcomes
Tibial Rotation, Medial Shift, Patellar Tilt, Patello-femoral Contact Stress, Patellar Tracking.

Study Design
Prospective Controlled Study

A group of 66 patients with a unilateral posterior stabilised SIGMA RPF knees implanted between 2006 and 2008 were included in this study. The initial diagnosis in all patients was osteoarthritis, but the decision to cement was not stated.

Intra-operatively, SIGMA FB PS and RPF tibial components were trialled in the same knee and evaluated using computer aided surgery (CAS, Vector Vision). Following the evaluation, all patients went on to have a SIGMA RPF knee.

Results
All of the following are intra-operative findings with FB and RPF components trialled on the same knee:

- Tibial rotation from extension to flexion was not significantly different between FB (6.93°) and RPF (7.83°) knees.
- With the FB tibial component there was significantly higher, medial shift of the patella (4.2mm vs. 3.35mm), patello-femoral contact pressure (1.42MPa vs. 0.98MPa) and lateral tilt of the patella (6.79° vs. 5.14°). All p values were stated as p<0.05.
- Patello-femoral (PF) contact stress increased during knee flexion in all knees. The FB knee had a greater PF contact stress intra-operatively especially in the last half of the range of knee flexion angle.

Study Conclusion
In intra-operative measurements using CAS, mobile bearing TKA with the SIGMA RPF knee significantly improved patellar tracking and decreased patello-femoral contact stress compared with the SIGMA FB PS knee.
Objective
To compare the early post-operative pain, function and recovery in simultaneous bilateral vs. unilateral computer assisted total knee arthroplasty (TKA).

Treatment
Simultaneous Bilateral TKA using the SIGMA Posterior Stabilised (PS) Fixed Bearing (FB) or Rotating Platform (RP) cemented knee

Comparator
Unilateral TKA using the SIGMA Posterior Stabilised (PS) Fixed Bearing (FB) or Rotating Platform (RP) cemented knee

Outcomes
Operative Details, Length of Stay, Visual Analogue Scale (VAS) Pain, Short Leg Raise, Range of Motion (ROM), Complications.

Study Design
Prospective Controlled Study

Between July 2008 and December 2008, the senior author (AM) performed 58 simultaneous bilateral TKAs (SBTKA) and these were compared to 46 unilateral TKAs.

The SIGMA FB (all-polyethylene tibia) was used for elderly, low demand patients with good bone quality, the SIGMA FB (metal backed tibia) was used in patients that were obese or with poor bone quality, and the SIGMA RP design was used in patients that demanded increased flexion post-operatively. The original diagnosis for all patients was osteoarthritis.

All implants were implanted using the Computer Aided Surgery (CAS) Ci System, and all were fixed with cement. All designs were cruciate sacrificing versions and all patients had patella resurfacing. Patients were followed until they were discharged from hospital.

Results
There was no difference in patient demographics or pre-operative clinical status between the groups. An exception was that the Hip-Knee-Ankle (HKA) angle was significantly greater in the unilateral group (172.1° v 168.6°, p=0.008).

There was no significant difference in tourniquet time between the two groups.

Length of stay was significantly shorter for the unilateral group compared to SBTKA group (4.2 days vs. 5.1 days, p=0.0005).

The mean difference in post-operative mean VAS pain score was significantly better in the unilateral group on day 1, but was not significantly different for the rest of the hospital stay and at the time of discharge.

Active short leg raise (SLR) was not possible in 18% of the unilateral group and 15% of the SBTKA group. Extensor lag was present in 22% of the unilateral group and 24% of the SBTKA group. Faradic stimulation due to extensor weakness and lag was needed for 28% of the unilateral group and 34% of SBTKA group. None of these differences were statistically significant (p=0.64, p=0.84, and p=0.57 respectively).

There was a statistically significant difference in the mean time it took for patients to walk with a stick. The SBTKA group lagged behind the unilateral group by approximately 24 h (49.4 hours vs. 72.3 hours; p=0.0001).

There was no difference in post-operative mean ROM, 97.1° for the unilateral group and 95.1° for the bilateral group (p=0.058).

There were 9 complications overall in the 150 knees, 5 in the SBTKA group and 4 in the unilateral group (p=0.05). However, post-operative haemoglobin levels were significantly lower in the SBTKA group (p<0.0001). Transfusion of packed cells was required in 18% and 6% of the SBTKA and unilateral groups respectively.

Study Conclusion
Duration of hospital stay, pain, and functional recovery for bilateral TKA are comparable to those after unilateral TKA. Patients with simultaneous bilateral SIGMA TKAs using CAS had excellent pain relief and functional recovery equivalent to patients with unilateral SIGMA TKAs. Functional results were helped by accelerated rehabilitation from the use of a multimodal peri-operative pain management and good pain control.
LEVEL III STUDIES: RETROSPECTIVE NON-RANDOMISED CONTROLLED TRIALS
39. MIDTERM RESULTS OF CEMENTED P.F.C. SIGMA TOTAL KNEE ARTHROPLASTY SYSTEM

Asif S, Choon D.

Objective
To evaluate and compare the midterm results of 50 patients who underwent total knee replacement (TKR) with a cruciate retaining and posterior stabilised SIGMA knees.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee.

Outcomes
Knee Society Score (KSS), Oxford Knee Score (OKS), Pain Score, Range of Motion (ROM), Survivorhip, Radiographic Analysis, Complications.

Study Design
Retrospective Controlled Study

The authors retrospectively reviewed 87 SIGMA knees implanted in 50 patients by a number of surgeons at 1 centre between Jan 1998 and Dec 1999.

There were 53 cruciate retaining (CR) and 26 cruciate sacrificing (CS) knees. All implants were cemented, and 34 patellas were resurfaced and 45 were not. Patients were followed for 5.4 years.

The initial diagnosis was osteoarthritis in 44 patients and rheumatoid arthritis in 6 patients.

Subgroup analyses of outcome by diagnosis for surgery, patella status, and cruciate ligament were performed.

Results
In all knees in the study, the mean post-operative KS knee score was 87 and mean post-operative KS function score was 72. The mean post-operative OKS was 22. 88% of knees were rated excellent, 4% good, 2% fair, and 6% poor.

Implant survival was 94% at 6 years.

Five knees (4 patients) required revision surgery: 4 knees (3 patients) because of deep infection and one knee due to aseptic loosening of the tibial component.

Comparison of CR and PS knees found no significant differences in mean post-operative KS knee score (CR:88 vs. PS: 85; p=0.43), mean post-operative KS function score (CR: 75 vs. PS: 66, p=0.38) and mean post-operative OKS (CR: 21 vs. PS: 24; p=0.21).

Sub-analysis compared osteoarthritis (OA) and rheumatoid arthritis (RA). No statistically significant difference was found for mean post-operative KS knee score (OA: 88 vs. RA: 79; p=0.1). However, OA patients had significantly better mean post-operative KS function score (OA: 73 vs. RA: 57; p=0.03) and mean post-operative OKS (OA: 21 vs. RA: 30; p=0.006).

Comparison of patella resurfacing (Yes) vs. no patella resurfacing (No) showed no significant differences in mean post-operative KS knee score (Yes: 85 vs. No: 88; p =0.26), mean post-operative KS function score (Yes: 71 vs. No: 72; p=0.76) and mean post-operative OKS (Yes: 22 vs. No: 22; p=0.9).

At final follow up 82% had no pain or very mild pain, 13% had pain while climbing stairs, and 5% had moderate pain. Mean active flexion was 105° and mean flexion contracture was 0.6° at final follow up.

Radiolucent lines were found around 6 tibial components and 4 femoral components.

Study Conclusion
The SIGMA total knee arthroplasty system has demonstrated good midterm results at this institution.
40. RANGE OF MOTION AND PATIENT SATISFACTION WITH TRADITIONAL AND HIGH FLEXION ROTATING PLATFORM KNEES

Boese C, Gallo T, Plantikow C.
Iowa Orthopaedic Journal 2011;31:73-7

Objective
The purpose of this study was to evaluate the performance of the SIGMA RP Knee vs. the SIGMA RPF Knee.

Treatment
SIGMA Rotating Platform Flex (RPF) Posterior Stabilised (PS) knee

Comparator
SIGMA Rotating Platform (RP) Posterior Stabilised (PS) knee

Outcomes
Range of Motion (ROM), Satisfaction, Complications.

Study Design
Retrospective Matched Controlled Study

A group of 64 SIGMA RPF knees were matched to 64 SIGMA RP knee controls. Subjects were matched by pre-operative flexion, gender, age and follow up. All patients were originally diagnosed with osteoarthritis. The surgical procedure was similar in all cases with a medial parapatellar arthrotomy and DePuy Endurance MV cement for all components. All knees were posterior stabilised. Mean follow up was 16.7 months (9-33).

Results
Matched Pair Analysis
There were no significant differences in the increase in flexion between the two groups. On average, flexion increased 3.1° with the RP knee and 1.6° with the RPF knee (p= 0.47). Satisfaction was similar for the two groups (RP: 4.4, RPF: 4.5, p= 0.82).

Patients with <120° flexion
On average, RP knees showed a significantly greater mean increase in flexion post-operatively than RPF knees, 11.4° gained compared to 4.8° (p= 0.004). Satisfaction was similar for the two groups (RP: 4.5, RPF: 4.3, p= 0.26).

Patients with > 120° flexion
For both implants flexion was on average lower post-operatively. With each design there was no difference in the average decrease in flexion, which was 8.3° for the RP group and 6.6° for the RPF group (p= 0.5). Satisfaction was also similar for the two groups (RP: 4.5, RPF: 4.6, p= 0.57).

There was no difference in the number of additional surgeries in each group (p=0.17). Of the 64 matched pairs, four of the RPF patients later had additional surgery on the same knee. Three for painful patella clunk syndrome and one revision because of a loose cement fragment. In the RP group, one had further surgery for painful patella clunk.

Three patients had bilateral implants with one RP knee and one RPF knee. When asked, all three said that they noticed no difference between them.

Study Conclusion
There were no short term improvements in functional or qualitative outcomes for patients with the SIGMA RPF knee vs. the SIGMA RP knee.
41. GAP BALANCING VS. MEASURED RESECTION TECHNIQUE FOR TOTAL KNEE ARTHROPLASTY

Dennis D, Komistek R, Kim R, Sharma A.  
Clinical Orthopaedics and Related Research 2010;468:102–7

Objective  
To compare the measured resection and gap balancing technique for condylar lift off and the location of this lift off.

Treatment  
Gap Balancing Technique with SIGMA Posterior Stabilised (PS) knee

Comparator  
Measured Resection Technique with SIGMA Cruciate Retaining (CR) or PS knee

Outcomes  
Instability, Femoral Lift Off, Femoral Lift Off Location

Study Design  
Retrospective Controlled Study

Variations of the SIGMA knee were used in three groups of 20 patients:  
- Measured Resection (CR)  
- Measured Resection (PS)  
- Gap Balancing (PS)

All patients had a pre-operative diagnosis of osteoarthritis.

All procedures were from 2003-2006, but patient selection was non sequential and non randomised. Treatment of the patella and use of cement were both not stated. Patients were evaluated clinically and fluoroscopically at a minimum of 6 months follow up (6-24 months).

Results  
The incidence of coronal instability (femoral condylar lift off) greater than 0.75mm at any flexion interval was significantly lower in the gap balancing group (7/20) than both of the measured resection groups (16/20 for CR and 14/20 PS) (p=0.003).

Femoral lift off of >1mm was significantly lower with the gap balancing group (0/20) than both of the measured resection groups (14/20 and 11/20 for CR and PS respectively) (p<0.0001).

Mean femoral lift off was significantly lower for the gap balancing group (0.67mm) compared to the measured resection CR group (1.45mm) and PS group (1.11mm) (p=0.0003).

Maximum femoral lift off was significantly lower in the gap balancing group (0.9mm) compared to the measured resection CR group (3.1 mm) and PS group (2.5 mm) (p=0.0002).

Lift off location (medial/lateral) was highly variable between all three cohorts, and there were no major differences between them in the lift off area.

Study Conclusion  
The gap balancing technique resulted in better coronal stability due to less femoral condylar lift off, and had improved results compared to the two measured resection groups (CR and PS).
42. THE JOHN INSALL AWARD: CONTROL-MATCHED EVALUATION OF PAINFUL PATELLAR CREPITUS AFTER TOTAL KNEE ARTHROPLASTY

Dennis D, Kim R, Johnson D, Springer B, Fehring T, Sharma A.
Clinical Orthopaedics and Related Research 2011; 469: 10–7

Objective
To identify when patellar crepitus typically occurs post-operatively and to determine the variables that increase the risk of developing painful, symptomatic patellar crepitus after posterior stabilised total knee arthroplasty (TKA).

Treatment
SIGMA Posterior Stabilised (PS) knee patients with patellar clunk/ patellar crepitus

Comparator
SIGMA Posterior Stabilised (PS) knee patients with no patellar clunk/ patellar crepitus

Outcomes
Multivariate logistic analysis for patellar clunk or crepitus.

Study Design
Retrospective Controlled Study

Between 2002 and 2008 a database of 4000 knees was searched for patients having TKA with patellar crepitus or patellar clunk. From this 60 patients were indentified (16 with patellar clunk, and 44 with patellar crepitus). Matched controls with well functioning TKA were identified from the same database.

All patients received a cruciate sacrificing SIGMA knee prosthesis. Neither the treatment of the patella or the use of cement was explicitly stated, but it appears all patellas were resurfaced. The average time to symptoms for the patellar crepitus group was 10.9 months (4-27 months), whereas the follow up of the control group was 31.3 months.

Patient (height, age, gender), clinical data (patella tilt, joint line etc) and surgical history (previous surgery, patella component size, etc) were extracted from patient records. Multivariate regression analysis was performed to identify if there was an association between any of the variables and patellar clunk or crepitus.

Results
Patient and radiographic variables found to increase the risk of patellar clunk and crepitus were: Pre or post-operative patella tendon length and thinner post-operative patella component thickness.

A history of knee surgery was found to be significantly higher in the patellar complications group. These patients had a mean of 1.18 previous procedures compared with 0.42 in the control group (p<0.05). In the patellar crepitus group, 63% had at least one previous knee surgery compared with 30% in the control group (p< 0.05).

The patella component size was smaller on average for the patellar crepitus group compared to control group, 35.6mm vs. 37.1mm (p<0.05).

Multivariate logistic analysis indicated that patients with increased risk of patellar crepitus were those with previous knee surgery (p= 0.0009), reduced pre-operative patella tendon length (p= 0.0098), and an increase in post-operative posterior femoral condylar offset (p<0.0001). Other risks identified were smaller femoral components (less than size 3; p=0.0253), thicker polyethylene bearings (greater than 12.5 m; p=0.0015) and femoral components implanted in flexion (p=0.0282).

Study Conclusion
Several factors have been found to effect the development of patellar crepitus. The authors believe that many of the factors associated with patellar crepitus are related to either increased irritation or contact forces in the distal quadriceps tendon as it traverses the superior aspect of the intercondylar box of a PS femoral component.
43. DOES GREATER KNEE FLEXION INCREASE PATIENT FUNCTION AND SATISFACTION AFTER TOTAL KNEE ARTHROPLASTY

Devers B, Condit M, Jamieson M, Driscoll M, Noble P, Parsley B.
Journal of Arthroplasty 2011;26(2):178-86

Objective
To determine whether high flexion leads to improved benefits in patient satisfaction, perception, and function after total knee arthroplasty (TKA).

Treatment
SIGMA Fixed Bearing (FB), Posterior Stabilised (PS) knee

Comparator
Range of Motion (ROM), Patient Satisfaction, Knee Society Score (KSS)

Outcomes
Range of Motion (ROM), Satisfaction, Complications.

Study Design
Retrospective Controlled Study

Data was collected on 122 knees in 111 patients previously implanted with a fixed bearing SIGMA knee at least 1 year before the study.

The initial diagnosis of the patients were osteoarthritis (80%), rheumatoid arthritis (8%), and prior trauma (3%). All surgeries were performed by a single surgeon with a posterior stabilised prosthesis. Treatment of the patella and use of cement were not stated.

Patients were sub-categorised by their pre-operative knee flexion into High Flexion (>130°), Mid-Flexion (110-130°) and Low Flexion (<110°) groups. Follow up was a mean of 4 years.

Results
Mean maximum knee flexion was 111° pre-operatively and improved to 120°, with a positive correlation between pre and post-operative flexion (p <0.0001).

Mean post-operative flexion was 134.8 for the High flexion group, 121.0 for the Mid-flexion group and 102.1 for the Low flexion group (p<0.0001).

There was no association between pre-operative knee flexion and post-operative KSS.

Mean post-operative KSS was 93.1 in the High flexion group, 91.4 in the Mid-flexion groups and 87.7 in the Low flexion group (p=0.54).

Greatest satisfaction rates were observed in patients with flexion higher than 130°, but the overall correlation was not statistically significant. However, no patients in the High flexion group were dissatisfied, whereas 17% of the Mid-flexion and 16% of the Low-flexion patients were dissatisfied (p= 0.23).

Increased flexion was positively correlated with the following:
1. Expectations being achieved (p=0.03)
2. No function limitations (p=0.009)
3. Normal feeling knee (p=0.01)
4. Patients More active (p=0.016)

Study Conclusion
Increased knee flexion, particularly to greater than 130°, is likely to lead to improved outcomes after TKA. At a minimum, greater than 110° of flexion is needed to achieve satisfactory function for most patients.
**Objectives**
To compare the radiological and functional outcomes of patients who underwent either computer-assisted or conventional total knee arthroplasty (TKA).

**Treatment**
SIGMA knee, implanted with Computer Aided Surgery (CAS)

**Comparator**
SCORPIO® (Stryker®) or Natural-Knee® (Zimmer®) implanted with conventional instruments

**Outcomes**
Surgical Details, Complications, Knee Alignment, Short Form 12 Score (SF-12), International Knee Score (IKS)

**Study Design**
Retrospective Controlled Study

Two groups of 50 patients each underwent either CAS (Ci System) or conventional total knee arthroplasty at one Australian hospital between December 2003 and March 2005.

The CAS group had 23 months follow up and received the SIGMA prosthesis. The conventional group had 18 months follow up and received the SCORPIO (Stryker) or Natural-Knee (Zimmer) prosthesis. Cruciate treatment was decided during treatment, and treatment of the patella was not stated.

**Results**
No intra-operative technical difficulties were encountered in either group.

The CAS group had a significantly longer mean surgery time (122 vs. 108 mins; p=0.002) but peri-operative blood losses were comparable (33 g/l) to the conventional group (32 g/l; p=0.8).

The CAS group resulted in more accurate alignments in both the coronal and sagittal planes and a significantly better overall IKS knee score (p=0.002).

For CAS and conventional groups respectively, the number of TKAs with a deviation of >5° were 0 and 5 (p=0.002). The number of deviations within 3° of neutral were 39/78 and 31/62 (p=0.046) and the mean deviation from neutral was 1.9° and 3.1° (p=0.02).

There were significantly more accurate alignments in the CAS group compared to the conventional group in non-obese patients (1.8° vs. 3.3°; p=0.01), but not in obese patients (2.9° vs. 2.1°; p=0.15). The CAS group also had significantly more patients within the optimal ±3° of neutral in both obese (80% vs. 64%, p=0.02) and non-obese (84% vs. 64%, p=0.002) patients.

The mean post-operative physical component of the SF-12 score was significantly better for the CAS group (41 vs. 37, p=0.04). The mean post-operative IKS knee score (84 vs 77, p=0.05) and combined IKS scores (164 v 106, p=0.002) were significantly higher (better) for the CAS group using the SIGMA knee.

**Study Conclusion**
The results of this study indicate that computer-assisted surgery may be attributed to improved implant positioning, limb alignment, and overall functional outcome. These results also indicate it’s particularly advantageous for improved alignment in obese patients.
45. COMPARATIVE FLEXION AFTER ROTATING PLATFORM VS. FIXED BEARING TOTAL KNEE ARTHROPLASTY


Objective
To identify any difference in post-operative flexion between fixed bearing (FB) and rotating platform (RP) articulations in an otherwise identical posterior cruciate retaining total knee arthroplasty (TKA). Furthermore, to assess the accuracy of intra-operative flexion as a predictor of post-operative motion in both groups.

Treatment
SIGMA Rotating Platform (RP), Cruciate Retaining (CR) hybrid/cemented knee

Comparator
SIGMA Fixed Bearing (FB), Cruciate Retaining (CR) hybrid/cemented knee

Outcomes
Multivariate logistic analysis for patellar clunk or crepitus.

Study Design
Retrospective Controlled Study

A consecutive series of 113 SIGMA RP knees in 87 patients with minimum 2 year follow up were selected for this study. A control group of 100 consecutive SIGMA FB knees in 83 patients was selected as the control group. Osteoarthritis was the original diagnosis in all patients

In the RP group, 65% of femoral components were cemented, compared to 98% in the FB group. All tibial components were cemented in both groups. All knees were cruciate retaining and the patellas were resurfaced in all cases.

All patients were seen by 1 of 2 surgeons at 1 of 2 institutions. All patients were followed for a minimum of 2 years.

Results
Patients in the FB group were older (67.7 v 63.4 years p<0.001), while there were more male patients (45% v 34%) and the patients were heavier (91.3 v 82 kg, p<0.001) in the RP group.

There were 4 complications in 3 patients in the RP group and 3 complications in the FB group.

There were no statistically significant findings from any of the range of motion aspects between the groups.

There was no difference in the mean post-operative flexion in the RP group, 116° (50°-135°), and the FB group, 113° (85°-140°), (p=0.08). The mean total range of motion was similar for both knees, 116° for the RP group, and 112° for the FB group (p=0.07). The mean change in flexion was also similar in both groups, 2° for the RP group and 4° for the FB group (p= 0.46).

Multivariate analysis revealed that the only independent factors predicting post-operative flexion were: Pre-operative flexion (p= 0.001), intra-operative flexion (p=0.01) and posterior cruciate ligament (PCL) recession (p=0.05). Patients with the PCL recessed generally have lower post-operative flexion than patients who do not.

Study Conclusion
There was no significant difference in knee flexion after either fixed bearing or rotating platform cruciate retaining total knee arthroplasty.
Objective
To assess the reasons for spinout after cruciate retaining mobile bearing design, and to assess the outcomes of revision to these patients.

Treatment
SIGMA Rotating Platform (RP), Cruciate Retaining (CR) knee.

Outcomes
Pre-Disposing Factors to Spinout, Activities at time of spinout, Surgeries after spin out.

Study Design
Retrospective Controlled Study

The study group included 1255 cruciate retaining mobile bearing total knee patients performed at 2 total joint centres. From this, 7 knees were identified as having bearing spin out. These were then compared to the 1248 without spinout. No patellas were resurfaced in this series and the use of cement was not stated. Of the 7 patients with spin-out, the original diagnosis of the patients was osteoarthritis (OA) in 5 and rheumatoid arthritis (RA) in 2.

Results
Patient factors found to have a statistically significantly increased risk of spin out were:

Female Gender
Of 785 women, 7 (0.89%) experienced spinout compared with 0 of 470 (0%) men (p=0.048).

Pre-operative varus knee alignment of greater than 7°
All 7 spinout patients (100%) had pre-operative varus knee alignment of greater than 7° compared with 188 (15.1%) of 1248 of non-spinout patients (P<0.0001).

Increased Body Mass Index (BMI)
All 7 spinout patients were obese, and had an average BMI of 38.7. BMI was greater than 30 in 100% (7/7) of spinout patients compared with 42.2% (527/1248) of non spinout patients (p = 0.0022).

Six of the bearing spinouts occurred within 6 months. Standing alignment radiographs of the spinout group were all within 2° of the stated goal. Patient reported activities at time of spin-out were sitting in or rising from a chair, sitting cross legged during a fall.

Three spin outs could be re-located by closed means, but 4 required surgical procedures. Six of the 7 eventually had a tibial bearing exchange and 1 had a revision of the femoral component to a posterior stabilised implant and bearing. Two patients who underwent bearing exchange developed deep sepsis and ultimately required a 2-stage revision to resolve the complication.

Study Conclusion
Female gender, obesity, and pre-operative valgus deformity are patient factors associated with spinout. In general, operative treatment was successful, but significant complications occurred in 3 of the 7 patients.
47. EFFECT OF FEMORAL COMPONENT DESIGN ON PATELLO-FEMORAL CREPITANCE AND PATELLA CLUNK SYNDROME AFTER POSTERIOR STABILISED TOTAL KNEE ARTHROPLASTY

Frye B, Floyd M, Pham D, Feldman J, Hamlin B.
Journal of Arthroplasty 2012;27(6):1166-70

Objective
To assess the femoral component design in a posterior stabilised total knee arthroplasty (TKA) and the incidence of patella-femoral complications. Also, to determine if changing the femoral component design of a particular posterior stabilised total knee prosthesis would affect the incidence of patello-femoral crepitance and patella clunk syndrome.

Treatment
SIGMA Posterior Stabilised (PS) Fixed Bearing (FB) and Rotating Platform (RP) cemented knees with a new deep trochlear groove femoral component

Comparator
SIGMA Posterior Stabilised PS Fixed Bearing (FB) and Rotating Platform (RP) cemented knees component with the original cruciate sacrificing (CS) femoral component

Outcomes
Patella Clunk, Patella Crepitance, Patello-Femoral Complications.

Study Design
Retrospective Controlled Study

Between October 2006 and September 2009, a posterior stabilised SIGMA knee was implanted in all patients. Group 1 consisted of 108 knees with an original CS femoral component, and Group 2 consisted of 136 knees with a new femoral component with a deeper trochlear groove and a smoother intercondylar box (a newer design of the same implant, the SIGMA PS component).

Both RP and FB inserts were used as determined by the surgeon. All patellas, apart from 1, were resurfaced. All components were cemented. The original diagnosis of the patients was not reported. Mean follow up was 17.7 months for Group 1 and 12.4 months for group 2.

Results
In group 1, there were 9 cases of patellar crepitance, and 4 cases of patellar clunk syndrome. In group 2, no patient reported any patella catching, grinding, clunking and no patello-femoral crepitance. This difference was statistically significant (12% vs. 0%, p<0.0001).

Four of the 9 patients with patellar crepitance in group 1 had arthroscopic debridement which revealed a large fibrous nodule. All four patients had complete relief after debridement of the nodule.

There were statistically significant differences in the rate of lateral release (15 v 8; p<0.03), post-operative flexion (114° v 107°; p<0.001), patella component size (34.5 v 35.6mm; p<.004) and degree of patella tilt (4.66 v 3.49; p=0.0078) between groups 1 and 2 respectively.

Using nominal logistic regression analysis and adjusting for each significantly different variable, there was still a significant difference in the number of patello-femoral complications between the groups.

No particular size of femoral or patella component was associated with an increased likelihood for patello-femoral crepitance or clunk.

Study Conclusion
The change in the shape of the trochlear groove and intercondylar box of the posteriorly stabilised SIGMA knee has led to the incidence of symptomatic patello-femoral complications decreasing from 12% to 0% in this series of patients. There were no significant confounding variables, suggesting that the design changes of the femoral component are responsible for the decrease in these types of complication.
48. COMPARISON OF A NEW MOBILE BEARING TOTAL KNEE PROSTHESIS
WITH A FIXED BEARING PROSTHESIS: A MATCHED PAIR ANALYSIS

Geiger F, Mau H, Krüger M, Thomsen M.
Archives of Orthopaedic and Trauma Surgery 2008;128:285–91

Objective
To compare the e.motion® knee prosthesis (Aesculap) to an established total knee arthroplasty (TKA) in a controlled matched-pair analysis, prior to its general introduction to the market.

Treatment
e.motion Mobile Bearing (MB), Cruciate Retaining (CR) cemented knee (Aesculap), implanted with Computer Aided Surgery (CAS)

Comparator
SIGMA Fixed Bearing (FB), Cruciate Retaining (CR) cemented knee, implanted with conventional instruments

Outcomes
Range of Motion (ROM), Knee Society Score (KSS), Pain Score, Stability, Radiographic Analysis, Complications.

Study Design
Retrospective Controlled Matched Pairs Study

A series of 30 consecutive patients, from one German hospital, with an e.motion MB prosthesis, implanted with CAS (Orthopilot), who achieved 1 year follow up, were retrospectively matched, to 30 patients receiving a SIGMA FB prosthesis which was implanted with conventional non-CAS instruments. Matching criteria were age, weight, ROM, pre-operative knee alignment and KSS.

All patients had an original diagnosis of primary osteoarthritis. All knees were cemented and cruciate retaining. Patients were followed up at 1 year.

Results
There were no significant differences in the mean post-operative ROM between the two groups, with 119.3° for the e.motion group and 113.2° for the SIGMA group (p= 0.078). The mean post-operative change in ROM was 14.3° for the e.motion group and 8° for the SIGMA group (p= 0.078).

Very good post-operative alignment was achieved in both groups and there was no difference between them, for all measures of alignment (p>0.05). Mean deviation from the mechanical axis was 1.6° for the CAS group (e.motion) and 2.4° for the conventional group (SIGMA). Deviation was less than 3° in 88% of the CAS group (e.motion), and 75% of the conventional SIGMA group. Deviation of more than 5° occurred in 3.1% of CAS group (e.motion) and 9.4% of the conventional SIGMA group. Good to excellent alignment was found in 93% of the CAS group (e.motion) and 70% of the conventional SIGMA group. Tibial slope was good to excellent in all knees (independent of the device or technique).

There were 3 revisions in the e.motion group and 1 in the SIGMA group. In the e.motion group, 1 knee with anterior knee pain required patella revision. Another knee with anterior knee pain at 2 years required a later revision. The third patient had anterior instability with revision at 19 months. In the SIGMA FB group, 1 patient complained of instability, and consequently was changed to a semi-constrained TKA. One patient showed radiolucent lines at 1 year, with no progression at 2 years, and the patient is pain free and remains under follow up.

Study Conclusion
The e.motion MB and the SIGMA FB knee provided similar results for a variety of clinical outcomes, and there were no statistical differences between the groups. There was a non-significant trend for better alignment with the e.motion knee due to the use of CAS when compared to the conventional technique with the SIGMA FB knee.
**Objective**

To analyse a large cohort of patients undergoing total knee arthroplasty (TKA) implanted with SIGMA components, where the polyethylene inserts were packaged and sterilised in an oxygen-free environment, and compare these to a large cohort of Original P.F.C. knees, with polyethylene components irradiated in air, studied previously.

**Treatment**

SIGMA Fixed Bearing (FB) knee (Oxygen Free Polyethylene Sterilisation)

**Comparator**

Original P.F.C. knee (Gamma Irradiated in air Polyethylene Sterilisation)

**Outcomes**

Wear Related Complications, Osteolysis, Survivorship, Hazards Ratio of Wear Related Failure.

**Study Design**

Retrospective Controlled Study

Between 1985 and June 1996, the Original P.F.C. knee system was used in 2091 knees, in 8 centres, having 7.8 years mean follow up. Polyethylene inserts were sterilised by gamma irradiation in air. The original diagnosis was osteoarthritis in 96% of knees, and 68% of knees were cruciate retaining.

Between June 1996 and December 1997, 1970 TKAs in 1512 were performed with the SIGMA knee at 8 centres, with 7 years mean follow up. These patients received polyethylene inserts sterilised and packaged in an oxygen free environment. The decision to cement was not mentioned and 80% of knees were cruciate retaining.

The incidence of wear related failure was compared. Cox proportional hazard analysis was used to determine whether any demographic or polyethylene manufacturing parameter (insert size, thickness, style etc) was related to wear-related failure.

**Results**

With the SIGMA prosthesis, 13 knees were revised for wear related reasons, 5 for polyethylene wear, 7 for major osteolytic lesions and 1 for other wear related revision. Therefore, wear related revision was 1.1% (13 of 1184 knees). Minor osteolysis was observed in an additional 31 knees (2.6%) within 5 years.

The wear related failure rate was significantly higher for the Original P.F.C. knee than for the SIGMA knee (8.3%, 101 of 1297, p=0.0001).

For wear related failure or major osteolysis, survivorship was significantly higher for the SIGMA knee, 97% at 10 years, than for the Original P.F.C. knee, 87.7% at 10 years (p=0.0001).

With the SIGMA knee, cox proportional hazards revealed patient age to be the only demographic or variable that correlated with wear related failure (p=0.0001). The hazard ratio was 0.91, indicating a 9% increase in the likelihood of wear related failure for every 1 year decrease in age.

For the original P.F.C. knee, gender, polyethylene sheet vendor, polyethylene finishing method, polyethylene shelf age and patient age were correlated with wear related failure.

**Study Conclusion**

The data emphasises the dramatic effect improvements in polyethylene manufacturing can have on implant survivorship. The incidence of wear related revision in the SIGMA knee, using polyethylene components sterilised in an oxygen free environment, was lower than in the original P.F.C. knee, with polyethylene sterilised in air.
50. THE P.F.C. SIGMA RPF TOTAL KNEE ARTHROPLASTY DESIGNED FOR IMPROVED PERFORMANCE: A MATCHED PAIR STUDY


Objective
To describe the authors the results and experience of the SIGMA RPF prosthesis in a matched pairs study.

Treatment
SIGMA Rotating Platform Flex (RPF), Posterior Stabilised (PS) cemented knee

Comparator
SIGMA Rotating Platform (RP), Posterior Stabilised (PS) cemented knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Radiographic Analysis, Complications.

Study Design
Retrospective Controlled Matched Pairs Study

A series of 50 consecutive SIGMA RPF knees in 45 patients implanted by the senior surgeon (CR) were retrospectively matched to 50 patients with a SIGMA RP knee. All patients had an original diagnosis of osteoarthritis. All implants were posterior stabilised, cemented and all patellas were resurfaced with an all-polyethylene button. Patients were followed for a mean of 12 months (6-21).

Results
There were no statistical differences between the two groups for KS knee or KS function scores, both p>0.05. For the RPF group, the mean KS knee score changed from 57 pre-operatively to 94 post-operatively and the mean KS function score from 54 to 96. For the RP group, the mean KS knee score changed from 57 pre-operatively to 95 post-operatively and the mean KS function score from 50 to 93.

The RPF group had a significantly better active post-operative mean ROM compared to the RP group (125° vs. 116°, p=0.0001). The mean difference in pre and post-operative ROM was also significantly higher for the RPF group compared to the RP group (17° vs. 6°, p=0.0011).

Sub analysis of patients with pre-operative ROM less than and greater than 120° showed that post-operative ROM was significantly better with the SIGMA RPF knee for both of these sub-groups. In patients with pre-operative ROM < 120° the mean difference in pre-operative and post-operative ROM was 27° and 16° in the RPF and RP groups respectively (p=0.006). In patients with pre-operative ROM > 120, this was 4° and -4° respectively (p=0.035).

Mean posterior slope was 3.9° for RPF and 2.9° for RP group (no p value). No RPF knees had radiolucent lines, but 7 RP knees had non-continuous lines in the posterior femoral condyle. There have been no operations or revisions in either group to date.

Study Conclusion
Range of motion was higher with the SIGMA RPF implant compared with the SIGMA RP implant. Patients with less motion have more to gain with the high flexion (RPF) design. Future primary total knee arthroplasty may need to incorporate the RPF design, especially in patients with limited pre-operative ROM. Other than ROM there were no differences between the designs in the other clinical outcomes.
51. MIDTERM OUTCOMES OF COMPUTER-ASSISTED TOTAL KNEE ARTHROPLASTY

Ishida K, Matsumoto T, Tsumura N, Kubo S, Kitagawa A, Chin T, Iguchi T, Kurosaka M, Kuroda R.

Knee Surgery, Sports Traumatology, Arthroscopy 2011;19:1107–12

Objective
To examine the results of computer aided surgery (CAS) at a minimum of 5 years, and compare these to the results of conventional surgery. The hypothesis was that the radiological benefit of CAS would be more apparent with time and have an influence of the clinical results.

Treatment
SIGMA Fixed Bearing (FB), Posterior Stabilised (PS) knee implanted with CAS

Comparator
SIGMA Fixed Bearing (FB), Posterior Stabilised (PS) knee implanted conventionally

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Radiographic Evaluations, Knee Alignment.

Study Design
Retrospective Controlled Study

Between 2002-2003, 30 posterior stabilised total knee arthroplasties (TKA) using CAS (Vector Vision) were performed by author NT. The remaining 30 patients were compared to 30 conventionally implanted TKAs. The original diagnosis of the patients was not mentioned. All patients received a posterior stabilised SIGMA prosthesis, but the decision to cement was not stated. This is a follow up paper of Matsumoto. Patients were followed for a minimum of 5 years.

Results
Patient demographic and pre-operative clinical status were the same in both groups. Mean patient age was 82 in both groups.

Mean range of motion was significantly higher for the CAS group at final follow up, changing from 105° pre-operatively to 120° post-operatively, compared to the conventional group, which changed from 105° pre-operatively to 105° post-operatively (p<0.01).

Radiographic evaluations revealed that the pre-operative coronal mechanical axis between the groups were almost the same (not significant). The alignment of the conventional group was significantly more varus than the CAS group both after the initial operation and at 5 year follow up (p<0.01).

Condylar twist angle was significantly smaller in the CAS group (2° vs. 4 o; p<0.05). There was also significantly less femoral internal rotation in relation to the clinical epicondylar axis. There were fewer long leg mechanical axis outliers of more than 3° varus/valgus in the CAS group compared to the manual group (18.5% v 33.3%; p<0.05).

There were no progressive radioluencies, and no radiographs showed radioluencies of greater than 5mm.

Study Conclusion
CAS led to a significant improvement in the alignment, including femoral and functional outcome alignment at a minimum of 5 years. Further studies may be required to identify the true clinical benefit of CAS.
52. THE TOTAL KNEE ARTHROPLASTY WITH P.F.C. SIGMA RPF: TWO YEAR SHORT-TERM RESULTS

Suh J, Shin W, Park W.
Journal of Korean Orthopaedic Association 2008;43:57-64

Objective
To compare the SIGMA Rotating Platform Flex (RPF) knee with conventional SIGMA Posterior Stabilised (PS) knee in order to assess the clinical results including the maximal flexion angle after a follow up of at least 2 years.

Treatment
SIGMA Rotating Platform Flex (RPF) Posterior Stabilised (PS) knee

Comparator
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Visual Analogue Scale (VAS) Pain.

Study Design
Retrospective Controlled Matched Pairs Study

A group of 41 SIGMA RPF knees were compared to a control group of 41 SIGMA FB PS knees. All implants were posterior stabilised. Patients were matched for gender, diagnosis, and pre-operative ROM.

Patients were followed for a mean of 26.7 months.

Results
Mean KS knee scores were 53.2 pre-operatively and 95.6 post-operatively for the SIGMA RPF group and 54.1 pre-operatively and 94.5 post-operatively for the SIGMA FB PS group.

Mean KS function scores were 49.7 pre-operatively and 96.1 post-operatively for the SIGMA RPF group and 50.9 pre-operatively and 95.1 post-operatively for the SIGMA FB PS group.

Between the two groups neither the difference in KS knee (p=0.351) or KS function score (p=0.417) were significant.

Mean post-operative ROM was higher in the RPF group (p=0.01). Mean ROM in the SIGMA RPF group was 124.3° pre-operatively and 128.2° post-operatively. Mean ROM in the SIGMA FB PS group was 122.2° pre-operatively and 123.6° post-operatively.

There was no difference in the mean post-operative VAS pain score (p=0.345). These were 7.6 pre-operatively and 1.6 post-operatively in the RPF group and 7.5 pre-operatively and 1.4 post-operatively in the FB group (a lower VAS score indicating less pain).

There were no differences in the clinical results between the SIGMA RPF knee and the SIGMA FB PS knee except for ROM, which was better with the RPF knee.

Study Conclusion
Total knee arthroplasty with the SIGMA RPF knee showed similar clinical results to the SIGMA FB knee, as well as excellent and predictable results of ROM at the short-term follow up.
53. OSTEOLYSIS IN WELL-FUNCTIONING FIXED AND MOBILE BEARING TOTAL KNEE ARTHROPLASTIES IN YOUNGER PATIENTS

Kim Y, Choi Y, Kim J.
Clinical Orthopaedics and Related Research 2010;468:3084–93

Objective
To assess whether the prevalence of osteolysis would be less in well-functioning mobile bearing total knee arthroplasties (TKAs) than in well-functioning contemporary fixed bearing TKAs in young patients.

Treatment
Fixed Bearing TKA; SIGMA Fixed Bearing (FB) cemented knees Rotating, AMK® (DePuy Synthes), NexGen® LPS NexGen® CR (Zimmer®)

Comparator
Mobile Bearing TKA: SIGMA Rotating Platform (RP) cemented knee, LCS RP knee, LCS Meniscal Bearing (MB) knee, LCS AP-Glide Knee

Outcomes
Knee Society Score (KSS), Hospital for Special Surgery Score (HSS), Range of Motion (ROM), Radiographic Analysis, Knee Alignment, Osteolysis, Complications, Survivorship.

Study Design
Retrospective Controlled Study

All of the author’s primary TKAs from January 1992 to January 1999 included 894 fixed bearing knees and 816 mobile bearing knees, all in patients younger than 65 years old. The study comprised of 4 types of fixed bearing prosthesis and 4 types of mobile bearing prosthesis. The fixed bearing group included 262 AMK knees, 350 NexGen LPS knees, 108 NexGen CR knees and 174 SIGMA FB knees. The mobile bearing group included 116 LCS MB knees, 336 LCS RP knees, 190 LCS AP-Glide knees and 174 SIGMA RP knees. All the SIGMA knees were cemented, and all received a polyethylene patella prosthesis. Ligament status was not stated.

The original diagnosis of the patients for the fixed bearing prosthesis was osteoarthritis in 890 knees (99.6%) and traumatic arthritis in four knees (0.4%). For mobile bearing TKAs it was osteoarthritis in 756 knees (92%), traumatic arthritis in 56 (8%), and osteonecrosis in four (1%).

Results
In the comparison of fixed and mobile bearing knees, there were no differences in KS knee or functions scores, HSS, ROM, survivorship or radiographic findings (all p>.05).

The significance of any differences between the individual types of knee replacement was not tested. However, the post-operative KSS, HSS, ROM, survivorship and radiographic findings appeared to be similar.

In the SIGMA FB group, the mean KS knee score was 28.7 pre-operatively and 91 post-operatively and the mean KS function score was 24 and 86. Mean post-operative HSS was 90 and mean post-operative ROM was 131°.

In the SIGMA RP group, the mean KS knee score was 28 pre-operatively and 90 post-operatively and the mean KS function score was 25 and 83. Mean post-operative HSS was 88 and mean post-operative ROM was 130°.

Knee alignment was similar in the two SIGMA groups for degrees varus (FB: 12° and RP: 7.9°) or degrees valgus (FB: 5.5° and RP: 5.4°).

In the SIGMA groups, osteolysis occurred in 2.3% of the FB group and 1.7% of the RP group. Radiolucent lines were seen in 34 (19.5%) FB knees and 30 (17%) RP knees.

Survivorship was 93.7% at 13.2 years for the FB group and 98% at 12.9 years for the RP group. There were 11 (6.3%) revisions in the FB group, 3 for polyethylene wear, 3 for aseptic loosening, 2 for instability, 1 for infection and 2 for osteolysis. In the RP group there were 4 (2.3%) revisions, 1 for aseptic loosening, 1 for instability and 2 for infection.

Study Conclusion
This study found that cemented fixed and mobile bearing knee replacement is durable in patients younger than 65 years at a minimum of 10 years follow up. The incidence of osteolysis was low in both well functioning, fixed and mobile bearing knees. Clinical outcomes were similar in the fixed and mobile bearing knee groups.
54. RESULTS OF CONTRALATERAL TOTAL KNEE ARTHROPLASTY IN PATIENTS WITH A HISTORY OF STIFF TOTAL KNEE ARTHROPLASTY


Objective
To investigate whether patients with a history of stiffness in a previous total knee arthroplasty (TKA) undergoing a primary TKA on the contralateral knee, would have a compromised long term functional outcome in their second TKA compared to TKA patients without a history of stiffness.

Treatment
SIGMA TKA patient with a history of post-operative knee stiffness in a previous contralateral TKA

Comparator
SIGMA TKA patient with no history of knee stiffness

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Complications, Pain Score.

Study Design
Retrospective Controlled Study

A review of patient records at a single institution identified 138 TKA patients as having stiffness after their primary TKA. The study group consisted of 15 of these patients who went on to have a TKA in the contra-lateral knee and met the inclusion criteria, pre-revision ROM ≤ 85° and minimum 2 years follow up. A cemented SIGMA knee was used in all patients, with 2 posterior stabilised designs and 13 cruciate sacrificing designs.

As a control, 109 age matched patients who had a primary TKA, with no history of knee stiffness, were selected. A cemented, posterior stabilised SIGMA knee was used in all patients, with a minimum of 2 years follow up.

Results
Flexion contracture was significantly smaller in the study group (1.8°) than the control group (5.1°) (p= 0.004).

The study group had better pre-operative flexion (110° p= 0.011) and arc of motion (108.5° p= 0.002) compared to the control group (101° and 96° respectively).

There were significantly more closed manipulations in the study group than in the control group (26.7% vs. 2.8%; p <0.001).

At minimum 2 year follow up, there was no significant difference between the groups in post-operative extension (p= 0.073), flexion (p=0.119) and arc of motion (p=0.187). All 15 of the study group achieved >90° flexion.

There were also no differences between the groups in KS pain score (Study: 42 Control: 45; p= 0.383), KS knee score (Study: 85.5 Control: 89.2; p= 0.420) or KS function score (Study: 71 Control: 76.7; p= 0.431).

Study Conclusion
Patients with a history of knee stiffness following primary TKA were more likely to have early post-operative knee stiffness in a contralateral primary TKA requiring closed manipulation. However, this did not predispose these patients to a poor functional outcome, which was similar to that of primary TKA patients without a history of knee stiffness.
Objective
To assess if there are any differences between subjective and objective criteria between computer aided surgery (CAS) total knee replacement (TKR) vs. conventional TKR at 2 years.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) knee implanted with CAS

Comparator
SIGMA Fixed Bearing (FB) Cruciate Retaining knee implanted conventionally

Outcomes
Knee Society Score (KSS), WOMAC, Knee Alignment, Varus/ Valgus Stability, Range of Motion (ROM).

Study Design
Retrospective Controlled Matched Pairs Study

Results
Between the CAS and conventional groups, there was no difference in mean post-operative WOMAC sub-scores (pain, stiffness and function), and p values ranged from 0.3 - 0.5. The overall WOMAC scores were also comparable (p= 0.45).

There was no difference in mean post-operative KS knee score (p= 0.24), KS function (p= 0.07), or overall KSS (p= 0.07).

For post-operative leg alignment (measured on standardised weight bearing long leg X-rays), the CAS group had statistically better outcomes. Deviation from the neutral leg axis was 1.32° for the CAS group vs. 2.24° for the conventional group (p= 0.04).

Varus – valgus stability in extension and flexion showed no significant differences between the groups. BiodexTM measurements showed no statistically significant values for isokinetic muscle force either.

There was no significant difference in maximum post-operative flexion between groups, which was 113° in the CAS group and 108.8° in the conventional group (p=0.06).

Study Conclusion
Post-operative KSS and ROM were better for patients in the CAS group, however the differences were not statistically significant. Post-operative leg alignment is statistically better after implantation with CAS. The hypothetical advantages of computer assistance in total knee replacement for functional parameters and patient’s satisfaction is still not yet proven.
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56. TWO YEAR FOLLOW UP ON JOINT STABILITY AND MUSCULAR FUNCTION COMPARING ROTATING VS. FIXED BEARING TOTAL KNEE REPLACEMENT

Lüring C, Bathis H, Oczypka F, Trepte C, Lufen H, Perlick L, Grifka J.
Knee Surgery, Sports Traumatology, Arthroscopy 2006;14:605–11

Objective
To assess the objective and subjective differences between with a mobile bearing and fixed bearing prosthesis at 2 years implanted using Computer Aided Surgery (CAS).

Treatment
SIGMA Rotating Platform (RP)
Cruciate Retaining (CR) knee

Comparator
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) knee

Outcomes
WOMAC, Knee Society Score (KSS), Range of Motion (ROM), Isokinetic Muscle Force, Knee Alignment.

Study Design
Retrospective Controlled Study

This study is a retrospective matched pair analysis of 40 primary total arthroplasties selected from 156 patients with osteoarthritis (OA) performed August to October 2002. The study groups comprise 20 patients with a SIGMA FB knee and 20 patients with a SIGMA RP knee. The decision to cement was not stated. Patients were matched into pairs by age, gender, BMI, treated leg, pre-operative deformity. Both groups were implanted with CAS (Vector Vision) and all surgeries were done by one surgeon. There was no learning curve period for CAS, and patellas were not resurfaced. Patients were followed up at 2 years.

Results
Pre-operative demographic and clinical status was the same in each group.

Post-operative leg alignment was varus or neutral for all knees in both groups, with mean leg axis of 1.21° for the FB group and 1.32° for the RP group.

Between the groups there were no differences in mean post-operative WOMAC scores (FB: 22.57 and RP: 23.05), and subgroup analysis for pain, stiffness and function components of the WOMAC score showed no differences. Mean post-operative KSS were almost identical for the two groups, for both knee score (FB: 86.5 and RP: 83.14) and function score (FB: 89.5 and RP: 91.6). No p values were given.

Isokinetic muscle force, measured using BiodexTM, was significantly superior in flexion, in the RP group in flexion but not in extension.

Varus–valgus stability in extension and flexion had statistically better values for the RP group, except in flexion for valgus stress.

There were no statistically significant differences in the mean post-operative ROM which was 112° in the FB group and 107° in the RP group (no p value).

Study Conclusion
At two years follow up, there were no statistically significant differences in outcome between RP and FB CAS TKR, except that ligament stability was better with the RP knee. The hypothetical advantages of mobile bearing TKR have still not been shown to improve subjective patient satisfaction and objective criteria such as Knee Society Score and isokinetic muscle force.
57. A FIVE TO SEVEN YEAR FOLLOW UP COMPARING COMPUTER-ASSISTED VS. FREEHAND TOTAL KNEE REPLACEMENT WITH REGARD TO CLINICAL PARAMETERS

Lüring C, Kauper M, Bäthis H, Perlick L, Beckmann J, Grifka J, Tingart M, Rath B.
International Orthopaedics (SICOT) 2012;36:553–8

Objective
To test whether there is any difference for subjective or objective criteria between Computer Aided Surgery (CAS) total knee replacement (TKR) and conventional TKR after 5.6 – 7.3 years.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) knee, implanted with CAS

Comparator
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) knee, implanted conventionally

Outcomes
WOMAC, Knee Society Score (KSS), Range of Motion (ROM), Complications.

Study Design
Retrospective Controlled Matched Pairs Study

This study is a retrospective matched pair analysis of 100 primary total arthroplasties divide into two groups both with a SIGMA FB CR knees with 50 knees implanted with CAS using Vector Vision (Group A) and 50 knees implanted conventionally (Group B). All patients were diagnosed with osteoarthritis (OA). Patients were matched by age, gender, BMI, American Society of Anesthesiologist Score, grade of osteoarthritis (OA). No learning curve for CAS was included, patellas were not resurfaced and patients had 5.6 to 7.3 years follow up. The use of cement was not stated.

Results
Pre-operative demographic and clinical status was the same in each group.

There was no difference in WOMAC scores between the CAS group and the conventional group:
- Mean post-operative WOMAC pain score was 7.72 and 7.82 for the CAS and conventional groups (p=0.87).
- Mean post-operative WOMAC stiffness score was 3.9 and 3.52 for the CAS and conventional groups (p=0.22).
- Mean post-operative WOMAC function score was 31.4 and 30.2 for the CAS and conventional groups (p=0.6).
- Mean post-operative WOMAC total score was 42.98 and 41.54 for the CAS and conventional groups (p=0.62).

There was no difference in KSS between the 2 groups (p=0.71):
- Mean post-operative KS knee scores were 93.1 and 92.6 in the CAS and conventional groups respectively (p=0.64)
- Mean post-operative KS function scores were 84.3 and 83.2 in the CAS and conventional groups respectively (p=0.71)

There was also no difference in post-operative ROM between the two groups. Mean flexion for the CAS group was 106° and for the conventional group was 107° (p=0.62).

There were no complications in terms of wound infection, venous thrombosis, deep infection, loosening or re-operation.

Study Conclusion
The hypothetical advantages of computer assistance in TKR for functional parameters and patient’s satisfaction are still not yet proven. A clinical investigation is needed on a larger time scale with loosening as the endpoint.
58. DOES HYPERFLEX TOTAL KNEE DESIGN IMPROVE POST-OPERATIVE ACTIVE FLEXION

Orthopaedic Traumatology Surgery Research 2010;96(4):376-80

Objective
To study and compare the increase in flexion (flexion gain, range of motion, active flexion) of 59 consecutive patients with the SIGMA Rotating Platform Flex (RPF) knee with another 59 consecutive matched patients who had received a SIGMA Rotating Platform (RP) knee.

Treatment
SIGMA Rotating Platform Flex (RPF) Posterior Stabilised (PS) cemented knee

Comparator
SIGMA Rotating Platform (RP) Posterior Stabilised (PS) cemented knee

Outcomes
Range of Motion (ROM), Knee Society Score (KSS) Score, Feller Patellar Score

Study Design
Retrospective Controlled Study

This was a multicentre study (four centres). All surgeons have previously implanted more than 50 knees.

From June 2005- June 2006, 61 consecutive SIGMA RP knees were implanted.

From June 2006 – June 2007, 63 consecutive SIGMA RPF knees were implanted.

Six exclusions were made to match flexion contracture between the two groups, leaving 59 patients in each group. All components were cemented for both prosthesis types.

The clinical and radiographic results were recorded at one year, with visual measurement of mobility using a goniometer.

Results
Baseline demographic and clinical status showed a higher proportion of females in the RP group, but pre-operative clinical and mobility values were similar.

In both groups, flexion gain was strongly and negatively associated with pre-operative flexion (p=0.001), meaning that patients with good pre-operative flexion lost flexion with both implants.

Overall, the RPF group had a significantly greater post-operative gain in mean ROM compared to the RP group (10° vs. 4°, p=0.02), as well as a significantly better mean post-operative gain in flexion (13° vs. 6°, p= 0.02). However, mean post-operative flexion was equivalent (RPF: 118° and RP: 116°, p= 0.47).

KS knee, function and Feller Patella Scores did not between the two groups differ (p= 0.1, p= 1.0 and p= 0.7 respectively). Patella and KSS scores for women who had received an RPF knee reached the same post-operative score as men, despite being lower pre-operatively.

In a sub-analysis of patients with pre-operative flexion less than 120°, patients with an RPF knee had a higher mean post-operative gain in active flexion (23° vs. 14°, p= 0.03), and significantly higher mean post-operative gain in ROM (26° vs. 17°, p=0.05). Final active flexion was also higher for patients receiving an RPF prosthesis (124° vs. 116°, p=0.02) compared to the RP prosthesis.

However, for patients with more than 120° pre-operative flexion, the results of gain in flexion, range of motion and mean final active flexion were all not significantly different between the groups (p= 1.0, p= 0.72 and p= 0.39 respectively). In particular, 9 patients with the RP knee (50%) and 10 with the RPF knee (37%) showed a decrease in flexion (p=0.7).

Study Conclusion
The SIGMA RPF knee gave significant additional flexion gain in patients with 90-120° pre-operative flexion compared to the SIGMA RP knee. Patients with pre-operative flexion greater than 120° were exposed to decreased flexion with both the RP and RPF prostheses.
59. CLINICAL VALUES IN COMPUTER-ASSISTED TOTAL KNEE ARTHROPLASTY

Matsumoto T, Tsumura N, Kurosaka M, Muratsu H, Yoshiya S, Kuroda R.
Orthopedics 2006;29(12):1115-20

Objective
To assess the effectiveness of a CT-free navigation system when implanting SIGMA knees, compared to a control group of the same knees with a conventional, freehand implantation.

Treatment
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) knee implanted with computer aided surgery (CAS)

Comparator
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) knee implanted conventionally

Outcomes
Knee Alignment, Operative Time, Crepitus, Knee Society Score (KSS), Range of Motion (ROM), Pain.

Study Design
Retrospective Controlled Study

This study is a retrospective matched pair analysis of two groups of 30 primary total knee arthroplasties with a SIGMA FB PS knee implanted either with CAS using Vector Vision or with conventional instruments by the same surgeon from October 2002 to May 2003.

Patients were matched by age, gender, body size and pre-operative status of the knee. Follow up was at 2 years. The original diagnosis for all patients was osteoarthritis. The use of cement was not stated.

Results
In the CAS group there were more patients with alignment within 2° of valgus/varus or flexion/extension for the following axes: Coronal femoral (p<0.05), coronal tibial (p=0.071) sagittal femoral (p=0.001), sagittal tibial (p=0.052). This difference is only significant for the coronal femoral alignment.

The mean operative time for the CAS group was higher than that of the conventional group (124 vs. 104 minutes, no p value). One patient in the CAS group and two in the conventional group had knee crepitus, but none of them reported any knee pain.

There were no significant differences between the groups in the mean KS knee and KS function scores pre-operatively or post-operatively. Mean KS knee scores reached 84.5 and 89.5 (p = 0.16) and mean KS function scores reached 94.3 and 95.5 (p= 0.58) post-operatively for the CAS and conventional groups respectively.

The mean post-operative ROM was higher in the CAS group, 113°, than in the conventional group, 105.5° (p= 0.011).

Study Conclusion
In this study there was an improvement in the quality of surgery with CAS, with respect to the mechanical axis, that could lead to better long term outcomes. In the shorter term, the SIGMA PS knee demonstrated equally good results out to 2 years when implanted with and without CAS.
60. A CEMENTED MOBILE BEARING TOTAL KNEE REPLACEMENT PREVENTS PERIPROSTHETIC LOSS OF BONE MINERAL DENSITY AROUND THE FEMORAL COMPONENT


Objective
To assess whether a cemented mobile bearing reduced the post-operative loss of Bone Mineral Density (BMD) compared to fixed bearing. (NexGen® FB vs SIGMA RP knee)

Treatment
SIGMA Rotating Platform (RP), Posterior Stabilised (PS) cemented knee

Comparator
NexGen® Fixed Bearing (FB), Posterior Stabilised (PS) cemented knee (Zimmer®)

Outcomes
Bone Mineral Density (BMD), Knee Society Score (KSS), Range of Motion (ROM), Radiographic Analysis.

Study Design
Retrospective Controlled Study

From June 2004 to Sep 2005, 28 NexGen (FB) implants had full follow up from a consecutive series. These were retrospectively matched to 28 SIGMA RP knees from a consecutive series of 76. Patients were matched by age, gender, body weight, height, diagnosis and date of surgery. All knees were posterior stabilised and cemented, with patella resurfacing in all cases. All total knee arthroplasties (TKA) were from the senior author, AK, and follow up was at 24 months by senior author YM.

52 patients had an original diagnosis of osteoarthritis and 4 had rheumatoid arthritis.

Dual-energy X-ray absorptiometry (DXA) was used to analyse bone mineral density BMD at the distal part of the femur at 6,12,18, and 24 months post-operatively in 3 regions of interest (ROI). On a lateral view, ROI 1 is the anterior third of the distal femur, ROI 2 is the central third, and ROI 3 is the posterior third.

Results

Bone Mineral Density
The relative change in BMD at 24 months was significantly better for the SIGMA RP knee in all ROI areas:

Relative Change in BMD at 24 Months
- ROI 1 NexGen FB = -14.9% SIGMA RP= +10.5% (p= 0.001)
- ROI 2 NexGen FB= -8.7% SIGMA RP= +8.1% (p= 0.027)
- ROI 3 NexGen FB= -0.7% SIGMA RP= +9.7% (p= 0.037)

In ROI 3, BMD was significantly increased at 12 months post-operatively (p= 0.047) in the SIGMA RP group. No knee exhibited radiolucent lines.

There were no significant differences in post-operative KSS scores or range of motion between the groups.

Mean post-operative KS knee scores were 95.8 for the NexGen FB knee and 93.8 for the SIGMA RP Knee (p=0.144). Mean post-operative KS function scores were 80.1 for the NexGen FB knee and 86.3 for the SIGMA RP knee (p= 0.114).

Mean post-operative extension was -2.0° for NexGen FB knees and -2.5° for SIGMA RP knees (p= 0.857). Mean flexion was 125° for NexGen FB Knees and 125.5° for SIGMA RP Knees (p= 0.676).

There was no difference in the BMD of the lumbar spine between groups (p= 0.903).

Study Conclusion
The findings suggest that a SIGMA RP knee has significantly better BMD recovery in the distal femur after surgery compared to the NexGen FB knee. There were no differences in the other outcomes and further follow up is needed to determine the long term clinical benefits of the RP mechanism.
61. PREDICTORS AND OUTCOMES OF LATERAL RELEASE IN TOTAL KNEE ARTHROPLASTY: A COHORT STUDY OF 1859 KNEES

Molyneux S, Brenkel I.
Knee 2012;19(5):688-91

Objective
To determine the pre-operative factors that predict lateral release (LR), and to assess the short term complications and long term functional outcomes associated with LR.

Treatment
SIGMA knee patients with lateral release

Comparator
SIGMA knee patients without lateral release

Outcomes
Multiple Logistic Regression for Lateral Release, Hospital Details, Surgical Details, Complications, Knee Society Scores (KSS)

Study Design
Retrospective Controlled Study

Patients in the Fife Knee Arthroplasty database from 1998-2008 with primary unilateral surgery all received SIGMA implants and were included into this study. There were 1713 patients (92.2%) with a diagnosis of osteoarthritis, while 147 (7.8%) had rheumatoid disease. Cruciate treatment, bearing type or the decision to resurface the patellas was not stated. The decision to cement was not stated.

There were 1859 patients, of which 154 had lateral release and 1705 did not.

Patients were followed for a mean of 5.49 years.

Results
Multiple logistic regression analysis carried out (using LR as the dependant variable) showed that valgus deformity, maximal flexion range, operating surgeon and year of surgery were all independent predictors of LR at the level of p<0.05.

Average length of stay for patients was 8.7 days, and length of stay was significantly longer for patients having LR (p< 0.005).

Patients with LR required more haemoglobin, and the proportion of patients requiring a blood transfusion was higher for patients with LR (p=0.005 for both).

There was a trend for more superficial and deep infections in the LR group, but this was not statistically significant (p=0.35).

There were no significant differences in KSS between the two groups, however ROM was significantly better (p<0.05) for the non LR group at 6 months, 18 months and 5 years (however not at 3 or 9 years).

Mean post-operative KSS in the LR group was 84.3, 86.2 and 59.3 at 3, 5 and 9 years respectively.

Mean post-operative KSS in the non-LR group was 85.7, 85.2 and 57.5 at 3, 5 and 9 years respectively.

Study Conclusion
Low pre-operative KSS, increasing valgus deformity, and the choice of surgeon all predict the need for LR. Lateral release is associated with increased levels of transfusion requirements in the early post-operative period, although there was only a minimal effect on the knee function long term.
62. A COMPARISON OF THE CLINICAL AND RADIOGRAPHIC RESULTS OF P.F.C. ROTATING PLATFORM HIGH FLEXION AND LOW CONTACT STRESS MOBILE BEARING PROSTHESIS IN TOTAL KNEE ARTHROPLASTY: SHORT-TERM RESULTS

Nam S, Lee Y, Kwak J, Kim N, Lee B.
Knee Surgery and Related Research 2012;24(1):7-13

Objective
To assess whether the SIGMA Rotating Platform Flex (RPF) knee results in more favourable clinical outcomes compared to the LCS Rotating Platform (RP) knee.

Treatment
SIGMA Rotating Platform Flex (RPF) Posterior Stabilised (PS) cemented knee

Comparator
Low Contact Stress (LCS) Rotating Platform (RP) cemented knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Radiographic Analysis, Complications.

Study Design
Retrospective Controlled Study

Between December 2006 and January 2010, 35 total knee arthroplasty patients from a possible 68 had minimum two year follow up, with a SIGMA RPF or LCS RP knee.

There were 24 SIGMA RPF knees in 16 patients with a mean follow up of 39.9 months, and 26 LCS knees in 19 patients with a follow up of 25.6 months. All knees were cemented and the patellas were not replaced. The diagnosis was degenerative arthritis in all of the knees studied.

Results
Patient demographic and clinical status were similar in both groups.

There were no significant differences in post-operative mean KSS and flexion between the LCS RP and SIGMA RPF knee.

Mean KS knee scores were 48.2 pre-operatively and 91.4 post-operatively, for the RPF group and 40.2 pre-operatively and 92.2 post-operatively for the LCS group.

Mean KS function scores were 42.9 pre-operatively and 87.8 post-operatively for the RPF group and 39.9 pre-operatively and 87.4 post-operatively for the LCS group.

Mean flexion was 111.7° pre-operatively and 126.3° post-operatively in the RPF group and was 112.7° pre-operatively and 125.0° post-operatively in the LCS group.

There were no differences between groups for Insall Salvati ratio (p=0.515) and congruence angle (p=0.059). Patella tilt was statistically significantly different, 5.1° for the RPF group and 6.6° for the LCS group (p= 0.026).

The mean tibiofemoral angle changed from 0.6° varus to 5.9° valgus in the RPF group and from 1.5° valgus to 5.8° valgus in the LCS group.

In the RPF group, in all cases, apart from one with severe osteolysis and loosening requiring revision, the radiolucent line score was ≤4. Most radiolucent lines were observed in the posterior femoral condyles, in 7 cases (29.2%). In the LCS group, the radiolucent line score was ≤4, and most of the radiolucent lines were observed in the posterior femoral condyle, in 4 cases (15.4%). The incidence of radiolucent lines was not statistically significantly different (p= 0.134).

Complications observed in the RPF group were 1 revision for early loosening (mentioned above), 1 patella crepitus and 1 patella clunk syndrome.

Study Conclusion
The short-term clinical and radiographic results of TKA did not show significant differences between the SIGMA RPF knee and the LCS RP knee. Regarding the complications, the RPF group had 3 compared to 0 in the LCS group.
Objective
The purpose of this study was to compare the fixed bearing (FB) and rotating platform (RP) designs of the SIGMA total knee system in the same patient.

Treatment
SIGMA Rotating Platform (RP) Posterior Stabilised cemented knee

Comparator
SIGMA Fixed Bearing (FB) Posterior Stabilised cemented knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Complications, Pain Score, Patient Satisfaction, Radiographic Analysis.

Study Design
Retrospective Controlled Study

Between December 2000 and October 2001, 3 surgeons performed surgeries in a series of 141 patients. From these 26 patients about to receive a SIGMA RP knee, who already had a SIGMA FB in the opposite knee, were identified. All components were cemented. Patellas were routinely resurfaced with a polyethylene button.

The diagnosis was osteoarthritis in 25 patients and rheumatoid arthritis in one patient.

Patients and assessors were blinded to implant type. Average follow up was 46 months (18-132) for FB knees and 16 months (13-21) for RP knees.

Results
There was no difference between the mean combined KSS with each knee post-operatively (RP: 191 and FB: 192, p=0.63). However, the RP group had a worse pre-operative combined KSS (RP: 97, FB: 106, p= 0.01).

Mean KS knee scores were 49 pre-operatively and 96 post-operatively in the RP group, and 56 pre-operatively and 96 post-operatively in the FB group.

Mean KS function scores were 48 pre-operatively and 95 post-operatively in the RP group and 50 pre-operatively and 96 post-operatively in the FB group.

Mean ROM was 117° for the FB group and 120° for the RP group at final follow up (p=023). There was also no difference in the pre-operative values (p= 0.24).

No revisions or infections occurred. No subluxation or dislocations of any bearings were seen. One RP knee underwent successful manipulation.

No other complications occurred.

Average knee pain (out of 10, with a higher score meaning more pain) was 0.80 and 0.92 for the FB and RP groups respectively (p=0.94). Overall satisfaction (out of 10) was 8.9 and 9.2 (p= 0.66). There were 5 patients that preferred the FB knee and 8 that preferred the RP knee. No knee had radiolucent lines in more than 2 zones around the tibial or femoral component. In 1 FB knee, a radiolucent line was seen in 2 zones around the patella component without osteolysis or synovitis. One mild patellar tilt was seen in each group.

Study Conclusion
It still remains to be seen whether the SIGMA RP design is a significant improvement over the existing FB version. At 1 year there has been excellent patient satisfaction as well as comparable clinical and radiographic results to the FB design.
64. PATELLAR CREPITATION IN THE P.F.C. SIGMA TOTAL KNEE SYSTEM

Ranawat A, Ranawat C, Slamin J, Dennis D. Orthopaedics 2006;29(9):S68-70

**Objective**

To describe the incidence, prevention, and treatment of patellar crepitation in the Fixed Bearing (FB) and Rotating Platform (RP) version of the SIGMA Posterior Stabilised (PS) Knee.

**Treatment**

SIGMA Rotating Platform (RP) Posterior Stabilised (PS) cemented knee

**Comparator**

SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) cemented knee

**Outcomes**

Knee Society Score (KSS), Range of Motion (ROM), Complications, Radiographic Analysis, Patello-femoral Complications.

**Study Design**

Retrospective Controlled Study

A group of 135 knees in 106 patients with a cemented posterior stabilised SIGMA FB knee implanted between May 1996 and December 1998 were identified with a minimum of 5 years follow up. These were compared with a group of 162 knees in 150 patients with a cemented posterior stabilised SIGMA RP knee, between January 2000 and October 2001, with minimum of 2 years follow up.

In all cases the patella was cemented with an all-polyethylene button. The original diagnosis was osteoarthritis in 102 patients (96%) in SIGMA FB group and 145 patients (97%) in SIGMA RP cohort.

**Results**

Pre-operative measurements and post-operative outcomes were similar in both the FB and RP groups.

Mean KS knee scores were 43 pre-operatively and 95 post-operatively in the FB group and was 42 pre-operatively and 96 post-operatively for the RP group.

Mean KS function scores were 42 pre-operatively and 95 post-operatively in the FB group and 42 pre-operatively and 90 post-operatively in the RP group.

Mean post-operative ROM was 118° for the FB knees and 119° for the RP knees.

The FB group had 1 re-operation for arthrofibrosis. There was also 1 closed manipulation performed.

The RP group had 4 re-operations: One hematoma evacuation, two debridement’s for painful peri-patellar scar formation, and one revision for limited ROM due to arthrofibrosis. There were also 7 closed manipulations performed.

Radiographic evaluation showed no evidence of osteolysis, loosening, malalignment or catastrophic failures in either of the two groups.

In the FB group, 2 patients (1.5%) had mild, non-debilitating, patellar crepitation. In the RP group, 6% of patients developed mild anterior knee pain, and 12% had painless crepitation.

**Study Conclusion**

Outcomes seemed to favour the fixed bearing prosthesis rather than the newer rotating platform design, both for patellar crepitation outcomes and fewer complications. The majority of patients with mildly painful or painless crepitus will improve within 6-12 months.
Objective
To assess the premature failure of the KINEMAX PLUS prosthesis, and compare it to the subsequent series of patients with SIGMA knees.

Treatment
KINEMAX PLUS cemented knee (Stryker®)

Comparator
SIGMA cemented knee

Outcomes
Survivorship, Complications, Wear Analysis, Correlations of KINEMAX Failures.

Study Design
Retrospective Controlled Study

From Jan 1998 to June 1999, a consecutive series of 71 KINEMAX PLUS knees were implanted. From July 1999 to Dec 2000, 63 SIGMA knees were used in 58 patients, with the change of implant due to the poor results with the KINEMAX PLUS prosthesis.

Cement was used for all cases, the patella was not routinely resurfaced but cruciate ligament treatment was not stated. Surgeries were performed by JH or one of his team under supervision.

Patients with the KINEMAX PLUS knee were followed for mean of 76 months, and the SIGMA knee for 72 months. Clinical, radiological and material analyses were all done to assess reasons for the difference in failure rates. The original diagnosis was osteoarthritis for 79% of the KINEMAX PLUS knees and 68% for the SIGMA knees.

Results
In total 7 Kinemax knees were revised, and 5 knees have been offered revision for failed implants, principally due to polyethylene wear. No SIGMA knees required revision.

Survivorship was 76% for the KINEMAX PLUS and 100% for the SIGMA knee at 9 years. However, survivorship was comparable for the first 5 years however.

Between the groups, there were no statistical differences in factors associated with revision. This included weight, pre-operative ROM, pre-operative valgus deformity or post-operative coronal/sagittal alignment. At least 80% of operations in each cohort were performed by a consultant.

Analysis of the revised UHMWPE KINEMAX PLUS inserts was done after revision. The majority of wear was found postero-medially. In some cases the insert was completely extruded. There was no correlation between batch number and failure. All inserts had a shelf life of less than 4 years, and although most implants were 10mm or less, there was no correlation between implant size and failure.

Analysis by electron microscope revealed areas of incomplete inter and intra molecular boundary diffusion at a molecular level within the polyethylene. Analysis of unused KINEMAX PLUS inserts from the same period showed similar defects due to incomplete boundary diffusion. An unused KINEMAX PLUS insert showed clear machine marks and occasional defects with inhomogeneity when analysed.

Study Conclusion
In this study the failure of the KINEMAX PLUS knee was believed to be due to material failure of the polyethylene insert due to post manufacturing oxidation. Between 1998-1999, when the KINEMAX PLUS knee was used in this study, the polyethylene inserts used in KINEMAX PLUS knee were sterilised by gamma irradiation in air. The effect of this on wear is thought to be a contributing factor to the higher revision rate observed with the KINEMAX PLUS knee. Further analysis of the implants is to be completed.
Objective
Ascertain dependence of patella inferior from patellar eversion during TKA and its influence on the post-operative Insall-Salvati ratio (ISR).

Treatment
SIGMA Fixed Bearing (FB) or Rotating Platform Flex (RPF) cemented knees with shortening of the patella tendon

Comparator
SIGMA Fixed Bearing (FB) or Rotating Platform Flex (RPF) cemented knees without shortening of the patella tendon

Outcomes
Knee Society Score (KSS), Patella Baja, Insall-Salvati Ratio (ISR), Patella Tendon Length.

Study Design
Retrospective Controlled Study

A group of 135 consecutive TKAs in 110 patients, done by authors CSR and ASR, were retrospectively reviewed. This included 84 SIGMA RPF knees and 51 SIGMA FB knees. There were 5 patients with shortening of the patella tendon. This was defined as a decrease in ISR of 10% post-operatively but without patella baja, which was defined as an ISR less than 0.8. These were compared to the remaining patients without patella shortening.

All implants were cemented but the treatment of the cruciate ligaments was not stated. The original diagnosis was osteoarthritis in 101 patients, rheumatoid arthritis in 8 patients, and osteonecrosis in 1 patient. Follow up was at 6 weeks, 12 weeks and 1 year.

Results
Incidence of patella baja was 1 from 135 knees (0.7%) and 5 knees had shortening of the patella tendon (3.7%)

In the whole group the mean pre- and post-operative Insall Salvati ratio (ISR) were similar (1.17 and 1.16, p=0.4). There was also no significant difference between pre- and post-operative patella tendon length (39.1mm vs. 39.7mm, p=0.2).

The number of RPF and FB knees with a shortened patella tendon were similar (2 RPF, 3 FB, p=0.3). None of these 5 knees reported anterior knee pain or difficulty with stairs.

There was no difference in the mean post-operative KSS and flexion in the knees with and without a shortened patella tendon (p>0.6).

In knees with a shortened patella tendon, mean post-operative KS knee, KS function and flexion were 94, 96 and 122° respectively.

In knees without a shortened patella tendon, mean post-operative KS knee, KS function and flexion were 93, 94 and 124° respectively.

There was no correlation between post-operative ISR and KS knee and function scores (p= 0.9 and p= 0.7 respectively). There also was no correlation between a reduction of the ISR and KS knee and function scores (p= 0.3 and p= 0.8 respectively).

Study Conclusion
The incidence of patella baja was less than 1% despite routine patellar eversion during TKA. Although patella baja was associated with a worse clinical outcome, shortening of the patella tendon, defined as a 10% or more reduction in the ISR without patella baja, had no adverse effect.
67. SECONDARY RESURFACING OF THE PATELLA IN TOTAL KNEE ARTHROPLASTY

Spencer S, Young D, Blyth M.
Knee 2010;17:187–90

Objective
To review the results of a consecutive series of patients who underwent secondary resurfacing of the patella. As far as the authors are aware, this represents the largest review in the literature of this procedure to date.

Treatment
SIGMA Fixed Bearing (FB) knee with patella resurfacing

Comparator
SIGMA Fixed Bearing (FB) knee without patella resurfacing

Outcomes
Patient Satisfaction, Oxford Knee Score (OKS), Range of Motion (ROM), Patient Reported Improvements.

Study Design
Retrospective Controlled Study

From 2002 to 2007, 1923 total knee arthroplasties (TKA) were performed in a single centre. In 598 of these the SIGMA FB knee was used and in the remaining knees the Kinemax knee was used. The outcomes of 90 of the SIGMA knees and 76 Kinemax knees where the patella was resurfaced was compared to those in the remaining 508 SIGMA knees and 1249 Kinemax knees that were not resurfaced. The decision to cement was not stated. Additionally, the outcomes of 31 knees in 30 patients that had secondary resurfacing of the patella for persistent anterior knee pain were analysed. In this group there was 1 death and 1 exclusion. This left 29 knees, of which 18 were SIGMA FB knees and 11 were Kinemax FB knees. The original diagnosis of the patients was not stated.

This gave a secondary patella resurfacing rate of 3.5% (18/508) for the SIGMA knee and 0.9% for the Kinemax knee (11/1249). Mean follow up was 28 months (12-61).

Results
Mean post-operative OKS, where a lower score is better, was 23.2 and 27.9 in the SIGMA knees, with and without patella resurfacing respectively. The mean pre-operative OKS was 45.5 and 44.4 respectively. Mean post-operative OKS, was 23.4 and 25.5 in the Kinemax knees, with and without patella resurfacing respectively. The mean pre-operative OKS was 45.3 and 44.4 respectively. No information on the significance or clinical importance of the difference was provided.

Among the patients with secondary resurfacing of the patella, the mean time to secondary resurfacing in these patients was 29 months. Of these 17 (59%) felt better after resurfacing, 10 (34%) felt the same and 2 (7%) felt worse.

Although the proportion of patients who felt better following secondary resurfacing of the knee was higher with the SIGMA knee, there was no statistical difference in satisfaction following secondary resurfacing between the prostheses (p= 0.125). For SIGMA knees, 12 (66%) felt better, 4 (22%) were same, and 2 (11%) felt worse. For Kinemax knees, 4 (36%) felt better, 7 (64%) were same, and 0 felt worse.

An improved OKS was seen in 26 of the 29 knees. The mean improvement was a decrease of 12.1 in OKS score.

There was a significant improvement following secondary patella resurfacing in the response to question 12 of the OKS, “could you walk down a flight of stairs”, (p= 0.001), from a mean pre-operation score of 4.2 (±0.76) to mean post-operative score of 2.9 (±0.79).

Before resurfacing, all patients were dissatisfied with TKA. After resurfacing 11 were very satisfied, 4 were satisfied, 4 were unsure and 10 were dissatisfied, which represents a significant improvement in satisfaction (p<0.001).

There was no correlation between time from TKA to secondary resurfacing and satisfaction.

Study Conclusion
While secondary resurfacing of the patella does not provide the solution for every case of anterior knee pain following total knee joint replacement, in greater than 50% of cases it can be effective at relieving symptoms and in this series carries a low risk of worsening symptoms or complications.
68. LACK OF AXIAL ROTATION IN MOBILE BEARING KNEE DESIGNS

Wasielewski R, Komistek R, Zingde S, Sheridan K, Mahfouz M.
Clinical Orthopaedics and Related Research 2008;466:2662–8

Objective
To assess whether the anticipated in vivo axial rotation magnitudes and patterns could be provided by mobile bearing total knee arthroplasty (TKA) designs. Also whether any differences were displayed by posterior stabilised (PS), cruciate retaining (CR), and posterior cruciate sacrificing (CS) mobile bearing (MB) knees or by knees implanted with different designs of prosthetics.

Treatment
SIGMA Rotating Platform Flex (RPF) PS knee

Comparator
SIGMA Rotating Platform (RP) Posterior Stabilised (PS) knee, SIGMA RP Cruciate Retaining (CR) knee, LCS, S-ROM® (DePuy Synthes), Legacy® (Zimmer®), MBKIII and Ceragyr® (Ceraver-Osteal) knees

Outcomes
Axial Rotation, Reverse Rotation

Study Design
Retrospective Controlled Study

A group of 527 primary TKAs implanted between 1994 and 2007 from four centres within the US were studied. Of these there were 75 SIGMA RP PS knees, 48 SIGMA RPF PS knees and 15 SIGMA RP CR knees. The decision to cement and the original diagnosis was not mentioned. The other prostheses included were the LCS, S-ROM, Legacy, MBKIII and Ceragyr knees.

This is a kinematic study assessing axial rotation and reverse rotation during deep knee bend (DKB) using fluoroscopy.

No p values were available for comparison of SIGMA prostheses due to there being many (12) prosthesis types.

Results
For all knees, only 14% of PS knees, 3% of CS knees, and 17% of CR knees attained greater than 10° axial rotation when measured from 0-90°. Axial rotation averaged 4.3°, 2.5° and 3.8° for the PS, CS, and CR knees, respectively.

Results for SIGMA knees are:
• SIGMA RP PS knees – 13% had greater than 10° rotation (Mean axial rotation = 4.8°)
• SIGMA RPF PS knees - 12% had greater than 10° rotation (Mean axial rotation = 5.6°)
• SIGMA RP CR knees - 20% had greater than 10° rotation (Mean axial rotation = 5.2°)

Reverse (Negative) Rotation for the SIGMA knees occurred in:
• SIGMA RP PS knees–11%
• SIGMA RPF PS knees – 10%
• SIGMA RP CR knees – 20%

Study Conclusion
In the analysis of all MB implants in the study, the magnitudes or patterns of axial rotation were not as expected. Only a small proportion of MB knees had axial rotation > 10°, and a minority had reverse rotation, which was expected to be rare. There are a number of factors that interact to give suboptimal mobile bearing rotational kinematics.
Objective
To assess the incidence of lateral retinacular release rates in fixed and mobile bearing total knee arthroplasties (TKA), and to assess the effect of patella tilt on the release rates.

Treatment
SIGMA Rotating Platform (RP) Posterior Stabilised (PS) cemented knee

Comparator
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) cemented knee

Outcomes
Lateral Release Rates, Patella Tilt

Study Design
Retrospective Controlled Study

Between September 2000 and March 2007, 1318 primary TKAs were performed by the senior author DD, with follow up ranging from 12 to 78 months. The original diagnosis of the patients was osteoarthritis or rheumatoid arthritis but the exact numbers were not stated.

All patients were implanted with a SIGMA knee, with fixed bearing or rotating platform tibial component. All knees were posterior stabilised and cemented. There were 940 RP and 378 FB (300 all-polyethylene tibia, 78 metal backed tibia).

Results
Lateral retinacular release rates were significantly higher for the FB group, 54 of 378, compared to the RP group, 50 of 940 (14.3 vs. 5.3%; p<0.0001).

In all knees, 9.1% (120 of 1317) had patella tilt of 5° or more. Residual patellar tilt was higher in the RP group, 10% (94 knees), compared to the FB group, 6.9% (26 knees; p= 0.0122).

Mean patella tilt was 2.89° for all knees, 3.0° for the RP group and 2.55° for the FB group. In patients where lateral retinacular release was not performed, the amount of patella tilt was higher for both the FB group (p= 0.0212) and the RP group (p=0.0002).

No patient in either group was observed to have patellar subluxation of more than 5mm, or patellar dislocation post-operatively.

Study Conclusion
It is thought that better extensor mechanism centralisation provided by bearing rotation has determined the fewer lateral releases needed in the mobile bearing group.
LEVEL IV STUDIES: CASE SERIES
Knee 2006;13(5):359-64

Objective
To present the survival analysis, clinical and radiographical outcomes of primary total knee arthroplasty in a district general hospital using the SIGMA knee at 5 years after surgery.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee

Outcomes
Knee Society Score (KSS), Operative Details, Survivorship, Radiographic Analysis, Knee Alignment, Pain Scores, Complications.

Study Design
Prospective Case Series
Between October 1998 and August 1999, 212 consecutive total knee arthroplasties (TKA) in 180 patients were performed with a SIGMA FB CR knee. These were followed for 5 years. Operations were performed by one of six surgeons. Cement was used for both components, and the patella was not routinely resurfaced.

The original diagnosis of the patients was osteoarthritis (187 knees, 88%), rheumatoid arthritis (19 knees, 9%) and post traumatic osteoarthritis (six knees, 3%). Follow up was at 6 months, 18 months, 3 years and 5 years after surgery.

Results
There were 15 knees that required patella resurfacing, and 39 knees required a lateral release to improve patellar tracking. Mean tourniquet time was 68 minutes and 37 patients required a blood transfusion, receiving a mean of 2.4 units of blood each. Mean inpatient hospital stay was 11 days.

Using KSS scores, 88.2% of knees were rated as excellent or good at 5 years.

Mean KS knee score was 30.9 pre-operatively and 89.3 post-operatively at 5 years. Mean KS function score was 48.3 pre-operatively and 79.9 post-operatively. Mean KS pain score was 3.3 pre-operatively and 46.2 post-operatively.

Of 14 knees that had a KS knee score less than 70, 8 described occasional and moderate pain, and one described severe pain. There were 4 other patients that described continuous and moderate pain, but there was no remediable causes found.

There were six knees that required revision, of which 5 were revised within 2 years for deep infection. The other, underwent re-operation for instability in flexion and extension in the coronal plane (59 months). This was a change to a larger size of polyethylene insert, without revision of the tibial or femoral components. Survivorship was 97% at 5 years, with revision for any reason. Survivorship was 99.4% at 5 years with revision for aseptic failure.

Radiographic analysis found that 11 (7.5%) of tibal components and 6 (4.1%) of the femoral components showed lucency, but by definition, no component was loose. The mean slope of the tibial component was 3.69° flexion. The mean sagittal alignment of the femoral component was 1.45° flexion.

Study Conclusion
The 97% survival at 5 years suggests that the SIGMA TKA easily meets an “entry benchmark” for 3 to 5 year survival which would be accepted by NICE in the UK. Taken along with the generally good clinical results in our study, our data strongly supports the recommendation for continued use of the SIGMA knee.
Objective
To evaluate the functional and radiological outcomes of total knee arthroplasty (TKA) in terms of stability and correction of deformity with a SIGMA RP CR knee in a Malaysian population.

Treatment
SIGMA Rotating Platform (RP) Cruciate Retaining (CR) cemented knee

Outcomes
Knee Society Score (KSS), Walking Ability, Stability, Knee Alignment, Radiographic Analysis, Wear Rate, Complications, Range of Motion (ROM)

Study Design
Prospective Case Series

From May 2001 to September 2002 a consecutive series of 18 primary TKAs in 10 patients with cemented, cruciate retaining SIGMA RP knees were followed up for a mean of 14 months (9-16) at a Malaysian centre. No patellas were resurfaced and the original diagnosis of the patients was not stated.

Results
Mean KS knee score was 28 pre-operatively and 91 post-operatively. Mean KS function score was 26 pre-operatively to 82 post-operatively.

Average duration of walking improved from less than 10 minutes pre-operatively to an average of 1 hour post-operatively.

Radiologically, all patients had an average post-operative correction of 5° valgus (4-7°). There was no evidence of radiolucent lines at the bone-cement interfaces, no osteolysis and no signs of loosening. There was no obvious asymmetrical wear, although 18 months is probably too early to show this.

There was 1 patient who had infection in both knees. After surgical intervention and debridement, her KSS scores were 92 and 94 in each knee. One patient had poor range of motion in both knees.

Study Conclusion
This study shows the safety and efficacy of the SIGMA RP knee, with satisfactory improvement in the range of motion, stability and function of the knee.
72. CAN A HIGH FLEXION TOTAL KNEE ARTHROPLASTY RELIEVE PAIN AND RESTORE FUNCTION WITHOUT PREMATURE FAILURE

Bauman R, Johnson D, Menge T, Kim R, Dennis D.
Clinical Orthopaedics and Related Research 2012;470:150–8

Objective
To determine the magnitude of pain relief, knee motion, function and radiographic appearance with a high flexion total knee arthroplasty (TKA). Also, to assess whether the pre-operative flexion affects the knee flexion gain post-operatively.

Treatment
SIGMA Rotating Platform Flex (RPF) Posterior Stabilised (PS) cemented knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Radiographic Analysis, Complications

Study Design
Prospective Case Series

From July 2004 to April 2007, 166 patients received 179 cemented primary. SIGMA RPF knees. The patella was resurfaced in all cases, and all knees were posterior stabilised.

Mean follow up was 46 months, with a minimum of 2 years, and 154 knees were available for evaluation after deaths and lost to follow up. The original diagnosis of the patients was osteoarthritis (136 knees; 88%), traumatic osteoarthritis (14 knees; 9%), rheumatoid arthritis (two knees; 1%), osteonecrosis (one knee; 1%), and conversion from a failed unicompartmental arthroplasty (one knee; 1%).

Pre-operative flexion in all patients was more than 100° and all patients were generally under the age of 70, apart from one exception.

Results
Mean KS knee score was 41 pre-operatively and 95 post-operatively. Mean KS function score was 59 pre-operatively and 90 pre-operatively. Mean flexion was 123° pre-operatively and 129° post-operatively.

Radiolucent lines were infrequent, <6% in most zones, apart from in zone 4 of the femoral component (the posterior femoral condyles), where 43% of knees had radiolucent lines. There were no radiolucent lines of more than 2mm, and none were progressive after 1 year.

For patients with 100°-120° pre-operative flexion, there was a significantly greater post-operative improvement in mean KS knee score compared to those with >120° pre-operative flexion (62 vs. 48; p<0.001).

The patients with 100°-120° pre-operative flexion also exhibited greater post-operative improvements in knee flexion than those with a greater pre-operative flexion, (13° vs. 3°; p<0.001).

There was no difference in mean improvement in KS function between patients with greater and less than120° flexion pre-operatively (p=0.11).

Complications occurred in 13 knees (8%), 4 arthrofibrosis, 3 patellofemoral crepitus, 1 DVT, 1 superficial cellulitis, 1 non displaced intra-operative lateral condyle fracture. There were 2 post-operative traumas and 1 implant required removal due to sepsis.

There were no failures due to implant loosening, instability or disabling pain were reported.

Study Conclusion
Increased flexion has been found to correlate with patient satisfaction following TKA. Excellent outcomes were reported in this series, similar to those reported elsewhere with high flexion designs. Complications and reoperation rates were similar to those reported with conventional designs of TKA, although there was a higher than expected incidence of posterior femoral radiolucent lines. Patients with less pre-operative range of motion appear to be more likely to benefit from a high flexion TKA.
73. PRIMARY TOTAL KNEE ARTHROPLASTY USING THE P.F.C. SIGMA ROTATING PLATFORM CRUCIATE RETAINING ENDOPROSTHESIS: A SIX YEAR FOLLOW UP

Bhatt H, Rambani R, White W, Chakrabarty G.
Knee 2012;19(6)856-9

Objective
To present 6 year data for the SIGMA Rotating Platform (RP) knee, specifically for outcomes and implant survival.

Treatment
SIGMA Rotating Platform (RP) Cruciate Retaining (CR) cemented knee

Outcomes
Knee Society Score (KSS), Oxford Knee Score (OKS), Range of Motion (ROM), Survivorship, Radiographic Analysis, Complications.

Study Design
Retrospective Case Series

A retrospective review was conducted on 161 consecutive primary knee replacements in 147 patients who received a cemented, cruciate retaining SIGMA RP knee. The original diagnosis was osteoarthritis 96%, rheumatoid arthritis 3% and one case of psoriatic arthritis. There was a minimum of 6 years follow up, 41 patients underwent patella resurfacing, and 1 knee was lost to follow up leaving 160 for analysis. Mean follow up was a 7.2 years (6-9).

Results
Mean KS knee score was 53 pre-operatively and 80 post-operatively. Mean OKS was 43 pre-operatively and 21 post-operatively, with low scores indicating a better outcome.

Mean ROM was 91° pre-operatively and 113° post-operatively.

Implant survival was 100% at 7.2 years with component revision as the end-point. If the patient lost to follow up is considered a failure, then the survival rate would be 99.3%.

One patient did require manipulation for a bearing dislocation.

120 knees (75%) had no radiolucencies, 40 (25%) scored 4 or less (no radiographic indication for revision) according to the KS rating system, with a mean of 2.3 for the femoral component and 1.9 for the tibial component. No knee scored more than 5 (which would require observation for progression).

One patient had a superficial infection, one patient had a DVT, one patient had dislocation for a fall (mentioned above,) and one patient needed manipulation for stiffness. Range of motion subsequently improved in this patient.

Study Conclusion
The SIGMA RP knee performed very well at midterm follow up. KSS and OKS both improved and survivorship showed good outcomes. These results are not inferior to those published using a fixed bearing prosthesis. Longer follow up is needed to determine if there are changes in the functional results.
Knee Surgery, Sports Traumatology, Arthroscopy 2009;17:369–73

Objective
To study the value of navigation system in evaluation of knee kinematics before and after posterior substituting rotating platform TKA.

Treatment
SIGMA Rotating Platform Flex (RPF) Posterior Stabilised (PS) knee implanted using Computer Assisted Surgery (CAS)

Outcomes
Knee Alignment, Varus/ Valgus Laxity, Anterior/ Posterior Laxity, Femoral Rollback, Tibial Axial Rotation.

Study Design
Prospective Case Series

A group of 10 patients, 8 male, 2 female from one centre each received a SIGMA RPF knee. Intra-operative measurements were made using CAS (KIN-Nav system). All implants were posterior stabilised, but the use of cement and treatment of the patella were not stated. Kinematic measurements were recorded before and after posterior sacrificing rotating platform TKA was completed. All patients had intact cruciate ligaments prior to surgery and were diagnosed with osteoarthritis.

Results
TKA improved alignment in pre-operative osteoarthritic varus knees. In the study there were 7 of these, all of which became neutral after surgery. In the 3 neutral knees, neutral alignment was maintained.

Post-operatively, Varus/Valgus (VV) laxity at 0° flexion was reduced by 2° ±2° p=0.006. At 30° of flexion, VV laxity was similar to that of the knee pre-operatively p=0.363.

Anterior/Posterior laxity at 90° flexion significantly increased after TKA. Before surgery there was a linear increase in femoral rollback with flexion and there was a total posterior translation of 23±8mm. Following TKA, the femur had an abnormal anterior translation up to 60° of flexion, followed by a small rollback of 12 ±5mm.

TKA influenced the tibial rotation pattern during flexion, but not the total amount of internal/external rotation throughout whole range of flexion, which was preserved after TKA (6°) p=0.094.

Study Conclusion
This study shows that CAS might be used to analyse kinematic patterns throughout flexion of a TKA at time zero. It could be used as a first time evaluation of the prosthetic function during surgery.
75. A COMPREHENSIVE JOINT REPLACEMENT PROGRAM FOR TOTAL KNEE ARTHROPLASTY: A DESCRIPTIVE STUDY

**Cook J, Warren M, Ganley K, Prefontaine P, Wylie J.**
BMC Musculoskeletal Disorders 2008;9:154-61

**Objective**
To assess the effectiveness of the Joint Replacement Program (JRP), which is an evidence based program for the management of total knee arthroplasty (TKA). The aim of this study is to report post-surgical outcomes of patients enrolled in this program.

**Treatment**
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee

**Outcomes**
Length of Stay, Range of Motion (ROM), Complications.

**Study Design**
Propective Case Series

The Joint Replacement Program (JRP) was designed to aid pre-operative, surgical and post-operative care and medical management to decrease hospital stay and improve patient outcomes. It is a pre- and post-operative protocol for medical care.

Patients with osteoarthritis (OA) requiring TKA, able to participate in physical therapy in hospital and caregiver support at home, were eligible for the JRP and this study. During the study enrolment period there were 87 consecutive patients with TKA (at one centre), of which 74 met the eligibility criteria and were implanted with a cemented, cruciate retaining SIGMA FB knee. Treatment of the patella was not stated. Patients were followed for 6 months.

**Results**
The length of hospital stay was 2 days for 53% of the patients, 3 days for 39% and 4 days for 7%.

The knee flexion ROM goal of 90° was achieved in 88% of all patients (mean ROM 91.7°). The extension ROM goal of 0° was achieved in 46% of all patients (mean ROM 2.4°).

Two patients had complications during their hospital stay, for transient arrhythmia and respiratory distress. A further 9 patients had complications during the 6 month follow up period. One patient was admitted for dehydration, two patients fell, and three required oral antibiotics. Three patients required knee joint manipulations and additional physical therapy approximately 6-7 weeks post-surgery in order to increase flexion ROM.

All patients who were discharged home achieved the medical criteria for hospital discharge and met their physical therapy goals.

**Study Conclusion**
The JRP for TKA was associated with satisfactory clinical outcomes and short lengths of stay. A high percentage of patients were discharged home with outpatient physical therapy and minimal complications. The JRP may represent an efficient, effective and safe protocol for providing care after TKA.
76. UNCEMENTED TIBIAL FIXATION IN TOTAL KNEE ARTHROPLASTY

Cossetto D, Gouda A.
Journal of Arthroplasty 2011;26(1):41-44

Objective
To provide midterm clinical and radiological results of total knee arthroplasty (TKA) with hydroxyapatite-coated uncemented tibial component fixation.

Treatment
SIGMA Fixed Bearing (FB) cementless knee (Uncemented AMK DUOFIX® Tibial Component)

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Radiographic Analysis, Survivorship, Complications.

Study Design
Prospective Case Series

A group of 205 consecutive knees between January 2002 and December 2004 were implanted with a cruciate retaining SIGMA FB knee by a single surgeon. An uncemented AMK DUOFIX tibial component was used in all, and the femoral component was an uncemented SIGMA component. The patella was resurfaced in 86% of patients.

The outcomes of 175 knees that had a mean follow up of 5 years and 7 months were reported. There were 11 patients lost to follow up. The original diagnosis of the patients was not stated. Mean patient age was 69.

Results
Mean KS knee score was 57 pre-operatively and 92 post-operatively. Using the KSS scores, 96.6% of knees were rated as excellent, 1.1% good, 1.7% fair, and 0.6% poor. Mean ROM at final follow up was 117° (85°-135°).

Radiographic analysis found that 9 patients had an incomplete lucent line. None of these lines extended around the pegs, and none showed any progression over time. No osteolysis occurred.

Survivorship at an average of 5 years and 7 months was 98.85%, considering revision due to aseptic loosening (1 case) and due to instability (1 case).

Complications included: 3 wound cellulites, 2 deep infections, and 5 patients with pain of the patello-femoral joint, which required resurfacing of the patella (12-38 months post-operatively). There were also two revisions, one for aseptic loosening and one for instability.

Study Conclusion
An uncemented tibial component with POROCOAT® and hydroxyapatite coating, with a smooth stem and coated pegs, provides a predictably stable fixation, with excellent midterm clinical and radiological outcomes.
77. MIDTERM RESULTS WITH THE P.F.C. SIGMA TOTAL KNEE ARTHROPLASTY SYSTEM

Dalury D, Gonzales R, Adams M, Gruen T, Trier K.
Journal of Arthroplasty 2008;23(2):175-81

Objective
To report a single surgeon’s experience with the midterm survival and radiographic results using a second-generation continuation of a highly successful total knee arthroplasty system.

Treatment
SIGMA Fixed Bearing (FB) cemented knee

Outcomes
Survivorship, Complications, Knee Society Scores (KSS), Range of Motion (ROM), Radiographic Analysis, Knee Alignment.

Study Design
Prospective Case Series

Between June 1996 and Dec 1997, 284 knees in 207 consecutive patients of a single surgeon received a cemented tri-compartmental SIGMA FB knee. Of these, 96% of were cruciate retaining and all patellas were resurfaced.

Patients were prospectively followed for a mean of 7.25 years.

Results
There was 1 revision, after a fall, and 1 drainage of a superficial infection. With component revision as the endpoint, survivorship was 99.6% at 8 years.

At 7 years follow up, median KS pain score was 20 pre-operatively and 50 (out of 50) post-operatively. Median KS function score was 50 pre-operatively and 100 post-operatively. Median total KSS was 50 pre-operatively and 95 post-operatively.

At a minimum of 6 years following surgery, there was a significant improvement in the mean range of knee motion, which was 122° pre-operatively and 125° post-operatively (p =0.014), and flexion (p <0.001). Overall femoral-tibial alignment measured 4.1° valgus. The mean femoral condylar angle was 84.6°, and the mean tibial alignment was 88.6°.

According to the Knee Society rating system, 67.5% of knees had no radiolucencies, 31% scored 4 or less (no radiographic indication for revision), and the remaining 1.5% scored 5-9 (requires observation for progression).

Study Conclusion
The study shows excellent clinical scores and survivorship at 8 years follow up. There were no implant related failures and few complications. Osteolysis was not a problem in this series.
78. MIDTERM SURVIVAL OF A CONTEMPORARY MODULAR TOTAL KNEE REPLACEMENT: A MULTICENTRE STUDY OF 1970 KNEES

Dalury D, Barrett W, Mason J, Goldstein W, Murphy J, Roche M.
Journal of Bone and Joint Surgery (Br) 2008;90:1594-6

Objective
The purpose of this multicentre study was to report the implant survival and the clinical and radiographic outcomes of the SIGMA total knee replacement (TKR) in a large group of patients with a minimum of five years clinical follow up.

Treatment
SIGMA Fixed Bearing (FB) cemented knee

Outcomes
Knee Society Score (KSS), Radiographic Analysis, Osteolysis, Complications, Range of Motion (ROM), Survivorship.

Study Design
Prospective Case Series

All patients from eight centres were prospectively entered into the study if they received a cemented SIGMA FB prosthesis. This totalled 1970 prostheses implanted into 1517 patients. The original diagnosis of the patients was osteoarthritis in 1894 knees (96.1%), rheumatoid arthritis in 42 knees (2.1%), posttraumatic arthritis in 22 knees (1.1%), avascular necrosis in ten knees (0.5%), Paget’s disease in one, and psoriatic arthritis in one (0.2%).

The cruciate ligament was retained in 80.1% of knees and 94.5% of patellas were resurfaced. Patients were followed for a mean of 7.3 years (5-10 years).

Results
Mean KS knee score was 52.9 pre-operatively and 87.3 post-operatively at 5 years follow up, the. The mean KS function was 47 pre-operatively and 70.8 post-operatively.

Radiographs showed osteolysis in 39 knees (2.2%) at a mean of 5.2 years.

There were a total of 40 (2%) revisions: 17 infections, 6 osteolysis or polyethylene wear, 4 due to pain, 4 component loosening, 3 fractures, 1 component malpositioning and 1 patellar tendon rupture.

The 10 year survival with revision for any cause other than infection as the endpoint was 97.2%.

Knees where the posterior cruciate ligament was sacrificed had a significantly better range of movement than those where posterior cruciate was retained (1.1° to 115.9° and 1.6° to 114.4°, p = 0.014). However, there was no difference between them in overall function or component survival (p=0.84 and 0.37 respectively).

Analysis of gender showed females had significantly poorer pre-operative function and pain scores (43.7 vs. 51.6 points and 13.3 vs. 15.5 points, respectively). The post-operative change in overall mean knee scores was significantly better for men (31.1 for women and 36 for men p= 0.003).

The estimated ten year survival was 97.8% for men and 96.9% for women, but this difference was not statistically significant (p = 0.96).

There was no significant difference in failure rates between patients with or without osteoarthritis (2.0% vs. 3.9% failures, p=0.2).

Study Conclusion
The SIGMA knee system provides excellent results in the medium term even with a large selection of patients across a multi-centre study.
**Objective**

To determine the function, occurrence of osteolysis and complications occurring in a cohort of obese patients receiving an all-polyethylene tibial component.

**Treatment**

SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knees with an all-polyethylene tibial component.

**Outcomes**

Survivorship, Complications, Knee Society Scores (KSS), Range of Motion (ROM), Radiographic Analysis, Knee Alignment.

**Study Design**

Retrospective Case Series

Between Sep 1996 and Dec 2002, 378 cemented SIGMA knees with all-polyethylene tibial (APT) components were implanted. Of these, 125 (90 patients) were implanted into obese patients (BMI >30 kg/m²). All surgeries were performed by DD. All surgeries were cruciate retaining and all patellas were resurfaced.

At a mean of 10.4 years (7.8-14 years), 75 knees in obese patients (53 patients, mean BMI 34 kg/m²) were available for follow up. The diagnosis was osteoarthritis in 52 of these patients.

**Results**

Mean KS knee score was 51.6 pre-operatively and 92.4 post-operatively.

Mean KS function score was 51.7 pre-operatively and 76.7 post-operatively.

Mean KS pain score was 17.9 pre-operatively and 46.8 post-operatively.

The mean knee extension was 3.3° (0°–19°) pre-operatively and 0.7° (0°–10°) at final follow up. The mean knee flexion was similar pre-operatively and at final follow up, 119.4° (82°–140°) vs. 118.2° (75°–135°), respectively.

There were 5 tibial radiolucencies in 4 patients, all of which were less than 1mm and non-progressive. There were 2 cases of femoral radiolucencies, and 1 case of minimal, non progressive tibial osteolysis.

No knee was radiographically positioned more than 3° relative to the mechanical axis. No femoral component was placed in more than 2° of femoral flexion, and no tibial component was placed in more than 6° of posterior slope. No patient had patella subluxation or dislocation.

One patient required revision for a traumatic event. There were no implant-related failures or any implants at risk of failure at latest follow up.

**Study Conclusion**

At an average 10 year follow up, total knee arthroplasty in obese patients using an APT component gave satisfactory clinical and radiographic results. These findings support the continued use of an APT component even in the obese population.
80. IN VIVO KINEMATICS OF MOBILE BEARING TOTAL KNEE ARTHROPLASTY DURING DEEP KNEE BENDING UNDER WEIGHT-BEARING CONDITIONS

Futai K, Tomita T, Yamazaki T, Tamaki M, Yoshikawa H, Sugamoto K.
Knee Surgery, Sports Traumatology, Arthroscopy 2011;19(6):914-20

Objective
To analyse the in vivo kinematics of high flexion mobile bearing total knee arthroplasty (TKA) including a polyethylene insert during deep knee bending up to 120° of knee flexion under weight-bearing conditions using a 2D to 3D registration technique.

Treatment
SIGMA Rotating Platform Flex (RPF)
Posterior Stabilised (PS) knee

Outcomes
Range of Motion (ROM), Axial Rotation, Anterior Posterior Translation.

Study Design
Prospective Case Series

Between 2006 and 2007, 13 consecutive SIGMA RPF prostheses were implanted into 12 patients who could achieve more than 120° flexion pre-operatively. The diagnosis was osteoarthritis in 9 knees.

One author performed all surgeries. Treatment of the cruciate ligaments and patella were not stated. Patients underwent fluoroscopic surveillance in the sagittal plane while performing deep knee bending and standing.

Results

Range of Motion: Mean hyperextension was 2.6° (-6.3 to 12.3°). Mean maximum flexion was 122.6° (115.4 – 133.0°), and mean arc of ROM was 125.2° (109.9 – 137.9°).

Axial Rotation: For flexion between 0-120°, external rotation of the femoral component and the polyethylene insert compared to the tibia was 10.4°, and 10.2° respectively. As this was the same for each component it means that the femoral and polyethylene component did not rotate relative to each other and that the axial rotation occurred between the polyethylene and the tibial components.

AP Translation: From 0-70° of flexion, the contact point between the polyethylene and femoral component translated 1.7 ±4.1 mm anteriorly on the medial side and 1.2±4.4 mm posteriorly on the lateral side. From 70° to maximum flexion, this point translated 6.2±5.9 mm posteriorly on the medial side and 6.6±3.8 mm posteriorly on the lateral side.

At knee flexion from 80-100°, the medial contact point was significantly anterior to the lateral contact point (p <0.05).

Study Conclusion
This study demonstrates the motion and contact points of the polyethylene insert relative to the femoral component in the SIGMA RPF knee. Even up to maximum flexion, femoral axial rotation was caused by rotation of the tibial insert on the tibial tray, and there was little rotation of the femoral component on the polyethylene insert. The anterior-posterior contact points of the medial and lateral sides were relatively close. This may contribute to reducing articular contact stress between the femoral component and polyethylene insert.
81. IN VIVO KINEMATICS OF MOBILE BEARING TOTAL KNEE ARTHROPLASTY INCLUDING POLYETHYLENE INSERT

Futai K, Tomita T, Watanabe T, Yamazaki T, Tamaki M, Yoshikawa H, Sugamoto K.
Journal of Bone and Joint Surgery (Br) 2008;92(SUPP I):120.

Objective
To clarify the in vivo motion of high flexion mobile bearing total knee arthroplasty (TKA), including the polyethylene insert, during weight-bearing deep knee bend motion.

Treatment
SIGMA Rotating Platform Flex (RPF)
Posterior Stabilised (PS) knee

Outcomes
Range of Motion (ROM), Tibial Rotation, External Rotation, Femoral Rollback.

Study Design
Retrospective Case Series
An analysis of 9 patients that received a SIGMA RPF prosthesis. Motion between components was measured using fluoroscopy. This was analysed using a two to three dimensional registration technique. This uses computer-assisted design (CAD) models to reproduce the spatial position of components. Cruciate ligament treatment, treatment of the patella and use of cement were all not reported.

Results
Mean range of hyperextension was 2.1° and the mean range of flexion of 121.2°.

The femoral component demonstrated 13.0° external rotation, relative to the tibial component, for 0–120° flexion. The tibial component rotated 12.1° externally relative to the polyethylene insert.

In the upright position the femoral component rotated 7.8° compared to the tibial component and the polyethylene component also rotated 8.2° relative to the tibial tray.

The femoral component (relative to tibial component) exhibited a central pivot pattern external rotation from extension to 80° flexion. Subsequently, from 80° to 120°, the bilateral condyles moved backward.

Similarly, the femoral component relative to the polyethylene component exhibited a central pivot pattern external rotation from extension to 70° flexion and subsequently bicondylar rollback from 70-120° flexion.

Study Conclusion
The mobile bearing mechanism has advantages over the fixed bearing prosthesis as it reduces contact stress and keeps high conformity, whilst range of motion was maintained. In the standing position, the femoral and tibial components rotated externally relative to the polyethylene insert in almost equal measures. This indicates that the self aligning mechanism, which is a feature of mobile bearing knees, may also work well.
Goldstein W, Gordon A, Branson J. Orthopaedics 2006;29(9):S71-S75

Objective
To assess the range of motion (ROM) in cruciate retaining mobile bearing total knee arthroplasty (TKA), with the experience of 2000 cases performed by a single surgeon.

Treatment
SIGMA Rotating Platform (RP) Cruciate Retaining (CR) cemented knee

Outcomes
Range of Motion (ROM), Knee Society Score (KSS), Complications.

Study Design
Retrospective Case Series

Between September 2000 and January 2006, one surgeon (WGM) performed 2000 consecutive cruciate retaining SIGMA RP knees. The results of the first 500 knees with 1 year follow up data were reported. All components were cemented. A cruciate retaining design is favoured by the surgeon, but in some circumstances it was resected. The original diagnosis of the patients was not reported.

Results
Results of the first 500 knees were:
• Mean KS knee score was 57 pre-operatively and 95 post-operatively.
• Mean KS function score was 84 post-operatively (no pre-operative value).
• Mean flexion was 123° post-operatively.

In the same 500 patients, 1 spin out occurred (a 6’5” man needed a larger implant than was available at the time of surgery), and there was 1 subluxation requiring revision to a thicker insert. There were also 7 deep infections which required surgical intervention.

Study Conclusion
The success of the SIGMA RP knee highlights the importance of having a natural 20° of lateral condyle rotation posteriorly in the first 120° of flexion.
Objective
Determine the quality of knee function at deep flexion and pain relief achieved at 1 year using the SIGMA RPF prosthesis.

Treatment
SIGMA Rotating Platform Flex (RPF)
Posterior Stabilised (PS) knee

Outcomes
Knee Society Score (KSS), Pain Score, Hi Flexion Function Score (HFF), Patient Activities, Multivariate Analysis, Radiographic Analysis, Complications.

Study Design
Prospective Case Series

During the study period 100 out of 298 patients from one surgeon (CSR) were treated with a posterior stabilised SIGMA RPF knee and enrolled into the study. The original diagnosis was degenerative joint disease in all patients. Of these, 83 were available for follow up at 1 year (10 declined, 3 moved away and 4 were lost). There were 17 bilateral knees, meaning that 100 knees were available. The patella was routinely resurfaced, and all implants were posterior stabilised. The use of cement fixation was not reported.

Results
One year after surgery, 57% of patients were able to kneel without significant difficulty, 69% were able to squat without significant difficulty, and 46% were able to sit on their heels without significant difficulty. Almost 80% could do at least one of the above activities.

Post-operatively, mean KS knee score was 95 and mean KS function score was 91. Mean knee flexion was 125°. Patient reported pain was: None (62%) Mild (18%) Moderate (16%) Severe (4%).

Function in deep flexion correlated with VAS pain scores but not with post-operative knee flexion angle. Surprisingly, patients with flexion of >130° scored lower (worse) on the Hi Flex Function score than patients with flexion of 120-129° (7.4 vs. 9.9 respectively; p<0.05). This indicates inferior function in deep flexion activities. Patients with <120° flexion also had a lower HFF score (7.4) than patients with 120-129°, but this was not statistically significant (p= 0.085).

In the multivariate analysis, only pain was significantly associated with the Hi Flex Function score (R =0.41 p=0.0001). The magnitude of the correlation was greater in patients with anterior knee pain. The presence of anterior knee pain was associated with a lower Hi Flex Function score (6.9 v 9.1 for those with and without anterior knee pain p=0.009).

There were no progressive radiolucent lines and no other radiographic signs of compromised fixation. Two surgical complications occurred, one manipulation under anaesthesia and one re-operation for anterior knee pain.

Study Conclusion
Results with the SIGMA RPF knee at 1 year are encouraging. However, one in five patients remained significantly limited in high flexion activities. High flexion (>130°) also did not ensure high function in flexion.
Objective
To report the clinical and radiological results of the SIGMA total knee arthroplasty (TKA) up to 9 years after surgery within a district general hospital.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee

Outcomes
Knee Society Score (KSS), Pain Scores, Complications, Survivorship, Range of Motion (ROM), Knee Alignment.

Study Design
Prospective Case Series

A total of 318 consecutive knees in 275 patients were treated with the SIGMA FB CR knee in a district general hospital. The original diagnosis was osteoarthritis (286 knees, 90%), rheumatoid arthritis (26 knees, 8%) and post-traumatic osteoarthritis (6 knees, 2%). The mean patient age pre-operatively was 68. Operations were performed by six different consultant surgeons or by a trainee under direct supervision. Some patellas were resurfaced, however this was not routine and all knees were cemented. Patients were followed for a mean 102 months (7-9 years). Data on these patients has been reported previously at an earlier time point by Clayton et al: Knee 2006 13(5):359-64.

Results
Mean KSS pre-operatively for 147 knees with 7-9 year follow up were 33 for KS knee, 48.2 for KS function and 3.1 for KS pain.

Mean KSS at 5 years post-operatively were 85.9 for KS knee, 79.9 for KS function and 44.9 for KS pain.

Mean KSS at 7-9 years post-operatively were 84 for KS knee, 64.1 for KS function and 41.3 for KS pain. There were 74% of patients with good or excellent results.

There were 7 knees requiring revision, of which 6 were due to deep infection. The other was for knee instability, requiring a change of the polyethylene insert. Survivorship was 97.7% considering revision for any reason and 99.6% considering revision for aseptic failure only.

Radiographic analysis showed that 66% of knees had no radiolucent lines. There were 33% that scored 4 or less (not indicated for revision) and 1.4% that scored 5-9 (requires follow up for progression).

Mean mediolateral alignment was 5.36 ±2.53° valgus, and 16% were out of the 7±3° suggested range. There were 2 knees (1.4%) with a single osteolytic lesion.

Mean Fixed Flexion Deformity (FFD) was 9±7.2 pre-operatively compared to 1±3.0 at 5 years and 1±2.8 at 9 years. Mean active flexion was 108° pre-operatively and 95° at 5 years and 96° at 9 years.

Study Conclusion
This study shows that the SIGMA FB CR knee performs well in the medium-term post-surgery, with excellent survival rates and good clinical and radiological outcomes. It represents results from a large cohort of consecutive patients with a follow up rate of over 98%, allowing a fair evaluation of the efficacy of the prosthesis which should be reproducible in any general orthopaedic unit.
Objective
The objective of this study was to evaluate the radiological and clinical correlations between implant design and patella positioning in patients who underwent total knee arthroplasty (TKA) using modern femoral implants.

Treatment
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) cemented knee

Outcomes
Radiographic Analysis, Patellar Tilt, Complications, Knee Society Score (KSS), Range of Motion (ROM), Patello-femoral Complications.

Study Design
Prospective Case Series

In 2009, a series of 30 consecutive patients with osteoarthritis (OA) scheduled for a TKA were randomly selected. All patients received a SIGMA FB PS knee using a new SIGMA PS femoral component. In all, the new ‘deep trochlear groove’ femoral design was used. All patellas were resurfaced and tibial and femoral components were all cemented. Mean patient age was 69 and all patients were reviewed at 2 years minimum follow up.

Results
The mean patella tilt was 18.5° pre-operatively and 3° post-operatively. The mean patellar congruence angle was 10.3° pre-operatively and -3° post-operatively. The mean lateral patellar displacement was 12.2mm pre-operatively and 2.7mm post-operatively. The mean posterior condyles angle was 5.7° pre-operatively and 2.8° post-operatively. All of these four post-operative changes were statistically significant (p<0.05).

Mean KS knee score was 43 pre-operatively and 89 post-operatively, and mean KS function score was 42 pre-operatively and 76 post-operatively. Mean post-operative knee flexion was 115° (97° - 115°).

There were no revisions in this series. Two patello-femoral complications occurred, one painful patellar crepititus during motion and one anterior knee pain when rising from a chair or stair climbing. The first complication was related to insufficient patellar bone removal, and the second revealed that there was an asymmetric patellar bone cut.

Study Conclusion
This study suggests that the newer SIGMA knee femoral design with softer edges and a prolonged femoral groove allows for correct reproducibility of patello-femoral conformity. The incidence of extensor mechanism complications appears to be more related to a poor surgical technique than implant design.
86. FIVE TO EIGHT YEAR RESULTS OF A PROSPECTIVE STUDY IN 118 ARTHROPLASTIES USING POSTERIOR STABILISED ROTATING PLATFORM KNEE IMPLANTS

Maniar R, Gupta H, Singh A, Johorey A, Singhi T.

Objective
To analyse a series of consecutive patients who had primary total knee arthroplasties (TKA) performed by a single surgeon using the posterior stabilised SIGMA Rotating Platform (RP) knee, which was introduced in the year 2000.

Treatment
SIGMA Rotating Platform (RP) Posterior Stabilised (PS) cemented knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Patient Activities, Complications, Patient Satisfaction, Osteolysis, Survivorship.

Study Design
Prospective Case Series

From September 2001 to December 2003, 478 TKAs were performed by the senior author (RNM). This study consists of a consecutive series of 133 of these knees in 118 patients that received a posterior stabilised SIGMA RP knee. The original diagnosis of the patients was 112 knees with osteoarthritis (15 bilateral) and 6 with rheumatoid arthritis. All implants were cemented, and the patella was replaced in every patient. Mean follow up was 6.5 years (five to eight years). One hundred and two patients (112 knees) were from India.

Results
Mean KS knee score was 27 pre-operatively and 96 post-operatively. Mean KS function score was 51 pre-operatively and 83 post-operatively. Mean flexion was 105° pre-operatively and 120° post-operatively. Post-operative flexion was greater than 130° in 34% of patients, 67% could sit cross legged, and 57% could sit on the floor for their activities.

Patello-femoral pain and crepitus were felt in 5% of knees. One knee had a clunk which settled without intervention, 3 had manipulation under anaesthesia between 3 and 6 months post-operatively, and 1 patient had a hypertrophic scar and was given a steroid injection.

98% of patients were happy with their outcome. There were no infections in the post-operative period, and no patient had spin out of the mobile bearing. None of the knees had visible osteolysis on radiographs. 8 knees had non progressive radiolucent lines.

Implant survival was 100% at an average of 6.5 years.

Study Conclusion
In selective Asian patients implanted with the SIGMA RP PS knee, survivorship was 100% at 6.5 years. Excellent flexion, excellent pain relief, and a low incidence of patello-femoral symptoms was also reported, with no spin out, despite patients sitting on the floor or cross legged.
87. HIGH FLEX ROTATING PLATFORM KNEE IMPLANTS TWO TO SIX YEAR RESULTS OF A PROSPECTIVE STUDY

Maniar R, Singhi T.  
Journal of Arthroplasty 2012;27(4):598-603

Objective  
To report the 2-6 year post-operative functional outcomes, and radiologic results of the SIGMA Rotating Platform Flex (RPF) knee, implanted consecutively in 53 knees by a single surgeon, in a prospective study.

Treatment  
SIGMA Rotating Platform Flex (RPF) Posterior stabilised (PS) cemented knee implanted using computer aided surgery (CAS)

Outcomes  
Knee Society Score (KSS), Range of Motion (ROM), Patient Activities, Pain, Knee Alignment, Patient Satisfaction, Radiographic Analysis, Complications.

Study Design  
Prospective Case Series

From February 2005 to September 2008, 1227 total knee arthroplasties (TKA) were implanted by the senior author (RNM). This study consists of a consecutive series of 53 of these knees in 48 patients that received a posterior stabilised SIGMA RPF knee. The original diagnosis for all patients was osteoarthritis.

All patients had patella resurfacing. All knees were implanted using CAS (Ci System). Cement was used in all cases and mean follow up was 4.2 years (2.2 to 6 years).

Results  
Mean KS knee score was 36 pre-operatively and 96 post-operatively, and mean KS function score was 55.2 pre-operatively and 90.6 post-operatively.

Mean flexion deformity was 2.8° pre-operatively and 0° post-operatively. Mean flexion was 124° pre-operatively and 130° post-operatively, with 31 knees (59.6%) having flexion of >130°, and 6 knees with 155° flexion.

Post-operatively, 81% of patients could sit cross legged, and 53% could sit on the floor for their activities. Only 21% could squat regularly for their activities.

Patello-femoral pain was reported in four knees. One of these had patellar clunk and one had significant patellar crepitus and pain. Both were treated arthroscopically. The patient with clunk had complete resolution of symptoms. The patient with significant patellar crepitus was left with mild crepitus and no pain. 95.7% of patients were happy with the outcome and said that they would opt to have the same implant in the contra-lateral knee.

Pre-operative deformity was varus in all knees and the femoral tibial angle varied from 3° valgus to 11° varus. Post-operative femoral tibial angles were from 1° to 8° valgus with an average of 4.9°. Tibial slope alignment averaged 4.4° and femoral component alignment averaged 1.5° flexion.

Radiographic analysis by 2 independent observers did not identify any loosening or evidence of progressive radiolucent lines. No knee had any visible osteolysis on the radiographs and there were no spin outs.

Study Conclusion  
In selective Asian patients implanted with the SIGMA RPF knee, survivorship was 100% survival at 2 to 6 years. Good knee flexion and excellent pain relief and a low incidence of patello-femoral symptoms was also reported, with no spin out, loosening, or osteolysis.
Objective
To show the safety and efficacy of a rotating platform high flexion design of total knee arthroplasty (TKA) and to investigate the degree of range of motion (ROM) and activities of daily living (ADL) requiring high flexion. Also, to identify factors for dissatisfaction.

Treatment
SIGMA Rotating Platform Flex (RPF) Posterior Stabilised (PS) knee

Outcomes
Knee Society Score (KSS), Range of Motion (ROM), Pain, Patient Activities, Satisfaction, Complications.

Study Design
Prospective Case Series

Between March 2004 and December 2006, 100 consecutive patients received 125 posterior stabilised SIGMA RPF knees. The original diagnosis of the patients was not stated. All patellas were resurfaced. The use of cement was not stated.

Patients were followed for a mean of 4.5 years (Range: 3-5 years).

Results
There were 109 knees available at final follow up. KSS outcomes were good or excellent for 96% of knees.

Mean KS knee score was 54.2 pre-operatively and 95.4 post-operatively. Mean KS function score was 59.1 pre-operatively and 91.4 post-operatively.

Mean ROM was 110.7° pre-operatively and 124° post-operatively. Post-operative flexion was more than 120° in 75%, more than 130° in 40% and more than 140° in 9%.

Anterior knee pain was present in 15 patients (18 knees, 16.5%). Crepitation was noted in 11 knees, of which 5 were painful and 6 were pain free. Two patients had painful crepitation requiring scar excision.

55% of patients were able to participate in sports activities or activities of daily living which required high flexion. 62% could squat, and 60% could kneel without considerable difficulty.

94.2% of patients were satisfied with their ability to use the operated knee (score ≥5/10). Mean patient satisfaction was 8.6 out of 10, a slight improvement on first year results (8.3). All dissatisfied patients complained of pain in the operated knee. Lower satisfaction correlated significantly with knee pain (r= -0.9, p= 0.005) and age (r= -0.8, p= 0.029).

There were no cases of loosening, osteolysis or spinout in this series.

Study Conclusion
The 3 to 5 year follow up in a series of patients with the SIGMA RPF knee showed that ROM was more than 130° in 40% of patients, that KSS was good to excellent in 96% of patients, and that 55% were able to participate in sports activities or activities of daily living which required high flexion. Anterior knee pain and painless crepitation were present in 14% and 9% of patients, respectively. Longer follow up for wear, fixation and durability are warranted.
Objective
The purpose of this study was to describe the authors technique of patellar replacement; to analyse pre-operative and post-operative radiographic parameters, especially patellar tilt, baja, and overstuffing, to investigate any correlation with anterior knee pain.

Treatment
SIGMA Fixed Bearing (FB) Posterior Stabilised (PS) cemented knee combined with original patellar replacement technique.

Outcomes
Range of Motion (ROM), Radiographic Analysis, Patella Tilt, Patello-femoral complications, Anterior Knee Pain.

Study Design
Prospective Case Series

From Jan 2007 to May 2008, 100 consecutive patients having total knee arthroplasty (TKA) from authors CR or AR were enrolled into this study. The original diagnosis of the patients was not stated. All patients received a cemented, posterior stabilised SIGMA FB knee implanted with the standard parapatellar approach. The mean follow up was 3.7 years (range, 2.6-4.3 years).

Results
Mean ROM was 109.1° pre-operatively and 117.2° at final follow up.

Radiographic analysis showed no malalignment or osteolysis. There were no complications such as infection, patella fracture, avascular necrosis, subluxation, dislocation, or patella baja.

Mean lateralisation of the femoral component was 6mm (0.2 -18.6mm) and no femoral components were medialised. None of the patients had femoral or tibial overhang.

There were no cases of overstuffing of the patella or cases where the difference in the joint line was more than 5mm compared to pre-operative measurements.

Patella displacement was corrected from 5.9mm lateral before surgery to 1.5mm medial after surgery.

Mean pre-operative patella tilt was 5.7° laterally, which was restored to 0.8° post-operatively.

Anterior knee pain was present in 11% of cases, but no cases were severe or disabling. Patellar crepitation occurred in 3 cases (3%). One case was associated with pain and required scar excision.

There were no correlations between anterior knee pain, ROM, patellar size and shape, or any of the radiographic parameters.

Study Conclusion
In conclusion, TKA with the SIGMA FB PS knee with patella resurfacing by the standard parapatellar approach described by the author is reproducible and safe. It prevents overstuffing or patellar fracture because it preserves the hard subchondral bone of the lateral facet. There were no correlations between various radiographic parameters and anterior knee pain.
Objective
To Investigate the long term clinical and radiographic results and the survival rate for the posterior stabilised SIGMA Rotating Platform (RP) knee.

Treatment
SIGMA Rotating Platform (RP) Posterior Stabilised (PS) cemented knee

Outcomes
Knee Society Score (KSS), WOMAC, Range of Motion (ROM), Patient Satisfaction, Pain, Knee Alignment, Tibial Slope, Radiographic Analysis, Survivorship

Study Design
Prospective Case Series

From January 2000 to October 2001, 138 posterior stabilised SIGMA RP knees were implanted and prospectively followed. Osteoarthritis was the diagnosis for more than 95% of knees. The patella was resurfaced and fixation was by cement in all cases.

There were 106 knees available at a mean of 10 years for clinical and radiographic assessment.

Results
Mean KS knee score was 44.1 pre-operatively and 94.3 post-operatively.
Mean KS function score was 39.4 pre-operatively and 90.2 post-operatively.
Mean WOMAC score was 32.2 pre-operatively and 6.6 post-operatively.
Mean ROM was 111.2° pre-operatively and 119° post-operatively.

All these post-operative changes in outcomes were significant (p<0.001).

15 knees had post-operative pain. Of these, 8 were anterior knee pain. All reported pain was either mild or moderate and intermittent. No severe pain was reported.

14 knees had crepitation, only four of which were symptomatic. 94% of patients were satisfied with their knee replacement. Five patients were dissatisfied and this was due to their pain.

Radiographic analysis showed no malalignment, spinout, aseptic loosening, or osteolysis. Mean femoral angle and femoral flexion were 95.3° and 3.6°, respectively.

The mean tibial angle and mean tibial slope were 88.7° and 84.9°, respectively.

There were 3 patients with non-progressive radiolucent lines.

Using revision as the endpoint, survivorship at 10 years was 97.7%.

Using re-operation as the endpoint survivorship was 95% at 10 years.

Using mechanical failure as the endpoint, survivorship was 100% at 10 years.

There were a total of 3 revisions, 1 for infection and 2 for treatment of traumatic supracondylar femoral fractures.

Study Conclusion
In this series, excellent clinical and survival results were reported with the SIGMA RP knee at 10 years. Further studies are however required to investigate the causes of anterior knee pain and crepitation of the knee.
91. VARIABILITY IN FEMORAL COMPONENT ROTATION REFERENCE AXES MEASURED DURING NAVIGATION-ASSISTED TOTAL KNEE ARTHROPLASTY USING GAP TECHNIQUE

Moon Y, Seo J, Lim S, Yang J. 
Journal of Arthroplasty 2010;25(2):238-43

Objective
To determine the reference axis establishing proper rotational alignment of the femoral component during total knee replacement done by gap equalisation technique.

Treatment
SIGMA Rotating Platform Flex (RPF) posterior stabilised (PS) knee implanted with computer aided surgery (CAS)

Outcomes
Mechanical axis alignment

Study Design
Prospective Case Series

A series of 28 patients with osteoarthritis that received a posterior stabilised SIGMA RPF knee were included in the study. The use of cement was not stated.

Post-operative analysis of knee axes and alignment in all knees was done. All knees were implanted with CAS (Ci system).

Results
The mean angle between the transepicondylar axis and the proximal tibia resection plane was 1.29° (±3.67°).

The mean angle between the Whiteside's line and the proximal tibia resection plane was 3.90° (±4.17°)

The mean angle between the posterior condylar line and the proximal tibia resection plane was −4.03° (±2.71°).

Of the 3 reference axes used widely for femoral component rotation, the angles from the posterior condylar line to the proximal tibia resection plane showed the smallest range of variance but this was not statistically significant.

Study Conclusion
Routine use of any fixed angle of external rotation relative to the proximal tibia resection plane will not compensate for the range of variations seen in femoral condyle anatomy.

The optimal flexion axis, as defined by the transepicondylar axis, will often be missed. Implant malpositioning will result from the sole dependency on the measured resection technique. Relative to the proximal tibia resection plane, the posterior condylar line showed the lowest variability, although not to a statistically significant degree.
Objective
To report the results and the financial impact on their institution of total knee arthroplasty (TKA) using an all-polyethylene tibial component.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) knee with all-polyethylene tibial components

Outcomes
Knee Society Score (KSS), Hospital for Special Surgery Score (HSS), Short Form 36 (SF-36), Complications, Cost Saving Calculations.

Study Design
Prospective Case Series

Between March 1992 and March 1998, 312 consecutive cruciate retaining SIGMA knees with an all-polyethylene tibial component and a cobalt chrome femoral component were included in the study. All patients had their patella resurfaced with an all-polyethylene component. After patient mortality, there were 298 knees in 231 patients available for clinical follow up at a mean of 35.3 months (24-84) post surgery. The decision to cement and original diagnosis of patients was not stated.

Results
The mean combined KSS was 55.9 pre-operatively and 83.4 post-operatively. Mean HSS was 38 pre-operatively and 78.9 post-operatively.

The mean KS function score decreased with time to 64.2, which was expected considering the age of the patients. However, the KS knee score was 91.2. When compared with a matched group of patients for age and activity with metal backed prosthesis, the KS knee score was identical.

SF-36 scores increased post-operatively, with all 8 domains of the score increasing. The most substantial increases were in the area of bodily pain (32 to 62.5), physical functioning (30.1 to 55.4) and physical role (18.5 to 47.8).

There were three revisions in the series, all due to late infections. Radiological indications of aseptic loosening have been seen in all the remaining patients. There has been no evidence of osteolysis.

Cost analysis indicated that in this series more than $75,000 was saved in implant costs, due to the 20-30% discount saved on each polyethylene implant compared to metal backed tibial components.

Study Conclusion
TKA with the SIGMA knee with an all-polyethylene tibial component is a viable option. If the longevity and revision rates are assumed to be similar to those of metal backed tibial components, the cost savings with all-polyethylene tibial components are significant.
93. EXPERIENCE WITH AN ALL-POLYETHYLENE TOTAL KNEE ARTHROPLASTY IN YOUNGER, ACTIVE PATIENTS WITH FOLLOW UP FROM TWO TO ELEVEN YEARS

Ranawat A, Mohanty S, Goldsmith S, Rasquinha V, Rodriguez J, Ranawat C.
Journal of Arthroplasty 2005;20(7,Suppl. 3):7-11

Objective
To document the results of total knee arthroplasty (TKA) with an all-polyethylene component fixed with cement in patients younger than 60 years old.

Treatment
Original P.F.C. or SIGMA PS Knees with all-polyethylene tibial components

Outcomes
Knee Society Score (KSS), Complications, Range of Motion (ROM), Radiographic Analysis.

Study Design
Retrospective Case Series

This study retrospectively reviewed the results of primary TKA in patients younger than 60 years old with a diagnosis of osteoarthritis (OA), presenting with adequate bone stock. Between January 1992 and December 2000 420 TKA were performed by the senior authors (CR, JR). Of these, 54 knees were performed in 38 non-consecutive patients that met the inclusion criteria and were included in the study. Of these 23 implants were original P.F.C. Modular knees and 31 were SIGMA FB knees.

All knees had a posterior stabilised all-polyethylene tibial component. All components were cemented and all patellas were resurfaced with an all-polyethylene cemented button. Average follow up was 5 years (Range 2-11 years).

Results
Mean KS knee score was 43 pre-operatively and 95 post-operatively. Mean KS function score 53 pre-operatively and 98 post-operatively and 95% of knees had a combined KSS of more than 170.

In total, 2 re-operations were required, 1 for deep infection and 1 for post-traumatic loosening of the tibial component. Considering this, the overall failure rate was considered as 1.8% (1/54).

Mean range of motion was 113° pre-operatively and was 110° post-operatively.

With the exception of 1 post-traumatic failure, there was no radiographic evidence of component loosening, progressive radiolucent lines, osteolysis or severe malalignment.

Average distal femoral angle was 96°, and average proximal tibial angle measured 89°.

In the radiographic review, 6 knees demonstrated non progressive radiolucent lines in zone 1 of the tibia, and 1 knee had a non progressive radiolucent line in zone 1 (lateral view) during subsequent follow up. No evidence of osteolysis was present at most recent follow up.

Study Conclusion
In younger active patients, the SIGMA and P.F.C. knees with all-polyethylene tibial components fixed with cement can provide excellent performance and survivorship at midterm follow up out to 5 years.
94. UNCEMENTED TOTAL KNEE ARTHROPLASTY: TWO YEAR FOLLOW UP OF 100 KNEES WITH A ROTATING PLATFORM, CRUCIATE RETAINING DESIGN

Signorelli J, Bernini P, Shirreffs T.
Journal of Arthroplasty 2011;26(3):427-31

Objective
This study is to assess the outcomes of the uncremented SIGMA Rotating Platform (RP) knee out to two years follow up.

Treatment
SIGMA Rotating Platform (RP) Cruciate Retaining (CR) uncremented knee

Outcomes
Knee Society Score (KSS), Radiographic Analysis, Survivorship, Complications.

Study Design
Prospective Case Series

From February 2006 to October 2006, 105 knees in 75 patients received an uncremented, cruciate retaining SIGMA RP knee. The senior author performed all operations in this series, apart from the contralateral knee in simultaneous bilateral arthroplasties.

Tibial and femoral components were both uncremented. All patella components were resurfaced with a polyethylene component.

Patients were followed up at a mean of 30 months (minimum 2 years).

Results
Mean KS knee score was 53 pre-operatively and 95 post-operatively at 2 years. The mean KS function score was 60 pre-operatively and 82 post-operatively.

Radiographic analysis found that 13% of patients had tibial peri-implant sclerosis in tibial zones 5 and 6. Of these, 3 also had a radiolucent line under the tibial tray. No other patients had radiolucent lines.

Implant survival was 99% at 2 years, with no further failures known to date.

No relationship between implant and technique related outcomes.

One patient died at 6 weeks due to a pulmonary embolus. One patient had a pulmonary embolus with no long term sequelae. One patient fell down the stairs and required open reduction and internal fixation of a distal femur fracture and one patient required manipulation under anaesthesia for limited flexion.

Study Conclusion
At 2 years, the survival rate of the SIGMA RP CR knee was 99% which rivals most reports for cemented TKA. These short term results are promising and therefore support the continued use of this implant. It also suggests that there is a need for a prospective randomised study comparing the cemented and uncremented versions of this design.
95. A CLINICAL AND RADIOSTEREOMETRIC STUDY OF THE CEMENTED P.F.C. SIGMA PROSTHESIS

von Schewelov T, Besjakov J, Sanzén L, Carlsson A.

Objective
To investigate the design changes impact on the stability of the cemented tibial components implanted with the SIGMA knee compared with that previously reported with the original P.F.C. knee implanted using the same surgical technique.

Treatment
SIGMA Fixed Bearing (FB) Cruciate Retaining (CR) cemented knee

Comparator
Original Modular P.F.C. cemented knee

Outcomes
Radiostereometric Analysis (RSA), Knee Society Knee Score (KSS), Patient Satisfaction, Radiographic Analysis.

Study Design
Prospective Case Series

From September 1999 to May 2000, 30 patients with 30 primary knee replacements received a cemented SIGMA FB CR knee, with a polyethylene insert with a posterior lipped design. One patient was excluded leaving 29 for analysis. The original diagnosis in all patients was primary osteoarthrosis. All components were cemented.

Patients were prospectively followed at 1, 2, 3 and 5 years. The RSA results and KSS for the SIGMA CR knee were compared to those reported in a previous study on the original P.F.C. modular knee including 29 knees.

Results
RSA analysis showed initial tibial migration with SIGMA FB CR knee, expressed as the maximum total point motion (MTPM) was 0.4mm at 3 months, with migration continuing to 0.64mm at 5 years. Tibial components also rotated longitudinally, initially 0.2° at 3 months, 0.4° at 5 years. Rotation around the transverse and sagittal axes stopped at 3 months.

At 60 months the migration of the tibial component of the SIGMA FB CR knee, expressed as MTPM was lower on average than that of the original P.F.C. modular knee. However, this difference was not significant.

With the SIGMA FB Knee CR replacement the median KS knee score was 48 pre-operatively and 91 (48-100) post-operatively and the median KS function score was 59 pre-operatively and 69 (30-100) post-operatively. Twenty five patients were satisfied, 3 were somewhat satisfied, and 1 was not satisfied. Compared with the Original P.F.C. knee, the median post-operative KS knee score with the SIGMA FB knee was higher (91 v 72, p=0.014), but there was no difference in KS function score between the 2 knees (69 v 69, p=0.95).

No radiolucent zones or abnormalities were observed around any femoral components. Radiolucent zones of less than 1mm width were observed at the bone-cement junction in 3 of 29 tibial components. All 3 knees were asymptomatic with KS knee scores of 88, 95, and 98 (i.e. all excellent) at 5 years.

Sub categorisation showed that patients with no pain had significantly better functional outcomes compared to those with either contralateral knee pain (p< 0.001) or who had pain in multiple joints (p= 0.009).

Study Conclusion
The SIGMA F8 CR knee showed RSA, radiographic and clinical outcomes comparable to other studies and the authors conclude that this prosthesis can be used with confidence.
96. MEDIUM TERM RESULTS WITH THE P.F.C. SIGMA KNEE PROSTHESIS: THE WRIGHTINGTON EXPERIENCE

Zaki S, Rafiq I, Kapoor A, Raut V, Gambhir A, Porter M.

Objective
The study presents the clinical and radiological results of the SIGMA knee implanted in the first year of its use, from November 1997 to December 1998.

Treatment
P.F.C. SIGMA KNEE PROSTHESIS.

Outcomes
Knee Society Score (KSS), Oxford Knee Score (OKS), Range of Motion (ROM), Radiographic Analysis, Survivorship, Complications.

Study Design
Retrospective Case Series

From November 1997 to December 1998, a consecutive series of 166 SIGMA FB knees were performed at one hospital. The diagnosis was osteoarthritis (OA) in 88% of patients and 136 (88%) knees were cruciate retaining and 19 (12%) were posterior stabilised. All implants were fixed with cement. The patella was resurfaced in 74 knees (48%). Patients were followed for a mean of 90 months (7.5 years).

Results
Mean KS knee score was 45 pre-operatively and 84 post-operatively. Mean KS function score was 38 pre-operatively and 73 post-operatively.

Mean OKS was 43 pre-operatively and 17 post-operatively (a lower score is better).

There were no differences in post-operative KSS and OKS when comparing patients with and without patella resurfacing, and cruciate retaining with cruciate sacrificing designs.

Mean ROM was 90° pre-operatively (range 50-125) and 100° post-operatively (range 65° to 130°).

Radiolucent lines were found in 17 (11%) femoral components and 54 (35%) tibial components.

1 knee was revised due to aseptic loosening and tibial stem subsidence.

Other complications include:

1 knee with superficial infection, 1 developing chronic infection, and 1 with deep infection. 3 patients had deep vein thrombosis, of which one developed into a pulmonary embolism. No patella components failed or required secondary resurfacing.

Survivorship was 99.4% at 8 year follow up (with the endpoint being revision for any reason).

Study Conclusion
Out to 8 years mean follow up, the SIGMA knee functions well. The prosthesis also has excellent survivorship up to this time point.