







**LINK GEMINI SL Total Knee System**



**CE 0482**

Explanation of Pictograms			
	Manufacturer		Item number
	Material (number)		Product meets the applicable requirements, which are regulated in the EU harmonization legislation for the affixing of the CE marking.

# LINK GEMINI SL Total Knee System

## Literature Research

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## Primary Total Knee Arthroplasty GEMINI SL

### Overview

The **GEMINI SL Total Knee Replacement** is a modular knee prosthesis system.

GEMINI SL Total Knee Replacement system accounts for greater versatility.




The GEMINI SL Knee System allows for native joint reconstruction with an extensive range of motion and good kinematics (20). Primary stability is guaranteed through accurate fit of the femoral and tibial components, and due to proper choice from an extensive selection of sizes (24). Three configurations (Fixed Bearing CR, Fixed Bearing PS and Mobile Bearing) and optional tibial stem extensions expand the range of indications and enable comprehensive treatment options.

The Knee System consists of femoral components, articular surfaces and tibial components. It comes in different sizes for femur and tibia and different heights for the articular surfaces. There are eight sizes left and eight sized right for femoral replacement and five sizes each left and right for the tibial replacement. There are four heights for the articular surface Mobile Bearing and five heights for the articular surface Fixed Bearing. The tibial component is available in monobloc or modular. The modular version has a taper connection allowing for assembly of various tibial stem extensions. For Femur and Tibia components there is a version for cemented application and a version for cementless application available. Additionally hybrid application is possible as well. For cementless application there is a double coating TiCaP applied.

All versions are offered with LINK PorEx (TiNbN) surface modification, which allow application for metal sensitive patients.



**GEMINI SL Configurations**

Cruciate Retaining Fixed Bearing (CR)	Posterior Stabilized Fixed Bearing (PS)	Mobile Bearing
		
<p>Cruciate Retaining configuration for use with intact ligaments and capsule and adequate joint stability. Identical tibial metal tray for Fixed Bearing CR and PS.</p>	<p>Posterior Stabilized configuration for use with absence of posterior cruciate ligament. Reduces the risk of dislocation and decreases contact pressure in deep flexion (21). Featuring bone preserving design with size specific intercondylar femoral box dimensions.</p>	<p>Rotating highly congruent articular surface for use with or without posterior cruciate ligament.</p>

**Heritage**

The **T.A.C.K.** (Total Articulating Cementless Knee) was the precursor of the GEMINI Total Knee System offered by LINK. It was available cementless and cemented consisting of a femoral component which is highly congruent and anatomically shaped, with left and right versions. The nonarticulating surfaces of tibia and femur are textured to encourage bone ingrowth, with or without hydroxyapatite coating. A version to be cemented was also available. The tibial part has two components. A metal tray with a conical stem is implanted on the bone, and a high-conforming ultrahigh-molecular-weight (UHMW) polyethylene bearing sits in the tray.

**GEMINI** was designed to extending the product portfolio for Total Knee Arthroplasty as Fixed Bearing CR and PS. GEMINI consists of an anatomically shaped femoral component in five sizes and respectively five sizes of anatomically shaped tibial components which can be extended with tibial stems. Finally there were articulating surfaces in different heights in the corresponding five sizes.

**GEMINI MKII** was then an additional portfolio extension with Mobile Bearing configuration which was marketed as GEMINI MKII. The fixation concept for Mobile Bearing of the articular surface on the tibia was maintained from T.A.C.K., design of femoral and tibial component was maintained from GEMINI.

## Purpose of the Research

The purpose of this literature research is to show different papers of the GEMINI SL Total Knee System. There are three groups of publications. First there are papers about clinical outcome. Here the focus is on the Hospital for Special Surgery Score, Knee Society Score, the survival rate and the range of motion. Second there are papers considering biomechanical results and finally there is data of registry considered survival outcome.

## Definitions

### Knee Society Clinical Rating System

The Knee Society Clinical rating System is subdivided into a Knee Score and a Functional Score. The Knee Society Score differentiates between knee rating and functional assessment. (1)

#### Knee Society Score (KSS)

With regard to the knee assessment, it was decided that only the three main parameters of pain, stability, and range of motion should be judged and that flexion contracture, extension lag, and misalignment should be dealt with as deductions. Thus, 100 points will be obtained by a well-aligned knee with no pain, 125° of motion, and negligible anteroposterior and mediolateral instability.

The Knee Society Score rates the Pain, the range of Motion and the stability of the knee. It's possible to award 100 points or different classes. Maximal 50 points for pain, 25 for range of motion and 25 for stability.

#### Knee Functional Score (KFS)

Patient function considers only walking distance and stair climbing, with deductions for walking aids. The maximum function score, which is also 100, is obtained by a patient who can walk an unlimited distance and go up and down stairs normally. The walking ability is expressed in blocks (100 meters). The stair climbing is considered if the patient can ascend and descend without holding the railing

### Hospital for Special Surgery-Score (HSS)

The Hospital for Special Surgery Knee Score was introduced in the late 1970s. As physicians and investigators at the Hospital for Special Surgery reported their results with different types of prosthesis, they modified their rating scales until they finally agreed to the data collected by the HSS Knee Score. The HSS Knee Score is based on a total of 100 points. The score is divided into seven categories, which include pain, function, range of motion, muscle strength, flexion deformity, instability, and subtractions.

The knee is initially given a score of 0, and additions or subtractions are made according to specific criteria. The higher the score, the better the outcome. Approximately 50% of the score is based on a patient interview and the remaining on physical exam. (2)

### Evaluation of HSS-Score

Table 1: Evaluation of HSS-Score (2)

Score	
90-100	Excellent
80-89	Good
70-79	Fair
Below 70	Poor

**Western Ontario an McMaster Osteoarthritis Index (WOMAC)**

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a widely used measure of symptoms and physical disability originally developed for people with osteoarthritis (OA) of the hip and/or knee. (3) The WOMAC evaluates 3 dimensions: pain, stiffness, and physical function with 5, 2, and 17 questions, respectively. The Likert version of the WOMAC is rated on an ordinal scale of 0 to 4, with lower scores indicating lower levels of symptoms or physical disability. Each subscale is summated to a maximum score of 20, 8, and 68, respectively.

There is also an index score or global score, which is most commonly calculated by summing the scores for the 3 subscales. A visual analog scale (VAS) version of the WOMAC is also available. The WOMAC score is for knee and/or hip. The WOMAC evaluate the pain, stiffness and function of patients with osteoarthritis. The score is focused just on the long-term consequences. The WOMAC is used for knee OA, chondral defects and anterior cruciate ligament deficiency. A higher score indicate worse pain, stiffness or physical function.

**Range of Motion**

The Range of Motion is routinely used to judge injuries and diseases in the locomotor system. With ROM angel of flexion are measured, extension and hyperextension before and after TKA. (4)

## Overview Tables

## Overview of all Clinical Studies

Study	Year of Publication	No of Patients	Mean Follow-up (range)	Mean Age (Range)	Reason for TKA	GEMINI SL MB PCL Preserving	GEMINI SL MB PCL Sacrificing	GEMINI SL FB CR	GEMINI SL FB PS	Scores
<a href="#">Ma</a>	2019	109	5 yrs	73.2 (67-83)	Primary knee, Degenerative OA	X				ROM KSS Clinical KSS function
<a href="#">Zhang</a>	2016	92	2 yrs	67.8 (59-76)	Primary knee OA	X				ROM KSS clinical KSS function
<a href="#">Yang</a>	2015	187	2 yrs	64.8 ± 5.3	Bilateral knee OA	X				SF-36 VAS ROM
<a href="#">Bignozzi</a>	2014	30	2 yrs	69 yrs (57-83)	Primary knee OA	X	X			WOMAC KSS SF36
<a href="#">Zhou</a>	2014	32	10 years (8-11)	57 yrs (47-63)	Primary severe valgus knee deformity RA   OA	X				ROM, HSS, Survival Rate
<a href="#">Zha</a>	2014	139	1.5 yrs	68.5 (51-85)	Primary degenerative OA	X				KSS clinical KSS function VAS
<a href="#">Vahtrik</a>	2014	14	6 months	60.2 yrs (46-68)	Degenerative Knee OA	X				Pain (VAS) ROM
<a href="#">Thabe</a>	2013	442	11,2	27-92 yrs	OA, Rheumatoid arthritis	X				HSS, ROM, Survival Rate
<a href="#">Gapeyeva</a>	2011	8	6 months	66 yrs (58-77)	Primary degenerative knee OA	X				AROM WOMAC
<a href="#">Gapeyeva</a>	2007	10	6 months	63 yrs (52-74)	Degenerative knee OA	X				KSS clinical KSS function VAS

NOTE: Hyperlinks to the summary of the studies available in PDF version



### Overview of all Biomechanical Studies

Study	Year of Publication	GEMINI SL MB PCL Preserving	GEMINI SL MB PCL Sacrificing	GEMINI SL FB CR	GEMINI SL FiB PS
<a href="#">Innocenti</a>	2019		X	X	
<a href="#">Innocenti</a>	2019	X		X	X
<a href="#">Innocenti</a>	2019				X

NOTE: Hyperlinks to the summary of the studies available in PDF version

### Overview Registry Data Survival Rate

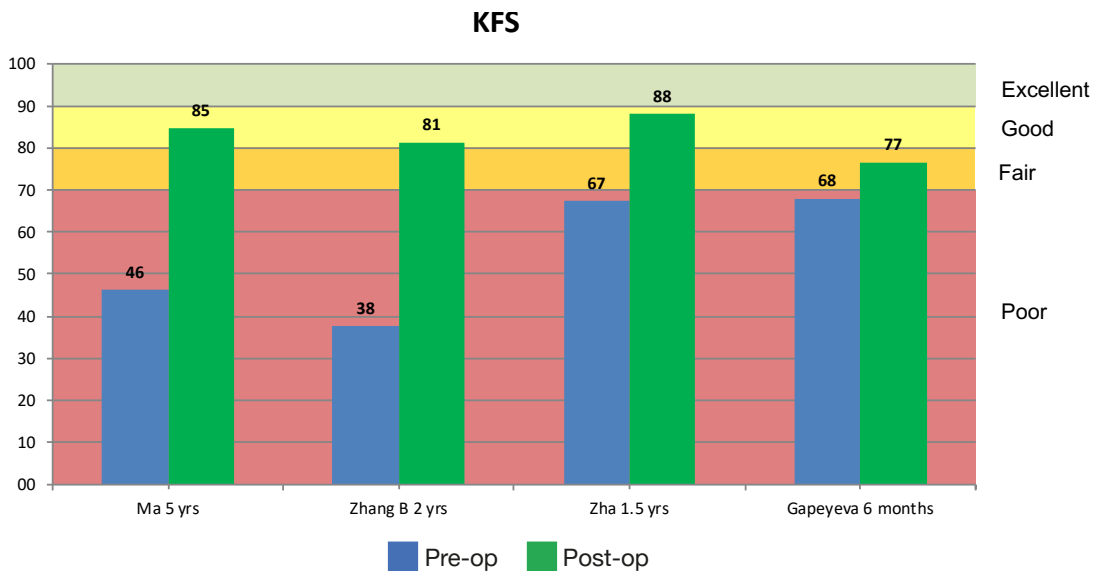
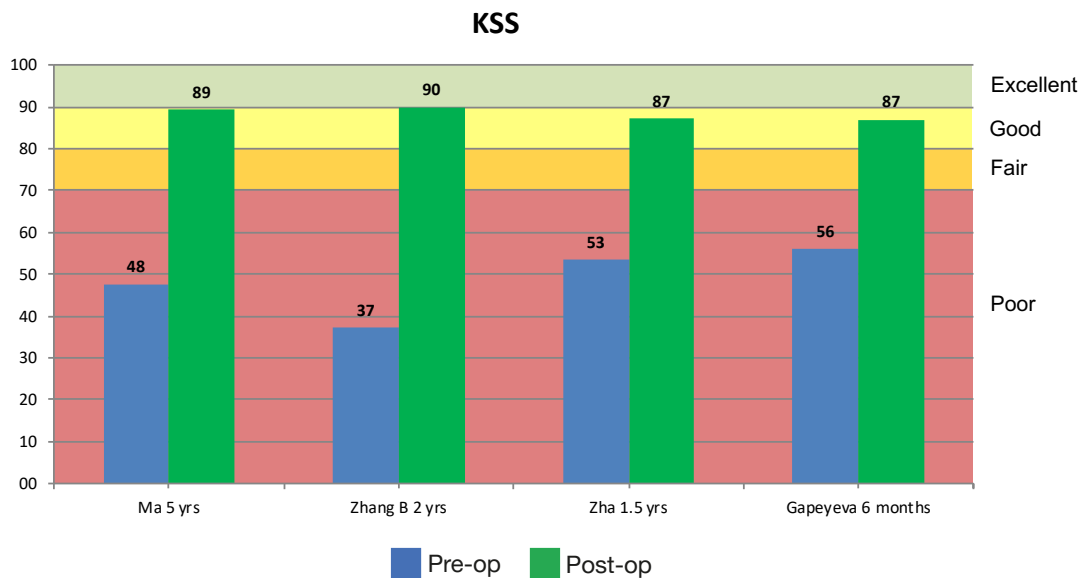
Registry	Year of Publication	No of Patients	GEMINI SL FB CR	GEMINI SL FB PS	GEMINI SL MB	Survival rate (%) after 2 yrs	Survival rate (%) after 4 yrs	Survival rate (%) after 5 yrs	Survival rate (%) after 10 yrs
<a href="#">R.I.P.O.</a>	2020	2446			X			97.2	95.1
<a href="#">SIRIS</a>	2021	144		X		96.5			
<a href="#">EPRD</a>	2021	462	X				94.9		
<a href="#">EPRD</a>	2021	845		X			96.9		

NOTE: Hyperlinks to the summary of the studies available in PDF version

Overview of KSS and KFS

Study	KSS Pre-op (range)	KSS Pos-op (range)	KFS Pre-op (range)	KFS Post-op (range)
<a href="#">Ma</a>	47.6 points (± 9.5)	89.2 points (± 3.6)	46.3 points (± 11.9)	84.6 points (± 9.8)
<a href="#">Zhang B</a>	37.2 points (± 4.0)	89.9 points (± 2.6)	37.6 points (± 4.1)	81.3 points (±1.9)
<a href="#">Zha</a>	53.4 points (± 16.1)	87.1 points (± 9.0)	67.3 points (± 7.3)	88.1 points (± 9.0)
<a href="#">Gapeyeva</a>	56.0 points (20-68)	87.0 points (62-93)	68.0 points (35-80)	76.5 points (47-100)

NOTE: Hyperlinks to the summary of the studies available in PDF version

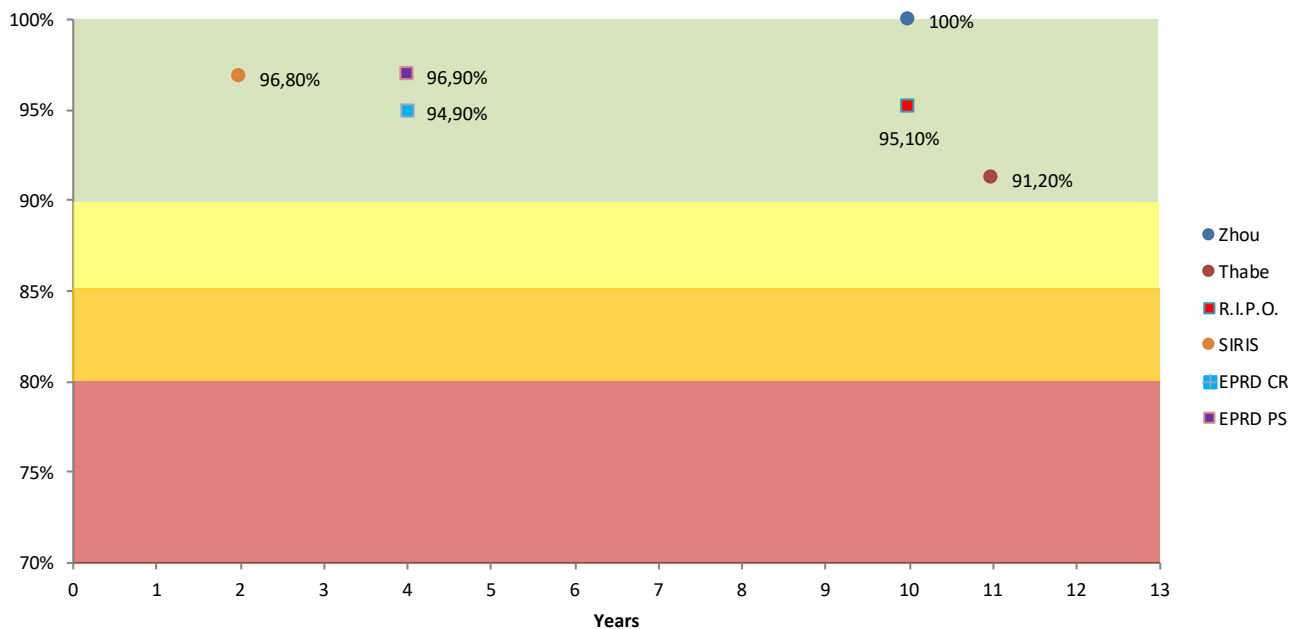


Overview Survival Rate

Study / Registry	2 yrs	4 yrs	6.3 yrs	10 yrs	11.2 yrs
<a href="#">Zhou</a>				100%	
<a href="#">Thabe</a>					91.2%
<a href="#">R.I.P.O.</a>				95.1%	
<a href="#">SIRIS</a>	96.5%				
<a href="#">EPRD CR</a>		94.9%			
<a href="#">EPRD PS</a>		96.9%			

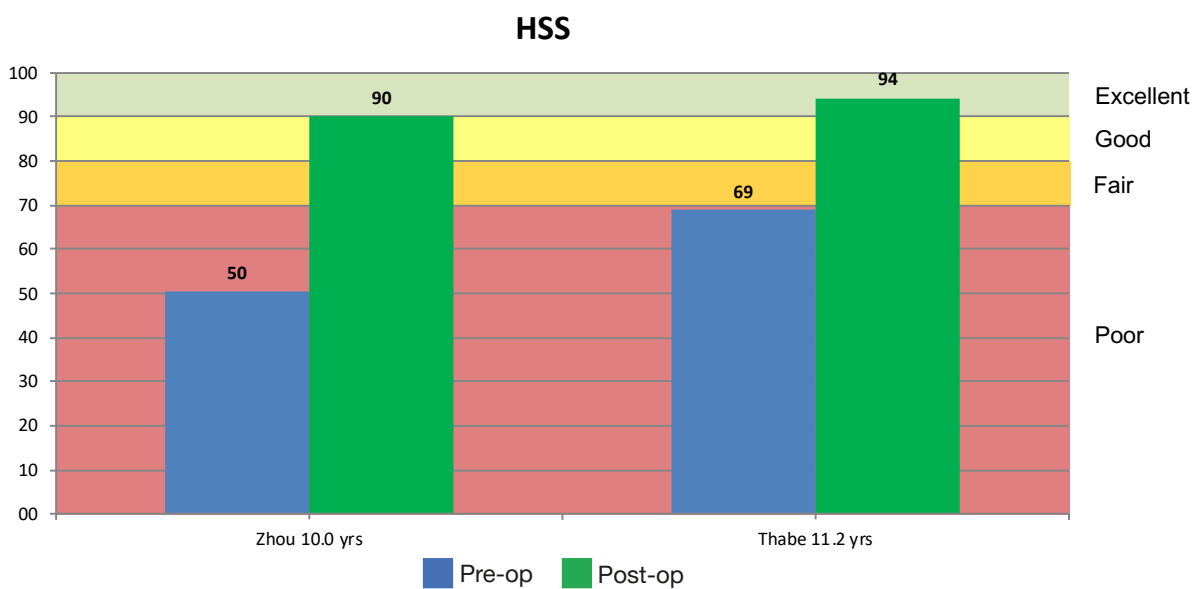
NOTE: Hyperlinks to the summary of the studies available in PDF version

Survival Rate



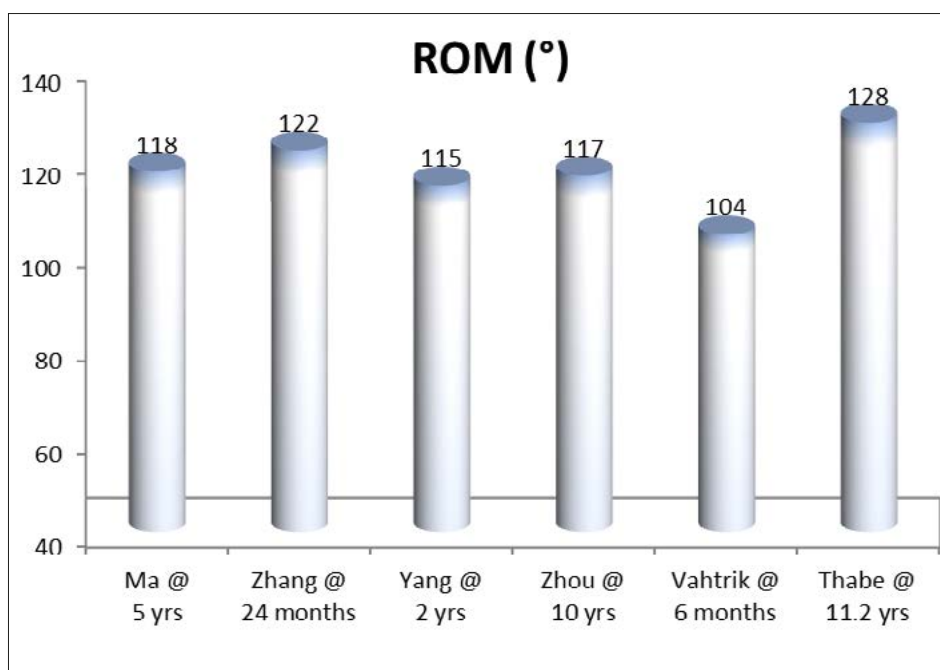
Overview of HSS

Study	Time	Pre-op	Post-op
<a href="#">Zhou</a>	10 yrs	50.33 Points	90.06 Points
<a href="#">Thabe</a>	11.2 yrs	68.8 Points	94.4 Points



Overview of ROM

Study	ROM Pre-op	ROM Post-op
<a href="#">Ma 5 yrs</a>	103.2°	117.5°
<a href="#">Zhang 24 months</a>	99.4°	122.0°
<a href="#">Yang 2 yrs</a>	88.2°	114.5°
<a href="#">Zhou 10 yrs</a>	93.72°	116.6°
<a href="#">Vahtrik 6 months</a>		104.0°
<a href="#">Thabe 11.2 yrs</a>		128°



## ODEP Rating

ODEP, the Orthopaedic Data Evaluation Panel was set up in 2002 to implement NICE guidance on primary hip implants. Hip resurfacing followed in 2004. Since then Knees (2014) have been added to the list of joints that ODEP benchmark and early in 2017 ODEP commenced benchmarking Shoulders [<http://www.odep.org.uk>]



The **Mobile Bearing** configuration of the **GEMINI SL** received this high quality rating for a knee implant awarded by the United Kingdom's Orthopaedic Data Evaluation Panel.

A **rating of 10A** is given to implants that have demonstrated at least **93% survival at 10 years** based on data meeting **ODEP's criteria** for the strongest data quality.

A **rating of 3A** is given to implants that have demonstrated at least **94.5% survival at 3 years** based on data meeting **ODEP's criteria** for the strongest data quality.

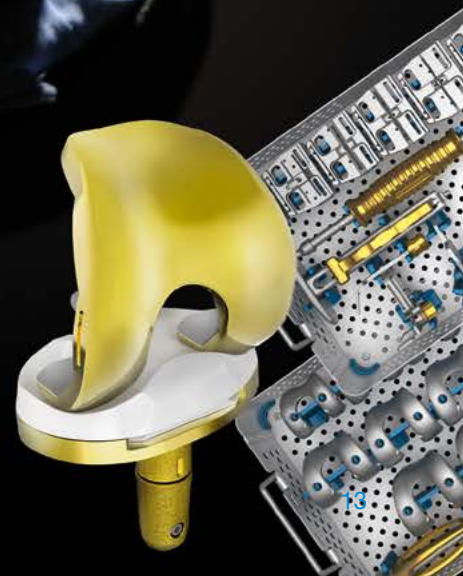
**10A:** A minimum cohort of 500 knees at the start of the study with a minimum of ten years followup and an actual revision rate of less than 7%. All deaths, loss to follow-up, failures and indications for revisions are recorded. Minimum at risk at benchmark time: 51.

**3A:** A minimum cohort of 150 knees at the start of the study with a minimum of ten years follow up and an actual revision rate of less than 5.5%. All deaths, loss to follow-up, failures and indications for revisions are recorded. Minimum at risk at benchmark time: 66.

What if you had a golden key?



**GEMINI SL PorEx**  
with SPAR-K Instruments  
Efficient Precise Reliable



## Literature

Here following a list of different papers related to LINK GEMINI Total Knee System. These papers include information about the survival rate, about mid-term and long-term follow-ups evaluated by HSS scores, results of functional and clinical score KSS and outcome of biomechanical studies.

### Intact, pie-crusting and repairing the posterior cruciate ligament in posterior cruciate ligament-retaining total knee arthroplasty: A 5-year follow-up

De-Si Ma, Liang Wen, Zhi-Wei Wang, Bo Zhang, Shi-Xiang Ren, Yuan Lin  
*World J Clin Cases 2019 December 26; 7(24): 4208-4217*

#### Purpose

The posterior cruciate ligament (PCL) is important for cruciate-retaining (CR) total knee arthroplasty (TKA). Whether the entire PCL should be retained during CR-TKA is controversial. The aim of this study is to evaluate the clinical outcomes of PCL preservation in CR-TKA and the methods used to deal with the PCL during surgery.

#### Methods

A retrospective review of patients with osteoarthritis undergoing primary CR-TKA (176 patients, 205 knees) in our institution between March 2012 and March 2014 was performed. A PCL protector was used to preserve the intact PCL bone block. The status of the PCL was recorded during surgery. Intact PCL preserved, pie-crusting and repairing were used to balance the tension of the PCL. Range of motion (ROM) and the Knee Society Clinical Rating System (KSS) were evaluated preoperatively and at the endpoint of follow-up.

#### Results

The mean ROM of the knee was  $103.2 \pm 17.2^\circ$ , KSS clinical score was  $47.6 \pm 9.5$  and KSS functional score was  $46.3 \pm 11.9$  before surgery. The mean ROM of the knee was  $117.5 \pm 9.7^\circ$ , KSS clinical score was  $89.2 \pm 3.6$  and KSS functional score was  $84.6 \pm 9.8$  at 5 years follow-up. ROM, KSS clinical scores and KSS functional scores were significantly improved after surgery ( $P < 0.01$ ). Thirty-two (23.7%) TKAs involved PCL pie-crusting and 18 (13.3%) involved PCL repair. Eighty-five (63.0%) TKAs applied standard operating procedures and preserved intact PCL. At 5 years follow-up, in the intact PCL group, the mean ROM of the knee was  $118.0 \pm 8.3^\circ$ , KSS clinical score was  $89.1 \pm 3.7$  and KSS functional score was  $84.9 \pm 9.6$ . In the PCL pie-crusting group, mean ROM of the knee was  $114.0 \pm 13.5^\circ$ , KSS clinical score was  $88.8 \pm 3.4$  and KSS functional score was  $83.8 \pm 10.5$ . In the PCL repair group, mean ROM of the knee was  $120.3 \pm 7.0^\circ$ , KSS clinical score was  $89.0 \pm 3.6$  and KSS functional score was  $89.4 \pm 4.5$ . There were no significant differences in ROM, KSS clinical scores and KSS functional scores among the three groups ( $P > 0.05$ ).

	5 yrs Post-op
KSS Clinical Scores	$89.2 \pm 3.6$
KSS Functional Scores	$84.6 \pm 9.8$
Range of Motion	$117.5^\circ \pm 9.7^\circ$

[Overview of all Clinical Studies...](#)



## Literature

### Partial versus Intact Posterior Cruciate Ligament-retaining Total Knee Arthroplasty: A Comparative Study of Early Clinical Outcomes

Bo Zhang, MD, Cheng-kung Cheng, PhD, Tie-Bing Qu, Yong Hai, PhD, Yuan Lin, PhD, Jiang Pan, MD, Zhi-wei Wang, PhD, Liang Wen, PhD  
*Orthopaedic Surgery* 2016;8:331–337

#### Objective:

Whether the entire posterior cruciate ligament (PCL) should be retained during cruciate-retaining total knee arthroplasty (CR TKA) is controversial. The goal of this study was to compare the early clinical outcomes of partial versus intact PCL-retaining TKA.

#### Methods:

Ninety-two patients who had undergone unilateral CR TKA from March 2012 to June 2013 were enrolled in this study. Forty-six of these patients were randomly selected to undergo intact PCL-retaining TKA (intact group), whereas the remaining 46 patients underwent tibial osteotomy together with anterolateral bundle and bone island resection (partial group). All operations were performed by a senior orthopedic surgeon and the PCL was released to some extent in both groups. After TKA, active and passive flexion and extension exercises of the knee and lower limb strength exercises were maintained until at least 3 months after surgery. Before surgery and 6, 12, and 24 months after surgery, range of motion, Knee Society Clinical Rating System scores (including clinical and functional scores of the knee) and maximum anteroposterior (AP) displacement of the knee at 30° and 90° of knee flexion were evaluated in both groups.

#### Results:

Fourteen patients were rejected from the final analysis because of loss to follow-up or development of complications. Thus, 40 patients from the partial group and 38 from the intact group were followed up for 24–41 months (mean 32.8 months). Knee functional scores were significantly higher in the intact than in the partial group (88.1 vs. 84.8 points) 24 months after surgery. There were no significant differences in range of motion or knee clinical scores between the two groups at any time point. However, 12 and 24 months after surgery, the mean maximum AP displacement of the knee in 90° knee flexion was significantly greater in the partial than in the intact group (12 months: 6.3 vs. 5.7 mm; 24 months: 7.0 vs. 6.2 mm).

	2 yrs Post-op
KSS Clinical Scores	91.9 ±1.8
KSS Functional Scores	88.1 ±1.4
Range of Motion	122.3° ±7.8°

## Literature

### Analysis of Interlimb Asymmetry in Patients Undergoing Simultaneous Bilateral Total Knee Arthroplasty

Yu Yang, Gong Long, Wang Zhenhu.

*PLoS ONE* 10(6): e0129783. doi:10.1371/journal.pone.0129783

#### Objective:

The purpose of the present study was to investigate the risk factors of asymmetric recovery in patients who underwent simultaneous bilateral TKA (SBTKA) and whether that affected quality of life.

#### Methods:

A total of 187 patients undergoing SBTKA were included. During this study, patients underwent physical examination (knee swelling, active range of motion (ROM) of knee and quadriceps strength) and completed three surveys (VAS pain rating, Short Form-36 and requisite information lists in this study).

#### Results:

Between-limb differences in active ROM, quadriceps strength, and VAS pain scores were significantly detected in our study. Risk factors included being female, being older, and having high BMI and high levels of anxiety and depression; different diagnosis and different component size could be risk factors. Finally, interlimb differences in VAS pain scores and active ROM were negatively associated with SF-36 scores. However, interlimb differences in swelling and quadriceps strength were unrelated to SF-36 scores. Risk factors of asymmetric recovery should be evaluated and appreciated due to their significant impact on patients' quality of life. Before performing SBTKA, clinicians should consider possible risk factors and inform patients of asymmetric recovery between limbs, which could help decrease the unnecessary consultations and postoperative patient dissatisfaction.

	2 yrs Post-op
VAS Pain Rating	1.15 ± 0.98
Range of Motion	114.5° ± 7.9°

## Literature

### Three different cruciate-sacrificing TKA designs: minor intraoperative kinematic differences and negligible clinical differences

Simone Bignozzi, Stefano Zaffagnini, Ibrahim Akkawi, Tedi Marko, Danilo Bruni, Maria Pia Neri, Francesca Colle, Maurilio Marcacci

*Knee Surg Sports Traumatol Arthrosc* (2014) 22:3113–3120

#### Purpose

The goal of this study was to compare three types of mobile-bearing posterior cruciate ligament (PCL)-sacrificing TKA. The hypothesis was that the three designs provide differences in flexion stability and femoral rollback and improved clinical score at 2-year follow-up.

#### Methods

Three groups of patients, divided according to implant design, were analysed retrospectively. All operations were guided by a non-image-based navigation system that recorded relative femoral and tibial positions in native and implanted knees during: passive range of motion and anterior drawer test at 90° flexion. WOMAC, KSS and SF36 scores were collected pre-operatively and at 2-year follow-up.

#### Results

There are no differences in kinematic or clinical performance of the three implants, except for the anteroposterior translation during stress test in flexion: only Cohort B had comparable pre- and post-operative laxity test values ( $p < 0.001$ ). All three TKA designs allowed to maintain pre-operative tibial rotation pattern through all range of knee flexion. All clinical scores of the three patient cohorts were significantly improved post-operatively compared to the pre-operative values ( $p < 0.001$ ). Moreover, we found no differences among post-operative results of the three designs.

#### Conclusion

Despite design variations, mobile-bearing PCL-sacrificing TKA reproduces femoral rollback and screw-home with little or no difference in clinical or functional scores at a follow-up of 2 years.

## Literature

### Total knee arthroplasty for severe valgus knee deformity

Zhou Xinhua, Wang Min, Liu Chao, Zhang Liang and Zhou Yixin  
*Chinese Medical Journal* 2014; 127 (6), January 2014

#### Purpose

Primary total knee arthroplasty (TKA) in severe valgus knees may prove challenging, and choice of implant depends on the severity of the valgus deformity and the extent of soft-tissue release. The purpose of this study was to review 8 to 11 years (mean, 10 years) follow-up results of primary TKA for variant-III valgus knee deformity with use of different type implants.

#### Material and Methods

Between January 2002 and January 2005, 20 women and 12 men, aged 47 to 63 (mean, 57.19±6.08) years old, with variant-III valgus knees underwent primary TKA. Of the 32 patients, 37 knees had variant-III deformities. Pie crusting was carefully performed with small, multiple inside-out incisions, bone resection balanced the knee in lieu of soft tissue releases that were not used in the series. Cruciate-retaining knees (Gemini MKII, Link Company, Germany) were used in 13 knees, Genesis II Smith & Nephew Company, USA) in 14 knees, and hinged knee (Endo-Model Company, Germany) in 10 knees. In five patients with bilateral variant-III TKAs, three patients underwent 1-stage bilateral procedures, and two underwent 2-stage procedures. All implants were cemented and the patella was not resurfaced. The Hospital for Special Surgery (HSS) knee score was assessed. Patients were followed up from 8 to 11 years.

#### Results

The mean HSS knee score were improved from 50.33±11.60 to 90.06±3.07 ( $P < 0.001$ ). The mean tibiofemoral alignment were improved from valgus 32.72°±9.68° pre-operation to 4.89°±0.90° post-operation ( $P < 0.001$ ). The mean range of motion were improved from 93.72°±23.69° pre-operation to 116.61±16.29° post-operation ( $P < 0.001$ ). No patients underwent revision. One patient underwent open reduction and internal fixation using femoral condylar plates for supracondylar femoral fractures secondary to a fall at three years. Three patients developed transient peroneal nerve palsies, which resolved within nine months. Two patients developed symptomatic deep vein thrombosis that was managed with rivaroxaban and thromboembolic deterrent stockings. There was no incidence of pulmonary embolism. Postoperative patient satisfaction was 80.7±10.4 points in the groups. Prosthetic survival rate was 100% at mean 10 years postoperative.

HSS	90.06 ± 3.07
Survival Rate @10 yrs	100%
Range of Motion	116.61° ± 16.29°

[Overview of all Clinical Studies...](#)

## Literature

### Less anterior knee pain with a routine lateral release in total knee arthroplasty without patellar resurfacing: a prospective, randomized study

Guo-Chun Zha, Jun-Ying Sun, Sheng-Jie Dong  
*Knee Surg Sports Traumatol Arthrosc* (2014) 22:517–525

#### Purpose

Anterior knee pain is a major cause of complaint in total knee arthroplasty (TKA) without patellar resurfacing. The concept of improved patellar tracking and decreased retropatellar contact pressure for lateral retinacular release theoretically suggests that patients with lateral retinacular release in TKA would achieve a lower incidence of anterior knee pain when compared without lateral retinacular release. We sought to determine (1) whether those patients who received a routine lateral retinacular release in TKA would attain lower incidence of anterior knee pain as compared to patients who received TKA without lateral retinacular release and (2) whether lateral retinacular release would increase the lateral retinacular release-related complications.

#### Methods

A total of 148 patients who underwent TKA with the use of the Gemini MK II mobile bearing were randomized to receive either routine lateral retinacular release (intervention group) or not (control group). Patients were assessed by the visual analogue scale for anterior knee pain, the Knee Society clinical scoring system of knee score and function score, and patellar score for clinical function. Patients' satisfaction and lateral retinacular release-related complications were also evaluated.

#### Results

The overall incidence of anterior knee pain in the intervention group at 18 months follow-up was 5.6 %, while that of the control group was 20.6 % ( $p = 0.009$ ). No statistical difference was detected between the two groups in terms of lateral retinacular release-related complications (n.s.), patients' satisfaction (n.s.), knee score (n.s.) at 18 months follow-up.

	18 months
Anterior Knee Pain	4 (1 mild   3 moderate) = 5.6%
KSS Clinical Scores	87.1 ± 9.0
KSS Functional Scores	88.1 ± 9.0

## Literature

### Postural stability in relation to anthropometric and functional characteristics in women with knee osteoarthritis following total knee arthroplasty

Doris Vahtrik, Jaan Ereline, Helena Gapeyeva, Mati Pääsuke  
*Arch Orthop Trauma Surg (2014) 134:685–692*

#### Purpose

Due to the controversial information about postural stability in patients with lower limb joints osteoarthritis (OA), the following main questions are raised: how serious is the postural stability disturbance and which factors have an impact on postural stability before and after total knee arthroplasty (TKA).

#### Materials and Methods

Force plate was used to assess postural stability and custom-made dynamometer was used to assess isometric maximal voluntary contraction (MVC) force of leg extensor muscles; besides, knee pain and knee range of motion (ROM) was evaluated in 14 female patients (aged 46–68 years) with knee OA 1 day before, and 3 and 6 months following TKA and once in healthy controls (aged 48–70). Relationship between postural stability during standing and selected anthropometric and functional characteristics were investigated with Spearman's correlation coefficients.

#### Results

Remarkable reduction of knee pain and improvement in active ROM for the operated leg were shown after unilateral TKA. MVC force of leg extensor muscles achieved the preoperative level half a year after TKA. The centre of pressure (COP) of sway displacement in anteroposterior (AP) and mediolateral direction and the equivalent area of COP sway for the operated leg did not differ before, 3 and 6 months after TKA and compared to the non-operated leg. The trace speed was 6 months after TKA equal to the preoperative level. Only the COP of sway displacement in AP direction is significantly greater in knee OA patients both before and after TKA compared with healthy controls. Conclusions Knee OA patients' postural stability characteristics did not differ significantly both before and after TKA. Compared to healthy controls, the COP of sway displacement in AP direction is mostly disturbed. Correlation analysis confirms that increased postural sway is associated with an increased equivalent area of COP. In knee OA patients higher body mass index ensures reduced trace speed and lower knee ROM.

Knee Pain (VAS) 6 months Post-op	1.5
Range of Motion	104°

[Knee pain was assessed by visual analogue scale (VAS) in points ranging from 0 (no pain) to 10 (unbearable pain)]

[Overview of all Clinical Studies...](#)

## Literature

### Long-Term Results with Different Designs in Knee Replacements

H. Thabe, M.Dafferner-Franzmann, J. Stening

*Akt Rheumatol Online Publication: 21.10.2013 Akt Rheumatol, 2013 - 38*

Total knee arthroplasty should be a step forward to restore a natural kinematics of a knee with an adapted anatomy (correct axis and restoring the joint line), an adequate function, a good longevity.

Our task to restore previous anatomic function has its best solution with the sledge prosthesis, as an anatomic restoration of defects in one or more compartments in cases of intact collateral and cruciate ligaments. The step towards resurfacing TKA is a step to restore a knee and correct severe deformities. This kind of prosthesis has to cover a defect in 2 or more surfaces and correct unphysiological function, e. g. by lack of an anterior cruciate ligament, a severe laxity of collateral ligaments by osteonecrosis, axis deviation. If the normal kinematics are gone, our prosthesis has to restore kinematics of a normal knee and guarantee an adequate stress transfer to our new knee. More congruency and therefore low contact stress and PE wear requires an excellent implantation technique and by the way at least more rotational capacity to avoid stress on the fixation especially in rising up from a chair, climbing stairs etc. To mimic natural kinematics is only possible with anatomic designs and freedom of motion (nearly impossible in a strongly defected knee) or predictable femoral motion in roll back with retention of the PCL, posterior stabilized versions with mobile bearings. Fully conforming articulation will lead to dorsal impingement in flexion degrees more than 120 °. Therefore a "hybrid type of mobile bearing TKA" conformity like a conventional fixed bearing knee in combination with rotation capacity does simulate normal kinematics on a high level. The Gemini MK II design with the deep dished plateau results in a good stabilisation, rotation and at least an excellent alignment for the patella tracking. Together with the denervation and resection of the ramus infrapatellaris of the saphenus nerve our results of anterior knee pain dropped down to only 1.4 %. in late results.

From July 1999 to December 2001 we implanted 771 primary knee arthroplasty. 567 were surface replacement prostheses (TKA) of the type Gemini MK II. 172 unicondylar sledges (157 medial and 15 lateral) in case of unilateral osteoarthritis and in cases of instability 47 Rotational Knee Implants.

In our replacements we got an average range of motion of 0/1/128 °. The HSS score increased from 68.8 to 94.4 postoperation. In cases of severe osseous necrosis and instability due to ligament destructions a so-called rotational hinge prosthesis like the Endo model is our first choice.

## Results

HSS	94.4 Points
Survival Rate @11.2 yrs	91.2%
Range of Motion	128°

[Overview of all Clinical Studies...](#)

## Literature

### Gait and muscle strength characteristics in total knee arthroplasty patients with patello-femoral pain syndrome before and six months after surgery

H. Gapeyeva, J. Ereline, T. Haviko, H. Aibast, M. Pääsuke  
*Acta Kinesiologiae Universitatis Tartuensis. 2011, Vol. 17; 37-52*

#### Purpose

The aim of the present study was to investigate the gait and muscle strength characteristics in total knee arthroplasty (TKA) patients with patellofemoral pain syndrome (PFPS) before and six months after surgery.

#### Material and Methods

Eight patients (4 men and 4 women) aged 58–77 years with PFPS following unilateral TKA who had primary degenerative knee OA participated in the study before and six months after reoperation. In patients was registered the active range of motion (AROM) of knee extension and flexion, hip abduction and adduction. Isometric maximal voluntary contraction (IMVC) force of knee flexors, extensors, abductors and adductors was measured and gait kinematic characteristics and kinetic characteristics of knee joint were recorded.

#### Results

Knee flexion AROM in the involved leg was significantly lower ( $p < 0.05$ ) as compared to the uninvolved leg pre- and post-surgery. The patients had greater ( $p < 0.05$ ) hip abduction AROM and significant increase (31%,  $p < 0.05$ ) of IMVC force of the involved leg's hip abductors postoperatively as compared before surgery. Six months after surgery 38 H. Gapeyeva et al. a significant ( $p < 0.05$ ) improvement of gait spatiotemporal characteristics (increase of swing time and stride length ( $p < 0.05$ ), together with decrease of stance time and cadence, as well increase of stride length) was noted in the involved leg. In TKA patients 6 months after reoperation due to PFPS the knee joint function in involved leg was significantly improved and the positive changes in gait with comfortable velocity took place as compared before surgery.

WOMAC scores of TKA patients with PFPS before and 6 months after surgery:

	Before Surgery				6 months after Surgery			
	mean	SE	min	max	mean	SE	min	max
WOMAC-Pain (0-20)	5.4	1.2	5	12	12.01	1.7	7	19
WOMAC-PF (0-68)	18.0	3.2	7	25	36.1	3.4	16	45

WOMAC – Western Ontario and McMaster Universities Index of Osteoarthritis questionnaire; WOMAC-Pain – pain subscale and WOMAC-PF – physical function subscale (smaller scores characterise greater impairment of function; estimation involved recent 48 hours before testing). Data are presented as mean  $\pm$  SE and range (minmax). \*\* $p < 0.01$  as compared with data before surgery.



## Literature

### Quadriceps femoris muscle voluntary isometric force production and relaxation characteristics before and 6 months after unilateral total knee arthroplasty in women

Helena Gapeyeva, Nele Buht, Katrin Peterson, Jaan Ereline, Tiit Haviko, Mati Pääsuke  
*Knee Surg Sports Traumatol Arthrosc* (2007) 15:202–211

#### Purpose

The present prospective intervention study was to evaluate voluntary isometric force production, relaxation and activation capacity of the quadriceps femoris (QF) muscle before and 6 months after unilateral total knee arthroplasty (TKA).

#### Material and Method

TKA was performed in ten women with primary knee osteoarthritis (OA) using the condylar endoprotheses. Isometric maximal voluntary contraction (MVC) force, rate of force development at 50% of MVC (RFD50) and their ratio to body mass, half relaxation time (HRT) and voluntary activation (VA) of the QF muscle were recorded in patients for operated and non-operated leg before and 6 months after TKA. Established characteristics were compared with data on the dominant leg of ten age- and gender-matched controls. The clinical examination was performed using the Knee Society System (KSS) scores and pain intensity was assessed by visual analogue scale.

#### Results

MVC force in operated leg was lower ( $P < 0.05$ ) before and 6 months after TKA as compared with the non-operated leg (31 and 32%, respectively) and controls (48 and 44%, respectively). Patients had lower ( $P < 0.05$ ) VA of the QF muscle in operated leg 6 months after TKA as compared to controls. Significant increase ( $P < 0.05$ ) of KSS clinical scores and the tendency for the increasing of explosive force production of QF muscle in the operated leg were observed 6 months after TKA (RFD50 was 60% lower before TKA and 40% lower 6 months after surgery as compared to controls). When compared with the preoperative value, HRT prolongation ( $P < 0.05$ ) was noted 6 months after TKA in QF muscle of both legs in patients. Therefore, the present study confirmed that patients with knee OA had reduced force generation ability of QF muscle before TKA and the improvement of explosive force was noted 6 months after surgery.

Range of Motion	128°
HSS @7.3 yrs	96.1
Pain Finding	0.8%

## Biomechanical Studies

### GEMINI SL Mobile Bearing / Fixed Bearing CR Biomechanical analysis in healthy and deficient PCL patient

Bernardo Innocenti, PhD

LINK 999\_WP\_003\_2017\_Gemini-SL\_en, 2019

#### Purpose

The purpose of this analysis was to analyze the biomechanics of the GEMINI SL MB design and of the GEMINI SL FB CR design (Figure 1) during squat activities, using finite element analysis (FEA), and to check the performance in a patient with a healthy PCL and in a patient with a deficient PCL.

#### Material and Methods

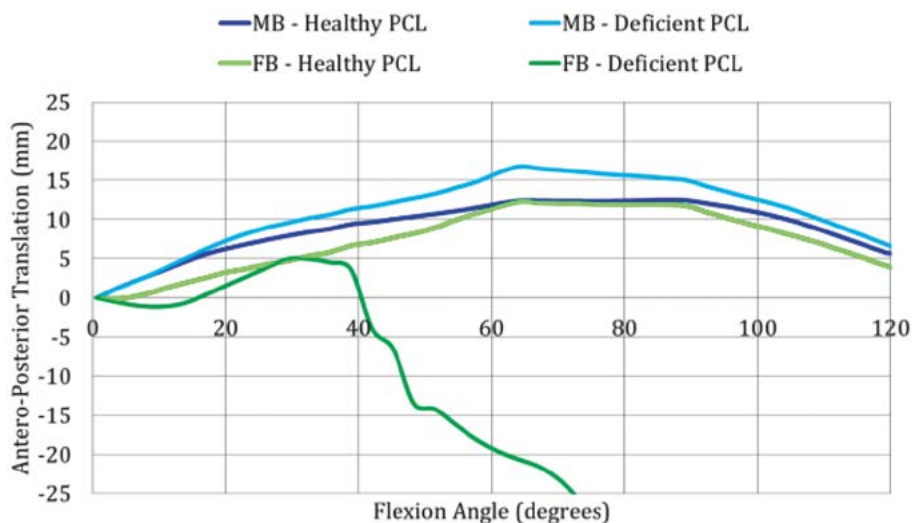
A GEMINI SL Fixed Bearing CR and a GEMINI SL Mobile Bearing, both right side, size medium, were selected for this study and implanted following, for each, the proper indication provided by the manufacturer. A 10 s loaded deep squat, up to 120°, was simulated. The boundary conditions of this movement, in terms of flexion-extension angle, axial and anterior-posterior force, were taken accordingly to previously experimental activities.

Even if the patellar bone and soft tissue envelope was not model in the present activity the adopted boundary conditions take in account also of forces exerted by the extensor mechanism. Similarly to the experimental tests, the other degrees of freedom were kept free.

#### Results

In this study the GEMINI SL MB design and of the GEMINI SL FB CR design were analyzed during squat using a validated finite element analysis. Results demonstrate how the high congruency of the MB design is able to guarantee the knee stability even when the PCL is deficient. Contrariwise, the FB insert, with a lower congruency is not able to stabilize the joint inducing an irregular kinematic pattern and enabling the dislocation of the components.

This findings are in accordance with clinical indications provided by the manufacturer.



[Overview of all Biomechanical Studies...](#)

## Biomechanical Studies

### Biomechanical analysis of GEMINI SL total knee replacement implant designs up to 155° of flexion

Bernardo Innocenti, PhD

LINK 999\_WP\_001\_2017\_Gemini-SL\_en, 2019

#### Purpose

In our study, we investigated the proximal interface on the UHMWPE insert contact surface areas and pressures of the GEMINI SL total knee replacement implants, using finite element analysis, throughout the range of motion from 0° to 155° of flexion with a standardized testing protocol and compare with the contact pressure and area of competitor High-Flex design analyzed under the same boundary conditions.

#### Material and Methods

A right side, size medium, was selected for each design.

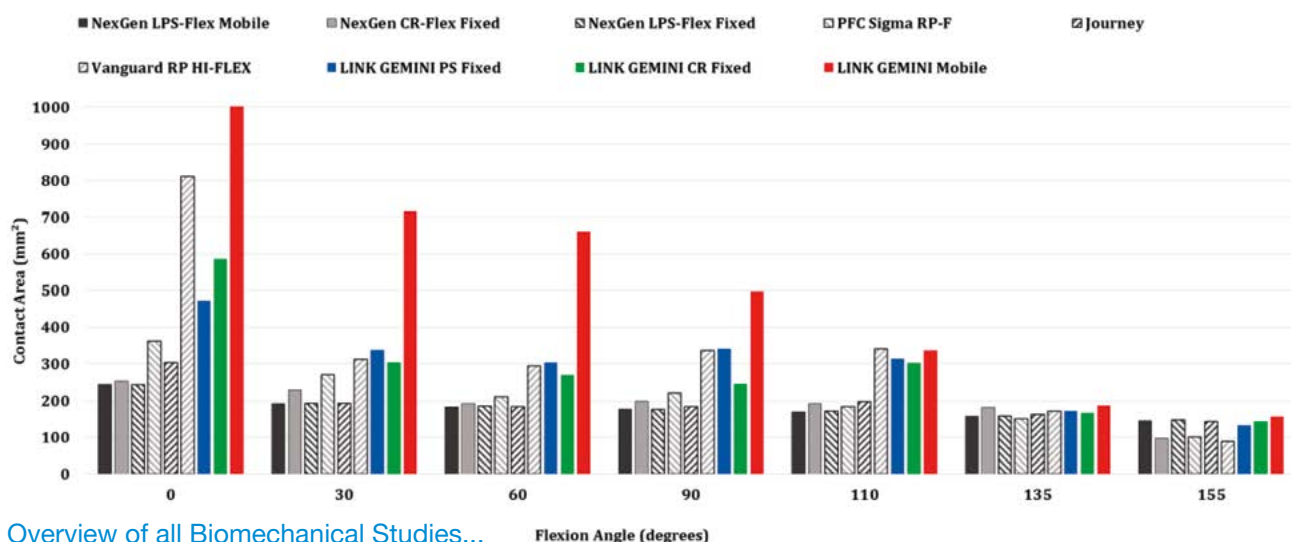
According to previous studies, linear elasticity was used for all the material models considered in this study. This allows for a good approximation of all the involved materials in order to gain a qualitative comparison among different configurations. The materials of the metal components, and tibial insert were respectively cobalt-chromium alloy (CoCr), and an ultra-high-molecular-weight-polyethylene (UHMWPE). The materials were assumed to be homogeneous and isotropic. The material properties were: for CoCr:  $E=240$  GPa,  $\nu=0.3$  and for UHMWPE:  $E=0.7$  GPa,  $\nu=0.4$ . Following a standardized testing protocol<sup>7-9</sup>, a load of 3600 N, corresponding five times the body weight of 73 kg person was applied at 0°, 30°, 60°, 90°, 110°, 135° and 155° of flexion, and the contact area and pressure were recorded. This load is approximately five times the body weight of a 73 kg person and was selected based on a report which demonstrated that three to six times the body weight is applied to the tibiofemoral joint during level walking and descending stairs. Each model was meshed using tetrahedral elements with an average element size of 1.5 mm. A convergence test was preliminary performed to check the mesh quality. Abaqus/Standard version 6.13-1 (Dassault Systèmes, Vélizy-Villacoublay, France) was used to perform all the finite element simulations.

#### Results

This study, using a validated finite element modeling and applying the same boundary conditions of a previous experimental study on different high-flex competitor designs, demonstrate that LINK GEMINI SL designs behave similarly to Hi-Flex competitor design.

In particular:

- between 0° and 110°, the behavior is in general better that competitor designs both in relation to contact area (that is higher) and contact pressure (that is smaller)
- at 135° and 155° of flexion the behavior is similar as the other competitor designs both in relation to contact area and contact pressure.



## Biomechanical Studies

### GEMINI SL Fixed Bearing PS: Biomechanical Analysis of the Post-Cam System

Bernardo Innocenti, PhD

LINK 999\_WP\_002\_2017\_Gemini-SL\_en, 2019

#### Purpose

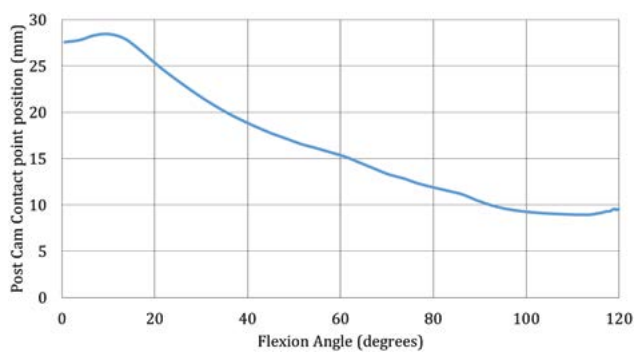
The purpose of this analysis was to analyze the biomechanics of the GEMINI SL Fixed Bearing PS during squat activities, using finite element analysis (FEA), and compare the results with the one achieved, under the same boundary condition, by different competitor's PS TKA design.

#### Material and Methods

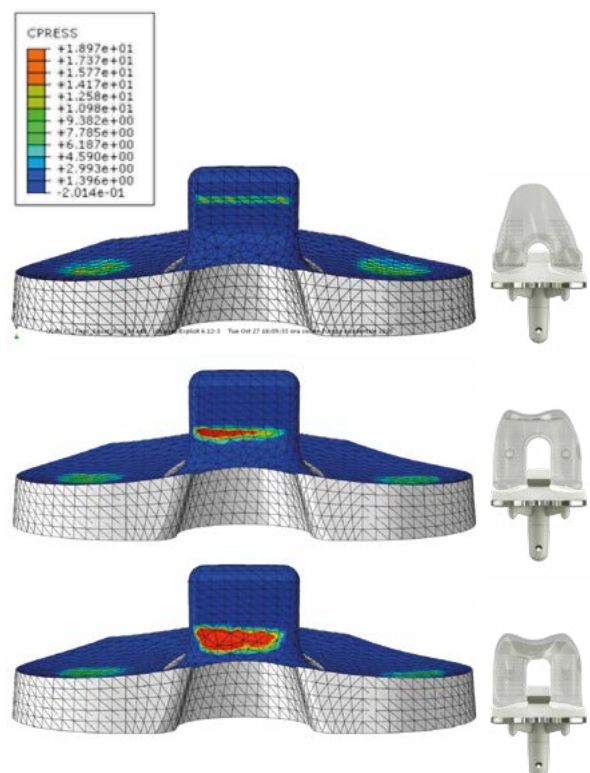
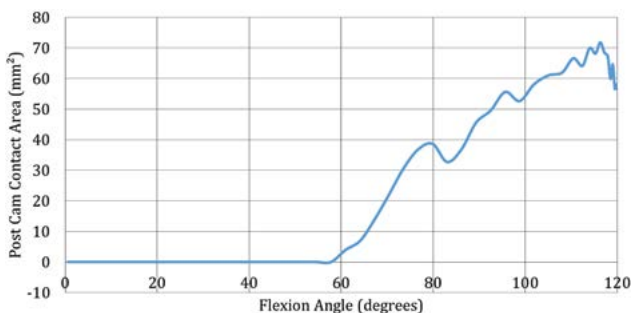
The Finite element model was based on an already validated and published knee finite element model 3-5 A GEMINI SL Fixed Bearing Posterior Stabilized, right side, size medium, was selected for this study and implanted in the femoral and tibial bone following the proper indication provided by the manufacturer. A 10 s loaded deep squat, up to 120°, was simulated. The boundary conditions of this movement, in terms of flexion-extension angle, axial and anterior-posterior force, were taken accordingly to previously experimental activities in which different competitor's PS TKA design were analyzed. Even if the patellar bone and soft tissue envelope was not model in the present activity the adopted boundary conditions take in account also of forces exerted by the extensor mechanism. Similarly to the experimental tests, the other degrees of freedom were kept free.

#### Results

The finite element analysis indicated that the post-cam mechanism and design of the GEMINI SL Fixed Bearing PS is very reliable, effective and safer. In particular, during flexion, the position of the contact point lower its position during flexion, reducing the risk of dislocation, the contact area is increasing reducing the contact pressure, reducing the risk of fracture and wear. Moreover, the engagement of the post-cam is in agreement on experimental study on native knee.



Vertical post-cam contact point position during flexion.



Post-cam contact areas at low flexion (upper picture), middle flexion (middle picture) and at higher flexion (lower picture).

[Overview of all Biomechanical Studies...](#)

## Registry Data

### R.I.P.O.

*Registro dell'implantologia Protesica Ortopedica (Register of the Orthopaedic Prosthetic Implants)*

Registry	Year of Publication	No of Patients	Survival Rate (%) after 10 yrs
R.I.P.O.	2020	2446	95.1

During 2017, with Regional Law n.9 of 1st June 2017, RIPO was recognized as a significant regional interest Registry, with the aim of guaranteeing an active and systematic collection of health and epidemiological data. According to these aims, we are now presenting the 18th report, elaborated by the Registry of Orthopaedic Prosthetic Implantology (RIPO). It presents the most significant results of the descriptive and survival statistical analyses performed on hip, knee and shoulder arthroplasty surgeries carried out in the Emilia-Romagna region, in Italy, between 1st January 2000 and 31st December 2018.

Altogether data of approx. 187.000 hip, 114.000 knee and 8.000 shoulder prostheses have been reported from 69 Orthopaedic Units in 63 Hospitals, either public or private.

During 2018, data on 7.881 primary knee prostheses and 584 partial or total revisions were registered, with an increase of 6% of primary knee prostheses and 10% of revisions from the past year. A high percentage of knee prostheses is implanted in private structures: 69% of primary knee prostheses in 2018 (vs 43% in 2000) and 60% of revisions in 2018 (vs 25% in 2000). In 2018, 13% of implanted prostheses are unicompartmental, 58% are bicompartmental with no patella resurfacing, and the remaining 29% have patella resurfacing. The number of prostheses with patella is increasing, in particular in public hospitals. Female patients are about twice as many as men. In 2018, 97,4% of implants are cemented, in the half of them, cement is loaded with antibiotic. Hybrid fixation is almost completely absent. Posterior Stabilization of insert is slightly increasing (67% during last year) compared to minimally stabilized. Mobile inserts are decreasing (16,6% in 2018). 57% of inserts is in Standard Poly and the remaining is in Crosslinked Poly with or without antioxidant. Femoral components with Co-Cr are decreasing, Ceramicised Zirconium alloy and Cobalt alloy treated are preferable. Types of implanted prostheses are less numerous and more stable during years compared to hip. Survival of bicompartmental is 92,5% at 17 yrs, survival of tricompartmental is 91,7% and survival of unicompartmental is significantly lower (76,4%). In these analyses, patella resurfacing after primary TKA is not considered as a failure. The incidence of revisions due to infection in the prosthesis remains high, in particular in total implants, where it represents approximately a quarter of the causes of failure (25%). For total implants, septic loosening represents one-third of the causes of failure. Total revisions are not revised a second time in 81,6% of cases at 17 yrs. Cox multivariate analysis shows that the survival of bi-tricompartmental knee prostheses is negatively influenced by the age of the patient (the expectancy of prosthesis survival is lower for patients with less than 60 yrs), by gender (survival is lower for male patients) and by type of insert (mobile insert is worse than fixed insert).

[Overview of all Registry Data Survival Rate...](#)

## Registry Data

### Swiss National Joint Registry

*SIRIS Report 2019 – Annual Report of the Swiss National Joint Registry, Hip and Knee)*

Registry	Year of Publication	No of Patients	Survival Rate (%) after 2 yrs
SIRIS	2021	144	96.5%

In 2020, the total number of registered primary TKAs in the Swiss Joint Registry reached 118,000 cases. The share of women (60.3%) and mean age (69.5 years) remained approximately constant during the entire period of time. The share of younger patients (younger than 45: 0.5% and 45–54 years old: 6.2%) and patients older than 85 years old (4.6%) did not change significantly over the past years. Gender, mean age, age groups and BMI did not differ in low or high volume hospitals, whereas hospitals with more than 200 TKAs per year seemed to treat more patients classified as ASA 3. Most reasons for TKAs were classified as primary OA (88.5% in 2020) although more reasons (such as ligament lesions or infection) were introduced in 2015 as possible underlying diagnosis for secondary OA and the knowledge about factors causing a knee OA have steadily increased over the past decades.

[Overview of all Registry Data Survival Rate...](#)

## Registry Data

### EPRD

*Endoprothesenregister Deutschland*

Registry	Product Configuration	Year of Publication	No of Patients	Survival Rate (%) after 4 yrs
EPRD	CR	2021	462	94.9%
	PS	2021	845	96.9%

From the start of data collection in November 2012 to the end of 2020, the EPRD has been able to collect data on more than 1.67 million hip and knee arthroplasty surgeries – and the trend is rising every year. This upward trend came to a halt when the corona pandemic reached Germany in spring 2020. After the EPRD was able to record around 70% of the hip or knee arthroplasties performed in Germany in one year in 2019, the documentation figures decreased for the first time in 2020. In 2020, 733 clinics submitted data sets for a total of 290,420 operations to the EPRD, 9% fewer than in the previous year.

For 2020, 111,365 first implantations of knee arthroplasties were registered in the EPRD. The patients are slightly younger than patients who have had a hip replacement, but have a higher body mass index. In almost half of knee patients, it is over 30 points, which means they are considered to be morbidly overweight according to the WHO.

Complete cementation is the standard treatment for both total knee arthroplasty and unicondylar restorations, accounting for 94% and 90% of primary restorations, respectively. The proportion of unicondylar knee applications has increased continuously in recent years, but has stabilized at 13.2% in 2020 at the level of the previous year. The use of posterior-stabilized systems has also increased in recent years (from 12.9% to 19.2%), as has the proportion of highly cross-linked polyethylenes (from 10.7% to 20.5% in total knee arthroplasties, in unicondylar configurations from 1.8% to 11.5% since 2014). On the other hand, the installation of mobile platforms continued to decline, both for total knee arthroplasties and for unicondylar knee arthroplasties.

A primary retropatellar replacement was performed in 11.8% of the total knee arthroplasty documented for 2020. However, the philosophy of the clinics seems to be very different in this respect: Some hospitals never perform a primary retropatellar replacement, while others do it every second operation. In 55% of the 13,767 follow-up surgeries on the knee joint documented for 2020, the implant components of the knee prosthesis were completely changed. In 59% of these complete replacements, hinged or varus-valgus-stabilized knee systems were implanted. The main reasons for knee replacement surgery were loosening (23.4%) and infections (14.8%).

[Overview of all Registry Data Survival Rate...](#)



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**GEMINI SL Mobile Bearing / Fixed Bearing CR Biomechanical analysis in healthy and deficient PCL patient**

*LINK 999\_WP\_003\_2017\_Gemini-SL\_en, 2019*

16) B. Innocenti

**Biomechanical analysis of GEMINI SL total knee replacement implant designs up to 155° of flexion**

*LINK 999\_WP\_001\_2017\_Gemini-SL\_en, 2019*

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**GEMINI SL Fixed Bearing PS: Biomechanical Analysis of the Post-Cam System**

*LINK 999\_WP\_002\_2017\_Gemini-SL\_en, 2019*

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Further Information



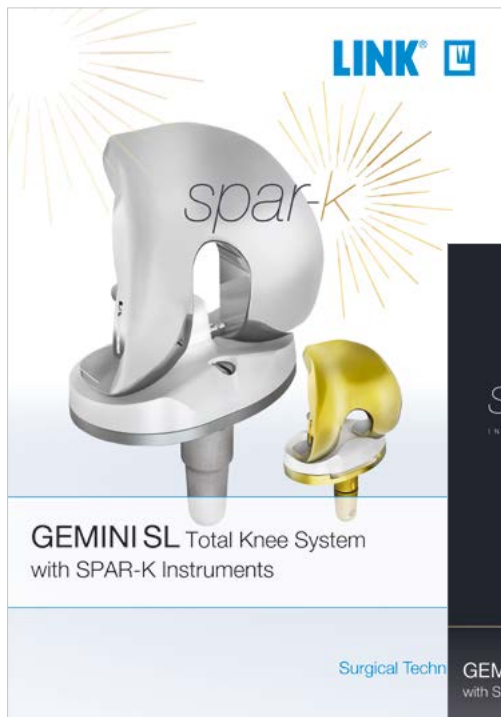
**GEMINI SL Total Knee System**

- Surgical Technique, Implants & Instruments
- Teaserflyer



**GEMINI SL**

- ODEP-Rating
- Teaserflyer



**GEMINI SL SPAR-K**

GEMINI SL Total Knee System  
with SPAR-K Instruments

- Surgical Technique, Implants & Instruments
- Teaserflyer



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