



## Criteria used when deciding on eligibility for total knee arthroplasty – Between thinking and doing



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### ABSTRACT

**Background:** Clinical decision-making in total knee arthroplasty (TKA) is a complex process needing further clarification. The aim of this study was to compare TKA eligibility criteria considered most important by orthopedic surgeons (OSs) to characteristics of patients with knee osteoarthritis (OA) eventually found eligible for TKA.

**Methods:** Nine OSs chose the five criteria most important when deciding on TKA eligibility. Cross-sectional data from 200 patients found either eligible ( $n = 100$ ) or not eligible ( $n = 100$ ) for TKA by one of the nine OS, were analyzed in a regression analyses with TKA eligibility as the dependent variable.

**Results:** Radiographic severity ( $n = 8$ ), pain ( $n = 9$ ), functional disability ( $n = 8$ ) and not responding to the recommended non-surgical treatment ( $n = 7$ ) were considered most important by OSs.

Associations ( $P < 0.25$ ) between TKA eligibility and criteria found important by the OS were demonstrated for worse radiographic severity and more functional limitations, but not for pain and not responding to the recommended non-surgical treatment.

Furthermore, more comorbidities and higher Body Mass Index (BMI) were associated with TKA-eligibility, but not found important for TKA eligibility by the OS.

**Conclusion:** Radiographic severity and functional limitations were confirmed as drivers for TKA eligibility, while pain was not. Not responding to non-surgical treatment was not included in the decision-making, suggesting low uptake of clinical guidelines in clinical practice. This study highlights the complexity of the decision-making with some overlap between the criteria that OSs think they apply and what is actually applied in clinical practice.

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### 1. Introduction

The incidence of total knee arthroplasty (TKA) in the US has increased markedly from 31.2 per 100,000 person-years in 1971 to 76 to 220.9 in 2005 to 2008 [1], and is expected to increase by almost 700% towards 2030 [2].

TKA is an effective treatment of end-stage knee osteoarthritis (OA) [3]. However, a systematic review have demonstrated that 20% undergoing TKA experiences only small or no improvements in pain [4], and more knee pain is known to be related to lower patient satisfaction [5]. One possible way to improve patient outcomes after TKA would be to refine eligibility criteria in order to select patients that are more likely to benefit from the procedure.

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Clinical disease severity in patients undergoing total joint arthroplasty is known to vary between countries [6]. Although patients found eligible for TKA and total hip arthroplasty (THA) have more severe pain and functional limitations than patients not eligible, there is a considerable overlap in patient status, even when adjusting for radiographic severity, thereby making it impossible to establish cut-off values for eligibility for arthroplasty [7]. This could be due to the fact that pain, disability, and radiographic severity poorly reflect the complexity of decision-making when the orthopedic surgeon (OS) evaluates eligibility for TKA/THA [3,6,8].

Other criteria considered important for TKA eligibility and/or suggested in the literature to affect the decision-making are: not responding to the recommended non-surgical treatments [3], duration of symptoms [9], being medically fit [3,10], age [3,9], and Body Mass Index (BMI) [3,9]. However, no reports exist on whether criteria considered important for TKA eligibility are actually applied in clinical practice, or which combination of criteria best reflect the complexity of the decision on eligibility. Studies on this topic would improve the understanding of the decision-making process and should be accompanied by an

investigation of how patient preferences affect whether or not they choose to proceed with surgery.

Therefore, the purpose of this study was to compare criteria regarded important by OSs when deciding on TKA eligibility to characteristics of patients with knee OA who were actually found eligible for TKA by the same OS. Our primary hypothesis was that the eligibility criteria considered important by OSs and the patient characteristics actually associated with TKA eligibility would be the same, and that a combination of criteria would explain most of the variance in TKA eligibility.

## 2. Material and methods

### 2.1. Study design

This was a cross-sectional study conforming to the STROBE statement for reporting cross-sectional studies [11].

### 2.2. Participants

Baseline data from 200 patients with knee OA (confirmed by radiography) enrolled in one of the two randomized controlled trials (RCTs) investigating the effectiveness of TKA ( $n = 100$ ) [12] and non-surgical treatments ( $n = 100$ ) [13] between September 2011 and December 2013 were analyzed. All patients were referred from primary care to

an OS in one of the two specialized public hospital units in The North Denmark Region for evaluation of TKA eligibility.

The main difference between the two RCT populations was eligibility for TKA, with one including only patients eligible [12] and the other only patients not eligible for TKA [13]. For a full list of eligibility criteria, see the published study protocols [12,13].

Ethics approval was obtained for both RCTs from the Ethics Committee of The North Denmark Region (N-20110024 and N-20110085) and both trials were registered on [clinicaltrials.gov](http://clinicaltrials.gov) (NCT01410409 and NCT01535001).

### 2.3. Outcome variable

Eligibility for TKA (yes/no) as assessed by the OS was the outcome variable, dividing the study population into two equally sized groups ( $n = 100$ ).

### 2.4. Predictor criteria for the decision on TKA eligibility

A list of ten potential criteria influencing the OS' decision on whether or not patients with knee OA are eligible for TKA was defined by the authors of the study based on recent recommendations [3], a review of the literature, and from interviews with two high-volume OSs: 1) radiographic severity of the knee OA, 2) knee pain during several activities of daily living (knee pain during activities of daily living), 3) knee pain

**Table 1**  
Description of predictor criteria for TKA eligibility used in the regression analyses.

Criterion	Assessment method	Dichotomization	A priori hypothesis
Radiographic severity	Semiflexed posteroanterior radiographs recorded in standing position (on both legs) with feet pointing forward and hips in neutral ab- and adduction. The X-ray beam was centered at the level of the knee joint with a tube to film distance of 100 cm. Radiographic severity was assessed by the surgeon using the original Kellgren–Lawrence scale (K&L) [14,15].	Yes, into low (K&L 1 to 2) and high (K&L 3 to 4) K&L score	A high K&L score is associated with being eligible for total knee arthroplasty (TKA).
Knee pain during ADL	This was assessed using the subscale pain from the KOOS [16,17].	No	A worse KOOS pain score is associated with being eligible for TKA.
Knee pain at night	The participants rated their pain on a 100 mm VAS in response to the question: "How much knee pain do you have at night?".	Yes, into pain (VAS $\geq 10$ ) and no pain (VAS $< 10$ ) at night	Pain at night is associated with being eligible for TKA.
Knee pain demanding morphine or morphine-like drugs.	The participants were asked to give information on any pain killers used because of knee pain.	Yes, into using morphine or morphine-like drugs (yes/no)	The need for morphine or morphine-like drugs to relieve the knee pain is associated with being eligible for TKA.
Functional limitations	This was assessed using the subscale ADL (function in daily living) from the KOOS [16,17].	No	A worse KOOS ADL score is associated with being eligible for TKA.
Not responding to the recommended non-surgical treatment	This implies that the participant had undergone the core treatments of OA (exercise, education and weight loss (if needed)) [18] before being referred to the orthopedic surgeon. This was evaluated from questions on previous treatments held together with the referral to the orthopedic surgeon due to continuous symptoms.	Yes, participants who had undergone the recommended non-surgical treatment without sufficient effect were rated as "not responding" while the rest were rated as "has not yet tried the recommended non-surgical treatment".	Not responding to non-surgical treatment is associated with being eligible for TKA.
Duration of symptoms	This was evaluated using the question: "When did your knee symptoms begin?". The participants chose one of the following categories: 0 to 6 months ago, 6 to 12 months ago, 1 to 2 years ago, 2 to 5 years ago, 5 to 10 years ago, or more than 10 years ago.	No	A longer duration of symptoms is associated with being eligible for TKA.
Comorbidities	Comorbidities were registered using the Charlson Comorbidity Index [19].	Yes, the index was dichotomized (0 to 1 and 2 or above) due to the non-linearity of the index and since a univariable analysis showed that there was no difference between 0 and 1 comorbidities, but between 0 and 2 comorbidities with respect to their association with the outcome variable.	Having comorbidities is inversely associated with being eligible for TKA, since being medically fit is important when considering surgery [3]
Age	Age in years	No	Increasing age is associated with being eligible for TKA.
Body Mass Index (BMI)	Height (seca 213, seca gmbh & co. kg., Hamburg, Germany) and weight (seca 813, seca gmbh & co. kg., Hamburg, Germany) were assessed in a standardized way to calculate BMI.	No	Increasing BMI is inversely associated with being eligible for TKA, since obesity is known to affect outcome variability [3]

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