



# The Endo-Model<sup>®</sup> rotating hinge for rheumatoid knees

## Functional results in primary and revision surgery

### Introduction

Rheumatoid arthritis (RA) is a chronic systemic autoimmune-mediated disease involving connective tissue that often results in a high degree of disability [1]. Chronic synovitis leads to progressive arthropathy with erosive changes, joint space narrowing, and peri-articular soft tissue destruction. These are pathologic anatomical features that eventually lead to severe functional joint failure.

Despite improvements in medical treatment, joint substitution with prosthetic implants still represents the final solution for pain relief and functional recovery [2]. Total knee arthroplasty (TKA) for rheumatoid joints is considered a challenging surgery because of the technical difficulties and greater risk of major peri- and postoperative complications [3]. In this setting, severe anatomic deformities with loss of bone stock, low bone quality, joint instability caused by peri-articular soft tissue deficiency and iatrogenic lowering of the immunologic surveillance are known risk factors threatening favorable outcome after TKA.

Highly constrained implants are often needed in order to deal with the gross anatomic and functional alterations of the rheumatoid knee. However, doubts still exist with regard to using rotating hinged devices, mainly due to the design-related intrinsic risk of mechanical failure and to the risk of infection [4–6]. Such risks are further increased when managing patients with RA. We reviewed a series of patients who had been treated with the Endo-

Model<sup>®</sup> rotating hinge prosthesis (Waldemar Link GMBH & Co, Hamburg, Germany) for severely affected rheumatoid knees. Functional and radiographic outcomes are described.

### Patients and methods

Between 1997 and 2011, we performed 152 TKAs in 138 patients with the Endo-Model<sup>®</sup> prosthesis at our institution. Among them, 88 were primary implants and 64 were revisions. Indications for surgery included primary osteoarthritis, posttraumatic osteoarthritis and inflammatory arthritis of the knee. For revision surgery, indications included aseptic loosening, infection and comminuted periprosthetic fracture. We chose the Endo-Model<sup>®</sup> device for patients showing severe axial deformities, severe bone loss and/or gross joint instability. Indeed our indications for constrained implant in rheumatoid arthritis knees were as follow: severely restricted joint mobility, insufficient or destructed collateral ligaments with severe knee instability, severe valgus/varus deformity, revision surgery with insufficient bone quality or bone loss. In the absence of these preoperative factors we chose a nonconstrained implant.

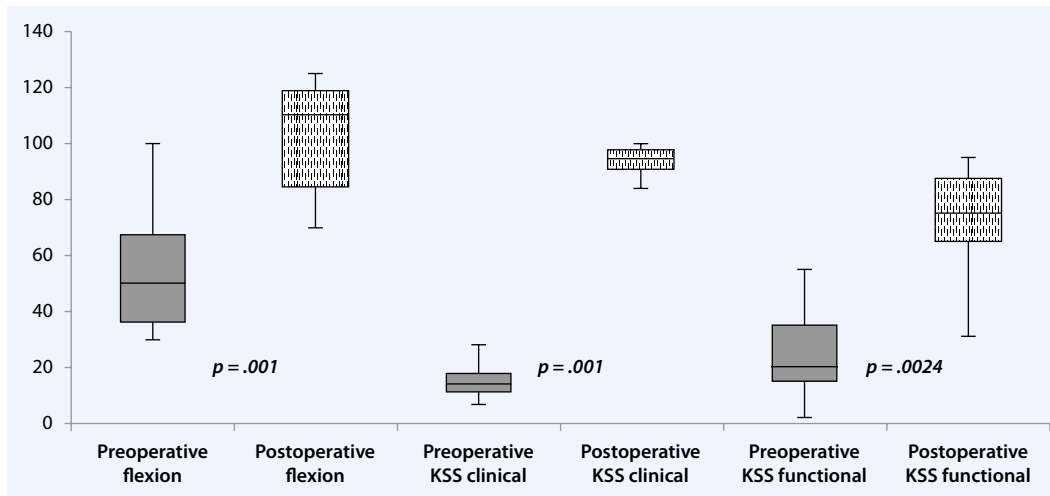
Indication for surgery was related to rheumatoid arthritis in 38 patients, and this subgroup was evaluated in the present study. Among them, 30 patients received the Endo-Model<sup>®</sup> prosthesis as a primary implant (27 varus and 3 valgus knee). In the remaining 8, it was used as a revision prosthetic implant.

The preoperative radiographic degree of joint destruction was classified according to the Larsen classification of rheumatically destroyed joints [7]. All the treated patients were classified as grade 4 or 5 with severe erosions, no joint space left, and partially preserved original bony outlines (grade 4) or mutilating changes and severely destroyed original bony profiles (grade 5).

The average follow-up was 6.1 years (range 42–134 months). There were 32 women and 6 men in our series. The average age at the time of surgery was 71.5 years (range 57–84 years). The mean duration of RA was 13.2 years (range 7–21 years). In the follow-up period, one patient died of causes not related to surgery and one patient was lost during the follow-up period, thus leaving 36 patients (36 implants) to be evaluated in this study.

All the surgeries were performed using a tourniquet at the thigh and a combination of intramedullary femoral and extramedullary tibial alignment guides. We used the same approach with all the patients, i.e. a straight midline incision combined with a lateral patella luxation. Great attention was paid to removing all posterior osteophytes in order to obtain full extension. Both spaces (flexion and extension) were balanced by using spacers to obtain a good range of motion. The patella was never resurfaced but patellar tracking was always verified and lateral release was performed in 7 cases with patellar subluxation.

We used cemented, long-stemmed implants with anti-luxant features in all cas-



**Fig. 1** ◀ Pre- and postoperative value of flexion, clinical Knee Society Score (KSS) and functional KSS (Wilcoxon signed-rank test)

es. Due to extensive bone loss, a wedged augmentation was used in the tibial side in 4 cases. A prophylactic, first-generation cephalosporin was used perioperatively and for 2 days postoperatively. Thromboprophylaxis involved peri- and postoperative administration of low-molecular weight heparin for 35 days. At the time of surgery, 12 patients were receiving methotrexate (MTX) therapy, 7 patients were taking oral corticosteroids and 7 patients were using both MTX and corticosteroids. These therapies were never discontinued during the perioperative period, while on the contrary, administration of biologic agents (such as TNF- $\alpha$  antagonists) was discontinued at least 1 month before surgery in 8 patients. The management of medications during perioperative period was comparable to that indicated in other studies and international guidelines [8, 47, 48, 50, 51].

After removal of the suction drain, usually on the second postoperative day, patients began knee motion using a continuous passive motion machine for about 2 h daily. Full weight bearing was allowed after 4 days using two canes. The patients were discharged soon after the first week.

Besides the routine postoperative follow-up visits (at 3, 6, 12 months after surgery, and annually thereafter), all of the patients were further evaluated in a single follow-up visit during which data were collected for this study by means of clinical and functional analysis. In this setting, the postoperative Knee Society rating system (0–100 clinical, 0–100 functional) was applied for each evaluated knee [9] and

new radiographs were obtained. Complete preoperative and postoperative data were available for all enrolled patients. The senior author (L.F.) examined the most recent follow-up anteroposterior and lateral radiographs for gross signs of loosening such as progressive radiolucency, changes in the implant position, dislocation or breakage of the implant, and signs of instability or malalignment. No radiographic rating system was used. Data were collected and statistically analyzed by a non-parametric test for paired values (Wilcoxon signed-rank test).

## Results

No cases of deep vein thrombosis nor intraoperative fractures were reported. Defining failure as revision for any reason, mean prosthesis survival in the evaluated series was 91.7% at an average of 6.1 years from surgery. Failure of the implant was reported in one case due to periprosthetic deep infection arising 3 years after revision surgery for septic mobilization of a primary TKA. The patient was managed with staged revision in another institution and was finally treated with knee arthrodesis. One patient was revised for aseptic loosening of the prostheses after 26 months and 1 patient had a periprosthetic femoral fracture after 4 years. No other cases of implant failure or major postoperative complications were observed. In all, 36 patients were clinically evaluated at their most recent follow-up visit during which the postoperative Knee Society Score was defined. Twenty-eight

primary implants and 8 revision implants were evaluated. A broad analysis of recent and previous radiographs was carried out in the same setting.

In this series, the mean flexion passed from 53.2° preoperatively (range 30–100°) to 102.7° postoperatively (range 75–125°;  $p=0.001$ ; **Fig. 1**). A lack of extension of 10° was present in one knee, most likely due to malpositioning of the femoral component in slight flexion. The mean Knee Society clinical score passed from a preoperative value of 15.6 (range 7–30) to 93.5 (range 84–100) at final follow-up ( $p=0.001$ ). The mean functional score passed from a preoperative value of 24.3 (range 2–55) to 67.1 (range 2–95;  $p=0.0024$ ). We found no evidence of postoperative tibiofemoral instability, patellar maltracking, or deficiencies at the knee extensor mechanism.

Pain was present in 10 patients (2 revision and 8 primary implants), but always at a mild or mild/occasional degree, never compromising daily activities. In 5 patients it was described as anterior pain, despite evidence of good patellar tracking. Thirty-one patients showed autonomous walking with the aid of one or two canes. Five patients were wheelchair-bound because of progressive disability. Two of them received a functional score of 2 and a clinical score of 97 and 98, respectively (**Fig. 2**). At broad radiological analysis, there was no evidence of changes in the tibiofemoral alignment as compared with early postoperative radiographs. No signs of implant loosening (progressive radiolucencies, breakage of the implant

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**The Endo-Model® rotating hinge for rheumatoid knees. Functional results in primary and revision surgery****Abstract**

**Background.** Major joints of the lower limbs are commonly affected by rheumatoid arthritis (RA), with consequent pain, loss of function, and progressive disability. Knee replacement represents a useful solution, but a highly constrained implant design is often needed in order to face the severe anatomical deformities and the gross instability that the surgeon may encounter in the rheumatoid knee.

**Objectives.** The aim of this work was to evaluate the Endo-Model® rotating hinge knee prosthesis implanted in patients affected by RA and severely damaged knees.

**Patients and methods.** We retrospectively evaluated a series of 38 patients with RA im-

planted with the Endo-Model® rotating hinge knee prosthesis for primary or revision surgery (mean follow-up 6.1 years; mean age at surgery 71.5 years). At the time of surgery, the mean duration of RA was 13.2 years. Patients were evaluated clinically and radiographically and the Knee Society Score (KSS) was used.

**Results.** Implant survival at most recent follow-up was 91.7%. Mean final knee flexion was 102.7°. The mean KSS was 93.5 (excellent) and 67.1 (good) for clinical and functional score, respectively. Mild pain was present in 10 patients. No sign of malalignment or residual instability was found. No evidence

of loosening or implant failure was observed in x-rays.

**Conclusion.** The Endo-Model® rotating hinge knee prosthesis provides excellent pain relief, functional recovery, and intrinsic knee stability both in complex primary and in revision knee arthroplasty in the majority of patients with severely affected rheumatoid knees.

**Keywords**

Knee prosthesis · Chronic pain · Arthroplasty, replacement, knee · Revision, joint · Prosthesis survival

**Die Rotations- und Scharnierprothese Endo-Model® bei rheumatoider Arthritis am Knie. Funktionelle Ergebnisse chirurgischer Primär- und Revisionseingriffe****Zusammenfassung**

**Hintergrund.** Die großen Gelenke der unteren Extremitäten sind häufig von rheumatoider Arthritis (RA) betroffen. Schmerz, Funktionsverlust und eine fortschreitende Behinderung sind die Folge. Eine Kniegelenkprothese ist in diesem Zusammenhang eine hilfreiche Behandlungsoption. Oft ist aber ein Implantat mit hochgradiger Koppelung erforderlich, um den schwerwiegenden anatomischen Deformitäten und der ausgeprägten Instabilität zu begegnen, die der Chirurg im betroffenen Knie vorfinden kann.

**Zielsetzung.** Ziel dieser Arbeit war es, die Rotations- und Scharnierknieprothese Endo-Model® nach Implantation in Patienten mit RA und schwer geschädigten Knien zu bewerten.

**Patienten und Methoden.** Eine Gruppe von 38 Patienten mit RA, denen die Rotations- und Scharnierknieprothese Endo-Model® in

chirurgischen Primär- oder Revisionseingriffen eingesetzt worden war, wurde retrospektiv untersucht (durchschnittliches Follow-up 6,1 Jahre; durchschnittliches Alter bei Operation 71,5 Jahre). Zum Zeitpunkt des chirurgischen Eingriffs lag die durchschnittliche Erkrankungsdauer der RA bei 13,2 Jahren. Die Patienten wurden klinisch sowie röntgenologisch untersucht und mithilfe des Knee Society Score (KSS) beurteilt.

**Ergebnisse.** Der Implantaterhalt lag in der aktuellsten Follow-up-Untersuchung bei 91,7%. Der letzte Kniebeugewinkel betrug 102,7°. Die durchschnittlichen Werte des KSS beliefen sich auf 93,5 (hervorragend) und 67,1 (gut) für den klinischen bzw. funktionellen Score. Bei 10 Patienten bestand ein leichter Schmerz. Zeichen einer Fehlstellung oder verbleibenden Instabilität fanden sich nicht. Die Röntgenuntersuchung ergab keine Hin-

weise auf eine Lockerung oder ein Implantatversagen.

**Schlussfolgerung.** Die Rotations- und Scharnierknieprothese Endo-Model® bietet der Mehrzahl der Patienten, die von einer schweren RA am Knie betroffen sind, eine hervorragende Schmerzlinderung, funktionelle Erholung und intrinsische Kniestabilität sowohl bei komplexer Primäroperation als auch bei Revisionsendoprothetik.

**Schlüsselwörter**

Kniegelenkprothese · Chronischer Schmerz · Knieendoprothetik · Revisionsoperation, Gelenk · Prothesenerhalt

or component migration) were found, nor were there any signs of polyethylene wear. We found no differences between the bone densities of the medial and lateral femoral condyles, or evidence of cortical hyperostosis around the stems of the components.

**Discussion**

Improvement in the medical treatment of RA in the last 25 years is reflected by a 40% decrease in the rate of hip and knee surgery, following a peak observed in the mid 1990s [2, 10]. However, 17% of patients with RA undergo orthopedic surgery within 5 years of their initial diagnosis [11], and over one third of them will eventually require a major joint replace-

ment, mainly a total hip or knee replacement. In this setting, the orthopedic surgeon is challenged by greater technical difficulties as well as by higher peri- and postoperative risks of prosthetic implant failure [3, 12–15].

Furthermore, in severely affected knees with serious bone and ligament defects, as is frequently seen in rheumatoid knees, a highly constrained total knee device represents the treatment option needed to re-



**Fig. 2** ◀ Radiographic evaluation of an 83-year-old patient treated with the Endo-Model® prosthesis: **a** 3-year follow-up X-ray analysis, **b** 7-year follow-up X-ray analysis showing preserved anatomical axes and no sign of implant loosening

store and maintain the correct anatomical axis as well as to confer the joint stability that is impossible to obtain with lower constraint implants [16–21]. Several authors have highlighted the risk of implant failure due to residual instability with posterior cruciate ligament (PCL) retaining and posterior-stabilized (PS) implants in rheumatoid patients [18–20].

The use of rotating hinge designs have been described for dealing with such instances of severe loss of bone stock, gross ligamentous instability, combined deformities, oncologic surgery and salvage situations both in primary and revision surgery [22]. By means of the rotational degree of freedom and design features, these implants provide high constraint and great inherent stability while avoiding patella–femoral instability and torsional stresses to load at the prosthesis/cement/bone interfaces [16, 17]. This ultimately leads to longer survival and bet-

ter clinical outcomes as compared to previous rotating hinged devices and results are comparable to the current lower constraint devices. However, published results using this kind of these kinds of implants for nontumor reconstruction have varied from acceptable to poor, leaving general questions about safety, survival and functional results still unsolved [5, 6, 23–35]. Despite a recent paper showing good results regardless of the indication for surgery [36], far more limited information is available about use in rheumatoid patients.

Furthermore, although RA has been reported as a possible indication for resurfacing the patella during total knee arthroplasty [37, 38], several papers reported good results without patellar resurfacing [39–41], avoiding potential complications of this additional procedure [42]. In this study we confirmed satisfying results

and low complication rate without patellar resurfacing.

We evaluated a series of patients affected by rheumatoid arthritis who were treated with the Endo-Model® rotating hinge knee prosthesis. As observed elsewhere [14, 32], in our series there was a high proportion of women (87.5%) and elderly patients (mean age 71.5 years). The implant we used is a fully cemented, non-modular implant with long intramedullary stems, endowed with an anti-luxant device. Despite the increased risk due to age, and disease- and steroid-related poor bone quality, no cases of intra-operative fractures were recorded. At an average follow-up of 6.1 years, implant survival was 91.7%, and both clinical and functional Knee Society Scores significantly improved with respect to preoperative values. The 93.5 mean clinical score was considered “excellent”, while the 67.1 functional score was within the “good” range. Mean knee flexion was 102.7°. Only 10 patients complained of mild pain, which however, never limited daily activities. In four cases, the reported pain was anteriorly located, even though no patellar maltracking was present. Similar findings have been previously described and are related to the inflammatory arthritis itself [16]. All of the patients but five were completely autonomous in walking, with the aid of one or two canes. No sign of residual tibiofemoral instability was noted, nor were any radiographic signs of component loosening or subsidence observed. Taking into consideration that all of our patients belonged to the same known low function category (i.e. Knee Society category C: multiple arthritis or medical infirmity), these results appear much more than acceptable. Similar results have been published by other authors [16, 30, 35, 36].

Several studies report increased infection rates in rheumatoid patients undergoing joint replacement surgery as compared to patients with an initial diagnosis of primary or posttraumatic osteoarthritis [3, 43]. Furthermore, infection is described as the most common cause of failure for rotating hinge devices, with rates ranging between 14.5 and 24% [24, 32, 44–46].

In our series, administration of biologic agents was discontinued at least



1 month prior to surgery, while MTX and steroid therapy was continued during the perioperative period. Current practice is in fact to interrupt the anti-TNF therapy prior to total joint arthroplasty to minimize the risk of infection and deep vein thrombosis, as recommended by international guidelines [47, 48]. We also recommend to continue MTX in the perioperative period to decrease complication rates and number of relapses of rheumatoid disease. Patients who stopped the methotrexate had consequently an increased infection rate (15 vs 2%) [50, 51]. Although the use of steroids in the perioperative period increases the infection risk and delayed wound healing [49], there is no published literature regarding the risk of steroid use in case of total knee replacement surgery in RA [50].

We observed a single case of periprosthetic deep infection in a patient who had undergone staged revision and implantation of the Endo-Model® device 3 years earlier. Although the infection rate we report is low, and taking into consideration the possible evolution of such a situation in terms of pain, loss of function and general condition, we recommend avoiding this kind of implant in cases of infection-related revision.

In our experience, the Endo-Model® rotating hinge total knee prosthesis proved to be a useful solution for severely affected rheumatoid knees with loss of bone stock, poor bone quality and complex instability, both in primary and revision surgery.

In the majority of our patients, the Endo-Model® was able to relieve pain and to recover the function needed for daily activities. Other constrained implants, used for primary and posttraumatic arthritis, might guarantee comparable results with similar rate of peri- and postoperative complications. However, due to technical and medical indications, the surgeon's experience and the rheumatologist's skills should be advocated and they should cooperate when managing total knee replacement in patients with RA. Attention should be paid when treating patients with previous prosthetic failure due to deep infection, since the risk of re-infection further increases on the basis of medical condition, previous infection and

revision surgery with an invasive implant design. In such cases, we think this kind of prosthesis should be avoided, if possible.

Our study has several shortcomings. It is a retrospective, noncontrolled study on a relatively small patient population. Furthermore, it combined two groups of patients, with primary and revision surgery, with heterogeneous follow-up times. However, we believe that the homogeneity related to the initial diagnosis and indication for surgery, as well as the surgical technique could represent points of strength and give scientific value to our work. Prospective studies on larger numbers of patients might reach a greater degree of significance and are needed.

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### Compliance with ethical guidelines

**Conflict of interest.** L. Felli, M. Coviello, M. Alessio-Mazzola and M. Cutolo state that there are no conflicts of interest.

All studies on humans described in the present manuscript were carried out with the approval of the responsible ethics committee and in accordance with national law and the Helsinki Declaration of 1975 (in its current, revised form). Informed consent was obtained from all patients included in studies

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## Smalltalk im OP kann Patienten gefährden

Mehr sachbezogene Kommunikation im Operationsteam senkt das Wundinfektionsrisiko für den Patienten. Wissenschaftler der Universitäten Neuenburg und Bern haben von 2010 bis 2013 während 167 Operationen am offenen Bauch die Gespräche im Berner OP-Team beobachtet und analysiert. Die Analysedaten aus den Eingriffen, welche im Durchschnitt 4,6 Stunden dauerten, wurden danach mit den dokumentierten Wundinfektionen verglichen. Das Ergebnis: Mehr fallrelevante Kommunikation während der gesamten Operation hatte weniger Wundinfektionen zur Folge. Zu viel Smalltalk während des Verschließens der Operationswunde bedeutete dagegen eine höhere Infektionsrate. Wundinfektionen nach operativen Eingriffen treten vor allem im Bauchbereich relativ häufig auf (Schweizer Durchschnitt: 13,8%) und haben längere Spitalaufenthalte und damit auch höhere Kosten zur Folge. Hauptrisikofaktoren sind der Zustand des Patienten und die Art und Dauer der Operation. Beides lässt sich vom OP-Team nicht oder nur bedingt beeinflussen. Es gibt aber qualitative Elemente wie Ablenkung und Lärm während der Operation, die sich steuern lassen.

### Literatur

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