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## **Obesity Influences the Knee Injury and Osteoarthritis Outcome Score**

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Abstract	<b>Purpose</b> The primary aim of this study was to report the outcome of the Knee Injury
	and Osteoarthritis Outcome Score (KOOS) in obese patients with a body mass index
	(BMI) > 35.
	Methods This is a prospective cohort study, including patients referred with the aim
	of planning bariatric surgery between October 2015 and January 2017. The primary
	outcome measurement was KOOS. An experienced radiologist obtained and evaluated
	standard radiological osteoarthritis examinations of the knee joints.
	<b>Results</b> The mean age was 43.1 years, and ages ranged from 24 to 69 years. The mean
	BMI was 48.3, and BMI ranged from 35 to 66. Results show that obese patients reported
	significantly worse in the KOOS subscales pain, activities of daily living, sport, and
	quality of life (QOL) compared with a reference population, due to nonoverlapping 95%
	confidence intervals. No significant differences between obese and superobese
	patients were observed on the KOOS subscales ( $p > 0.08$ ). The KOOS subscales showed
Keywords	worse outcome with increasing severity of radiological knee osteoarthritis; however,
<ul> <li>KOOS score</li> </ul>	only significant differences were observed for the KOOS subscales sport and QOL
<ul> <li>joint pain</li> </ul>	( <i>p</i> < 0.05).
<ul> <li>patient-reported</li> </ul>	<b>Conclusion</b> Results imply that the KOOS scores vary significantly with obesity. When
outcomes	utilizing KOOS outcome, considering obesity in the interpretation of outcome is highly
<ul> <li>obesity</li> </ul>	recommended.
<ul> <li>osteoarthritis</li> </ul>	Level of Evidence This is an observational, level III study.

#### Introduction

Worldwide, the prevalence of obesity is ever-increasing, and World Health Organization estimated that more than 650 million adults are obese.<sup>1,2</sup>

Obesity is associated with a variety of severe health problems, including increased risk of chronic diseases such as musculoskeletal pain, osteoarthritis, heart diseases, dia-

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betes, vascular diseases, sleep apnea, and reduced physical function and quality of life (QOL).<sup>1,3</sup>

In an orthopaedic setting, obese patients with joint pain and reduced physical function represent a challenging patient group.<sup>1</sup> The association between joint pain, osteoarthritis, and obesity is well established.<sup>1,3</sup> Moreover, obesity is a significant risk factor for both an increasing incidence of osteoarthritis and progression of osteoarthritis.<sup>3</sup>

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A wide range of different measurements has been used to capture musculoskeletal pain and physical function in the obese patient.<sup>1,4–6</sup> Both generic and joint-specific patientreported measurements in combination with objective measurements are commonly used.<sup>1,4–6</sup> Most patient-reported measurements used are not specifically designed to capture the health status of obese patients, and the literature lacks studies investigating the effect of obesity on the outcome of patient-reported measurements.<sup>7</sup> One such commonly used score is the Knee Injury and Osteoarthritis Outcome Score (KOOS).<sup>8</sup> KOOS is a standardized and validated instrument developed to evaluate knee and associated knee problems. Although the effect of obesity on osteoarthritis is well established, little is known about the effect of obesity on KOOS in absence of osteoarthritis. To investigate the effect of obesity, KOOS scores from obese patients without a medical history of osteoarthritis are needed. Obesity is expected to constitute an important ceiling effect on KOOS outcome, and as a consequence, this information is important for both clinicians and patients when utilizing KOOS in the evaluation of treatment and when informing patients on expected outcomes of treatment.

The primary aim of this study was to report the outcome of the KOOS in obese patients with a body mass index (BMI) > 35 and without a medical history of osteoarthritis.

The hypothesis of the study was that obese patients would report worse KOOS score compared with a reference population even in the absence of radiological knee osteoarthritis.

#### Methods

#### **Study Design**

The study design was a prospective cohort design, including all patients referred to clinical examination and interview between October 2015 and January 2017 at Aalborg University Hospital, Denmark, with the aim of planning bariatric surgery preceded by written information. To be considered for bariatric surgery in Denmark, patients are "superobese" with a BMI  $\geq$  50 with severely impaired QOL or "obese" with a BMI  $\geq$ 35 and with at least one of the following comorbidities: (1) type II diabetes, (2) serious obesity-related hypertension, (3) sleep apnea, (4) polycystic ovary syndrome, or (5) serious osteoarthritis in the hip or knee. Moreover, other nonsurgical means of weight loss were unsuccessful. Before surgery, patients must participate in a 3-month presurgery program, including general information about bariatric surgery, education regarding nutrition, and daily routines of physical activity. The study excluded patients below 24 years and patients with mental disability or abuse of alcohol or drugs and a history of symptomatic knee osteoarthritis in their medical history. Patients were excluded from radiological examination if they were pregnant.

Basic characteristics, including age, gender, BMI, smoking, diabetic, measurements of hip, waist, and shoulder circumference, education, and employment, were obtained. All patients were systematically examined at the outpatient clinic. The primary outcome measurements of this study were the joint-specific patient-reported questionnaires: KOOS. Secondary outcome scores were Eq. 5D-5L index score and Knee Society Score (KSS). An experienced radiologist obtained and evaluated standard radiological osteoarthritis examinations of the knee joints.

The Danish Data Protection Agency (J. nr. 2008-58-0028 ID: 2015-71) and the local ethics committee (J.nr: N-20150044) approved the study, which was performed in accordance with the principles of the Helsinki Declaration. All participants gave written informed consent before inclusion. The reporting of the study complies with the Strengthening the Reporting of Observational Studies in Epidemiology statement.<sup>9</sup>

#### **Measurement Methods**

The KOOS<sup>8</sup> is a standardized and validated instrument to evaluate knee and associated knee problems. The questionnaire includes five subscales: pain, activities of daily living (ADL), symptoms, sport, and QOL. A total score of 100 indicates no symptoms, and 0 indicates major symptoms. Historically, KOOS reference data from a general populationbased sample in southern Sweden are available.<sup>10</sup>

The KSS is a clinical reported outcome score developed to assess patients' outcome after total knee arthroplasty.<sup>11</sup> The score combines subjective and objective assessment and separates the knee score (pain, stability, range of motion, etc.) from the functional score (ability to walk, go up, and down stairs). The score range is from 0 to 100 points, with higher scores indicating a better outcome.

Eq. 5D-5L is a standardized and validated instrument to assess health outcome.<sup>12</sup> It consists of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression, and a self-rated health scale on a 20-cm vertical, visual analog scale with endpoints labeled "the best health you can imagine" and "the worst health you can imagine." An Eq. 5D-5L index at 1.0 indicated full health, and -0.59 denoted death.

The radiological evaluation of osteoarthritis included standing anteroposterior and lateral views of both knees. Tibiofemoral osteoarthritis was classified as described by Kellgren and Lawrence (normal or with one of four increasing levels of osteoarthritis).<sup>13</sup>

#### **Data Analysis**

Normal distribution was checked visually by QQ plots. Categorical data were expressed by frequencies. Continuous data were expressed with mean and median, standard deviations, and 95% confidence intervals (95% CI).

The Student's *t* test was used for analysis of the effect of obese (BMI: 35–49) and superobese patients (BMI > 50) and osteoarthritis on the KOOS subscales.

The results of the Kellgren and Lawrence classification were divided into two categories of knee osteoarthritis for analysis. No radiological signs and grade I of osteoarthritis were defined as "none or doubtful osteoarthritis," and grades II, III, and IV were defined as "definite osteoarthritis."

A *p*-value of < 0.05 was considered significant. The statistical analysis was performed using SPSS (version 22).

#### Results

Between October 2015 and January 2017, a total of 52 patients were included in this study. Fifteen percent of the invited patients declined to participate. All included patients completed the KOOS score, and 45 patients (87%) completed the radiological examination.

The mean age was 43.1 years, and the ages ranged from 24 to 69 years. The mean age for males was 45.2 (27–66) years and for females 41.7 (24–69) years. The gender distribution was 32 (61.5%) females and 20 (38.5%) males. The mean BMI was 48.3, and the BMI ranged from 35 to 66. The mean BMI for males was 48.3 (37–66) and for females 48.2 (35–59). **Table 1** presents detailed baseline characteristics.

The joint-specific, patient-reported KOOS score shows that obese patients reported significant worse in the sub-scales pain, ADL, sport, and QOL compared with the reference population, because of nonoverlapping 95% Cl<sup>10</sup> (**~Table 2**).

Table 1 Baseline characteristics

Age, mean (range), years	43.1 (24–69)		
Sex, n (%)			
Male	20 (38.5)		
Female	32 (61.5)		
Height, mean (SD)	170.7 (10.1)		
Weight mean (SD), kg	142.3 (25.0)		
BMI, mean (SD)	48.3 (6.4)		
Obese (BMI 35-50), n (%)	34 (65)		
Superobese (BMI > 50), <i>n</i> (%)	18 (35)		
Hip circumference, mean (SD)	132.9 (13.8)		
Waist circumference, mean (SD)	139.3 (15.5)		
Shoulder circumference, mean (SD)	156.3 (13.2)		
Smoking habits, n (%)			
Yes	13 (25)		
No	39 (75)		
Diabetic, n (%)			
Yes	16 (31)		
No	36 (69)		
Education, n (%)			
Student	1 (2)		
Primary school	26 (50)		
Short-length education or craftsman	17 (32)		
Undergraduate education	7 (14)		
Graduate education or higher	1 (2)		
Work status, n (%)			
Employed	26 (50)		
Subsidized employed	3 (6)		
Unemployed	23 (44)		

Abbreviation: SD, standard deviation.

**Table 2** Values of the Knee Injury and Osteoarthritis OutcomeScore

	KOOS		
Pain			
Mean	80		
SD	18.9		
Median	81.0		
95% CI	74.7-85.3ª		
95% CI reference population	86.7-88.2		
Symptoms			
Mean	81.7		
SD	20		
Median	88		
95% CI	75.6-86.7		
95% CI reference population	85.4-86.9		
ADL			
Mean	80.4		
SD	19.1		
Median	85		
95% CI	75.1-85.8 <sup>a</sup>		
95% CI reference population	86.5-88.1		
Sport			
Mean	37.2		
SD	30.9		
Median	38		
95% CI	28.6-45.8ª		
95% CI reference population	72.5–75.1		
QOL			
Mean	62.8		
SD	24.9		
Median	56		
95% CI	55.9–69.8ª		
95% CI reference population	77.4–79.6		

Abbreviations: ADL, activities of daily living; CI, confidence intervals; KOOS, Knee Injury and Osteoarthritis Outcome Score; QOL, quality of life; SD, standard deviation. <sup>a</sup>Significant difference.

The effect of BMI (obese [BMI: 33–50] vs. superobese patients [BMI > 50]) on the KOOS subscales showed that superobese patients reported worse KOOS scores on all the KOOS subscales; however, no significant differences between obese and superobese patients were observed (p > 0.08) (**~ Table 3**).

The mean Eq. 5D-5L index score was 0.610 (95% CI: 0.558–0.662). The mean Eq. 5D-5L VAS score was 59.9 (95% CI: 54.1–65.6). Compared with the Danish reference population, the obese population reported significantly worse Eq. 5d-5L index score.<sup>14</sup>

The Kellgren and Lawrence scores grade 0 and I showed none or doubtful osteoarthritis in 71% of the knees. Severe

	Pain	Symptoms	ADL	Sports	QOL
Obese <sup>a</sup>	77.2	78.8	78.9	36.2	58.5
Superobese <sup>b</sup>	85.4	85.7	83.3	39.2	70.9
p-Value	0.12	0.21	0.39	0.75	0.08

**Table 3** Values of the Knee Injury and Osteoarthritis OutcomeScore divided into obese and superobese

Abbreviations: ADL, activities of daily living; BMI, body mass index; QOL, quality of life.

<sup>a</sup>Obese = BMI 35–50.

<sup>b</sup>Superobese = BMI > 50.

osteoarthritis (Kellgren & Lawrence grades III and IV) was observed in only six patients.

**- Table 4** presents the results of the primary outcome KOOS and the secondary outcomes KSS divided into two groups: none or doubtful radiological osteoarthritis and defined radiological signs of knee osteoarthritis. The scores showed worse outcome with increasing severity of radiological knee osteoarthritis; however, only significant differences were observed for the KOOS subscales sport and QOL (p < 0.05).

 Table 4
 Outcome between severity of radiological osteoarthritis

Primary outcome		KOOS				
		n	Mean	Median		
Pain	None or doubtful osteoarthritis	32	82.6	83		
	Definite osteoarthritis	13	71.8	81		
Symptoms	None or doubtful osteoarthritis	32	80.8	86		
	Definite osteoarthritis	13	78.2	82		
ADL	None or doubtful osteoarthritis	32	82.9	89		
	Definite osteoarthritis	13	74.2	82		
Sport	None or doubtful osteoarthritis	32	41.1	40		
	Definite osteoarthritis	13	30.3	20		
QOL	None or doubtful osteoarthritis	32	66.7	63		
	Definite osteoarthritis	13	48.6	44		
Secondary	Secondary outcome		KSS			
		n	Mean	Median		
KSS	None or doubtful osteoarthritis	32	72.3	74		
	Definite osteoarthritis	13	59	59		
KSS function	None or doubtful osteoarthritis	32	70.8	70		
	Definite osteoarthritis	13	70.4	70		

Abbreviations: ADL, activities of daily living; KSS, Knee Society Score; QOL, quality of life.

#### Discussion

This work reports the severity of knee complaints from an obese patient population without a medical history of knee osteoarthritis, measured with the commonly used joint-specific patient-reported measurement KOOS. Findings suggest that it is important to consider obesity in the interpretation of outcome of the KOOS measurement. An understanding of the expected values of the KOOS measurement in obese patients without a medical history of osteoarthritis is important when advising clinicians and patients on the expected outcome of treatment under the influence of obesity.

In an orthopaedic setting, reference material, including normative values, is widely used in the evaluation of the treatment effect following surgery and in the interpretation of disability.<sup>15–17</sup> Most joint-specific patient-reported measurements available are not developed specifically for the evaluation of obese patients. Normative reference values from the general population are available for some patientreported measurements.<sup>10,14,18,19</sup> General reference populations are available for KOOS<sup>10,17</sup> and Eq. 5D.<sup>14</sup>

The KOOS subscales pain, ADL, sport, and QOL and the Eq. 5D index showed a significantly worse outcome for the studied obese patient group compared with the general reference populations. This indicated a significant influence of obesity on these patient-reported measurements and that reference values from a general population are of limited value, in an obese setting. Large-scale studies are needed to fully understand the influence of obesity on joint-specific patient-reported measurements.

Previous analyses of joint-specific patient-reported measurements such as KOOS, KSS, and general health questionnaires such as Eq. 5d have reported that outcomes vary along baseline characteristics such as age, gender, education, and nationality.<sup>10,14,18</sup> Based on findings from this study, considering weight and/or BMI is highly recommended in the interpretation of joint-specific patient-reported measurements. However contradictory, this study found nonsignificant difference between obese and superobese patients on the KOOS score. This may be explained by the high BMI (35-66) in the study population, representing a ceiling effect in several of the KOOS subscales (e.g., one cannot run with a BMI of either 44 or 66). The development of adjusted joint-specific patientreported measurements designed to capture outcome from obese patient groups may be of clinical interest in the future, especially in an orthopaedic setting. These tools may assist in guiding both surgeon and patient expectations when considering the expected function level following knee joint surgery such as total knee replacement.

The effect of radiological osteoarthritis in obese patients on the KOOS score showed worse joint-specific patientreported outcomes with increased radiological severity of osteoarthritis. This is comparable to other studies reporting on nonobese patients.<sup>20</sup> Changes in KOOS score between the two levels of osteoarthritis showed worse scores with increasing degrees of osteoarthritis but did not exceed the minimal clinical important changes of 8 to 10 points.<sup>8</sup> However, these results should be interpreted with caution, as only a few patients in the study group presented with definite or severe signs of radiological osteoarthritis (Kellgren & Lawrence grades III and IV).

This study aims to investigate the influence of obesity on the KOOS score. Several known and unknown factors other than symptomatic osteoarthritis and obesity may influence the outcome of the KOOS score. However, this study lacks power to utilize multivariate analysis and more research is needed to fully understand the influence of obesity.

The main limitation of this study is the observational design, implying that no conclusions regarding causality can be made. However, the main purpose of the study was to provide useful descriptive information, relevant for the interpretation of the KOOS score in an obese population without a medical history of osteoarthritis. Furthermore, the early development of osteoarthritis is not likely to be detected by standard standing X-ray examination of the knee joints, which implies that subchondral bone diseases or other intra-articular knee pathology would not have been detected at the time of inclusion. Moreover, the low number of patients implies that multivariate analysis is not feasible and, as a consequence, some of the outcomes may lack power. Moreover, other factors such as age and gender are known factors to influence the outcome of KOOS, but this study lacks power to utilize multivariate analysis and large-scale studies are needed to fully understand the influence of obesity.

In conclusion, results of this study imply that the KOOS score varies significantly with obesity. When utilizing KOOS outcome, considering obesity in the interpretation of outcome is highly recommended.

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Conflict of Interest None declared.

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