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

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The three original papers are

1. 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. Hip Int. 2013 Sep 20:0. [Epub ahead of print]

2. 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. J Arthroplasty. 2013 Oct 1. [Epub ahead of print]

3. 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. Submitted

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^{o} 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).

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 $<25^0$, a congruent hip-joint, flexion of the hip $>110^0$, and internal rotation $>15^0$. 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 12^0 (range -29^0-30^0) and postoperatively the mean CE-angle was 29^o (range 4^0-52^0). 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).

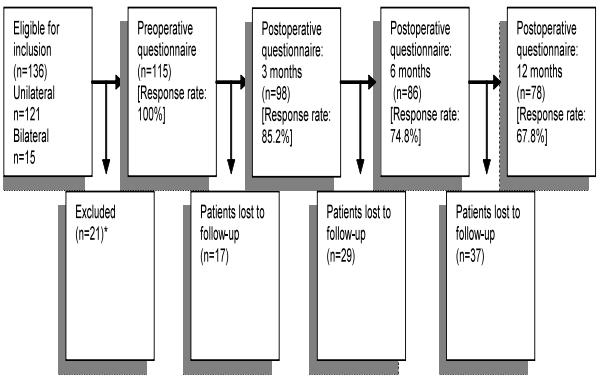
Design and Methods of Study II +III

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.

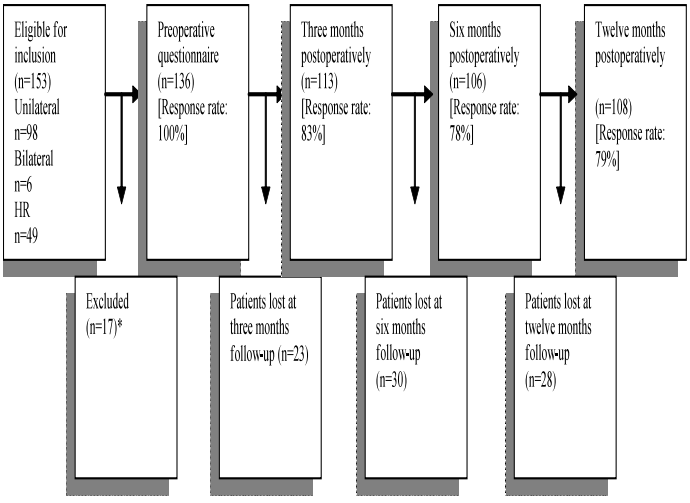
The studies were reported to the National Data Protection Agency and according to local legislation specific ethics committee approval was not needed for this prospective questionnaire based study. Prior to inclusion the studies were reported to Clinicaltrials.gov (No.:NCT01305759).

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

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

Table III a

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

More than one second joint	0

Surgical approach and concepts

All TKA patients *(Study II)* where 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

STUDY II: TKA CONCEPTS	
CRUCIATE RETAINING, FIXED BEARING (AGC BIOMET®, PFC DEPUYSYNTHES®, TRIATHLON STRYKER®)	N=71
CRUCIATE RETAINING, ROTATING PLATFORM (PFC-SIGMA DEPUYSYNTHES®, VANGUARD ROCC BIOMET®, NEXTGEN ZIMMER®)	N=39
POSTERIOR STABILIZED, FIXED BEARING (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

STUDY III: THA AND HR CONCEPTS	
UNCEMENTED STEM WITH UNCEMENTED ACETABULAR CUP AND POLYETHYLENE LINER (BIMETRIC STEM BIOMET® AND EXCEED ACETABULAR CUP BIOMET®)	N=78
CEMENTED STEM WITH UNCEMENTED ACETABULAR CUP AND POLYETHYLENE LINER (EXETER STEM STRYKER® AND EXCEED ACETABULAR CUP BIOMET®)	N=2
UNCEMENTED STEM AND UNCEMENTED CUP WITH METAL-ON-METAL BEARING (BIMETRIC STEM BIOMET® AND MAGNUM ACETABULAR CUP BIOMET®, ECCO STEM AND MAGNUM ACETABULAR CUP BIOMET®)	N=14
HR WITH METAL-ON-METAL BEARING (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 ≥ 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*
QUALITY OF LIFE MEDIAN	1= EXTREME DISABLED 2= DISABLED IN SOME DEGREE 3=MODERATELY DISABLED 4= ALMOST NOT DISABLED 5= NOT DISABLED	2.0 (IQR: 1-5)	4.0 (IQR: 3-5)	P<0.001	5 (IQR: 4-5)
ABILITY TO DO SPORTS	1=ALWAYS DISABLED BY MY HIP 2=NEARLY ALWAYS DIS-ABLED BY MY HIP 3=SOMETIMES DISABLED BY MY HIP 4=RARELY DISABLED BY MY HIP 5=NEVER DIS-ABLED BY MY HIP	2.0 (IQR: 1-5)	3.0 (IQR: 2-5)	P<0.001	4.0 (IQR: 3-5)
ABILITY TO PARTICIPATE IN SOCIAL ACTIVITIES	SAME SCORE AS ABOVE	3.0 (IQR: 2-3)	4.0 (IQR: 3-4)	P<0.001	4.0 (IQR: 3-5)
ABILITY IN SEX-LIFE FEMALE	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 DIS-ABLED BY MY HIP 4= SOMETIMES DISABLED BY MY HIP 5=RARELY DISABLED BY MY HIP 6=NEVER DIS-ABLED BY MY HIP	4.0 (IQR: 2-5)	5.0 (IQR: 4-5)	P=0.008	4.0 (IQR: 4-5)
ABILITY IN SEX-LIFE MALE	SAME SCORE AS ABOVE	5.5 (IQR: 5-6)	6.0 (IQR: 5-6)	P=0.102	5.0 (IQR: 5-5)
PAIN	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)
LIMP	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)
STABILITY	1=NEVER STABLE 2=SOMETIMES UNSTABLE AT REST 3=UNSTABLE UNDER PHYSICAL ACTIVITY 4=UNSTABLE UNDER HARD PHYSICAL ACTIVITY 5=NEVER UNSTA-BLE	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*

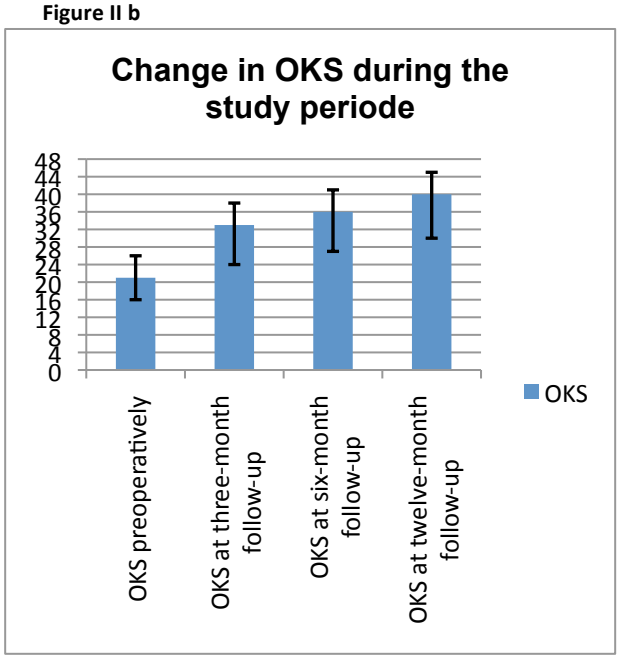
Conclusion: Our results suggest that it is possible to achieve lasting improvements in the patients 1) sex life, 2) ability to do sports, 3) social life, and 4) the patients are satisfied with the outcome of the procedure at medium to long term follow-up.

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% (67of 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

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

Table II d

Fulfillment of expectations at twelve-month follow-up	
1) all my expectations are fulfilled	n=30
2) most of my expectations are fulfilled	n=22
3) to some extent my expectations are fulfilled	n=16
4) few of my expectations are fulfilled	n=3
5) none of my expectations are fulfilled	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 ≥ 20 (corresponding a depression), seven remained having a MDI score ≥ 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
SF-36 PCS median score (IQR)	31.3(26.7-36.6)	40.9(32.9-47.5)	44.0(38.1-52.2)	46.8(37.8-53.2)
Study population	*32.2(27.1-37.1)*	*41.6(33.4-48.7)*	*48.1(38.9-52.6)*	*48.6(38.7-53.4)*
No depression preoperatively	*27.6(23.4-32.0)*	*36.4(31.1-44.4)*	*38.1(25.3-43.0)*	*36.7(23.8-43.7)*
Depression preoperatively				
SF-36 MCS median score (IQR)	50.6(39.0-61.5)	54.9(44.9-61.0)	57.4(50.2-62.4)	58.5(52.9-61.6)
Study population	*55.2(47.0-62.7)*	*56.9(46.2-61.4)*	*59.5(51.3-63.3)*	*59.2(53.3-61.7)*
No depression preoperatively	*43.6(29.7-40.1)*	*46.0(36.6-50.2)*	*45.3(36.8-55.4)*	*46.8(35.9-55.9)*
Depression preoperatively				
OKS median score(IQR)	21(16-26)	33(24-38)	36(27-41)	40(30-45)
Study population	*23(18-27)*	*33(25-38)*	*38(29-42)*	*41(34-45)*
No depression preoperatively	*16(12-20)*	*26(21-35)*	*26(15-38)*	*28(16-41)*
Depression preoperatively				

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)

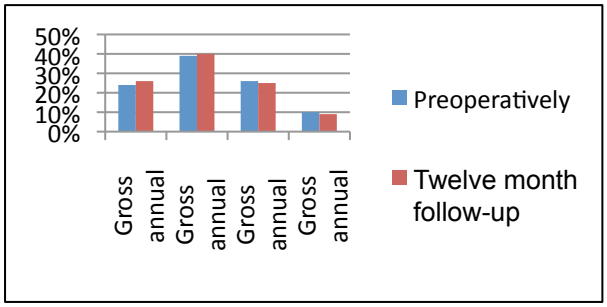
SF-36 MCS median score for a cohort from the population similar with respect to age and sex: 54.1(IR:51.6-59.4)

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 ≤ 12 weeks. At the twelve-month follow-up only 64% (39 of 61 patients) reported a sick leave ≤ 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

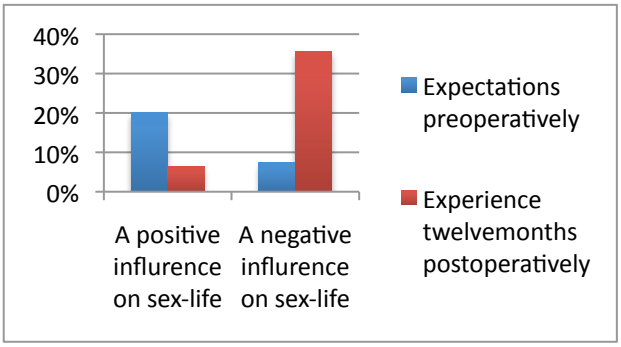
Figure II c



Distrubution of income preoperativly 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 ≤ 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



Comparrison of the preoperativly expectations to sex-life postoperatively and the postoperativly experience in sex-life. Preoperatively 83% where sexually active and postoperatively 80% where sexually active

Twelve patients where 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.

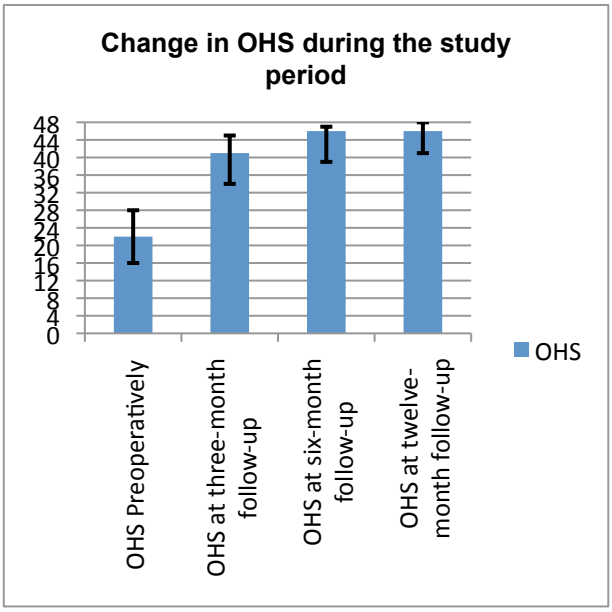
Conclusion: Our results showed significant improvements in both joint function and HRQoL. Satisfaction with the outcome of TKA and fulfillment of expectations do, however, not fully mirror the observed significant improvements in knee function and HRQoL. Patients with a preoperative depression experience 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
SF-36 PCS median score (IQR)				
Study population	31.5 [27.2-36.8]	48.1 [39.3-53.9]	53.4 [44.3-55.9]	53.1 [46.7-56.9]
Cohort from the population similar with respect to age and sex	*53.5 [47.0-56.7]*	*53.5 [47.0-56.7]*	*53.5 [47.0-56.7]*	*53.5 [47.0-56.7]*
SF-36 MCS median score (IQR)				
Study population	49.8 [40.4-59.5]	57.8 [52.5-60.4]	58.8 [53.7-61.4]	59.2 [54.7-62.1]
Cohort from the population similar with respect to age and sex	*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

Satisfaction with the outcome	
1) very satisfied	n=78
2) satisfied	n=23
3) neutral	n=3
4) dissatisfied	n=1
5) very dissatisfied	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 ≥ 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 ≤ 12 weeks and at twelve-month follow-up 89% (77 of 86) reported a sick-leave ≤ 12 weeks.

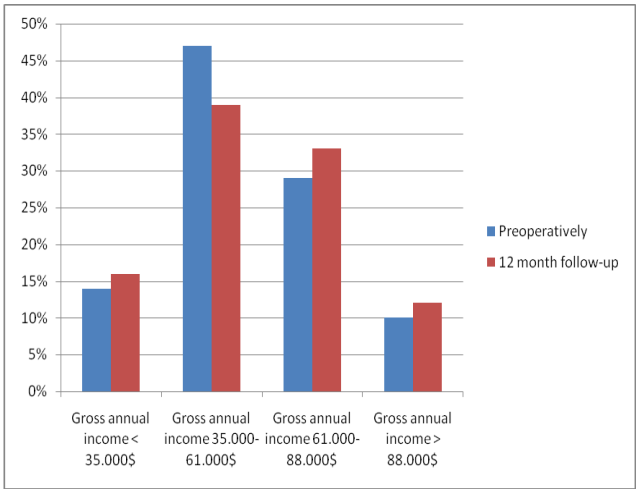


Figure III c
Distrubution of income preoperativly and at twelve month follow-up

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 where scheduled for HR. Only sex distribution and sick-leave differed statistically significant (P-values <0.015) (table III e).

Table III e

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

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 initiates 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 investi-

gate 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 socio-economic 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 S*tudy 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.

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