



## PhD thesis

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# Results of total joint arthroplasty and joint preserving surgery in younger patients evaluated by alternative outcome measures



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## Preface

This PhD thesis constitutes my work as a research fellow at CORH – Clinical Orthopaedic Research Hvidovre, Department of Orthopaedic Surgery at Copenhagen University Hospital Hvidovre, from 2010 to 2013. The work was funded by the Copenhagen University Hospital Hvidovre and The Ministry of Health.

The thesis is based on the following three scientific papers:

- I. Jakob Klit, Charlotte Hartig-Andreasen, Steffen Jacobsen, Kjeld Søballe, Anders Troelsen.  
The ability of patients in sports, social activities and sexual life 9 to 12 years after periacetabular osteotomy.  
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- II. Jakob Klit, Steffen Jacobsen, Stig Sonne-Holm, Signe Rosenlund, and Anders Troelsen  
.Total Knee Arthroplasty in Young Patients Evaluated by Alternative Outcome Measures: A prospective study.  
*Manuscript submitted*
- III. Jakob Klit, Steffen Jacobsen, Stig Sonne-Holm, Victoria Schmiegelow, and Anders Troelsen  
Alternative Outcome Measures in a Cohort of Young Total Hip Arthroplasty Patients: A prospective study.  
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In this thesis the papers will be referred to by their Roman numerals. Figures and tables will as a prefix be named by its corresponding Roman numerals and consecutive named with Arabic letters in alphabetical order.

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## Abbreviation

FAI	Femoroacetabular impingement
HR	Hip Resurfacing
HRQoL	Health Related Quality of Life
OA	Osteoarthritis
OHS	Oxford Hip Score
OKS	Oxford Knee Score
PAO	Periacetabular osteotomy
PRO	Patient Reported Outcome
PROM	Patient Reported Outcome Measure
ROM	Range of motion
SF-36	Short Form-36 version 1
THA	Total Hip Arthroplasty
TKA	Total Knee Arthroplasty

## Introduction

Osteoarthritis (OA) is the clinical and pathological result of disorders leading to functional and structural failure of synovial joints, resulting in pain and dysfunction of the affected joint (1,2). Traditionally this was thought to be due to a progressive breakdown of articular cartilage, but now the current thought holds that the entire joint is affected (1,3,4). The etiology of OA is believed to be multifactorial and not entirely understood, but is considered to be due to an interaction between genetic, systemic, and environmental risk factors. Despite the similarity in clinical presentation of knee and hip OA, the pathogenesis and distribution of predisposing factors differs. In general genetic and systemic factors known to constitute a risk factor for OA are gender, age and ethnicity; with female sex and being Caucasian constituting risk factors, with increasing OA prevalences of the aging. A few congenital abnormalities i.e. Legg-Calvé-Perthes disease and slipped capital femoral epiphysis are known to cause premature hip OA. Obesity is strongly correlated to knee OA whereas the correlation to hip OA is weaker, if present at all. Additionally knee injury or trauma to the knee constitutes an important risk for knee OA (1,2,5,6).

It has become increasingly evident that subtle hip deformities and resulting femoroacetabular impingement (FAI) initiates premature hip OA. FAI is caused by different hip deformities: deep acetabular sockets (coxa profunda or protrusio acetabuli), pistol grip deformity of the head-neck junction, and acetabular dysplasia causing wide, flat sockets (3,4,7–9). The deformities, from subtle to excessive, can all cause pincer impingement, cam impingement, and shearing impingement(3,4,7–9). It is hypothesized, that repeated trauma to the acetabular labrum and adjacent chondral structures results in subsequent labral degeneration, tearing of the labrum, chondral delamination, and initiates OA development(3,4,10).

Since Wiberg's thesis in 1939, there have been numerous studies confirming the relationship between acetabular dysplasia and secondary OA in the young patient (11–16). In an attempt to prevent or postpone the development of OA in these patients, the periacetabular osteotomy (PAO) first described by Ganz et al. in 1988, and later modified, is used worldwide as a joint-preserving procedure (9,16–28). The aim of the procedure is a reorientation of the acetabulum to increase the coverage of the femoral head, and thereby improve the weight bearing area improve stability and decrease the abnormal high loads across the hip joint. Several studies have reported good medium to long term hip joint survivorship and functional outcome of PAO (9,19,22,25,26,28–31).

Total knee arthroplasty (TKA) and total hip arthroplasty (THA) is the mainstay in the treatment of end stage OA, when conservative treatment is insufficient. Replacement surgery is well accepted as means to relieve pain and return patients to near normal function (32–46). In both Europe and North America the prevalence of OA is estimated to increase approximately 40% from 2005 to 2030 (47–49). THA replacements are estimated to increase by 200% and TKA surgeries by as much as 673% from 2005 to 2030(50–52). In recent years the utilization of TKA and THA in younger age groups, less than 60 years of age have been increasing, and will continue to increase given the estimated increases in performed TKA and THA surgeries(50–52). The expectations and demands concerning the function of the TKA and THA expressed by these younger and high demanding patients are expected to differ from elderly patients.

The traditional main outcomes in the literature have primarily focused on implant survival, complications, radiographic results, and range of motion(ROM) (32,33,35,36,38–41). Patient perceived outcomes are known to differ from the surgeon evaluation of the outcome (53–55), and patient reported outcome measures (PROMs) are now recommended as the core set of outcomes and reported in much contemporary literature reporting PAO, TKA, and THA outcomes. Patient reported outcomes (PRO) assess the outcome from the patient's perspective; however this implies only that the patient provides the information, it does not indicate whether the information is conceived to be relevant for the patient or of the aim of the study. There is a wide range of PROM instruments, of different methodological quality and different purposes, used in contemporary literature. When evaluating a study or planning a study using PROM as the core set of outcome, there are some basics that need to be taken into account. Firstly the PROM instrument should be reliable and validated, secondly close considerations of the number of questions should be paid as a high responder burden may lead to responder fatigue and a low response rate, finally the design of the PROM should aim at the study population and the aim of the study. This is a general consideration when evaluating the outcome in younger patients following joint surgery, when using standardized and serial PROMs developed for OA patients, this group may show a ceiling-effect, i.e. the majority of patients will get a high score without the sensitive range of the scale. In this group of patients it is not possible to detect changes over time or to categorize the success of the procedure.

## **PAO**

PAO in its modern form was performed by Ganz et al. in 1984 and the procedure initiated a new era of joint-preserving surgery in hip dysplasia (9,18,19,27,56). The Ganz osteotomy allowed a three dimensional reorientation of the acetabulum, while the blood supply to the acetabulum was maintained, the posterior column remains intact allowing immediate mobilization and partial weight bearing, and the geometry of both the pelvic inlet and outlet remains intact (56). The procedure has been modified since its introduction, and in 2003 a new, minimally invasive approach was introduced by Søballe et al. however the patients evaluated in this thesis were operated from December 1998 through December 2002 with a more classical approach(57).

The typical patient with symptomatic dysplasia of the hip indicating PAO, is a female of childbearing age(31,56); however the male/female ratio of radiographic hip dysplasia is nearly equal to 1 in a large Danish radiographic study(3,58). This disparity between the prevalence of radiographic hip dysplasia and the prevalence of symptomatic hip dysplasia remains to be understood.

The aim of the procedure is to increase the coverage of the femoral head and thereby improve joint stability and decrease the overload of the acetabular rim to prevent or postpone the development of OA in these patients. Since its introduction the Ganz osteotomy (PAO) have performed good medium to long term hip joint survivorship and functional outcome of PAO (9,19,22,25,26,28–31). However, the main endpoints for estimation of success have been survival and function of the joint, and only a few studies has focused on Health Related Quality of Life (HRQoL) and other aspects important to the these young patients (25,29,30). These patients have high demands and expectations to the function of their hip, both in everyday life, and during recreational and social activities. Alternative outcome measures should therefore be considered when estimating the success of the PAO. and remains to be explored at medium to long term follow-up.

## **TKA**

TKA is the gold standard of treatment of end stage knee OA, when the patient, despite adequate conservative treatment, experiences unacceptable pain and physical dysfunction. TKA is normally done with the standard anterior midline incision. The type of prosthesis and prosthesis concept differ and has developed over time to fit the individual patient and his or her needs. In general, one of the following concepts is used; cruciate ligament retaining, fixed bearing, cruciate retaining,

rotating platform, and posterior stabilized, fixed bearing. The posterior stabilized TKA is shown to result in a higher degree of flexion than the cruciate retaining. However, an increased flexion beyond 110° do not give a statistically significant gain in patient satisfaction (59). Around 60% of patients undergoing TKA are woman. In recent years this has led to the introduction of gender specific prosthesis, to address the anatomical differences' between male and female knees. However, no statistically significant differences' has been found in the clinical outcomes (60). Despite the estimated increase by as much as 673% from 2005 to 2030 the indication for TKA has remained consistent over time(50–52,61). TKA in younger age groups, less than 60 years of age, have been increasing, and will continue to increase given the estimated increases in performed TKA surgeries(50–52). Expectations and demands concerning the function of the TKA expressed are expected to differ from that in older age groups, and at the same time this patient group is expected to outlive their implant and have revision surgery.

TKA is well accepted as a reliable surgical procedure, evaluated on traditional outcomes; implant survival, complications, radiographic results, and ROM(42–46,62,63). However, patient perceived outcomes are known to differ from the surgeon evaluation of the outcome (53–55), and patient reported outcome measures (PROMs) are now recommended as the core set of outcomes when reporting TKA outcome. Patient satisfaction is considered a highly relevant outcome in arthroplasty surgery. However, 8% to 19% of patients are dissatisfied with the outcome of TKA, and young age is being recognized as a predictor for low, overall satisfaction(45,62,64–67). Dissatisfaction with the outcome is strongly correlated with preoperative expectations not being fulfilled(66,67).

However, fulfillment of preoperative expectations range from a near 100% fulfillment concerning reduction in knee pain to only around 20% fulfillment concerning the ability to participate in sports and leisure activities (46). It seems that many aspects of patient perceived success of treatment and the corresponding outcome estimation are still to be understood. This has in recent years lead to a growing focus on HRQoL and alternative outcomes, such as the effect on personal welfare, leisure activities and sex-life after TKA(42–44,46,62,68–76). However, only few studies have focused on these outcomes in a younger patient population, although these outcomes are of crucial importance during the everyday-life of young patients(77,78).

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## **THA**

From the early 1960s THA revolutionized the treatment of patients with end stage hip arthritis.

THA is now considered the mainstay in treatment of end stage OA of the hip, and is well accepted as a reliable surgical treatment to relieve pain and return patients to near normal function(32–41).

Where THA were initially designed for the elderly part of the population over 70 years of age, today approximately 20% of the THA patients are younger than 60 years(79). In recent years the utilization of THA in the younger age groups, less than 60 years of age, have been increasing, and will continue to increase given the estimated increase in performed THA(50,52). The expectations and demands concerning the function of the THA expressed by these younger patients are expected to differ from that in older age groups.

The traditional main outcomes in the literature are primarily focusing on implant survival, complications, radiographic results, and ROM (32,33,35,36,38–41).

A highly relevant outcome in arthroplasty surgery is patient satisfaction, and despite of pain relieve not all patients are satisfied with their artificial hip. One year postoperatively the satisfaction rate has been reported to be approximately 90%(34,37,80). As described above, it is well known that there exist an inconsistency between the patients' and the surgeons' evaluation of success in treatment (53,55). This recognition has led to the increasing utilization of PROMs in the evaluation of THA outcome, and PROMs are now recommended as the core set of outcomes. Despite of this, it seems that many aspects of patient perceived success of treatment and the corresponding outcome estimation are still to be understood. Some studies have focused on HRQoL and alternative outcomes, such as the effect on personal welfare and sex-life after THA(42,43,69,72,76). Only a few studies has focused on the outcome in young patients, including their satisfaction and what challenges they are facing(30,81–83).

## **Aim of the thesis**

The utilization of alternative outcome measures in the evaluation of outcome after PAO, TKA, and THA in young adults seem warranted to better understand the patients perception of successful treatment. Due to the lack of focus in contemporary literature on alternative aspects of outcome measurement in younger PAO, TKA, and THA patients our aims were, to explore patient satisfaction, fulfillment of expectations, symptoms of depression, the effect on socioeconomic status, and abilities in sex-life in younger PAO, TKA, and THA patients using PROMs. These alternative endpoints were collected in addition to traditional measures of function and HRQoL. Our aims were:

1. To investigate the consequences of TKA, and THA treatment in younger patients in regard to patient satisfaction, expectations, symptoms of depression, socioeconomic effects, and abilities in sex-life. To generate important new information, important to both patients and surgeons during the decision making process prior to TKA and THA surgery.
2. To create a database that can follow this well-defined high-demanding younger patient group over years, and reveal complications and revision rates due to a higher wear in this group. To support the surgeon and patient with information, when deciding the right time for surgery.
3. To investigate functional and quality of life aspects after PAO surgery in relation to the effect on the patient's sex-life, the patient's ability to participate in sports, the patient's ability to interact socially, and are the patients satisfied with the outcome of the procedure at medium to long term follow-up.

## Material and Methods

### Design and Methods of Study I

The study is a cross-sectional survey of preserved hip joints in patients a minimum of nine years after PAO surgery performed at Aarhus University Hospital. The patients eligible for inclusion were 100 patients (121 PAO's) operated by a single surgeon from December 1998 through December 2002, using the ilioinguinal approach (25).

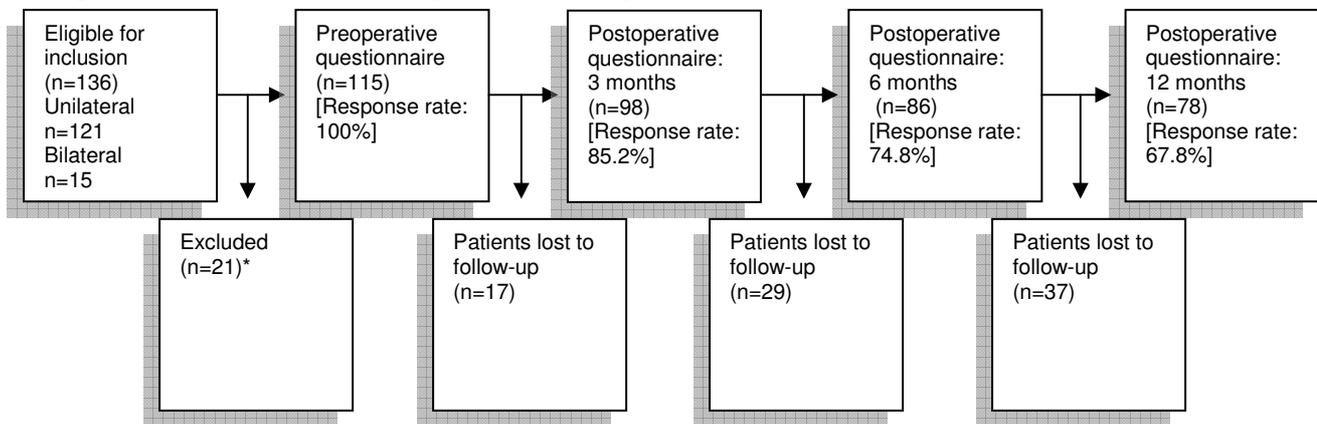
Indications for PAO were, symptomatic acetabular dysplasia of the hip defined by persistent hip or groin pain, a Wiberg (84) center-edge angle  $<25^{\circ}$ , a congruent hip-joint, flexion of the hip  $>110^{\circ}$ , and internal rotation  $>15^{\circ}$ . Five of the 121 PAO's were performed in four foreign citizens and were lost to follow-up. At the time of the present survey an inquiry to the National Patient registry identified 36 of PAO's (in 35 patients) being converted to THA. The 61 remaining patients (80 preserved hip joints) were asked to participate in this questionnaire based follow-up. Fifty-five patients (70 preserved hip-joints) accepted and constituted the study population. All patients received a questionnaire concerning aspects of functional ability, patient satisfaction, expectations, and quality of life following PAO. Fifty-two patients (68 preserved hip-joints) returned the questionnaire (response rate: 85%), 77% females. Thirty-six patients had been operated with PAO uni-laterally and sixteen bi-laterally. The mean age at surgery was 31 years (range 14-56) and at follow-up 41 years (range 24-67). The mean follow up time was ten years (range 9-12). One author (AT), uninformed of the status of the hip, assessed all radiographs. The mean preoperative CE-angle was  $12^{\circ}$  (range  $-29^{\circ}$ - $30^{\circ}$ ) and postoperatively the mean CE-angle was  $29^{\circ}$  (range  $4^{\circ}$ - $52^{\circ}$ ). Preoperatively all hips had a Tönnis grade 0-1 and at follow-up 83% had a Tönnis grade 0-1. The study was reported to the National Data Protection Agency and according to local legislation specific ethics committee approval was not needed for this retrospective questionnaire based study. Prior to inclusion the study was reported to Clinicaltrials.gov (No.:NCT01305759).

### Design and Methods of Study II +III

Both studies are prospective multicenter cohort studies, conducted at three arthroplasty units in the Copenhagen area, Denmark. Consecutive patients less than 60 years of age scheduled for (*study II*)

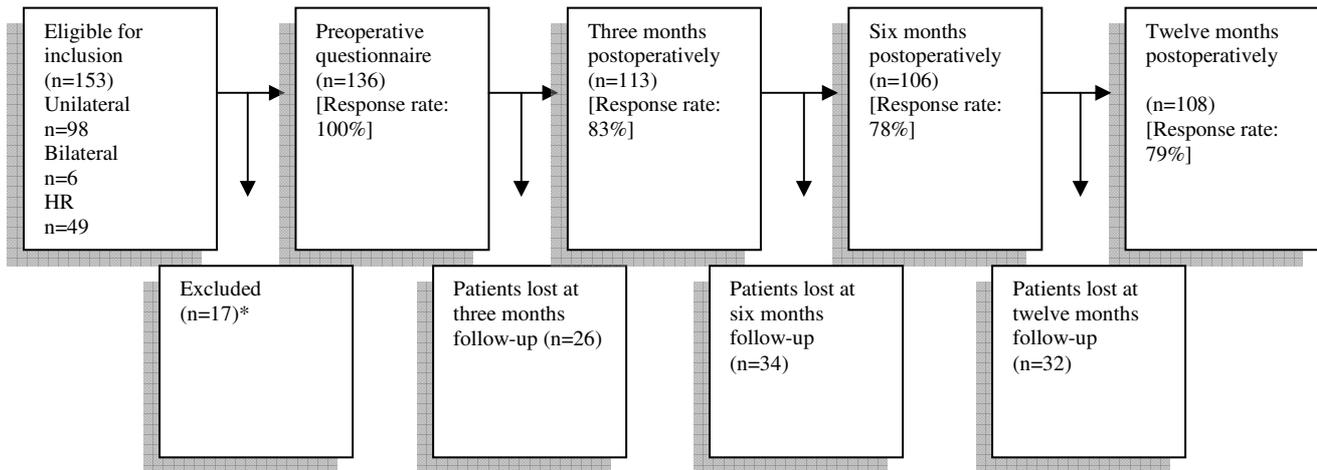
unilateral or bilateral simultaneous primary TKA or (*study III*) scheduled for unilateral or bilateral simultaneous primary THA or Hip Resurfacing (HR) from April 2010 to May 2011 were eligible for inclusion (figure II a. and III a.). Patients were excluded if they did not give informed consent to participate, if they were unable to understand and fill in the questionnaires, if they did not return the preoperative questionnaire prior to surgery, if they suffered from cognitive dysfunction, or if they suffered from a malignant disease. Consequently the study populations consisted of; (*Study II*) 115 primary TKA patients; 103 scheduled for unilateral TKA and 12 scheduled for bilateral simultaneous TKA, and (*study III*) consisted of 136 primary THA patients; 86 scheduled for unilateral THA, 6 scheduled for bilateral simultaneous THA, and 44 scheduled for HR. Patient demographics and clinical history are presented in table II a (*Study II*) and table III a (*Study III*). All bilateral simultaneous TKAs and THAs were performed at Copenhagen University Hospital, Hvidovre, and received the same type of prosthesis on both sides. The studies were reported to the National Data Protection Agency and according to local legislation specific ethics committee approval was not needed for this prospective questionnaire based study. Prior to inclusion the studies were reported to Clinicaltrials.gov (No.:NCT01305759).

Figure II a: Patient flow diagram for Study II



\***Excluded:** did not give informed consent to participate (n=7), if they were unable to understand and fill in the questionnaires (n=12), if they did not return the preoperative questionnaire prior to surgery (n=2), if they suffered from cognitive dysfunction (n=0), or if they suffered from a malignant disease (n=0)

Figure III a: Patient flow diagram for Study III



\***Excluded:** did not give informed consent prior to participation (n=8), if they were unable to understand and fill in the questionnaires (n=2), if they did not return the preoperative questionnaire prior to surgery (n=5), if they suffered from cognitive dysfunction (n=1), or if they suffered from a malignant disease (n=1).

Table II a

<b>Study II: TKA patients demographic data and clinical history</b>	
<b>Age at time of surgery</b>	
<i>Median (interquartile range)</i>	54 yrs (49-57)
<b>Sex</b>	
<i>No. of females/males</i>	61/54
<b>Relation to work</b>	
<i>No. of employed</i>	78
<i>No. of unemployed</i>	27
<i>No. of early age retired</i>	10
<b>Gross annual income in US Dollars (n=114)</b>	
<i>&lt;35.000</i>	28
<i>35.000-61.000</i>	45
<i>61.000-88.000</i>	30
<i>&gt;88.000</i>	11
<b>Social class (n=113)</b>	
<i>Unskilled worker</i>	20
<i>Skilled worker</i>	27
<i>Salaried or white collar</i>	23
<i>Mid-level manager or 3-4 years of higher education</i>	29
<i>Manager or highly educated (holding at least a graduate degree)</i>	14
<b>Previous arthroplasty in another joint</b>	
<i>Contralateral Knee</i>	15
<i>Hip</i>	2

Table III a

<b>Study III: THA and HR patients demographic data and clinical history</b>	
<b>Age at time of operation</b>	
<b>Median (Interquartile range)</b>	53 yrs (48-57)
<b>Sex</b>	
<i>No. of females/males</i>	68/68
<b>Relation to work</b>	
<i>Employed</i>	102
<i>Unemployed</i>	17
<i>Early age retirement</i>	17
<b>Gross annual income in US Dollars</b>	
<i>&lt;35.000</i>	19
<i>35.000-61.000</i>	63
<i>61.000-88.000</i>	39
<i>&gt;88.000</i>	13
<b>Social class</b>	
<i>Unskilled worker</i>	19
<i>Skilled worker</i>	25
<i>Salaried or white collar worker</i>	35
<i>Mid-level manager or 3-4 years of higher education</i>	32
<i>Manager or highly educated (holding at least a graduate degree)</i>	23
<b>Previous arthroplasty</b>	
<i>Contraileteral hip (n=17)</i>	17
<i>Knee (n=2)</i>	2
<i>Another joint (n=0)</i>	0
<b>Arthritis or severe discomfort in a second joint or multiple joints</b>	
<i>The second hip</i>	10
<i>Knee</i>	25
<i>Another joint</i>	16
<i>More than one second joint</i>	0

### Surgical approach and concepts

All TKA patients (*Study II*) were operated with a standard anterior midline incision. The type of prosthesis used was dictated by the preference of the surgeon (table II b). In one case of a cruciate retaining, fixed bearing TKA a stemmed tibia component was implanted due to an intra-operative fracture.

Table II b

<b>Study II: TKA concepts</b>	
<b>Cruciate retaining, fixed bearing</b> (AGC Biomet®, PFC DePuySynthes®, Triathlon Stryker®)	n=71
<b>Cruciate retaining, rotating platform</b> (PFC-Sigma DePuySynthes®, Vanguard ROCC Biomet®, NextGen Zimmer®)	n=39
<b>Posterior stabilized, fixed bearing</b> (LPS-Flex Zimmer®)	n=5

Sixty-seven THA patients (*Study III*) were operated with the posterior approach and 25 THA patients with the anterolateral approach. All 44 HR patients were operated with an extended posterior approach. The type of prosthesis used was dictated by the preference of the surgeon and availability at the individual hospitals.

Table III b

<b>Study III: THA and HR concepts</b>	
<b>Uncemented stem with uncemented acetabular cup and polyethylene liner</b> (Bimetric stem Biomet® and Exceed acetabular cup Biomet®)	n=78
<b>Cemented stem with uncemented acetabular cup and polyethylene liner</b> (Exeter stem Stryker® and Exceed acetabular cup Biomet®)	n=2
<b>Uncemented stem and uncemented cup with metal-on-metal bearing</b> (Bimetric stem Biomet® and Magnum acetabular cup Biomet®, Ecco stem and Magnum acetabular cup Biomet®)	n=14
<b>HR with metal-on-metal bearing</b> (BHR smith-nephew® and Re-Cap Biomet®)	n=42

## **Questionnaires**

### **Study I**

No existing questionnaires met our requirements and therefore we developed our own questionnaire. A semi structured interview was conducted including 20 members of the staff comparable to PAO patients with respect to age and gender. After corrections a new semi structured interview was conducted including 20 patients in the orthopedic department at the Copenhagen University Hospital, Hvidovre, Denmark. The last round of interviews revealed no need for changes. This validation process, validate the content by face validity.

The questionnaire consist of 11 items concerning; 1: Satisfaction with the outcome of PAO, 2: Quality of life, 3: Social-ability, 4: Daily-activity, 5: Work-life, 6: Sexual-life, 7: Sports-activity, 8: Pain, 9: Limp, 10: Stability of the hip and 11: Willingness to repeat PAO surgery. Item two to ten consisted of three questions; 1: Preoperative status, 2: Status at follow-up, 3: Satisfaction with the current status. Answers were given on 5-point or 6 point-likert scales with 1 being the worst status and 5 or 6, respectively, the best status.

### **Study II + III**

The study groups received a paper-format questionnaire within one month of scheduled surgery. At three, six, and twelve months after surgery the study groups received a paper-format follow-up questionnaire by mail in a handwritten envelope. If the patient did not return one of the postoperative questionnaires within three weeks of the set time-point for the follow-up, a reminder was mailed to the patient in a handwritten envelope. If the questionnaire was still not returned within another two weeks the patient was contacted by phone and encouraged to participate. If the patient still did not return the questionnaire or answered the phone, the patient was not reminded further, but was still scheduled to receive a questionnaire at the next follow-up. If the patient did not return the twelve-month follow-up questionnaire, the collected data where included in the analysis. The overall response rates for return of questionnaires varied between 68 % and 84 % (Figure II a. and III a.). Patients who sustained a complication were included in the analysis.

Both the preoperative and the three postoperative collections of questionnaires consisted of the following questionnaires: Oxford Knee Score (OKS) (*Study II*) or Oxford Hip Score (OHS) (*Study III*), Short Form-36 version 1(SF-36), The Major (ICD-10) Depression inventory (MDI), a self developed and validated questionnaire concerning socioeconomic aspects, and a self developed and

validated questionnaire concerning the patients sex-life. In addition the preoperative questionnaire covered the patients' functional category

(1 =unilateral disease, 2= bilateral disease, and 3= multiple joint disease) and information regarding earlier arthroplasty surgery in other joints. The postoperative questionnaires covered additional information concerning frequency of postoperative physiotherapy. The twelve month questionnaire covered the patients' satisfaction and fulfillment of expectations on two five level Likert scales: 1) very satisfied, 2) satisfied, 3) neutral, 4) dissatisfied, 5) very dissatisfied and 1) all my expectations are fulfilled, 2) most of my expectations are fulfilled, 3) to some extent my expectations are fulfilled, 4) few of my expectations are fulfilled, 5) none of my expectations are fulfilled.

Willingness to repeat was addressed.

### **Oxford Knee and Hip score**

Since the OKS was originally described by Dawson et al. in 1998, both the OKS and OHS has undergone thorough assessment of reliability and validity (70,85–87). The score consist of 12 items regarding daily activities. Originally each item was scored from 1 to 5, with 1 being the best outcome. The scores from the 12 items were added, giving a score from 12 to 60 with 12 being the best possible score(70). This scoring was easy, but the score were found to be unintuitive, and later modified. Today it is recommended, that each item is scored on a five-level Likert scale 0(greatest disability) to 4(no disability), resulting in a score from 0 to 48, with 48 being the best possible score(87). The 0 to 48 system may be converted to the 12 to 60 system, by subtracting the score from 60 and vice versa.

### **Short Form-36**

The SF-36 is a instrument has been widely used since the early nineties to assess HRQoL(88,89). Today it is the most frequently used generic PROM instrument(90). It consists of 36 items and measures eight domains; Physical functioning (PF), Social functioning (SF), Role-Physical (RP), Bodily Pain (BP), Mental Health (MH), Role-Emotional (RE), Vitality (VT), and General Health (GH). The Theoretical scoring scales for all eight item-scores runs from 0-100 with 100 being the best possible score. The eight item scores can be transformed in to two summery scores; the physical component summery (PCS) and mental component summery (MCS). Both PCS and MCS contain information from all eight item scores. The advantage of PCS and MCS is a smaller confidence interval and elimination of both floor and ceiling effect(91). In *Study II* and *Study III* the

PCS and MCS were compared with a group from the population similar with respect to age and sex(92,93).

### **The Major (ICD-10) Depression Inventory**

MDI contains ten items, where item 8 and 10 are divided into two sub-items (A and B), and only the highest score (A or B) are included in the statistical analysis. Each item represents a symptom, and is scored on a six-level Likert scale, measuring how much of the time the symptom have been present over the last 14 days; 0 (the symptom has not been present at all) to 5 (the symptom has been present all of the time). Resulting in a score from 0 to 50, where a score  $\geq 20$  represents depression. The MDI has demonstrated a high specificity and sensitivity as a screening tool in a somatic patient group(94,95).

### **Questionnaire concerning socioeconomic outcome**

Due to the unique labor and welfare models in different parts of the world no existing questionnaires met our requirements and therefore we developed our own questionnaire. To validate the content of the questionnaire, a semi-structured interview was conducted including 20 members of the staff comparable to TKA and THA patients with respect to age and gender. After corrections a new semi structured interview was conducted including 20 patients comparable to TKA and THA patients with respect to age and gender in the orthopedic department at the Copenhagen University Hospital, Hvidovre, Denmark. The last round of interviews revealed no need for changes. This validation process, validate the content by face validity. The questionnaire consists of six questions regarding current work-status, sick-leave, welfare or early-age retirement, annual-income, and expectations to life-income. In addition the preoperative questionnaire consists of one extra item regarding social-class. This item divides the study group in to five social-classes: 1) manager or highly educated (holding at least a graduate degree), 2) mid-level manager or 3-4 years of higher education, 3) salaried or white collar worker, 4) skilled worker, and 5) unskilled worker.

### **Questionnaire concerning effects on sex-life**

We knew of no existing questionnaires regarding the TKA or THA patients' sex-life, and therefore we developed our own questionnaires. We used the same method as described above to validate the content of the questionnaires. The questionnaires consist of seven items regarding sex-life before

and after surgery. Focusing on what, if any, positive or negative effect TKA or THA surgery may have had on sexual frequency and sexual practice, and the cause.

## **Statistics**

In all three studies data were tested visually for normality. Normally distributed data were presented as means with 95% confidence intervals (CI), if normality could not be presumed data were presented as medians with interquartile range (IQR). A p-value < 0.05 was in all cases considered statistically significant. Data were analyzed using SPSS 20.0 (IBM, Chicago, Illinois, USA.)

## **Study I**

Descriptive statistics were performed and data primarily presented as prevalences. The Wilcoxon Signed Rank test for paired data was used to compare preoperative and postoperative data. This non-parametric test looks for differences between two related samples often referred to, as the non-parametric equivalent of the related t-test.

## **Study II+III**

Descriptive statistics were performed and data primarily presented as percentages with actual numbers of the underlying data distribution. Data are presented as the mean with 95% CI and range when normally distributed and as median value with IQR if not normally distributed. The Wilcoxon Signed Rank test for paired data was used to compare preoperative and postoperative outcome measures. The Mann-Whitney U test was used to compare outcomes between groups. This non-parametric test is functionally the same as the Wilcoxon Signed Rank test, but is used to detect differences between two independent groups. SF-36 data were processed using the supplied software for SPSS.

## Summary of results

### Study I

**Research questions:** We aimed to answer the following questions; 1) does PAO affect the patient's sex-life, 2) does PAO affect the patient's ability to participate in sports, 3) does PAO affect the patient's ability to interact socially, and 4) are the patients satisfied with the outcome of the procedure at medium to long term follow-up.

**Results:** The median overall satisfaction with the outcome of treatment was 5 at follow-up (IQR: 3-5). At follow-up 44 of 49 patients were willing to undergo treatment again with the experience and knowledge they have today (three patients returned invalid answers). Improvements were seen in all quality of life parameters except for ability in sex-life for males,  $p=0.102$ ) (Table I a).

Table I a

	Score	Preop. status	Postop. status	P-value	Satisfaction with the result at follow-up*
<b>Quality of life</b>	1= extreme disabled				
Median	2= disabled in some degree	2.0	4.0	P<0.001	5
	3=moderately disabled	(IQR: 1-5)	(IQR: 3-5)		(IQR: 4-5)
	4= almost not disabled				
	5= not disabled				
<b>Ability to do sports</b>	1=always disabled by my hip				
	2=nearly always disabled by my hip	2.0	3.0	P<0.001	4.0
	3=sometimes disabled by my hip	(IQR: 1-5)	(IQR: 2-5)		(IQR: 3-5)
	4=rarely disabled by my hip				
	5=never disabled by my hip				

<b>Ability to participate in social activities</b>	Same score as above	3.0 (IQR: 2-3)	4.0 (IQR: 3-4)	P<0.001	4.0 (IQR: 3-5)
<b>Ability in sex-life female</b>	0=no sex-life due to other reasons than the hip** 1=no sex-life due to my hip 2=always disabled by my hip 3= nearly always disabled by my hip 4= sometimes disabled by my hip 5=rarely disabled by my hip 6=never disabled by my hip	4.0 (IQR: 2-5)	5.0 (IQR: 4-5)	P=0.008	4.0 (IQR: 4-5)
<b>Ability in sex-life male</b>	Same score as above	5.5 (IQR: 5-6)	6.0 (IQR: 5-6)	P=0.102	5.0 (IQR: 5-5)
<b>Pain</b>	1= pain that disturbed the sleep 2=pain when in rest 3=pain under physical activity 4=pain under hard physical activity 5=never pain	2.0 (IQR: 1-3)	4.0 (IQR: 2-4)	P<0.001	4.0 (IQR: 3-5)
<b>Limp</b>	1=always limp 2=limped after a few hundred meters 3=limped after 1 kilometer 4=limped after 3 kilometer 5=never limp	2.0 (IQR: 1-3)	4.0 (IQR: 2-4)	P<0.001	4.0 (IQR: 3-5)
<b>Stability</b>	1=never stable 2=sometimes unstable at rest 3=unstable under physical activity 4=unstable under hard physical activity 5=never unstable	3.0 (IQR: 2-4)	4.0 (IQR: 3-5)	P<0.001	4.0 (IQR: 4-5)

Pre- and postoperative scores, p-values and satisfaction for Quality of life, four alternative functional outcomes and three traditional functional outcomes

\*1=not at all satisfied 2=very little satisfied 3= satisfied in some degree 4= mostly satisfied 5=fully satisfied

\*\*not included in statistics

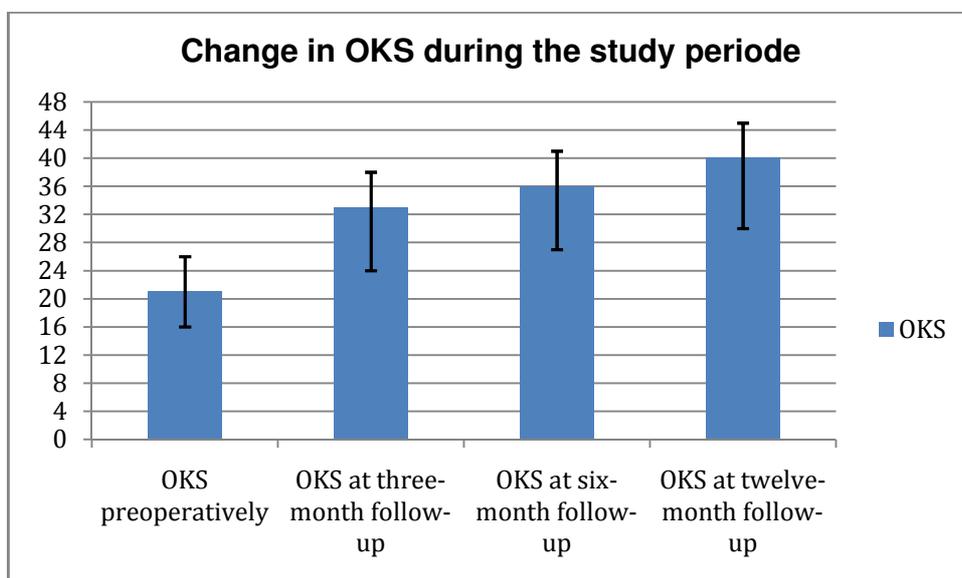
**Conclusion:** Our results suggest that it is possible to achieve lasting improvements in the patients 1) sex life, 2) ability to do sports, 3) social life, and 4) the patients are satisfied with the outcome of the procedure at medium to long term follow-up.

## Study II

Research questions: We aimed, in a prospective setting with the use of PROMs, to explore patient satisfaction and fulfillment of expectations after TKA and its effect on, symptoms of depression, the effect on socioeconomic status, and abilities in sex-life. These alternative endpoints were collected in addition to traditional measures of function and HRQoL.

Results: At the three-month follow-up median OKS had increased statistically significant ( $P < 0.0001$ ) compared with the median preoperative score. OKS increase throughout the study period (figure II b).

Figure II b



At three-month follow-up median SF-36 PCS had increased statistically significant ( $P > 0.0001$ ), compared with the median preoperative score. The median SF-36 PCS were at all follow-up time points below that of a cohort from the population similar with respect to age and sex. The median SF-36 MCS increased throughout the study period, and were at all follow-up time points above that of a cohort from the population similar with respect to age and sex; however it did not reach statistical significance (table II c).

At twelve-month follow-up; 88% (67 of 76 patients) were willing to repeat TKA surgery, 71% (55 of 77 patients) were “very satisfied” or “satisfied” with the outcome, and 68% (52 of 77 patients)

reported “all of my expectations are fulfilled” or “most of my expectations are fulfilled”. On the contrary 12% (9 of 77 patients) were “dissatisfied” or “very dissatisfied” and 12% (9 of 77 patients) reported that “few of my expectations are fulfilled” or “none of my expectations are fulfilled” (table II c and II d).

Table II c

<b>Satisfaction with the outcome</b>	
<b>1) very satisfied</b>	n=34
<b>2) satisfied</b>	n=21
<b>3) neutral</b>	n=13
<b>4) dissatisfied</b>	n=4
<b>5) very dissatisfied</b>	n=5

Table II d

<b>Fulfillment of expectations at twelve-month follow-up</b>	
<b>1) all my expectations are fulfilled</b>	n=30
<b>2) most of my expectations are fulfilled</b>	n=22
<b>3) to some extent my expectations are fulfilled</b>	n=16
<b>4) few of my expectations are fulfilled</b>	n=3
<b>5) none of my expectations are fulfilled</b>	n=6

The median MDI score for the study population were 9(IQR: 5-17) preoperatively and 4(IQR: 1-10) at twelve-month follow-up. Preoperatively 23 patients had a MDI score  $\geq 20$  (corresponding a depression), seven remained having a MDI score  $\geq 20$  at twelve-month follow-up. Preoperatively depressed patients had a median SF-36 PCS, SF-36 MCS, and OKS statistically significant (P-values $<0.007$ ) below preoperative non-depressed patients preoperatively and at all follow-ups, and an absolute increase below the non-depressed patients of the physical parameters (SF-36 PCS and OKS) but an absolute increase above the non-depressed patients of the mental parameters (MCS and MDI) (table II e ). There were no statistically significant (P-values  $>0.06$ ) differences in the outcome of preoperatively depressed and non-depressed patients concerning satisfaction, work-life, income or sex-life after TKA.

Table II e

	Preoperatively	Three-month follow-up	Six-month follow-up	Twelve-month follow-up
<b>SF-36 PCS median score (IQR)</b>				
<b>Study population</b>				
<i>No depression preoperatively</i>	31.3(26.7-36.6)	40.9(32.9-47.5)	44.0(38.1-52.2)	46.8(37.8-53.2)
<i>Depression preoperatively</i>	32.2(27.1-37.1)	41.6(33.4-48.7)	48.1(38.9-52.6)	48.6(38.7-53.4)
	27.6(23.4-32.0)	36.4(31.1-44.4)	38.1(25.3-43.0)	36.7(23.8-43.7)
<b>SF-36 MCS median score (IQR)</b>				
<b>Study population</b>				
<i>No depression preoperatively</i>	50.6(39.0-61.5)	54.9(44.9-61.0)	57.4(50.2-62.4)	58.5(52.9-61.6)
<i>Depression preoperatively</i>	55.2(47.0-62.7)	56.9(46.2-61.4)	59.5(51.3-63.3)	59.2(53.3-61.7)
	43.6(29.7-40.1)	46.0(36.6-50.2)	45.3(36.8-55.4)	46.8(35.9-55.9)
<b>OKS median score(IQR)</b>				
<b>Study population</b>				
<i>No depression preoperatively</i>	21(16-26)	33(24-38)	36(27-41)	40(30-45)
<i>Depression preoperatively</i>	23(18-27)	33(25-38)	38(29-42)	41(34-45)
<i>Depression preoperatively</i>	16(12-20)	26(21-35)	26(15-38)	28(16-41)

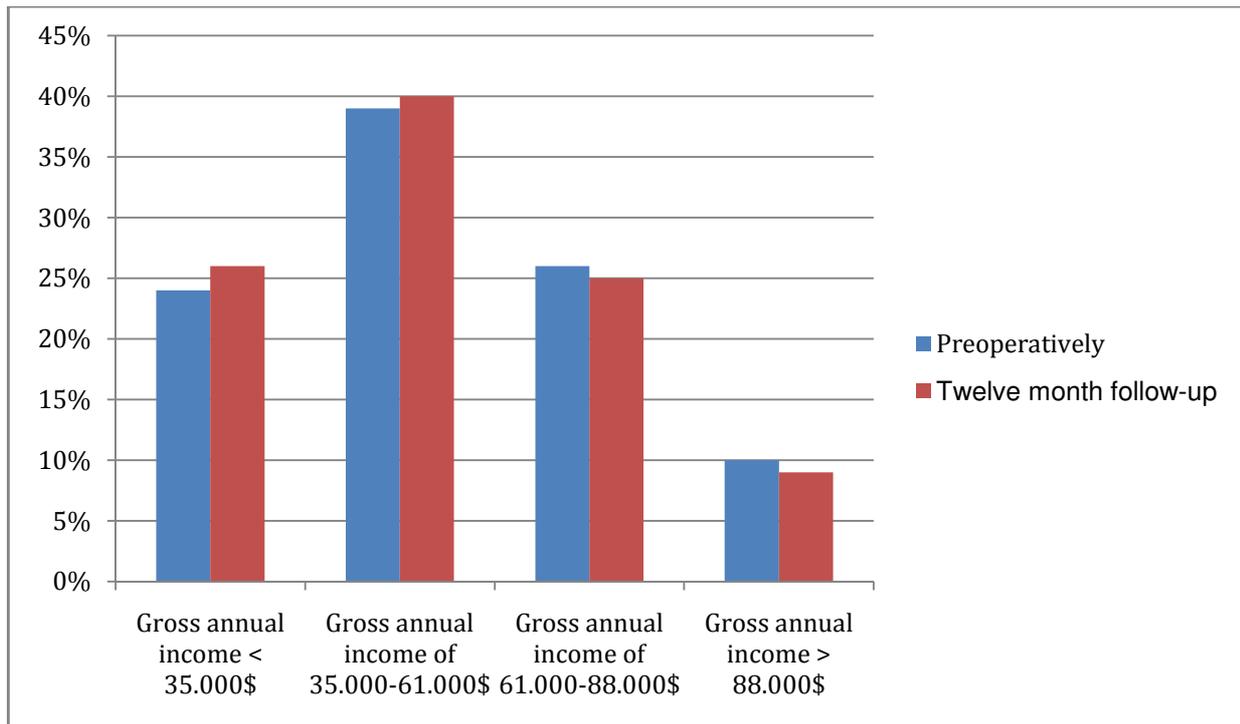
*SF-36 PCS median score for a cohort from the population similar with respect to age and sex: 50.4(IR:47.0-56.7)*

*SF-36 MCS median score for a cohort from the population similar with respect to age and sex: 54.1(IR:51.6-59.4)*

*No depression preoperatively (n=92) Depression preoperatively (n=23)*

At twelve-month follow-up 81% (62 of 77 patients) had experienced no change in their relation to work compared with the preoperative status, 5% (4 of 77) had gone from part time to full time employment, 3% (2 of 77 patients) had lost their job, and 4% (3 of 77 patients) had went on to early-age retirement. Preoperatively 24% (28 of 115 patients) reported that they expected a change in annual income due to the operation. At the twelve-month follow-up the distribution of gross annual income groups for the study population showed no or little change compared with the preoperative gross annual income (figure II c). Preoperatively 89% (80 of 90 patients) expected a sick leave  $\leq$  12 weeks. At the twelve-month follow-up only 64% (39 of 61 patients) reported a sick leave  $\leq$  12 weeks, and the median sick-leave were 12 weeks (IQR: 6-15). No statistically significant (P=0.147) difference where seen among the two sexes

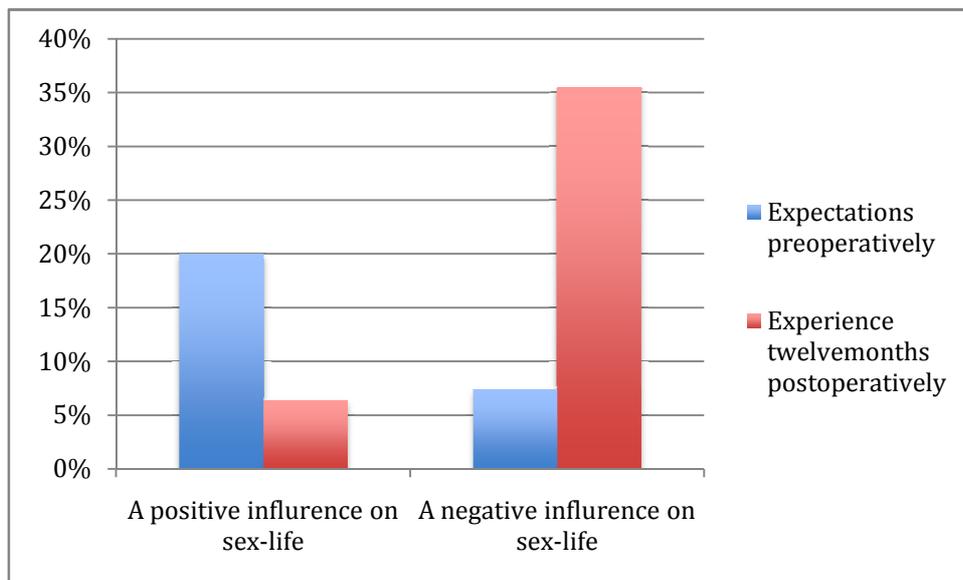
Figure II c



Distribution of income preoperatively and at twelve-month follow-up

Preoperatively 83% (95 of 115) were sexually active and at twelve-month follow-up 94% (62 of 66 patients) had resumed their sex-life. Sixty-two percent (41 of 66) reported that they resumed their sex-life  $\leq 8$  weeks after surgery, 24% (15 of 62 patients) found this question too intimate to answer. Preoperatively 21% (19 of 95) expected the operation to have a positive influence on their sex-life, and 7% (7 of 95) of the patients expected a negative influence. At twelve-month follow-up 32% (20 of 62 patients) reported a decreased frequency in sexual activities and 42% (26 of 62 patients) a change in their normal sexual practice. Nineteen of these associated it with a negative outcome with increased pain and fear, and decreased ROM, and four patients associated it with a positive outcome with decreased pain and fear, and increased ROM (figure II d). No statistically significant ( $P$ -values $<0.06$ ) differences were found comparing males and females concerning the influence of TKA surgery on sex-life.

Figure II d



Comparison of the preoperatively expectations to sex-life postoperatively and the postoperatively experience in sex-life. Preoperatively 83% where sexually active and postoperatively 80% where sexually active

Twelve patients were scheduled for bilateral simultaneous TKA. At the twelve-month follow-up the median OKS for the bilateral subgroup was 45 (IR: 40-46). This is statistically significant ( $P=0.04$ ) more than the OKS in the unilateral group. No other statistically significant ( $P$ -values  $> 0.171$ ) differences were found comparing unilateral and bilateral simultaneous TKA.

Four patients experienced a major complication.

Conclusion: Our results showed significant improvements in both joint function and HRQoL.

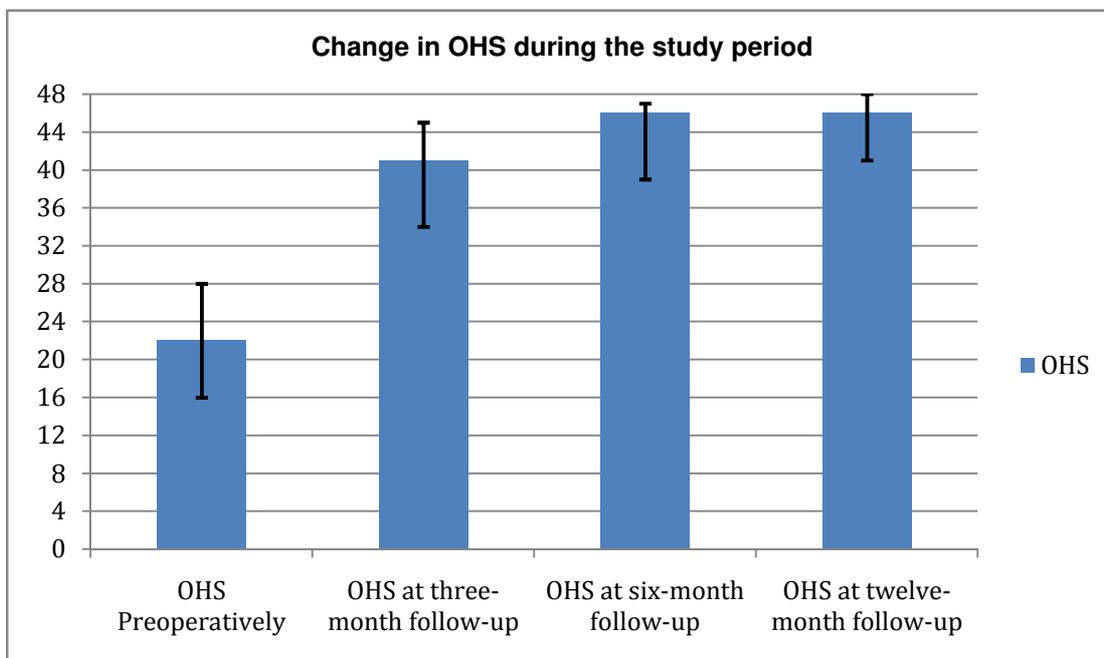
Satisfaction with the outcome of TKA and fulfillment of expectations do, however, not fully mirror the observed significant improvements in knee function and HRQoL. Patients with a preoperative depression experience an inferior result evaluated by OKS and SF-36 PCS and MCS, but not concerning satisfaction, work-life, income or sex-life. In general, TKA surgery in younger patients cannot be expected to change relation to work or annual income. Patients stay sexually active after TKA, but a decrease in frequency and a negative affection of sexual practice should be expected.

### Study III

*Research questions:* We aimed, in a prospective setting with the use of PROMs, to explore patient satisfaction, fulfillment of expectations, symptoms of depression, the effect on relation to work and income, and abilities in sex-life of younger THA patients. These alternative endpoints were collected in addition to traditional outcome measures of function and HRQoL.

*Results:* At the three-month follow-up the median OHS had increased statistically significant compared with the median preoperative score ( $p < 0.0001$ ), and continued to increase throughout the study period (figure III b).

Figure III b



At the three-month follow-up both the SF-36 PCS and MCS had increased statistically significant compared with the preoperative score;  $p < 0.0001$  and  $p = 0.028$ , respectively. At the six and twelve-month follow-up the SF-36 PCS was at the level of a cohort from the population similar with respect to age and sex. The SF-36 MCS was above that of the population cohort at all postoperative follow-ups (table III b).

Table III b

	Preoperatively	Three-month follow-up	Six-month follow-up	Twelve-month follow-up
<b>SF-36 PCS median score (IQR)</b>				
<b>Study population</b>	31.5 [27.2-36.8]	48.1 [39.3-53.9]	53.4 [44.3-55.9]	53.1 [46.7-56.9]
<i>Cohort from the population similar with respect to age and sex</i>	53.5 [47.0-56.7]	53.5 [47.0-56.7]	53.5 [47.0-56.7]	53.5 [47.0-56.7]
<b>SF-36 MCS median score (IQR)</b>				
<b>Study population</b>	49.8 [40.4-59.5]	57.8 [52.5-60.4]	58.8 [53.7-61.4]	59.2 [54.7-62.1]
<i>Cohort from the population similar with respect to age and sex</i>	57.0 [51.6-56.7]	57.0 [51.6-56.7]	57.0 [51.6-56.7]	57.0 [51.6-56.7]

At twelve-month follow-up 94% (101 of 107 patients) were willing to repeat the treatment, 94% (101 of 108 patients) were “very satisfied” or “satisfied”, and 92% (99 of 108 patients) declared all or most of their expectations fulfilled (table III c and III d). During the twelve months follow-up eight major complications were reported, all in the THA subgroup. Only patients with major complications were not willing to repeat.

Table III c

<b>Satisfaction with the outcome</b>	
<b>1) very satisfied</b>	n=78
<b>2) satisfied</b>	n=23
<b>3) neutral</b>	n=3
<b>4) dissatisfied</b>	n=1
<b>5) very dissatisfied</b>	n=3

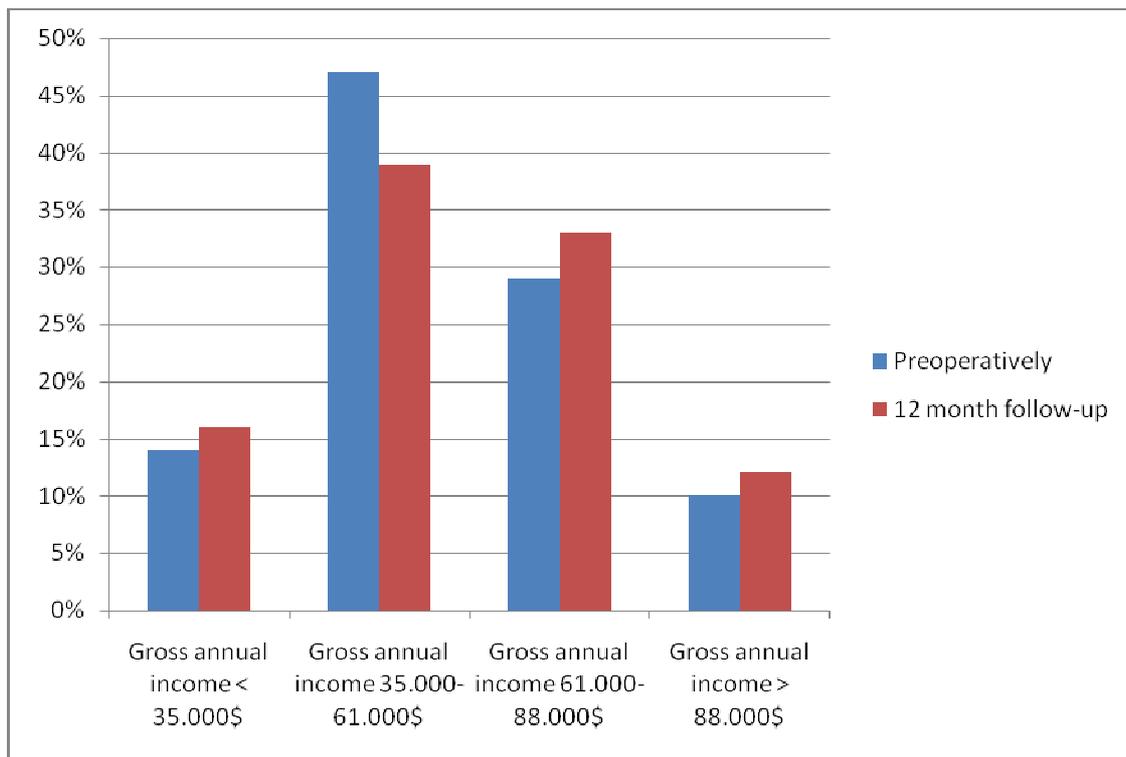
Table III d

Fulfillment of expectations at twelve-month follow-up	
1) all my expectations are fulfilled	n=73
2) most of my expectations are fulfilled	n=26
3) to some extent my expectations are fulfilled	n=4
4) few of my expectations are fulfilled	n=4
5) none of my expectations are fulfilled	n=1

Preoperatively 26% (35 of 136) of patients had a MDI score  $\geq 20$  (indicative of a depression) and 3% (3 of 108) at twelve-month follow-up. The median MDI score for the study population decreased from 10 (IQR: 5-20) preoperatively to 3 (IQR: 0-7) at twelve-month follow-up. Preoperatively, patients with a depression had a statistically significant ( $p < 0.0001$ ) lower SF-36 PCS, SF-36 MCS and OHS compared with the non-depressed patients. However, at the twelve-month follow-up the preoperatively depressed patients only had a SF-36 MCS statistically significant ( $p = 0.006$ ) below the preoperative non-depressed patients. Measured by physical parameters (SF-36 PCS and OHS) the preoperative depressed patients had a score comparable ( $p$ -values  $> 0.853$ ) to the preoperative non-depressed patients.

At twelve-month follow-up 84% (91 of 108) reported that the operation had not changed their relation to work. Prior to surgery, 75 of those were employed and 16 were retired at early age. Of the 16% (17 of 108) who experienced a change in relation to work: 6 had lost their jobs, 4 had gone from full-time employment to part-time employment, 4 had gone on to early age retirement, and 3 had gone from part-time to full-time employment. Preoperatively 10% (13 of 136) expected an increase in annual income, 9% (12 of 136) expected a decrease in annual income due to the operation. At twelve-month follow-up the distribution of gross annual income groups for the study population showed no statistically significant ( $P = 0.739$ ) change compared with the preoperative gross annual income (figure III c). Preoperatively 89% (91 of 102) of the employed patients expected a sick-leave  $\leq 12$  weeks and at twelve-month follow-up 89% (77 of 86) reported a sick-leave  $\leq 12$  weeks.

Figure III c



Distribution of income preoperatively and at twelve month follow-up

Preoperatively 80% (108 of 135 patients) were sexually active and at twelve month-follow-up 77% (83 of 108 patients) of the study population sexually active prior to surgery responded; all had regained their sex-life. Sixty-six percent (55 of 83 patients) had regained their sex-life within eight weeks, 12% (10 of 83 patients) after eight weeks, and 22% (18 of 83 patients) found the question too intimate to answer. Preoperatively 47% (23 of 49) of the female patients and 39% (24 of 62) of the male patients expected a change in sexual frequency, and 68% (34 of 50) of the female patients and 31% (18 of 59) of the male patients expected a change in sexual practice. At twelve-month follow-up 27% (11 of 41) female patients had experienced a change in frequency (5 an increase, and 6 a decrease). Thirty-eight percent (19 of 40) of the female patients experienced better abilities in sexual practice. Of those, 84% associated it with an increased ROM and decreased pain and fear. No changes were seen in sexual frequency or sexual practice among males. Three male patients experienced erectile dysfunction during the follow-up period. Forty-four patients were scheduled for HR. Only sex distribution and sick-leave differed statistically significant (P-values <0.015) (table III e).

Table III e

	<b>HR at 12-month follow-up</b>	<b>THA at 12-months follow-up</b>
<b>OKS median score (IR)</b>	47 (43-48)	46 (40-48)
<b>SF-36 PCS</b>	54.2 (48.8-56.9)	51.6 (45.4-56.5)
<b>SF-36 MCS</b>	59.9 (54.7-62.1)	58.6 (53.8-62.1)
<b>MDI Median score (IR)</b>	3 (0-7)	3 (0-7)
<b>Willingness to repeat</b>	97% (31 of 32 patients)	92% (70 of 76 patients)
<b>Very satisfied or satisfied</b>	100% (32 of 32 patients)	91% (69 of 76 patients)
<b>All or most of my expectations are fulfilled</b>	97% (31 of 32 patients)	89% (68 of 76 patients)
<b>No changes in relation to work</b>	88% (28 of 32 patients)	78% (47 of 60 patients)
<b>Sick-leave <math>\leq</math> 12 weeks*</b>	90% (28 of 31 patients)	65% (39 of 60 patients)
<b>Postoperatively regain of sex-life</b>	94% (29 of 31 patients)	81% (54 of 67 patients)
<b>Regain of sex-life <math>\leq</math> 8 weeks</b>	89% (24 of 27 patients)	82% (32 of 38 patients)
<b>Decrease in sexual frequency</b>	3% (1 of 30 patients)	13% (7 of 54 patients)
<b>Changes in sexual practice</b>	17% (5 of 29 patients)	17% (5 of 29 patients)

Comparison of HR and THA at the 12 month follow-up

\*Statistically significant difference

**Conclusion:** Our results show significant improvements in joint function and HRQoL and high degrees of patient satisfaction and fulfillment of expectations. Only patients with major complications were not willing to repeat. In general THA surgery in younger patients cannot be expected to change the patient's relation to work or annual income. Patients stay sexually active after THA, and female patients experiences positive changes.

## **Discussion**

### **PAO**

We noticed improvement in the sex-life of both females and males 9 to 12 years after PAO surgery. However, only improvements observed in females were statistically significant ( $p=0.102$ ).

Valenzuela et al. reported that 25%-40% of female patients experienced positive changes in their sex-life after PAO(30). However, in addition Valenzuela reported that the majority of females were able to deliver a child vaginally following the unchanged geometry of both the pelvic inlet and outlet, (30,56). The ability of males in sexual performance following PAO has not previously been investigated.

Van Bergayk et al. reported improvements in sports participation at short term follow-up after PAO surgery(29). We found a significant improvement in the ability to participate in sports at long term follow-up. A general decrease in the ability in sports participation is expected during a 10 year period, and this is probably the reason why the improvement is only marginal. The lasting improvements after PAO observed with respect to pain reduction, increased hip stability, and reduction of limping supports that patients would achieve improved abilities to do sports.

We found a significant improvement in the patients' ability to interact in a social context (meeting friends, going to the movies, concerts, shopping etc.). We acknowledge that our results may be affected by recall bias, changes in lifestyle during the approximately 10 year follow-up period. Furthermore the cohort is highly selected as it includes only patients with preserved hip joints. This may bias the outcomes reported. to be better than can be expected in general. However, as in other studies we found statistically significant improvements in HRQoL at medium to long term outcome (25,29,30), and both satisfaction with the result and willingness to repeat were high indicating lasting success of PAO surgery.

### **TKA in the young**

The incidence of hip and knee replacements have increased dramatically during the past decade and are estimated to increase by as much as 673% from 2005 to 2030 (50–52). In recent years the utilization of TKA in younger age groups, less than 60 years of age, have been increasing. These patients are expected to have higher demands and expectations to surgery. and the function of their knee.

TKA is well accepted as a reliable surgical procedure to relieve pain and return patients to near normal function, evaluated on traditionally clinically objective and surgeon-reported endpoints(42–46,62,63). In contemporary literature the focus of outcome measurement has shifted towards the use of PROM's and alternative endpoints, such as influence on socioeconomic status and sex-life after TKA(42–44,46,62,68–76). However, few studies have focused on these outcomes in young patients(77,82).

It has been recognized that these alternative endpoints are of crucial importance to the patients' everyday-life(78). Thus, alternative endpoints need to be considered when evaluating the success of TKA, especially in younger high demanding patients.

Traditional outcomes: Our results confirm the results in contemporary literature, that measured by the OKS and SF-36 PCS and MCS, TKA is effective in reducing pain and improving function with significantly improvements(42–46,62,63). However, the outcome measured by SF-36 PCS is still below that of a cohort from the population similar with respect to age and sex (42–46,62,63).

Expectations and satisfaction: At twelve-month follow-up 68% reported either “all expectations” or “most expectations” to be fulfilled, and 71% reported to be “very satisfied” or “satisfied” with the outcome. These findings are consistent with contemporary literature where 75-85% are reported to be satisfied with the outcome, and with young age being recognized as a predictor for lower satisfaction(64–67). At twelve-month follow-up 12% (9 of 77 patients) stated not willing to repeat. Summarized, these findings support that satisfaction with the outcome of TKA and the fulfillment of expectations following TKA surgery do not fully mirror the observed significant improvements in knee function and health related quality of life measured with SF-36 and OKS after TKA surgery.

Depression: Depression is known as a predictor of an inferior outcome of TKA evaluated by measures of pain and function(96–98). Similarly we found that patients with a preoperative depression achieved less improvement and had statistically significant lower OKS, SF-36 PCS, and SF-36 MCS scores at twelve-month follow-up compared with non-depressed patients. Regardless of this, a preoperative depression had no influence on satisfaction with the outcome, fulfillment of expectations, willingness to repeat, work-life, income or sex-life. It should be considered that patients may either have inferior outcomes measured by the OKS or SF-36 subscales because they

suffer a depression or they may be depressed because of a poor knee function. I recommend that depression is not perceived as a contraindication to perform TKA as patients gain significantly from surgery, but I do recommend, that patients suffering from a depression are well informed about what outcome to be expected. I know of no other studies that have explored depression's influence on these alternative endpoints, there has been recognized as crucial to the patients' everyday-life(78).

Socioeconomic outcome: During the decision making process prior to TKA surgery in patients in the working age sick-leave and the influence on postoperatively employability is essential. Preoperatively 89% of the study population expected a sick leave  $\leq$  12 weeks, likely reflecting the preoperatively information they have received. Styron et al. reported that 72% having returned to work within 12 weeks postoperatively, with male sex as a significant predictor for prolonged sick-leave (99). Our results are not that positive with only 64% of the study population reporting a sick leave  $\leq$  12 weeks, and our results do not support male sex as a predictor for prolonged sick-leave. According to Statistics Denmark, the risk of being unemployed were increasing due to international economic changes in our study period. In the last official report statement for a one year period (2008-2009), the unemployment risk range from 0.2-5.5% with a large variance according to age, education, profession, and geographical region(100). Our findings are within this range. In general we found no change in relation to work or the annual income of the patient. When interpreting these results it should be noted, that different nations and different states have different social welfare and job markets, which could limit the generalizability in these findings. Denmark has economically supportive government financed welfare and job market systems, which could mask the consequences on income seen in other parts of the world. However, the findings constitutes important information to patients and to surgeons during the decision making process prior to undertaking TKA surgery in younger patients.

Sex-life: In a TKA population  $>$  70 years of age, it has been reported that, about 20% of the patients reporting to be sexually active after TKA experienced limitations due to their TKA while participating in these activities(78). We found that 95% of patients who reported to be sexually active preoperatively had resumed their sex-life at twelve-month follow-up. Sixty-six percent had resumed their sex-life within eight weeks postoperatively. However, 26% reported a decrease in sexual frequency and 31% reported that the TKA knee had resulted in changes in sexual practice.

Our data indicates that patients in general stay sexually active after TKA surgery, but a decrease in frequency of sexual activities and negative affection of sexual practice patterns should be anticipated following TKA surgery in younger patients. I know of no other studies that have explored the influence of TKA surgery on the sex-life of younger TKA patients. Previous studies has showed that patients would like to have this information preoperatively, and that surgeons despite of this knowledge rarely discusses issue whit the patient(101–103). I believe this should be an important part of the preoperative information.

*Bilateral TKA:* Despite of the small sample size for bilateral simultaneous TKA, we conducted a subgroup analysis. The bilateral simultaneous TKA group had a statistically significant better OKS at the twelve-month follow-up. For all other parameters no statistically significant differences between the two groups were found. Based on the small number of patients no final conclusions can be drawn. However, the outcome for bilateral simultaneous TKA seems to be equal to that of unilateral TKA.

### **THA in the young**

In recent years the greatest increase in THA surgery has occurred in younger age groups (< 60 years), and this increase will continue given the estimated increases in performed THA surgeries(52,79). Expectations and demands concerning function of the THA expressed by these high demanding younger patients differ from that in older age groups. Traditionally, the success of THA has often been evaluated by clinically objective surgeon-reported endpoints, such as implant survival, complications, ROM, and radiographic results. In this traditional paradigm, THA is well accepted as a reliable treatment to relieve pain and return patients to near normal function. However, it has become evident that patient perceived outcome differ from the surgeon's evaluation of outcome(32–38,53,55). In both clinical practice and research, this has led to an increasing utilization of PROMs in evaluation of THA outcomes(34,37,42,43,68,69,72,76,80,82,83,104–107). It seems however, that many aspects of patient perceived success of treatment and the corresponding outcome estimation are still to be understood. Some studies have focused on Health Related Quality of Life (HRQoL) and alternative outcomes, such as the effect on personal welfare and sex-life after THA(42,43,69,72,76). However, only few studies have focused on these outcomes in young THA patients(30,81–83). Thus, alternative endpoints need to be considered when evaluating the success of THA, especially in younger high demanding patients.

Traditional outcomes: In our young THA patients OHS showed a “ceiling effect” and the SF-36 PCS and MCS were at the level of or above the age matched standard population, at the six and twelve months follow-up (92,93). These results confirm the results in contemporary literature, that measured by OHS and SF-36 PCS and MCS, THA is effective in reducing pain and improving function with significant improvements (32–38). The pronounced ceiling effect in these outcomes, however limits the ability to discriminate “good” from “very good”.

Expectations and satisfaction: At the twelve month follow-up 94% reported to be very satisfied or satisfied with the outcome, 92% reported either all or most expectations to be fulfilled, and 94% declared that they were willing to repeat the treatment. Patients suffering a major complication had markedly lower fulfillment of expectation and satisfaction, and only patients with major complications declared not willing to repeat. These findings are consistent with contemporary literature where around 90% reports satisfied with the outcome(34,37,80).

Depression: Depression is a known predictor of an inferior outcome in TKA considering pain and function(96–98). However, to our knowledge this link has not been explored or shown for THA. Measured by the physical parameters (SF-36 PCS and OHS) the patients with preoperative signs of a depression scored below the non-depressed part of the study population preoperatively but similar to the non-depressed part of the study population at twelve-month follow-up. There were no differences in satisfaction, fulfillment of expectations, and willingness to repeat between the two groups. Thus, it seems that preoperative signs of a depression do not limit the positive effect of THA surgery.

Socioeconomic outcome: During the decision making process prior to THA surgery in patients in the working age sick-leave and the influence on postoperatively employability is essential. Sixteen percent reported to have experienced a change in relation to work-life, however these changes did not result in any statistically significant changes in gross annual income, and as for TKA our unemployment risk are within the official range(100). We found a high degree of consensus between preoperative expectations to sick-leave and the actual sick-leave experienced. It cannot be expected that THA surgery changes the patient’s relation to work or the gross annual income. Despite different nations and different states having different social welfare and job markets, these

findings are consistent with contemporary literature(83). I find that this constitutes important information to patients and to surgeons during the decision making process prior undertaking THA surgery in younger patients.

Sex-life: Compared with male OA patients female OA patients more frequently experiences sexual problems, probable due to higher loads on female hip joints during intercourse (101,108). We found that nearly 40% of the female patients experienced a positive change in sexual practice postoperatively due to increased ROM and decreased pain and fear. Preoperatively nearly 50% of the female patients expected a change in sexual frequency postoperatively. Despite the positive change in ROM and decreased pain, we found no change in frequency of intercourse among the female patients. Despite that preoperatively approximately one third of the male patients expected a change in sexual frequency and practice postoperatively, due to increased ROM and decreased fear and pain; we found no change in the male patients' sex-life. Three male patients experienced erectile dysfunction during the follow-up period, this number is expected for the age group(109). It has been reported that OA patients have a wish for information regarding their expected sex-life postoperatively(101,102). Despite of this, surgeons fail to provide their patients with this information prior to surgery(103). The course for this could be the lack of focus on this topic in contemporary literature. I know of no other prospective studies which have examined young THA patients' sex-life.

## **Methodological considerations and limitations to the studies**

Population and design: The study population in *Study I* is highly selected as it includes only preserved hips. This may bias the outcome to be better than can actually be expected in general. Secondly, the patients were operated from 1998-2002 and the surgical approach and the indication for PAO have changed since then. Finally, recall bias is introduced by the questions regarding the preoperative status. However, the retrospective design is known to hold these disadvantages for bias and confounding, which therefore always should be kept in mind. However, the retrospective design holds the advantages of viewing outcomes in a historical context and in large cohorts identifying rare outcomes and risks.

For *Study II* the overall response rates for return of questionnaires varied between 68 % and 84% and for *Study III* between 79% and 83%. Younger patients  $\leq 55$  years of age are known to have a lower response rate(110). Closer consideration of this could have been made when designing the comprehensive questionnaires used in *Study II* and *Study III* as a high responder burden may lead to responder fatigue and a low response rate(111). Non-responders are known as a general problem in studies collecting PROMs, where a high response rate is important to ensure generalizability and minimize the risk of selection bias. Response rates of 80% is normally considered adequate, however rates as low as 65% has shown not to bias the result(112,113).

In *Study II* different arthroplasty concepts were used in the cohort. Different arthroplasty concepts have different indications and theoretically different outcomes. However, to my knowledge it has not been shown that an increased flexion beyond 110° gives a statistically significant gain in patient satisfaction(59). Also the indication for bilateral simultaneous TKA differs from staged bilateral TKA or unilateral TKA. However, we found only minor statistically significant differences between the two groups. The same considerations regarding arthroplasty concepts apply for *Study III*. However, as in *Study II*, we found only minor statistically significant differences between THA and HR, and no statistically significant differences between the simultaneous bilateral THA subgroup and the study population. These findings are consistent with contemporary literature(114). Thus this does not seem to affect our endpoints.

The self-developed questionnaires: This PhD thesis was not set-up to construct, validate, or test the reliability of a new questionnaire. However, when initiating the thesis it soon became clear that no existing questionnaires met our requirements in *Study I* regarding the PAO patients and in *Study II* and *Study III* regarding socioeconomic conditions and sex-life for young TKA and THA patients.

We therefore developed our own questionnaires. The construction and design of a new questionnaire is comprehensive when it comes to validation and reliability.

As I described in the questionnaire section we evaluated the content of the questionnaires by face validity. Content validity refers to questionnaires comprehensiveness, or how adequate the instrument reflects its purpose. Content validity is in general established by content experts. For a clinical based outcome physicians or a group of physicians are usually the regarded ad content experts. However, for a PROM a group of patients is usually recommended as experts. In all three studies the new questionnaires were PROM, and we therefore used patients as our experts.

Reliability of a questionnaire refers to its ability to measure something the same way twice.

Reliability is normally tested by test-retest or inter-observer test. Where the test-retest describes how close a result a questionnaire is able to give for the same patient on two different occasions, the inter-observer test measures how close observer a agrees with observer b on the same patient. To strengthen our design it would have been advisable to have tested the reliability of the questionnaires by test-retest(115).

PROMs: The recognition of inconsistency between the patients' and the surgeons' evaluation of success of a given treatment have led to an increasing utilization of PROMs in the evaluation of outcome, and PROMs are now recommended as the core set of outcomes and used extensively when evaluating PAO, TKA, and THA. Like the majority of joint specific PROMS, the OKS and OHS were developed for the elderly patient population. However, with the increasing proportion of younger arthroplasty patients OKS and OHS is being extensively used in the younger patient population. In an elderly TKA population the OKS has shown floor and ceiling effect before and after surgery, respectively(85). This means that since the answers are outside the sensitive range of the scale it is not possible to detect changes over time. The effect cannot be expected to be less pronounced in a younger high demanding patient group or in a THA group. We have not calculated the percentages, however figure II b and III b seems to show a pronounced postoperative ceiling effect, and we acknowledge the problem. However, this is a general problem when evaluating the outcome in younger patients following joint preserving hip surgery, TKA or THA, where there is a lack of standardized outcome measures that are able to differentiate improvements in these high demanding and high functioning patients. I believe that a joint specific PROM for young high demanding patients needs to be developed, to minimize the ceiling effect.

For the SF-36, the ceiling and floor effects have been documented for the eight subscale scores(93). We used the two summary scores PCS and MCS. The advantages of using these two summary scores instead of the eight subscale scores are; 1) the reduced change of a random finding of significant result due to a large number of scales, 2) PCS and MCS due not show floor or ceiling effect, and 3) the reliability for the PCS and MCS is higher than for the eight scale scores(92).

## Conclusion

Based on the findings in this thesis the following conclusions can be drawn, with regard to young high demanding PAO, TKA and THA patients.

Our results suggest that it is possible to achieve lasting improvements in the patients' sex life, social life and ability to do sports 9 to 12 years following PAO.

We found that TKA in younger patients is successful in significantly improving joint function and HRQoL. Satisfaction with the outcome of TKA and the fulfillment of expectations following TKA surgery do not fully mirror the observed significant improvements in knee function and health related quality of life after TKA surgery. In general TKA surgery in younger patients cannot be expected to change the patient's relation to work or the annual income of the patient. Patients in general stay sexually active after TKA surgery, but decreases in frequency of sexual activities and negative affection of sexual practice patterns should be anticipated following TKA surgery in younger patients.

As for TKA we found that THA in younger patients is successful in significantly improving joint function and health related quality of life. We found a high degree of satisfaction and fulfillment of expectations following THA surgery, and only patients with major complications were not willing to repeat. In general THA surgery in younger patients cannot be expected to change the patient's relation to work or the annual income of the patient. Patients stay sexually active after THA surgery, and the female patients' experiences positive changes in sex-life.

In conclusion these alternative endpoints of PAO, TKA, and THA surgery surveyed in this thesis constitutes important new information important to both patients and surgeons during the decision making process prior to surgery. I recommend that this information is included as part of the preoperative information.

## Perspectives and future research

The three studies bring forth important new information to be used by patients and surgeons during preoperative decision making. The alternative outcomes measured in the studies reflect issues that are essential in the everyday life for the young patient. This new information is easy to apply in the preoperative information.

In *Study I*, we showed that PAO is capable of providing lasting improvements in the patients' sex life, social life and ability to do sports. This constitutes important information to the young patient prior to PAO surgery. The design of the study is however retrospective with the limitations and weaknesses this study design has, and the questionnaire is only validated and not tested for reliability. To elevate the evidence of the information a prospective database needs to be constructed, collecting preoperatively patient data, surgical data, and long term postoperative data including PROMs as a core outcome measure. The PROM should be developed to suite this young high-demand patient group to avoid floor and ceiling effect. In this young patient population the database could be entirely web-based with a yearly e-mail reminder to the patient. With these data it would be easier for the surgeon to tailor the preoperative information to each patient.

In *Study II* and *Study III*, we showed that TKA and THA are successful in significantly improving joint function and HRQoL. However, satisfaction with the outcome and fulfillment of expectations are not fully mirrored by the significant improvements measured traditionally used PROMs surveying function of the joint and HRQoL. This knowledge ought to be used, when PROMs hopefully soon is integrated as an important part of the Danish Knee Arthroplasty Register and the Danish HIP Arthroplasty Register. Due to the more heterogenic patient population, three different PROMs will be advantageous; one for the really young (< 40 years of age), one for the middle aged (40-65 years of age) and one for the elderly (>65 years of age). In addition these PROMs should also focus on the alternative outcomes surveyed in this thesis, besides the traditionally outcomes.

# Summaries

## English summary

### Background

Knee and hip OA is the clinical and pathological outcome of a functional and structural failure of the joint, resulting in pain and physical dysfunction. Despite the similarity in clinical presentation the pathogenesis seems to differ. Where knee OA is associated with obesity and trauma, hip OA is associated with FAI covering three fundamentally different hip deformities, including acetabular dysplasia; all hypothesized to initiate OA development. Where PAO is used worldwide as a joint-preserving procedure in acetabular dysplasia, TKA and THA are the treatment of choice of end stage OA. Traditional main outcomes are clinically objective surgeon-reported endpoints. Patient perceived outcomes are known to differ from these and PROMs are now recommended as the core set of outcomes. When evaluating the outcome in younger patients, this high demanding group can show ceiling-effects of the scores. The overall aim of this thesis was to investigate the consequences of PAO, TKA, and THA in younger patients evaluated by alternative outcomes in relation to satisfaction, fulfillment of expectations, symptoms of depression, the socioeconomic effects, and abilities in sex-life; to improve patient information prior to PAO, TKA and THA surgery.

### Material and Methods

This PhD thesis is based on three studies. *Study I* is a cross-sectional survey of preserved hip joints with a mean follow-up of ten years after PAO. One hundred patients (121 PAO's) were eligible for inclusion. An inquiry to the National Patient registry identified 36 of PAO's (in 35 patients) being converted to THA. The 61 remaining patients (80 preserved hip joints) were asked to participate in this questionnaire based follow-up. Fifty-five patients (70 preserved hip-joints) accepted and constituted the study population. All patients received a questionnaire concerning aspects of functional ability, patient satisfaction, expectations, and quality of life following PAO.

Both *Study II* and *Study III* are prospective multicenter cohort studies. Consecutive patients less than 60 years of age scheduled for (*study II*) unilateral or bilateral simultaneous primary TKA or (*study III*) scheduled for unilateral or bilateral simultaneous primary THA or HR were eligible for inclusion. *Study II* consisted of 115 primary TKA patients; 103 unilateral and 12 simultaneous, and

*Study III* consisted of 136 primary THA patients; 86 unilateral THA, 6 simultaneous bilateral THA, and 44 HR.

The study groups received a paper-format questionnaire within one month before surgery and at three, six, and twelve months postoperatively.

## **Results**

*Study I* showed a high willingness to undergo PAO again with the experience and knowledge they have today and improvements were seen in all quality of life parameters except for ability in sex-life for males. *Study II* showed significantly improvements in joint function and HRQoL.

Satisfaction and fulfillment of expectations do, however, not fully mirror the observed significant improvements in knee function and HRQoL. Patients with a depression preoperative experience an inferior result evaluated by OKS and SF-36 PCS and MCS, but not concerning satisfaction, work-life, income or sex-life. In general TKA surgery in younger patients cannot be expected to change relation to work or annual income. Patients stay sexually active after TKA, but a decrease in frequency and a negative affection of sexual practice should be expected. *Study III* showed significantly improvements in joint function and HRQoL and a high degree of satisfaction and fulfillment of expectations. Only patients with major complications were not willing to repeat. THA surgery in younger patients cannot be expected to change the patient's relation to work or annual income. Patients stay sexually active after THA, and female patients experiences positive changes.

## **Conclusion**

Based on the findings in this thesis PAO patients are satisfied with the outcome at medium to long term follow-up, and lasting improvements is seen in the patients' sex life, ability to do sports, and social life. TKA and THA are reliable surgical procedures in younger patients. In addition to significantly improving joint function and HRQoL, patients' stay employed and sexually active postoperatively. However, a decrease in frequency of sexual activities and negative affection of sexual practice patterns should be anticipated following TKA surgery, THA surgery have a positive influence on female THA patients sex-life.

## Danish summary

Grundet den fremadskridende nedslidning af brusken ved slidgigt (SG) i knæ og hofte, oplever patienterne en tiltagende smerte og tab af leddets funktion. Sygdommen er multifaktoriel, men hvor knæ SG især er associeret med overvægt og skader på knæet, er SG i hofteleddet vist at kunne skyldes blot små deformiteter i form af FAI. FAI dækker over tre fundamentalt forskellige deformiteter i hofteleddet, herunder hoftedysplasi. Alle tre er mistænkt for at kunne danne forudsætningen for SG i hoften. PAO benyttes til at standse eller udskyde udviklingen af hofteslidgigt ved hoftedysplasi, hvorimod TKA og THA begge er centrale i behandlingen af SG, når konservativ behandling har vist sig insuffICIENT. Alle tre behandlingsformer har vist sig pålidelige, når kvaliteten vurderes ud fra traditionelle kriterier vurderet af kirurgen. Patient reporterede resultater er dog vist at afvige fra disse resultater, hvorfor PROMs nu anbefales som et væsentligt parameter når resultatet skal vurderes. Når man skal vurdere resultatet i en yngre patientgruppe, kan denne gruppe dog, grundet dens høje funktionsniveau, score højere end disse skalaer kan måle. Målet med denne afhandling var at undersøge konsekvenserne af PAO, TKA og THA hos disse yngre patienter, vurderet ud fra alternative resultater med hensyn til tilfredshed, opfyldelse af forventninger, depression, socioøkonomiske konsekvenser og konsekvenser for patientens sexliv. Dette for at forbedrer den præoperative information.

## Materiale og metode

Denne PhD bygger på tre studier. *Studie I* er en tværsnitsundersøgelse af bevarede hofteled med en gennemsnitlig opfølgning på 10 år efter PAO. Det var muligt at inkludere 100 patienter (121 PAO'er). En forespørgsel til Landspatientregistret afslørede at 36 PAO'er (hos 35 patienter) var konverteret til THA. De resterende 61 patienter (80 bevarede hofteled), blev opfordret til at deltage i denne spørgeskema baserede opfølgning. Af disse indvilligede 55 patienter (70 bevarede hofteled) og udgjorde studiepopulationen. Patienterne fik tilsendt et spørgeskema omhandlende forskellige aspekter af funktionsevne, deres tilfredshed, forventninger og livskvalitet efter PAO.

*Studie II* og *III* er begge prospektive multicenter kohorte studier. Patienter under 60 år der var planlagt til (*Studie II*) unilateral eller simultan bilateral TKA eller (*Studie III*) planlagt til unilateral eller simultan bilateral THA eller HR kunne inkluderes. Studiepopulationen i *Studie II* bestod af 115 primær TKA patienter: 103 unilateral og 12 bilateral. Studiepopulationen i *Studien III* bestod af 136 THA patienter: 86 unilateral THA, 6 bilateral THA og 44 HR. Studiepopulationerne modtog et spørgeskema inden for en måned før kirurgi samt tre, seks og tolv måneder efter kirurgi.

## **Resultater**

*Studie I* viste stor villighed til at undergå PAO med den erfaring og viden som patienterne havde i dag, og forbedringer kunne ses i alle livskvalitets parametre undtagen mænds sexliv. *Studie II* viste signifikante forbedringer i led funktionen og HRQoL. Disse resultater afspejlede sig dog ikke til fulde i tilfredsheden og opfyldelse af forventninger. Patienter med en depression præoperativt fik et inferiort resultat evalueret med OKS og SF-36 PCS og MCS, men ikke hvad angår tilfredshed, arbejdsliv, indtægt eller sexliv. Generelt kan det ikke forventes at TKA kan ændre den unge patients relation til arbejdsmarkedet eller dennes indkomst. Patienter vedbliver med at være seksuelt aktive efter operationen, men et fald i frekvens og en negativ påvirkning af sexlivet kan forventes. *Studie III* viste signifikante forbedringer i led funktionen og HRQoL, og en høj tilfredshed samt opfyldelse af de præoperative forventninger. Kun patienterne som havde oplevet en større komplikation, var ikke villig til at undergå THA igen. Det kan ikke forventes at THA vil ændre patienternes relation til arbejdsmarkedet eller dennes indkomst. Patienter vedbliver med at være seksuelt aktive efter operationen, og de kvindelige patienter kan opleve en forbedring i deres sexliv.

## **Konklusion**

PAO patienter er tilfredse med deres resultater cirka 10 år efter PAO, og blivende forbedringer kan forventes i patienternes sexliv, muligheder for at dyrke sport samt deres sociale liv. Både TKA og THA er pålidelige kirurgiske indgreb hos yngre patienter. Der ses ikke blot signifikante forbedringer i patienternes ledfunktion og HRQoL, patienter i job vedbliver også med at være i job, og både TKA og THA patienter vedbliver med at være seksuelt aktive, men dog med et fald i frekvens og negativ påvirkning for TKA patienterne. THA har derimod en positiv påvirkning på de kvindelige patienters seksualliv.

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# Papers

## Paper I

### **The ability of patients in sports, social activities and sexual life 9 to 12 years after periacetabular osteotomy**

Jakob Klit, Charlotte Hartig-Andreasen, Steffen Jacobsen, Kjeld Søballe, Anders Troelsen

#### **Abstract**

Hip joint survivorship and functional outcome are traditional endpoints in follow-up after periacetabular osteotomy (PAO). However, young adults have great demands and expectations to the function of the hip joint that are not covered using traditional endpoints.

The main purpose of this study was to explore alternative functional and quality of life aspects after PAO.

A cross sectional survey of preserved hip joints following PAO was performed. Fifty-two patients (68 hips), mean age 41 years (range 24-67), returned the questionnaire concerning satisfaction, willingness to repeat surgery, quality of life, abilities in social activities, sports and sex-life, pain, limp, and stability of the hip.

Median satisfaction was 5 (range: 1-5) and 44 of 49 patients were willing to repeat surgery.

Significant improvements were seen in quality of life, ability to do sports, participate in social activities and sex-life ( $p$  values  $< 0.001$ ), except ability in sex-life for males ( $p = 0.102$ ). Traditional outcomes (pain, stability and limp) showed significantly improvements ( $p < 0.001$ ).

We found lasting improvements in the patients' sex life, social life and ability to do sports 9 to 12 years following PAO. Given the high demands to the performance of the hip joint young patients have, these outcome measures are important to document.

#### **Introduction**

Since Wiberg's thesis in 1939, there have been numerous studies confirming the relationship between acetabular dysplasia and secondary osteoarthritis (OA) in the young patient(1-6). In the attempt to prevent or postpone the development of OA in these patients, the periacetabular osteotomy (PAO) first described by Ganz et al., and later modified, is used worldwide as a joint-

preserving procedure (6–19). The aim of the procedure is, by reorientation of the acetabulum, to increase the coverage of the femoral head, and thereby improve the stability and decrease abnormal high loads across the hip joint. Several studies have reported good medium to long term hip joint survivorship and functional outcome of PAO (9,12,13,16,17,19–22).

In contemporary literature, the main focus has been survival and function of the joint, and only a few studies have focused on Health Related Quality of Life (HRQoL) and other aspects important to the patients' everyday-life (16,20,21). The patients are often young and have high demands and expectations to the function of their hip, both in everyday life, during recreational activities, and at work. These other aspects should be considered when estimating the success of the PAO and needs to be investigated at medium to long term follow-up.

Due to the lack of focus in contemporary literature on alternative, yet very important, aspects of outcome measurement, our aims were to explore other functional and quality of life aspects after PAO surgery. We aimed to answer the following questions; 1) does PAO affect the patient's sex-life, 2) does PAO affect the patient's ability to participate in sports, 3) does PAO affect the patient's ability to interact socially, and 4) are the patients satisfied with the outcome of the procedure at medium to long term follow-up.

## **Material and Methods**

The study is a cross-sectional survey of preserved hip joints a minimum of nine years following PAO surgery. The patients eligible for inclusion were 100 patients (121 PAO's) operated by KS from December 1998 through December 2002. The medium term outcome for this cohort has previously been reported (16). Indications for PAO were, symptomatic acetabular dysplasia of the hip defined by persistent pain in the hip or groin, a Wiberg (23) center-edge angle  $<25^{\circ}$ , a congruent hip-joint, flexion of the hip  $>110^{\circ}$ , and internal rotation  $>15^{\circ}$ . The patients were operated using an ilioinguinal approach (16).

Five of the 121 PAO's were performed in four foreign citizens and were thus lost to follow-up. At the time of the present survey an inquiry to the National Patient registry identified 36 of PAO's (in 35 patients) being converted to THA. The 61 remaining patients (80 preserved hip joints) were asked to participate in a questionnaire based follow-up. Fifty-five patients (70 preserved hip-joints) accepted and constituted the study population. A questionnaire concerning aspects of functional

ability, patient satisfaction, expectations, and quality of life following PAO was developed, and validated by the authors. Fifty-two patients (68 preserved hip-joints) returned the questionnaire (response rate: 85%), 77% females. Thirty-six patients had been operated with PAO uni-laterally and sixteen bi-laterally. The mean age at surgery was 31 years (range 14-56) and at follow-up 41 years (range 24-67). The mean follow up time was ten years (range 9-12). The mean preoperative CE-angle was  $12^{\circ}$  (range  $-29^{\circ}$ - $30^{\circ}$ ) and postoperatively the mean CE-angle was  $29^{\circ}$  (range  $4^{\circ}$ - $52^{\circ}$ ). Preoperatively all hips had a Tönnis grade 0-1 and at follow-up 83% had a Tönnis grade 0-1. One author (AT), uninformed of the status of the hip, assessed all radiographs.

### **Development of the questionnaire**

No existing questionnaires met our requirements and therefore we developed our own questionnaire. A semi structured interview was conducted including 20 members of the staff comparable to PAO patients with respect to age and gender. After corrections a new semi structured interview was conducted including 20 patients in the orthopedic department at the Copenhagen University Hospital, Hvidovre, Denmark. The last round of interviews revealed no need for changes. This validation process, validate the content by face validity. The questionnaire consist of 11 items concerning the status at follow-up; 1: Satisfaction with the outcome of PAO, 2: Quality of life, 3: Social-ability, 4: Daily-activity, 5: Work-life, 6: Sexual-life, 7: Sports-activity, 8: Pain, 9: Limp, 10: Stability of the hip and 11: Willingness to repeat PAO surgery. Item two to ten consisted of three questions; 1: Preoperative status, 2: Status at follow-up, 3: Satisfaction with the current status. Answers were given on 5-point or 6 point-likert scales with 1 being the worst status and 5 or 6, respectively, the best status.

### **Statistical Analysis**

Descriptive statistics were performed and data primarily presented as prevalences. The Wilcoxon Signed Rank test for paired data was used to compare preoperative and postoperative data. A p-value  $< 0.05$  was considered statistically significant. Data were analyzed using SPSS 20.0 (IBM, Chicago, Illinois, USA.)

## Results

The median overall satisfaction with the outcome of treatment was 5 at follow-up (range: 1-5). At follow-up 44 of 49 patients were willing to undergo treatment again with the experience and knowledge they have today (three patients returned invalid answers). Improvements were seen in all quality of life parameters; quality of life, ability to do sports, ability to participate in social activities and sex-life (p values<0.001), except for ability in sex-life for males, p=0.102) (Table 1). The median pain score before PAO was 2.0 and 4.0 at follow-up (p<0.001). The median limp score was 2.0 before PAO and 4.0 at follow-up, indicating statistically significantly less limping (p<0.001). The median stability score was 3.0 before PAO and 4.0 at follow-up, indicating a reduced feeling of hip instability (p<0.001).

Table 1

	Score	Preop. status	Postop. status	P-value	Median (range) satisfaction with the result at follow-up*
<b>Quality of life</b>	1= extreme disabled	2.0	4.0	P<0.001	4.0
<b>Median score (range)</b>	2= disabled in some degree 3=moderately disabled 4= almost not disabled 5= not disabled	(Range: 1-5)	(Range: 1-5)		(Range: 1-5)
<b>Ability to do sports</b>	1=always disabled by my hip 2=nearly always disabled by my hip 3=sometimes disabled by my hip 4=rarely disabled by my hip 5=never disabled by my hip	2.0 (Range: 1-5)	3.0 (Range: 1-5)	P<0.001	4.0 (Range: 1-5)
<b>Ability to participate in social activities</b>	Same score as above	3.0 (Range: 1-5)	4.0 (Range: 1-5)	P<0.001	4.0 (Range: 1-5)

<b>Ability in sex-life female</b>	0=no sex-life due to other reasons than the hip** 1=no sex-life due to my hip 2=always disabled by my hip 3= nearly always disabled by my hip 4= sometimes disabled by my hip 5=rarely disabled by my hip 6=never disabled by my hip	4.0 (Range: 1-6)	5.0 (Range: 2-6)	P=0.008	4.0 (Range: 1-5)
<b>Ability in sex-life male</b>	Same score as above	5.5 (Range: 3-6)	6.0 (Range: 5-6)	P=0.102	5.0 (Range: 4-5)
<b>Pain</b>	1= pain that disturbed the sleep 2=pain when in rest 3=pain under physical activity 4=pain under hard physical activity 5=never pain	2.0 (Range: 1-5)	4.0 (Range: 1-5)	P<0.001	4.0 (Range: 1-5)
<b>Limp</b>	1=always limp 2=limped after a few hundred meters 3=limped after 1 kilometer 4=limped after 3 kilometer 5=never limp	2.0 (Range: 1-5)	4.0 (Range: 1-5)	P<0.001	4.0 (Range: 1-5)
<b>Stability</b>	1=never stable 2=sometimes unstable at rest 3=unstable under physical activity	3.0 (Range: 1-5)	4.0 (Range: 1-5)	P<0.001	4.0 (Range: 1-5)

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4=unstable under  
hard physical activity  
5=never unstable

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Pre- and postoperative scores, p-values and satisfaction for Quality of life, four alternative functional outcomes and three traditional functional outcomes

\*1=not at all satisfied 2=very little satisfied 3= satisfied in some degree 4= mostly satisfied 5=fully satisfied

\*\*not included in statistics

## Discussion

Several studies have reported good medium to long term outcome of PAO (9,12,13,16,17,19–21). However, the main endpoints for estimation of success have been survival and function of the joint, and only a few studies has focused on Health Related Quality of Life (HRQoL) and other aspects important to the patients everyday-life (16,20,21). These relative young patients have high demands and expectations to the function of their hip, both in everyday life, and during recreational or social activities. Alternative outcome measures should be considered when estimating the success of the PAO and remains to be explored at medium to long term follow-up.

The following limitations to our study should be acknowledged. First, the study cohort is selected as it includes only preserved hips. This may bias the outcome to be better than can be expected in general. Second, recall bias is introduced by the questions regarding the preoperative status. This might result in a bigger difference between the preoperative and postoperative scores than is actually the case. Finally, the used questionnaire was designed specifically for this study, which could result in generalisability problems. However, this is a general problem when evaluating the outcome in younger patients following joint preserving hip surgery. There is a lack of standardized outcome measures that are able differentiate improvements in these high demand patients. When using standardized patient reported outcome measures developed for osteoarthritic hips, this group will show a ceiling-effect.

Valenzuela et al. reported that 25%-40% of female patients experienced positive changes in their sex-life after PAO(21). Our results showed improvements in the sex-life of both females and males lasting 9 to 12 years after PAO surgery. However, only the improvements observed in females were statistically significant as the improvements in males failed to show statistical significance (p=0.102). The ability of males in sexual performance following PAO has not previously been reported. Van Bergayk et al. reported improvements in participation in sports at short term follow-

up after PAO surgery(20). We found a significant improvement in the ability to do sports at long term follow-up. A general decrease in the ability to do sports is expected during a 10 year period and this is probably the reason why the improvement is only marginal. The lasting improvements after PAO observed with respect to pain reduction, increased hip stability, and reduction of limping supports that patients would achieve improved abilities to do sports. We found a significant improvement in the patients' ability to interact in social contents (meeting friends, going to the movies, concerts, shopping etc.). We previously acknowledged that our results may be affected by recall bias, and in addition changes in lifestyle during the approximately 10 year follow-up period may also affect the findings. As in other studies we found statistically significant improvements in HRQoL (16,20,21), and both satisfaction with the result and willingness to repeat were high indicating lasting success of PAO surgery.

In conclusion, our results suggest that it is possible to achieve lasting improvements in the patients' sex life, social life and ability to do sports 9 to 12 years following PAO. Only few previous reports document the outcome of these alternative outcome measures. However, given the high demands to the performance of the hip joint that these young patients have, these outcome measures are important to document all aspects of the long term success of PAO surgery.

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## **Paper II**

### **Title page**

#### **Total Knee Arthroplasty in Young Patients Evaluated by Alternative Outcome Measures A prospective study**

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**Abstract:**

In a prospective multicenter cohort study including patients  $\leq 60$  years of age scheduled for primary total knee arthroplasty (TKA), we investigated satisfaction, expectations, socioeconomic-outcome, and sex-life after TKA. Endpoints potentially of crucial importance, but rarely discussed in contemporary literature. Questionnaires including Oxford Knee Score (OKS), SF-36, and alternative endpoints, were collected preoperatively and three, six, and twelve months postoperatively. OKS and SF-36 showed significant improvements. However, assessment of patient satisfaction and fulfillment of expectations do not mirror these improvements. Overall TKA did not change the younger patients' socioeconomic status. Patients stay sexually active, but decreased frequency and negative affection of sexual practice should be anticipated. Alternative outcomes of TKA surgery surveyed in this prospective study constitute important new information to patients and surgeons.

Key words: total knee arthroplasty, patient reported outcome measure, satisfaction, young patients, socioeconomic outcome, sex-life.

**Introduction**

Total knee arthroplasty (TKA) is the mainstay in modern treatment of end stage knee osteoarthritis (OA), when the patient, despite adequate conservative treatment, experiences unacceptable pain and physical dysfunction. In both Europe and North America the prevalence of OA is estimated to increase approximately 40% from 2005 to 2030[1–3]. TKA surgeries have been estimated to increase by as much as 673% from 2005 to 2030[4–6]. In recent years the utilization of TKA in the younger age groups, less than 60 years of age, have been increasing, and will continue to increase given the estimated increases in performed TKA surgeries[4–6]. The expectations and demands concerning the function of the TKA expressed by these younger patients are expected to differ from that in older age groups.

TKA is well accepted as a reliable surgical procedure to relief pain and return patients to near normal function[7–13]. The traditional main outcomes in the literature are primarily focusing on implant survival, complications, radiographic results, and range of motion(ROM). However, patient perceived outcomes are known to differ from the surgeon evaluation of the outcome [14–16], and patient reported outcome measures (PROMs) are now recommended as the core set of outcomes

and reported in much contemporary literature reporting TKA outcome. A highly relevant outcome in arthroplasty surgery is patient satisfaction. However, 8 % to 19% of patients are dissatisfied with the outcome of TKA[8,17,18]. Dissatisfaction with the outcome is strongly correlated with preoperative expectations not being fulfilled[19,20]. However, fulfillment of preoperative expectations range from a near 100% fulfillment concerning reduction in knee pain to only around 20% fulfillment concerning the ability to participate in sports and leisure activities [10]. It seems that many aspects of patient perceived success of treatment and the corresponding outcome estimation are still to be understood. Some studies have focused on Health Related Quality of Life (HRQoL) and alternative outcomes, such as the effect on personal welfare and sex-life after TKA[7,8,10,12,13,21–29]. However, only few studies have focused on these outcomes in a younger patient population, although these outcomes are of crucial importance during the everyday-life of young patients[30,31]. The utilization of alternative outcome measures in the evaluation of outcome after TKA in young adults seem warranted to better understand the patients perception of successful treatment.

Due to the lack of focus in contemporary literature on alternative aspects of outcome measurement in younger TKA patients our aims were, in a prospective setting with the use of PROMs, to explore patient satisfaction, fulfillment of expectations, symptoms of depression and the effect on socioeconomic status and abilities in sex-life. These alternative endpoints were collected in addition to traditional measures of function and HRQoL.

## **Material and Methods**

The study is a prospective multicenter cohort study, conducted at three arthroplasty units in the Copenhagen area, Denmark. Consecutive patients less than 60 years of age scheduled for unilateral or bilateral simultaneous primary TKA from April 2010 to May 2011 were eligible for inclusion (n=136 patients, 121 unilateral TKA / 15 bilateral simultaneous TKA). Patients were excluded if they did not give informed consent to participate (n=7), if they were unable to understand and fill in the questionnaires (n=12), if they did not return the preoperative questionnaire prior to surgery (n=2), if they suffered from cognitive dysfunction (n=0), or if they suffered from a malignant disease (n=0). Consequently the study population consisted of 115 primary TKA patients; 103 scheduled for unilateral TKA and 12 scheduled for bilateral simultaneous TKA. Patient demographics and clinical history are presented in table 1. All bilateral simultaneous TKAs were performed at one of the three hospitals, and received the same type of prosthesis on both sides. All

patients where operated with the standard anterior midline incision. The type of prosthesis used was dictated by the preference of the surgeon and availability at the individual hospitals. The following TKA concepts were used; Cruciate retaining, fixed bearing in 71 patients (AGC Biomet®, PFC DePuySynthes®, Triathlon Stryker®), Cruciate retaining, rotating platform in 39 patients (PFC-Sigma DePuySynthes®, Vanguard ROCC Biomet®, NextGen Zimmer®), and Posterior stabilized, fixed bearing in 5 patients (LPS-Flex Zimmer®). In one case of a cruciate retaining, fixed bearing TKA a stemmed tibia component was implanted due to an intra-operative fracture. The study was reported to the National Data Protection Agency and according to local legislation specific ethics committee approval was not needed for this prospective questionnaire based study. Prior to inclusion the study was reported to Clinicaltrials.gov (No.:NCT01305759).

The study group received a paper-format questionnaire within one month before the scheduled surgery, and at three, six, and twelve months after surgery. If the patient did not return one of the postoperative questionnaires within three weeks of the set time-point, a reminder was mailed to the patient. If the questionnaire was still not returned within another two weeks the patient was contacted by phone and encouraged to participate. If the patient still did not return the questionnaire, the patient were not reminded further, but were still scheduled to receive a questionnaire at the next follow-up. The overall response rates for return of questionnaires varied between 68 % and 84 % (Figure 1). Patients who sustained a complication were included in the analysis.

## **Questionnaires**

Both the preoperative and the three postoperative collections of questionnaires consisted of the following: Oxford Knee Score (OKS), Short Form-36 version 1(SF-36), The Major (ICD-10) Depression inventory (MDI), a self developed and validated questionnaire concerning socioeconomic aspects, and a self developed and validated questionnaire concerning the patients sex-life. In addition the preoperative questionnaire covered the patients functional category (1 =unilateral knee disease, 2= bilateral knee disease, and 3= multiple joint disease) and information regarding earlier arthroplasty surgery in other joints. The postoperative questionnaires covered additional information concerning frequency of postoperative physiotherapy. The twelve month questionnaire covered the patients' satisfaction and fulfillment of expectations on two five level Likert scales, running from 1) very satisfied, 2) satisfied, 3) neutral, 4) dissatisfied, 5) very

dissatisfied and from 1) all my expectations are fulfilled, 2) most of my expectations are fulfilled, 3) to some extent my expectations are fulfilled, 4) few of my expectations are fulfilled, 5) none of my expectations are fulfilled. Willingness to repeat was addressed.

#### *The Oxford Knee Score (OKS)*

The OKS has undergone thorough assessment of reliability and validity [23,32–34]. The score consist of 12 items regarding daily activities. Each item is scored on a five-level Likert scale 0(greatest disability) to 4(no disability), resulting in a score from 0 to 48, with 48 being the best possible score[34].

#### *Short Form-36*

The SF-36 is a instrument that has been used since the early nineties to assess HRQoL[35,36]. It consists of 36 items and measures eight domains; Physical functioning (PF), Social functioning (SF), Role-Physical (RP), Bodily Pain (BP), Mental Health (MH), Role-Emotional (RE), Vitality (VT), and General Health (GH). The Theoretical scoring scales for all eight item-scores runs from 0-100 with 100 being the best possible score. The eight item scores can be transformed in to two summery scores; the physical component summery (PCS) and mental component summery (MCS). Both PCS and MCS contain information from all eight item scores. The advantage of PCS and MCS is a smaller confidence interval and elimination of both floor and ceiling effect[37]. PCS and MCS were compared with a group from the population similar with respect to age and sex[38,39].

#### *The Major (ICD-10) Depression Inventory*

The Major (ICD-10) Depression inventory (MDI), contains ten items. However, item 8 and 10 are divided in to two sub-items (A and B), where only the highest score (A or B) are included in the statistical analysis. Each item represents a symptom, and is scored on a six-level Likert scale, measuring how much of the time the symptom have been present over the last 14 days; zero (the symptom has not been present at all) to five (the symptom has been present all of the time). The resulting score is in the interval 0 to 50, where a score  $\geq 20$  represents depression. The MDI has demonstrated a high specificity and sensitivity as a screening tool in a somatic patient group[40,41].

### *Questionnaire concerning socioeconomic outcome*

Due to the unique labor and welfare models in different parts of the world no existing questionnaires met our requirements and therefore we developed our own questionnaire. To validate the content of the questionnaire, a semi-structured interview was conducted including 20 members of the staff comparable to TKA patients with respect to age and gender. After corrections a new semi structured interview was conducted including 20 patients comparable to TKA patients with respect to age and gender in the orthopedic department at the Copenhagen University Hospital, Hvidovre, Denmark. The last round of interviews revealed no need for changes. This validation process, validate the content by face validity. The questionnaire consists of six questions regarding current work-status, sick-leave, welfare or early-age retirement, annual-income, and expectations to life-income. In addition the preoperative questionnaire consists of one extra item regarding social-class. This item divides the study group in to five social-classes: 1) manager or highly educated (holding at least a graduate degree), 2) mid-level manager or 3-4 years of higher education, 3) salaried or white collar worker, 4) skilled worker, and 5) unskilled worker.

### *Questionnaire concerning effects on sex-life*

We knew of no existing questionnaires regarding the TKA patients' sex-life, and therefore we developed our own questionnaire. We used the same method as described above to validate the content of the questionnaire. The questionnaire consists of seven items regarding sex-life before and after surgery. Focusing on what, if any, positive or negative effect TKA surgery may have had on sexual frequency and sexual practice, and the cause.

### **Statistical Analysis**

Descriptive statistics were performed and data primarily presented as percentages with actual numbers of the underlying data distribution. Data are presented as the mean with 95% confident interval (CI) and range when normally distributed and as median value with interquartile range (IR) if not normally distributed. The Wilcoxon Signed Rank test for paired data was used to compare preoperative and postoperative outcome measures. The Mann-Whitney U test was used to compare outcomes between groups. A p-value < 0.05 was considered statistically significant. SF-36 data were processed using the supplied software for SPSS. Data were analyzed using SPSS 20.0 (IBM, Chicago, Illinois, USA.)

## Results

At the three-month follow-up the median OKS had increased statistically significant ( $P < 0.0001$ ) compared with the median preoperative score. The score continued to increase throughout the study. The Median OKS at twelve-month follow-up was 40 (IR: 30-45) (table 2). At the three-month follow-up the median SF-36 PCS score had increased statistically significant ( $P > 0.0001$ ), compared with the median preoperative score. The median SF-36 MCS score showed improvements comparing the postoperative and preoperative scores, however it did not reach statistical significance. However, the median SF-36 MCS scores at all follow-up time points were above that of a cohort from the population similar with respect to age and sex. The median SF-36 PCS score, despite the statistically significant increase, were at all follow-up time points below that of a cohort from the population similar with respect to age and sex (table 2).

Preoperatively 23 patients had a MDI score  $\geq 20$  (corresponding a depression). The median MDI score for the study population decreased from 9 (IR: 5-17) preoperatively to 4 (IR: 1-10) twelve months postoperatively. Seven of the responding patients remained having a MDI score  $\geq 20$  twelve months postoperatively. Both preoperatively and twelve months postoperatively the patients with a preoperative MDI score  $\geq 20$  had a median SF-36 PCS, SF-36 MCS, and OKS statistically significant ( $P$ -values  $< 0.007$ ) below patients with preoperative MDI scores  $< 20$ . Patients with a preoperative depression had an absolute increase below the non-depressed patients of the physical parameters (SF-36 PCS and OKS) and an absolute increase above the non-depressed patients of the mental parameters (MCS and MDI) (table 2). There were no statistically significant ( $P$ -values  $> 0.06$ ) differences in the outcome of preoperatively depressed and non-depressed patients concerning satisfaction, work-life, income or sex-life after TKA.

With the knowledge they had at the twelve-month follow-up 88% (67 of 76 patients) were willing to repeat TKA surgery. Seventy-one percent (55 of 77 patients) reported to be very satisfied or satisfied with the outcome at the twelve-month follow-up, and 68% (52 of 77 patients) reported “all of my expectations are fulfilled” or “most of my expectations are fulfilled”. On the contrary 12% (9 of 77 patients) reported that “few of my expectations are fulfilled” or “none of my expectations are fulfilled”, and 12% (9 of 77 patients) reported dissatisfied or very dissatisfied. All but one patient received multiple postoperative training sessions by a physiotherapist.

At the twelve-month follow-up 81% (62 of 77 patients) had experienced no change in their relation to work compared with the preoperative status, 5% (4 of 77) had gone from part time to full time employment, 3% (2 of 77 patients) had lost their job, and 4% (3 of 77 patients) had went on to early-age retirement. Preoperatively 24% (28 of 115 patients) reported that they expected a change in annual income due to the operation. Seventeen of the 28 patients expected a decrease and 11 of the 28 patients an increase in annual income. At the twelve-month follow-up the distribution of gross annual income groups for the study population showed no or little change compared with the preoperative gross annual income (figure 3). Preoperatively 89% (80 of 90 patients) expected a sick leave  $\leq 12$  weeks. At the twelve-month follow-up only 64% (39 of 61 patients) reported a sick leave  $\leq 12$  weeks, and the median sick-leave were 12 weeks (IR: 6-15). No statistically significant ( $P=0.147$ ) difference where seen among the two sexes

Preoperatively 83% (95 of 115) reported to be sexually active. Of these, 21% (19 of 95) patients expected the operation to have a positive influence on their sex-life due to increased ROM and decreased pain and fear and 7% (7 of 95) of the patients expected a negative influence due to decreased ROM and increased pain and fear. At the twelve-month follow-up 94% (62 of 66 patients) of the preoperatively sexually active had regained the abilities in their sex-life. Sixty-two percent (41 of 66) reported that they resumed their sex-life  $\leq 8$  weeks after surgery, 24% (15 of 62 patients) found this question too intimate to answer it. Thirty-two percent (20 of 62 patients) reported a decrease in frequency of sexual activities. Eleven of these associated it with a negative outcome with increased pain and fear, and decreased ROM, one patient reported an increase in sexual frequency due to a positive outcome with decreased pain and fear and increased ROM. Forty-two percent (26 of 62 patients) report a change in their normal sexual practice. Nineteen of these associated it with a negative outcome with increased pain and fear, and decreased ROM, and four patients associated it with a positive outcome with decreased pain and fear, and increased ROM (see figure 2). No statistically significant ( $P\text{-values}<0.06$ ) differences were found comparing males and females concerning the influence of TKA surgery on sex-life.

Twelve patients where scheduled for bilateral simultaneous TKA, eleven filled in the twelve-month questionnaire. At the twelve-month follow-up the median OKS for the bilateral subgroup was 45 (IR: 40-46). This is statistically significant ( $P=0.04$ ) more than the OKS in the unilateral group. No other statistically significant ( $P\text{-values} > 0.171$ ) differences were found comparing unilateral and bilateral simultaneous TKA (table 3).

Four patients experienced a major complication: One patient sustained a femur fracture 3 months postoperatively and was treated with locking plate osteosynthesis. One patient had a dislocation of the knee immediately postoperative and a subsequent deep infection, treated with two-stage revision. Four months postoperatively the patient had a hinged revision arthroplasty. One patient had an intra-operative proximal tibia fracture, treated with a revision long stem tibia component. One patient had a deep venous thrombosis, treated medically. All patients with complications were included in data analysis according to our intention-to-treat protocol.

## **Discussion**

The incidence of inserted TKA's have increased by more than 100 % during the past decade and are estimated to increase by as much as 673% from 2005 to 2030[4–6]. The proportion of younger TKA patients (< 60 years) has been increasing, and these patients are expected to have higher demands and expectations to the function of their knee. TKA is well accepted as a reliable surgical procedure to relief pain and return patients to near normal function[7–13]. Traditionally the success of TKA has often been reduced to clinically objective surgeon-reported endpoints, such as implant survival, complications, ROM, and radiographic results. In contemporary literature the focus of outcome measurement has shifted towards the use of PROM's and alternative endpoints, such as influence on socioeconomic status and sex-life after TKA[7,8,10,12,13,21–29]. However, few studies have focused on these outcomes in young patients[30,42]. It has been recognized that these alternative endpoints are of crucial importance to the patients' everyday-life[31]. Thus, alternative endpoints need to be considered when evaluating the success of TKA, especially in younger high demanding patients.

The following limitations to our study should be acknowledged. First, different states and different nations have unique welfare systems and job markets. Thus, changes in relation to work may have different socioeconomic impacts depending on geographical locality. Second, when evaluating the outcome in younger patients following TKA, there is a lack of standardized outcome measures that are able to differentiate improvements in patients with high functional demands. When using standardized patient reported outcome measures developed for OA knees, this group may show a ceiling-effect. However, this is a general problem when evaluating the outcome in younger patients

following joint surgery. Finally, younger patients  $\leq 55$  years of age are known to have a lower response rate[43]. Closer considerations of this could have been made when designing the comprehensive questionnaire used in this study as a high responder burden may lead to responder fatigue and a low response rate[44]. Non-responders are a general problem in studies collecting PROMs, where a high response rate is important to ensure generalizability and minimize the risk of selection bias. Response rates of 80% is normally considered adequate, however rates as low as 65% has shown not to bias the result[45,46].

Measured by the OKS and SF-36 physical and mental subscales our results confirm the results in contemporary literature, that TKA is effective in reducing pain and improving function with significantly improvements. However, the outcome measured by SF-36 PCS is still below that of a cohort from the population similar with respect to age and sex [7–13]. Depression is known as a predictor of an inferior outcome in TKA evaluated by measures of pain and function[47–49]. Similarly we found that patients with a preoperative depression achieved less improvement and had statistically significant lower OKS, SF-36 PCS, and SF-36 MCS scores at the twelve-month follow-up compared with non-depressed patients. Despite of this, a preoperative MDI score  $\geq 20$  (indicating depression) had no influence on satisfaction with the outcome, fulfillment of expectations, willingness to repeat, work-life, income or sex-life. It should be considered that patients may either have inferior outcomes measured by the OKS or SF-36 subscales because they suffer a depression or they may be depressed because of a poor knee function. Depression is not a contraindication to perform TKA as patients gain significantly from surgery, but we recommend that patients suffering from a depression should be informed about what outcome they can expect. We know of no other studies that have explored depression's influence on alternative endpoints.

At the twelve-month follow-up 68% reported either “all expectations” or “most expectations” to be fulfilled, and 71% reported to be “very satisfied” or “satisfied” with the outcome. These findings are consistent with contemporary literature where 75-85% are reported to be satisfied with the outcome, and with young age being recognized as a predictor for lower satisfaction[17–20]. At the twelve-month follow-up 12% (9 of 77 patients) stated not willing to repeat. Summarized, these findings support that satisfaction with the outcome of TKA and the fulfillment of expectations following TKA surgery is not only reflected by the observed significant improvements in knee function and health related quality of life measured with SF-36 and OKS after TKA surgery.

Preoperatively 89% of the study population expected a sick leave  $\leq 12$  weeks. At the twelve-month follow up only 64% of the study population reported a sick leave  $\leq 12$  weeks. This result is marginally worse than what is reported by Styron et al. with 72% having returned to work within 12 weeks postoperatively[50]. The authors found male sex to be a significant predictor for prolonged sick-leave. We did not find this difference comparing the two sexes. Preoperatively, it cannot be expected that TKA surgery changes the patient's relation to work or the annual income. This constitutes important information to patients and to surgeons during the decision making process prior undertaking TKA surgery in younger patients.

In a TKA population  $> 70$  years of age, it has been reported that, about 20% of the patients reporting to be sexually active after TKA experienced limitations due to their TKA while participating in the activity[31]. In the present study of younger patients receiving a TKA 95% of patients who reported to be sexually active preoperatively reported they had regained the abilities in their sex-life at the twelve-month follow-up. Sixty-six percent had regained the abilities in their sex-life within eight weeks postoperatively. However, 26% reported a decrease in sexual frequency and 31% reported that the TKA knee had resulted in changes in sexual practice. Our data indicates that patients in general stay sexually active after TKA surgery, but that a decrease in frequency of sexual activities and that negative affection of sexual practice patterns should be anticipated following TKA surgery in younger patients. We know of no other studies that have explored the influence of TKA surgery on the sex-life of younger TKA patients and we believe this should be important parts of the preoperative information to patients.

Despite of the small sample size for bilateral simultaneous TKA in this study group we conducted a subgroup analysis. The bilateral simultaneous TKA group had a statistically significant better OKS at the twelve-month follow-up. For all other parameters no statistically significant differences between the two groups were found at twelve-month follow-up. Based on the small number of patients no final conclusions can be drawn. However, the outcome for bilateral simultaneous TKA seems to be equal to that of unilateral TKA.

In conclusion, TKA in younger patients is successful in significantly improving joint function and health related quality of life. Satisfaction with the outcome of TKA and the fulfillment of expectations following TKA surgery is not only reflected by the observed significant improvements

in knee function and health related quality of life after TKA surgery. In general TKA surgery in younger patients cannot be expected to change the patient's relation to work or the annual income of the patient. Patients in general stay sexually active after TKA surgery, but decreases in frequency of sexual activities and negative affection of sexual practice patterns should be anticipated following TKA surgery in younger patients. The alternative endpoints of TKA surgery surveyed in this prospective study constitutes important new information important to patients and surgeons during the decision making process prior to TKA surgery.

Table 1

<b>Demographic data and clinical history</b>	
<b>Age at time of surgery</b>	
<i>Median (interquartile range)</i>	54 yrs (49-57)
<b>Sex</b>	
<i>No. of females/males</i>	61/54
<b>Relation to work</b>	
<i>No. of employed</i>	78
<i>No. of unemployed</i>	27
<i>No. of early age retired</i>	10
<b>Gross annual income in US Dollars (n=114)</b>	
<i>&lt;35.000</i>	28
<i>35.000-61.000</i>	45
<i>61.000-88.000</i>	30
<i>&gt;88.000</i>	11
<b>Social class (n=113)</b>	
<i>Unskilled worker</i>	20
<i>Skilled worker</i>	27
<i>Salaried or white collar</i>	23
<i>Mid-level manager or 3-4 years of higher education</i>	29
<i>Manager or highly educated (holding at least a graduate degree)</i>	14
<b>Previous arthroplasty in another joint</b>	
<i>Contralateral Knee</i>	15
<i>Hip</i>	2
<i>Another joint</i>	1
<b>Arthritis or severe discomfort in another or multiple joints</b>	
<i>Contralateral Knee</i>	20
<i>Hip</i>	3
<i>Another joint</i>	18
<i>In two or more joints</i>	8

Table 2

	Preoperatively	Three months postoperatively	Six months postoperatively	Twelve months postoperatively
<b>SF-36 PCS median score</b>				
<b>(Interquartile range)</b>				
<b>Study population</b>	31.3(26.7-36.6)	40.9(32.9-47.5)	44.0(38.1-52.2)	46.8(37.8-53.2)
<i>No depression</i>	32.2(27.1-37.1)	41.6(33.4-48.7)	48.1(38.9-52.6)	48.6(38.7-53.4)
<i>preoperatively(n=92)</i>	27.6(23.4-32.0)	36.4(31.1-44.4)	38.1(25.3-43.0)	36.7(23.8-43.7)
<i>Depression</i>				
<i>preoperatively (n=23)</i>				
<b>SF-36 MCS median</b>				
<b>score (IR)</b>	50.6(39.0-61.5)	54.9(44.9-61.0)	57.4(50.2-62.4)	58.5(52.9-61.6)
<b>Study population</b>	55.2(47.0-62.7)	56.9(46.2-61.4)	59.5(51.3-63.3)	59.2(53.3-61.7)
<i>No depression</i>	43.6(29.7-40.1)	46.0(36.6-50.2)	45.3(36.8-55.4)	46.8(35.9-55.9)
<i>preoperatively</i>				
<i>Depression</i>				
<i>preoperatively</i>				
<b>OKS median score(IR)</b>				
<b>Study population</b>	21(16-26)	33(24-38)	36(27-41)	40(30-45)
<i>No depression</i>	23(18-27)	33(25-38)	38(29-42)	41(34-45)
<i>preoperatively</i>	16(12-20)	26(21-35)	26(15-38)	28(16-41)
<i>Depression</i>				
<i>preoperatively</i>				

The SF-36 PCS, SF-36 MCS and OKS for the total study population, the study population without a preoperatively depression and for the study population with a preoperative depression.

SF-36 PCS median score for a cohort from the population similar with respect to age and sex: 50.4(IR:47.0-56.7)

SF-36 MCS median score for a cohort from the population similar with respect to age and sex: 54.1(IR:51.6-59.4)

Table 3

	<b>Unilateral TKA at 12-month follow-up</b>	<b>Simultaneous bilateral TKA at 12-months follow-up</b>
<b>OKS median score (IR)*</b>	40 (30-45)	45 (40-46)
<b>SF-36 PCS</b>	46.9 (37.78-53.2)	50.6 (45.1-54.6)
<b>SF-36 MCS</b>	58.5(52.9-61.6)	58.4 (50.9-61.9)
<b>MDI Median score (IR)</b>	4 (1-10)	4 (1-5)
<b>Willingness to repeat</b>	88% (67 of 76 patients)	82% (9 of 11 patients)
<b>Very satisfied or satisfied</b>	71% (55 of 77 patients)	82% (9 of 11 patients)
<b>All or most of my expectations are fulfilled</b>	68% (55 of 77 patients)	82% (9 of 11 patients)
<b>No changes in relation to work</b>	81% (62 of 77 patients)	73% (8 of 11 patients)
<b>Sick-leave ≤ 12 weeks</b>	64% (39 of 61 patients)	46% (5 of 11 patients)
<b>Postoperatively regain of sex-life</b>	94% (62 of 66 patients)	80% (8 of 10 patients)
<b>Regain of sex-life ≤ 8 weeks</b>	62% (41 of 66 patients)	50% (5 of 10 patients)
<b>Decrease in sexual frequency</b>	32% (20 of 62 patients)	30% (3 of 10 patients)
<b>Changes in sexual practise</b>	31% 19 of 62 patients	30% (3 of 10 patients)

Comparison of unilateral and simultaneous bilateral TKA at the 12 month follow-up

\*Statistically significant difference

Figure 1: Patient flow diagram

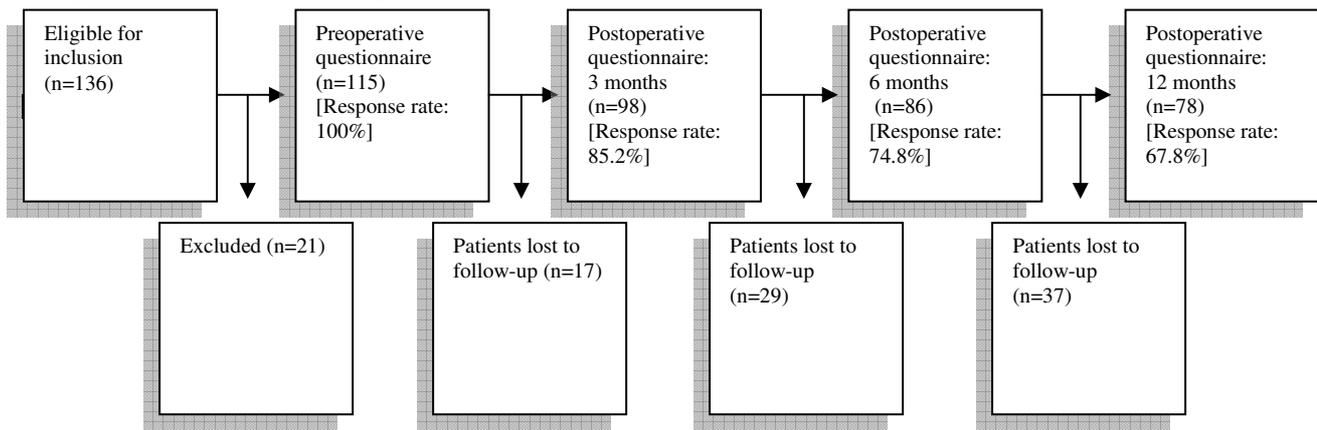
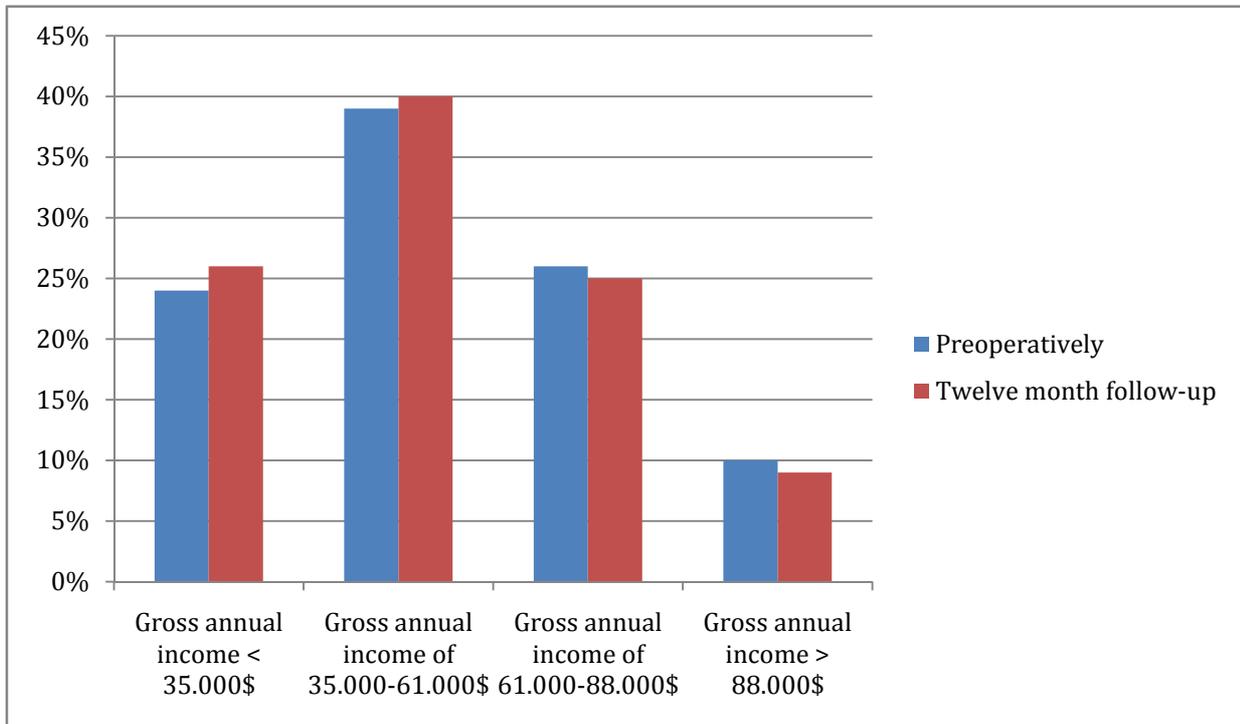
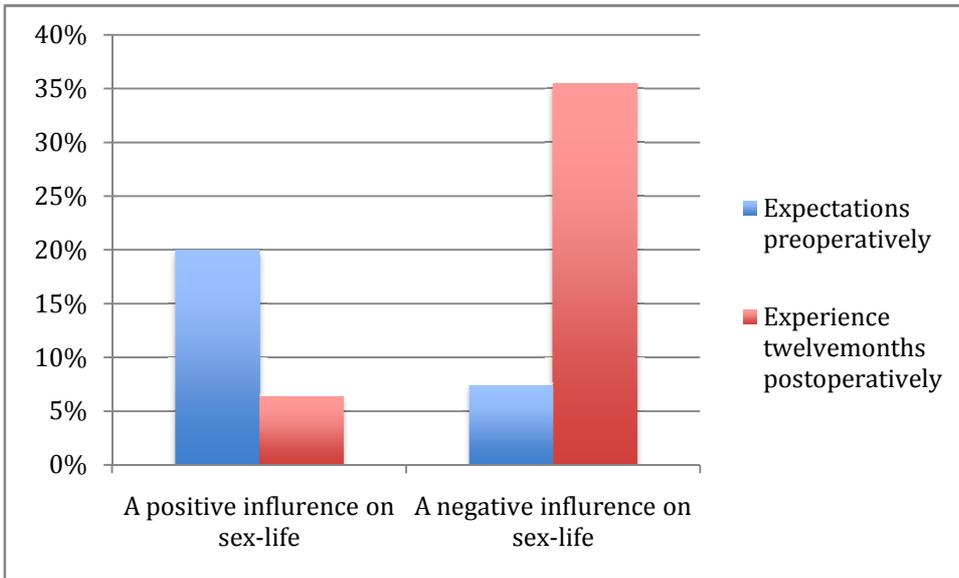


Figure 2



Distribution of income preoperatively and at twelve-months follow-up

Figure 3



Comparison of the preoperatively expectations to sex-life postoperatively and the postoperatively experience in sex-life.  
Preoperatively 83% where sexually active and postoperatively 80% where sexually active

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**Paper III**

**Title page**

**Alternative Outcome Measures in a Cohort of Young Total Hip Arthroplasty Patients**

**A prospective study**

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## **Abstract**

**Background:** Positive effects of total hip arthroplasty (THA) on joint function and pain are well documented. In contemporary literature other outcomes affecting the everyday life of patients have been neglected. We investigated the effect of THA on relation to work, income and sexual activity to improve preoperative patient information.

**Material and methods:** In a prospective cohort study performed at 3 arthroplasty units during a 1 year period we included 135 patients  $\leq 60$  years (median 53 years, range:31-60) scheduled for primary THA. Questionnaires including oxford hip score (OHS), SF-36, questions regarding relation to work, income and sexual activity were collected preoperatively, and at 3, 6 and 12 months postoperatively.

**Results:** At 12 month follow-up the OHS and SF-36 scores showed significant improvements ( $p < 0.028$ ). Of 90 patients in work preoperatively 81 had an unchanged relation to work, 6 patients lost their jobs, and 3 patients changed from part-time to full-time employment. The income level for the cohort did not change, despite 9% (12 of 136) expected a decreased income. Increased frequency of intercourse or better abilities in intercourse positions were experienced by 18 of 39 females due to reduced pain and increased range of motion. Males did not experience improvements. Patients sexually active before THA surgery remained active.

**Interpretation:** There is little affection of relation to work and income following THA surgery in patients  $\leq 60$  years. Patients remained sexually active, and one third of females experience improved sexual activity. These findings constitutes important new information important to patients and surgeons during the decision making process.

## **Introduction**

Total hip arthroplasty (THA) is the mainstay in treatment of end stage osteoarthritis (OA), and well accepted as a reliable surgical treatment to relieve pain and return patients to near normal function(1–10). Today, approximately 20% of the THA patients are younger than 60 years(11). In recent years the utilization of THA in the younger age groups, less than 60 years of age, have been increasing, and will continue to increase given the estimated increase in performed THA(12,13). The expectations and demands concerning the function of the THA expressed by these younger patients are expected to differ from that in older age groups.

The traditional main outcomes in the literature are primarily focusing on implant survival, complications, radiographic results, and range of motion (ROM) (1,2,4,5,7–10). A highly relevant outcome in arthroplasty surgery is patient satisfaction, and despite of pain relieve not all patients are satisfied with their artificial hip. One year postoperatively the satisfaction rate has been reported to be approximately 90%(3,6,14). It is well known that there is inconsistency between the patients' and the surgeons' evaluation of success in treatment (15,16). This has lead to an increasing utilization of patient reported outcome measures (PROMs) in the evaluation of THA outcome. PROMs are now recommended as the core set of outcomes and reported in much contemporary literature reporting THA outcome. It seems that many aspects of patient perceived success of treatment and the corresponding outcome estimation are still to be understood. Some studies have focused on Health Related Quality of Life (HRQoL) and alternative outcomes, such as the effect on personal welfare and sex-life after THA(17–21). Only a few studies has focused on the outcome in young patients, including their satisfaction and what challenges they are facing(22–25). Due to the lack of focus in contemporary literature on alternative, yet very important aspects of outcome measurement in the young THA population, our aims were to explore patient satisfaction, fulfillment of expectations, symptoms of depression, the effect on relation to work and income, , and abilities in sex-life of younger THA patients. These alternative endpoints were collected in addition to traditional outcome measures of function and HRQoL.

## **Patients and methods**

The study is a prospective multi-center cohort study, conducted at three arthroplasty units in the Copenhagen area, Denmark. Consecutive patients less than 60 years of age scheduled for unilateral or bilateral simultaneous primary THA or hip resurfacing (HR) from April 2010 to May 2011 were eligible for inclusion (n=153 patients, 98 unilateral THA / 6 simultaneous bilateral THA / 49 HR ). Patients were excluded if they did not give informed consent prior to participation (n=8), if they were unable to understand and fill in the questionnaires (n=2), if they did not return the preoperative questionnaire prior to surgery (n=5), if they suffered from cognitive dysfunction (n=1), or if they suffered from a malignant disease (n=1). Consequently the study population consisted of 136 primary THA patients; 86 scheduled for unilateral THA, 6 scheduled for bilateral simultaneous THA, and 44 scheduled for HR. Patient demographics and clinical history are presented in table 1. All bilateral simultaneous THAs were performed at one of the 3 hospitals, received the same

prosthesis on both sides, and were all operated with the posterior approach. Sixty-seven THA patients were operated with the posterior approach and 25 THA patients with the anterolateral approach. All 44 HR patients were operated with an extended posterior approach. The type of prosthesis used was dictated by the preference of the surgeon and availability at the individual hospitals. The following THA concepts were used: uncemented stem with uncemented acetabular cup and polyethylene liner in 78 cases (Bimetric stem Biomet® and Exceed acetabular cup Biomet®), cemented stem with uncemented acetabular cup and polyethylene liner in 2 cases (Exeter stem Stryker® and Exceed acetabular cup Biomet®), uncemented stem and uncemented cup with metal-on-metal bearing in 14 cases (Bimetric stem Biomet® and Magnum acetabular cup Biomet®, Ecco stem and Magnum acetabular cup Biomet®), and HR with metal-on-metal bearing in 42 cases (BHR smith-nephew® and Re-Cap Biomet®).

The study group received a paper-format questionnaire within one month of the scheduled surgery, and at three, six, and twelve months after surgery. If the patient did not return one of the postoperative questionnaires within three weeks of the set time-point for the follow-up, a reminder was mailed to the patient. If the questionnaire was still not returned within another two weeks the patient was contacted by phone and encouraged to participate. If the patient still did not return the questionnaire, the patient was not reminded further, but was still scheduled to receive a questionnaire at the next follow-up. The overall response rates for return of questionnaires varied between 79 % and 84 % (Figure 1). Patients who sustained a complication were included in the analysis.

## **Questionnaires**

Both the preoperative and the three postoperative collections of questionnaires consisted of the following: Oxford Hip Score (OHS), Short Form-36 version 1(SF-36), The Major (ICD-10) Depression inventory (MDI), a self developed and validated questionnaire concerning socioeconomic aspects, and a self developed and validated questionnaire concerning the patients sex-life. In addition the preoperative questionnaire covered the patients functional category (1 =unilateral hip disease, 2= bilateral hip disease, and 3= multiple joint disease) and information regarding earlier arthroplasty surgery in other joints. The postoperative questionnaires covered additional information concerning frequency of postoperative physiotherapy. The twelve month questionnaire covered the patients' satisfaction and fulfillment of expectations on two five level

Likert scales: 1) very satisfied, 2) satisfied, 3) neutral, 4) dissatisfied, 5) very dissatisfied and 1) all my expectations are fulfilled, 2) most of my expectations are fulfilled, 3) to some extent my expectations are fulfilled, 4) few of my expectations are fulfilled, 5) none of my expectations are fulfilled. Willingness to repeat was addressed.

#### *The Oxford Hip Score (OHS)*

The OHS has undergone thorough assessment of reliability and validity (26–29). The score consists of 12 items regarding daily activities. Each item is scored on a five-level Likert scale 0 (greatest disability) to 4 (no disability), resulting in a score from 0 to 48, with 48 being the best possible score (29).

#### *Short Form-36*

The SF-36 is an instrument that has been used since the early nineties to assess HRQoL (30,31). It consists of 36 items and measures eight domains; Physical functioning (PF), Social functioning (SF), Role-Physical (RP), Bodily Pain (BP), Mental Health (MH), Role-Emotional (RE), Vitality (VT), and General Health (GH). The theoretical scoring scales for all eight item-scores runs from 0-100 with 100 being the best. The eight item scores can be transformed into two summary scores; the physical component summary (PCS) and mental component summary (MCS). Both MCS and PCS contain information from all eight item scores. The advantage of PCS and MCS is a smaller confidence interval and elimination of both floor and ceiling effect (32). PCS and MCS were compared with a group from the Danish [Blinded] population similar with respect to age and sex (33,34).

#### *The Major (ICD-10) Depression Inventory*

The Major (ICD-10) Depression inventory (MDI), contains ten items. However, item 8 and 10 are divided into two sub-items (A and B), where only the highest score (A or B) are included in the statistical analysis. Each item represents a symptom, and is scored on a six-level Likert scale, measuring how much of the time the symptom has been present over the last 14 days; zero (the symptom has not been present at all) to five (the symptom has been present all of the time). The resulting score is in the interval 0 to 50, where a score  $\geq 20$  represents a depression. The MDI has demonstrated a high specificity and sensitivity as a screening tool in a somatic patient group (35,36).

### *Questionnaire concerning socioeconomic outcome*

Due to the unique labor and welfare models in different parts of the world no existing questionnaires met our requirements and therefore we developed our own questionnaire. To validate the content of the questionnaire, a semi-structured interview was conducted including 20 members of the staff comparable to THA patients with respect to age and gender. After corrections a new semi structured interview was conducted including 20 patients comparable to THA patients with respect to age and gender in the orthopedic department at the Copenhagen University Hospital, Hvidovre, Denmark. The last round of interviews revealed no need for changes. This validation process, validate the content by face validity. The questionnaire consists of six questions regarding current work-status, sick-leave, welfare or early-age retirement, annual-income, and expectations to life-income. In addition the preoperative questionnaire consists of one extra item regarding social-class. This item divides the study group in to five social-classes; 1) manager or highly educated (holding at least a graduate degree) 2) mid-level manager or 3-4 years of higher education 3) salaried or white collar worker 4) skilled worker and 5) unskilled worker.

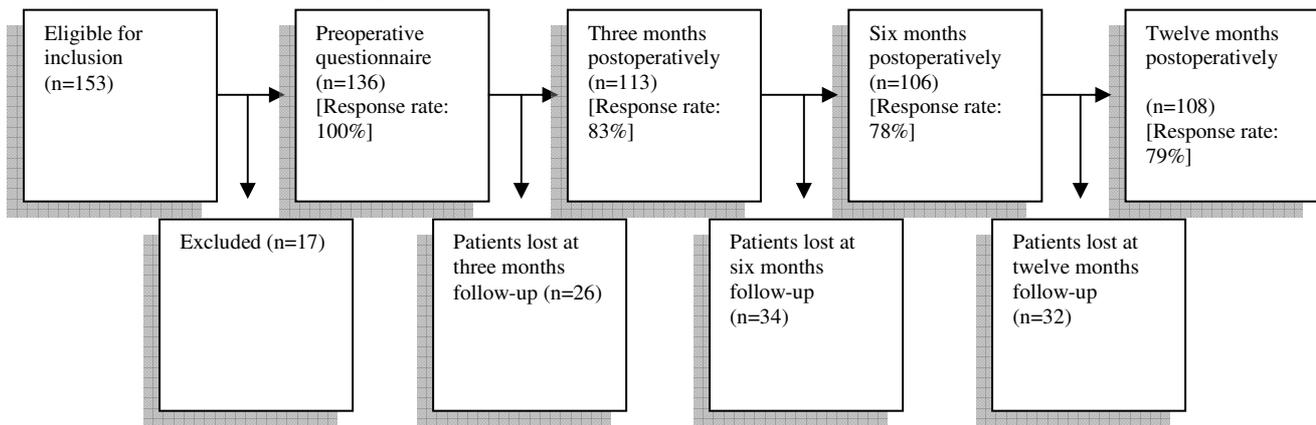
### *Questionnaire concerning effects on sex-life*

We knew of no existing questionnaires regarding the THA patients' sex-life, and therefore we developed our own questionnaire. We used the same method as described above to validate the content of the questionnaire. The questionnaire consists of seven items regarding sex-life before and after surgery. Focusing on what, if any, positive or negative effect THA surgery may have had on sexual frequency and sexual practice, and the cause. In addition male patients were asked about erectile function.

Table 1

<b>Demographic data and clinical history</b>	
<b>Age at time of operation</b>	
<b>Median (Interquartile range)</b>	53 yrs (48-57)
<b>Sex</b>	
<i>No. of females/males</i>	68/68
<b>Relation to work</b>	
<i>Employed</i>	102
<i>Unemployed</i>	17
<i>Early age retirement</i>	17
<b>Gross annual income in US Dollars</b>	
<i>&lt;35.000</i>	19
<i>35.000-61.000</i>	63
<i>61.000-88.000</i>	39
<i>&gt;88.000</i>	13
<b>Social class</b>	
<i>Unskilled worker</i>	19
<i>Skilled worker</i>	25
<i>Salaried or white collar worker</i>	35
<i>Mid-level manager or 3-4 years of higher education</i>	32
<i>Manager or highly educated (holding at least a graduate degree)</i>	23
<b>Previous arthroplasty</b>	
<i>Contraileteral hip (n=17)</i>	17
<i>Knee (n=2)</i>	2
<i>Another joint (n=0)</i>	0
<b>Arthritis or severe discomfort in a second joint or multiple joints</b>	
<i>The second hip</i>	10
<i>Knee</i>	25
<i>Another joint</i>	16
<i>More than one second joint</i>	0

Figure 1: Patient flow diagram



### Statistical Analysis

Descriptive statistics were performed and data primarily presented as percentages with actual numbers of the underlying data distribution. Data are presented as the mean with 95% confidence interval (CI) and range when normally distributed and as the median value with interquartile range (IR) if not normally distributed. The Wilcoxon Signed Rank test for paired data was used to compare preoperative and postoperative outcome measures. The Mann-Whitney U test was used to compare groups. A p-value < 0.05 was considered statistically significant. SF-36 data were processed using the supplied software for SPSS. Data were analyzed using SPSS 20.0 (IBM, Chicago, Illinois, USA.)

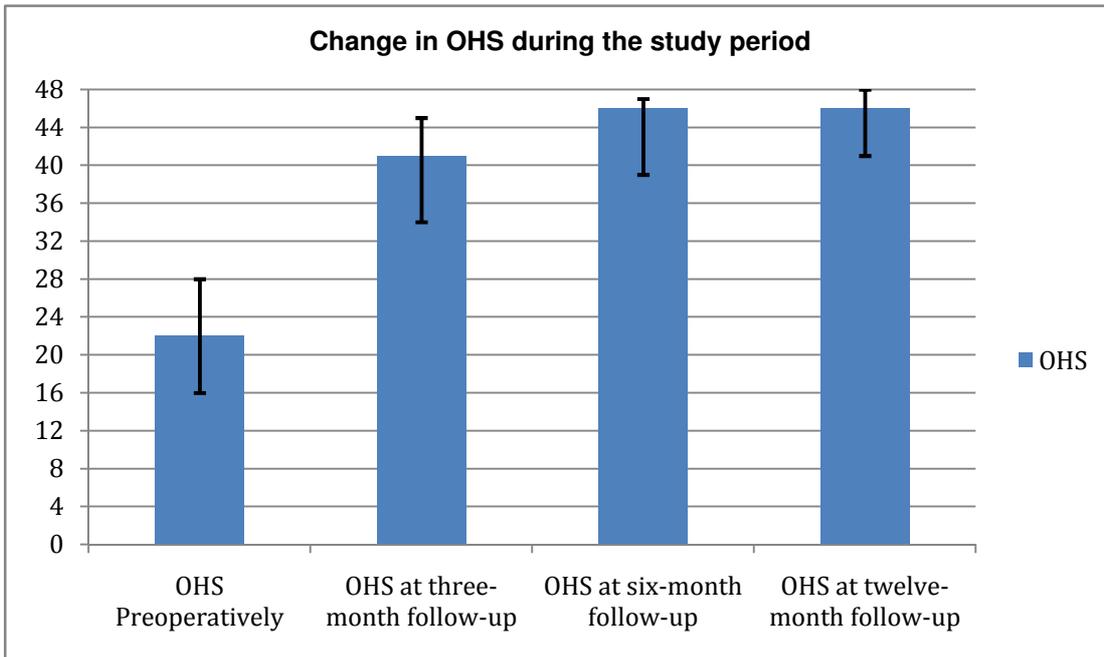
### Ethics

The study was reported to the data protection agency authorities and according to local legislation specific ethics committee approval was not needed for this prospective questionnaire based study. Prior to inclusion the study was reported to Clinicaltrials.gov:NCT01305759

### Results

The median preoperative OHS of 22 (IR: 16-28) had increased statistically significant to a median OHS of 46 (IR: 41-48) at the twelve-month follow-up. At the three-month follow-up the median OHS had increased statistically significant compared with the median preoperative score (p<0.0001), and the OHS continued to increase throughout the study period.

Figure 2



OHS over time with IQR.

At the three-month follow-up both the SF-36 PCS and MCS had increased statistically significant compared with the preoperative score;  $p < 0.0001$  and  $p = 0.028$ , respectively. The SF-36 PCS was at the six and twelve-month follow-up at the level of a cohort from the population similar with respect to age and sex. The SF-36 MCS was above that of the population cohort at all postoperative follow-ups (see table 2).

Table 2

	Preoperatively	Three months postoperatively	Six months postoperatively	Twelve months postoperatively
<b>SF-36 PCS median score</b>				
<b>[Interquartile range]</b>				
<b>Study population</b>	31.5 [27.2-36.8]	48.1 [39.3-53.9]	53.4 [44.3-55.9]	53.1 [46.7-56.9]
<i>Cohort from the population similar with respect to age and sex</i>	53.5 [47.0-56.7]	53.5 [47.0-56.7]	53.5 [47.0-56.7]	53.5 [47.0-56.7]
<b>SF-36 MCS median score</b>				
<b>[Interquartile range]</b>				
<b>Study population</b>	49.8 [40.4-59.5]	57.8 [52.5-60.4]	58.8 [53.7-61.4]	59.2 [54.7-62.1]
<i>Cohort from the population similar with respect to age and sex</i>	57.0 [51.6-56.7]	57.0 [51.6-56.7]	57.0 [51.6-56.7]	57.0 [51.6-56.7]

Preoperatively 26% (35 of 136) of patients had a MDI score  $\geq 20$  (indicative of a depression). 3% (3 of 108) of the responding patients remained having a MDI score  $\geq 20$  twelve months postoperatively. The median MDI score for the study population decreased from 10 (IR: 5-20) preoperatively to 3 (IR: 0-7) at the twelve month follow-up. Preoperatively, patients with a MDI score  $\geq 20$  had a statistically significant ( $p < 0.0001$ ) lower SF-36 PCS, SF-36-MCS and OHS compared with the patients with a MDI score  $< 20$ . At the twelve-month follow-up the patients with a preoperative MDI score  $\geq 20$  had a SF-36 MCS statistically significant ( $p = 0.006$ ) below the patients with a preoperative MDI score  $< 20$ .

20. Measured by the two physical parameters (SF-36 PCS and OHS) the patients with a preoperative MDI score  $\geq 20$  had a score comparable ( $p$ -values  $> 0.853$ ) to the patients with a preoperative MDI score  $< 20$ .

20. Patients with a preoperative MDI score  $\geq 20$  (indicative of a depression) had a statistically significant lower gross annual income ( $p = 0.007$ ) and were of lower social class ( $p = 0.03$ ).

At twelve-month follow-up 94% (101 of 107 patients) were willing to repeat treatment. At twelve-month follow-up 92% (99 of 108 patients) declared all or most of their expectations fulfilled, and 94% (101 of 108 patients) declared to be very satisfied or satisfied (Table 3 and 4).

Table 3

<b>Fulfillment of expectations at twelve-month follow-up</b>	
<b>1) all my expectations are fulfilled</b>	n=73
<b>2) most of my expectations are fulfilled</b>	n=26
<b>3) to some extent my expectations are fulfilled</b>	n=4
<b>4) few of my expectations are fulfilled</b>	n=4
<b>5) none of my expectations are fulfilled.</b>	n=1

Table 4

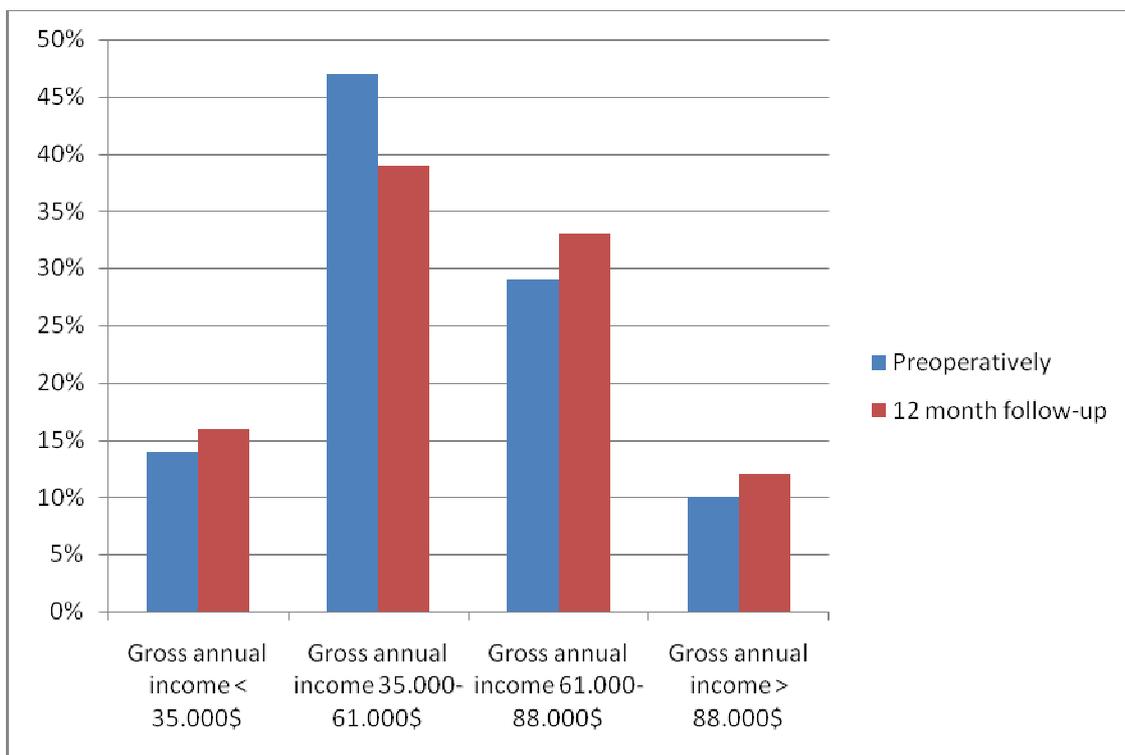
<b>Satisfaction with the outcome</b>	
<b>1) very satisfied</b>	n=78
<b>2) satisfied</b>	n=23
<b>3) neutral</b>	n=3
<b>4) dissatisfied</b>	n=1
<b>5) very dissatisfied</b>	n=3

Preoperatively six patients expected that the operation would lead them to loose their jobs. At the twelve month follow-up 84% (91 of 108) reported that the operation had not changed their relation to work. Of those, 75 were employed and 16 were retired at early age prior to THA surgery. 16 % (17 of 108) of patients had experienced a change in their relation to work: 6 had lost their jobs, 4 had gone from full-time employment to part-time employment, 4 had gone on to early age retirement, and 3 had gone from part-time to full-time employment. Preoperatively 10% (13 of 136) expected an increase in annual income, 9% (12 of 136) expected a decrease in annual income, and 81% (110 of 136) expected no change in income, due to the operation. At the twelve-month follow-up the distribution of gross annual income groups for the study population showed no statistically significant ( $P=0.739$ ) change compared with the preoperative gross annual income (figure 3). Preoperatively 89% (91 of 102) of the employed patients expected a sick-leave  $\leq 12$  weeks. At the twelve months follow-up 89% (77 of 86) reported a sick-leave  $\leq 12$  weeks.

Preoperatively 80% (108 of 135 patients) reported to be sexually active. Seventy-seven percent (83 of 108 patients) of the study population being sexually active prior to surgery responded at the twelve months follow-up. All had regained their sex-life. Sixty-six percent (55 of 83 patients) had

regained their sex-life within eight weeks, 12% (10 of 83 patients) after eight weeks, and 22% (18 of 83 patients) did not answer this question. Preoperatively 47% (23 of 49) of the female patients and 39% (24 of 62) of the male patients expected a change in sexual frequency, and 68% (34 of 50) of the female patients and 31% (18 of 59) of the male patients expected a change in sexual practice. Eighty-two percent (41 of 50) of the female patients and 94% (58 of 62) of male patient expected an improvement in hip function with increased ROM and decreased pain and fear to be the reason for the change in sex-life. At twelve months follow-up 27% (11 of 41) female patients had experienced a change in frequency (5 an increase, and 6 a decrease). Thirty-eight percent (19 of 40) of the female patients had experienced a change with better abilities in sexual practice. Of those, 84% associated it with an increased ROM and decreased pain and fear. No changes were seen in sexual frequency, sexual practice among males. Three male patients experienced erectile dysfunction during the follow-up period.

Figure 3



Distribution of income preoperatively and at twelve month follow-up

Forty-four patients were scheduled for HR. Thirty-two filled in the twelve month questionnaire. The HR subgroup consisted of six females and 26 males and the THA subgroup of 56 females and 20 males (P=0.0001). Seventy-two percent of THA patients (39 of 54) reported a sick-leave  $\leq$  12 weeks and 90% of HR patients (28 of 31) reported a sick-leave  $\leq$  12 weeks (P=0.015). No other statistically significant (P-values  $<$  0.171) differences were found comparing THA and HR (table 3). No statistically significant (P-values  $>$ 0.469) differences were found between the simultaneous bilateral THA subgroup and the study population.

Table 3

	<b>HR at 12-month follow-up</b>	<b>THA at 12-months follow-up</b>
<b>OKS median score (IR)</b>	47 (43-48)	46 (40-48)
<b>SF-36 PCS</b>	54.2 (48.8-56.9)	51.6 (45.4-56.5)
<b>SF-36 MCS</b>	59.9 (54.7-62.1)	58.6 (53.8-62.1)
<b>MDI Median score (IR)</b>	3 (0-7)	3 (0-7)
<b>Willingness to repeat</b>	97% (31 of 32 patients)	92% (70 of 76 patients)
<b>Very satisfied or satisfied</b>	100% (32 of 32 patients)	91% (69 of 76 patients)
<b>All or most of my expectations are fulfilled</b>	97% (31 of 32 patients)	89% (68 of 76 patients)
<b>No changes in relation to work</b>	88% (28 of 32 patients)	78% (47 of 60 patients)
<b>Sick-leave <math>\leq</math> 12 weeks*</b>	90% (28 of 31 patients)	65% (39 of 60 patients)
<b>Postoperatively regain of sex-life</b>	94% (29 of 31 patients)	81% (54 of 67 patients)
<b>Regain of sex-life <math>\leq</math> 8 weeks</b>	89% (24 of 27 patients)	82% (32 of 38 patients)
<b>Decrease in sexual frequency</b>	3% (1 of 30 patients)	13% (7 of 54 patients)
<b>Changes in sexual practice</b>	17% (5 of 29 patients)	17% (5 of 29 patients)

Comparison of HR and THA at the 12 month follow-up

\*Statistically significant difference

During the twelve months follow-up eight major complications were reported: acute deep infection treated by debridement and liner and prosthetic head change (n=2), femur fracture (n=3): one treated conservatively, and two treated with plate osteosynthesis, dislocation treated by closed reduction (n=1), deep venous thrombosis treated by anticoagulant medication (n=1), fissure in the acetabulum treated conservatively with six weeks without weight bearing (n=1). All major complications were in the THA subgroup.

## Discussion

In recent years the greatest increase in THA surgery has occurred in the younger age group (< 60 years), and this increase will continue given the estimated increases in performed THA surgeries(11,13). Expectations and demands concerning function of the THA expressed by these high demanding younger patients differ from that in older age groups. Traditionally, the success of THA has often been evaluated by clinically objective surgeon-reported endpoints, such as implant survival, complications, ROM, and radiographic results. In this traditional paradigm THA is well accepted as a reliable treatment to relieve pain and return patients to near normal function.

However, it has become evident that patient perceived outcome differ from the surgeon's evaluation of outcome(1–7,15,16). In both clinical practice and research, this has led to an increasing utilization of PROMs in evaluation of THA outcome(3,6,14,17–21,23,24,37–41). It seems however, that many aspects of patient perceived success of treatment and the corresponding outcome estimation are still to be understood. Some studies have focused on Health Related Quality of Life (HRQoL) and alternative outcomes, such as the effect on personal welfare and sex-life after THA(17–21). However, only few studies have focused on these outcomes in young THA patients(22–25). Thus, alternative endpoints need to be considered when evaluating the success of THA, especially in younger high demanding patients.

The following limitations to our study should be acknowledged. First, different nations and different states have different social welfare and job markets. Thus, changes in relation to work may have different socioeconomic impacts depending on geographical locality. Second, when evaluating the outcome in younger patients following THA, there is a lack of standardized outcome measures that are able to differentiate improvements in these high demanding and high functioning patients. When using standardized patient reported outcome measures developed for OA hips, this group may show a ceiling-effect. However, this is a general problem when evaluating the outcome in younger patients following joint surgery. Different arthroplasty concepts have different indications. However, we found only minor statistically significant differences (sick-leave and sex distribution) between THA and HR, and no statistically significant differences between the simultaneous bilateral THA subgroup and the study population. Thus this does not seem to affect our endpoints. Finally, younger patients  $\leq 55$  years of age are known to have a lower response rate(42). Closer consideration of this could have been made when designing the comprehensive questionnaire used in this study as a high responder burden may lead to responder fatigue and a low response rate(43). However, non-responders are a general problem in studies collecting PROMs, where a high

response rate is important to ensure generalizability and minimize the risk of selection bias. However, where response rates of 80% is normally considered adequate, rates as low as 65% has shown not to bias the result(44,45).

Measured by OHS and SF-36 physical and mental subscales our results confirm the results in contemporary literature, that THA is effective in reducing pain and improving function with significant improvements (1–7). However, OHS showed ceiling effect, and the SF-36 physical and mental subscales were at the level of or above the age matched standard population, at the six and twelve months follow-up(33,34). This pronounced ceiling effect limits the ability to discriminate “good” from “very good”.

Depression is a known predictor of an inferior outcome in TKA considering pain and function(46–48). We did not have similar findings in our young THA population. Measured by the physical parameters (SF-36 PCS and OHS) the patients with preoperative signs of a depression scored below the non-depressed part of the study population preoperatively but similar to the non-depressed part of the study population at the twelve months follow-up. There were no differences in satisfaction, fulfillment of expectations, and willingness to repeat between the two groups. Thus, it seems that preoperative signs of a depression do not limit the positive effect of THA surgery.

At the twelve month follow-up 92% reported either all or most expectations to be fulfilled, 94% reported to be very satisfied or satisfied with the outcome, and 94% declared that they were willing to repeat the treatment. Patients suffering a major complication had markedly lower fulfillment of expectation and satisfaction and declared not willing to repeat. Summarized these findings consistent with contemporary literature where around 90% reports satisfied with the outcome(3,6,14).

Seventeen percent reported to have experienced a change in relation to work-life, however these changes did not result in any statistically significant changes in gross annual income. We found a high degree of consensus between preoperative expectations to sick-leave and the actual sick-leave experienced. It cannot be expected that THA surgery changes the patient’s relation to work or the gross annual income. Despite different nations and different states having different social welfare and job markets, these findings are consistent with contemporary literature(24). This constitutes important information to patients and to surgeons during the decision making process prior undertaking THA surgery in younger patients.

Due to the higher load on the female hip joint during intercourse, sexual problems are more frequently seen in female OA patients compared with male patients(49,50). Nearly 40% of the female patients experienced a positive change in sexual practice postoperatively due to increased ROM and decreased pain and fear. Despite of the positive change in ROM and decreased pain, we found no change in frequency of intercourse among the female patients. Preoperatively, approximately one third of the male patients expected a change in sexual frequency and practice postoperatively due to increased ROM and decreased fear and pain. Despite of this we found no change in the male patients' sex-life. Three male patients experienced erectile dysfunction during the follow-up period, this number is within the expected for the age group(51). OA patients have a wish for information regarding their expected sex-life postoperatively(49,52). Despite of this, surgeons fail to provide their patients with this information prior to surgery(53). We know of no other prospective studies which have examined young THA patients' sex-life.

In conclusion, THA in younger patients is successful in significantly improving joint function and health related quality of life. We found a high degree of satisfaction and fulfillment of expectations following THA surgery, and only patients with major complications were not willing to repeat. In general THA surgery in younger patients cannot be expected to change the patient's relation to work or the annual income of the patient. Patients stay sexually active after THA surgery, and the female patients experiences positive changes in sex-life. The alternative endpoints of THA surgery surveyed in this prospective study constitutes important new information important to patients and surgeons during the decision making process.

### **Contribution of authors**

The study was designed with contribution from JK, SJ, SH, and AT. JK and VS gathered all data, and the data were analyzed by JK and AT. All authors ensured the accuracy of the data. The initial manuscript draft were made by JK and AT. The final article was approved by all authors.

### **Conflict of interest and funding**

There was no external funding source for the study

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## Postscript

What you get by achieving your goals is not as important as what you become by achieving your goals.

*Henry David Thoreau*

Despite thorough search on the internet, it has not been possible to obtain the photographer of the cover image. However, I would like to thank for the use of the image.