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ORIGINAL STUDY

Indications for primary rotating-hinge total knee arthroplasty. Is there consensus?

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The use of rotating-hinge systems in total knee arthroplasty is most often seen in revision setting where excessive bone loss, ligamentous instability and/or extensor mechanism dysfunction may necessitate an increased level of component constraint. However, this implant type is also being increasingly used in the primary setting. The aim of this study is to review literature concerning the use of third generation rotating-hinge devices focusing on the indications for primary cases.

Literature was searched for following search terms: total knee arthroplasty, primary indication, constraint, rotating hinge knee, knee prosthesis, hinged knee, total knee replacement. Additional papers were identified by screening references and similar articles. All papers dealing with first or second generation rotating-hinge implants and revision cases were discarded.

After conducting a large literature search, we concluded that third generation rotating-hinge implants should be considered in limited indications in which ligamentous tibiofemoral instability is the core indication.

Keywords: Rotating-hinge ; primary ; total knee arthroplasty ; hinged knee.

INTRODUCTION

Rotating-hinge knee prostheses are fully constraint knee implants that offer maximal stability to the knee joint. Evidence found in literature regarding the use on rotating-hinge prostheses in total knee arthroplasty (TKA) is contradictory. Several authors consider such devices to be useful in salvage procedures after numerous failed revisions. Others have described encouraging outcomes regarding revision surgery; especially for (a)septic loosening and persistent ligamentous instability *(10,11,14,15,20)* and even primary TKA for severe varus/valgus deformities or instable knee joints *(10)*. Data reported in literature about fully constraint knee implants in revision setting are abundant, while evidence on the use of rotating-hinge knee systems in primary TKA is scarce. However, rotating-hinge devices in total knee arthroplasty are increasingly used in primary setting *(2)*. The small number of published clinical studies pertaining to primary hinged knee replacement suggests that this type of implant involves functional improvements and rates of survival comparable to conventional cemented knee replacements *(1-3,6,7,13,17-19,22,26,31,33,35-37)*. Nevertheless, Martin et al. recently published data showing that the survival free from revision surgery is significantly lower in rotating-hinge devices

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compared to unconstraint implants, especially after a long-term follow-up *(30)*.

The aim of this study is to review literature concerning the use of third generation rotating-hinge implants in primary cases focusing on the operative indications.

The amelioration in biomechanical design of the hinged knee prosthesis has had a big impact on clinical results. Therefore, we present a short overview of the history and evolution in design of the rotating-hinge knee implant.

The first hinged total knee prosthesis was introduced by Walldius in 1951. First generation hinge prostheses were highly constraint, allowing only simple flexion and extension. These constraint designs transferred high stresses to the implant-cement-bone interfaces, resulting in early prosthetic loosening. Overall, these generation of prostheses had unacceptable complications and early failure rates *(16)*. Literature also learned us that relative maltracking of the patella was described when using simple fixed hinged implants.

A second generation of hinged prostheses followed with design modifications that decreased prosthetic constraint by including axial rotation and varus-valgus motion of the hinge. These hinged knee designs were a clinical improvement, but unacceptably high failure rates and numerous complications continued *(16,24,32)*. Generally, second generation implants are no longer used.

Further design evolution led to third generation modular, mobile bearing, hinged prostheses. These implants demonstrated significant improvements in design with concomitant improvements in clinical results in short- and midterm follow-up *(3,4,18,19)*. Besides, the phenomena of relative maltracking of the patella has been solved with the rotational hinged prostheses allowing internal and external movement in the knee joint *(9,23)*.

Additional follow-up and research is necessary to evaluate the long-term success of third generation implants. However, a very recent study published in The Bone and Joint Journal showed some contrasting results *(30)*.

MATERIALS AND METHODS

A literature search was conducted in databases PubMed and Web of Science using the following search terms: total knee arthroplasty, primary indication, constraint, rotating hinge knee, knee prosthesis, hinged knee, total knee replacement. Systematic reviews and clinical trials with at least evidence level IV were included. A minimum follow-up of two years was required and clinical trials older than fifteen years were discarded. Other exclusion criteria were the use of first or second generation rotating-hinge prostheses and revision TKA. Additional papers were found by screening reference lists and similar articles. Abstract was the first step for evaluation and full text was obtained where needed. All clinical trials withheld from literature matching our inclusion criteria were searched for primary indications. Furthermore, our review was supported using the PRISMA guidelines *(27)*.

RESULTS

Eleven retrospective clinical studies published in medical literature matched our provided inclusion criteria and are enlisted in table I. This overview table shows a promising series of survival rates ranging from 75% to 100% with a minimum follow-up of twenty-eight months and a maximum of fifteen years. In every clinical trial failure was defined as revision surgery for any cause.

Indications for the use of rotating-hinge implants in primary setting were predominantly collateral ligament insufficiency, bony destruction of the distal femur or proximal tibia, hyperlaxity, hyperextension, axial deformity of more than 20 degrees, severe rheumatoid arthritis or Charcot arthropathy. These indications proposed by Gehrke et al. *(9)* are a brief summary of all indications summed up in other clinical studies we extracted from literature. Furthermore, this research group stated that patients younger than 75 years in whom stability could be obtained with unconstraint implants are contraindicated for the use of a rotating-hinge device. This limitation is based on the fact that possible revisions and fixations

techniques could be problematic after cementing the tibial and femoral long stems of the implant at index procedure.

Gehrke et al. *(9)* and Martin et al. *(30)* published both comprehensive retrospective clinical trials, respectively including 238 and 246 patients. These studies were the biggest clinical trials found in literature. The latter is the only paper presenting long-term results of primary TKA using rotating-hinge implants. After a follow-up period of twenty years, Martin et al. *(30)* presented a survival rate of 40.3% whereas at ten years of follow-up the overall implant revision-free survival was 74.6%. In this study the data were compared to those for routine, non-constraint TKA, and showed a survival rate at ten years and twenty years of respectively 94.2% and 84.6%.

Additionally, primary neuromuscular indications for rotating-hinge TKA in primary setting were not described in any clinical trial enlisted in table I. However, Jones et al. *(19)* published a review in which flail knee and poliomyelitis were cited as neuromuscular indications for this implant type. Patients with these deficits might benefit from the rotating-hinge knee system as hyperextension stop.

DISCUSSION

To our knowledge, indications for rotating-hinge devices in primary TKA are very vague and barely reported in literature. Several authors are somewhat aloof with the use of this implant because of its notorious history of complications and assess none or very narrow indications. Anyhow, the small number of published reports suggests that these implants produce functional improvement and rates of survival comparable to conventional unconstraint TKA. Furthermore, it should be noted that rotating-hinge devices are being increasingly used in primary setting by orthopaedic and trauma surgeons all over the world.

In a level II prospective cohort study, Baker et al. *(2)* revealed promising findings concerning primary third generation rotating-hinge prostheses. The research group concluded that hinged knee replacement can be considered as a viable alternative to traditional unconstraint designs in complex primary setting. Implant survival and functional improvements after primary rotating-hinge TKA were comparable to conventional unconstraint knee replacement designs. Rates of failure were similar irrespective of the indications for surgery. The five-year survival rate was 96.8% in a large analysis of 964 patients undergoing primary hinged TKA between 2003 and 2010. Various hinged models were used but commonest implants were third generation rotating hinges. Primary indications were not reported clearly. In contrast to this cohort study, Martin et al. *(30)* presented findings of implant failure rates significantly higher in rotating-hinge population compared to patients undergoing unconstraint primary TKA. It is likely that the implant survivorship in the rotating-hinge group was lower than in the unconstraint group because of the nature of the underlying abnormalities present in this cohort of patients. To our best of knowledge, Martin et al. conducted the largest series of 246 primary rotating-hinge patients in one clinical trial and were the first publishing long-term results of twenty years follow-up.

Analogously with data of Baker et al. *(2)*, our literature search revealed survival rates ranging from 75 to 100% at short-and midterm follow-up (Table I). These numbers have to be interpret carefully. A first remark comprised the survival rate of 89% in both clinical trials of Guenoun et al. *(12)* and Hernandez-Vaquero et al. (13) respectively at three and four years follow-up. Guenoun et al. included 33 of 85 patients undergoing a rotating-hinge TKA in revision setting, whereas Hernandez-Vaquero et al. included only five patients undergoing primary rotating-hinge TKA of a total of twenty-six patients. Secondly, Kowalczewski et al. *(25)* included a very small number of twelve patients resulting in a less reliable but maximal survival rate of hundred percent at ten years follow-up.

Lozano et al. *(28)* conducted an observational clinical study comparing preoperative WOMAC (Western Ontario and McMaster Universities) index to postop WOMAC score after primary third generation rotating-hinge TKA. Lozano et al. reported a statistically significant improvement in WOMAC index in patients with a BMI (Body Mass Index) of 35-40 kg/m^2. The change in obese

Table I. — Literature summary of third generation rotating-hinge implants used in primary total knee arthroplasty ranked chronologically. Survival rate in all clinical studies is free from revision for any cause.

Clinical study	Year	Number of implants	Primary indications	Follow-up	Results
Petrou et al. (33)	2004	100	Osteoarthritis, rheumatoid arthritis	11 years (7-15)	Survival rate: 96% (15 years)
Guenoun et al. (12)	2009	52/85	Osteoarthritis, tumour (1 case)	36 months (0-75)	Survival rate: 89% (3 years)
Hernandez-Vaquero et al. (13)	2010	5/26	Bone loss, medial ligamentous instability, varus/valgus deformity	46 months (24-107)	Survival rate: 89% (4 years)
Yang et al. (37)	2011	50	Osteoarthritis, rheumatoid arthritis, ligament instability, axial deformity, posttraumatic arthritis	15 years (10-18)	Survival rate: 87% (15 years)
Efe et al. (8)	2012	21/49	Osteoarthritis, rheumatoid arthritis, posttraumatic arthritis	55 months (10-133)	Survival rate: 95% (prim)
Lozano et al. (28)	2012	111	Osteoarthritis and varus/valgus deformity due to rheumatoid arthritis and posttraumatic arthropathy	28 months (17-36)	Survival rate was not clearly declared. Six deep infections were reported.
Bistolfi et al. (5)	2013	72	Axial defects, rheumatoid arthritis, tibial plateau fracture, secondary arthritis after tibial osteotomy	174 months (156-193)	Survival rate: 86% (5 years)
Kowalczewski et al. (25)	2013	12	Joint destruction, axial deformities, MCL disruption	Minimum 10 years	Survival rate: 100% (10 years)
Sanguineti et al. (34)	2014	25/45	Osteoarthritis, rheumatoid arthritis, posttraumatic arthritis	42 months (20-128)	Survival rate: 96% (5 years) (prim)
Gehrke et al. (9)	2014	238	Patients >75 years: + collateral ligament insufficiency or + bony destruction of tibial plateau or femoral condyles + hyperlaxity or + hyperextension or + fixed varus/valgus deformity > 20° or + severe rheumatoid arthritis or Charcot joint	13,5 years	Survival rate: 90% (13 years)
Martin et al. (30)l	2016	246	Degenerative joint disease, post-traumatic arthritis, inflammatory arthritis, congenital or paediatric condition	20 years	Survival rate: 75% (10 years), 40% (20 years)

patients was statistically significant with respect to both non-obese and overweight patients. To our knowledge, this clinical study was the only one found in literature assuming that this type of implant device could be functionally more beneficial in a severe and morbid obesity population. The research group did not suggest possible explanations for this significant improvement in obese patients. In our opinion and experience, primary rotating-hinge devices could be an indication in severe and morbid

obesity patients since the higher risk of progressive ligamentous insufficiency of the knee joint due to extra weight. However, it should be taken into account that Katzer et al. *(21)* reported that obesity was a predisposing factor for prosthetic loosening. Anyhow, Body Mass Index should be considered as an important factor in preoperative planning of primary rotating-hinge total knee arthroplasty.

The principle aim in the current literature review was to provide indications for the use of rotating-hinge devices in primary setting. Recent literature was consulted and primary indications were extracted out of eleven retrospective clinical trials. We suggest that indications for the use of rotating-hinge implants in primary setting should be collateral ligament insufficiency, bony destruction of the distal femur or proximal tibia, hyperlaxity, hyperextension, axial deformity of more than 20 degrees, severe rheumatoid arthritis or Charcot arthropathy in patients older than seventy-five. An exception should be made for oncological indications. We were not able to find new or modern indications in current literature. Although we propose considering severe and morbid obesity (BMI ≥35-40 kg/m2) as an extra positive criteria in primary rotating-hinge knee surgery after correct indication assessment.

In our opinion, this literature review cannot be considered as a guideline for indications of rotating-hinges in primary setting but provides us of a summary of most important and most frequent indications. There are no randomised controlled trials existing in literature comparing survival rates or outcomes between third generation rotating-hinge designs and routine unconstraint implants in primary TKA. This lack of high evidence studies may seem obvious taking the ethical point of view into account. We agree that randomisation of patients for an unconstraint implant or a fully constraint rotating-hinge device, without correcting for possible indications requiring a more constraint design, would be an ethical issue. First of all will an unconstraint knee implant most certainly fail when using in conditions of severe bone loss or ligamentous insufficiency. Secondly, the results of conventional primary TKA for well-assessed indications such as end-stage osteoarthritis are generally excellent *(29)*. Nevertheless, we suggest that a prospective randomised controlled trial concerning 'border indications' e.g. severe or morbid obesity, neurological diseases eventually resulting in insufficient muscular control, should be considered for approval by the ethical boards. It is clear that in those situations preoperative knee stability is endangered. According to us, those high-quality clinical studies in order to improve the evidence based medicine information concerning the use of fully constraint implants in primary TKA are required.

By conclusion, hinged total knee arthroplasty in general has undergone a unique design evolution. Despite this evolution, the lowest amount of implant constraint to achieve a stable and functional knee should be used at primary surgical procedure based on mid-term and especially long-term results presented in the current review. Third generation rotating hinges should be reserved for specific indications with ligamentous instability as overall indication since we believe that tibiofemoral instability is the final result of all other indications mentioned in medical literature.

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