NexGen Flex Implants: design rationale

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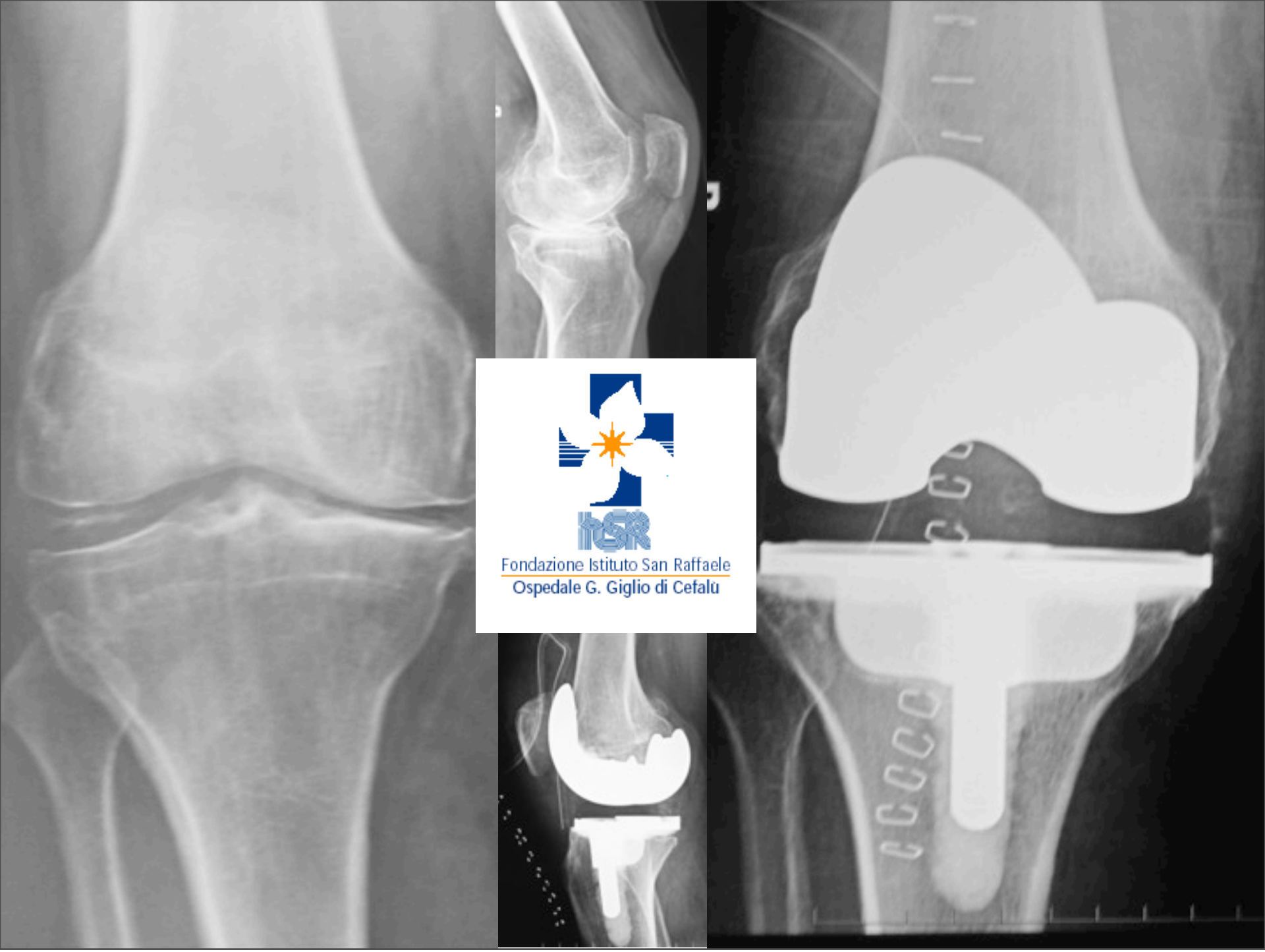
Ortho Unit 2006

- ✓6674 out-patiens
- ✓1098 surgical procedures
- ✓298 joint replacements
- ✓158 knee replacents
- ✓32 revisions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Design rationale

Headlines

- normal knee kinematics
- total knee arthroplasty kinematic
- femoral sizing
- evidence based medicine
- clinical trials

Normal knee kinematics

ANATOMY OF THE KNEE IN FULL FLEXION

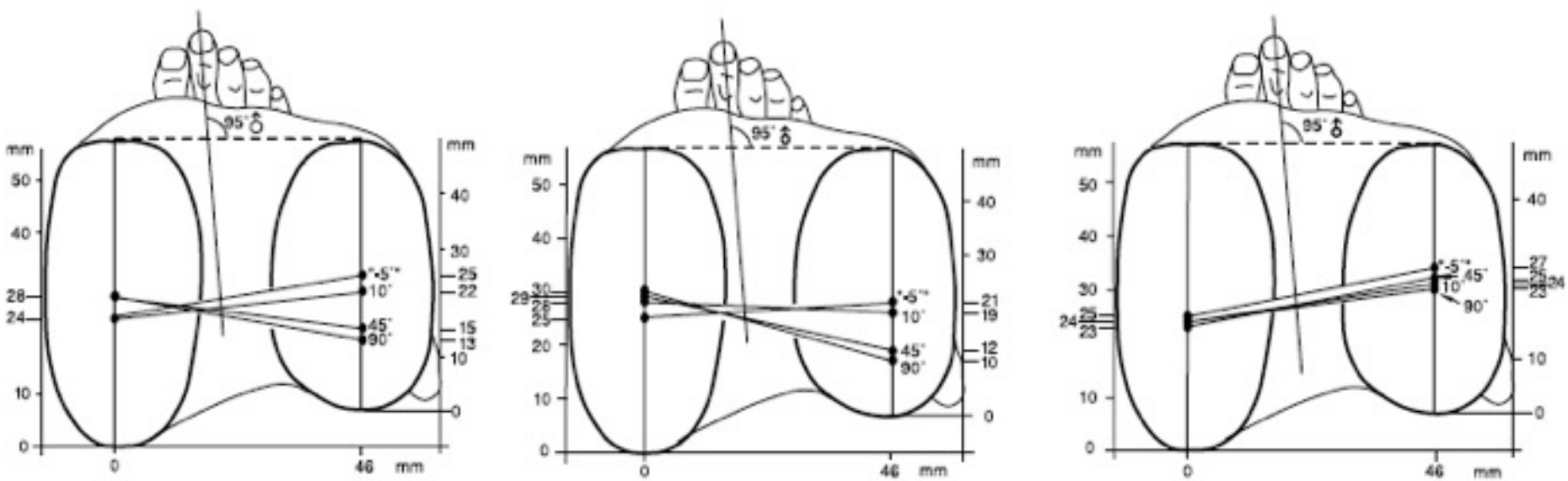
PinskeroVa et al. JBJS br 2009

- active flexion stops at 120°
- >120° femoral condyle rolls posteriorly
- Anteriorly, the femur lifted away from the tibia
- At 140° femur moves up on the posterior horn of the medial meniscus. > resistance to flexion
- the posterior horn of the **medial meniscus** is a key structure in deep flexion

Normal knee kinematics

Biomechanics
Hill et al JBJS br 2000

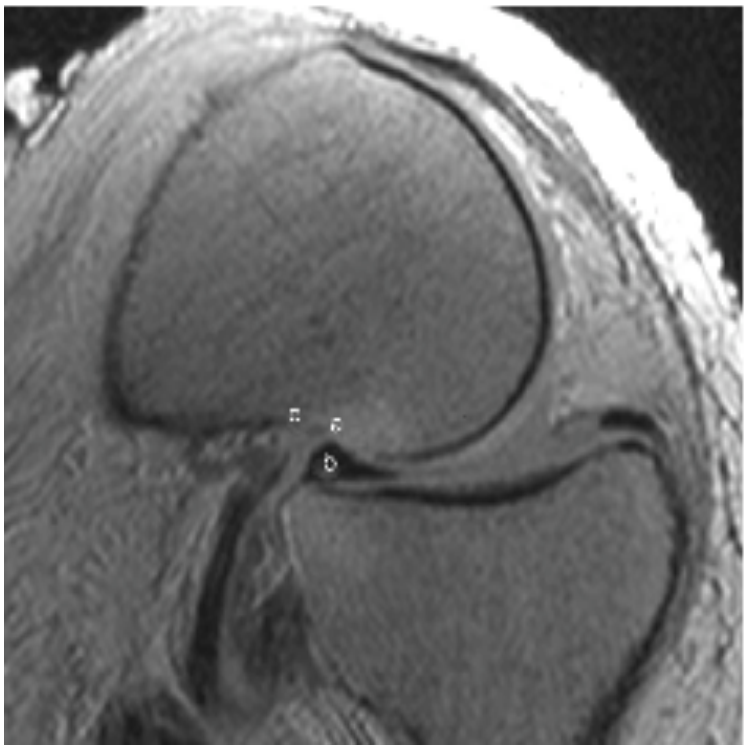
position of the posterior centres of the femoral condyles during squats in neutral tibial rotation (a), internal rotation (b) and external rotation



Normal knee kinematics

Ligaments
Freeman et al. JBJS Br 2003

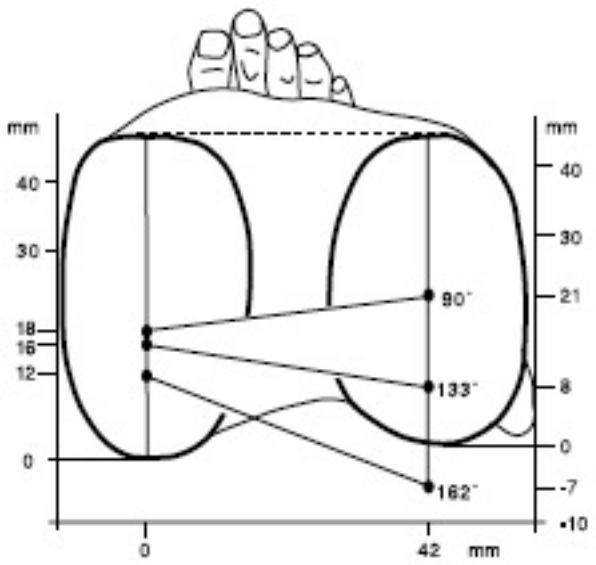
PCL is not loaded in the unloaded cadaver knee and that it is also unloaded in the living knee during flexion.



Normal knee kinematics

ETHNIC
Nakagawa et al. JBJS br 2000

In the Japanese knee, medial movement may start at 90° but amounts to only 2.0 mm by 133° and a further 4.5 mm from 133° to 162°



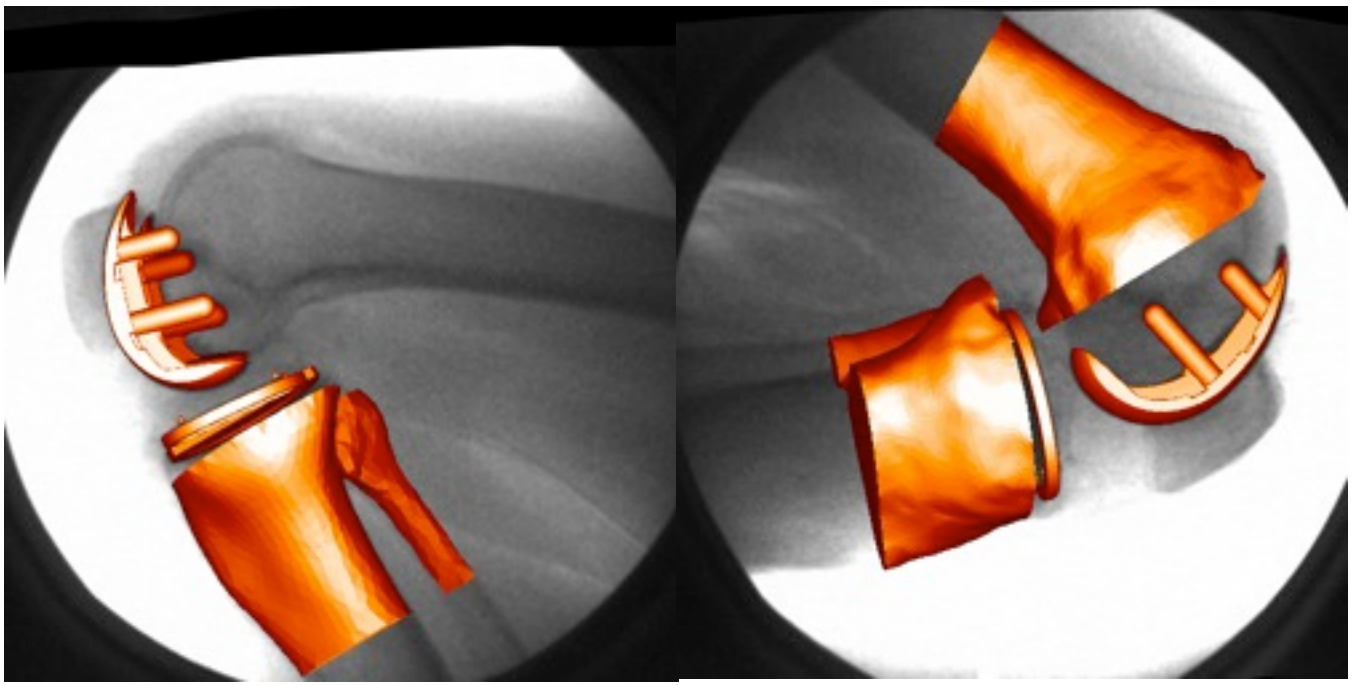
Total knee arthroplasty kinematics

Fluoroscopy
Banks et al. JBJS am 2003

Total knee arthroplasty

In Vivo Kinematics of Unicondylar Knee Arthroplasties

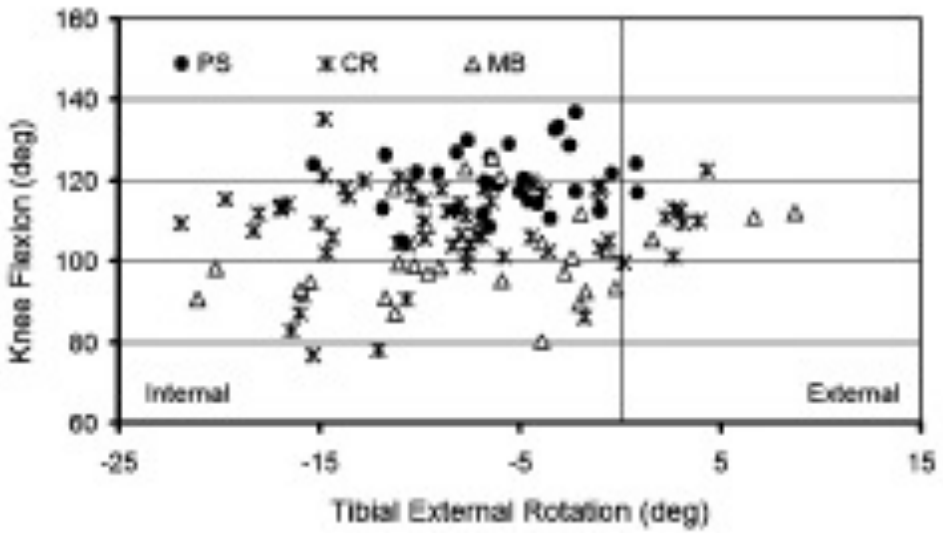
S. Banks, B.J. Fregly, F. Boniforti, S. Romagnoli, C. Reinschmidt
Biomotion Foundation, West Palm Beach, FL
University of Florida, Gainesville, FL



Total knee arthroplasty

Fluoroscopy
Banks et al. JBJS am 2003

- **no correlation between rotation and maximum flexion CR, PS, MB**



Surgical balancing of the ligaments and soft tissues can have a major effect on weight-bearing knee kinematics, particularly when unconstrained prosthetic designs are employed.

When using unconstrained tibiofemoral articulations, the surgeon has the opportunity to restore nearly physiologic knee motion.

However, many kinematic studies of unconstrained devices have demonstrated abnormal knee motions, with the femur sliding forward instead of moving backward with flexion

Fluoroscopic analysis of the kinematics of deep flexion in total knee arthroplasty
J Bellemans, S Banks et al
JBJS br, 84 - 2002

To identify the factors limiting the range of active flexion after TKA
30 pts TKA: 90-100 KKS

27 forward slide of the femur
Fluoroscopic measurements < goniometer
21 femur posterior impingement on tibial insert

Total knee arthroplasty

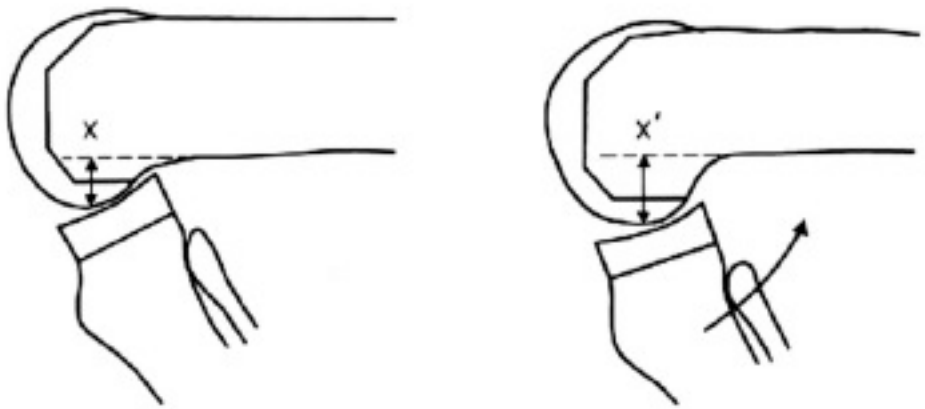
Fluoroscopy
Banks et al. JBJS am 2003

Fig. 5-A Bottom


Fig. 5-B Bottom

Total knee arthroplasty

Fluoroscopy
Banks et al. JBJS am 2003



Femoral sizing

Femoral offset
Pandit et al. JBJS br 2005

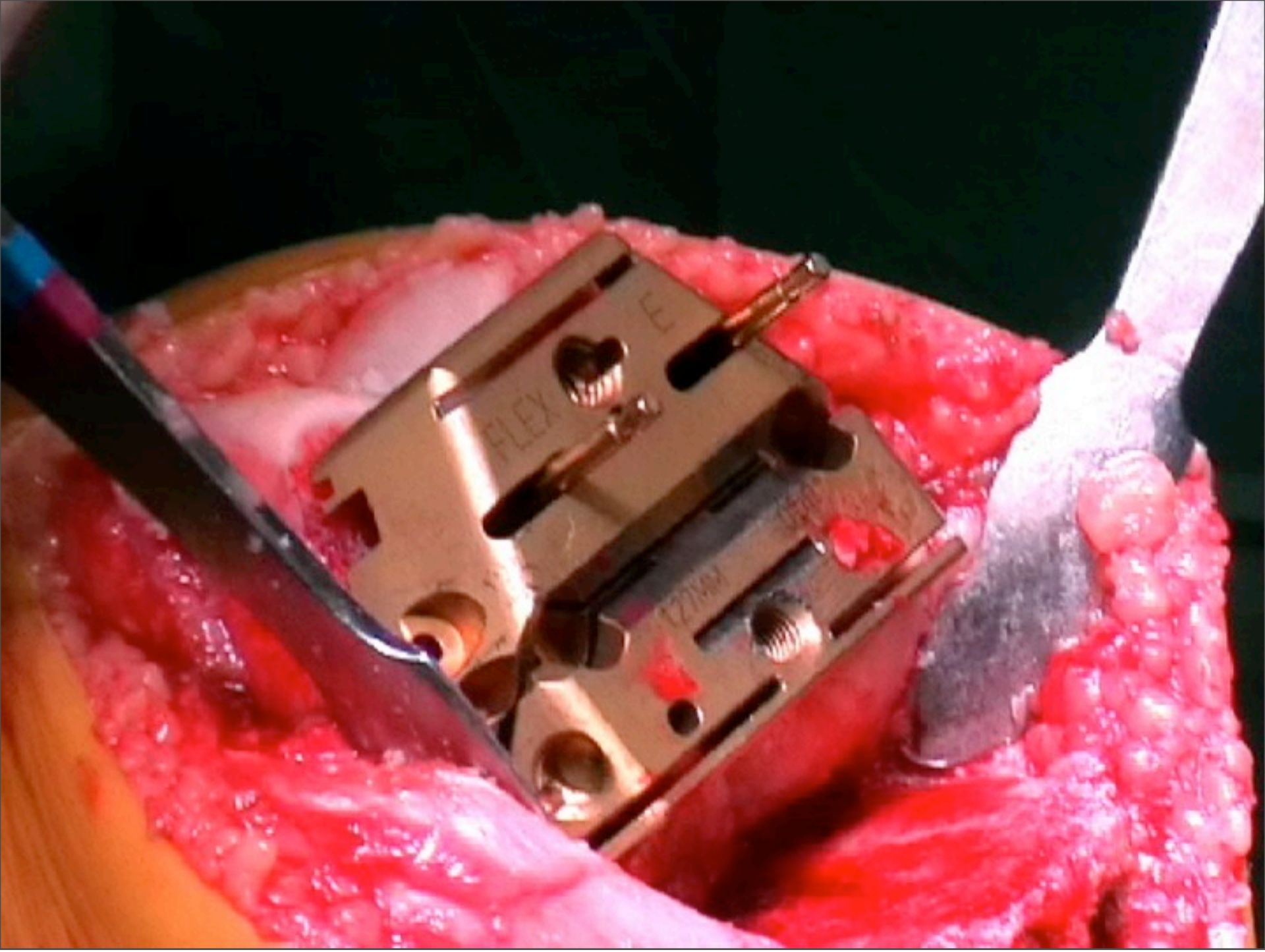
… a more normal pattern of movement can provide the best outcome.

manufacturers have sought to reproduce the form and function of various anatomical structures in the knee.

Femoral sizing

Murray et al JBJS br 2005

all the TKR groups (PS/CR/MB) exhibited
very different kinematics
from that of the normal knee.



Femoral sizing

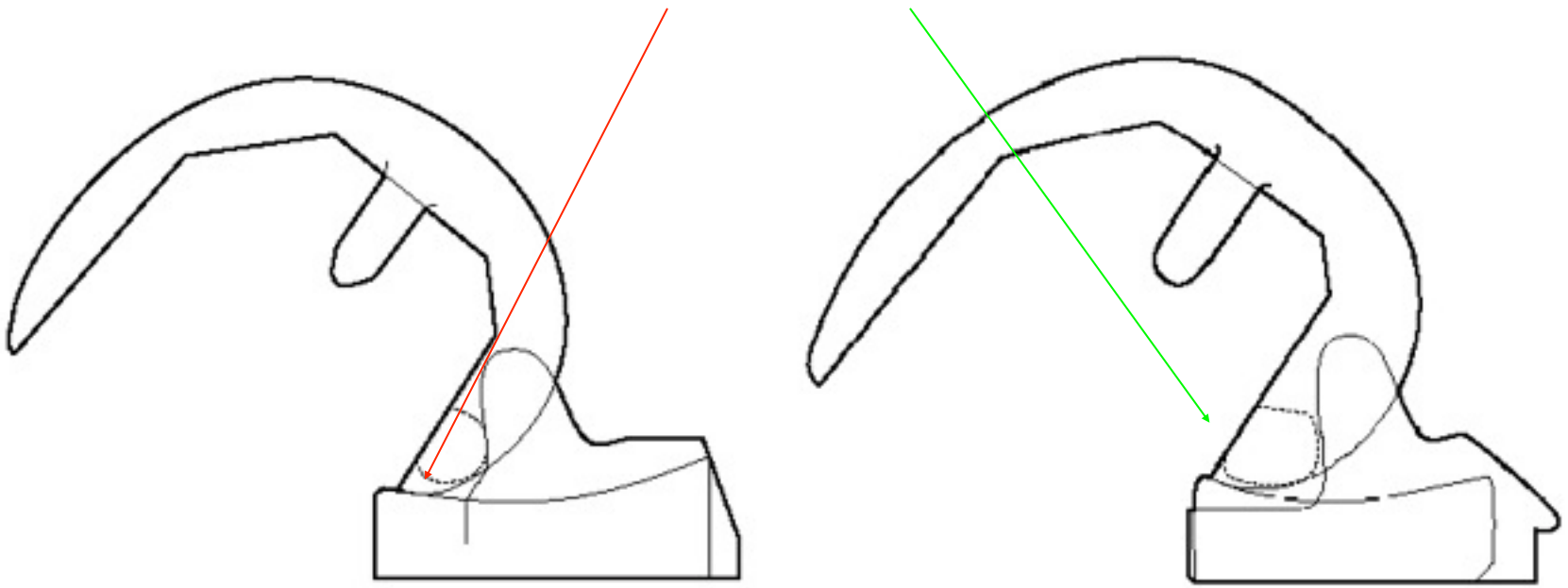
Patellar tendon angle

…abnormalities in tibiofemoral kinematics may cause large changes in Q angle.

With a femur lying posteriorly on the tibia, the patellar tendon angle will decrease.

Conversely, with a femur positioned anteriorly the angle will increase.

NO DIGGING IN AT 155°



Evidence Based Medicine

What type of research will best improve clinical practice?

- **A Carr JBJS br 2005**

Level of evidence

I° livello: studio prospettico ad alta randomizzazione test/controllo.

II° livello: comparativo prospettico a minor qualità di randomizzazione test/controllo.

III° livello: comparativo retrospettivo test/controllo.

IV° livello: descrizione di casi clinici.

V° livello: opinione di un esperto.

Evidence Based Medicine

Survival curve at follow-up

Evidence Based Medicine

The Swedish Knee Arthroplasty Register
Dept. of Orthopedics, Lund University Hospital

Swedish Knee Arthroplasty Register

The Swedish Arthroplasty Register is celebrating 32 years of auditing knee replacement, and compares over 58,000 TKR procedures in the latest report (2007). It is the only register that is captures data fully nationwide, has a very high compliance, and has such a long history. It also lists the comparative clinical success of most popular knee implants in Sweden. The register is exhaustive, covering every surgeon in every hospital regularly performing knee arthroplasty. The 2007 report continues to demonstrate both the superior clinical performance of NexGen and ongoing success from previous reports.

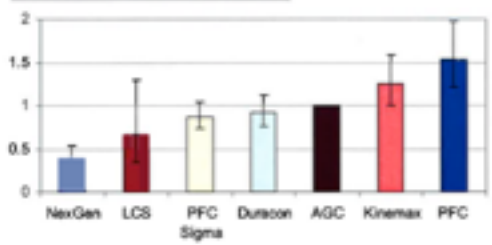
The main results are

- **NexGen is the best performing knee on the register** (it has the lowest Relative Risk Ratio – the measure of risk of revision, 0.40, 95% confidence interval of 0.30-0.54)
- **NexGen has a statistically significant lower revision rate than**
  - **AGC, PFC, PFC Sigma, Duracon, Kinemax, Scan, AMK, Axiom.**
- **A user of AGC, PFC, PFC Sigma, Duracon, or Kinemax can expect a revision rate ranging from over double, rising to as much four times the Revsion rate of NexGen.**
- The only other knee that demonstrated superior results than the reference standard is also a Zimmer product.
- The PFC and AMK both had survivourship significantly worse than the reference standard.

Relative survivourship for TKR implants when used for the majority indication (Osteoarthritis). Only the popular implants are listed, the remaining implants appear under the heading "other".

OA / TKA	n	p-value	RR	95% CI
AGC	14,307		ref.	
PFC Sigma	13,128	0.12	0.87	0.74-1.04
NexGen	6,154	<0.01	0.40	0.30-0.54
Duracon	4,280	0.41	0.92	0.76-1.12
LCS	3,163	<0.01	0.65	0.53-0.81
Kinemax	2,195	0.01	1.26	1.00-1.59
Scan	1,467	0.20	1.18	0.91-1.57
PFC	1,415	<0.01	1.54	1.20-1.97
AMK	529	0.02	1.55	1.08-2.23
Profix	517	0.22	0.64	0.32-1.30
MillerGalante II	499	0.28	1.26	0.83-1.91
LCS	391	0.24	0.67	0.35-1.30
Natural II	251	0.61	1.29	0.48-3.47
Other	665	0.17	1.26	0.84-1.91
Gender (male is ref.)	-	0.33	0.95	0.86-1.06
Age (per year)	-	<0.01	0.96	0.95-0.97
Year of op. (per year)	-	0.95	1.00	0.97-1.03

Comparative revision rates



Evidence Based Medicine

National Joint Registry for England and Wales
4th Annual Report

The National Joint Registry (NJR) for England and Wales
4th Annual Report September 2007

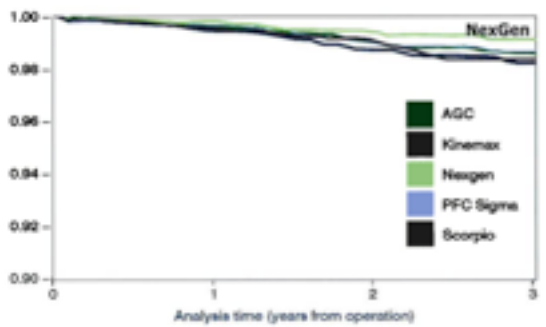
The UK NJR is the most exhaustive and complete audit , providing the most reliable and relevant data about total knee replacement in the UK. This has been generated from collecting data in

- **381 hospitals**
- **Including almost 41,000 Knee Replacements**

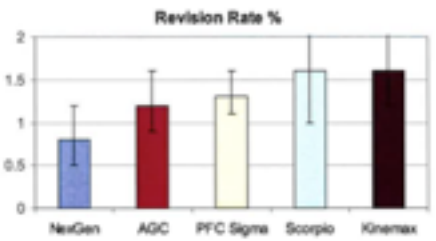
The register has sufficient data to report up to 3 years survivorship, and in the latest report, includes the 5 most popular implants. Once again, NexGen, even at the early 3 year review demonstrated dramatic differences to the other available implants.

Compared to NexGen

- **Scorpio and Kinemax have double the revision rate**
- **AGC has a 50% higher revision rate**
- **PFC Sigma has a 61% higher revision rate.**



Stand (n)	3 years
AGC (10,203)	1.2% (0.9% - 1.6%)
Kinemax (5,091)	1.6% (1.2% - 2.2%)
Nexgen (9,857)	0.8% (0.5% - 1.2%)
PFC Sigma (26,833)	1.3% (1.1% - 1.6%)
Scorpio (5,366)	1.8% (1.0% - 2.5%)



http://www.nsw.njrcentre.org.uk/njrcentre/AboutNJR/PublicationsandReports/AnnualReports/tabid/86/Default.aspx

Preoperative knee ROM is the most important factor that influence postoperative knee motion

Ritter et al. JBJS am 2003

Shurman, CORR 1998
Bourne, J Orth Sci 2001
Miner, J Arthr 2003

F Boniforti, F Giacco, G Lombardo, G Pomara

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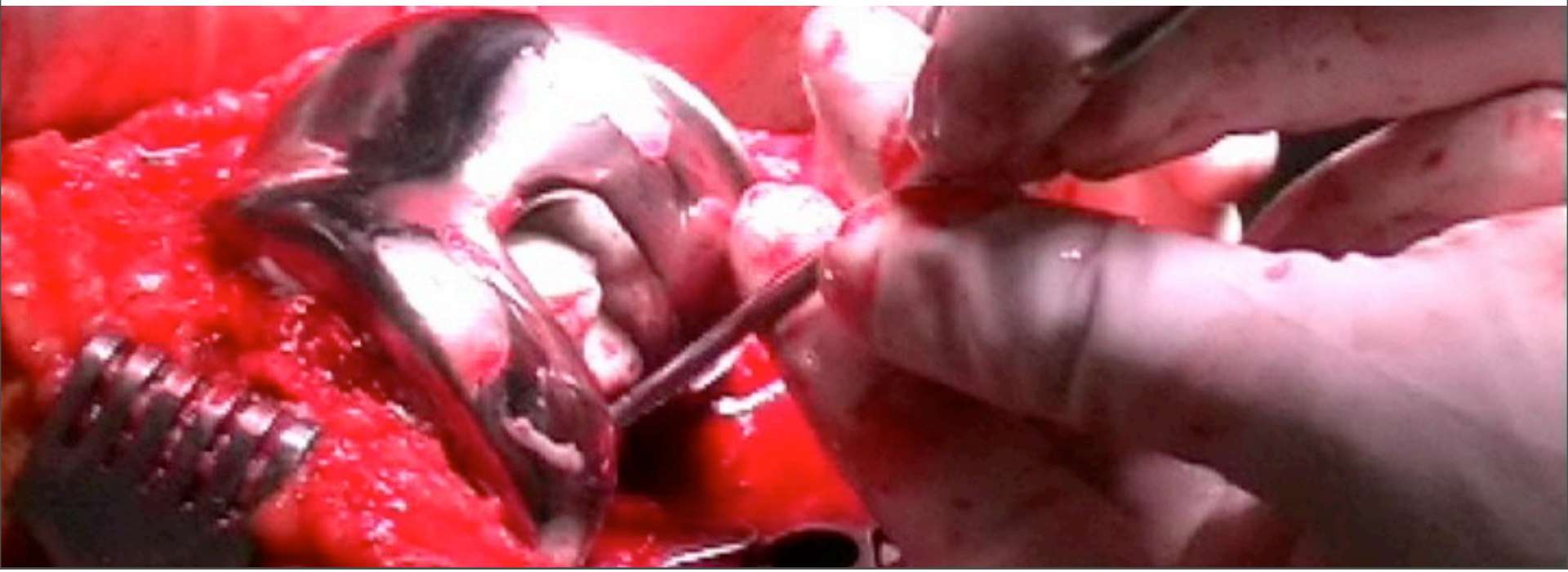
Ospedale G. Giglio di Cefalù

PROSPECTIVE STUDY COMPARING TKR HIGH FLEX AND STANDARD FEMORAL COMPONENT

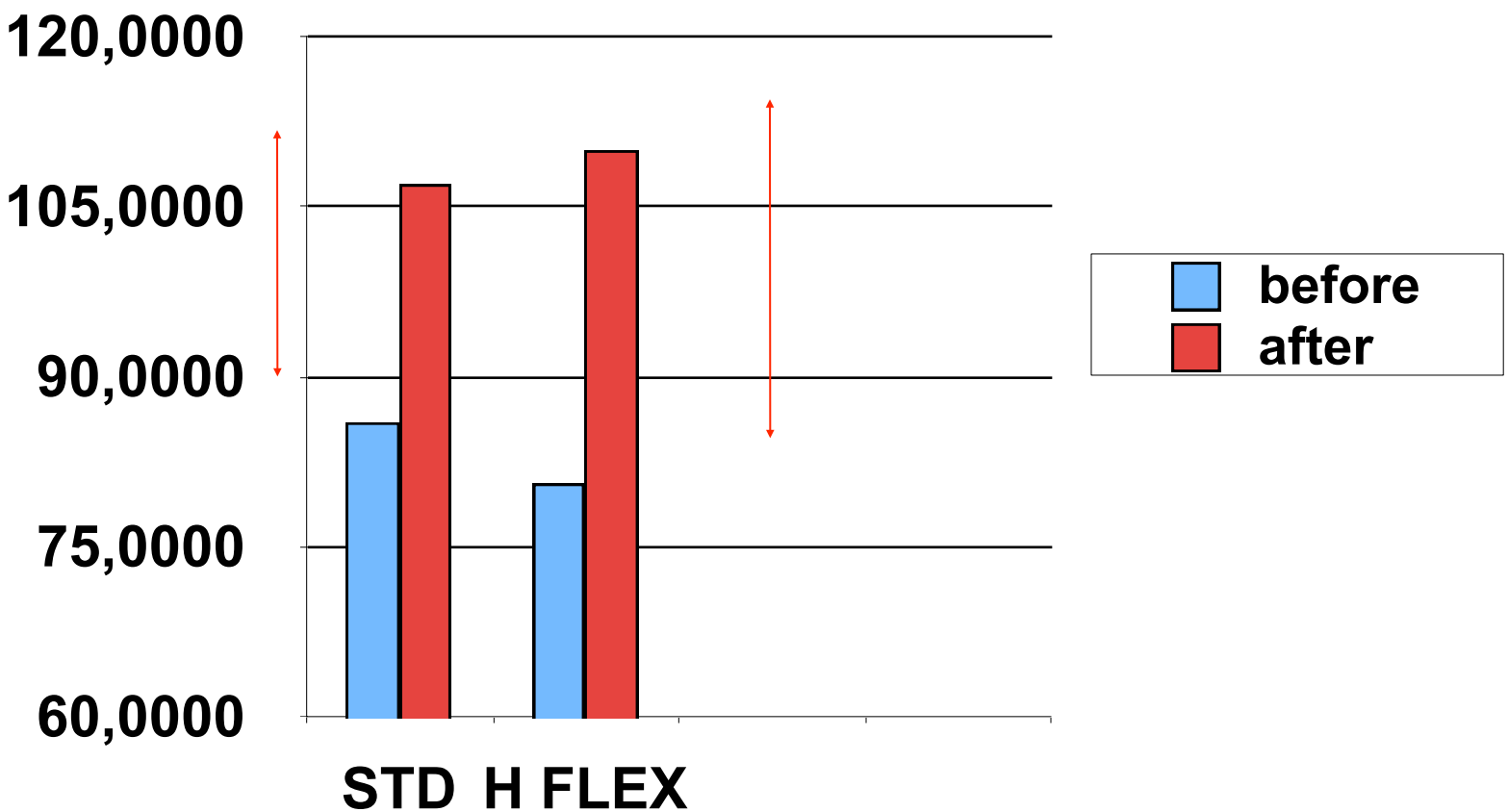
- Component alignment
- Patellar track
- ROM before and 4 wks after surgery



Results

	STANDARD	HIGH FLEX
Age yrs	69,8	68,3
BMI Kg/m2	29,2	29,3
Time for surgery mn	70	78
Patellar track	no Lat Rel	no Lat Rel
Alignment		
sigma ang°	88,1	89,2
beta ang°	86,3	87,3
HSS		
before	30,5	28,9
4 wks after	91,3	80,8

ROM before and after



KNEE BENDING GAINED

STANDARD
21.3 (10°-40°)

H FLEX
30.3° (20°-40°)

P= 0,008

Range of Motion of Standard and High-Flexion Posterior Cruciate-Retaining Total Knee Prostheses*

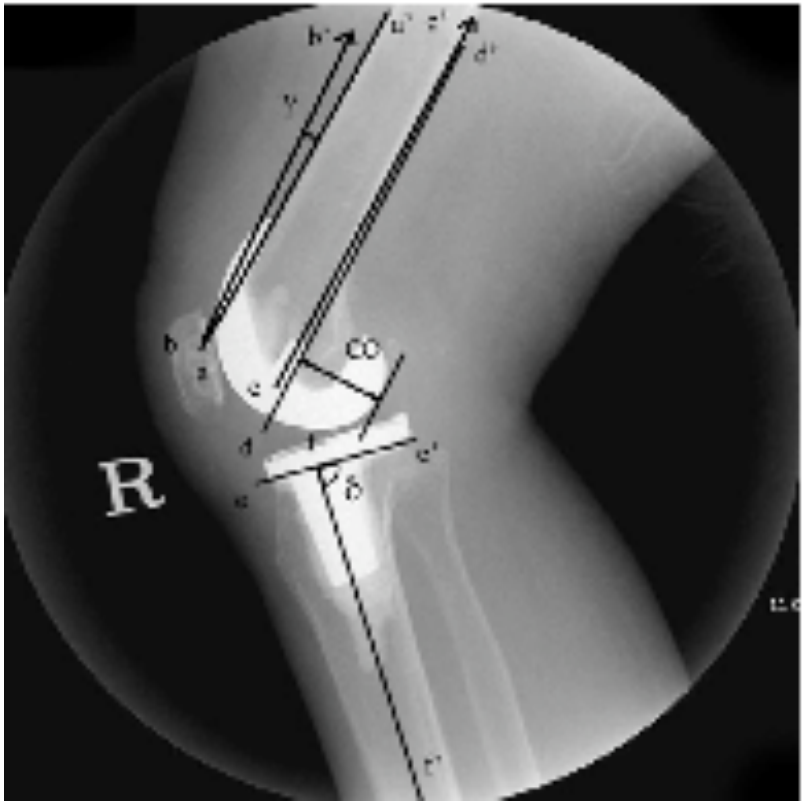
A Prospective Randomized Study

By Young-Hoo Kim, MD, Yoowang Choi, MD, and Jun-Shik Kim, MD

Investigation performed at The Joint Replacement Center of Korea at Ewha Womans University MokDong Hospital, Seoul, South Korea

Background: The main goals of total knee arthroplasty are pain relief and improvement in function and the range of motion. The purpose of this study was to compare the ranges of motion of the knees of patients treated with a standard posterior cruciate-retaining total knee prosthesis in one knee and a high-flexion posterior cruciate-retaining total knee prosthesis in the other.

Methods: Fifty-four patients (mean age, 69.7 years) received a standard posterior cruciate-retaining total knee prosthesis in one knee and a high-flexion posterior cruciate-retaining total knee prosthesis in the contralateral knee. Five patients were men, and forty-nine were women. At a mean of three years postoperatively, the patients were assessed clinically and radiographically with the knee-rating systems of the Knee Society and the Hospital for Special Surgery and with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score.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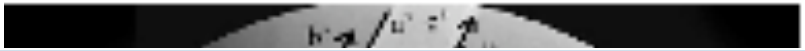

TABLE III Knee Flexion (Degrees)

	Preoperative		3 Months		1 Year		3 Years	
	Non-Weight-Bearing	Weight-Bearing	Non-Weight-Bearing	Weight-Bearing	Non-Weight-Bearing	Weight-Bearing	Non-Weight-Bearing	Weight-Bearing
NexGen CR								
Mean and stand dev.	128 ± 13.9	125 ± 12.8	123 ± 10.2	102 ± 13.1	125 ± 11.9	109 ± 14.1	131 ± 13.9	115 ± 14.1
Range	70-150	70-140	80-135	60-113	90-145	75-140	90-150	75-145
NexGen CR-Flex								
Mean and stand dev.	128 ± 11.2	126 ± 10.5	125 ± 10.4	104 ± 12.9	129 ± 12.9	114 ± 14.9	133 ± 10.4	118 ± 13.9
Range	90-145	80-140	75-129	55-115	90-145	75-140	90-150	75-145
P value	0.819	0.823	0.266	0.265	0.506	0.253	0.172	0.168
Effect size	—	—	0.20	0.15	0.34	0.35	0.14	0.21

High flexion design
Better ROM

but

> Wear and Stability

Ritter, J Arth 2006

summary

High flex femoral component

- normal knee kinematics: recent knowledge
- total knee arthroplasty: peculiar kinematic
- femoral sizing: medio-lateral or femoral off-set
- evidence based medicine: how is the patients!
- flexion – extention balance

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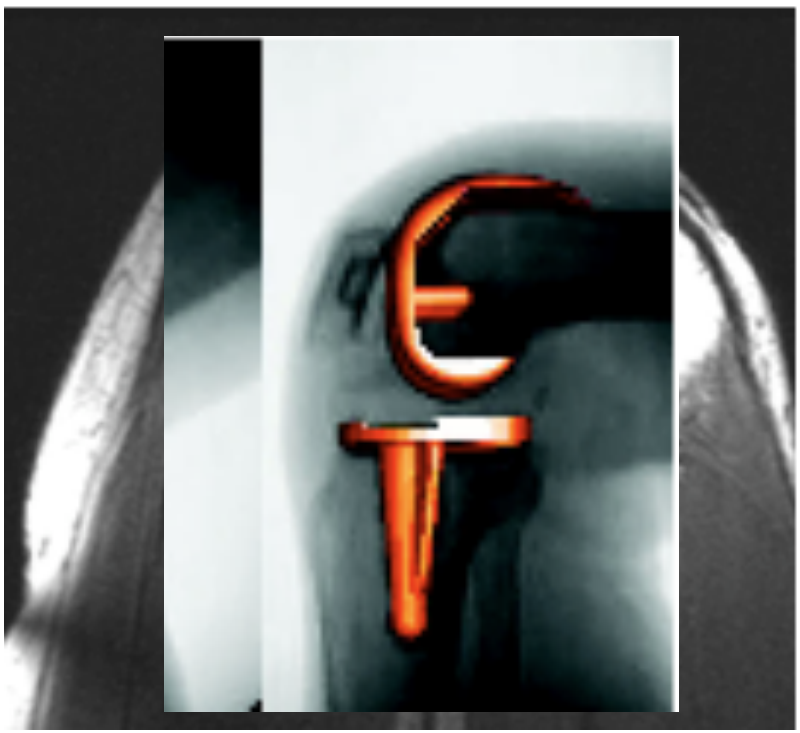

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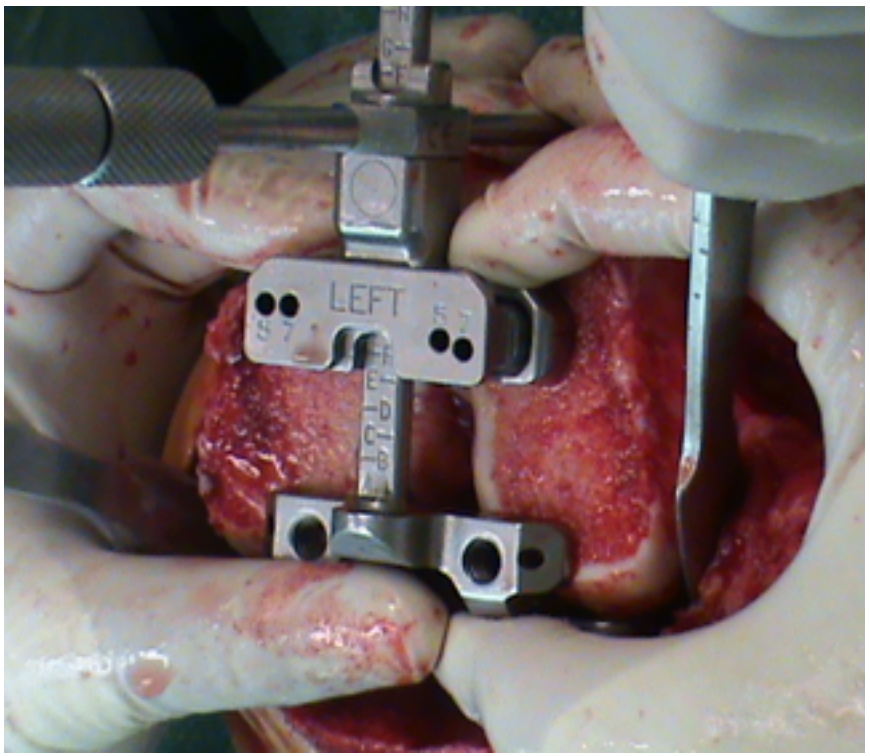

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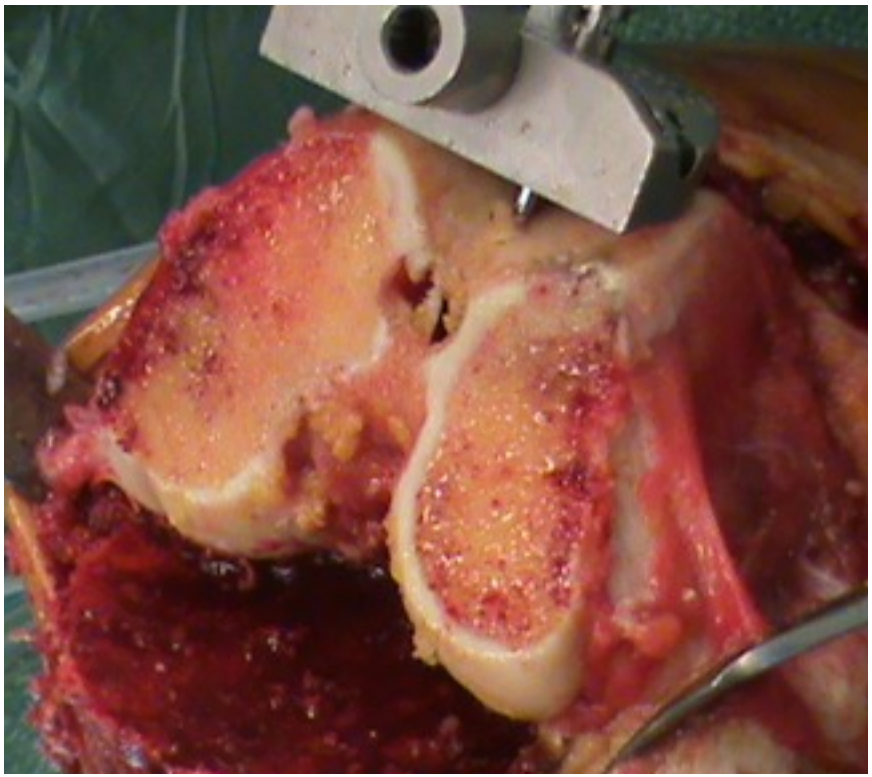


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Grazie