





LINK® Endo-Model® Knee System

Literature Research



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Presented by:



LINK® Endo-Model® Knee System

Literature Research

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Purpose of the Research

The purpose of this Literature Research is to highlight the key papers of the LINK® Endo-Model®. The focus is on the different scores (knee society score, knee function score, western ontario an McMaster osteoarthritis index, hospital for special surgery score and knee injury and osteoarthritis outcome score) and the survival rate.





Definitions

Knee Society Clinical Rating System

The Knee Society Clinical Rating System is subdivided into a knee score and a functional score.

Knee Society Score (KSS)

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. (1)

Knee Functional Score (KFS)

The Functional Score rates the patient's ability to walk and climb stairs. 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 (1)

Evaluation of KSS and KFS

Table 1: Evaluation of KSS and KFS (1)

| Score | |
|----------|-----------|
| 80-100 | Excellent |
| 70-79 | Good |
| 60-69 | Fair |
| Below 60 | Poor |

Western Ontario an McMaster Osteoarthritis Index (WOMAC)

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. (2) The WOMAC is used for knee OA, chondral defects and anterior cruciate ligament deficiency. A higher score indicate worse pain, stiffness or physical function. (3)

Knee Injury and Osteoarthritis Outcome Score (KOOS)

The KOOS is an extension of the WOMAC score with the purpose of evaluating the short-term and long-term results. THE KOOS have five category groups: pain, other symptoms, function in daily living, function in sport and recreation and knee related quality of life. (2)

Hospital for Special Surgery-Score (HSS)

The HSS-Score evaluates pain, functional limitations, tenderness, impingement maneuvers and range of motion.

Evaluation of HSS-Score

Table 2: Evaluation of HSS-Score (4)

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

Oxford Knee Score (OKS)

The Oxford knee score is for patients undergoing total knee replacement. The OKS evaluates pain, mobility, limping, stairs, standing after sitting, kneeling, giving way, sleep, personal hygiene, house-work, shopping and transport. Patients can award 1 to 5 points for the different classes or 0 to 4 points in the modified version. A higher score reflects a poorer outcome and consequently, lower score reflects a better outcome. (3)

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. (5)





Overview Tables: Overview of all Studies

| Study | Year of Publication | No of Patients | Mean Follow-up (Range) | Mean Age (Range) | Reason for TKA | Hinge Knee (HK) or Rotating Hinge Knee (RHK) | Primary | Revision | Scores |
|------------------------------|------------------------|----------------|---------------------------------|-----------------------------------|---|--|---------|----------|--|
| Primary Gehrke et al. (6) | 2014 | 238 | More than 13 years | 67 years (26-88 years) | Collateral ligament insufficiency, bony destruction of the tibial plateau or femoral condyles, hyperlaxity, fixed valgus/varus deformity, severe theumatoid arthritis | - | х | | ROM, HSS, Survival Rate |
| Fujiang et al. (7) | 2014 | 30 | 18 months (18-48) | 65.2 years (53-78) | Osteoarthristis, rheumatoid arthritis, baker knee deformi- ty, 15°-34° deformi- ty, 31°-45° buckling deformity | RHK | х | | KSS, ROM |
| Lozano et al. (8) | 2012 | 111 | 28 months | 72.77 years | Degenerative knee joint disease | RHK | x | | WOMAC, ROM |
| Malviya et al. (9) | 2011 | 26 | 38.8 months (12-104) | 80 years (67-92) | Fractures of tibia and femur | - | x | | KSS, KFS |
| Bae et al. (10) | 2009 | 9 | 12.3 years (10-22) | 60.1 years (46-68) | Charcot joint | RHK | х | | KSS, KFS, ROM |
| Mavrodontidis et al. (11) | 2008 | 127 | 2-15 years | 68.6 years (62.5- 74.7) | Osteoarthritis | RHK | х | | HSS, Survival Rate |
| Petrou et al. (13) | 2004 | 80 | 11 years (7-15) | 70 Years (56-85) | Osteoarthritis, rheumatoid arthritis, osteonecrosis | RHK | X | | KSS, KFS, HSS, Survival RAte |
| Nieder et al. (14) | 1996 | - | More than 10 years | 66 years (22-99) | Ostheoartritis, rheumatoid arthritis, posttraumatic disease, postinfec- tion arthritis | RHK | х | | Survival rate |
| Bistolfi et al. (4) | | 97 | 166 months (65-193 month) | 68.8 years (34-84 years) | Arthritis due to axial defects, knee arthritis due to rheumatoid arthritis, tibial plateau fractures and high tibial osteotomy | RHK | x | | HSS, Survival Rate |





Overview of all Studies

| Primary/ Revision Felli et al. (15) | 2016 | 138 | 6.1 years (3.5-11.2) | 71.5 years (57-84) | Rheumatoid arthritis | RHK | x | х | KSS, KFS, ROM |
|---|------|-----|---------------------------------|---|--|-----|---|---|--|
| Sanguineti et al. (16) | 2014 | 118 | 42.2 months (20-128) | 74 years (50-84) | Primary: OA, rheu- matoid arthritis Revision: aseptic loosening, Infection, fracture | RHK | x | x | KSS, KFS, ROM, Survival Rate |
| Efe et al. (17) | 2012 | 113 | 55 months (10-133) | 73.7 years (prima- ry) 72.5 years (revi- sion) | Difficult primary and complex revision cases | RHK | x | х | KSS, KFS, ROM, Survival Rate |
| Revision Zahar et al. (19) | 2016 | 70 | 10 years (9-11 | 70 years (60-81) | Prosthetic joint infection | RHK | | х | HSS, Survival rate |
| Rodrìguez- Merchàn et al. (20) | 2015 | 96 | 7.3 years (5-10) | 79 years (75-86) | Instability | RHK | | х | KSS, KFS, ROM |
| Bistolfi et al. (21) | 2013 | 50 | 155 months (78-240 month) | 69.7 years (45-85 years) | Revision because of mild and severe instability | RHK | | х | HSS, ROM, Survival Rate |
| Gudnason et al. (22) | 2010 | 38 | 8.8 years (6-18) | 72 years (55-88) | Aseptic loosening | RHK | | х | KSS, KFS, HSS, ROM, Survival Rate |
| Joshi et al. (23) | 2008 | 78 | 7.83 years (56-130) | - | Aseptic loosening | RHK | | х | KSS, KFS, ROM |
| Pradhan et al. (24) | 2006 | 50 | 4 years (2-6) | 70.25 years (39-85) | Infection, aseptic loosening, stiffness, fracture | RHK | | х | HSS |



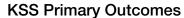
Overview of KSS and KFS

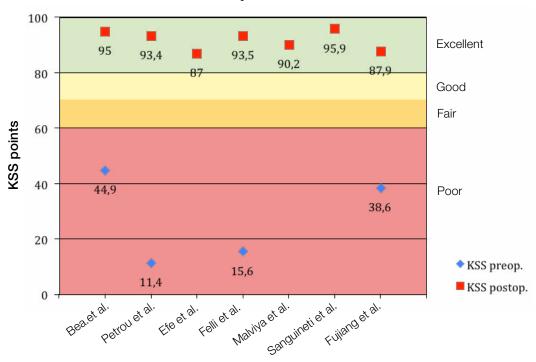
| Study | KSS Preoperative (Range) | KSS Postoperative (Range) | KFS Preoperative (Range) | KFS Postoperative (Range) | Primary or Revision |
|-----------------------------------|-----------------------------|---------------------------------|-----------------------------|---------------------------------|------------------------|
| Bae et al. (10) | 44.9 points (30-54) | 95.0 points (85-98) | 45.0 points (25-60) | 93.6 points (80-98) | Primary |
| Petrou et al. (13) | 11.4 points (0-46) | 93.4 points (75-100) | 19.7 points (0-50) | 69.7 points (15-100) | Primary |
| Malviya et al. (9) | - | 90.2 points (67-96) | - | 35.5 points (-10-80) | Primary |
| Fujiang et al. (7) | 38.6 points (+/- 12.7) | 87.9 points (+/- 12.5) | 36.3 points (+/- 15.1) | 68.8 points (+/- 18.1) | Primary |
| Efe et al. (17) | - | 87 points (57-97) | - | 50 points (-20-100) | Primary |
| | - | 86 points (46-94) | - | 45 points (20-100) | Revision |
| Felli et al. (15) | 15.6 points (7-30) | 93.5 points (84-100) | 24.3 points (2-55) | 67.1 points (2-95) | Primary and revision |
| Sanguineti et al. (16) | - | 95.9 points | - | 82.6 points | Primary |
| | - | 92.0 points | - | 86.8 points | Revision |
| Rodrìguez- Merchàn et al. (20) | 37 points | 79 points | 34 points | 53 points | Revision |
| Gudnason et al. (22) | - | 85 points (73-96) | - | 29 points (0-100) | Revision |
| Joshi et al. (23) | 38 points (10-75) | 86 points (44-98) | 33 points (0-85) | 61 points (20-100) | Revision |

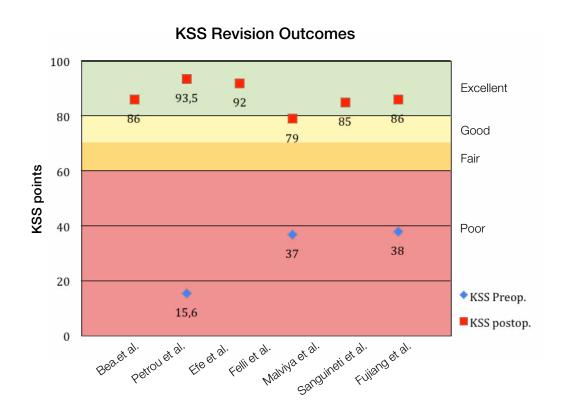








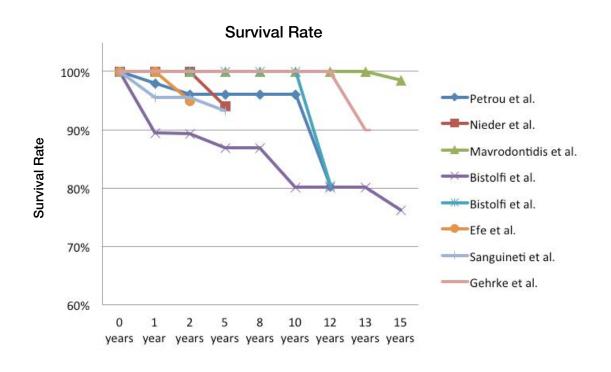






Overview Survival Rate

| Study | After 1 Year | After 2 Years | After 5 Years | After 8 Years | After 10 Years | After 15 Years |
|---------------------------|-----------------|------------------|-----------------------------|------------------|-------------------|-------------------|
| Petrou et al. (13) | 98% | 96.1% | - | - | 80.3%* | |
| Nieder et al. (14) | - | - | - | 94% | - | - |
| Mavrodontidis et al. (11) | - | - | - | - | - | 98.5% |
| Bistolfi et al. (21) | 89.3% | - | 86.9% | - | 80.2% | 76.2% |
| Efe et al. (17) | - | - | 95% primary 76% revision | - | - | - |
| Sanguineti et al. (16) | 95.5% | - | 93.3% | - | - | - |
| Zahar et al. (19) | - | - | - | - | 75% | - |
| Gudnason et al. (22) | - | - | - | - | 65.1% | - |
| Bistolfi et al. (4) | - | - | - | - | 80.4%** | - |
| Gehrke et al. (6) | - | - | - | - | - | 90%*** |



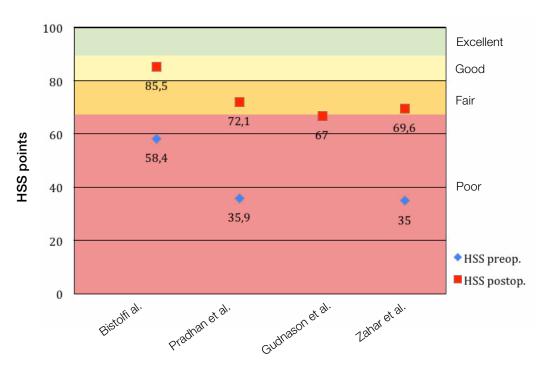


Overview of HSS

| Study | Preoperative | Postoperative | Primary or Revison |
|--------------------------|--------------|---------------|-----------------------|
| Bistolfi et. al (21) | 58.4 points | 85.5 points | Revision |
| Pradhan et. al (24) | 35.9 points | 72.1 points | Revision |
| Gudnason et. al (22) | - | 67 points | Revision |
| Zahar et. al (19) | 35 points | 69.6 points | Revision |
| Mavrodontidis et al (11) | 57.5 points | 89.3 points | Primary |
| Bistolfi et. al (4) | 64.4 points | 82.2 points | Primary |

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

HSS Revision Outcomes





Overview of ROM

| Study | ROM Preoperative | ROM Postoperative | Primary or Revision |
|-------------------------------|---------------------|----------------------|------------------------|
| Bae et al. (10) | 121.8° (90°-140°) | 133.3° (100°-145°) | Primary |
| Efe et al. (17) | - | 88° (63°-113°) | Primary |
| | - | 89° (66°-112°) | Revision |
| Felli et al. (15) | 53.2° (30°-100°) | 102.7° (75°-125°) | Primary and revision |
| Lozano et al. (8) | 90° | 120° | Primary |
| Sanguineti et al. (16) | - | 112.6° | Primary |
| | - | 102.1° | Revision |
| Gehrke et al. (6) | - | 118° (95°-130°) | Primary |
| Rodrìguez-Merchàn et al. (20) | 80° | 120° | Revision |



Here follows a list of different papers related to LINK® Endo-Model® Knee System. These papers include information about the survival rate of the different rotating hinge knee systems and also about mid-term and long-term follow-ups (evaluated by KSS, KFS, WOMAC, KOOS or HSS scores).

Endo-Model® (WALDEMAR LINK® GmbH & Co.KG)

The Role of Hinges in Primary Total Knee Replacement (6)

T.Gehrke, D. Kendoff, C. Haasper
The Bone & Joint Journal Vol 96-B, no.11 November 2014

The aim of this study was to tread patients older than 75 years with the following indications: Collateral ligament insufficiency, bony destruction of the tibial plateau or femoral condyles, hyperlaxity, fixed valgus/varus deformity >20° and severe rheumatoid arthritis.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

In 1993 238 patients were treated with a primary prosthesis from LINK. The mean age of the patients at surgery was 67 years (range from 26 to 88). The follow-up was performed after more than 13 years.

Results

ROM postoperative was 118° (range from 95° to 130°).

The HSS has 54% excellent results, 20% good, 12% fair and 14% poor results.

The survival rate after 13 years was 90%. The survival rate of the patients older than 60 years was 97%. Otherwise the survival rate of patients younger than 60 years was 77% after 13 years. Patients with a preoperative varus deformity have a better survival rate after 13 years (97%) than patients with a valgus deformity (79%).



Clinical Outcomes of Primary Rotating-hinge Knee Arthroplasty for Knees with Severe Deformity (7)

Zhang Fujiang, Liu Yabin, Xiao Yu and Liu Wenbin Chinese Medical Journal 2014

The aim of the study was an evaluation of patients with severe deformities. All the patients were treated with the Endo-Model[®]. Indications for operations were: osthearthritis, rheumatoid arthritis, 15° to 34° deformity and 31° to 45° buckling deformity.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

Between 2005 and 2010 the evaluate 30 patients (17 men and 13 women). The mean age of the patients at time of operation was 65.2 years (range from 53 to 78). The mean follow-up was 18 months (range from 18 to 48 months).

Results

| | Preoperative | Postoperative |
|-----|------------------------|------------------------|
| KSS | 38.6 points (+/- 12.7) | 87.9 points (+/- 12.5) |
| KFS | 36.3 points (+/- 15.1) | 68.8 points (+/- 18.1) |



Better Outcomes in Severe and Morbidly Obese Patients (BMI > 35 kg/m2) in Primary Endo-Model® Rotating-Hinge Total Knee Arthroplasty (8)

Luis M. Lazono, Vicente Lòpez, Josè Riòs, Dragos Popescu, Pere Torner, Fèlix Castillo, and Francisco Maculè *The scientific WorldJOURNAL, 2012*

The aim of the study was to show that the Endo-Model® is useful for severe and morbidly obese patients with ligament instability or bone defects. This paper evaluates the results by the WOMAC and the ROM.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prostheses (WALDEMAR LINK® GmbH & Co.KG).

In the period from January 2006 to January 2009 they implanted 120 primary knees in 111 patients (84 female and 27 male). The minimum follow-up was one year. The mean follow-up was 28 months. The mean BMI was 30.81 kg/m^2 . The mean age of the patients was 72.77 years.

Results

| ВМІ | < 30 kg/m ² | >30 kg/m ² |
|--------|------------------------|-----------------------|
| WOMAC | -32.1 (-39.5/ 24.7) | -38.9 (-46.4/ -31.6) |
| Gender | Women | Men |
| WOMAC | -30.9 (-37.4/ 24.5) | -40.1 (-48.8/ -31.5) |

ROM: The ROM the median flexion was 90° preoperative. After the surgery the median flexion was 120°.



Acute Primary Total Knee Arthroplasty for Peri-articular Knee Fractures in Patients over 65 Years of Age (9)

Ajay Malviya, Mike R. Reed, Paul F. Partington *Elsevier 22 June 2011*

The aim of the Study was to show a follow-up of patients over 65 years with peri-articular knee fractures (both tibia and femur fractures). These fractures are difficult because of poor bone quality, pre-existing arthritis, comminution, osteochondral damage at time of injury. The cause of failure of fixation in this group of patients is not technical failure of the implant but the poor bone quality.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

In this paper 26 patients were treated between May 2000 and December 2008. All cases were a primary surgery to treat femoral and tibial fractures. The mean age of the patients was 80 years (range from 67 to 92 years). The mean follow-up was 38.8 months (range from 12 to 104 months).

Results

| KSS | 90.2 points (67 to 96 points) |
|-------------------|--------------------------------|
| KFS | 35.5 points (-10 to 80 points) |
| OKS | 39.5 cpoints (23 to 44 points) |
| Range of movement | 87.3° |



Long-Term Outcome of Total Knee Arthroplasty in Charcot Joint – A 10- to 22-Year Follow-up (10)

Dae Kyung Bae, MD, Sang Jun Song, MD, Kyoung Ho Yoon, MD, and Jung Ho Noh, MD *The Journal of Arthroplasty Vol. 24 No.8 2009*

The aim of this study was to evaluate the long-term follow-up of patients with Charcot Joint. The Charcot Joint is characterized by development of bone destruction and attenuation of ligaments. The outcome of TKA in the Charcot joint secondary to neurosyphilis is likely to be less favorable because of the unstable neurological status, development of ataxia, severe joint destruction, bone defects and deformity.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

In total 9 patients and 11 TKA's were evaluated in the period from January 1985 until August 1997. This study was a retrospectively study for patients with a Charcot Joint. The mean age of the patients was 60.1 years (range from 46 to 68 years). The mean follow-up was 12.3 years. The BMI of the patients were 23.3 kg/m² (range from 20.1 kg/m² to 38.2 kg/m²).

Results

| | Preoperative | Postoperative |
|-----|---------------------------------|---------------------------------|
| KSS | 44.9 points (range 30-54 pints) | 95 points (range 85- 98 points) |
| KFS | 45 points (range 25-60 pints) | 93,6 points (range 80-98 pints) |
| ROM | 121° (range 90°- 140°) | 133.3° (range 100°-145°) |



Application of the Endo-Model® Rotating Hinge Knee Prostheses for Knee Osteoarthritis (11)

Alexandros N. Mavrodontidis, MD; Sofia I. Andrikoula, MD; Vasileios A. Kontogeorgakos, MD; George C. Babis, MD; Theodoros A. Xenakis, MD; Alexandros E. Beris, MD; and Panayotis N. Soucacos, MD, FACS *Journal of surgical orthopaedic advances volume 17, number 3, fall 2008*

The aim of the study was to show results for the Endo-Model® for knee osteoarthritis. The indications were osteoarthritis, rheumatoid arthritis and osteonecrosis.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

Between January 1990 and December 2003 they implanted 150 rotating hinge knee systems in 127 patients. The patients were subdivided into 4 groups:

| | Follow-up | Mean Follow-up | Number of Knees | Number of Patients | Mean Age |
|---------|----------------|-------------------|--------------------|-----------------------|------------|
| Group A | 10 to 15 years | 12.9 years | 34 | 30 | 66.8 years |
| Group B | 8 to 10 years | 9 years | 35 | 27 | 69 years |
| Group C | 5 to 8 years | 6.5 years | 37 | 31 | 66.4 years |
| Group D | 2 to 5 years | 4.2 years | 30 | 25 | 66 years |

Results

In total the HSS-Score improved from 59.3 to 90.7 (range from 83.6 to 97.8).

| Parameter | | Group A | Group B | Group C | Group D |
|-----------|---------------|-------------------|-------------------|-------------------|-------------------------|
| HSS | Preoperative | 57.5 (42.7-72.3) | 59.7 (48-71.4) | 62.1 (54.4-69.8) | 58.9 (50.6-67.2) |
| поо | Postoperative | 89.3 (83.6-95) | 88.9 (79-98.8) | 93.6 (90.2-97) | 92.1 (86.8-97.4) |
| 5014 | Preoperative | 9.4° (8.4°-10.4°) | 9.2° (7.8°-10.6°) | 9.7° (8.6°-10.8°) | 8.5° (7.5°-9.5°) |
| ROM | Postoperative | 14° (13°-15°) | 13° (10.9°-15.1°) | 14° (12.3°-15.7°) | 14.4° (12.9°- 15.9°) |



Medium-term Results with a Primary Cemented Rotating-hinge Total Knee Replacement – A 7- to 15-Year Follow-up (13)

G. Petrou, H.Petrou, C.Tilkeridis, T. Stavrakis, T. Kapetsis, N. Kremmidas, M. Gavras *The Journal of Bone and Joint Surgery British Volume Number 86B August 2004*

The aim of this study was to show mid-term results for the Endo-Model® Rotating Hinge Knee TKA. To evaluate the results of this study the HSS, KSS and KFS were used.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

In the period from 1987 till 1995 they evaluated 100 knees in 80 patients. They used a cemented, long-stemmed Endo-Model® Rotating Hinge TKA. The mean follow-up was 11 years (range from 7 to 15 years). The mean age of the patients was 70 years (range from 56 to 85 years).

Patient category:

| Category | Description |
|----------|---|
| А | Unilateral or bilateral |
| В | Unilateral, other knee symptomatic |
| С | Multiple arthritis or medical infirmity |

Results

Knee society score and knee functional score:

| | | KSS | | KFS | |
|---------------------|-----------------|----------------|------------------|----------------|------------------|
| Patient Category | Number of Knees | Preoperative | Postoperative | Preoperative | Postoperative |
| Α | 44 | 13.4 (0 to 46) | 95.3 (90 to 110) | 22.4 (0 to 50) | 84.2 (70 to 100) |
| В | 1726 | 12.7 (0 to 31) | 93.6 (87 to 99) | 22.1 (0 to 50) | 71.3 (60 to 80) |
| С | 2027 | 8 (0 to 38) | 91.2 (75 to 99) | 14.6 (0 to 40) | 53.6 (15 to 80) |
| Total | 9797 | 11.4 (0 to 46) | 93.4 (75 to 100) | 19.7 (0 to 50) | 69.7 (15 to 100) |

Hospital for special surgery score:

| HSS | Number of Knees |
|------------------|-----------------|
| 85 to 100 points | 70 |
| 70 to 84 points | 21 |
| 60 to 69 points | 6 |
| 0 to 59 points | 3 |

Survival rate:

| Years after Surgery | Survival Rate |
|---------------------|-----------------------------------|
| 1 | 98% (range from 95.5% to 100%) |
| 2 | 96.1% (range from 92.2% to 99.9%) |
| 12 | 80.3% (range from 68.6% to 94.1%) |



Reconstruction of the Knee Joint Ten to Twenty Years of Knee Arthroplasty at the Endo-Klinik – A Report on the Long-term Follow-up of the St.Georg Hinge and the Medium-term Follow-up of the Rotating Knee Endo-Model® (14)

Eckart Engelbrecht, Elmar Nieder and Dietrich Klüber Springer-Verlag

The aim with the new Endo-Model® Rotating Knee design was not only to improve the implantation and explantation technique but also the axial relations and the different model sizes. Also the paper wanted to investigate the effects of the modified design on the operative technique, the clinical results, prosthesis-related and unrelated complications and also the survival rate and the indications.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

From 1981 until 1989 they implanted 1837 prostheses. The indications for an Endo-Model® were osteoarthritis, rheumatoid arthritis, post-traumatic disease and post-infection arthrosis. The follow-up was between 6 to 8 years. The mean age of the patients was 66 years (range from 22 to 99 years).

Results

The survival rate is depending on the diagnoses of the patients. When the patients have the indication of osteoarthritis or rheumatoid arthritis the survival rate after 7 years is 96%. When the indication is post-traumatic disease the survivorship after 7 years is 88%. For all diagnoses the survivorship after more than 8 years is 94%.



Endo-Model® Rotating-hinge Total Knee for Revision Total Knee Arthroplasty (21)

Alessandro Bistolfi, MD; Federica Rosso, MD; Maurizio Crova, MD; Giuseppe Massazza, MD ORTHOPEDICS Volume 36, number 10, 2013

The aim of the study was to analyse the clinical and radiographic results and the survival rate for revision cases in mild and severe instability. The indications for revision were aseptic loosening, septic loosening, implant wear, polyethylene fracture, tibial-femoral instability, periprosthetic fracture and femorotibial dislocation. To evaluate the results they used the HSS-Score. The patients were evaluate preoperative, 3 and 6 months after the surgery and then annually.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

Between December 1991 and June 2004 they implanted 53 prostheses in 50 patients (33 women and 17 men). In the final follow-up 32 patients were left. The mean age of the patients was 69.7 years (range from 45 to 85 years). The mean follow-up was 155 months (range from 78 to 240 months).

Results

The ROM and HSS-Score in total:

| | Preoperative | Postoperative |
|-----|--------------------------------|--------------------------------|
| ROM | 81.3° (77.8°-84.8°) | 102.6° (97.2°-107.9°) |
| HSS | 58.4 points (55.1-61.8 points) | 85.5 points (79.6-87.5 points) |

The ROM and the HSS-Score grouped in aseptic loosening, septic loosening. Total revision and partial revision:

| | Aseptic Loosening | Septic Loosening | Total Revision | Partial Revision |
|-----|--------------------------------|-----------------------------------|--------------------------------|-----------------------------------|
| ROM | 99.3° (88.9°-109.5°) | 92.3° (90.3°-106.3°) | 98.9° (93.7°-104.2°) | 101.4° (96.8°-105.9°) |
| HSS | 78.5 points (70.7-86.3 points) | 77.6 points (68.4-86.8 points) | 78.3 points (73.7-82.7 points) | 84.8 points (82.5-87.2 points) |



The Endo-Model® Rotating Hinge for Rheumatoid Knees - Functional Results in Primary and Revision Surgery (15)

L. Felli; M. Coviello, M. Alessio-Mazzola, M. Cutolo *Orthopäde November 2015*

The aim of this study was to show the functional results in primary and revision surgery for patients with rheumatoid arthritis. To evaluate the results the KSS, KFS, ROM and the survival rate were used. Patients with rheumatoid arthritis have a higher risk for peri- and postoperative complications.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

Between 1997 and 2011 they performed 152 TKA in 138 patients. In 88 cases it was a primary surgery and in 64 cases a revision surgery. The mean age of the patients was 71.5 years (range from 57 to 84 years). The mean follow-up was 6.1 years (range from 3.5-11.2 years).

Results

Survival rate: 91.7% after 6.1 years

| | Preoperative | Postoperative |
|-----|------------------------------|--------------------------------|
| KSS | 15.6 points (7 to 30 points) | 93.5 points (84 to 100 points) |
| KFS | 24.3 points (2 to 55 points) | 67.1 points (2 to 95 points) |
| ROM | 53.2° (30° to 100°) | 102.7° (75° to 125°) |



Total Knee Arthroplasty with Rotating-hinge Endo-Model® Prosthesis: Clinical Results in Complex Primary and Revision Surgery (16)

F. Sanguineti, T. Mangano, M. Formica, F. Franchin *Arch Orthop Trauma Surg, Springer Verlag, 2014*

This study shows the results with the rotating hinge knee system from LINK in complex primary and revision surgeries. For these results the KSS, KFS and ROM were used. The indications for the primary cases were osteoarthritis, post-traumatic osteoarthritis, and rheumatoid arthritis. The indications for the revision cases were aseptic loosening, infection or periprosthetic fracture.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

Between 1997 and 2009 they implanted 123 implants in 118 patients. 75 of the implants were primary implants and 48 revision implants. In the end they evaluated 25 primary and 20 revision cases. The mean age of the patients was 74 years (range from 50 to 84 years). The mean follow-up was 42.2 months (range from 20 to 128 months).

Results

| | ROM | KSS | KFS |
|----------|-----------------|--------------------------------|----------------------------|
| Primary | 112.6° | 95.9 points | 86.8 points |
| Revision | 102.1° | 92.0 points | 77.6 points |
| Total | 108° (70°-125°) | 94.2 points (71-100 points) | 78.7 points (0-100 points) |

They found no significant difference between the KSS in primary and revision cases.



Mid-term Results after Implantation of Rotating-hinge Knee Prostheses: Primary Versus Revision (17)

Turgay Efe, Philip P. Roessler, Thomas J. Heyse, Carsten Hauk, Caroline Pahrmann, Alan Get-good, Jan Schmitt

Orthopedic Reviews 2012; Volume 4:e35

The aim of this study was to show the mid-term results and survivorship for the Endo-Model[®]. To evaluate the results they used the KSS, ROM and the survival rate in primary and revision surgery.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

They implanted 121 prostheses in 113 patients between 1995 and 2005. In the primary cases 46 females and 7 males were operated on. In the revision cases they opereated on 42 females and 17 males. The mean follow-up was 55 months (range from 10 to 133 months). The average BMI was in the primary cases 30kg/m^2 (range of 17.7kg/m^2 to 37.7kg/m^2). In the revision cases the average BMI was 30 kg/m^2 (range from 19.1 kg/m^2 to 47.3 kg/m^2). The mean age of the primary patients was 73.7 years and the mean age of the revision patients was 72.5 years.

Results

| | Primary | Revision | |
|---------------|------------------------------------|------------------------------------|--|
| KSS | 87 points (57 points to 97 points) | 86 points (46 points to 94 points) | |
| KFS | 50 points (0 points to 100 points) | 45 points (0 points to 100 points) | |
| ROM | 88+/-25° | 89+/-23° | |
| Survival rate | 95% after final follow-up | 76% after final follow-up | |

 $\underline{\text{Overview table of all studies on page 04 and 05}}...$



Can Good Infections Control Be Obtained in One-stage Exchange of the Infected TKA to a Rotating Hinge Design? 10-year Results (19)

Akos Zahar MD, Daniel O. Kendoff MD, PhD, Till O. Klatte MD, Thorsten A. Gehrke MD *Clinical Orthopaedics and Related Research, 23 June 2015*

The aim of the study was to show if good infection control could be obtained in one-stage exchange of the infected TKA to a Rotating Hinge design. The target was to show the survival rate of the prosthesis without any infection or revision.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

They evaluated 70 patient with prosthetic joint infection. The mean follow-up was 10 years (range from 9 to 11 years). The mean age of the patients was 70 years (range from 60 to 81 years). 31 of the patients were female and 39 male.

Results

The survival rate without any reoperation after 10 years was 75 %.

| | HSS |
|---------------|-----------------------------|
| Preoperative | 35 points (13 to 99 points) |
| Postoperative | 69.6 points (22 to 100) |



Revision Knee Arthroplasty with a Rotating-hinge Design in Elderly Patients with Instability Following Total Knee Arthroplasty (20)

E. Carlos Rodrìguez-Merchàn MD, PhD; Primitivo Gòmez-Cardero MD; Àngel Matrìnez-Lloreda MD *Journal of Clinical Orthopaedics and Trauma 6, 2015*

The aim of the study was to show the clinical, functional and radiographic outcomes of patients with a revision surgery. 10-22% of the revisions were due to instability of the knee prosthesis. Instability is the third most frequent cause of failure by primary implants. To evaluate the results they checked the KSS, KFS and ROM.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

They implanted 96 implants in 72 women and 24 men. The mean age of the patients was 79 years (range from 75 to 86 years). The mean follow-up was 7.3 years (range from 5 to 10 years). The mean BMI was 30 kg/m² (range from 17 to 51 kg/m²). All femur and tibia implants are cemented.

Results

| | Preoperative | Postoperative |
|-----|--------------------------------|--------------------------------|
| KSS | 37 points | 79 points |
| KFS | 34 points | 53 points |
| ROM | -15° extension and 80° flexion | -5° extension and 120° flexion |



Results with the Endo-Model Rotating Hinged Knee Prosthesis after 18-years of Follow-up (4)

Alessandro Bistolfi, MD; Giuseppe Massazza, MD Prof.; Federica Rosso, MD; Carla Olivero, MD; Francesco Lagalla, MD; Maurizio Crova, MD Prof.

Department of Orthopedics ans Traumatology, University of the Studies of Turin, CTO/M. Adelaide Hospital, Turin, Italy

The aim of the study was to show the clinical results for the Endo-Model® after 18 years of follow-up. The indications were arthritis due to axial defects, rheumatoid arthritis, tibial plateau fractures and outcomes of high tibial osteotomy. To evaluate the results they used the HSS-Score.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

Between November 1992 and July 2003 they implanted 114 prostheses in 97 patients (13 males and 84 females). The mean age of the patients was 68.8 years (range from 37 to 84 years). The mean follow-up was 166 month (range from 65 to 193 months). For the results the HSS Score was evaluate preoperative, 3 months after the surgery, 6 months after the surgery and then annually.

Results

Survival rate after 1 year was 89.3%, after 5 years 86.9% and after 15 years 76.2%.

| | Preoperative | Postoperative | |
|-----------|--------------------------------|--------------------------------|--|
| ROM | 89.4° (86.5°-92.3°) | 110.3° (105.5°-114.9°) | |
| HSS-Score | 64.4 points (62.3-66.6 points) | 82.2 points (75.5-85.9 points) | |



Implant Survival and Outcome after Rotating-hinge Total Knee Revision Arthroplasty: a Minimum 6-years Follow-up (22)

Asgeir Gudnason, Jan Milbrink, Nils P.Hailer Arch Orthop Trauma Surg, Springer-Verlag, 2010

The aim of the study was to show the survival of a rotating-hinge total knee revision arthroplasty. To evaluate the results the HSS, KSS, KFS and the ROM were used. The indication was aseptic loosening of the primary Implant.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

Between 1991 and 2003 they implanted 42 implants in 38 patients (26 women, 12 men). The mean age of the patients was 72 years (range from 55 to 88 years). The mean follow-up was 8.8 years (range from 6 to 18 years).

Results

| HSS | 67 points (36-90 points) |
|-----|------------------------------------|
| KSS | 85 points (73-96 points) |
| KFS | 29 points (0-100 points) |
| ROM | Mean knee flexion 108° (100°-120°) |



Is there a Place for Rotating-Hinge Arthroplasty in Knee Revision Surgery for Aseptic Loosening? (23)

Nayana Joshi, MD, PhD and Antonio Navarro-Quilis, MD, PhD *The Journal of Arthroplasty Vol. 23 No 8, 2008*

The aim of the study was to show the results for knee revision surgery in case of aseptic loosening, ligamentous instability, extensor mechanism failure with instability and periprosthetic fracture. To evaluate the results the KSS, KFS and ROM were used.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

Between January 1993 and March 2002 78 knees were implanted in 78 patients (15 men and 63 female). The mean age of the patients was 72 years (range from 53 to 88 years). The mean follow-up was 7.83 years (range from 56 to 130 months).

Results

| | Preoperative | Postoperative | |
|-----------------|-----------------------------|------------------------------|--|
| KSS | 38 points (10 to 75 points) | 86 points (44 to 98 points) | |
| KFS | 33 points (0 to 85 points) | 61 points (20 to 100 points) | |
| ROM (extension) | -4° (-20° to 0°) | -1° (-20° to 0°) | |
| ROM (flexion) | 103° (90° to 135°) | 97° (50 to 130°!) | |



Salvage Revision Total Knee Replacement Using the Endo-Model® Rotating Hinge Prosthesis (24)

N.R. Pradhan, L. Bale, P. Kay, M.L. Porter *The Knee 11 (Elsevier), 2004*

The aim of the study was to show the results for salvage revision cases with the Endo-Model[®]. The indications were infection, aseptic loosening, implant failure, stiffness, peri-prosthetic fracture. The results were evaluated by the HSS-Score.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

They implanted 51 prosthesis in 50 patients (29 females and 21 males). The mean age of the patients was 70.25 years (range from 2 to 6 years). The mean follow-up was 4 years (range from 2 to 6 years). The clinical and radiological results were evaluated.

Results

The HSS increased from 35.9 points (poor) to 72.1 points (good).

| HSS | Excellent | Good | Fair | Poor |
|---------------|-----------|------|------|------|
| Preoperative | 0 | 0 | 1 | 22 |
| Postoperative | 11 | 22 | 10 | 8 |

After one year of follow-up the ROM was 89.9° (range from 40° to 110°).



Complications Following Rotating Hinge Endo-Model® (LINK®) Knee Arthroplasty (18)

B. Guenoun, L. Latargez, M.Freslon, G, Defossez, N.Salas, L.-E. Gayet Elsevier Masson, Orthopadics & Traumatology: Surgery & Research (2009) 95, 529-536

The aim of this study was to evaluate the complications with the Endo-Model®. Indications for primary surgery were: primary gonarthrosis with ligament laxity, varus/valgus, tumor and secondary gonarthrosis (Posttraumatic, Rheumatoid arthritis). Indications for revision surgery were: Sepsis and aseptic loosening.

Material and Methods

System: LINK® Endo-Model® Rotating Hinge Prosthesis (WALDEMAR LINK® GmbH & Co.KG).

Between 1998 and 2006 they implanted 85 Endo-Model® in 85 patients (61 females and 24 males). 52 patients get a primary surgery and 33 a revision surgery. The mean age of the patients at time of operation was 72.4 years (range from 32 to 92 years). The mean follow-up was 36 months (range from 0 to 75 months).

Results

The Survival Rate after 1 year was 75.1 % and after 3 years 65.2%.

Statement Mr. Helmut D. Link (22.02.2010):

The authors report on follow-up of 85 patients which have been operated between 1998 and 2006 with 85 Endo-Model® Rotating Hinge Prostheses. The report states an unusually high (28.2%) complication rate. Interestingly, the complications listed in table 2 are almost totally surgeon or patient related. Starting with infections (10.6%) via patella problems (the authors state "a patellar prosthesis was never implanted") up to synovitis shock reaction, ischemia nerve involvement and cutaneous complications. It is really incomprehensible why the authors make the implant responsible for their own mistakes and failures (this is similar if a bad driver, causing many traffic accidents, blames it to the performance of his car).

From the article itself it becomes clear that the problems are originated by the authors. Looking at the highest complication, the infection with the rate of 10.6% in only 85 patients compared to 2% in 210 patients (Reignier) or 2% in 1837 respectively 2682 patients (Nieder, Zink).

Finally, the first sentence of this publication stating "Rotating Hinge Knee Prosthesis are indicated in revision especially when major ligament laxity or substantial AP deformities are present". This is in direct conflict with the author's directions that the rotating hinge should never be used in ligament laxity or severe deformation (Nieder E. "Sled Prosthesis, Rotating Knee and Hinge Prosthesis Model St. Georg® and Endo-Model®: Differential therapy in primary knee arthroplasty").

Conclusively, one can state that in this publication wrong indications, performance deficiencies and irregular methods are blamed on the worldwide highly successful Endo-Model® Rotating Hinge Prosthesis that serves patients and surgeons extremely well in about 150.000 cases for over 31 years.



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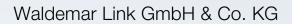


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