Functioning Before and After Total Hip or Knee Arthroplasty

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Chapter 1

General Introduction

Osteoarthritis, total hip or knee arthroplasty

Osteoarthritis (OA) of the hip or knee is a common locomotor disease characterized by degradation of articular cartilage. In the Netherlands, in the year 2000 about 257,400 persons above the age of 55 years had hip OA and about 335,700 persons had knee OA[1]. Because the prevalence of OA will increase with the aging of the Western population, the percentage of persons with OA is expected to increase by about 38% from the year 2000 to 2020[1]. OA not only causes pain and loss of joint mobility, but also leads to restriction of physical functioning: patients can no longer walk as far or as fast as they could before, they have difficulties with climbing stairs, standing up from a sitting position, dressing themselves, etc.[2,3]. Initial treatment aims to suppress the symptoms and to improve or maintain functioning by means of self-administered pain medication, or focuses on advice about avoiding overuse of the joint, on injections with corticosteroids into the joint, and on physical therapy[1].
In advanced stage OA, when these options no longer provide sufficient pain relief or solve functional problems, a total hip or knee arthroplasty is the most common alternative[1]. In total hip arthroplasty (THA) or total knee arthroplasty (TKA) the joint surface is replaced with an artificial device (prosthesis). In the Netherlands, the numbers of primary THAs have increased from 6,571 procedures in 1980 to 18,186 procedures in 2000, which is an increase of 270%[4]. From 1996 to 2005, the numbers of TKAs increased by 255%, from 4,046 to 10,329[5]. Moreover, the annual number of both THAs and TKAs is expected to increase in the coming decades[6]. The majority of patients undergoing a total hip or knee arthroplasty do experience a reduction of pain and improvement of quality of life[7,8].

Measuring outcomes of osteoarthritis and total hip or knee arthroplasty

As mentioned in the first paragraph, OA results in a variety of symptoms and other functional consequences. One point of view to look at these consequences is the International Classification of Functioning, Disability and Health (ICF)[9]. The ICF, illustrated by Figure 1, provides a framework for the description of health and health-related domains and consists of two parts: Part 1 covers functioning and disability and includes the domains 'body function and structure', 'activities' and 'participation': within the domain 'activities' the two subdomains 'capacity' (i.e. personal abilities, such as the distance a person can walk) and 'actual performance' (i.e. personal accomplishments, such as the distance a person actually walks) are distinguished. Part 2 covers contextual (environmental and personal) factors. Environmental and personal factors can modify these domains of physical functioning and their mutual relationships. The ICF classification aids to describe the consequences of OA and the patients'

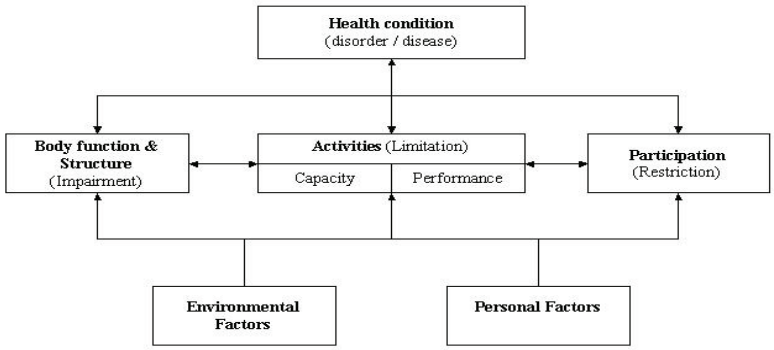

Figure 1. The ICF model

level of physical functioning, which is helpful in deciding on which treatment or intervention is needed and in studying on which aspects treatment or intervention is effective.
Nowadays, many different outcome measures are used to evaluate the outcome of OA treatment, both in clinical practice and in research. In the same way as the consequences of OA can be studied from an ICF perspective, also outcome measures can be categorized within the different ICF domains. Some of these outcome measures were developed decades ago and are used worldwide, whereas others were developed relatively recently. Initially, outcome measures mainly focused on the domain 'function & structure'. Surgeons developed new prostheses and were particularly interested in the impact of a prosthesis on pain, mobility of the joint, and radiological changes. Subsequently, interest focused on other, more functional, domains of patient functioning, such as the domain of 'activities'. It was recognized that, in order to obtain full insight into the impact of OA and the effects of its treatment on a patient's functioning in daily life, outcome measures should cover all the domains of the ICF[10].

The main domain of interest in this thesis (which consists of three parts) is the domain of 'activities'. Items within this domain can be measured with either self-reported or objective outcome measures. The first part of the thesis focuses on the validity of self-reported outcome measures. Currently used self-reported outcome measures include clinical rating scales, such as the Harris Hip Score and the Knee Society Clinical Rating Scale, and questionnaires like the Oxford Hip Score, the Oxford Knee Score, and the Short-Form 36[11-14].
The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index, which measures the ICF domains 'function & structure', 'activities' and 'participation'[10] is particularly recommended for patients with OA in order to assess their self-reported physical functioning and their treatment[15]. This latter questionnaire was especially developed for the older OA patient because, formerly, mainly elderly people were candidates for total hip arthroplasty or total knee arthroplasty[16]. However, due to improvements in operative techniques and

prosthesis quality, younger patients are now operated for a THA or TKA. Additionally, due to improved general health and increased life span, elderly people nowadays have higher demands of physical function, both before and after surgery. Consequently, other or different activities have become relevant for people with hip or knee OA, or for the total hip or knee arthroplasty patient, which the outcome measures currently available do not taken into account. As a result, the WOMAC may not be valid for the current group of OA patients, especially for the younger and more active ones. In order to improve its validity, in Sweden the WOMAC was extended and the Hip disability and Osteoarthritis Outcome Score (HOOS)[17] and the Knee injury and Osteoarthritis Outcome Score (KOOS) came into being[18]. These extended questionnaires include questions about disease-specific symptoms, sport and recreation, and quality of life. So far, they have been formally translated and validated in several languages, but not yet in Dutch. In this thesis we describe the validation of the Dutch-language versions of the HOOS and KOOS.

The second part of the thesis focuses on the effects of OA and joint arthroplasty, with special interest for actual performance of patients as objectively measured. Using devices based on body-fixed motion sensors, the actual performance of patients can be assessed objectively[19]. Before the introduction of these devices, the actual walking activity in patients after total hip or knee arthroplasty had been assessed using a pedometer. With a pedometer it is possible to count the number of steps taken per day, but this represents only one aspect of activities of daily living[20-22]. However, OA and a total hip or knee arthroplasty not only affect the walking ability of these patients, but also influence other motions such as stair walking and cycling. Postures like standing and sitting, and movements between postures like the sit-to-stand movements, are also influenced by the disease and its treatment. These aspects of actual performance have not yet been assessed. The impact of OA and total hip or knee arthroplasty on detailed aspects of actual physical performance is therefore still unclear. Additionally, relationships between the different domains of the ICF have mainly been studied between a limited number of domains, and relationships with objectively measured actual performance have not yet been assessed.
In this thesis we evaluate the impact of OA and the effect of a total joint arthroplasty of hip or knee on the different domains of the ICF classification, including the level of actual performance.

Besides the functional consequences of OA, patient satisfaction is also an important outcome of an intervention. For example, for surgeons it is not only important to know whether surgery leads to less pain or improved joint mobility, but also to know whether patients are satisfied after the intervention. Knowledge about the preoperative determinants that influence satisfaction after total hip or knee arthroplasty can help in decision making, patient selection and formulating reasonable expectations for a patient. Furthermore, knowledge on post-operative

factors that are related with patient satisfaction can be helpful in the treatment of patients after surgery. So far, few studies have investigated patient satisfaction post surgery, and none of the studies examined which ICF-related determinants may be associated with patient satisfaction[23-25]. Therefore, in the third part of this thesis we determined which determinants predict patient satisfaction and which determinants are associated with patient satisfaction post surgery.

Aims and outline of this thesis

The first aim of this thesis is to validate two questionnaires used for relatively young and active hip and knee patients with different stages of OA: i.e. the Hip disability and Osteoarthritis Outcome Score (HOOS) and the Knee injury and Osteoarthritis Outcome Score (KOOS). **Chapter 2** describes the validation of the Dutch-language Version of the HOOS. **Chapter 3** describes the validation of the Dutch-language Version of the KOOS in five patient groups with different stages of knee OA.

The second aim of this thesis is to assess the impact of OA and the recovery after total hip or knee arthroplasty on the different domains of the ICF, including the actual physical activity. **Chapter 4** describes the actual physical activity in patients with end-stage OA compared with a group of healthy controls. The study in **Chapter 5** evaluates the recovery of different parts of physical functioning after total hip and total knee arthroplasty. **Chapter 6** describes the relationships between the different domains of physical functioning.

The third aim is to assess the determinants of patient satisfaction. **Chapter 7** describes the determinants which predict patient satisfaction and which determinants are related with patient satisfaction after surgery.

Chapter 8 discusses the results of the studies, addresses some theoretical and practical implications for the field of orthopaedics, and makes recommendations for further research.

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Chapter 2

Validation of the Dutch version of the hip disability and osteoarthritis outcome score

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Abstract

Objective: The Hip disability and Osteoarthritis Outcome Score (HOOS) was constructed in Sweden; this questionnaire has proved to be valid for persons with hip disability with or without hip osteoarthritis (OA) and with high demands of physical function. The objective of this study was to evaluate the internal consistency, reliability, construct validity, and floor and ceiling effects of the Dutch version of the HOOS questionnaire.

Methods: After translation with a forward/backward protocol, 74 hip arthroplasty patients and 88 hip OA patients filled in the Dutch HOOS, as well as a Short Form-36 (SF-36), an Oxford Hip Score (OHS) and a VAS pain questionnaire.

Results: The Dutch version of the HOOS questionnaire achieved excellent scores in all of the clinimetric properties.

Conclusion: The Dutch HOOS questionnaire has a good internal consistency and reliability. Moreover, the construct validity is good and no floor and ceiling effects were found. The HOOS is a good instrument for patients with different stadia of hip OA.

Introduction

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a widely used, patient-administered and disease-specific instrument used by older patients[1,2]. In 1988 it was validated for patients with osteoarthritis (OA) of the hip or the knee[2]. The WOMAC is recommended by the Osteoarthritis Research Society for use in clinical trials in people with hip OA to measure pain and disabilities[3]. However, because the WOMAC does not evaluate the whole domain of patient-relevant outcome in young and active patients, it was extended, to improve its validity for those with high demands of physical function. Dimensions concerning sport and recreation and hip-related Quality of Life were added to the WOMAC and thus the Hip disability and Osteoarthritis Outcome Score (HOOS) was constructed in Sweden[4].
The Swedish version of the HOOS has been validated for use in patients with hip disability with or without hip OA in secondary care and is considered to be useful for the evaluation of patient-relevant outcomes in patients after a total hip replacement (THR)[5]. The content validity was ensured through a literature search involving interviews with more than 100 patients with hip disability[6] and by questioning 90 patients undergoing THR[5]. A high test-retest reliability was found (intraclass correlation coefficients: ICCs 0.78 to 0.91) for all subscales of the HOOS[6]. For the construct validity Spearman correlations of 0.49 to 0.66 were found between the HOOS subscales and Short Form-36 (SF-36) subscales[5].

After a systematic review of the literature on psychometric evaluation of OA questionnaires Veenhof *et al*. reported that the HOOS questionnaire was one of the top three questionnaires with the best ratings for its descriptive and psychometric qualities to evaluate both pain and physical functions[7]. Futhermore, Veenhof *et al*. concluded that the HOOS has not been studied extensively and that its rating would probably improve if more studies were conducted on its psychometric qualities[7] .

The purpose of this study was to translate the HOOS into Dutch and to evaluate the clinimetric quality of the Dutch version of the HOOS as expressed by internal consistency, reliability, construct validity, and floor and ceiling effects in patients with OA of the hip in primary care and in patients with a THR in secondary care.

Methods

The study was divided into two stages: first, the Swedish version of the HOOS was translated into Dutch according to a standardized procedure described by Beaton *et al*.[8], and secondly it was tested for clinimetric quality in a prospective study.

Procedure of translation

The procedure of translation included three steps[8]. Firstly two persons (T1 and T2) translated independent of each other the Swedish version of the HOOS into Dutch (forward translation); one translator had a technical background and the other had a medical background but both were native speakers. Based on a consensus meeting one final version (T-12) was formed.
Secondly, two bilingual persons (T3 and T4), one with a background in education and the other with a chemical background but both native Swedish speakers, independently re-translated this Dutch version (T-12) into Swedish (backward translation). They were blind to the original Swedish version.
Eventually all translators had a consensus meeting to consolidate the final version of the Dutch version of the HOOS which was used in the present study. This final version was presented to a subset of 15 patients. These patients were asked whether they understood all items and whether they had problems with the formulation of the items of the Dutch version of the HOOS. None of the patients reported problems with the items of the HOOS.

Patients

Two study populations with mild to moderate and severe OA participated in this study to evaluate the Dutch version of the HOOS. The first group consisted of a random selection of patients with hip OA who participated in the Glucosamine sulphate OsteoArthritis Long-term efficacy study[9]. These patients were recruited from general practitioners in the Rotterdam area, and were included in the study when they met one of the American College of Rheumatology criteria for hip OA. Patients who had already undergone THR or those on the waiting list for THR were not included in the study; nor were patients with a Kellgren & Lawrence score of grade 4[9].
The second study population consisted of patients who had undergone THR because of primary or secondary OA at the Department of Orthopaedics (Erasmus Medical Centre, Rotterdam). Mean duration after THR was 9.5 months (SD 3.7). Of the patients who had undergone THR between September 2003 and October 2004, 87 were invited to participate in the present study. Patients unable to understand Dutch written language were excluded. The study was approved by the Medical Ethics Committee of the Erasmus Medical Centre.
Participants where asked to fill in four questionnaires at home, namely the Dutch HOOS, the SF-36[10], the Oxford Hip Score (OHS)[11] and a visual analogue scale (VAS) for pain[12]. For test-retest studies the time interval needs to be sufficiently short to support the assumption that the patients remain stable, and sufficiently long to prevent recall[13]; a retest interval of 2 - 14 days is usual[14]. We considered a time interval of 3 weeks to be appropriate for the current population.

Questionnaires

HOOS

The HOOS includes five subscales: Pain, other Symptoms, Function in Daily living (ADL), Function in Sport and Recreation (Sport/Rec), and hip-related Quality of Life (QoL). Standardized response options are given (5-point Likert scale) and each question is scored from 0 to 4; then a normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale. The user's guide can be downloaded from www.koos.nu. The format is user-friendly and takes about 10 minutes to fill in. HOOS is self-explanatory and can be administered in the waiting room or used as a mailed survey[5].

SF-36

The SF-36 is a generic health status questionnaire which contains 36 items. It measures eight major attributes (bodily pain; physical function; social function; role limitations because of physical problems; role limitations because of emotional problems; mental health; vitality; general health perceptions)[15]. It is widely used, reliable and validated into Dutch, and is easy to fill in[10].

Oxford Hip Score

The OHS is a disease-specific questionnaire consisting of 12 questions assessing pain and function of the hip in relation to different activities of daily life. Standardized response options were given (5-point Likert scale) and each question was scored from 1 to 5; then a summary score (12 indicating no difficulties and 60 indicating most difficulties) was calculated. The OHS was developed specifically to assess outcomes of hip arthroplasty and has shown to be consistent, reliable, valid and sensitive to clinical change[16]. The Dutch OHS has shown to be valid and reliable in measuring outcome in THR patients[11].

VAS for pain

The VAS for pain is a simple way of measuring the intensity of pain. The 100-mm VAS is a uni-dimensional scale and it is considered to be valid and reliable[12].

Statistical analysis

Hypotheses were formulated about the expected magnitude and direction of relationships between (subscales of) the HOOS and the other instruments (see Table 1). We defined the construct validity of the HOOS as good if $\geq$ 75% of the hypotheses could be confirmed[17]. Data were analysed with SPSS statistical software version 10.1. The level of significance for all statistical procedures was $P \leq 0.05$.

Table 1 Hypotheses and the confirmation or rejection of the hypotheses for hip OA and THR group

HIP OA	THR
1. A correlation of at least 0.5 between the HOOS subscale pain and the SF-36 subscale bodily pain.	
yes	**yes**
2. A correlation of at least 0.5 between the HOOS subscale pain and the SF-36 subscale physical function.	
yes	**yes**
3. The correlation between the HOOS subscale ADL and the SF-36 subscale physical function is higher than the correlation between the HOOS subscale sport/recreation and the SF-36 subscale physical function.	
yes	**yes**
4. The correlation between the HOOS subscale pain and the SF-36 subscale bodily pain should be at least 0.1 higher than the correlation between the HOOS subscale pain and the other subscales of the SF-36.	
yes	**yes**
5. The correlation between the HOOS subscale ADL and the SF-36 physical function should be at least 0.1 higher than the correlation between the HOOS subscale ADL and the other subscales of the SF-36.	
no	**no**
6. The correlation between the HOOS subscale Sport/recreation and the SF-36 subscale physical function should be at least 0.1 higher than the correlation between the HOOS subscale sport/ recreation and the other subscales of the SF-36.	
no	**no**
7. A correlation of at least -0.5 between all the subscales of the HOOS and the Oxford Hip Score.	
yes	**yes**
8. A correlation of at least -0.5 between the HOOS subscale pain and the VAS for pain.	
yes	**yes**
75.0% confirmed	**75.0% confirmed**

Internal consistency

A high degree of homogeneity is desirable in a scale. This has two implications: (1) the items should be moderately correlated with each other, and (2) each should correlate with the total scale score[14]. These two factors form the basis of the various tests of homogeneity or internal consistency of the scale. The internal consistency was determined by calculating the Cronbach's alpha. The widely-accepted social science cut-off is that Cronbach's alpha should be 0.70 or higher for a set of items to be considered a (sub)scale[14,18].

Reliability

Reliability concerns the degree to which the results of measurement are consistent across repeated measurements[14]. To estimate the test-retest reliability of the Dutch HOOS, ICCs (two-way mixed effects model absolute agreement) with 95% confidence interval (95% CI) were calculated. The ICC is generally considered to be good at 0.70 and above[14]. The standard error of measurement (SEM) is the variability in measurements of the same individual and is expressed in the dimension of the measurement. The SEM is calculated by the square root of the sum of the between measures variance and the residual variance[19].

Validity

Validity is the degree to which an instrument measures the construct it is intended to measure. Because of the absence of a gold standard, construct validity was examined. Construct validity is concerned with the extent to which a particular measure relates to other measures consistent with theoretically derived hypotheses for the constructs that are being measured[14]. The construct validity of the HOOS was determined by comparing its results with the generic SF-36, the OHS and the VAS for pain. To evaluate the construct validity of the Dutch HOOS version, Pearson's correlation coefficients were calculated.

Floor and ceiling effects

The presence of floor and ceiling effects may influence the reliability, validity and responsiveness of an instrument. An intervention effect might be missed for people who occupy the maximum score[14]. Floor and ceiling effects were considered present if more than 15% of the respondents achieved the highest or lowest possible score[20].

Results

Table 2 presents the baseline characteristics of the two study groups. The first group consisted of patients with hip OA. For the test-retest reliability 65 patients were asked to fill in the HOOS questionnaire twice, of which 49 patients replied (response rate of 75%). For the cross-sectional validity 50 other hip OA patients were asked to fill in the HOOS questionnaire, the SF-36, the OHS and the VAS for pain. Thirty-nine patients replied these questionnaires for the cross-sectional validity (response rate of 78%). The second group consisted of patients with a THR. Eighty-five patients were asked to fill the questionnaires for both the cross-sectional validity and the test-retest reliability. Seventy-four patients filled in the questionnaires for the cross-sectional validity (response rate of 87%). Of these 74 patients, 68 patients filled in the HOOS questionnaire twice for the test-retest reliability. No differences were found in the THR group and the hip OA group concerning age (P-value of 0.97 and 0.32 respectively) and gender (P-value of 0.95 and 0.69 respectively) between the responders and non-responders.

Internal Consistency

Table 3 presents the internal consistency expressed by Cronbach's alpha. For each HOOS subscale Cronbach's alpha was above 0.70 in both groups, indicating a sufficient homogeneity of all items in the (sub)scale.

Table 2 Baseline characteristics of the two study groups

	Hip OA (n=49) test-retest reliability	*Hip OA (n=39) cross-sectional validity*	*THR (n=68) test-retest reliability*	*THR (n=74) cross-sectional validity*
Age in years, median (range)	68.0 (48-80)	66.0 (50-79)	63.1(31-88)	64.5 (31-88)
Gender, women %	63.3	66.7	67.6	67.6
OA: mild-moderate (%)	49-51	46-54		

Mild: Kellgren & Lawrence score of grade 1. Moderate: Kellgren & Lawrence score of grade 2-3.

Table 3 Internal consistency of the HOOS subscales, expressed by Cronbach's alpha

Subscales HOOS	*Hip OA (n=39)*	*THR (n=74)*
Pain (10 items)	0.74	0.76
Symptoms (5 items)	0.95	0.94
ADL (17 items)	0.98	0.95
Sport/Recreation (4 items)	0.91	0.80
QoL (4 items)	0.75	0.86

Abbreviations: ADL; function in daily living, QoL; hip-related quality of life.

Table 4 Descriptive statistics and test-retest reliability of the HOOS

		Baseline mean (SD)	**Retest mean (SD)**	**Change scores mean (SD)**	**SEM**	**ICC agreement**	**95% CI**
Hip OA (n= 49)	Pain	51.7 (18.8)	49.3 (21.2)	1.2 (9.8)	6.94	0.88	0.80-0.93
	Symptoms	50.7 (20.1)	50.2 (21.9)	-0.1(5.4)	3.77	0.97	0.94-0.98
	ADL	51.9 (19.5)	48.5 (21.5)	2.2 (7.0)	5.16	0.94	0.89-0.96
	Sport/ recreation	38.9 (27.7)	34.9 (27.0)	1.7 (8.1)	5.77	0.96	0.92-0.98
	QoL	43.5 (21.5)	42.8 (22.6)	0.4 (5.3)	3.71	0.97	0.95-0.98
THR (n=68)	Pain	64.2 (15.3)	65.4 (14.3)	-0.9 (7.0)	4.97	0.89	0.82-0.93
	Symptoms	59.3 (16.6)	60.1 (14.6)	-1.1 (9.2)	6.49	0.82	0.73-0.89
	ADL	60.7 (15.9)	62.3 (14.5)	-1.4 (6.7)	4.78	0.90	0.84-0.94
	Sport/ recreation	43.7 (20.4)	47.2 (20.8)	-3.2 (14.0)	10.07	0.76	0.64-0.85
	QoL	40.0 (14.1)	42.8 (14.1)	-2.6 (9.7)	7.03	0.75	0.62-0.84

Abbreviations: SD, standard deviation; SEM, standard error of measurement; ICC agreement, intraclass correlation coefficient for agreement; CI, confidence interval. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale.

Reliability

Table 4 shows the ICC of all subscales of the HOOS for the two study groups. The HOOS questionnaire was completed within 7.6 days range 3-20 days. For all subscales of the HOOS the ICC was between 0.75 and 0.97 in both groups, indicating a good test-retest reliability.

Validity

The correlations between the HOOS subscales, the SF-36 subscales, the OHS and the VAS for pain are presented in Table 5.

The highest correlations between the HOOS and the SF-36 were found for the subscales which intended to measure similar constructs (pain vs bodily pain, r = 0.76/0.75, ADL vs physical function r = 0.68/0.72, Sport/Rec vs physical function r = 0.58/0.59). Correlations between the HOOS subscales and the OHS were between r = -0.62 and -0.88. Correlations between the HOOS subscale Pain and the VAS-pain were between r = -0.76 and -0.68. Of the eight predefined hypotheses about construct validity, 75% could be confirmed (see Table I).

Table 5 Validity of the HOOS expressed by Pearson correlations between HOOS subscales and SF-36 subscales, Oxford hip scale and VAS-pain for hip OA (n=39) / THR (n=74)

	HOOS Pain	*HOOS Symptoms*	*HOOS ADL*	*HOOS Sport/Rec*	*HOOS QOL*
SF-36 Subscale					
BP	0.76/0.75	0.57/0.48	0.78/0.65	0.63/0.64	0.65/0.53
PF	0.63/0.59	0.56/0.46	0.68/0.72	0.58/0.59	0.47/0.43
SF	0.48/0.34	0.38/0.30	0.46/0.46	0.36/0.40	0.41/0.15
RF	0.49/0.56	0.38/0.49	0.52/0.67	0.55/0.56	0.41/0.41
RE	0.29/0.38	0.18/0.24	0.38/0.43	0.38/0.20	0.14/0.13
MH	0.06/0.25	0.09/0.25	0.10/0.42	0.17/0.23	-0.12/0.13
VT	0.11/0.30	0.14/0.28	0.10/0.34	0.13/0.24	-0.08/0.16
GH	0.33/0.23	0.13/0.04	0.35/0.28	0.31/0.23	0.10/0.02
Oxford	-0.83/-0.85	-0.71/-0.70	-0.88/-0.85	-0.74/-0.69	-0.66/-0.62
VAS for pain	-0.76/-0.68	-0.06/-0.51	-0.73/ -0.56	-0.68/ -0.49	-0.58/-0.42

Abbreviations: BP, bodily pain; PF, physical function; SF, social function; RF, role limitations because of physical problems; RE, role limitations because of emotional problems; MH, mental health; VT, vitality; GH, general health perception

Floor and ceiling effects

No patient reported the worst or best possible score (floor/ceiling effect) in the HOOS subscales Pain, Symptoms, ADL and QoL. Floor effects (indicating worst possible score) were found only in the subscale Sport/Rec in 5.1% in the hip OA group and in 4.1% in the THR group. No ceiling effects were found in either of the two groups.

Discussion

Based on the results of this validation study of the Dutch version of the HOOS, we consider the HOOS to be an internally consistent, reliable and valid questionnaire, (without floor and ceiling effects), for patients with hip OA or a THR.

In a study on hip pain patients without operation, Klassbo *et al*. reported the highest Cronbach's alpha for the subscale ADL and the lowest Cronbach's alpha for the subscale QoL[6]. In the present study the highest Cronbach's alpha was also found for the subscale ADL. The lowest Cronbach's alpha in our study was found for the subscale Pain, which was still considered good (present study vs the study of Klassbo *et al*. Pain 0.76 vs 0.93, Symptoms 0.94 vs 0.82, ADL 0.95 vs 0.96, Sport/Rec 0.80 vs 0.88 and Quality of life 0.86 vs 0.77). In the present study some Cronbach's alpha were above 0.90; this means that some of the items of the HOOS questionnaire could have been removed because they may be redundant. Klassbo *et al*. reported that they could have removed some WOMAC items to form a shorter questionnaire; however, they decided to keep all WOMAC items in the HOOS because of the worldwide use of the WOMAC and also because of the possibility to calculate scores for both instruments. Moreover, they could ensure validity for elderly people and also for later stages of hip OA[6].

Klassbo *et al*. validated the Swedish HOOS questionnaire in patients with hip pain without operation of the hip and found a good test-retest reliability (ICC 0.78 to 0.98)[6]. Our results of the test-retest reliability were similar to that of Klassbo *et al*. (ICC 0.75 to 0.97). Based on the results of these two studies we conclude that the HOOS is a reliable questionnaire.

To determine whether the test is measuring what was intended to measure requires evidence of validity. Because of the absence of a gold standard, the construct validity was assessed. Correlations between constructs which measure the same constructs were examined. In our study we found the highest correlations between the HOOS subscales and the SF-36 subscales which are intended to measure the same constructs, similar to the study of Nilsdotter *et al*. (THR population)[5]. Compared to the study of Nilsdotter *et al*. we found higher correlations (present study vs study of Nilsdotter *et al*. ADL vs PF r = 0.72 vs 0.66, Sport/Rec vs PF r = 0.59 vs 0.49 and Pain vs BP r = 0.75 vs 0.61)[5]. The population in the study of Nilsdotter *et al*. was older (mean age 71.5, range 49-85 years) compared to our THR population (mean age 62.5, range 31-88 years). In a study comparing the epidemiology of THR in the Netherlands and Sweden Ostendorf *et al*. reported that the Swedish THR population is generally older compared to the Dutch population[21]. We also compared the HOOS questionnaire with the Dutch version of the OHS; all correlations between HOOS subscales and the OHS were above 0.60. Based on these results we conclude that the HOOS is a valid questionnaire for patients with a THR and for those with hip OA.

The strength of the present study is that we used two different study groups with different stages of hip OA. Besides, we used two questionnaires to evaluate the construct validity of

the Dutch version of the HOOS, i.e., a general health questionnaire (SF-36) and a disease-specific questionnaire (OHS).
A measurement tool can also be used to monitor the efficacy of an intervention or the disease process of the patient. For this goal the tool needs to be sensitive to detect clinically relevant changes during a certain period (responsiveness), therefore the responsiveness of the HOOS needs to be evaluated in a future study.

Conclusion

We conclude that the Dutch HOOS questionnaire has a good internal consistency and reliability. Moreover, 75% of the predefined hypotheses about construct validity could be confirmed and we therefore conclude that the construct validity of the HOOS questionnaire is also good. No floor and ceiling effects were found. The HOOS is a good instrument for patients with different stadia of hip OA.

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Chapter 3

The Dutch version of the knee injury and osteoarthritis outcome score: A validation study

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Abstract

Objective: The Knee Injury and Osteoarthritis Outcome Score (KOOS) was constructed in Sweden. This questionnaire has proved to be valid for several orthopedic interventions of the knee. It has been formally translated and validated in several languages, but not yet in Dutch. The purpose of the present study was to evaluate the clinimetric properties of the Dutch version of the KOOS questionnaire in knee patients with various stages of osteoarthritis (OA).

Methods: The Swedish version of the KOOS questionnaire was first translated into Dutch according to a standardized procedure and second tested for clinimetric quality. The study population consisted of patients with different stages of OA (mild, moderate and severe) and of patients after primary TKA, and after a revision of the TKA. All patients filled in the Dutch KOOS questionnaire, as well as the SF-36 and a Visual Analogue Scale for pain. The following analyses were performed to evaluate the clinimetric quality of the KOOS: Cronbach's alpha (internal consistency), principal component analyses (factor analysis), intraclass correlation coefficients (reliability), spearman's correlation coefficient (construct validity), and floor and ceiling effects.

Results: For all patients groups Cronbach's alpha was for all subscales above 0.70. The ICCs, assessed for the patient groups with mild and moderate OA and after revision of the TKA patients, were above 0.70 for all subscales. Of the predefined hypotheses 60% or more could be confirmed for the patients with mild and moderate OA and for the TKA patients, for the other patient groups less than 45% could be confirmed. Ceiling effects were present in the mild OA group for the subscales Pain, Symptoms and ADL and for the subscale Sport/Recreation in the severe OA group. Floor effects were found for the subscales Sport/Recreation and Qol in the severe OA and revision TKA groups.

Conclusion: Based on these different clinimetric properties within the present study we conclude that the KOOS questionnaire seems to be suitable for patients with mild and moderate OA and for patients with a primary TKA. The Dutch version of the KOOS had a lower construct validity for patients with severe OA on a waiting list for TKA and patients after revision of a TKA. Further validation studies on the Dutch version of the KOOS should also include a knee specific questionnaire for assessing the construct validity.

Introduction

There is consensus that patient-reported outcomes have additional value to clinical variables to evaluate patients' health. The underlying principle is that functional status and quality of life can better be described by the patients themselves than by a physician[1]. With regards to knee surgery, however, at the start of the present study almost no reliable and validated Dutch versions of disease-specific questionnaires were available to evaluate the functional status of patients and quality of life after surgery. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is recommended for the assessment of treatment effects in patients with osteoarthritis (OA) and was developed for elderly with OA and assesses pain, stiffness and function in daily living[2-4].

Traumatic knee injuries often cause damage to structures such as ligaments, menisci and cartilage, and may lead to early development of OA. To be able to follow patients after a trauma and to monitor the changes in functional status and quality of life over time, a questionnaire is needed which covers both the short and long-term consequences of an injury of the knee[5]. In other words, there is a clear need for an instrument that not only monitors the outcome in elderly knee OA patients, but also monitors the consequences of acute knee injury in physically active patients in their early adulthood.

Therefore, Roos *et al*. developed such a questionnaire in Sweden[6,7]. The Knee Injury and Osteoarthritis Outcome Score (KOOS) evaluates the functional status and quality of life of patients with any type of knee injury who are at increased risk to develop OA; i.e. patients with anterior cruciate ligament (ACL) injury, meniscus injury or chondral injury. Until now, the KOOS questionnaire has been validated for several orthopedic interventions such as ACL reconstruction[7], total knee arthroplasty (TKA)[8], and menisectomy[9]. It has been formally translated and validated in several languages, but not yet in Dutch.

The purpose of this study was therefore to translate the KOOS questionnaire into Dutch and to evaluate the clinimetric properties of the Dutch version of the KOOS questionnaire, in terms of internal consistency, reliability, validity, and floor and ceiling effects.

We studied the Dutch version of the KOOS in patients with different stages of OA: mild, moderate and severe OA and in patients after a primary TKA and after revision of the TKA.

Methods

The study was divided into two stages. First, the Swedish version of the KOOS questionnaire was translated into Dutch according to a standardized procedure[10]. Second, the translated version was tested for clinimetric quality in a prospective study.

Procedure of translation

The procedure of translation included three steps[11]. First two persons (T1 and T2) translated independently of each other the Swedish version of the KOOS questionnaire into Dutch (forward translation); one translator had a technical background and the other had a medical background; both were native Dutch speakers. Based on a consensus meeting one final version (T-12) was formed[10].

Second, two bilingual persons (T3 and T4), one with a background in education and the other with a chemical background, both native Swedish speakers, independently re-translated this Dutch version (T-12) into Swedish (backward translation). They were blind to the original Swedish version.

Finally, all translators had a consensus meeting to consolidate the final version of the Dutch version of the KOOS questionnaire, which was used in the present study. This final version was presented to a subset of 15 patients suffering from knee complaints. These patients were asked whether they understood all items and whether they had any problems with the formulation of the items on the Dutch version of the KOOS questionnaire. None of the patients reported problems with the items of the KOOS questionnaire.

Patients

We used five patient groups with different stages of OA of the knee of the knee, based on clinical and radiographic signs, to evaluate the clinimetric properties of the Dutch version of the KOOS questionnaire. All patients were under medical treatment at the department of Orthopedics at the Erasmus Medical Center in Rotterdam between 1990 and 2005.

The first patient group consisted of patients with mild OA, who had undergone ACL reconstruction between 1994 and 1996. The second patient group consisted of patients with moderate OA who had undergone HTO between 1998 and 2000. All patients in this group had a valgus correction within a range of 5 to 14 degrees. The third patient group consisted of patients with severe OA who were on the waiting list for a TKA. The fourth patient group consisted of patients 6 months after a TKA, who were operated between 2004 and 2006. The fifth patient group consisted of patients who had undergone a revision of the primary TKA because of a failure of the primary TKA between 2001 and 2006. Patients unable to understand Dutch written language were excluded. The Medical Ethics Committee at the Erasmus Medical Center approved all studies. The choice of our study population, except for the TKA population, was based on existing retrospective cohort studies.

All participants were asked to complete three questionnaires at home: the Dutch KOOS, the SF-36[12], and a Visual Analogue Scale for pain[13] between June 2004 and July 2006. They were asked to fill in the Dutch KOOS at home again after two till three weeks. For test-retest studies the time interval needs to be sufficiently short to support the assumption that the patients remain stable and to be sufficiently long to prevent recall[14]. We considered a time interval of

three weeks to be appropriate for these patient populations. The local Medical Ethics Committee approved the study and all participants gave their written informed consent.

Questionnaires

KOOS

The KOOS questionnaire covers five dimensions that are reported separately: Pain (nine items), Symptoms (seven items), activities of daily living (ADL, 17 items), sport and function (Sport/recreation, five items), and knee-related quality of life (QoL, four items). Standardized answer options are provided and each question is rated on a scale from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is then calculated for each subscale. The format is user-friendly and the questionnaire takes about 10 minutes to complete. The KOOS questionnaire is self-explanatory and can be administrated in the waiting room or used as a mailed survey[7]. The KOOS questionnaire includes the WOMAC Osteoarthritis Index LK 3.0[2,3] in its complete and original format (with permission), and WOMAC scores can be calculated. The WOMAC is worldwide used in elderly subjects with knee or hip OA[2]. The Dutch version of the WOMAC is validated for hip OA patients[15].

Short Form-36 (SF-36)

The SF-36 is a generic health status questionnaire that contains 36 items. It measures eight dimensions (bodily pain; physical function; social function; role limitations because of physical problems; role limitations because of emotional problems; mental health; vitality; general health perceptions) and is widely used, has shown to be reliable and valid in the Dutch general population, and is easy to complete[1,16].

Visual Analogue Scale for pain

The Visual Analogue Scale (VAS) for pain is a simple way of measuring the intensity of pain. The 100-mm VAS is a unidimensional scale that is versatile, easy to use, and has been adopted in many settings. It has shown to be valid and reliable[13].

Statistical Analysis

Internal Consistency

A high degree of homogeneity is desirable in a scale. This has two implications: 1) the items should be at least moderately correlated with each other, and 2) each item should correlate above 0.20 with the total scale score[14]. These two factors form the basis of the various tests of homogeneity or internal consistency of the scale. The internal consistency was determined by

calculating Cronbach's alpha. The widely accepted cut-off is that Cronbach's alpha should be 0.70 or higher for a set of items to be considered a (sub) scale[14,17].

Factor analysis

Factor analysis is a technique designed to reveal whether or not the pattern of responses on a number of tests can be explained by a smaller number of underlying traits or factors, with each factor reflecting a different construct[14]. Streiner *et al*. noted that an absolute minimum of five subjects per variable is necessary, with the proviso that there are at least 100 subjects. Exploratory factor analyses were conducted on all KOOS items using principal component analyses (PCA) with varimax rotation on the combined study population, because all subgroups had a number lower than 100. We first extracted factors with eigenvalues greater than 1. Next, we carried out a forced five, four, three, two and one factor solution.

First, we identified the number of meaningful factors based on the Scree plot and on the interpretation of the factor solutions. Using the Scree plot, we looked for a break between the factors with relatively large eigenvalues and those with smaller eigenvalues. Factors that appeared before the break were assumed to be meaningful, and factors that appeared on the approximately horizontal line after the break were considered to account for only a trivial amount of variance and were therefore not considered meaningful. Second, we looked at the factor structure and factor loadings after varimax rotation. Items with a factor loading less than 0.50 on all factors could be considered for exclusion. In other words factor analysis was performed in order to determine whether the KOOS questionnaire actually consists of 5 subscales.

Reliability

Reliability involves the degree to which the results of measurement are consistent across repeated measurements[14]. To estimate the test-retest reliability of the Dutch KOOS subscales, we calculated intraclass correlation coefficients (ICCs) with a 95% confidence interval (95% CI). Due to practical problems we only assessed the test-retest reliability at the mild and moderate OA group and the revision TKA group. We used the ICC two-way random effects model type agreement to measure the reliability[18]. The ICC is generally considered to be good at 0.70 and above[14]. The standard error of measurement (SEM) is a measure of the absolute measurement error of a score, expressed in the unit of measurement of the instrument[19]. The SEM was calculated as the square root of the sum of the between administration variance and the residual variance[20].

Validity

Validity is the degree to which an instrument measures the construct it is intended to measure. Because of the absence of a gold standard the validity was expressed in terms of

construct validity, which concerns the extent to which a particular measure relates to other measures consistent with theoretically derived hypotheses for the constructs that are being measured[21]. The construct validity of the KOOS questionnaire was determined by comparing its results with the generic SF-36 and the VAS for pain.
Hypotheses were formulated about the expected magnitude and direction of relationships between the subscales of the KOOS questionnaire and the other instruments. The formulation of the hypotheses was based on the starting point that there is a clear distinction between the subscales of the KOOS questionnaire. We defined the construct validity of the KOOS questionnaire as good if $\geq$ 75% of the hypotheses could be confirmed[22], moderate in case of 50-75% confirmation, and low when under 50% of confirmation. To evaluate the construct validity of the Dutch KOOS version, Spearman's correlations were calculated.

We formulated four hypotheses about convergent relations between the KOOS questionnaire, SF-36 and VAS for pain. The correlation between KOOS Pain and SF-36 BP, between KOOS Pain and SF-36 PF, KOOS (all subscales) and VAS for Pain and KOOS ADL and SF-36 PF should be $\geq$ 0.60. We expected that KOOS Pain has a stronger correlation with SF-36 BP compared to the correlation with SF-36 PF. This difference should be at least 0.05 higher. We further expected that KOOS Pain has a stronger correlation with VAS for pain compared to the correlation of the other subscales of the KOOS with the VAS for Pain. This difference should be at least 0.05 higher. KOOS ADL was expected to have a 0.05 higher correlation with SF-36 PF compared to the correlation of the other subscales of the SF-36.
We formulated five hypotheses about divergent relations between all subscales of the KOOS questionnaire and SF-36 GH: with correlations of $\leq$ 0.30. All other correlations between the KOOS subscales and the SF-36 should be higher than 0.30 and lower than 0.60.

Floor and ceiling effects

The presence of floor and ceiling effects may influence the reliability, validity and responsiveness of an instrument. An intervention effect might be missed for people who occupy the maximum score. Floor and ceiling effects were considered present if more than 15% of the respondents achieved the highest or lowest possible score[22].
Data were analysed with SPSS statistical software version 10.1. The level of significance for all statistical procedures was $p \leq 0.05$.

Results

Table 1 presents the characteristics of five patient groups. The first patient group consisted of 36 patients with mild OA (response rate of 79%). All patients filled in the questionnaires for the cross-sectional validity. For the test-retest reliability 35 patients filled in the KOOS

Table 1 Characteristics of the five patient groups

	Mild OA (n=36)	Moderate OA (n=62)	Severe OA (n=47)	TKA (n=63)	Revision of TKA (n=54)
Age in years	36 (27-50)	56 (27-72)	65 (42-81)	61(42-78)	77 (36-89)
Gender, women %	22	32	52	51	78
VAS pain	0.7 (0.0-6.7)	3.9 (0.0-10.0)	6.1 (1.0-10.0)	1 (0.0-9.4)	5.0 (0-10)
KOOS					
Pain	85.3 ± 18.5	62.9 ± 25.7	41.8 ± 18.9	70.1 ± 24.5	61.6 ± 23.4
Symptoms	78.6 ± 7.1	63.2 ± 24.4	46.4 ± 18.7	72.3 ± 18.5	64.7 ± 21.5
ADL	91.2 ± 15.1	69.3 ± 24.2	43.4 ± 19.4	72.8 ± 23.3	56.6 ± 21.9
Sport/recreation	71.0 ± 23.4	36.2 ± 32.0	29.1 ± 39.2	33.2 ± 24.1	26.8 ± 34.1
QoL	67.0 ± 21.6	44.6 ± 26.3	30.9 ± 25.5	52.2 ± 23.8	36.6 ± 26.6
SF-36					
BP	84.7 ± 19.7	63.6 ± 24.0	34.6 ± 22.1	70.7 ± 24.9	55.4 ± 27.2
PF	86.4 ± 17.2	61.1 ± 24.8	34.9 ± 20.6	61.7 ± 23.9	32.9 ± 24.4
SF	92.4 ± 10.5	82.8 ± 21.9	61.7 ± 28.1	81.8 ± 28.6	64.1 ± 29.0
RF	77.8 ± 38.2	64.8 ± 39.7	26.6 ± 34.7	57.4 ± 43.7	31.0 ± 38.8
RE	91.7 ± 25.7	87.4 ± 28.5	57.4 ± 44.3	69.7 ± 43.6	59.9 ± 42.6
MH	86.8 ± 13.4	79.6 ± 19.2	69.1 ± 20.0	74.6 ± 21.7	70.3 ± 20.7
VT	75.4 ± 13.4	68.9 ± 19.3	53.9 ± 19.3	66.5 ± 21.8	55.5 ± 19.1
GH	84.0 ± 12.8	65.0 ± 20.8	60.2 ± 23.0	66.8 ± 24.1	51.4 ± 21.3

Results are presented as median (range) or mean ± SD. Abbreviations: OA; osteoarthritis, TKA; total knee arthroplasty, Revision of TKA; Revision of total knee arthroplasty; VAS, Visual Analogue Scale; BP, bodily pain; PF, physical function; SF, social function; RF, role limitations because of physical problems; RE, role limitations because of emotional problems; MH, mental health; VT, vitality; GH, general health perception; ADL, Activities of daily living; QoL, Quality of life.

questionnaire twice. The second patient group consisted of 62 patients with moderate OA (response rate of 76%) who filled in the questionnaires for the cross-sectional validity. Of these patients 53 filled in the KOOS questionnaire twice for the test-retest reliability. The third patient group consisted of 47 patients with severe OA (response rate of 54%). The fourth group consisted of 63 TKA patients (response rate of 77%) and the fifth group of 54 patients with a revision of the TKA (response rate of 75%). These patients filled in all questionnaires for

Table 2 Internal consistency of the KOOS subscales, expressed by Cronbach's alpha

KOOS subscales	Mild OA	Moderate OA	Severe OA	TKA	Revision of TKA
Pain (9 items)	0.94	0.93	0.80	0.92	0.87
Symptoms (7 items)	0.71	0.83	0.56	0.74	0.78
ADL (17 items)	0.78	0.97	0.94	0.94	0.93
Sport/Recreation (5 items)	0.87	0.95	0.98	0.88	0.95
QoL (4 items)	0.81	0.85	0.73	0.81	0.90

Abbreviations: OA; osteoarthritis, TKA; total knee arthroplasty, Revision of TKA; Revision of total knee arthroplasty, ADL, Activities of daily living; QoL; Quality of life.

the cross-sectional validity and 47 patients filled in the KOOS questionnaire twice for the test-retest reliability.

Internal Consistency

Table 2 presents the internal consistency expressed by Cronbach's alpha. For all patients groups Cronbach's alpha was for all subscales above 0.71, indicating a good internal consistency of all items in these scales and subscales. Except for the subscale Symptoms in the severe OA group a Cronbach's alpha of 0.56 was found, which indicates a moderate internal consistency.

Table 3 Reliability of all subscales of the KOOS

		Baseline mean (SD)	**Retest mea n (SD)**	**Change scores mean (SD)**	SEM	**ICC agreement**	**95% CI**
Mild OA (n=35)	Pain	85.3 (18.5)	89.7 (12.5)	-4.4 (9.4)	7.2	0.80	0.60-0.90
	Symptoms	78.6 (7.1)	81.3 (16.8)	-2.2 (12.8)	9.0	0.74	0.54-0.86
	ADL	91.2 (15.1)	93.5 (10.8)	-2.3 (7.1)	5.2	0.85	0.71-0.92
	Sport /recreation	71.0 (23.4)	73.0 (22.9)	-1.7 (12.8)	9.0	0.85	0.73-0.92
	QoL	67.0 (21.6)	69.6 (20.5)	-2.5 (10.3)	7.4	0.88	0.77-0.94
Moderate OA (n=53)	Pain	62.9 (25.7)	63.2 (23.7)	0.0 (12.9)	9.0	0.87	0.78-0.92
	Symptoms	63.2 (24.4)	66.2 (21.9)	-1.5 (11.3)	8.0	0.87	0.79-0.92
	ADL	69.3 (24.2)	69.2 (23.7)	0.6 (8.2)	5.8	0.94	0.90-0.97
	Sport /recreation	36.2 (32.0)	39.7 (32.5)	-4.8 (15.9)	11.6	0.87	0.78-0.92
	QoL	44.6 (26.3)	47.3 (25.4)	-2.1 (10.3)	7.4	0.91	0.86-0.95
Revision of TKA (n=47)	Pain	61.6 (23.4)	63.9 (21.9)	-2.3 (14.3)	10.1	0.80	0.67-0.88
	Symptoms	64.7 (21.5)	62.9 (21.7)	1.7 (10.2)	7.2	0.89	0.81-0.94
	ADL	56.6 (21.9)	59.5 (22.9)	-2.9 (16.4)	11.7	0.73	0.56-0.83
	Sport /recreation	26.8 (34.1)	27.4 (34.2)	-2.2 (35.1)	24.6	0.45	0.19-0.66
	QoL	36.6 (26.6)	40.3 (27.5)	-3.7 (14.9)	10,8	0.84	0.73-0.91

Abbreviations: OA; osteoarthritis, SD, standard deviation; SEM, standard error of measurement; ICC agreement, intraclass correlation coefficient for agreement; CI, confidence interval. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale. Revision of TKA; Revision of total knee arthroplasty, AD; Activities of daily living; QoL; Quality of life

Factor analysis

The Scree plot showed a distinct break before factor 3, suggesting that only the first two factors were meaningful enough to be retained. This indicates that two factors may be adequate to describe the data. This initial solution accounted for 64% of the total variance for the Dutch

Table 4 Validity of the KOOS for the patient group with **mild OA**

	KOOS Pain	*KOOS Symptoms*	*KOOS ADL*	*KOOS Sport/Rec*	*KOOS QOL*
SF-36 Subscale					
BP	**0.60***	0.44	**0.63**	0.41	0.38
PF	**0.64**	0.53	**0.63***	0.46	0.56
SF	0.23	0.13	0.25	0.09	0.26
RF	0.28	0.37	0.35	0.36	0.40
RE	0.31	0.24	0.19	0.25	0.24
MH	0.42	0.20	0.42	0.30	0.38
VT	0.42	0.27	0.37	0.34	0.31
GH	*0.34*	*0.28*	*0.35*	*0.30*	*0.30*
VAS for pain	**-0.79***	**-0.71**	**-0.78**	**-0.57**	**-0.59**

Validity is expressed by Spearman correlations between KOOS subscales, SF-36 subscales and VAS-pain. Abbreviations: OA; osteoarthritis, BP, bodily pain; PF, physical function; SF, social function; RF, role limitations because of physical problems; RE, role limitations because of emotional problems; MH, mental health; VT, vitality; GH, general health perception; ADL, Activities of daily living; QoL, Quality of life. In bold: convergente correlations that should be ≥ 0.60, In Italic: divergente correlations that should be ≤ 0.30. All other hypotheses are expected to be between 0.30 and 0.60. Correlations marked by * have to be 0.05 higher than the other convergent correlations.

Table 5 Validity of the KOOS for the patient group with **moderate OA**

	KOOS Pain	*KOOS Symptoms*	*KOOS ADL*	*KOOS Sport/Rec*	*KOOS QOL*
SF-36 Subscale					
BP	**0.63***	0.57	**0.71**	0.43	0.62
PF	**0.72**	0.60	**0.75***	0.60	0.70
SF	0.36	0.48	0.50	0.05	0.42
RF	0.23	0.32	0.36	0.12	0.26
RE	0.33	0.39	0.41	0.16	0.46
MH	0.23	0.36	0.27	-0.01	0.25
VT	0.37	0.35	0.48	0.05	0.37
GH	*0.32*	*0.22*	*0.32*	*0.13*	*0.29*
VAS for pain	**-0.69***	**-0.57**	**-0.69**	**-0.38**	**-0.75**

Validity is expressed by Spearman correlations between KOOS subscales, SF-36 subscales and VAS-pain. Abbreviations: OA; osteoarthritis, BP, bodily pain; PF, physical function; SF, social function; RF, role limitations because of physical problems; RE, role limitations because of emotional problems; MH, mental health; VT, vitality; GH, general health perception; ADL, Activities of daily living; QoL, Quality of life. In bold: convergente correlations that should be ≥ 0.60, In Italic: divergente correlations that should be ≤ 0.30. All other hypotheses are expected to be between 0.30 and 0.60. Correlations marked by * have to be 0.05 higher than the other convergent correlations.

version of the KOOS questionnaire (eigenvalue of 21.5 for the first factor and 3.7 for the second factor). However, in the two-factor solution, many items loaded on both factors. Therefore, we chose a forced one-factor solution, which accounted for 51.0% of the variance. The loading factors ranged from 0.37 - 0.85. The loading factor of the question S4 was lower than 0.40.

Table 6 Validity of the KOOS for the patient group with **severe OA**

	KOOS Pain	*KOOS Symptoms*	*KOOS ADL*	*KOOS Sport/Rec*	*KOOS QOL*
SF-36 Subscale					
BP	**0.57***	0.55	**0.72**	0.37	0.47
PF	**0.36**	0.27	**0.54***	0.12	0.22
SF	0.36	0.42	0.33	0.12	0.49
RF	0.28	0.21	0.37	0.04	0.32
RE	0.13	0.18	0.28	-0.04	0.25
MH	0.11	0.12	0.36	-0.07	0.18
VT	0.26	0.24	0.46	0.10	0.29
GH	*0.14*	*0.03*	*0.21*	*-0.11*	*0.16*
VAS for pain	**-0.28***	**-0.43**	**-0.29**	**-0.19**	**-0.19**

Validity is expressed by Spearman correlations between KOOS subscales, SF-36 subscales and VAS-pain. Abbreviations: OA; osteoarthritis, BP, bodily pain; PF, physical function; SF, social function; RF, role limitations because of physical problems; RE, role limitations because of emotional problems; MH, mental health; VT, vitality; GH, general health perception, ADL; Activities of daily living, QoL; Quality of life. In bold: convergente correlations that should be ≥ 0.60, In Italic: divergente correlations that should be ≤ 0.30. All other hypotheses are expected to be between 0.30 and 0.60. Correlations marked by * have to be 0.05 higher than the other convergent correlations.

Table 7 Validity of the KOOS for the patient group with a primary **TKA**

	KOOS Pain	*KOOS Symptoms*	*KOOS ADL*	*KOOS Sport/Rec*	*KOOS QOL*
SF-36 Subscale					
BP	**0.62***	0.58	**0.72**	0.48	0.62
PF	**0.66**	0.56	**0.83***	0.67	0.64
SF	0.39	0.35	0.48	0.26	0.51
RF	0.53	0.53	0.68	0.57	0.49
RE	0.22	0.27	0.39	0.37	0.23
MH	0.46	0.46	0.52	0.37	0.52
VT	0.61	0.48	0.52	0.31	0.49
GH	*0.43*	*0.41*	*0.49*	*0.31*	*0.55*
VAS for pain	**-0.70***	**-0.58**	**-0.59**	**-0.51**	**-0.27**

Validity is expressed by Spearman correlations between KOOS subscales, SF-36 subscales and VAS-pain. Abbreviations: OA; osteoarthritis, BP, bodily pain; PF, physical function; SF, social function; RF, role limitations because of physical problems; RE, role limitations because of emotional problems; MH, mental health; VT, vitality; GH, general health perception; ADL, Activities of daily living; QoL, Quality of life. In bold: convergente correlations that should be ≥ 0.60, In Italic: divergente correlations that should be ≤ 0.30. All other hypotheses are expected to be between 0.30 and 0.60. Correlations marked by * have to be 0.05 higher than the other convergent correlations.

Reliability

Table 3 presents the ICCs of all subscales of the KOOS questionnaire for patient groups with mild and moderate OA and after revision of the TKA patients. In these patient groups the ICCs were 0.70 or higher, indicating a good reliability. Only an ICC of 0.45 was found for the subscale Sport/recreation in the revision TKA group.

The SEM ranged for the mild OA group between 5.2 and 9.0, for the moderate OA group between 5.8 and 11.6 and for patients after revision of the TKA between 7.2 and 24.6.

Validity

Of the predefined hypotheses 60% or more could be confirmed for the study groups with mild OA and moderate OA and for the TKA patient population. For the severe OA group and the revision TKA group less than 45% could be confirmed. Tables 4-8 show the correlations

Table 8 Validity of the KOOS for the patient group with a **revision of the TKA**

	KOOS Pain	*KOOS Symptoms*	*KOOS ADL*	*KOOS Sport/Rec*	*KOOS QOL*
SF-36 Subscale					
BP	**0.49***	0.39	**0.50**	0.30	0.54
PF	**0.26**	0.20	**0.44***	0.32	0.36
SF	0.20	0.11	0.24	0.16	0.42
RF	0.12	0.18	0.14	0.24	0.26
RE	0.10	0.09	0.00	-0.01	0.15
MH	0.15	0.26	0.21	0.05	0.28
VT	0.15	0.28	0.18	0.05	0.39
GH	*0.09*	*0.27*	*0.24*	*0.22*	*0.33*
VAS for pain	**-0.47***	**-0.47**	**-0.29**	**-0.30**	**-0.21**

Validity is expressed by Spearman correlations between KOOS subscales, SF-36 subscales and VAS-pain. Abbreviations: OA; osteoarthritis, BP, bodily pain; PF, physical function; SF, social function; RF, role limitations because of physical problems; RE, role limitations because of emotional problems; MH, mental health; VT, vitality; GH, general health perception; ADL, Activities of daily living; QoL, Quality of life. In bold: convergente correlations that should be $\geq$ 0.60, In Italic: divergente correlations that should be $\leq$ 0.30. All other hypotheses are expected to be between 0.30 and 0.60. Correlations marked by * have to be 0.05 higher than the other convergent correlations.

Table 9 Percentage ceiling/floor effects of the KOOS (best possible score/worst possible score)

	Pain	**Symptoms**	**ADL**	**Sport/ Recreation**	**QoL**
Mild OA (n=36)	**28**/0	**22**/0	**42**/0	14/0	11/0
Moderate OA (n=62)	13/2	3/0	8/0	10/11	5/2
Severe OA (n=47)	0/2	0/2	0/0	**20/38**	0/**15**
TKA (n=63)	10/0	3/0	7/0	0/7	6/3
Revision of TKA (n=54)	2/0	4/0	2/0	6/**38**	4/4

Abbreviations: OA; osteoarthritis, Revision of TKA, Revision of total knee arthroplasty; ADL, Activities of daily living; QoL, Quality of life.

between the KOOS subscales, the SF-36 subscales and the VAS for pain. Overall, the highest correlations between the KOOS subscales and the SF-36 bodily pain and physical function were found. Correlations between the KOOS subscale Pain and the VAS-pain were between $r = 0.28$ and 0.79.

Floor and ceiling effects

Neither floor effects (indicating worst possible score) nor ceiling effects (indicating best possible score) were found for the patients with moderate OA patients and the TKA patients (Table 9). Only ceiling effects were present in the mild OA group for the subscales Pain, Symptoms and ADL and for the subscale Sport/Recreation in the severe OA TKA group. Floor effects were found for the subscales Sport/Recreation and Qol in the severe OA and revision TKA.

Discussion

The results of this validation study of the Dutch KOOS questionnaire showed a good internal consistency for all study groups. Reliability was also good in the mild and moderate OA group and the revision TKA group. It was not assessed in the patients with severe OA and patients with a TKA. The construct validity was moderate for the patient groups with mild and moderate OA and for TKA patients, and lower for the severe OA and revision TKA patients. Ceiling effects were present in the mild OA group and in the severe OA group. Floor effects were seen in the patient group with severe OA group and the revision TKA group.

In this validation study Cronbach's alphas were above 0.70 for almost all subscales in our patient groups. This indicates a good internal consistency, which is in line with the study of Roos *et al*[6,8]. However, for the subscale Symptoms in the severe OA population we found a Cronbach's of 0.56, indicating a moderate internal consistency. Deleting one or more questions did not result in a higher internal consistency. Kessler *et al*. and Xie *et al*. also found a lower Cronbach's alpha (<0.70) for this subscale in patients with OA of the knee[23,24].

In our study, factor analysis was performed on the whole study population and we found that all items of the Dutch version of the KOOS questionnaire loaded on one factor. Our results are in contrast with the conclusion of Roos *et al*. that the KOOS items loaded on five factors[6]. However, our findings are in line with Thumboo *et al*. and Faucher *et al*. who claimed that the subscales Pain and Physical function of the WOMAC loaded on the same factor[25-28]. In the present study, the factor loading of the question S4 (can you straighten your leg fully) was lower than 0.40 which suggests that this item might be excluded from the questionnaire. Despite our preliminary results indicating that the Dutch version of the KOOS questionnaire contains one single factor, we retained in our analyses the original subscales of the Swedish version

of the KOOS questionnaire. However, based on our findings we recommend additional factor analyses on other data sets, before changing the number of subscales of the Dutch version of the KOOS questionnaire.

In the present study the test-retest reliability was good for the patient groups with mild OA (ICC 0.74–0.88), moderate OA (ICC 0.87-0.94) and patients after a revision TKA (ICC 0.73-0.89). A lower ICC (0.45) for patients after a revision TKA for the subscale Sport/recreation was found. When deleting all outliers the ICC is still smaller then 0.70 (ICC 0.62). It is plausible that for these older patients questions about sport and recreation are less relevant.

The construct validity of the KOOS questionnaire was determined by comparing the KOOS subscales with the subscales of the SF-36 and the VAS for pain. Correlations between subscales, which measure the same construct, were compared. In our study we found the highest correlations between the KOOS subscales and the SF-36 subscales which are intended to measure the same constructs. Within the TKA patient group we found some higher correlation coefficients compared to the study of Roos *et al*. (ADL vs PF r = 0.83 vs 0.48 and Pain vs PF r = 0.66 vs 0.19)[8]. The correlations we found within the severe OA patient group (ranging from r = 0.12 to 0.57) were lower than found by Xie *et al*. They found correlations between r = 0.37 and 0.65 for the English version and r = 0.24 and 0.64 for the Chinese version of the KOOS[24]. Kessler *et al*. compared the subscales of the KOOS with the SF-12 for the same population and found a low correlation between the subscale Symptoms and the SF-12 (r = 0.05); the other subscales showed correlations of 0.60 or higher[23].
By only reporting the correlations coefficients it is not clear whether the construct validity of a questionnaire is sufficient or not. Therefore Terwee *et al*. developed quality criteria for design, methods and outcomes of studies to compare the measurement properties of health status questionnaires[22]. These authors recommended assessing the construct validity by testing predefined hypotheses (e.g., about expected correlations between measures or expected differences in scores between 'known' groups). Without specific hypotheses there is a risk of bias, because retrospectively it is tempting to generate alternative explanations for low correlations instead of concluding that the questionnaire may not be valid. Terwee *et al*. give a positive rating for construct validity if hypotheses are specified in advance and at least 75% of the results are in correspondence with these hypotheses[22]. Our choice that convergent correlations should have a correlation coefficient of ≥ 0.60 and divergent correlations of ≤ 0.30 is arbitrary. However, there is no consensus in literature how to deal with this issue. From our pre-defined hypotheses 60% or more could be confirmed in both the mild and moderate OA group and in patients after a TKA (moderate construct validity). Less than 45% from our hypotheses could be confirmed for patients with severe OA and after a revision TKA (lower construct validity).

The formulation of the hypotheses was based on the starting point that there is a clear distinction between the subscales of the KOOS questionnaire. However, with factor analysis we found that all items of the Dutch version of the KOOS questionnaire seem to load on one factor. This may explain the overlap between the correlations of the different constructs of the KOOS questionnaire with the SF-36. This is most obvious for the subscales Pain and ADL of the KOOS in relation to the subscales BP and PF of the SF-36. Previous studies showed that the WOMAC subscale pain and physical function loaded on the same factor[25-27]. Apparently it is difficult for patients to make a distinction between questions about pain and physical functioning in ADL. In our opinion this can be ascribed to the formulation of the questions; the term difficulty (translated in Dutch: 'moeite') may be not clear for some patients. The meaning of this term should be clarified or re-formulated. This was also suggested by Stratford *et al*, and Terwee *et al*[29,30].

Because it is known that clinimetric properties are variable in different study populations[14], it is recommended to validate a questionnaire in the target population. This study showed that the clinimetric properties of the Dutch version of the KOOS questionnaire differed between the 5 different patient groups, which confirms the above described recommendation. Additionally, in future validation studies of the KOOS questionnaire, it may be of interest to evaluate the validity of the Dutch KOOS questionnaire by comparing the subscales of the KOOS questionnaire with the Dutch Oxford 12-item knee questionnaire. This latter questionnaire was considered to be valid and reliable in patients with OA of the knee[31]; however, it was not validated when we started the present study.

We observed ceiling effects only in the mild OA patient group for the subscales Pain, Symptoms and ADL of the KOOS questionnaire. It is plausible that these patients have few complaints of their knee and have no or minor clinical signs of OA, which can explain the presence of ceiling effects in this group of patients. Floor effects were only found in the subscale Sport/recreation in the patients with severe OA and in patients after revision of the TKA. Roos *et al*. stated that questions about sport and recreation also are relevant for older patients[8]. However, this does not seem to apply for patients after revision of the TKA. Because of severity of the disease and/or higher age, it is plausible that these patients do not participate in sport and recreational activities. Dividing the revision population into those younger than 65 years and older than 65 years resulted in floor effects of over 50% in the older patients. Questions about sport may be more relevant to younger patients than to older patients. Because the KOOS questionnaire was originally developed for younger patients this finding is not surprising.

Our study is not without limitations. First, because the selection of patients in the present study only allows statements on the reliability and validity of the KOOS questionnaire in patients with different stages of OA and it's treatment. The questionnaire was not studied in

patients after a menisectomy or an ACL reconstruction. The results of the present study could not be generalized to patients with an acute knee trauma.
Second, a measurement tool can also be used to monitor the efficacy of an intervention or the disease process of the patient. For this goal the tool needs to be sensitive to detect clinically relevant changes during a certain period of time (responsiveness). ICCs are strongly influenced by the heterogeneity of the study population.
The interpretation of the SEM, i.e. whether it should be regarded as a large or a small measurement error, depends on what changes are minimal important on the KOOS subscales. The smallest detectable change (defined as $1.96^{*}\sqrt{2}^{*}$SEM) has to be smaller than the minimal important changes[20]. Future studies should look at what changes in scores on the KOOS subscales constitutes minimal important change. In addition, the responsiveness of the KOOS questionnaire needs to be evaluated in a future study.

Conclusion

Based on these different clinimetric properties within the present study we conclude that the KOOS questionnaire seems to be suitable for patients with mild and moderate OA and for patients with a primary TKA. The Dutch version of the KOOS had a lower construct validity for patients with severe OA on a waiting list for TKA and patients after revision of a TKA. However, the construct validity is only assessed by comparing it with the SF- 36 and the VAS for pain, not with a knee specific questionnaire. Further validation studies on the Dutch version of the KOOS should include knee specific questionnaires for assessing the construct validity.

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Chapter 4

Actual everyday physical activity in patients with end-stage hip or knee osteoarthritis compared with healthy controls

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Abstract

Objective: Few data are available on the level of actual physical activity in patients with osteoarthritis (OA) of the hip and knee. The aim of this study was to measure the level of actual physical activity of patients with end-stage OA of the hip and the knee, to compare this with that of matched healthy controls, and to analyze the data in order to ascertain the factors of influence.

Methods: The actual physical activity was measured with an activity monitor (AM) in 40 hip and 44 knee OA patients, and compared with measurements obtained from healthy controls. Data were also collected on pain and psychological aspects as anxiety, depression and mental functioning. The primary outcome parameter of the actual physical activity was the percentage movement-related activity.

Results: The percentage movement-related activity did not differ between the two OA groups. It was 8.8(4.2)% for the hip and 8.1(3.8)% for the knee OA patients. The matched controls were significantly higher movement-related active than OA patients (about 11.0 (2.9)%). Increasing age and body mass index were negatively associated with the percentage of movement-related activity (ß = -0.29 and ß = -0.25 respectively), whereas mental functioning was positively related (ß = 0.30).

Conclusion: The impact of end-stage OA on the level of actual physical activity is equal for hip and knee OA patients. The actual physical activity for both of the OA groups was significantly and clinically relevantly lower compared to controls. However, this difference was smaller than expected and less dominant than patients' perception of limitations in daily life. Clinicians must be aware that the patients' perception of physical functioning in daily life does not always correspond to the actual physical activity.

Introduction

Osteoarthritis (OA) of the hip or knee causes pain and loss of joint mobility which leads restriction in physical functioning: patients can no longer walk as far or as fast, they have difficulties in climbing stairs, getting in or out of the car, and standing up from a chair[1,2]. These examples show that the term 'physical functioning' covers different aspects. First, it may include the patient's perception of his/her functioning in daily life as measured with the self-report questionnaires such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[3,4]. Second, it may include the capability of patients to perform tasks and activities as measured by the 6-min walk test or the timed up-and-go test[5,6]. A third aspect of physical functioning may include the actual performance of physical activity in everyday life. The low correlations reported between these three aspects of physical functioning indicate that they measure different aspects of physical functioning[6,7].

The restriction of physical activity reported by the patients serves as an indication for joint replacement surgery[8,9]. Furthermore, it can be assumed that the level of everyday activity is related to quality of life and satisfaction. So far, however, the level of everyday physical activity has been measured only roughly and indirectly. From the literature we cannot determine whether there is a difference in actual physical activity between hip and knee OA patients or between OA patients and healthy controls.

Many factors influence physical functioning in general. These factors are population-dependent. Studies found several patient-related factors as well as disease-related factors to correlate with the functional consequences of OA. Patient-related factors include age, gender, obesity, co morbidity. Disease-related factors include grade of OA, pain and stiffness of the joint, anxiety, mental health, self-efficacy, social support and self-reported level of physical activity[10-13]. It is not known whether these OA related factors influence the level of actual physical activity in patients with OA of the hip or knee.

The main aim of our study was to measure the level of actual physical activity of patients with end-stage OA of the hip or knee and to compare this with healthy controls. In addition, we investigated if patient-related factors and disease-related factors influence the level of actual physical activity in patients indicated for total hip or total knee arthroplasty.

Methods

This study was designed as a prospective follow-up study. Patients with end-stage OA of the hip or knee were monitored for 6 months after the total joint replacement. However, only the baseline data of the end-stage OA patients were used in this case-control study.

Patients

Patients who were scheduled for a total joint replacement within 3 months at the department of Orthopaedics of the Erasmus University Medical Center, Rotterdam in the period April 2004 to May 2006 were eligible. During the pre-operative check-up in the outpatient clinic all patients were consecutively approached and were informed about the study. They received information about the study and also received written information about this study. The patients could indicate if they wanted to participate or not or that they needed some additional time for a decision. Indications for surgery were primary or secondary OA. Exclusion criteria for the study were age > 80 years (n = 15), wheelchair-bound, not living independent (n = 2), the presence of disorders other than OA that could affect the level of actual physical activity (n = 14), living more than 1.5 hours away from the Institute (n = 10), insufficient command of the Dutch language spoken or written (n = 4), the presence of OA in the contralateral hip or knee which would require operation within 6 months (n = 11), not willing to sign an informed consent (n = 1), no primary or secondary OA (n = 9), unknown if the patient would remain available for the follow-up measurements (n = 3).

The Rehabilitation Department of the Erasmus University Medical Center has created a database of 95 healthy persons in the age of 8 up to 82 years without symptomatic hip or knee OA or other health problems. At all these controls activity monitor (AM) measurements were performed previously. To compare the level of activity in patients with OA we matched patients for gender and age (± 5 years) with healthy controls from this database (Table 1). The local Medical Ethics Committee approved the study and all patients signed an informed consent.

Measurements

The actual level of actual physical activity of each patient was measured. In addition, data were collected on the age, gender, weight, height, affected joint, grade of OA and perceived pain, anxiety, depression, mental health and physical functioning of each patient.

Actual everyday physical activity

In both the patients and their controls, 48-h measurements were performed with the AM during consecutive weekdays (from Monday to Wednesday or from Wednesday to Friday). To avoid bias, the principles of the AM were explained to the participants only after the measurements. All participants agreed with this procedure. Validity studies have shown that the AM is valid to quantify mobility-related activities. Sensitivity for the detection of mobility-related postures and movements ranged from 79%-99% and predictive value from 87%-99%. Furthermore, the AM can detect differences in everyday activities between groups, which supports its validity and utility in clinical research[14-16].

The AM is described in more detail elsewhere[16]. In short, four ADXL 201 piezo-resistive accelerometers (size 1 x 1 x 1cm) were used in the following configurations: one sensor on the

Table 1 Characteristics of the OA patients and the matched controls

Characteristics	OA total (n=84)	OA hip total (n=40)	OA knee total (n=44)	P-Value	OA hip match (n=34)	Controls (n=34)	P-Value	OA knee match (n=37)	Controls (n=37)	P-Value
Age in years, mean (SD)	61.7 (11.0)	61.4 (12.2)	62.1 (9.9)	0.761	60.2 (12.6)	59.4 (12.3)	0.785	60.7 (10.1)	60.2 (10.8)	0.867
Gender, women (%)	57.1	60.0	54.5		52.9	52.9		51.4	51.4	
BMI **(kg/m2), mean (SD)**	29.5 (5.5)	26.9 (4.2)	32.1 (5.3)	0.000	27.2 (3.9)	26.8 (3.8)	0.625	32.4 (5.4)	26.6 (3.9)	0.003
Grade of OA, number (%)										
Doubtful	2 (2.4)	2 (5.0)	0 (0.0)							
Mild OA	4 (4.8)	2 (5.0)	2 (4.5)	0.257*						
Moderate OA	25 (29.8)	12 (30.0)	13 (29.5)							
Severe OA	53 (63.1)	24 (60.0)	29 (65.9)							
Pain *(WOMAC)*	38.0 (4.0-72.0)	36.0 (12.0-60.0)	40.0 (4.0-72.0)	0.843						
Stiffness *(WOMAC)*	30.0 (0.0-80.0)	30.0 (0.0-80.0)	30.0 (0.0-80.0)	0.395						
Physical functioning *(WOMAC)*	42.5 (9-79)	41.0 (9-69)	44.0 (12-79)	0.179						
Anxiety *(HAD)*	5.0 (0.0-19.0)	4.0 (1.0-15.0)	6.0 (0.0-17.0)	0.488						
Depression *(HAD)*	5.0 (0.0-19.0)	5.0 (0.0-19.0)	5.0 (0.0-15.0)	0.591						
Mental health *(SF-36)*	72.0 (16.0-100.0)	72.0 (16.0-100.0)	72.0 (32.0-100.0)	0.852						

Note: Values are mean (SD) or as median (range). Abbreviations: BMI = Body Mass Index, SD = standard deviation.. WOMAC = Western and McMaster Universities Osteoarthritis Index (0-100), HAD= Hospital Anxiety and Depression scale (0-21) and SF-36= Shor Form 36 (0-100). * categorical variables by chi-square test.

sternum and one sensor at each thigh (standard configuration). During standing, the sensors on the thigh and the trunk are sensitive in anterior-posterior direction; the trunk sensor is also sensitive in longitudinal direction. The accelerometers were connected to a digital recorder (Rotterdam Activity Monitor based on Vitaport technology, Temec Instruments, Kerkrade, the Netherlands; size 15 x 9 x 3.5 cm, weight 500 g), which was worn in a padded bag around the waist. Accelerometer signals were stored digitally on a personal computer memory card international association (PCMCIA) flash card with a sampling frequency of 32 Hz. After the measurement, the data were downloaded on a computer for analysis. The main output of the analysis is the automatic 1-s detection of a number of body postures, body motions and changes in body postures. In the analysis the short-lasting activities (< 5 s) were disregarded. Motility is one of the features calculated from each measured signal. This signal is created by high-pass filtering (0.3 Hz), rectifying, and smoothing the data, and depends on the variability of the measured signal around the mean. The four motility signals were averaged to obtain one body motility signal. The level of body motility during walking is related to walking speed [17].

Data of the AM measurement were calculated per day (24-h period) and averaged over the two measurement days. The level of actual physical activity was expressed by different outcome measures which involves the percentage of activity during a 24-h period: the percentage of movement-related activity which includes walking, cycling, general movement (primary outcome), the percentage of walking (which includes walking stairs), the percentage 'upright' position (which comprises standing and walking) the number of sit-to-stand movements, and the body motility during walking (expressing walking speed).

Body composition

Height and weight were measured with participants wearing indoor clothing without shoes and the body mass index (BMI) was calculated.

Grade of OA

One experienced reader (JV) evaluated the radiographs of the hip and knee, unaware of the clinical status of the patients. Radiological OA of the hip or knee was graded by the Kellgren & Lawrence (K&L) grading system in five grades[18,19].

Pain and stiffness and physical functioning

The WOMAC consists of three dimensions: pain (five items), stiffness (two items), and physical functioning (17 items)[4]. The 5-point Likert version of the WOMAC was used and a 0-100 scale was calculated (e.g. 0 indicating extreme pain and 100 indicating no pain). The WOMAC is reliable and responsive and validated in Dutch[20].

Anxiety and depression

The hospital anxiety and depression scale was developed for use with physically ill patients. It provides clinicians and scientists with a reliable, valid and practical tool for identifying and quantifying anxiety and depression in medical patients. The scale consists of 14 items. It is a reliable and valid scale[21].

Mental health

The Short Form-36 (SF-36) is a generic health status questionnaire which contains 36 items. It measures eight major attributes: bodily pain; physical function; social function; role limitations because of physical problems; role limitations because of emotional problems; mental health; vitality; and general health perceptions. It is widely used, reliable and validated into Dutch, and is easy to fill in[22,23]. In this study we used only the item 'mental health' from this questionnaire.

Statistical analysis

Statistical analysis was performed using SPSS 10.1 for Windows. First, the variables were explored to establish or not they were of a normal distribution, with the Kolmogorov-Smirnov normality test. Based on this exploration the results are presented as means with standard deviations (SDs) or as median and range. The differences between the two OA patient groups and their controls were evaluated by the independent T-test (when the variables were normally distributed) or by the Mann-Whitney U-test (when the variables were not normally distributed). A $P \leq 0.05$ was considered statistically significant.

Linear regression was performed to assess which factors were associated with the percentage of movement-related activity as a dependent variable. The independent variables were age, gender, BMI, pain, stiffness, anxiety, depression and mental health. All factors that showed a significant univariate relationship ($P < 0.10$) with the level of movement-related everyday activity were entered in a backward multiple linear regression analysis to construct a regression model for the level of movement-related activity.

Results

In the period April 2004 to May 2006 174 patients were scheduled to a total joint replacement within 3 months and visited the outpatient clinic for the pre-operative check-up. Of these 174 patients 69 were excluded due to exclusion criteria. Twenty-one patients did not want to participate in this study ($n = 21$). The research sample included 84 patients (Table 1). The hip OA patients did not differ in age compared to the knee OA patients. Hip OA patients had a

significantly lower BMI than knee OA patients. To compare the level of activity in patients with OA, they were matched by gender and age (±5 years) with healthy controls from a database of AM measurements previously performed in controls (Table I). We matched 34 hip OA patients and 37 knee OA patients with controls. The knee OA group had a higher BMI than its control group (P = < 0.001).

Table 2 shows the outcome parameters of actual physical activity of the patients with OA of the hip and knee and their controls.

The mean percentage movement-related activity did not differ between the two OA groups. It was 8.8% for the hip and 8.1% for the knee OA patients, which is equal to 127 and 117 minutes of activity, respectively, per 24-h period. Similar results were found for the other variables, except for the variable of 'number of sit-to-stand movements'. The knee patients made significantly fewer sit-to-stand movements during the day than the hip OA patients (46.2 vs 53.5, P = 0.017). In comparison with the matched OA groups, the control groups showed a significantly lower percentage of movement-related activity; that is, 11.0% and 11.3%, which is equal to 158 and 163 minutes of activity, respectively, per 24-h period. Similar results were found for the percentage of 'walking'.

Table 2 Outcome parameters of actual physical activity in the OA patients and the matched controls

Variables of physical activity	**OA total** (n=84)	**OA hip** (n=40)	**OA knee** (n=44)	**P-Value**	**OA hip match** (n=34)	**Controls** (n=34)	**P-Value**	**OA knee match** (n=37)	**Controls** (n= 37)	**P-Value**
Movement-related activity (% of 24 h)	8.4 (4.0)	8.8 (4.2)	8.1 (3.8)	0.458	8.9 (4.3)	11.0 (2.9)	**0.020**	8.2 (3.7)	11.3 (3.0)	**0.000**
Walking (% of 24 h)	6.1 (2.9)	6.4 (3.1)	5.9 (2.7)	0.429	6.5 (3.2)	8.6 (2.8)	**0.007**	6.0 (2.5)	8.7 (2.7)	**0.000**
Upright (standing and walking) (% of 24 h)	19.8 (7.2)	20.7 (6.3)	19.1 (7.9)	0.321	20.8 (6.2)	24.7 (6.2)	**0.011**	19.4 (8.1)	25.9 (6.5)	**0.000**
Sit-to-stand movements (n/24h)	49.7 (14.2)	53.5 (13.9)	46.2 (13.7)	**0.017**	53.4 (14.2)	60.9 (22.8)	0.283	46.7 (14.2)	61.2 (22.6)	**0.003**
Body motility during walking (g)	.141 (.025)	.144 (.028)	.139 (.020)	0.791	.145 (.029)	.153 (.020)	0.051	.142 (.020)	.151 (.020)	0.096

Note: Values are mean (SD). P-Values are differences between hip OA patients and their comparison subjects and knee OA patients and their controls. Abbreviations: OA= Osteoarthritis, hr = hour, n = number, body motility during walking represents walking speed (1g = 9.81 m/s^2). In bold: significant p-values ($P \leq 0.05$).

The mean percentage of being upright did not differ between the two OA groups. It was 20.7% for the hip and 19.1% for the knee OA patients, which is equal to 298 and 275 minutes of activity per 24-h period. In comparison with the control groups, the matched OA groups showed a significantly lower percentage of being upright; that is 24.7 and 25.9%, which is equal to 356 and 373 minutes of activity, respectively, per 24-h period.
The matched knee OA patients made significantly fewer sit-to-stand movements in comparison with their controls. Walking speed, expressed by body motility during walking, tended to be lower in the matched OA patients than in the controls ($P = 0.051$ and $P = 0.096$).

Univariate linear regression showed that the variables age, BMI, depression and mental functioning were related to the percentage movement-related activity ($P < 0.10$) (Table 3). In a multivariate linear regression analysis, age, BMI and mental health remained significant. The explained variance of this final model was 0.224. When the two OA groups were analyzed separately, mental health was the only significant factor in the multivariate model in the hip OA patients (ß = 0.378, $P = 0.016$), whereas age (ß = -0.355, $P = 0.015$) and BMI (ß = -0.349, $P = 0.016$) were significant in the knee OA patients.

Table 3 Results of linear regression analysis on the total OA group

	Univariate	**Multivariate**
	ß* (P-Value)	ß* (P-Value)
Age	-0.250 (0.022)	-0.292 (0.006)
Body Mass Index	-0.282 (0.010)	-0.246 (0.018)
Depression	-0.204 (0.067)	-
Mental health	0.280 (0.011)	0.297 (0.005)

* standardized beta

Discussion

In this study, we measured actual everyday physical activity in patients with end-stage OA of hip or knee. Patients with OA of the hip and OA of the knee were compared with each other, as well as OA patients with control subjects without symptomatic hip or knee OA. Additionally, patient-related and disease-related factors which potentially influence patients' everyday physical activity were examined. OA patients were less active for 30-45 minutes per day than control subjects. No significant difference in actual physical activity was found between both

OA groups. Age, BMI and mental functioning influenced the level of actual physical activity in these groups.

Comparison of the activity data of our study with that of other studies is not feasible because related studies generally focused on whether or not hip and knee OA patients feel disabled when performing activities such as walking, rising from a chair and climbing stairs[24,25]. We found only one study in which a kind of activity monitor was used to study actual physical activity in OA patients[26]. However, the outcome parameters of that study were different from ours. Additionally, their study population was different with respect to age, type and grade of OA, and gender distribution, and they did not compare OA patients with control subjects. Therefore, our study is unique regarding the data provided on actual daily physical activity.

When comparing OA patients with the controls, we found that patients with hip and knee OA were less active than non-OA control subjects. This was expected, since OA patients frequently report that they limit their level of actual physical activity to avoid pain or due to their inability to perform certain activities. Although when expressed in minutes per day the difference in activity between OA patients and controls is less than we expected, when expressed as a percentage it is considerable (19-27%) and in our opinion clinically relevant. However, it is not reported in the literature which differences between OA patients and controls are considered as clinically relevant, which makes the appraisal of our data slightly subjective. The WOMAC physical functioning score (mean 43) confirms our assumption that people with OA perceive limitations in their physical functioning. These perceived limitations seem, however, to be more dominant than, and not directly related to, the decrease in actual physical activity. A similar result was found in studies using the AM in other patient groups, e.g. patients with post-polio syndrome or Guillain-Barré syndrome[27,28]. It may be that patients keep their actual activity level as high as possible. Pain medication, used by most of the end-stage OA patients may have the effect that people maintain a certain level of physical activity. Although the most hindering factors seem to be pain and discomfort, the actual physical activity remains for the most part possible. Clinicians should realize that the patient's perception of physical functioning in daily life does not always correspond to the actual physical activity.

The AM provides many outcome measures. Some of them can be expected to be strongly interrelated because they measure similar concepts. However, other parameters represent different concepts, and the effects of a disease may be parameter specific. For example, compared to the percentage being active the difference between OA and control subjects was larger for the parameter 'being upright', and this parameter was also strongly discriminative between the two OA groups: hip OA patients were 'upright' for 58 minutes less and knee OA patients for 98 minutes less than the controls. Another parameter that showed a significant difference between OA subgroups was the number of sit-to-stand movements. Knee OA patients made

15 fewer sit-to-stand movements than the controls, and seven fewer sit-to-stand movements than hip OA patients. The load on the knee joint is high during the sit-to-stand movement, which could explain the difference in this outcome parameter between knee OA patients and controls and not for the hip OA patients and controls.
Another parameter of interest is the walking speed. In our study, walking speed tended to be slower in the OA patients than in their controls. A reduced walking speed in OA patients compared to controls is reported in the literature, although Landry *et al*. and Mundermann *et al*. did not find any differences in walking speed between knee OA patients and controls[29-35]. The non-significant results on walking speed in our study can have different explanations. First of all, the effect of OA on walking speed may not be unambiguous, as the findings from literature also suggest. Secondly, in most studies walking tests are carried out in a laboratory setting, and these measurements may provide other data than our measurements that are based on walking speed during walking at home. Another explanation may be that in our study walking speed was indirectly measured by the parameter body motility during walking, which is a proven indicator for walking speed, but possibly less discriminative than direct measures of walking speed. Finally, we may have failed to show a significant difference in walking speed due to the relatively small study population.

The difference in the actual physical activity per day between OA patients and the controls does not depend only on the data from the OA group, but also on that of the control group. It is possible that the control group was not a representative group. However, in three other studies with control groups of similar age and gender distribution, the percentage of movement-related activity was between 11. 3 and 11.6 per day, which is comparable with our results and allows us to conclude that our selection of controls did not deviate from others[36-38]. Therefore, we feel that the findings of our study do not depend on unreliable data of the control group.

When comparing the results of the WOMAC subscales, the SF36 mental health subscale and the hospital anxiety and depresson scale (HADS) which measures anxiety and depression, we found that our OA patients showed similar results to other studies in OA patients who had yet to undergo a total joint replacement[25,39-41].

Age and BMI were negatively related to movement-related activity, whereas mental functioning was positively related to movement-related activity. These results are in line with the general assumption that the older a person is, the less active he/she is, and that a person with a higher BMI will be less active[26]. The positive relationship between mental functioning and physical activity is reported frequently, although Bussmann *et al*. found a negative relationship between mental functioning and physical functioning[7,42-45]. Analyses performed on the two subgroups separately, showed that age and BMI were only related in knee patients and mental functioning in hip patients. We do not have an univocal explanation for the difference

of results between hip and knee patients. The number of patients in each subgroup may not be large enough to pick up some relationships. Surprisingly, pain was not associated with movement-related activity, whereas pain is reported as the most significant factor in relation to functional consequences of OA[10]. However, in the study of Hirata *et al*. in which actual activity was also objectively measured, pain was also not related to the level of actual everyday activity[26]. One possible explanation for the lack of correlation between pain and the actual physical activity may be use of (pain) medication as mentioned above. Another reason is that patients may find it difficult or may not want to decrease their normal movement behavior: for example certain tasks simply have to be performed, despite perceived limitations in physical performance.

When comparing the movement-related activity to other patient groups measured with the same AM we found that OA patients were rather limited in their everyday life. The percentage of movement-related activity in the OA patients (8.4%) was lower than in Guillain-Barré patients (10.7%), in patients with spastic cerebral palsy (10.6%) and in chronic pain patients (9.9%)[28,37,46]. However, the percentage of movement-related activity in the OA patients was higher than in chronic heart failure patients (7.6%), in young adults with meningomyelocele (6.5%), in amputation patients (4.3%) and in spinal cord injury patients (3.4%)[14,38,47,48]. Some patient groups are physically not able to maintain a high level of actual physical activity. In other patient groups, such as OA patients, the more important problem is pain and difficulty in performance. Overall it can be stated that OA patients seem to be moderately limited in the actual physical activity compared to the other patient groups.

This study has some limitations. First, because the study group comprised a relatively small number of patients, we may have missed significant determinants for explaining the level of actual physical activity. However, in the comparison of groups, we feel that the number of patients was not a crucial factor. The fact that we found significant differences between the patient group and the control group indicates that reliability and type-II error were not an important issue. Second, it has been suggested that at least four days of activity monitoring are needed to characterize an individual's habitual physical activity pattern[49]. However, we are convinced that 48-h sampling is adequate for comparison at group level. Furthermore, there are several studies in which 48-h appeared to be adequate to show the effectiveness of a treatment and/or differences between a patient group and control group[7,50]. Third, we used data of controls from a database and matched the patients for gender and age; perhaps this was not the optimal match for comparing the actual physical activity. However, the data from our control groups were comparable with that of other studies[36-38]. Fourth, our data from the control group was obtained from an existing database and did not contain measurements from questionnaires. However, the focus of our study was the actual physical activity in OA patients compared to controls and between the two OA subgroups. Finally, some

subjects reported that the AM was not comfortable to wear during daily activities or during the night. However, this did not lead to non-compliance of the AM. We are convinced that this discomfort had no, or only a slight effect on the habitual activity pattern. Moreover, because both the patient group and the control group experienced this discomfort and we believe that this did not influence the conclusions of this study. Furthermore, we emphasize that both patients and their controls did not know what was being measured with the AM until the end of the study.

Conclusion

This study addresses the impact of OA on the actual physical activity of hip and knee patients waiting for total arthroplasty. The actual physical activity for both of the OA groups was significantly and clinically relevant lower compared to controls. However, this difference was smaller than expected and less dominant than patients' perception of limitations in daily life. We found no difference in the actual physical activity levels between the hip and knee OA patient groups. Pain was not associated with the actual physical activity level. The actual physical activity level did decrease in those patients who were older, had a higher BMI, or had deteriorating mental functioning. Clinicians must be aware that the patients' perception of physical functioning in daily life does not always correspond to the actual physical activity. Future research should focus on the effect of total joint arthroplasty on the actual physical activity and should assess whether the actual physical activity of patients after surgery reaches the same level as that of healthy controls.

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Chapter 5

Small Increase of Actual Physical Activity 6 Months After Total Hip or Knee Arthroplasty

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Abstract

Objective: Limitation in daily physical activity is one of the reasons for total hip arthroplasty (THA) or total knee arthroplasty (TKA). However, studies of the effects of THA or TKA generally do not determine actual daily activity as part of physical functioning. We determined the effect of THA or TKA on patients' actual physical activity and body function (pain, stiffness), capacity to perform tasks, and self-reported physical functioning. We also assessed whether there are differences in the effect of the surgery between patients undergoing THA and TKA and whether the improvements vary between these different outcome measures.

Methods: We recruited patients with longstanding end-stage osteoarthritis of the hip or knee awaiting THA or TKA. Measurements were performed before surgery and 3 and 6 months after surgery.

Results: Actual physical activity improved by 0.7%. Patients' body function, patients' capacity, and their self-reported physical functioning also improved. The effects of the surgery on these aspects of physical functioning was similar for THA and TKA. The effect on actual physical activity (8%) was smaller than on body function (80-167%), capacity (19-36%) and self-reported physical functioning (87%-112%).

Conclusion: In contrast to large effect on pain and stiffness, patients' capacity, and their self-reported physical functioning, the improvement in actual physical activity of our patients was less than expected 6 months after surgery.

Introduction

Limitation in daily physical activity is one of the reasons for THA or TKA. However, some studies on the effects of THA or TKA do not include actual daily physical activity as an outcome. Two studies on other diseases suggest no or only weak relationships among the actual physical activity, patients' capacity, and self-reported physical functioning[1,2]. This means actual physical activity is a different aspect of physical functioning. There is no doubt that THA and TKA effectively alleviate pain and improve function for patients, but whether that translates into more actual physical activity is unclear.

We hypothesized that patients' actual physical activity, body function, capacity and self-reported physical functioning would be markedly different after THA or TKA. We therefore specifically sought to determine the effect of THA or TKA 3 and 6 months after surgery on patients' (1) actual physical activity as measured with an activity monitor (primary research question); and (2) body function as measured by the WOMAC subscales pain and function, patients' capacity measured by the 6-MWT, a rising from chair test and a stair walk test and patients' reported physical functioning measured by the WOMAC function subscale, SF-36 function subscale and the Physical Activity Scale for Individuals with Physical Disabilities (PASIPD). We also assessed whether (3) the effects of surgery differ between patients undergoing THA or TKA in actual physical activity, body function, capacity and self-reported physical functioning; and (4) the improvements vary between these different outcome measures.

Methods

We recruited and prospectively followed 84 patients with end-stage Osteoarthritis (OA) of the hip or knee awaiting THA or TKA. All patients had long-standing end-stage OA of the hip or knee refractory to nonoperative treatment and were scheduled between April 2004 and May 2006. All data were collected before surgery (t0), 3 months postsurgery (t3), and 6 months postsurgery (t6). We excluded patients (1) older than 80 years (n=15); (2) who were wheelchair-bound or not living independently (n=2); (3) with comorbidities other than OA that could affect the level of actual physical activity (n=14); this was determined by questions about general health and the presence and/or absence of diseases; (4) living more than 1.5 hours away from the medical center (n=10); (5) with insufficient command of the Dutch language (spoken or written) (n=4); (6) with OA in the contralateral hip or knee requiring surgery within 6 months (n=11); (7) not willing to sign an informed consent (n=1); and (8) who were questioned whether they would be available for followup measurements (n=3). Among the 84 recruited, four with inadequate followup data (3 month and/or 6 month data missing) were excluded, leaving 80 for the study (Table 1). With a power of 80% and a significance level of 0.05, 72 subjects would be needed to show a minimum clinically relevant improvement of 10% in the primary outcome parameter,

Table 1 Preoperative characteristics

Characteristics	Total OA Group (n = 80)	Hip OA (n = 36)	Knee OA (n = 44)	P-Value
Age (years)	61.8 ± 11.2	61.5 ± 12.8	62.1 ± 9.7	0.818
Gender (women; %)	58.8	63.9	54.5	0.401
Body mass index (kg/m²)	29.6 ± 5.5	26.6 ± 4.2	32.1 ± 5.3	0.000
Side of surgery (left; %)	48.8	52.8	45.5	0.517
Indication for surgery (number; %)		Primary OA: 32 (88.9) Secondary OA: 4 (11.1)	Primary OA: 40 (90.9) Secondary OA: 4 (9.1)	
Kellgren and Lawrence (number; %)		No OA : 0 (0) Doubtful: 2 (5.6) Mild: 2 (5.6) Moderate: 10 (27.8) Severe: 22 (61.1)	No OA: 0 (0) Doubtful: 0 (0) Mild: 2 (4.5) Moderate: 13 (29.5) Severe: 29 (65.9)	

Values are mean ± standard deviation unless otherwise indicated; OA = osteoarthritis

'movement-related activity', between baseline and 6 months after treatment. The Mean age of the patients with OA was 61.8 years (standard deviation, 11.2). The Medical Ethics Committee of the Erasmus Medical Center approved the study and all patients signed informed consent. During their initial visit to the outpatient clinic before surgery, we approached all patients and informed them about the study. All received verbal and written information about the study and could indicate whether they wanted to participate or they could decide later after examining the written information. As noted, the inclusions and exclusions left us with 80 patients.

We collected data during the checkup before surgery. The mean duration from their checkup until surgery was 43 days (median, 30 days). Data were collected on age, gender, height and weight (wearing indoor clothing without shoes), affected joint, and grade of OA. Patients with hip OA only differed (p = 0.000) from those with knee OA with regard to body mass index. We also obtained data on different aspects of physical functioning, ie, patients' actual physical activity, function, capacity, and self-reported physical functioning.

One experienced reader (JV), who was unaware of the clinical status of the patients, graded the preoperative radiographs of the hips and knees using the Kellgren and Lawrence grading system in five grades (from 0 to 4)[3,4].

The Activity Monitor (AM) is based on long-term ambulatory monitoring of signals from body-fixed accelerometers. From these signals, it is possible to detect a set of movement-related activities (e.g., walking, cycling), body postures (e.g., sitting and standing), and changes in body posture (e.g., sit-to-stand movement)[5-8]. We performed measurements during 48 hours with the AM during two consecutive weekdays (from Monday to Wednesday or from Wednesday to Friday). To avoid bias, the principles of the AM were explained to the participants only after the measurements were made. All participants agreed with this procedure. Validity studies show the AM is valid to quantify movement-related activities and body postures[5,7,9]. The AM is described in more detail elsewhere[7]. In short, three accelerometers were used

in the following configurations: one sensor on the sternum and one sensor on each thigh (standard configuration) (Fig 1). Data from the AM measurement were calculated per day (24-hour period) and averaged over the two measurement days. The level of actual physical activity was expressed as the percentage activity during a 24-hour period.

The WOMAC consists of three dimensions: pain (five items), stiffness (two items), and physical functioning (17 items)[10]. The 5-point Likert version of the WOMAC was used. The WOMAC is reliable and responsive and validated in Dutch[11]. In this domain, the pain and stiffness subscales were used.

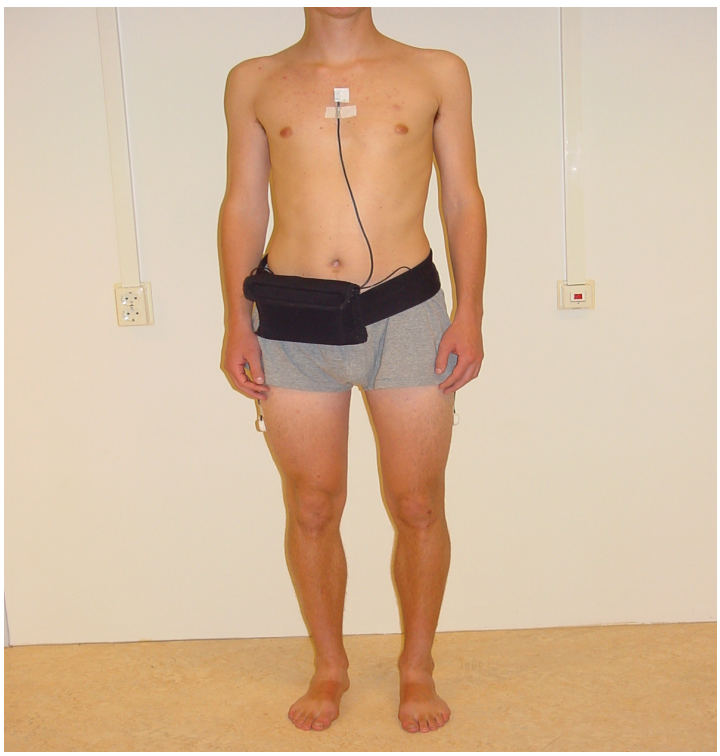

Figure 1 Patient wearing the activity monitor with accelerometers at the thighs and trunk

The 6-minute-walk-test was performed to quantify walking ability. It is a valid and inexpensive clinical tool that involves recording the distance participants cover while walking indoors at their own speed for 6 minutes[12,13]. It has good test-retest reliability and has been used to measure the effectiveness of interventions in populations with hip or knee OA[14-18].

To investigate stair climbing, the time required to ascend five steps, turn around, and descend five steps was used. This stair climbing task has a good test-retest reliability[19].

Various methods have been used in an attempt to determine how well older adults can rise from a chair[20-24]. We asked patients to complete five repetitive sit-to-stand movements as

quickly as possible without using their arms, if possible. The score was the time needed to perform the test. The sit-to-stand test has been used for people with arthritis and is a valid test[25].

The PASIPD evaluates the physical activity and is a modification of the Physical Activity Scale for the Elderly. The questionnaire requests the number of days a week and hours daily (categories) of participation in recreational, household, and occupational activities during the past 7 days[26]. Washburn *et al*. reported supportive results for construct validity and Van der Ploeg *et al*. concluded the criterion validity is comparable to well established self-report physical activity questionnaires from the general population. The test-retest reliability Spearman correlation of the PASIPD was 0.77[27].

We recorded the physical function subscales of the SF-36[28,29] and WOMAC[3]. The SF-36 is a generic health status questionnaire and is widely used, reliable, and validated into Dutch[28,29]. Function of the hip or knee was also assessed by the Harris hip score[30] and the Knee Society clinical rating scale,[31] which are instruments used worldwide to assess patients undergoing total joint arthroplasty of the hip or knee.

Surgery was performed in a clean air operating room equipped with vertical laminar airflow, and the team used body exhaust systems. For THA, a posterolateral approach with posterior capsular repair. For TKA a central skin and medial capsular incision was used. All patients had second-generation cephalosporin at anaesthetic induction followed by two additional doses. For the first 24 hours postoperatively, prophylactically, low-molecular-weight heparin was administered for deep vein thrombosis during the patients' in-hospital stays. This was continued after discharge for 6 weeks. For TKA, numerous procedures were performed using computer navigation (Brainlab – Germany)

Patients underwent routine postoperative rehabilitation. They were mobilized early with full weightbearing as tolerated. After surgery, all patients received physical therapy as long as deemed necessary. In the majority of patients, physical therapy was limited to the first 6 weeks postoperatively.

We first established whether the variables had a normal distribution using the normality Kolmogorov-Smirnov test. We computed either means and standard deviations or median and range based on the findings of the normality test. The differences between pre- and postoperative measurements were evaluated by the dependent t-test (when the variables were normally distributed) or by the Wilcoxon test (when the variables were not normally distributed). Analysis was performed using SPSS 10.1 for Windows (SPSS Inc, Chicago, IL).

Results

For the total patient group, the mean percentage of movement-related activity was 0.7% higher ($p = 0.03$) 6 months after surgery compared with preoperatively (Table 2). This is an

Table 2 Actual Everyday Physical Activity (objective) before surgery (t0) and 3 months (t3) and 6 months (t6) after surgery

Variables of Physical Activity	Total Group			Hip Group			Knee Group			P-Value Delta Scores t3-t0/t6-t0
	t0 (n = 80)	t3 (n = 77)	t6 (n = 77)	t0 (n = 36)	t3 (n = 36)	t6 (n = 35)	t0 (n = 44)	t3 (n = 41)	t6 (n = 42)	
Movement-related activity (percent of 24 hours)	8.4 ± 3.9	9.1 ± 4.0 (0.07)	9.1 ± 3.9 (0.03)	8.7 ± 4.0	9.1 ± 3.9 (0.22)	9.2 ± 3.7 (0.26)	8.1 ± 3.8	9.0 ± 4.1 (0.18)	9.1 ± 4.0 (0.06)	0.67/0.48
Walking (percent of 24 hours)	6.1 ± 2.8	6.4 ± 3.0 (0.41)	6.6 ± 2.9 (0.06)	6.3 ± 3.0	6.8 ± 3.0 (0.12)	6.9 ± 2.8 (0.16)	5.9 ± 2.7	6.0 ± 2.9 (0.91)	6.4 ± 3.0 (0.21)	0.28/0.90
Upright (percent of 24 hours)	19.8 ± 7.1	19.5 ± 6.1 (0.57)	20.5 ± 6.2 (0.35)	20.7 ± 5.9	20.5 ± 6.4 (0.86)	21.4 ± 6.3 (0.49)	19.1 ± 7.9	18.7 ± 5.8 (0.58)	19.8 ± 6.1 (0.53)	0.74/0.99
STS movements (number per 24 hours)	49.6 ± 14.1	52.1 ± 15.2 (0.18)	54.4 ± 17.7 (< 0.01)	53.7 ± 13.8	55.9 ± 15.2 (0.40)	58.4 ± 19.2 (0.08)	46.2 ± 13.7	48.7 ± 14.6 (0.28)	51.0 ± 15.7 (0.06)	0.98/0.86
Motility during walking (g)	0.142 ± 0.026	0.144 ± 0.030 (0.49)	0.145 ± 0.027 (0.15)	0.145 ± 0.029	0.150 ± 0.034 (0.22)	0.149 ± 0.022 (0.08)	0.139 ± 0.023	0.140 ± 0.027 (0.77)	0.141 ± 0.030 (0.69)	0.25/0.33

Values are mean ± standard deviation; movement-related activity (primary outcome) includes walking, cycling, and general movement; upright comprises standing and walking; STS movements = sit-to-stand movements, motility during walking represents walking speed (1 g = 9.81 m/s^2); p value delta scores, significance for differences in changes between THA and TKA group in parameters from t3 to t0 and t6 to t0

improvement from 121 minutes preoperatively to 131 minutes 6 months after surgery. Patients with total THA or TKA had more (p = 0.01) sit-to-stand movements 6 months postsurgery compared with before surgery.

Compared with before surgery, there was a reduction in pain (p = <0.001) and stiffness (p = <0.001), and an improvement (p = <0.001) in the 6-minute-walk distance at t3 and t6 (Table 3). Patients needed less time to perform stair walking and rising from a chair 3 and 6 months after surgery, and patients also reported their physical functioning and actual physical activity (subjective) as improved. Similar data were found for the two subgroups. Between t0 and t3, the effect on pain and stiffness was greater (p = 0.04) for patients undergoing THA. Compared with before surgery, the changes at t3 and t6 on rising from a chair and self-reported physical functioning (WOMAC) were greater (p = 0.03 and p = 0.03) for patients undergoing THA than for patients undergoing TKA.

Three and 6 months after surgery, there were no improvements in any of the parameters of the AM compared with before surgery in the THA and TKA groups. Also, there were no differences in the changes between the two groups.

The changes in actual physical activity between the data before surgery and followup data are smaller than the changes in the other three aspects of physical functioning among these measurements data (patients' function, capacity and self-reported physical functioning) (Figure 2).

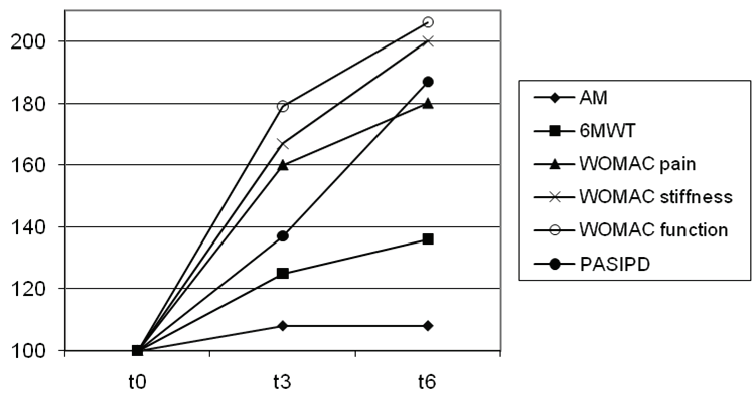

Figure 2 Comparison of proportion of actual physical activity, function, capacity, and self-reported physical functioning before (t0) and after surgery (t3 and t6). AM = Activity Monitor; 6MWT = 6-minute walk test; PF = physical functioning; PASIPD = Physical Activity Scale for Individuals with Physical Disabilities

Table 3 Other parameters before surgery (t0) and 3 months (t3) and 6 months (t6) after surgery

Domains and Outcome Measures	Total Group			Hip Group			Knee Group			P-Value Delta Scores t3-t0/t6-t0
	t0 (n = 80)	t3 (n = 77)	t6 (n = 77)	t0 (n = 36)	t3 (n = 36)	t6 (n = 35)	t0 (n = 44)	t3 (n = 41)	t6 (n = 42)	
Function										
Pain	40 (4-72)	64 (24-80) (< 0.001)	72(4-80) (< 0.001)	44(12-68)	74 (24-80) (< 0.001)	76 (36-80) (< 0.001)	32 (4-72)	60 (24-80) (< 0.001)	68 (4-80) (< 0.001)	0.04/0.82
Stiffness	30 (0-80)	50 (0-80) (< 0.001)	60 (0-80) (< 0.001)	25 (0-60)	60 (10-80) (< 0.001)	60 (0-80) (< 0.001)	30 (0-80)	40 (0-80) (< 0.001)	60 (0-80) (< 0.001)	< 0.01/0.30
Capacity										
6MWT (m)	290 (48-523)	361 (48-605) (< 0.001)	395 (133-580) (< 0.001)	309 (64-485)	370 (133-480) (0.01)	399 (190-570) (< 0.001)	280 (48-523)	343 (48-605) (< 0.01)	385 (133-580) (< 0.001)	0.74/0.65
STR (s)	10.3 (4.7-28.6)	9.1 (4.8-24.1) (0.01)	8.1 (4.3-22.8) (< 0.001)	9.5 (4.7-28.2)	8.8 (4.8-21.1) (0.03)	7.8 (4.3-17.2) (< 0.001)	11.4 (5.4-28.6)	9.4 (5.6-24.1) (0.22)	8.8 (5.0-22.8) (<0.01)	0.54/0.23
Rising chair (s)	18.3 (7.7-35.7)	16.2 (5.6-35.3) (< 0.01)	14.8 (5.0-33.0) (< 0.001)	18.5 (7.7-32.7)	16.0 (5.6-32.8) (0.05)	13.4 (5.0-23.0) (< 0.001)	17.5 (8.9-35.7)	16.7 (10.4-35.3) (0.19)	15.6 (10.0-33.0) (0.04)	0.44/0.03
Reported actual activity										
PASIPD	9.1 (0.2-51.3)	12.5 (0.7-82.6) (0.04)	17.0 (0.2-93.3) (< 0.001)	7.7 (0.9-40.9)	9.2 (0.7-81.9) (0.19)	15.3 (0.2-93.3) (< 0.001)	9.5 (0.2-51.3)	13.8 (1.1-82.6) (0.13)	17.9 (0.3-88.8) (0.01)	0.75/0.65
Reported functioning										
WOMAC PF	33 (9-64)	59 (15-80) (< 0.001)	68 (6-80) (< 0.001)	31 (14-55)	65 (15-80) (< 0.001)	68 (24-80) (< 0.001)	34 (9-64)	55 (24-80) (< 0.001)	65 (6-80) (< 0.001)	0.07/0.03
SF-36 PF	33 (0-80)	58 (10-100) (< 0.001)	70 (10-100) (< 0.001)	33 (0-80)	60 (25-100) (< 0.001)	70 (20-100) (< 0.001)	33 (0-80)	55 (10-90) (< 0.01)	65 (10-100) (< 0.001)	0.08/0.25
HHS/KSS				28 (17-42)	37 (22-47) (< 0.001)	43 (28-47) (< 0.001)	50 (20-100)	57 (28-100) (0.10)	65 (37-100) (< 0.001)	

Values are median (range); 6MWT = 6-minute walk test; STR = stairclimbing; PASIPD = Physical Activity Scale for Individuals with Physical Disabilities; PF = physical functioning; HHS = Harris hip score; KSS = Knee Society score; p value delta scores, significance for differences in changes between THA and TKA group in parameters from t3 to t0 and t6 to t0

Discussion

Limitation in daily physical activity is one of the reasons for THA or TKA. However, some studies on the outcomes after THA or TKA do not determine actual physical activity as part of physical functioning. Based on the literature, we hypothesized patients' actual physical activity, body function, capacity, and self-reported physical functioning would be markedly different after THA or TKA. We therefore determined the effect of the of THA or TKA on patients' (1) actual physical activity (primary research question); (2) body function (pain, stiffness and muscle strength), capacity to perform tasks, and self-reported physical functioning. We also assessed whether (3) there are substantial differences in effect of surgery between patients having THA or TKA in actual physical activity, body function, capacity and self-reported physical functioning; and (4) the improvements vary between these different outcome measures.

This study has some limitations. First, the study group was relatively small. In the total patient group, there were differences on all outcome measurements among the three measurement times. For the subgroups, however, we observed no differences in AM outcome parameters. This suggests the study could be underpowered. A larger subgroup population would probably have shown differences between the measurement moments. However, we question whether these differences would be clinically relevant. We therefore believe that our conclusions would not change. Second, the followup period may be too short to demonstrate relevant changes in patients' actual activity level. However, most of the changes in physical functioning occur within 6 months[32,33]. Kennedy *et al*. reported greatest improvements in the first 12 weeks after TKA and that slower improvements continued to occur from 12 to 26 weeks[21]. We believe that after 26 weeks some improvement may occur, but we believe that only a rather limited improvement of physical functioning may be expected after the first 6 months. Future research should examine the long-term impact of THA or TKA on actual physical activity. Third, the THA and TKA groups differed regarding body mass index. Although we did not examine which factors in addition to type of surgery (hip or knee) influence the effect of the surgery, we realize body mass index may be an influence. Other factors that may influence the effect of surgery include the number of physical therapy treatments, whether a patient lives alone, and whether a patient uses pain medication. We did not register these factors, because the aim of our study was not to describe the determinants of recovery. Fourth, it has been suggested that at least 4 days of activity monitoring are needed to characterize an individual's habitual activity pattern. However, we are convinced that 48 hours sampling is adequate for comparison at group level. Finally, some subjects reported the AM was not comfortable to wear during daily activities or during the night. Because this discomfort was probably experienced both before and after surgery, we believe this did not influence the conclusions of this study.

When comparing the actual physical activity before and after treatment in the total group, the percentage of movement-related activities and the number of sit-to-stand movements

improved 6 months after surgery. The percentage of movement-related activities increased by 0.7% and the number of sit-to-stand movements by 9.7%. The changes we found suggest that 6 months after surgery the activity level had not approached that of healthy subjects, who are about 11% active per day[34]. Therefore, the influence of the surgery on the objectively measured actual physical activity level was less than expected. However, the percentage of patients' self-reported improvement in actual physical activity measured by the PASIPD increased by 86%. Therefore, there seems to be a discrepancy between patients' self-reported actual physical activity and the objectively measured actual physical activity. It is possible many patients had OA for numerous years and had adapted their lifestyle to the limitations caused by the disease. It may take longer for them to readjust to a better functioning joint and to adopt a more active lifestyle. The 6-month followup be too short to adequately show clinically relevant changes in the patients' actual activity level. However, it may be questioned whether patients would change their lifestyle spontaneously 6 months after surgery, when most rehabilitation programs have stopped. Another reason for the relatively minor changes in the actual physical activity level before and after surgery may be the actual physical activity level before the surgery. De Groot *et al*.[34] reported many patients with end-stage OA of the hip or knee maintain a relatively high activity level before surgery, despite pain and limitations, so less extreme changes after surgery are expected. Because patients reported many limitations in their capacity and physical functioning before surgery, it is not surprising they reported greater changes after surgery for these aspects of physical functioning.

Our findings regarding the patients' body function, capacity, and self-reported physical functioning are in line with those of other studies[35-38]. Considerable pain reduction has been reported by others[35,36]. An increase in the 6-minute-walk distance, improvement in stair climbing, and a better reported physical functioning have been reported[35,36].

The type of surgery did not influence actual physical activity, but the effect was present in the other aspects of physical functioning. It has been reported that the effect of THA on pain and physical functioning is greater than the effect of TKA[35,39]. Patients undergoing THA experienced a larger reduction in pain and stiffness than patients undergoing TKA 3 months after surgery; however, this difference was no longer present 6 months after surgery. The improved performance in the rising-from-a-chair capacity test and the perceived improvement in physical functioning (WOMAC PF) were greater for patients undergoing THA than for patients undergoing TKA 6 months after surgery. However, no such difference was observed in actual physical activity 6 months after surgery. The impact of TKA on actual activity is the same as that of THA.

Our data suggests the effect of THA or TKA on actual activity was not only small, but even smaller than the effect on function, capacity, and perceived limitations. The patients did not adopt a more active lifestyle despite improved function, capacity, and self-reported physical functioning 6 months after surgery. After surgery, patients' capacity during performance

tests improved, whereas their activity level remained constant. It is possible that before surgery, there is a discrepancy between patients' capacity and their actual physical activity; patients' capacity is lower than or close to their actual physical activity, which may be related to complaints of overload, such as pain, fatigue and so on). After surgery, because of increased capacity, the discrepancy between capacity and actual physical activity becomes smaller. The patients perform their actual activity after surgery with less pain and less perceived limitations than before. Perhaps the patients are satisfied knowing they can do more if they want to without having to perform the actual activity. For patients with Guillain-Barré syndrome, similar results were found, although the evaluated intervention was a training program instead of surgery; patients' capacity and self-reported physical functioning improved but did not lead to a more active lifestyle[1]. Garssen *et al*[1] also suggested raising the level of daily physical activity was not the initial adaptation strategy for these patients, and this may also apply to our study population. Decreasing pain and discomfort may be more important for them than increasing their actual physical activity, which they kept at a relatively high level before surgery. Overall, our study shows that improvements in physical functioning vary from aspect to aspect. Clinicians should be aware that postoperative evaluation of effect is dependent on which aspect is being measured.

We found that effects of THA or TKA on patients' function, patients' capacity, and their self-reported physical functioning were larger than the effect on patients' actual physical activity. Patients did not adopt a more active lifestyle 6 months after surgery despite improvements in the other aspects of physical functioning. When assessing the impact of THA or TKA, physicians bear this in mind and consider which aspect of physical functioning patients they are most interested in achieving.

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Chapter 6

Consequences of hip or knee osteoarthritis and effects of total hip or knee arthroplasty: relationships between domains of functioning

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Submitted

Abstract

Objective: To obtain insight into the relationships between different domains of functioning in patients with hip or knee osteoarthritis (OA) and a total hip arthroplasty (THA) or total knee arthroplasty (TKA). Five domains of functioning were defined: body function, capacity, actual physical activity, perceived physical functioning, and perceived mental functioning.

Methods: In this prospective cohort study, the population consisted of patients with OA of the hip or knee who underwent a primary THA or TKA. Relationships between the five functional domains were studied in the cross-sectional data and the change score data, expressing the consequences of OA and the outcome of THA or TKA, respectively. The percentage of significant relationships between each pair of domains was also determined.

Results: Before surgery the strongest relationship was found between capacity and perceived physical functioning (5/6, 83%). Change score data after surgery showed largely the same pattern as before surgery. Both in the cross-sectional data and the change score data the 'capacity' domain was the most frequently related to the other domains, and 'actual physical activity' the least frequently.

Conclusion: The results suggest that capacity and/or the imbalance between capacity and actual physical activity are key factors in treating patients with OA before and after surgery.

Introduction

Osteoarthritis (OA) most often affects the hip or knee and is characterized by degradation of articular cartilage, which causes pain and loss of joint function. In end-stage OA total hip arthroplasty (THA) or total knee arthroplasty (TKA) is the final option for treatment[1]. Patients with OA and patients who receive a THA or TKA not only have impairments related to pain and joint function, but also have problems in other domains of functioning. In accordance with the International Classification of Functioning, Disability and Health (ICF) OA and THA or TKA may affect several domains of functioning: body function, activity, and participation. Within the activity domain, the sub domains capacity and performance are distinguished[2], where performance can be objectively and subjectively assessed[3]. Studies have indicated that OA has an effect on these domains[4-8]. Additionally, it is also suggested that OA may also result in problems in mental functioning, such as depression and fear of movement[9,10], which can be regarded as a separate domain.

Many studies focusing on the effects of OA and THA or TKA provide relevant information, but give little insight into the mechanisms behind these effects. For example, OA may result in impairments in function (e.g. pain, less joint mobility), but it is unclear to what extent these impairments are related to limitations while performing activities or to the impact on mental functioning. A better understanding of the relationships between the different domains of functioning provides a rationale for the management of these patients. Until now, the relationships between only a few domains have been studied and certainly not in connection with each other. For example, only relationships between the domains function and capacity, capacity and perceived physical functioning, and between perceived physical and mental functioning have been described separately[6,11,12]. The relationships between all of these domains and the domain actual physical activity has not yet been studied.

We previously described the effects of OA and THA or TKA on functioning; differences in all domains of functioning were found between OA patients and controls, although the difference in actual physical activity was relatively small[8]. Patients who received a THA or TKA improved in all domains, although the effect on actual physical activity was not clinically relevant[13]. These data also allow us to study the relationship between different aspects of functioning.

The aim of the present study was to obtain insight into the relationships between different domains of functioning in patients with OA and the effect of THA or TKA. For this purpose we constructed a theoretical model with five domains of functioning, based on the ICF (Fig. 1). We hypothesised that the strongest relationships would be between those domains that are closer to each other: e.g. OA causes pain and stiffness of the joint and weakens muscles, and leads to decreased capacity in terms of walking and rising from a chair. Limitations of capacity negatively influence actual physical activity, and a lower level of actual physical

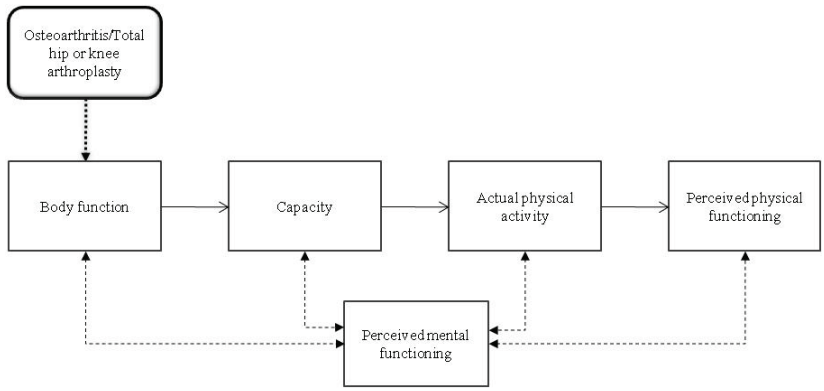

Figure 1 Theoretical model of the relationships between the domains in osteoarthritis and after total hip or knee arthroplasty

activity may then lead to lower perceived physical functioning. The deterioration in these domains could lead to worse mental functioning (e.g. fear of falling).

Methods

Between April 2004 and May 2006 we recruited and prospectively followed patients with long-standing end-stage OA of the hip or knee, refractory to nonoperative treatment and scheduled for THA or TKA. All data were collected before surgery (t0), 3 months postsurgery (t3), and 6 months postsurgery (t6). In the present study we used the cross-sectional data (data before surgery) and the change scores data (i.e. data at 6 months after surgery minus data before surgery). Excluded were: 1) patients older than 80 years (n=15), 2) those who were wheelchair-bound or not living independently (n=2), 3) those with comorbidities other than OA that could affect the level of actual physical activity (n=14), 4) those living more than 1.5 hours away from the medical center (n=10), 5) patients with insufficient command of the Dutch language (spoken or written) (n=4), 6) those with OA in the contralateral hip or knee requiring surgery within 6 months (n=11), 7) those not willing to sign an informed consent (n=1), and 8) patients for whom it was questionable whether they would be available for the follow-up measurements (n=3). Finally, 80 patients were recruited in the study (36 hip and 44 knee patients); their mean age was 61.8 (SD 11.2) years, and 58.8% was female. The Medical Ethics Committee of the Erasmus Medical Center approved the study.

Body function

In this domain we used the stiffness subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[14,15] and the pain intensity measured with a Visual Analog

Scale[16]. The strength of the knee extensors was measured bilaterally with a hand-held dynamometer[17].

Capacity

The sub-maximal 6-min walking test was performed. Patients were instructed to walk as far as they could along a 25 m marked tape during a 6-min period[18,19]. To assess stair climbing, we measured how long the patients took to ascend 5 steps, turn around, and then descend[20]. We also measured how long these patients took to perform five sit-to-stand movements[21-27].

Actual physical activity

Actual physical activity during normal life was measured objectively using an Activity Monitor (AM). The AM, based on body-fixed accelerometers and a portable recorder (Rotterdam Activity Monitor, Temec Instruments, Kerkrade, the Netherlands; size 15 x 9 x 3.5 cm, weight 500 g), has been extensively validated and used[28-30]. The AM data were collected over 2 days and then averaged. Three AM outcome measures were included in the present analysis: the percentage of time a patient was active (e.g. walking, cycling, climbing stairs, and general movement), the percentage of being upright per day (e.g. standing and walking), and the body motility value - which can be regarded as being related to the overall level of physical activity during the measurement[31].

Perceived physical functioning

The perceived physical functioning was calculated using the 36-Item Short Form Health Survey (SF-36)[32]. The items are categorized into 8 subscales; from these subscales a physical and mental score was calculated. In this domain the physical summary score was used. The subscale physical functioning of the WOMAC was also used in this domain[14,15].

Perceived mental functioning

Perceived mental functioning was measured with the mental summary score of the SF-36 [32,33] and the anxiety and depression subscales of the Hospital Anxiety and Depression Scale (HAD)[34].

Data analysis

Each domain was presented by three outcome measures, except for the domain perceived physical functioning. Spearman correlation coefficients were calculated between all outcome measures of different domains. If a p-value of a correlation was ≤ 0.05 the correlation was considered significant. In this way the number and percentage of significant correlations between domains could be calculated, which reflects the strength of the relationship between

two domains[31]. We defined the strength of the relationship between domains as follows: 0-20% no relationship, 20-40% a poor relationship, 40-60% a weak relationship, 60-80% a moderate relationship, and 80-100% a strong relationship.

Results

Table 1 summarizes the scores on the variables before and after surgery of the different domains of the ICF. A part of these variables was previously presented in our effect paper[13]. Table 2 presents the correlation coefficients between all outcome measures of the cross-sectional data and the change scores data. Table 3 presents these data as a proportion and a percentage of the correlations between the domains. Figures 2 and 3 present the strength of the relationships between the domains.

Table 1 Median (range) or mean ± SD of the variables before surgery and 6 months after surgery of the five domains of the International Classification of Functioning Disability and Health (ICF).

Domains and outcome measures	**Before surgery (t0)** (n=80)	**6 months after surgery (t6)** (n=77)	**Differences t6-t0**
Body function			
Pain	6.8 (0.20-10.0)	0.3 (0.0-9.4)	-4.9 (-10;6.5)*
Stiffness**	29 (0-80)	75 (0-100)	30 (-20;80)*
Muscle strength	173 ± 62.6	208.6 ± 51.0	13.9 ± 48.0*
Capacity			
6-MWT (m)**	283 (48-522)	395 (133-580)	104 (-144;470)*
STR (s)**	12.0(4.7-28.6)	8.9 (4.3-22.8)	-2.9 (-18.4;8.9)*
Rising chair (s)**	19.1 (7.7-35.7)	15.1 (5.0-33.0)	-3.8 (-21.3;10.1)*
Actual activity			
Movement related activity (%)**	8.5 ± 4.0	9.1 ± 4.0	0.7 ± 2.8*
Upright (%)**	19.8(7.1)	20.5 (6.2)	0.70 (6.6)
Body Motility (g)	0.017 (0.004-0.0467)	0.020 (0.0097-0.043)	0.0009 (-0.02;0.03)*
Perceived physical functioning			
WOMAC PF**	35 (9-64)	62 (6-80)	29 (-7;60)
SF-36 PF**	35 (0-85)	65 (10-100)	30 (-50;85)*
Perceived mental functioning			
SF-36 MH	70 (16-100)	78 (20-100)	6.8 (-28;68)*
HAD Anxiety	5.7 (0-17)	4.0 (0-14)	-1.6 (-11;5)*
HAD Depression	5.5 (0-19)	3.3 (0-13)	-2.2 (-14;6)*

Follow-up data compared with baseline data, $p < 0.05$ (Wilcoxon signed-rank test). Abbreviations; 6-MWT, six-minute walk test; STR, stair climbing; STS, sit-to-stand; PASIPD, physical activity Scale for Individuals with Physical Disabilities; PF; physical functioning; MH, mental functioning; HAD, Hospital Anxiety and Depression scale. * P-Value ≤ 0.05, ** data which are also presented in the effect study.

Table 2 Correlation coefficients between all outcome measures, categorized according to the five domains. The coefficients of change scores are shown in the upper-right section of the table, the cross-sectional data in the lower-left section. Significant relationships between outcome measures of different domains are highlighted in bold.

	Body function			**Capacity**			**Actual physical Activity**			**Perceived physical functioning**		**Perceived mental functioning**		
	Pain	Stiffness	Strength	6MWT	STR	STS	%MRA	BM	%Upr	WPF	SF36PF	SF36M	Anx.	Depr.
Pain	-	-0.49**	-0.08	**-0.33***	**0.31***	**0.49****	0.07	-0.03	-0.05	**-0.63****	**-0.45****	**-0.45****	0.13	**0.43****
Stiffness	-0.46**	-	0.15	**0.27***	**-0.24***	**-0.43****	-0.11	0.18	-0.11	**0.64****	**0.48****	**0.33****	-0.16	**-0.28***
Strength	-0.17	0.11	-	0.17	-0.12	-0.21	0.04	0.04	-0.09	0.03	0.07	-0.02	-0.08	-0.03
6MWT	-0.04	0.08	**0.33****	-	-0.51**	-0.34**	0.18	0.21	0.04	**0.42****	**0.48****	**0.38****	-0.06	**-0.29***
STR	0.10	-0.09	**-0.40****	-0.57**	-	0.59**	-0.16	-0.16	-0.05	**-0.27***	**-0.24***	**-0.42****	0.22	**0.39****
STS	0.16	**-0.23***	**-0.35****	-0.46**	0.67**	-	-0.07	-0.02	0.16	**-0.46****	**-0.39****	**-0.39****	0.21	**0.36****
%MRA	-0.08	0.07	0.04	**0.39****	**-0.29***	-0.20	-	0.59**	0.58**	0.01	-0.08	0.08	0.03	0.03
BM	-0.08	0.14	0.12	**0.39****	**-0.31****	**-0.24***	0.85**	-	0.47**	0.10	0.02	-0.16	0.01	0.02
% Upr	-0.07	-0.12	-0.05	0.21	0.02	0.03	0.65**	0.56**	-	-0.01	-0.05	0.05	0.03	0.06
WPF	**-0.56****	**0.58****	0.01	0.20	**-0.26***	**-0.34****	0.11	0.17	-0.01	-	0.73**	**0.42****	-0.10	**-0.29***
SF36PF	**-0.28****	**0.37****	0.02	**0.40****	**-0.35****	**-0.37****	0.13	0.14	-0.00	-0.64**	-	**0.31****	-0.13	**-0.29***
SF36M	-0.20	0.08	0.18	**0.32****	**-0.28***	**-0.25***	**0.26***	0.14	0.20	0.22	0.20	-	-0.37**	-0.54**
Anx.	**0.31****	-0.11	-0.19	-0.17	0.20	0.11	-0.18	-0.14	-0.08	-0.16	-0.06	-0.68**	-	0.37**
Depr.	**0.34****	-0.20	-0.14	-0.18	0.18	**0.23***	-0.20	-0.10	0.10	-0.22	-0.22	-0.67**	0.74**	

** Correlation is significant at the 0.01 level (2-tailed), * Correlation is significant at the 0.05 level (2-tailed). Abbreviations; 6MWT, six-minute walk test; STR, stair climbing; STS, sit-to-stand; %MRA, percentage of movement related activities; BM, body motility; %Upr, percentage of being upright; WPF, WOMAC physical functioning; SF36PF, SF-36 physical functioning; SF36M, SF-36 mental functioning; Anx, subscale anxiety of the Hospital Anxiety and Depression scale; Depr., subscale depression of the Hospital Anxiety and Depression scale.

Table 3 Strength of the correlations between the five domains. The strength of the change scores are shown in the upper-right section of the table, the cross-sectional data in the lower-left section.

	Body function	Capacity	Actual physical activity	Perceived physical functioning	Perceived mental functioning
Body function	-	6/9 (67%)	0/9 (0%)	4/6 (67%)	4/9 (44%)
Capacity	4/9 (44%)	-	0/9 (0%)	6/6 (100%)	6/9 (66%)
Actual physical activity	0/9 (0%)	5/9 (56%)	-	0/6 (0%)	0/9 (0%)
Perceived physical functioning	4/6 (67%)	5/6 (83%)	0/6 (0%)	-	4/6 (67%)
Perceived mental functioning	2/9 (22%)	4/9 (44%)	1/9 (11%)	0/6 (0%)	-

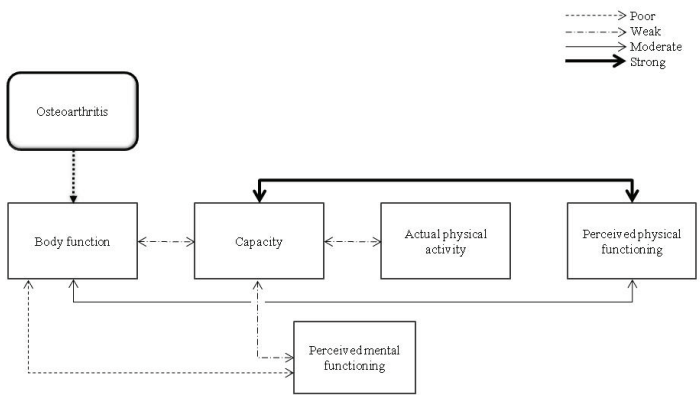

Figure 2 Relationships between cross-sectional data in the five domains.

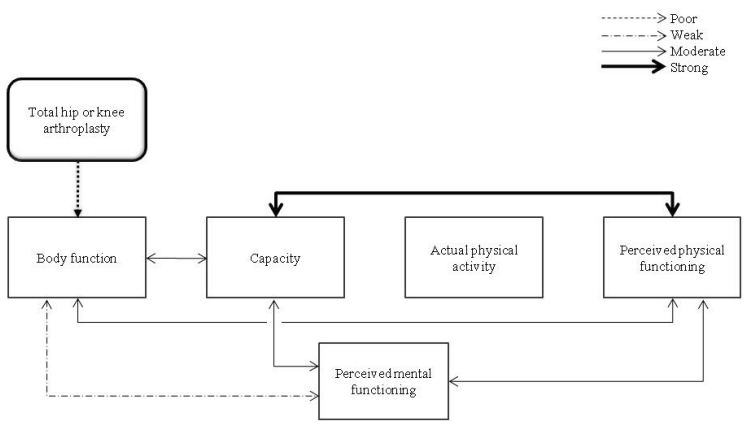

Figure 3 Relationships between change scores data in the five domains.

Before surgery, the strongest relationships were found between capacity and perceived physical functioning. The relationship between body function and perceived physical functioning was moderate, whereas the relationship between body function and perceived mental functioning was poor. Weak relationships were found between body function and capacity, and between capacity and actual physical activity. Change scores data after surgery showed largely the same pattern as before surgery, although the strength of some relationships was slightly different. Both in the cross-sectional data and the change scores data the capacity domain related most frequently to the other domains, and actual physical activity the least.

Discussion

The aim of the present study was to obtain insight into the relationships between the different domains of functioning in patients with OA of the hip or knee. Additionally, the effects of THA and TKA were studied. Both the cross-sectional data and change scores data showed relationships that significantly differed from those that we had expected. Capacity emerged as the central domain, with the strongest and highest number of relationships with other domains. In contrast, actual physical activity showed only one weak relationship. The emerging relationships also differed from what had been expected. We had assumed that the relationships between the different domains would be as expressed in Fig. 1, with the strongest relationships between domains close to each other; however, this was not confirmed in the present study. This indicates that the consequences of OA on functioning and the effects of THA and TKA are more complex than we had assumed. The relationships in the cross-sectional data compared with those in the change scores data were similar (Figs. 2 and 3).

In both data sets, capacity had a central position in the relationships between domains and also had a particularly strong relationship with perceived physical functioning. This might be explained by the fact that the ability to perform more activities, and perform them faster or more easily, leads to fewer perceived limitations. If improving perceived physical functioning would be the focus of treatment, this explanation would imply that improving patients' capacity should be of major interest in the treatment of hip and knee OA patients. Capacity was not only related to perceived physical functioning, but also to perceived mental functioning; this gives additional support to the importance of capacity. Because both perceived physical functioning and mental functioning are based on patients' perception, it can be argued that these domains are similar to each other. However, the absent or only moderate relationship between these domains does not reflect this. Only a moderate relationship was found between capacity and actual physical activity, and this only in the cross-sectional data. This can be partly explained by the fact that OA has a relatively small impact on actual physical activity and by the small effect of the surgery on actual physical activity[13]. This indicates that actual

physical activity is a type of independent domain, with results differing from those of the other domains. This independent nature is supported by the data of the current study.

The central position of capacity can also be explained from the perspective of load and load capacity. The balance between load and load capacity is a crucial factor in exercising, developing complaints, etc. Our capacity domain can be regarded as expressing load capacity, whereas the domain actual physical activity can be regarded as reflecting load. Generally, the ideal situation in daily life is to have a larger load capacity than load; however, the gap between them should not be too large because this would lead to an undesirable situation of underloading. When a person's capacity is lower than or close to their actual physical activity, this may be related to complaints of overload, such as pain, fatigue and experienced problems in physical functioning. Before surgery, at the group level capacity was lowered whereas the level of actual physical activity was found to be relatively high. This may indicate that this particular group tends to have a situation of overloading, resulting in pain, fatigue, experienced problems, etc. After surgery, capacity improves considerably with relatively small changes in actual physical activity, which may result in a better balance between load capacity and capacity, and less pain, less fatigue, etc.
From this perspective, not only capacity, but also the imbalance between capacity and actual physical activity, may be key factors when treating these patients. Improving capacity, by increasing muscle strength and functional training of (stair) walking and sit-to-stand movements, can lead to a better balance between capacity and actual physical activity. But the point of departure can also be the domain of actual activity: i.e. treatment can also focus on adapting the level of actual activity to the level of capacity. From this perspective, the recommendation of being as active as possible might not be effective for this patient group, and pain might be an indicator of the presence or absence of the balance between load and load capacity.

In the present study, body function was related to both capacity and perceived physical functioning. More detailed analysis showed, however, that these relationships depended on which aspect of body function was studied (Table 2). For example, pain and stiffness were more strongly related to perceived physical functioning, whereas strength showed the strongest relationships with capacity. Others have also reported higher correlations between pain and perceived physical functioning than between pain and capacity[6,7], and others have also described the factor strength as being different from the factors pain and stiffness[5,35]. However, in our change score data the relationship between body function and capacity was only found in the parameters pain and stiffness. Therefore, a significant reduction of pain and stiffness leads to better capacity.

Higher correlations were found within the individual domains than between the different domains. This was expected because each domain contains outcome measures that measure approximately the same aspect of physical functioning. Within a domain correlation coefficients should not be too high: in such a case outcome measures would actually be measuring the same aspect of physical functioning. Similarly, they should not be too low: in such a case they would be measuring a different aspect of physical functioning. The only parameter with low correlation coefficients within a domain was muscle strength: muscle strength did not correlate with the other parameters within the domain in either the cross-sectional or change scores data. Low correlations between the parameters strength and pain have been reported earlier[35]. However, muscle strength is clearly defined in the ICF domain function and, moreover, muscle strength is reported to be an essential parameter when treating OA patients[4]. Therefore, we decided to include muscle strength in this domain.

Some study limitations need to be addressed. One limitation concerns validity: were the appropriate outcome measures chosen and to what degree do they represent a specific domain? We carefully selected these outcome measures using an extensive procedure and based on recommendations reported in the literature. They had to be valid, reliable, and suitable for patients with OA of both the hip and knee; moreover, they had to fit into different domains. Therefore, we believe that we have selected the proper outcome measures per domain. The second limitation concerns the method of using several outcome measures per domain and looking for the number of significant relationships between all outcome measures. Although this method may be unconventional we feel that it is an adequate way to describe relationships, as also reported previously[31]. The third limitation is the inclusion in this study of both hip and knee patients; the number of patients was too small to separate them into two subgroups. Because some domain relationships might differ between hip and knee patients, it may be worthwhile to present a subgroup analysis. However, secondary analyses of our present data showed no significant difference in the patterns of relationships between the domains.

In summary, this study provides insight into how OA and THA and TKA affect the different ICF domains. Relationships weaker than expected were found between domains closer to each other, and relationships stronger than expected were found between domains with a greater distance between them. Comparison of the relationships in the cross-sectional data with those in the change scores data showed that they were largely the same. Capacity related the most frequently to the other domains, and actual physical activity the least. Our results suggest that capacity, or the imbalance between capacity and actual physical activity, are key factors when treating OA patients before and after surgery.

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Chapter 7

Patient satisfaction after a total hip or knee arthroplasty

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Submitted

Abstract

Objective: This prospective study investigated which patient-related determinants, expectations, and preoperative and postoperative determinants of functioning are related with patient satisfaction after total hip or knee arthroplasty.

Methods: 79 patients were extensively examined before and six months after surgery. This included three capacity tests, measurement of actual physical activity of patients by means of the Activity Monitor (48 hours measurement), physical examination and questionnaires.

Results and conclusion: 80% of the patients was very satisfied (62%) or moderately satisfied (18%). Patients with a better preoperative mental health (high versus low: 71% versus 45%) and those whom received a hip arthroplasty (hip versus knee: 77% versus 50%) were more often satisfied. Patients who were satisfied six months after surgery experienced less pain (0.1 versus 4.8) and less stiffness (70 versus 40). Those with a better mental health (high versus low: 75% versus 13%), and with fulfilled expectations (yes versus no: 86% versus 23%) were more often satisfied.

Introduction

Total hip and knee arthroplasties are relatively safe and cost-effective surgical interventions for patients with end-stage osteoarthritis (OA)[1,2]. Different types of outcomes can be used to evaluate total hip and knee arthroplasty. Many studies on health outcomes in total hip or knee arthroplasty have focused on measuring pain and functional status, whereas recently more attention has been given to patient satisfaction[3]. Knowledge on preoperative determinants that predict satisfaction after total hip or knee arthroplasty may support the selection of patients for surgery, as well as help to communicate reasonable expectations to patients. Knowledge on which postoperative determinants are associated with patient satisfaction is important to optimise patient care after total hip or knee arthroplasty. A few studies have explored patient satisfaction after total hip or knee arthroplasty[4-6] and reported that patient-related determinants, as well as expectations, are associated with patient satisfaction. However, those studies examined only a limited number of determinants.

Patients with OA and patients who received total hip or knee arthroplasty experience limitations in functioning. Functioning can be divided into different independent domains, which have been described by the International Classification of Functioning, Disability and Health (ICF)[7]. The domains of the ICF that are related to functioning are body function and structure (pain, stiffness and strength), capacity to perform activities, actual physical activity, self-reported physical functioning, and self-reported mental functioning[7,8].

The present study examines patient-related determinants, expectations, and determinants on all domains of functioning as outlined by the ICF. The determinants of functioning include capacity tests and measurement of the actual physical activity of patients by means of the Activity Monitor (AM)[9].

The first aim of this study was to determine which patient-related determinants, preoperative expectations, and preoperative determinants of functioning, best predict patient satisfaction after total hip or knee arthroplasty. The second aim was to determine which postoperative determinants of functioning are associated with patient satisfaction after total hip or knee arthroplasty, and whether fulfilled expectations have any influence on satisfaction.

Methods

For the present study we used the data of a prospective follow-up study in which we determined the recovery of physical functioning after total hip or knee replacement[8].

Patient selection

Patients with end-stage OA of the hip or knee, who were scheduled for a hip or knee replacement at the Erasmus University Medical Centre Rotterdam in the period April 2004 to May 2006, were eligible. Exclusion criteria for the study were: age >80 years, wheelchair-bound, not living independently, the presence of disorders other than OA that could affect the level of actual physical activity, living more than 1.5 hours away from the medical center, insufficient command of the Dutch language (spoken or written), the presence of OA in the contralateral hip or knee requiring surgery within 6 months, not willing to sign an informed consent, and unknown if the patient would remain available for the follow-up measurements.
The Medical Ethics Committee of the Erasmus MC approved the study and all patients signed an informed consent form. Patients underwent all measurements on average six weeks preoperatively and 6 months post-surgery.

Outcome

Six months after surgery, patient satisfaction with the result of the surgery was assessed. Response regarding satisfaction was graded on a 5-point Likert scale: very satisfied, moderately satisfied, neutral, moderately dissatisfied, and very dissatisfied. The responses were dichotomised into satisfied and dissatisfied. The highest response was classified as 'satisfied' and all other responses were classified as 'dissatisfied'.

Potential determinants of satisfaction

Preoperative subject-related characteristics

Preoperatively, the following subject-related characteristics were measured: gender, age, body mass index (BMI) and the type of arthroplasty (hip or knee).

Preoperative expectations

Preoperatively, questions about expectations of pain after surgery, expectations of limitations of activities of daily living after surgery, and expectations of the overall success of the operation were asked. Questions regarding patient expectations of pain and limitations were graded on a 4-point Likert scale: not at all painful/limited, slightly painful/limited, moderately painful/limited, and very painful/limited. Expectations regarding overall success were recorded on a Visual Analogue Scale (VAS) ranging from 0 to 10 (0 indicating no success and 10 indicating optimal success).
The responses were dichotomised into high versus low expectations according to Mahomed *et al.*[10]. For the questions regarding expectations about pain and limitations, the highest response level was classified as 'high expectations' and the other responses were classified as 'low expectations'. The responses to the questions on patient's expectations about the

overall success of the surgery were dichotomised by a VAS score > 9 of success as having 'high expectations', and other scores as 'low expectations'.

Functioning determinants according to the ICF

Body function and structure

The domain body function and structure was evaluated by the strength of the knee extensors, the experienced stiffness, and the intensity of the experienced pain. The strength of the knee extensors was measured bilaterally, with a Microfet hand-held dynamometer. The absolute strength of the affected side was used in the present study[11,12] . The expected stiffness was evaluated by the stiffness subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[13,14]. The intensity of the experienced pain was measured with a VAS; the 100-mm VAS is a uni-dimensional scale and is considered to be valid and reliable (0 indicating no experienced pain and 100 indicating the worst experienced pain)[15].

Capacity

Capacity was expressed by the performance tests walking, stair climbing, and sit-to-stand. The Six-Minutes Walk Test was performed to quantify walking ability[16,17]. It is a valid and inexpensive clinical tool that involves recording the distance participants cover while walking indoors at their own speed for 6 minutes. It has good test-retest reliability and has been used to measure the effectiveness of interventions in populations with hip or knee OA[16,17]. Patients were allowed to use walking aids. To assess stair climbing, we measured how long the patients took to ascend 5 steps, turn around, and descend[18]. The patients were allowed to use the stair railing. We also measured how long these patients took to perform 5 sit-to-stand movements. The patients were asked to perform this task as fast as possible[19]. The patients were allowed to use their arms while performing the 5 sit-to-stand movements.

Actual physical activity

Actual physical activity during normal life was measured objectively using an AM[20]. The AM, based on body-fixed accelerometers and a portable recorder (Rotterdam Activity Monitor based on Vitaport technology, Temec Instruments, Kerkrade, the Netherlands; size 15 x 9 x 3.5 cm, weight 500 g), has been extensively validated and used previously[9,21,22]. The AM data were collected for two days and then averaged. Three AM outcome measures were included in the present study: the percentage of time a patient was active (e.g. walking, cycling, climbing stairs, and general movement), the percentage of being upright per day (e.g. standing and walking), and the body motility value which can be regarded as being related to the overall level of physical activity during the measurement.

Self-reported physical functioning

The self-reported physical functioning was calculated using the 36-Item Short Form Health Survey (SF-36)[23] and the subscale physical functioning of the WOMAC[13,14]. The items of the SF-36 are categorized into 8 subscales, and from these subscales a physical and mental score was calculated. In this domain the physical summary score was used. The subscale physical functioning of the WOMAC was also used in this domain[13,14].

Self-reported mental functioning

Self-reported mental functioning was measured with the mental summary score of the SF-36[23] and the anxiety and depression subscales of the Hospital Anxiety and Depression Scale (HADS). The HADS is a self-administered rating scale which has a total of 14 items. These can be separated into two subscales (measuring anxiety and depression), each containing seven items. The individual items are each rated on a 4-point scale, scored from 0 to 3, resulting in maximum subscale scores of 21 and an overall distress score ranging from 0 to 42, with higher scores indicating greater levels of distress[24]. In this study we used the anxiety and depression subscales separately.

Patients were dichotomized into a group with a high versus those with a low self-reported mental health score measured with the SF-36. Those with a mental health score of beneath 60 were classified as low and patients with a score of 60 or higher were classified as high. This cutoff point was based on reference data of a healthy study population in the Netherlands with a mean of 77 and a standard deviation of 17[25]. We used the mean minus one standard deviation as cutoff point.

Fulfilled expectations

Six months after surgery patients were asked whether their expectations regarding the overall success of the surgery have been fulfilled. Responses of expectations that have been fulfilled were graded on a 4-point Likert: totally fulfilled, considerably fulfilled, slightly fulfilled, and not at all fulfilled. The responses were dichotomized into fulfilled and unfulfilled expectations. The highest response was classified as 'fulfilled expectations' and the other responses were classified as 'unfulfilled expectations'.

Statistical analysis

Statistical analyses were performed using SPSS 12.0 (SPSS Inc., Chicago, USA). First, it was established whether the variables had a normal distribution using the normality Kolmogorov-Smirnov test. Based on these analyses, the results are presented as means and standard deviations, or if not normally distributed as median and minimum-maximum.

To answer the questions which preoperative determinants predict satisfaction, and which postoperative determinants were associated with satisfaction, after a total hip or knee arthroplasty, logistic regression analyses were used to calculate odds ratios (OR). Satisfaction 6 months after a total hip or knee arthroplasty was used as dependent variable. The independent variables were gender, age, BMI, hip or knee arthroplasty, expectations, pain, stiffness, muscle strength, Six-Minutes Walk Test, stair rising, rising chair, movement-related activity, the percentage of being upright per day, the body motility value, self-reported physical functioning, mental health, anxiety, and depression.

For the univariate logistic regression analysis the 6-months postoperative determinants were adjusted for the baseline scores using analysis of covariance.

Because of the high number of determinants and the relatively low number of cases we chose to cluster the determinants per domain. This was done by including only the principal component (PC) with the largest *eigenvalue* for each domain in the analysis. The first PC is in sense the linear combination of the variables in a domain that is most representative of that domain[26]. The orientation of the first PCs was chosen in such a way that a high value means a higher chance of being satisfied. With these first PCs for each domain we performed multivariate, stepwise (backward) logistic regression.

In all analyses, a two-sided p-value of less than 0.05 was considered significant

Results

In the period April 2004 to May 2006, 174 patients were scheduled for a total joint replacement within 3 months and visited the outpatient clinic for the preoperative check-up. Of these 174 patients, 69 were excluded due to the exclusion criteria and 21 patients did not want to participate. Finally, 84 patients complied with the inclusion criteria and were willing to participate in this study. Baseline and follow-up data were available for 79 patients (35 hip OA and 44 knee OA patients); the only difference between hip OA patients and knee OA patients was for BMI (p = <0.0001) (Table 1).

Table 1 Baseline characteristics of the study population.

	Total study population n = 79	**Hip OA group n = 35**	**Knee OA group n = 44**	**P-Value**
Gender, % women (n)	59.5 (47)	65.7 (23)	54.5 (24)	0.315
Age at baseline, years	62.0 ± 11.2	61.9 ± 12.8	62.1 ± 9.9	0.920
BMI at baseline, kg/m2	29.6 ± 5.5	26.6 ± 4.3	32.1 ± 5.3	<0.0001

* Values are presented as mean ± standard deviation, unless otherwise indicated. Abbreviation: OA, osteoarthritis; BMI, Body Mass Index

Six months post-surgery, 62.0% of the patients was very satisfied, 17.7% was moderately satisfied, 8.9% was neutral, 7.6% was moderately dissatisfied, and 3.8% was very dissatisfied with the results of the surgery.

Table 2 presents the univariate associations between preoperative determinants and satisfaction after a total hip or knee arthroplasty 6 months post-surgery. Patients with a higher mental health score (more optimistic patients) measured with the SF-36 at baseline have a significantly higher chance to be satisfied 6 months post-surgery (OR 1.04; 95% confidence

Table 2 Baseline determinants associated with satisfaction six months post-surgery.

Determinants	Satisfied n = 49 (62%)	Dissatisfied n = 30 (38%)	OR (95% CI)	P-Value
Subject-related characteristics				
Gender, % women (n)	63 (31)	53 (16)	1.51 (0.60; 3.79)	0.384
Age, years	61.0 (42;78)	63.5 (27;78)	1.01 (0.97; 1.05)	0.819
BMI, kg/m^2	27.9 (18.4;40.8)	29.0 (20.6;44.9)	1.06 (0.98; 1.16)	0.147
Arthroplasty, % hip (n)	**55 (27)**	**27 (8)**	**3.38 (1.26; 9.04)**	**0.016**
Expectations				
Expectations of pain, % high (n)	**19 (9)**	**11 (3)**	1.85 (0.45; 7.50)	0.391
Expectations of limitations of daily living, % high (n)	22 (11)	13 (4)	1.88 (0.54; 6.56)	0.321
Expectations of overall success of the operation, % high (n)	57 (28)	47 (14)	1.52 (0.61; 3.80)	0.366
Body function and structure				
Strength, Newton	165 (17;323)	173 (53;298.5)	1.00 (0.99; 1.01)	0.448
WOMAC Stiffness	30 (0;80)	30 (0;80)	1.00 (0.97; 1.03)	0.989
Pain (VAS)	6.9 (1.7;10)	6.8 (0.2;10)	0.94 (0.76; 1.16)	0.538
Capacity				
6-MWT (m)	300 (59;499)	268 (48;523)	1.00 (1.00; 1.01)	0.737
STR (s)	10.2 (5.9;28.0)	10.6 (5.3;28.6)	1.03 (0.95; 1.11)	0.463
Rising chair (s)	18.5 (8.9;35.7)	17.3 (7.7;34.3)	0.96 (0.89; 1.04)	0.326
Actual physical activity				
Movement-related activity, %	7.7 (2.2;17.8)	7.3 (2.7;17.3)	1.01 (0.90; 1.14)	0.817
Upright, %	18.9 (7.3; 37.2)	21.3 (6.2; 32.7)	1.01 (0.94; 1.07)	0.833
Body motility, g	0.1391 (0.10; 0.23)	0.1347 (0.11; 0.18)	2.97 (0.00; 9.0*10^8)	0.913
Self-reported physical functioning				
WOMAC PF	32.9 (9.4;62.4)	32.9 (9.4;63.5)	1.01 (0.97; 1.05)	0.574
SF-36PF	35 (0;80)	30 (0;80)	1.00 (0.98; 1.02)	0.961
Self-reported mental functioning				
SF-36 MH	**80 (28;100)**	**60 (16;96)**	**1.04 (1.01; 1.07)**	**0.005**
HADS anxiety	**4 (0;12)**	**7 (0; 17)**	**1.22 (1.07; 1.40)**	**0.004**
HADS depression	**4 (0; 14)**	**7 (1; 19)**	**1.17 (1.03; 1.32)**	**0.013**

Univariate logistic regression analysis was used. The significant determinants are highlighted in bold. Values are presented by median (minimum; maximum), unless otherwise indicated. Abbreviations; OR, Odds Ratio; CI, Confidence Interval; BMI, Body Mass Index; 6-MWT, six-minute walk test; m, meters; STR, stair climbing; s, seconds; g, 1 g= 9.81 m/s^2; PF; physical functioning; MH, mental functioning

interval (CI) 1.01; 1.07). In other words, patients with a 10-point higher mental health score at baseline have a 10-fold higher chance to be satisfied after this surgery compared with the lowest score. Patients with less anxiety and depression measured with the HADS have a significantly higher chance to be satisfied 6 months post-surgery (OR 1.21; 95% CI 1.07; 1.40 and

Table 3 Postoperative determinants associated with satisfaction six months post-surgery.

Determinants	Satisfied n = 49 (62%)	Dissatisfied n = 30 (38%)	OR (95% CI)	P-Value
Body function and structure				
Strength, Newton	210 (98; 307)	195 (106; 293)	1.01 (1.00; 1.02)	0.191
WOMAC Stiffness	**70 (20; 80)**	**40 (0; 80)**	**1.09 (1.05; 1.13)**	**<0.0001**
Pain (VAS)	**0.1 (0; 3.2)**	**4.8 (0.1; 9.4)**	**3.94 (1.90; 8.20)**	**<0.0001**
Capacity				
6-MWT (m)	**406.3 (153; 580)**	**356.3 (133; 499)**	**1.01 (1.00; 1.02)**	**0.003**
STR (s)	**7.3 (4.3; 18.0)**	**9.1 (4.6; 22.8)**	**1.25 (1.07; 1.46)**	**0.006**
Rising chair (s)	**14.1 (7.7; 22.6)**	**16.9 (5.1; 32.5)**	**1.16 (1.03; 1.32)**	**0.019**
Actual physical activity				
Movement-related activity, %	8.4 (3.2; 22.7)	9.3 (2.8; 18.8)	1.01 (0.90; 1.14)	0.833
Upright, %	20.5 (13.04; 43.40)	19.2 (7.2; 30.2)	1.08 (0.99; 1.17)	0.094
Body motility, g	0.1442 (0.08; 0.21)	0.1445 (0.07; 0.19)	354.97 (0.00; $1.4^{*}10^{10}$)	0.511
Self-reported physical functioning				
WOMAC PF	**74.1 (21.2; 80)**	**45.9 (5.9; 74.1)**	**1.14 (1.07; 1.21)**	**<0.0001**
SF-36PF	**77.5 (20; 100)**	**40.0 (10; 90)**	**1.06 (1.03; 1.10)**	**<0.0001**
Self-reported mental functioning				
SF-36 MH	**92 (36; 100)**	**62 (20; 96)**	**1.08 (1.04; 1.11)**	**<0.0001**
HADS anxiety	**1 (0; 12)**	**6 (0; 14)**	**1.33 (1.14; 1.54)**	**<0.0001**
HADS depression	**1 (0; 9)**	**6 (1; 13)**	**1.53 (1.24; 1.89)**	**<0.0001**
Fulfilled expectations				
Totally, % (number)	**86 (42)**	**23 (7)**	**19.71 (6.15; 63.17)**	**<0.001**

Univariate logistic regression analysis was used. The six-month postoperative determinants were adjusted for the baseline scores using analysis of covariance. The significant determinants are highlighted in bold. Values are presented as median (minimum; maximum), unless otherwise indicated. Abbreviations; OR, Odds Ratio; CI, Confidence Interval; 6-MWT, six-minute walk test; m, meters; STR, stair climbing; s, seconds; g, 1 g= 9.81 m/s^2; PF; physical functioning; MH, mental functioning.

Table 4 Associations between clustered domains and satisfaction six months post-surgery.

	Univariate		Multivariate	
	OR (95% CI)	P-Value	OR (95% CI)	P-Value
Body function and structure	45.64 (8.25; 252.38)	<0.0001	14.96 (2.70; 82.96)	<0.0001
Capacity	2.31 (1.34; 4.00)	0.003	n.s.	n.s.
Self-reported physical functioning	6.40 (2.88; 14.21)	<0.0001	n.s.	n.s.
Self-reported mental functioning	4.58 (2.22; 9.44)	<0.0001	**3.12 (0.98; 9.92)**	**0.044**
Fulfilled expectations	19.71 (6.15; 63.17)	<0.0001	**7.98 (1.06; 59.96)**	**0.037**

For multivariate regression analysis only data of the domains with an independent association with satisfaction are presented. For the multivariate regression analysis only the data of the significant determinants are presented. Abbreviations; OR, Odds Ratio; CI, Confidence Interval; n.s. not significant.

OR 1.17; 95% CI 1.03; 1.32). Patient who receive a total hip arthroplasty have a more than three times higher chance to be satisfied 6 months post-surgery than patients who receive a total knee arthroplasty (OR 3.38; 95% CI 1.26; 9.04).
In a multivariate regression analysis both a higher score on the SF-36 mental health (OR 1.04; 95% CI 1.01; 1.07) and the type of arthroplasty (hip compared to knee) (OR 3.65; 95% CI 1.24; 10.79) have an independent association with satisfaction after a hip or knee arthroplasty 6 months post-surgery. Of the patients with a high self-reported mental health score were 71% satisfied compared to 45% of the patients with a low preoperative self-reported mental health score. Of those who received a hip arthroplasty was 77% satisfied compared to 50% of the patients who received a knee arthroplasty.

Table 3 presents the associations between the 6-month postoperative determinants and satisfaction after total hip or knee arthroplasty 6 months post-surgery. All postoperative determinants were adjusted for their baseline values by analysis of covariance; this revealed that determinants on all domains (except on the domain actual physical activity) had a significant association with satisfaction. Because many postoperative determinants appeared to be associated with satisfaction, the determinants were clustered per domain. Then, with these clustered components a multivariate regression analysis was performed (Table 4). This showed that a better score on the domain body function and structure (less pain and stiffness) (OR 14.96; 95% CI 2.70; 82.96), a better self- reported mental functioning (OR 3.12; 95% CI 0.98; 9.92), and fulfilled expectations (OR 7.98; 95% CI 1.06; 59.96), had an independent association with satisfaction after total hip or knee arthroplasty. Patients who were satisfied six months after surgery experienced less pain (0.1 versus 4.8) and less stiffness (70 versus 40) compared to those who were not satisfied. Those with a better mental health (high versus low score: 75% versus 13%), and with fulfilled expectations (yes versus no: 86% versus 23%) were more often satisfied.

Discussion

The aim of this study was to examine which preoperative determinants predicted patient satisfaction 6 months post-surgery, and to examine which postoperative determinants were associated with patient satisfaction 6 months post-surgery.
In our study, 88.5% of the hip patients was either very satisfied or moderately satisfied (77.1% and 11.4%, respectively); similar results were found by Mancuso *et al*., i.e. an overall satisfaction rate of 89% after total hip arthroplasty[4]. We also found that 72.7% of the knee patients was either very satisfied or moderately satisfied (50% and 22.7%, respectively); Noble *et al*. reported similar results, i.e. 75% of their patients was very satisfied (57%) or satisfied (18%) after knee replacement[5].

In this follow-up study, we found that a better mental health and the type of arthroplasty (hip or knee) predicted patient satisfaction 6 months post-surgery. Postoperatively, patient satisfaction was associated with a better body function and structure (less pain and stiffness), a better-self reported mental function, and fulfilled expectations 6 months post-surgery. The level of actual physical activity of patients had no association with patient satisfaction 6 months after total hip or knee arthroplasty.

The results of our study suggest that it is useful to measure the preoperative mental health score of patients. Special attention should be paid to patients with a poor mental health (anxiety and depression), because these patients appear to have a greater risk of being dissatisfied with the final results. Because fulfilled expectations were associated with patient satisfaction 6 months after total hip or knee arthroplasty, patients should be extensively informed about the expected results of hip or knee replacement. Caregivers should help patients arrive at reasonable expectations. Patients scheduled to undergo total knee arthroplasty should perhaps receive even more information, because they have a higher chance of being dissatisfied than patients who receive total hip arthroplasty.

The primary goal of total hip or knee arthroplasty is to reduce pain and stiffness. Postoperatively, the two most important determinants of patient satisfaction proved to be pain and stiffness. This means that the patient's satisfaction depends to a large extent on these aspects of the total hip or knee arthroplasty. The satisfaction of patients who experience pain and stiffness after this type of surgery can be increased by treatment with pain medication or physiotherapy. Another option is to increase the capacity (what a patient can do) of these patients, as indicated by an earlier study from our group[27]. In the present study, capacity had no direct independent relationship with patient satisfaction. However, we previously found that capacity does have a relationship with perceived mental functioning; therefore, increasing the capacity of patients after total hip or knee arthroplasty may lead to higher perceived mental health, which may lead to higher patient satisfaction.

The determinants in the present study found to be associated with patient satisfaction were similar to those in other studies reporting that less postoperative pain and stiffness[6] and better fulfilled expectations[4,5] were associated with patient satisfaction after total joint arthroplasty.

In contrast to our study, Mancuso *et al.*[4,5] found no difference in patient satisfaction after total hip arthroplasty between patients with a high mental health score on the SF-20 and patients with a low mental health score. Furthermore, in contrast to our study, they found that preoperative expectations were related to satisfaction after total hip arthroplasty. However, they asked patients about their preoperative expectations 2 to 3 years after surgery[4,5]; this retrospective design may have led to a recall bias regarding the preoperative expectations.

The present study has some strengths and limitations. One strength is its prospective design; we included information on both preoperative and postoperative determinants associated

with patient satisfaction after total hip or knee arthroplasty. Furthermore, we extensively examined determinants in all domains of the ICF, including capacity tests and the domain actual physical activity. Therefore, our study is unique regarding the determinants of patient satisfaction after total hip or knee arthroplasty.

On the other hand, because the study population was relatively small it was not possible to separate the analysis for hip and knee patients. The question then arises whether the determinants associated with satisfaction are different for hip and knee arthroplasty. However, when we examined the data for hip and knee patients separately this showed that the determinants associated with satisfaction were similar. However, these results should be interpreted with caution because of the relatively small numbers in both groups; for this reason these particular data are not presented. Future research should examine separately the determinants of satisfaction after both total hip and knee arthroplasty, in a prospective study with a larger study population.

Another point is that we had a relatively short follow-up period of 6 months. On the other hand, similar patient satisfaction rates after total hip and knee arthroplasty were reported by comparable studies with a longer follow-up period[4,5].

Finally, all patients were included at an university hospital. Besides patients with an age of 80 years or older, patients who were wheel-chair bound, patients who were not living independently, patients with the presence of OA in the contralateral hip or knee requiring surgery within six months, and patients with the presence of disorders other than OA that could affect the level of physical activity were excluded. These inclusion criteria may have hampered the representativeness of our study sample.

In conclusion, this study shows that patients with a better preoperative mental health and patients who will receive a hip replacement are more often satisfied with the results of the surgery 6 months post-surgery. Postoperatively, patients who were satisfied had less pain and less stiffness compared to those who were not satisfied. Patients with a better postoperative self-reported mental function and fulfilled expectations, were more often satisfied with the results of the surgery.

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Chapter 8

General discussion

Introduction

This thesis focuses on a patient's functioning before and after total hip arthroplasty (THA) or total knee arthroplasty (TKA). We approached this functioning from the perspective of the International Classification of Functioning, Disability and Health (ICF), with its different domains of functioning. In our studies, the ICF domain 'activities' had a central position with its subdomains 'capacity' (i.e. personal abilities, such as the distance a person can walk) and 'actual performance'(i.e. personal accomplishments, such as the distance a person actually walks). Items within the domain of activities can be measured using subjective or objective outcome measures.

The first part of the thesis addresses the subjective outcome measures based on the opinion of the patient. The studies include validation of the Dutch Hip disability and Osteoarthritis Outcome score (HOOS) and the Knee injury and Osteoarthritis Outcome Score (KOOS), both of which are extended versions of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (**Chapters 2 and 3**).

The second part of the thesis addresses objectively measured aspects of actual performance. The impact of osteoarthritis (OA) on a patient's actual performance and other aspects of functioning are compared with a group of healthy controls (**Chapter 4**). Also, the effect of a total joint arthroplasty of hip or knee on the different domains of functioning, including the level of actual performance, is evaluated (**Chapter 5**). In addition, we explored the relationships between these different domains (**Chapter 6**).

In the third part of this thesis we investigated which determinants predict patient satisfaction and which determinants are related to patient satisfaction after surgery (**Chapter 7**).

Validation of the Dutch versions of the HOOS and the KOOS

The first part of the thesis focuses on the validity of self-reported outcome measures. The WOMAC is considered the instrument of choice to evaluate the outcome of osteoarthritis and total hip or knee arthroplasty[1]. In order to improve its validity, the WOMAC has been extended: researchers in Sweden have developed the HOOS[2] and the KOOS[3]. This extended version includes, for example, dimensions concerning sport and recreation (Sport/Rec) and hip or knee-related quality of life (QoL). The Swedish versions of the HOOS and KOOS have been validated for patients with OA of hip or knee assigned for THA or TKA; these proved to be internally consistent and the test-retest reliability was sufficient. The extra items in the HOOS and KOOS were found to be relevant for younger and more active individuals with OA as well as for older patients with OA. As a result the validity has improved compared with the original WOMAC[3].

At the start of our study only the Swedish version was available; therefore, the original questionnaires were translated into Dutch for use in the Netherlands. Patrick *et al*. reported that a translation of a questionnaire into a new language and culture has to be considered as a

modified instrument[4]. It is therefore recommended to verify basic measurement properties of the translated version, such as distribution of responses, internal consistency, as well as test-retest reliability and validity[4].
In our HOOS study (chapter 2) the Dutch version was validated for OA and THA patients. The clinimetric properties of this version were similar to those of the Swedish version[2] and we conclude that the Dutch version of the HOOS is a valuable tool for use in hip OA and THA patients. The clinimetric results of the KOOS study were, however, more ambiguous (chapter 3): the clinimetric properties varied between the subgroups.

The construct validity was low for the severe OA patients and for revision TKA patients. An explanation for the lower construct validity in these subgroups may be that part of the hypothesis for our validity testing study was based on the assumption that pain and function are different constructs. However, analyses showed that pain and function subscales in fact loaded on the same factor, indicating that they measure the same construct. The function scale appears to measure not only function, but also pain or a combination of pain and function. When loading on the same factor, items should be in the same subscale. However, from a conceptual viewpoint it is preferable to keep these items in two different subscales in order to report the impact of a disease or its treatment on these aspects separately and thus help clinicians identify treatment goals. However, it is sometimes difficult for patients to separate questions about pain and function; this was noted particularly for those suffering from severe pain[5]. This applies not only to severe knee OA patients, but also to hip patients. Difficulty in separating pain and function may be due to the formulation of the questions. In the questionnaire the word 'difficulty' is used (in Dutch: '*moeite*'), which may not be clear to all patients. For example, they may interpret this as the time to complete the task, or as perceived pain and exertion. In contrast, the questions of the SF-36 physical functioning subscale ask about limitations with the performance of activities, which may be interpreted more specifically as the ability to complete the tasks. The meaning of the word 'difficulty' should therefore be clarified, or the question should be re-formulated. Stratford *et al*. and Terwee *et al*. also reported these problems with the factor structure of WOMAC and suggested to re-formulate some of the questions[5,6]. Future studies should explore ways to improve the validity of these subscales by adapting the question format.
In addition, the order in which the questions appear may also affect the validity of the questionnaire. In the HOOS and KOOS, the pain items are placed before the functioning items, which may trigger patients to think about pain when answering questions about physical functioning. It would be interesting to examine whether the physical functioning scores of the WOMAC would be different if the pain items were placed after the function items instead of before them. This was also suggested by Terwee *et al*. in their aim to improve the validity of the WOMAC[5].

The percentage of confirmed hypotheses depends on the number and formulation of the hypotheses. Although Terwee *et al*. provide universal guidelines concerning the magnitude and direction of correlations, there is no consensus about a universal number of hypotheses[7]. Due to the lack of a validated Dutch knee-specific questionnaire we were unable to assess the construct validity against such a questionnaire. Hypotheses concerning the correlations between subscales of the KOOS and a knee-specific questionnaire might have influenced our percentage of confirmed hypotheses and consequently the conclusion on construct validity. Moreover, there is no consensus concerning how the hypotheses should be formulated.

Another factor related to validity is the sample size. Sample sizes for quantitative analyses should be large enough to meet a desired level of measurement precision or standard error. Although there are no guidelines about the sample sizes, requirements for the assessment of reliability and validity depend on the specific circumstances; a range between 40 and 200 cases has been reported[8]. Our sample sizes are comparable to those commonly used in validation studies. However, so far, no publication has presented confidence intervals around the correlations. This should be considered in future studies in order to provide more insight into the precision of the results. For the implementation of factor analysis, however, recommendations are made regarding the sample size. Frost *et al*. recommend at least 5 cases per variable and a minimum of 300 cases, while Streiner *et al*. recommend 5 cases per variable and a minimum of 100 cases[8,9]. Due to these requirements, in our sample it was not possible to perform the factor analysis on the separate patient groups. Therefore, factor analysis was performed on the entire knee patient group in the validation study of the KOOS questionnaire. This warrants larger validation studies of the Dutch versions in order to ratify the results, which may provide more evidence for the results followed by a greater confidence in the value of the data.

Another aspect studied was the floor and ceiling effects. Only the KOOS questionnaire showed floor and ceiling effects. Ceiling effects were only perceived in the mild knee OA patient group for the subscales Pain, Symptoms and ADL. The presence of these ceiling effects can be explained by the fact that these knee patients have few complaints. The summed subscales of Sport/Rec and QoL did not show floor and/or ceiling effects in this patient group. Floor effects were only found in the subscale Sport/Rec for patients with severe OA and after revision of TKA. Roos *et al*. stated that questions on sport and recreation are also relevant for older patients[3]; however, this may not apply to patients after revision of TKA, as these older patients probably do not participate in sports. Therefore, it is suggested to use the WOMAC for this group, as the WOMAC does not include questions on sports. Utilizing the WOMAC in revision TKA patients has also recently been endorsed by Mullhall *et al*.[10].

Despite the ambiguous results of the KOOS study, the question remains whether we have to conclude that the KOOS cannot be used in all knee OA patients. In contrast to our study, other validity studies on the KOOS reported good construct validity[3,11,12]. Closer examination of these studies showed, however, that whereas the results are similar, the conclusions are different. Our study was based on predefined hypotheses, and our assessment criteria might have been stricter than those e used in the other studies. However, without specific hypotheses there is a risk of bias because retrospectively it is tempting to generate alternative explanations for low correlations, instead of concluding that the questionnaire may not be valid. We are therefore convinced that the method we used in both our validation studies was appropriate. Additionally, validation is an ongoing process and to fully validate an outcome instrument it has to be performed over time in different settings[13]. Because the Dutch version of the WOMAC has not been validated in (severe) knee OA patients we recommend to use the KOOS instead of the WOMAC in this patient group. Our findings will have to be confirmed by other studies evaluating other sub-populations, for example, men and women, the young and the elderly.

Recommendations for future research

Based on our findings, several recommendations for future research can be made. A measurement tool is mostly used to monitor the efficacy of an intervention or process of a disease. Therefore, the tool needs to be sensitive in detecting clinically relevant changes over a certain period. In other words, it must be responsive. So far, we have not assessed the responsiveness of the Dutch version of the HOOS and KOOS and this still needs to be evaluated. Such a study is currently being carried out at the Erasmus MC.

The KOOS questionnaire was not developed only for OA patients and patients with a TKA, it was also intended for use in patients with an anterior cruciate ligament reconstruction or menisectomy. However, the Dutch version of the KOOS has not been validated in these latter patients and, because they differ substantially from OA patients, clinimetric properties should be examined in these groups.

Furthermore, construct validity of the Dutch version of the KOOS questionnaire was determined by comparing the constructs with a VAS scale and a generic questionnaire (SF-36). However, it is suggested to include a knee-specific questionnaire which, due to the absence of such a questionnaire, was not possible at the start of our study. Meanwhile, this questionnaire has since become available; i.e. the Dutch Oxford 12-item knee questionnaire, which is a valid and reliable questionnaire in patients with OA of the knee[14]. Therefore, in future validation studies of the Dutch version of the KOOS questionnaire we recommend the use of the Dutch Oxford 12-item knee questionnaire.

Recovery from total hip or knee arthroplasty

The second part of the thesis addresses the functional effects of hip or knee OA and hip or knee arthroplasty, with special focus on the actual physical performance of a patient as objectively measured. An important finding of our study was that patients with hip and knee OA were less active than healthy control subjects (Chapter 4). The difference was, however, less than expected based on patients' reports that they limit their level of actual physical activity to avoid pain. We assume that patients try to keep their actual activity level as high as possible, despite the hindering factors of pain and discomfort. Because of the relatively small effect on actual movement behaviour, we did not expect a large impact of surgery on the patient's movement behaviour. Our effect study (Chaper 5) showed that the influence of the surgery on the actual physical activity was indeed rather small. The effect on other aspects of physical functioning (such as patients' function, their capacity to perform activities, and perceived physical functioning) was larger than the effects on actual performance. These results suggest that after surgery patients perform more-or-less the same activities, but with less pain and less perceived limitations than before. However, after surgery patients are still less active than healthy controls. Perhaps a longer follow-up period is necessary for patients to adapt their movement behavior to their new situation. Many patients had suffered from OA for many years and had adapted their lifestyle to the limitations caused by the disease.

The effect of OA and surgery on the actual physical activity (Chapters 4 and 5) was the same for hip and knee patients both before and after surgery. However, the type of surgery had an impact on other aspects of physical functioning. For example, 3 months after surgery the THA patients experienced a larger reduction in pain and stiffness than TKA patients, and 6 months after surgery THA patients showed a larger improvement in the 'rising from a chair' capacity test and the self-reported improvement in physical functioning. It is frequently reported that the effect of a THA on pain and physical functioning is greater than the effect of a TKA[15,16]. However, the results of our study indicate that THA does not lead to a greater improvement in actual physical activity than TKA.

In Chapter 6 we studied the relationships between the different ICF domains. It was found that capacity was most frequently related to the other domains. This implies that the patient's capacity might be of major interest in the treatment of hip and knee OA patients. However, it must be noted that capacity literally had a central position in our model, which partly explains its many relationships. The relationships found between capacity and the other domains suggest that the ability to perform more activities, and perform them faster or more easily, may result in fewer self-reported physical and mental limitations. The relationship between capacity and actual physical activity was weaker than expected, which indicates that what a patient 'can do' is not automatically related to what he/she actually does. The difference between capacity and actual physical activity is also obvious in the longitudinal data: after surgery, capacity improved considerably with relatively small changes in actual physical activity. This gap between capacity and actual physical activity is

expected to be related to complaints of overload. The surgery may have resulted in a better balance between capacity and actual physical activity, with less pain, less fatigue, etc. Thus, we believe that not only capacity, but also the balance between capacity and actual physical activity, are important when treating these patients.
When placing the results of our research in a broader perspective, they seem to concur with the capability theory of Amartya Sen[17]. This theory is from the field of microeconomics and its focus is on capabilities, which refers to things a person can achieve or could have achieved in life. The central idea is that capability is essential for a feeling of freedom. This theory may partly explain the central role of a patient's capacity in the present study. When a patient is able to walk for a longer period and for a longer distance after surgery, this opens up additional possibilities. For example, visiting a zoo or a museum becomes possible again; the mere fact that the person has the possibility to do it (even without actually doing it) provides a better quality of life and better physical functioning.

Overall, our results show that the impact of OA and the effect of surgery on physical functioning vary from aspect to aspect. Clinicians must be aware that the patient's perception of physical functioning and their experienced limitations in daily life do not always correspond to the patient's actual physical activity. Moreover, they should be aware that postoperative evaluation is dependent upon which aspect is being measured.

If the clinician or investigator is interested in actual physical activity, both subjective and objective techniques are available. Observation, questionnaires and diaries are examples of subjective techniques, whereas physiological markers and activity monitors are examples of objective techniques. Several types of activity monitors can be distinguished, including pedometers, actometers, gait analyzers, and posture & movement monitors. Each device has its own advantages and disadvantages and measures specific aspects of actual performance. For example: pedometers are inexpensive, easy to use, and may be suitable for measuring quantitative assessment of walking performance in both small and larger outcome studies[18]. Nonetheless, OA and a total THA or TKA influence not only the walking ability of these patients, but also other motions (such as climbing stairs and cycling) and postures (such as standing and sitting), and movements between postures (like the sit-to-stand movements). Additionally, OA will also affect the way people perform (e.g. walking speed, symmetry, etc). These aspects of actual performance can be assessed with a 'posture & movement' monitor such as the AM, which we used in the present study. However, because the AM is expensive, burdensome and labour-intensive it is less suitable for larger population studies. Which device should be used depends on several factors, such as type of application, aim of the study, budget availability and number of subjects.

Patient satisfaction

The third part of the thesis addressed another important outcome of the surgery: that of patient satisfaction. High satisfaction rates emerged, that were similar to those reported by others[19,20]. We also searched for factors which influence patient satisfaction and found that patient's mental functioning before surgery correlate with patient satisfaction 6 months after the operation. After surgery not only mental functioning, but also body function and fulfilled expectations, correlated with patient satisfaction. The actual physical activity before and after surgery had no association with patient satisfaction 6 months after THA or TKA and, therefore, seems a less important factor for patient satisfaction in this group.

Recommendations for actual physical performance

It is important to be physically active; especially in the older population those who are physically active enjoy a better quality of life and are better able to perform daily activities independently[21]. Additionally, a physically active lifestyle is important for general health; e.g. performing activities helps to diminish obesity and helps prevent health problems. Currently, two guidelines give recommendations on the amount of physical activities needed daily to remain healthy. According to the Dutch and International Standard for Healthy Exercise, adults need to be moderately active for 30 minutes for at least 5 days of the week to develop and maintain cardio-respiratory and muscular fitness, and flexibility[22,23]. Examples of moderate activities are walking 3-4 km/h and cycling 10 km/h. These activities do not need to be carried out for 30 minutes successively; it is also allowed to do the activities in 3 periods of 10 minutes. The AM is able to detect movements such as walking and cycling, but at this moment cannot classify the intensity of activities in terms of low, moderate and high. However, the AM is potentially able to provide data on intensity, based on the accelerometer signals and/or the heart rate; this might be an interesting development for future studies.

Another popular guideline is the 10,000 steps per day norm[24-26], although the value of this guideline is debated by some. Bohannon *et al*. recently showed with a meta-analytic approach that the number of daily steps taken by healthy adults is less than the recommended 10,000 steps and that it is especially low in adults 65 years or older: their daily count step averaged 6,565[27]. However, even compared with this less strict norm, unpublished data on the number of steps in our study indicated (as already suggested) that the groups in our study tended to be hypo-active. Both before and after the operation patients were able to perform 4,080 to 4,457 steps a day, while the healthy controls made an average of 5,352 steps per day.

In summary, before surgery the actual physical activity level of OA patients was lower compared to controls, although the difference was less than expected. The effect of the surgery on patients' actual activity level was small; even after surgery OA patients tend to be hypo-active to some degree. As a consequence, patients' general health may be negatively influenced and a substantial number of people may be 'at risk'. From this perspective, stimulation of actual activity might be recommended in hip and knee OA patients, both

before and after surgery. However, the balance between activity and capacity must be kept in mind. Although we have made a first step in our study, we feel that future studies should further elucidate the determinants of the level of physical activity in OA patients, both before and after surgery.

Another treatment to encourage patients to be more physically active is the Behavioral Graded Activity (BGA). The aim of BGA is for the patients to attain a more active lifestyle (e.g. through walking or cycling) and integrate these activities into the ADL[28]. A BGA program was found to result in beneficial long-term outcomes, but the outcome was not superior to usual care. However, BGA was more effective in people who are restricted in their movements and have a relatively low level of physical functioning[28].

We have presented our results at group level; however, there are also individual differences. In our study population we found that a small proportion of the patients was extremely hypo-active compared to controls; 18% hip OA patients and 22% of the knee OA patients were very hypo-active versus 3% of the controls. BGA might be effective in these hypo-active patients. However, not all patients tend to avoid physical activities. Some patients are too active and need to be slowed down and regulated in their activities. In our study, 8% of the hip OA and 3% of the knee OA patients were extremely hyperactive compared with 5% in the controls. Thus it seems that the two groups of patients need a different treatment approach. Measurements with the AM could be used to select patients for an individually-tailored treatment.

Limitations of the study

Methodological and practical issues

Because actual performance is a separate and important aspect of functioning, instruments such as the AM can be considered relevant in descriptive, explorative and evaluative studies. Nonetheless, there are some practical and methodological issues. Because the person actually wears the device, it might hamper them from performing their regular activities (such as sports), and the activity pattern of the person may be influenced by being aware that they are being monitored. Secondly, seasonal factors may influence the patient's activity pattern; however, in our studies this was not applicable since our patients were recruited over a period of more than two years. Thirdly, in our studies the AM was used during two days, while it has been suggested that at least four days of activity monitoring are needed to characterize an individual's habitual physical activity pattern[29]. However, we used the AM in a group study, and in other group studies based on 48-hour measurements the AM was adequate to show the effectiveness of a treatment and/or differences between a patient group and control group[30,31]. Fourthly, a cohort study is liable to selection bias. Our inclusion and exclusion criteria ensured that this research does not concern all OA patients; therefore it

is not appropriate to generalize our results to the whole OA population. Some patients met the inclusion and exclusion criteria but nevertheless did not participate in the study (n=21); reasons for not participating were: 'not in the mood', 'no time', 'the research is too much of a burden', and 'bad experiences with participating in research in the past'. Unfortunately we did not register any data on the non-participants and therefore do not know whether the participants differed significantly from the non-participants. Finally, the current AM is an expensive device and causes some inconvenience during wearing (e.g. it cannot be used in a wet environment, and the cables can cause some discomfort during dressing/undressing). In spite of these restrictions people did not experience too much hindrance wearing the AM. Progress is currently being made with a new wireless prototype which is considerably cheaper, more user-friendly, and will allow measurement for a longer a period (>2 days).

Recommendations for further research

Future applications

Not all AM data were analyzed and used for this thesis. Three aspects of the activities in daily living can be distinguished: quantity (which posture/motion is performed, when, how often, and for how long), quality (how is the posture/motion performed), and the physical strain (the physiological reaction of the body related to performing postures/motions). Our research has focused on the quantitative aspects, but the available data also allow investigation of the qualitative parameters. In walking, parameters such as stride frequency, walking speed, symmetry and stability can be derived from the acceleration signals. For the sit-to-stand movements, parameters such as movement time, movement pattern, and phasing of leg and trunk movements are considered important quality aspects and need to be explored. Furthermore, it is possible that these patients do not walk more per day after the surgery, but that walking costs less effort. For this reason it could be valuable to measure the physical effort during walking in the patient's daily surroundings.

Other study populations

The development of new operation techniques and the improvement of prostheses is an ongoing process and is aimed at accelerating recovery so that work and/or sport activities can be resumed more rapidly. Total hip or knee arthroplasty patients operated by means of minimally invasive surgery, or a prosthesis like a resurfacing hip prosthesis, are examples of these new techniques and prostheses and they claim to enable a quicker recovery[32,33]. However, the impact of these new techniques on the actual performance in daily life is unknown. It has not yet been confirmed whether these patients have a higher actual physical activity level and whether they are able to carry out the activities better than patients with a conventional total hip or knee prosthesis. Another group of patients that deserves attention are the revision

THA and TKA patients. With the growing amount of arthroplasties, the number of prostheses needing revision will increase. The actual performance level in patients after a revision of THA or TKA is unknown. Neither is it known whether it is comparable with recovery after primary total hip or knee arthroplasty. Furthermore, activity monitoring with all its possibilities, is useful not only in OA patients but may also prove useful in other orthopaedic groups, such as in patients after anterior cruciate ligament surgery or those with upper limb disorders.

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Summary

This thesis focuses on the patient's functioning before and after total hip arthroplasty (THA) or total knee arthroplasty (TKA). Osteoarthritis (OA) of hip or knee results in a variety of symptoms and other functional consequences. One way of assessing these consequences is to use the International Classification of Functioning, Disability and Health (ICF). The ICF provides a framework for the description of health and health-related domains and consists of two parts. Part 1 covers functioning and disability and includes the domains 'body function and structure', 'activities' and 'participation'. Part 2 covers contextual (environmental and personal) factors. The ICF classification helps to describe the consequences of OA and the patient's level of physical functioning; this is useful when deciding which treatment or intervention is needed and to study which aspects of treatment or intervention are effective.
Nowadays, many different outcome measures are used to evaluate the outcome of OA treatment, both in clinical practice and in research. In the same way that the consequences of OA can be studied from an ICF perspective, the outcome measures can also be categorized within the different ICF domains. The main domain of interest in this thesis (which consists of three parts) is the domain of 'activities'. Items within this domain can be assessed with either self-reported or objective outcome measures.
The first part of the thesis focuses on the validity of a self-reported outcome measure. The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index is particularly recommended to measure patients' perceived physical functioning and the effect of treatment in patients with OA of hip or knee. However, it was originally designed for use in the older OA patient. Nowadays, due to improvements in operation techniques and prosthesis quality, younger and more active patients are now candidates for total joint arthroplasty. Moreover, people have higher demands of physical function both before and after surgery. Consequently, activities that are not yet included in the current outcome measure have become relevant for the patient with OA. Therefore, as the WOMAC may no longer be valid for current OA patients (especially for the young and active ones), two extended versions of the WOMAC questionnaire have been developed in Sweden to improve its validity: i.e. the Hip disability and Osteoarthritis Outcome Score (HOOS) and the Knee injury and Osteoarthritis Outcome Score (KOOS). In this thesis, validation of the Dutch versions of the HOOS and KOOS is described.

The second part of the thesis addresses the effects of OA and joint arthroplasty, focusing on the actual performance of patients as objectively measured. Devices using motion sensors fixed to the body objectively evaluate the patient's actual performance. Until now, the patient's actual walking activity after THA or TKA was assessed using a pedometer. However, OA and a total joint arthroplasty not only influence walking ability, but also other motions such as stair walking and cycling, other postures such as standing and sitting, and movements between postures such as sit-to-stand movements. Because these aspects of actual performance have not yet been assessed, the impact of OA and total joint arthroplasty on detailed aspects of

actual physical performance has remained unclear. In this thesis we evaluated the impact of OA and the effect of a total joint arthroplasty of hip or knee on the different domains of the ICF classification, including the level of actual performance. Relationships between all these ICF domains were also investigated.
Besides the functional consequences of OA, patient satisfaction is also an important outcome of intervention. Knowledge on preoperative determinants that influence satisfaction after THA or TKA can help in decision making, the selection of patients, and in formulating reasonable expectations for the individual patient. Furthermore, knowledge on postoperative factors related to patient satisfaction can be helpful in the treatment of patients after surgery. Therefore, in the third part of this thesis we determined which determinants best predict patient satisfaction and which determinants are associated with patient satisfaction post-surgery.

Chapter 2 describes the validation of the Hip disability and Osteoarthritis Outcome Score (HOOS). This questionnaire was constructed in Sweden and has proven valid for persons with hip disability, with or without hip OA, and who have high demands for their physical functioning. The purpose of this study was to evaluate the internal consistency, reliability, construct validity, and floor and ceiling effects of the Dutch version of the HOOS questionnaire. After translation from the original Swedish version of the HOOS with a forward/backward protocol, 74 hip arthroplasty patients and 88 hip OA patients filled in the Dutch HOOS, as well as an SF-36, an Oxford Hip Score and a VAS pain questionnaire. The Dutch version of the HOOS questionnaire achieved excellent scores in all of the clinimetric properties. The Dutch HOOS questionnaire has good internal consistency and reliability. Moreover, the construct validity is good, and no floor and ceiling effects were found. We concluded that HOOS is an effective instrument for patients in different stages of hip OA.

In **Chapter 3** the Dutch version of the Knee Injury and Osteoarthritis Outcome Score (KOOS) was validated. The KOOS was constructed in Sweden and has proven valid for several orthopedic interventions of the knee. The purpose of this study was to evaluate the internal consistency, reliability, construct validity, and floor and ceiling effects of the Dutch version of the KOOS questionnaire in knee patients with various stages of OA. The Swedish version of the KOOS questionnaire was first translated into Dutch according to a standardized procedure and then tested for clinimetric quality. The study population consisted of patients with different stages of OA (mild, moderate and severe), and of patients after primary TKA and after a revision of the TKA. All patients filled in the Dutch KOOS questionnaire, as well as the SF-36 and a VAS pain questionnaire. For all patient groups Cronbach's alpha was above 0.70 for all subscales. The ICCs, assessed for the patient groups with mild and moderate OA and after revision of the TKA patients, were above 0.70 for all subscales. Of the predefined hypotheses, 60% or more could be confirmed for patients with mild and moderate OA and for TKA patients. For the other patient groups less than 45% could be confirmed. Ceiling effects were present in the mild OA

group for the subscales Pain, Symptoms and ADL, and for the subscale Sport/Recreation in the severe OA group. Floor effects were found for the subscales Sport/Recreation and Quality of Life in the severe OA and revision TKA groups. We concluded that the KOOS questionnaire seems suitable for patients with mild and moderate OA and for patients with a primary TKA. Further validation studies on the Dutch version of the KOOS should also include knee-specific questionnaires to assess the construct validity.

In **Chapter 4** the aims were to measure the level of actual physical activity of patients with end-stage OA of the hip or knee, to compare this with that of matched (by age and gender) healthy controls, and to determine the factors of influence. The actual physical activity was measured with an activity monitor (AM) in 40 hip and 44 knee OA patients, and compared with measurements obtained from healthy controls. Data were also collected on pain and psychological aspects such as anxiety, depression and mental functioning. The primary outcome parameter of the actual physical activity was the percentage of movement-related activity, which was similar between the two OA groups; i.e. 8.8% (SD 4.2) for the hip and 8.1 (SD 3.8) % for the knee OA patients. The matched controls showed significantly more movement-related activity than OA patients, i.e. about 11.0% (SD 2.9). Increased age and body mass index were negatively associated with the percentage of movement-related activity (ß = -0.29 and ß = -0.25, respectively), whereas mental functioning was positively related (ß = 0.30). The impact of end-stage OA on the level of actual physical activity was equal for hip and knee OA patients. The actual physical activity for both OA groups was significantly and clinically relevantly lower compared to controls. However, this difference was smaller than expected and less dominant than the patient's perception of limitations in daily life. Clinicians must be aware that the patient's perception of physical functioning in daily life does not always correspond with the actual physical activity.

Chapter 5 describes the effect of a total joint arthroplasty on different aspects of physical functioning. Limitation of daily physical activity is one of the reasons for THA or TKA. However, studies on the effects of THA or TKA generally do not address actual daily activity as part of physical functioning. We determined the effect of THA or TKA on patients' actual physical activity and body function (pain, stiffness), on capacity to perform tasks, and on their self-reported physical functioning. We also assessed whether there are differences in the effects of surgery between patients undergoing THA or TKA, and whether the improvements vary between these different outcome measures. We recruited patients with longstanding end-stage OA of the hip or knee awaiting THA or TKA. Measurements were performed before surgery, and at 3 and 6 months after surgery. Actual physical activity improved by 0.7%. Patients' body function, capacity, and self-reported physical functioning also improved. The effects of surgery on these aspects of physical functioning were similar for THA and TKA. The effects on actual physical activity (8%) were smaller than on the body functions pain and stiffness (80-167%), capacity

(19-36%), and self-reported physical functioning (87-112%). Therefore, in contrast to the large effects on pain and stiffness, patients' capacity, and self-reported physical functioning, the improvement in actual physical activity of our patients was less than expected 6 months after surgery.

Chapter 6 focuses on the relationships between different domains of functioning in patients with hip or knee OA and a THA or TKA. We defined five domains of functioning: body function, capacity, actual physical activity, perceived physical functioning, and perceived mental functioning. In this prospective cohort study, the study population consisted of patients with OA of the hip or knee who had undergone a primary THA or TKA. Relationships between the five functional domains were studied in the cross-sectional data and the change score data, expressing the consequences of OA and the outcome of THA or TKA, respectively. The percentage of significant relationships between each pair of domains was also determined. Before surgery the strongest relationship was found between capacity and perceived physical functioning (5/6, 83%). Change score data after surgery showed largely the same pattern as before surgery. Both in the cross-sectional data and the change score data the 'capacity' domain related the most frequently to the other domains, and 'actual physical activity' the least frequently. The results suggest that capacity and/or the imbalance between capacity and actual physical activity are key factors in treating patients with OA before and after surgery.

In **Chapter 7** we investigated which patient-related determinants, expectations, and preoperative and postoperative determinants of functioning are related with patient satisfaction after total hip or knee arthroplasty. 79 patients were extensively examined before and six months after surgery. This included three capacity tests, measurement of actual physical activity of patients by means of the Activity Monitor (48 hours measurement), physical examination and questionnaires. 80% of the patients was very satisfied (62%) or moderately satisfied (18%). Patients with a better preoperative mental health (high versus low: 71% versus 45%) and those whom received a hip arthroplasty (hip versus knee: 77% versus 50%) were more often satisfied. Patients who were satisfied six months after surgery experienced less pain (0.1 versus 4.8) and less stiffness (70 versus 40). Those with a better mental health (high versus low: 75% versus 13%), and with fulfilled expectations (yes versus no: 86% versus 23%) were more often satisfied.

The general discussion of **Chapter 8** brings together some previously addressed issues, considers them from a more general viewpoint, and also introduces some new and related issues.

Samenvatting

Dit proefschrift richt zich op het functioneren van patiënten voor en na een totale heup arthroplastiek (THA) of totale knie arthroplastiek (TKA). Artrose resulteert in een variëteit van symptomen en andere functionele consequenties. Een manier om naar deze consequenties te kijken is door gebruik te maken van de International Classification of Functioning, Disability and Health (ICF). De ICF verschaft een raamwerk voor het beschrijven van gezondheid en gezondheidgerelateerde domeinen en bestaat uit 2 delen: Deel 1 omvat het functioneren en beperkingen en bevat de domeinen 'functie en anatomische eigenschappen', 'activiteiten' en 'participatie'. In deel 2 zijn de contextuele (omgeving en persoonlijke) factoren verwerkt. De ICF helpt om de consequenties van artrose en het niveau van functioneren van de patiënten te beschrijven. Dit kan helpen bij het bepalen welke interventie effectief is voor de patiënt. Er zijn tegenwoordig verschillende meetinstrumenten om het effect van artrose en de behandeling in de klinische praktijk en in onderzoek te beoordelen. Op dezelfde manier als de consequenties van artrose kunnen worden bestudeerd vanuit de ICF classificatie, kunnen ook de meetinstrumenten worden ondergebracht in deze ICF domeinen. Het domein 'activiteiten' staat centraal in dit proefschrift, dat uit 3 delen bestaat. Items binnen het domein 'activiteiten' kunnen zowel met subjectieve of objectieve meetinstrumenten gemeten worden.
Het eerste deel van het proefschrift is gericht op het bestuderen van de validiteit van een 'zelfrapportage' vragenlijst. De Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) wordt veel gebruikt en aanbevolen om de beleving van het lichamelijk functioneren van patiënten met artrose en de behandeling hiervan te meten. Dit instrument is ontwikkeld voor de oudere patiënt. Door verbeteringen in operatietechnieken en in de kwaliteit van arthroplastieken, zijn momenteel ook jongere en actievere patiënten kandidaat voor een gewrichtsvervangende operatie. Ook stellen personen hogere eisen aan het fysieke functioneren, zowel vóór als na de operatie. Het gevolg is dat ook activiteiten, waarmee het huidige meetinstrument geen rekening houdt, belangrijk zijn geworden voor mensen met artrose of een gewrichtsvervangende operatie. Daarom is de WOMAC niet meer voldoende valide voor de huidige artrose populatie, vooral niet voor de jonge en actieve patiënten. Er zijn 2 uitgebreidere versies van de WOMAC vragenlijst ontwikkeld in Zweden om de validiteit te verbeteren: de 'Hip disability and Osteoarthritis Outcome Score (HOOS) en de 'Knee injury and Osteoarthritis Outcome Score (KOOS). In dit proefschrift worden de validatiestudies van de Nederlandse versies van de HOOS en KOOS beschreven.

Het tweede gedeelte van dit proefschrift is gericht op het objectief meten van verschillende aspecten van werkelijke uitvoering van activiteiten in het dagelijkse leven. Met instrumenten waarbij sensoren op het lichaam worden geplakt, is het mogelijk de werkelijke activiteiten van patiënten objectief te meten. Tot nu toe zijn de werkelijke loopactiviteiten van patiënten na een gewrichtsvervangende operatie van heup of knie gemeten met behulp van een stappenteller. Artrose of een gewrichtsvervangende operatie beïnvloeden echter niet alleen loopactiviteiten van deze patiënten, maar ook andere bewegingen, zoals traplopen en fietsen, andere

houdingen zoals staan en zitten en bewegingen tussen houdingen, zoals de beweging van het opstaan. Deze aspecten van werkelijke activiteiten zijn tot nu toe nooit eerder gemeten, waardoor de invloed op artrose en een gewrichtsvervangende operatie op deze gedetailleerde aspecten van werkelijke activiteiten nog niet duidelijk is. De relaties tussen de verschillende ICF domeinen zijn bovendien tot nu toe in een beperkt aantal domeinen bestudeerd en relaties met objectief gemeten werkelijke activiteiten zijn tot nu toe niet gemeten. In dit proefschrift evalueren we het effect van artrose en een gewrichtsvervangende operatie van heup of knie op de verschillende aspecten van de ICF classificatie, inclusief het niveau van werkelijke activiteiten. De relaties tussen deze ICF domeinen zijn ook onderzocht.

Naast de functionele consequenties van artrose is patiënttevredenheid ook een belangrijke uitkomst van een interventie. Kennis over de preoperatieve determinanten die tevredenheid beïnvloeden na de gewrichtsvervangende operatie kan helpen bij het maken van keuzes, patiëntselectie en het formuleren van redelijke verwachtingen van een patiënt. Bovendien kan kennis over postoperatieve factoren die gerelateerd zijn aan patiënttevredenheid helpen in de behandeling na de operatie. Daarom hebben we in het derde deel van dit proefschrift de determinanten die patiënttevredenheid voorspellen en determinanten die geassocieerd zijn met tevredenheid na de operatie bepaald.

Hoofdstuk 2 beschrijft een validatieonderzoek naar de Hip Disability and Osteoarthritis Outcome Score (HOOS). Deze vragenlijst is ontwikkeld in Zweden en is valide voor mensen met heupbeperkingen met en zonder artrose, die hoge eisen stellen aan hun lichamelijk functioneren. Het doel van deze studie was om de interne consistentie, betrouwbaarheid, construct validiteit en de bodem- en plafond effecten te beoordelen. Na het vertalen van de Zweedse HOOS vragenlijst met een voorwaarts/achterwaartse vertaalprocedure, hebben 74 patiënten met een gewrichtsvervangende operatie van de heup en 88 heup artrose patiënten zowel de Nederlandse HOOS vragenlijst als de SF-36, de Oxford Heup Score en een VAS score voor pijn ingevuld. De Nederlandse versie van de HOOS vragenlijst behaalde uitstekende scores op alle klinimetrische eigenschappen. De Nederlandse HOOS vragenlijst heeft een goede interne consistentie en betrouwbaarheid. De construct validiteit is bovendien goed en er werden geen bodem- en plafond effecten gevonden. We concluderen dat HOOS vragenlijst een goed instrument is voor patiënten met verschillende stadia van artrose.

In **hoofdstuk 3** werd de Nederlandse versie van de Knee Injury and Osteoarthritis Outcome Score (KOOS) gevalideerd. De KOOS is ontwikkeld in Zweden en is valide voor verschillende orthopaedische interventies van de knie. Het doel van deze studie was om de interne consistentie, betrouwbaarheid, construct validiteit en de bodem- en plafond effecten te beoordelen in patiënten met verschillende stadia van artrose te meten. De Zweedse versie van de KOOS vragenlijst werd eerst vertaald in het Nederlands volgens een gestandaardiseerde procedure

en vervolgens getest op klinimetrische eigenschappen. De studiepopulatie bestond uit patiënten met verschillende stadia van artrose (mild, matig en ernstig), patiënten na een primaire gewrichtsvervangende operatie en patiënten na een revisie van de primaire gewrichtsvervangende operatie. Alle patiënten vulden de Nederlandse KOOS vragenlijst in, als ook de SF-36 en een VAS voor pijn. Voor alle patiëntengroepen werd in alle subschalen een Cronbach's alfa van hoger dan 0.70 gevonden. De ICC's, beoordeeld voor de patiënten met milde and matige artrose en na een revisie van de TKA, waren hoger dan 0.70 voor alle subschalen. Van alle vooraf opgestelde hypotheses werd 60% of meer bevestigd voor de patiënten met milde en matige artrose en een TKA. Voor de andere patiëntengroepen kon minder dan 45% worden bevestigd. Plafond effecten waren aanwezig bij de groep met milde artrose wat betreft de subschalen pijn, symptomen, en ADL en wat betreft de ernstige artrose groep voor de subschaal sport/recreatie. Bodem effecten werden gevonden voor de subschalen Sport/recreatie en kwaliteit van leven (QoL) in de groep patiënten met ernstige OA en in de revisie TKA patiënten. We concluderen dat de KOOS vragenlijst geschikt lijkt voor patiënten met milde en matige artrose en voor patiënten met een primaire TKA. Verdere validatiestudies van de (Nederlandse versie van de) KOOS zouden ook een kniespecifieke vragenlijst moeten gebruiken voor het beoordelen van de constructvaliditeit.

Het doel van **hoofdstuk 4** was om het niveau van werkelijke activiteiten van mensen met eindstadium artrose van heup of knie te meten en dit te vergelijken met bijpassende gezonde controle personen (wat betreft leeftijd en geslacht). Daarnaast was het doel om de data te analyseren op factoren die deze werkelijke activiteiten beïnvloeden. De werkelijke lichamelijke activiteiten werden gemeten met een activiteiten monitor (AM) in 40 heup en 44 knie artrose patiënten en vergeleken met metingen verkregen van gezonde controle personen. Er werden tevens gegevens verzameld over pijn en psychologische aspecten als angst, depressie en mentaal functioneren. De primaire uitkomst parameter van de werkelijke activiteiten was het percentage bewegingsgerelateerde activiteiten, hetgeen niet verschilde tussen de twee artrose groepen. Het was 8.8% (SD 4.2%) voor de heup en 8.1% (SD 3.8%) voor de knie artrose patiënten. De controle personen waren significant meer bewegingsgerelateerd actief dan de artrose patiënten (ongeveer 11.0% SD 2.9%). Toename in leeftijd en body mass index was negatief geassocieerd met het percentage bewegingsgerelateerde activiteit (ß = -0.29 en ß = -0.25 respectievelijk), terwijl mentaal functioneren positief was gerelateerd (ß = 0.30). De invloed van eindstadium artrose op het niveau van werkelijke activiteiten was voor beide artrose groepen significant en klinisch relevant lager vergeleken met de controle personen. Echter, het verschil was kleiner dan verwacht en minder dominant dan de beleving van patiënten over beperkingen in het dagelijkse leven. De clinicus dient zich bewust te zijn dat de beleving van patiënten van hun functioneren in het dagelijkse leven niet altijd overeenkomt met de werkelijke lichamelijke activiteiten.

Hoofdstuk 5 beschrijft het effect van een totale gewrichtsvervangende operatie op verschillende aspecten van lichamelijk functioneren. Beperkt zijn in de dagelijkse activiteiten is een van de redenen om te besluiten een totale heup arthroplastiek (THA) of totale knie arthroplastiek (TKA) te plaatsen. Echter, studies naar het effect van een THA of TKA bepalen over het algemeen niet de werkelijke dagelijkse activiteiten als deel van lichamelijk functioneren. Het effect van een THA en TKA op de werkelijke activiteiten, lichaamsfunctie (pijn, stijfheid), capaciteit om taken te kunnen uitvoeren en zelfgerapporteerd lichamelijk functioneren werd bepaald. Tevens werd bepaald of er verschillen zijn in het effect van de operatie tussen patiënten die een THA en TKA ondergaan en of de verbetering varieerden tussen de verschillende uitkomstmaten. Patiënten met langdurig eindstadium artrose van heup of knie die op de wachtlijst stonden voor een THA of TKA werden geselecteerd. Metingen werden verricht voor de operatie en 3 en 6 maanden na de operatie. De werkelijke lichamelijke activiteit verbeterde met 0.7%. De lichaamsfunctie van de patiënt, zijn capaciteit en zelfgerapporteerde lichamelijk functioneren verbeterden ook. Het effect van de operatie op deze aspecten van lichamelijk functioneren was gelijk voor THA en TKA patiënten. Het effect op de werkelijke lichamelijke activiteit (8%) was kleiner dan op de lichaamsfuncties pijn en stijfheid (80%-167%), capaciteit (19-36%) en zelfgerapporteerde lichamelijk functioneren. In tegenstelling tot het grote effect op pijn en stijfheid, de capaciteit van patiënten en hun zelfgerapporteerde lichamelijk functioneren, is de verbetering in werkelijke activiteiten van deze patiënten veel minder dan verwacht 6 maanden na de operatie.

In **hoofdstuk 6** richten we ons op de relaties tussen verschillende domeinen van functioneren van patiënten met heup of knie artrose en een totale heup arthroplastiek (THA) of knie arthroplastiek (TKA). Er werden vijf domeinen van functioneren gedefinieerd: lichaamsfunctie, capaciteit, werkelijke lichamelijke activiteit, ervaren lichamelijk functioneren en ervaren mentaal functioneren. In deze prospectieve studie bestond de populatie uit patiënten met artrose van heup of knie die THA of TKA kregen. Relaties tussen de vijf functionele domeinen werden bestudeerd in de crosssectionele data en de verschildata, wat respectievelijk de consequenties van artrose en de uitkomst van een THA of TKA uitdrukt. Het percentage van significante relaties tussen elk paar domeinen was ook bepaald. Voor de operatie werd de sterkste relatie gevonden tussen capaciteit en ervaren lichamelijk functioneren (5/6, 83%). De verschildata toonden ongeveer hetzelfde patroon als voor de operatie. Zowel in de crosssectionele data als in de verschildata was het domein capaciteit het frequentste gerelateerd aan de andere domeinen, en werkelijke lichamelijke activiteit het minst vaak. De resultaten suggereren dat capaciteit en/of de disbalans tussen capaciteit en werkelijke lichamelijke activiteit sleutelfactoren zijn in de behandeling van mensen met artrose voor en na operatie.

In **hoofdstuk 7** werd onderzocht welke patiëntgerelateerde determinanten, verwachtingen, en pre- en postoperatieve determinanten van functioneren gerelateerd zijn aan

patiënttevredenheid na een totale heup of knie arthroplastiek. 79 patiënten werden uitgebreid bestudeerd voor en zes maanden na operatie. Er werden drie capaciteitstesten afgenomen, metingen van de werkelijk lichamelijke activiteiten werden verricht met een Activiteiten Monitor (48 uur meting), een lichamelijke beoordeling werd gedaan en vragenlijsten afgenomen. 80% van de patiënten was erg tevreden (62%) of matig tevreden (18%). Patiënten met een betere preoperatieve mentale gezondheid (hoog versus laag: 71% versus 45%) en zij met een heup arthroplastiek (heup versus knie: 77% versus 50%) waren vaker tevreden. Patiënten die zes maanden na de operatie tevreden waren hadden minder pijn (0.1 versus 4.8) en minder stijfheid van het gewricht (70 versus 40). Degenen met een betere mentale gezondheid (hoog versus laag: 75% versus 13%), en met uitgekomen verwachtingen (ja versus nee: 86% versus 23%) waren vaker tevreden.

De algemene discussie in **hoofdstuk 8** brengt een aantal eerder bediscussieerde onderwerpen uit de verschillende hoofdstukken bij elkaar en beschouwt ze van een meer algemeen oogpunt en introduceert ook enkele nieuwe onderwerpen.

Dankwoord

Dankwoord

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Curriculum Vitae

Ingrid de Groot was born on 30 January 1975 in Dordrecht. After finishing high school in Breda in 1994, she attended the College of Physical Therapy in Breda. In her final year she chose the focus 'Method and Technique' and became familiar with the scientific method. Her first research project investigated the functionality of questionnaires about patients' daily activity and ability to cope with chronic pain.

Inspired by this experience, she went on, in 1998, to study Health Science at the University of Maastricht. There she specialized in Movement Science. In 2001, she earned her degree with a scientific paper on the long term efficacy of exercise in patients with heart failure. She performed the research at the Department of Rehabilitation Medicine at the Erasmus MC in Rotterdam.

While at University, Ingrid also worked as a physiotherapist at 'RugAdvies Centrum' in Breda. Here Ingrid used exercise programs based on the principles of 'Graded Activity'.

Since September 2003 Ingrid has worked at the Department of Orthopedics at the Erasmus MC in Rotterdam. Mid-2004, Ingrid started her doctoral degree program, as described in this thesis, upon receipt of a grant from the Nuts Ohra Insurance company. In 2007, she received her Master's of Education in Epidemiology A.

At the moment, Ingrid works at Fysergo as a in 'company' physiotherapist. This clinic helps companies and occuptional health services with a fast and effective re-integration into the work-force of people with physical complaints.