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Patient Relevant Outcomes after total hip replacement. A comparison between different surgical techniques

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Abstract

Objective: To investigate differences in pre- and postoperative patient-relevant outcome between hybrid total hip replacement (THR) and cemented THR in patients with primary osteoarthritis (OA).

Methods: 245 consecutive patients were included in the study. 68 of the patients (mean age 62) were operated on with hybrid THR and 177 (mean age 74) were operated on with cemented THR. All patients were investigated preoperatively and 0.5, 1 and 3.6 years postoperatively with two self-administered questionnaires, SF-36 and WOMAC (Western Ontario and MacMaster Universities Osteoarthritis Index, LK 3.0).

Results: Preoperatively, there was a difference in the SF-36 subscales RP (role physical) and GH (general health) where the patients with the hybrid THR attained better scores. At 3.6-years the patients with the hybrid THR reached better scores in all SF-36 subscales except BP (bodily pain) and GH. Further, they had better scores in WOMAC function. However, after adjusting for age, sex, follow-up time and baseline values there were no differences in outcome between the two different surgical techniques.

Conclusion: This medium term (3–5 years), controlled, open cohort study, using patient-relevant outcome measures, did not reveal any differences between hybrid THR and cemented THR for OA at 3.6 years after surgery. Since the study had 75–94% power to detect the clinically significant score difference of 10 points, we suggest that any difference in outcome between these two methods is small and may require a large-scale, blinded, randomized trial to show.

Introduction

Since the development of total hip replacement (THR) there has been a wish to evaluate the results of the intervention. Approximately 20 different hip scores have been introduced [1]. The variables measured have been pain, walking distance, use of walking assistance, range of motion, ability to put on shoes, climb stairs, use of public transport, etc. Inconsistent results have been found when comparing outcomes with scores which used descriptive terms such as excellent, good or failure, whereas there was better correlation between outcomes when using different numerical scores [1]. Callaghan et al. [2] compared five different rating systems and found no uniformity in the results between ratings, nor any uniformity between the ratings and the patients impressions. In particular, a marked disparity has been shown between the patient's and the physician's scores after THR [3]. It is therefore important and necessary to take into consideration the patient's point of view when evaluating health status and outcome after this intervention.

At the OMERACT conference 1997 a core set of outcome measures was established for joint disease. Four domains were to be evaluated: pain, physical function, patient global assessment and joint imaging. Crucial importance was attached to patient-relevant measures [4]. The information in patient-relevant measures relies exclusively on the information provided by the patient, generally collected by questionnaires, either self-administered or administered by interviewers.

The definition for failure used in most large joint replacement registries is surgical revision (exchange or removal of the implant) [5,6]. However, surgical revision as a definition of outcome failure does not fully consider the patient's point of view, and outcomes based on surgical revision or questionnaire-based data provided by the patient differ significantly [7]. However, there are few or no studies comparing different surgical techniques or joint implants, where validated and patient-relevant outcome measures have been used as the primary outcome. Considerable difficulties are associated with the design and practise of controlled, randomized trials of surgical interventions [8,9]. These problems are particularly evident for methods that have already reached clinical practise, where the surgeon's and sometimes the patient's lack of equipoise can make recruitment into a randomized trial very difficult [10].

A large number of different implant configurations for THR have been introduced into the market, often in the absence of controlled trials. 'Hybrid' THR designs, where an uncemented acetabular cup is used with a cemented femoral stem, have seen increased recent use. This configuration is sometimes preferred for younger patients, in the belief that this cup configuration will provide less risk for loosening and easier revision [11]. However, little or no information based on patient-relevant outcomes exist to guide the surgeon in the choice of implant for the younger patient.

With knowledge of the difficulties and costs associated with blinded, randomized trials in this area, we have performed a prospective, controlled open cohort study comparing hybrid THR with traditional cemented THR, using patient-relevant outcomes. The purpose was to investigate differences in postoperative medium term outcome between these two groups. Results from open studies such as this provide a basis for assessing the need for larger, randomized and blinded trials.

Patients and Methods

Two-hundred and forty-five patients (133 women, 112 men) with a mean age at time of surgery of 69 years (50–92) were included in the study (Fig. 1).

All patients were assigned for THR because of primary osteoarthritis (OA). The patients were consecutively included during September 1995 to October 1998 at the Department of Orthopaedics in Halmstad, Sweden. All patients had a primary unilateral THR performed.

68 patients (29 women, 39 men) with a mean age at time of surgery of 62 years (50–72) were operated with a hybrid THR. The THR were performed using the uncemented Trilogy (N = 62) or HGC (N = 6) acetabular component (Zimmer®) and the cemented Lubinus SP II (N = 55) (Link®) or Anatomic (N = 13) (Zimmer®) femoral component. All acetabular components were fixed with bone screws. The incision was either antero-lateral or postero-lateral. The femoral component was inserted with a second generation cementing technique, which includes the use of a medullary plug, a cement gun to introduce cement in a retrograde fashion and pressurization of the cement. The indication for hybrid THR instead of cemented THR was principally a younger age of the patient. Another important reason for the decision was the competence of the surgeon and his personal opinion about the method.

177 of the patients (104 women, 73 men), received a cemented Lubinus acetabular component and a cemented Lubinus SP II femoral component was used as a reference group. Their mean age at time of surgery was 75 (61–92). Seven different surgeons were involved, all experienced hip surgeons. One of them made one third of the hybrid THR. The patients were evaluated preoperatively, at 3, 6, 12 months and at 3.6 years (26–65 months, mean 43 months, median 40 months) after the index THR surgery.

Patients with the hybrid prosthesis were advised to partially bear weight for the first 8 weeks after surgery, whereas patients with cemented prosthesis were full weight bearing. Surgical technique, cementing technique, rehabilitation and follow-up evaluation was otherwise all identical for both groups.

The preoperative hip radiographs were classified by one radiologist according to OARSI criteria with a radiographic atlas as a guide [12]. OA was graded from 0–3 in accordance with the joint space narrowing where 3 indicates severe OA. 45 patients had severe OA and 19 moderate OA in the hybrid group and 109 patients had severe

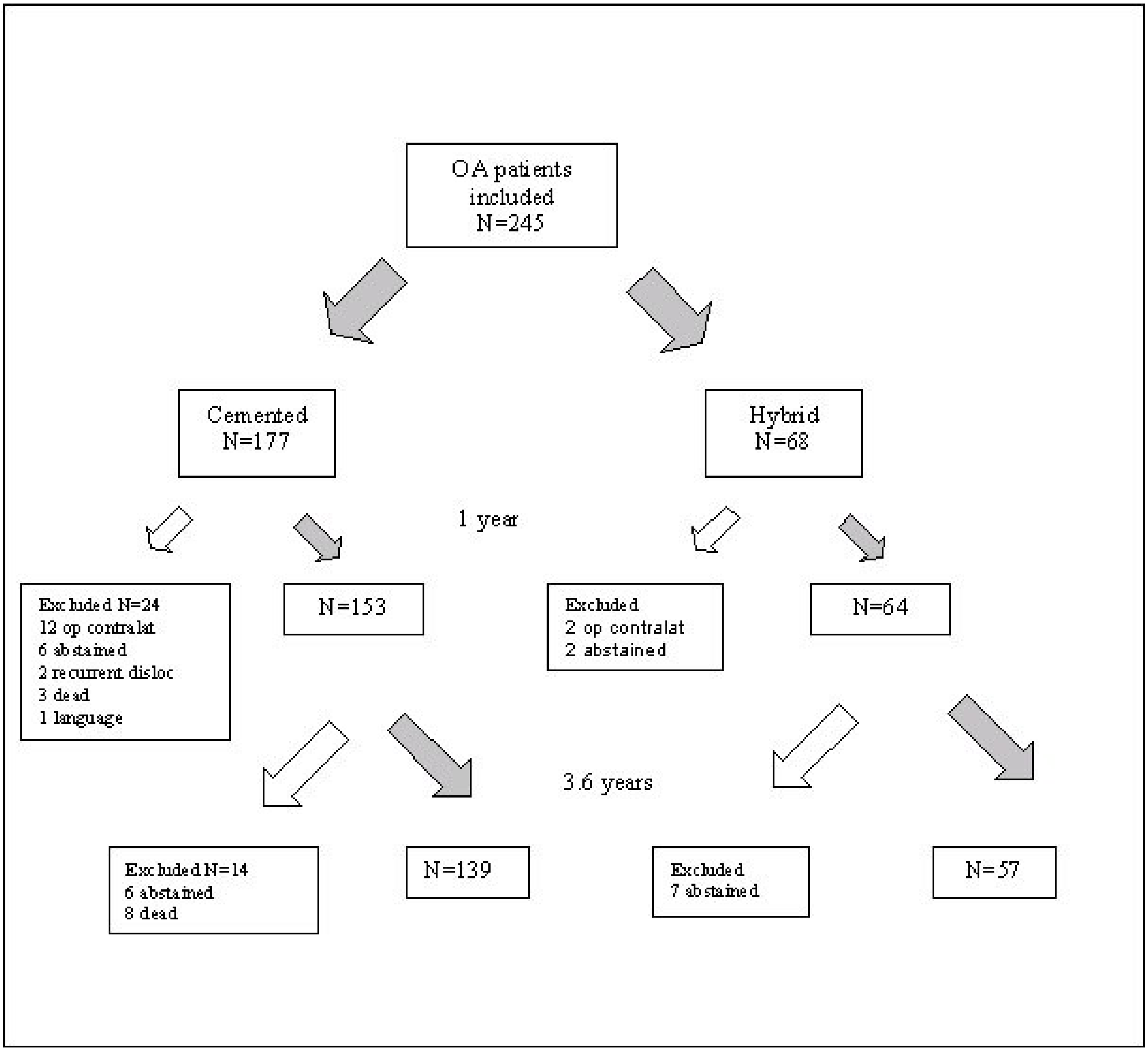

Figure 1
Flowchart showing the number of patients included in the beginning of the study and excluded at the 1 year and 3.6 years (26–65 months) follow-up.

OA and 40 moderate in the cemented group (the radiographs for 4 patients were not found).

Questionnaires

SF-36

Evaluation with SF-36 was made at the hospital the day before operation and three, six and twelve months postoperatively. The SF-36 measures three major health attributes (functional status, well being, overall health) in eight subscales. These include (1) physical function, (2) role limitations due to physical health, (3) bodily pain, (4) general health, (5) vitality, (6) social function, (7) role limitations due to emotional health and (8) mental health [13]. The SF-36 scores are calculated on 0–100 worst to best scale. Together, the eight subscales provide a health profile. SF-36 is translated and validated for Swedish conditions [14]. It has previously been used in follow up studies of THR [15,16].

WOMAC

WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index, LK 3.0) was used as the disease specific instrument. Evaluation with WOMAC was made preoperatively, three, six and twelve months postoperatively. However, since this instrument was not available and validated for Swedish conditions when the study was initiated, it was used at baseline for the last 92 patients only. There were no differences concerning age and sex between these 92 patients and the 106 that were included earlier. WOMAC is a self-administered instrument validated for OA in the lower extremities and for evaluating outcome after THR [17,18]. It consists of twenty-four multiple-choice items grouped into three categories: pain (five questions), stiffness (two questions), and physical function (seventeen questions). It is reliable and valid for Swedish conditions [19]. To make comparisons easier with SF-36, WOMAC was transformed to 0–100 worst to best scale [19–21].

In the measurement of outcome it is desirable to include both a generic instrument and a disease specific instrument [22–24]. Thus, both SF-36 and WOMAC were chosen for this study.

Additional Questions

Questions about postoperative complications, and preoperative and postoperative comorbidity, were asked at the 3.6 year follow-up.

Postoperative complications

Three questions were asked about serious postoperative complications; dislocation of the prosthesis, deep infection in the hip joint and reoperation. The self reported data was compared with data from the patients' case records.

General co-morbidity

Fourteen questions were asked about intercurrent diseases preoperatively and in the present situation [16,25]. Questions were asked for the presence of 12 co-morbid conditions or body areas with problems (heart, hypertension, peripheral arteries, lung, diabetes, neurological problems, cancer, ulcer, kidney disease, vision, back pain, and psychiatric disease). The questions were multiple choice (yes, no, don't know). The total number of conditions or problems reported was used as a summary variable (0, 1, 2 or more), a method shown to be valid in this kind of follow-up [16].

Musculoskeletal co-morbidity

Two questions were asked about the need of walking assistance and walking distance, preoperatively and in the present situation [26], two questions were asked about the need of analgesics due to pain in the operated hip joint or due to pain elsewhere. One question was asked about the experience of regional or widespread pain lasting more than 3 months during the last 12 months [25]. One question was asked about joint replacement in the contra-lateral hip or in the knees since the THR. The last questions concerned fractures in the spine, wrist, hip or elsewhere.

Statistics

Statistical analysis was done with the SPSS 10.0 package. For comparison between two subgroups Mann-Whitney test was used. For comparing the frequency of co-morbidities in subgroups chi-square test was used. The results were adjusted for age, sex, follow-up time and baseline values with a multivariate logistic analysis of regression.

Results

Of the 245 patients 28 were excluded during the first follow up year, 14 had surgery on the contra-lateral side, 8 declined to participate, 3 had died, 2 had recurrent dislocations and 1 could not participate because of difficulties with the language. At the final follow-up 13 patients declined to participate and 8 had died since the one year follow-up. Thus the result of 196 patients (105 women, 91 men) with a mean age at surgery of 68 years (50–88) are presented (Fig 1). Of those 57 were operated on with hybrid THR and 139 with cemented THR.

Major postoperative complications

Two patients had been re-operated after the first follow-up year (one patient was re-operated due to recurrent hip implant dislocations and one due to a deep infection). Another three patients suffered from recurrent dislocations after the first follow-up year and one of those also sustained an infection. None of these patients were operated on with the hybrid technique. At the 3.6 year follow-up there was no difference in the three WOMAC subscales between the patients with and without major postoperative complications (data not shown).

The frequency of comorbidity

There were no differences in the frequency of co-morbidities preoperatively between the patients operated with the hybrid technique and the patients operated with the cemented technique. Neither were there any differences between the two groups at the 3.6 year follow up.

The frequency of musculoskeletal comorbidity

The patients with cemented THR used walking assistance in a higher frequency than those with hybrid implants both preoperatively (hybrid 16/56, cemented 77/136, $p < 0.001$) and at the 3.6 year follow-up (hybrid 8/56, cemented 60/136, $p < 0.0001$). There was also a difference in the walking distance preoperatively were the patients operated with the hybrid technique reported a higher frequency of a walking distance more than 3 km than the patients operated with the cemented technique (hybrid 28/56, cemented 39/135, p = 0.005). The walking distance at the 3.6 year follow-up also differed between the two groups with an advantage for the patients operated with the hybrid technique (hybrid 46/54, cemented 82/134, p = 0.001).

There was no difference between the two groups concerning the consumption of analgesics against pain from the operated hip (hybrid 15/56, cemented 38/137) or pain with another origin (hybrid 24/55, cemented 64/135).

The patients operated with the cemented technique in a higher degree reported pain from the knees at the 3.6 year follow-up (hybrid 5/57, cemented 31/139, p = 0.026). There was no difference concerning regional pain (hybrid 33/54, cemented 83/129) or widespread pain (hybrid 3/24, cemented 10/56) between the two groups.

Comparison between outcomes of hybrid and cemented techniques

Preoperatively, there were no differences in the WOMAC subscales pain, stiffness or physical function between the patients operated with hybrid technique and the patients operated with cemented technique (Table 2). Neither were there any differences in the SF-36 subscales, except RP (role physical) and GH (general health) between the two groups at this time (Table 1). At 12 months after surgery the patients operated on with hybrid technique reached better scores in all the SF-36 subscales except BP (bodily pain), (Table 1) and a better score in WOMAC physical function (p = 0.014) (Table 2). At 3.6 years follow-up the patients operated on with hybrid technique reached better scores in all SF-36 subscales except BP and GH (Table 2) and a better score in WOMAC physical function (p = 0.001) (Table 2). The difference in mean age between these two groups, 12.3 years (61.9 vs. 74.2), was significant.

Comparison of hybrid and cemented technique after adjusting for age, sex, follow up time and baseline values

In the univariate analysis the OR for SF-36 PF and WOMAC function was significant (Table 3). After adjusting for age, sex, follow up time and baseline values by using a multivariate logistic regression analysis at the 3.6 year follow up, there were no differences between the two surgical techniques in the outcome of SF-36 PF and WOMAC function (Tables 4,5). It should be noted that the odds ratios are expressed per one year or scale unit difference. Neither were there any differences in the other SF-36 subscales or WOMAC dimensions (data not shown).

Discussion

This prospective study did not reveal any differences in patient-relevant outcomes between patients operated on with cemented technique or hybrid technique in either preoperative or postoperative health-related quality of life at the 3.6 year (26–65 months) follow-up, when the results had been adjusted for age, sex, follow-up time and baseline values.

The frequency of comorbidities did not differ between the two groups of patients although one of the groups was significantly younger. That may be due to the fact that relatively healthy patients are assigned for THR. This is consistent with previous observations in that OA is not predictive for development of future co-morbidities [16,27].

Table 1: SF-36 results before, and at one year and 3.6 years (26–65 months) after THR for OA. Mean scores and (standard deviations) of the SF-36 subscales for patients operated on with cemented total hip replacement (81 women), mean age 74 (61–88) and hybrid total hip replacement (24 women) mean age 62 (50–72).

SF-36 subscale	Preop Cemented (N = 139)	Preop Hybrid (N = 57)	1 year Postop Cemented (N = 139)	1 year Postop Hybrid (N = 57)	3.6 year Postop Cemented (N = 139)	3.6 year Postop Hybrid (N = 57)
PF	30.43 (20.4)	30.4 (17.7)	61.6 (22.4)	*74.2 (19.7)	56.5 (24.2)	*68.2 (25.3)
RP	6.8 (17.1)	*15.5 (28.7)	51.7 (42.3)	*72.4 (37.1)	39.7 (42.9)	*63.9 (41.6)
BP	30.5 (15.6)	30.3 (20.0)	72.3 (24.9)	78.0 (21.7)	64.9 (25.6)	69.2 (27.9)
GH	66.4 (19.6)	*72.4 (20.3)	68.9 (20.5)	*78.7 (21.6)	64.4 (21.1)	70.1 (23.9)
VT	47.8 (21.3)	51.2 (20.2)	68.7 (22.0)	*78.0 (20.8)	61.0 (24.0)	*70.0 (24.1)
SF	62.6 (26.5)	67.0 (25.3)	84.7 (23.5)	*92.7 (17.2)	81.0 (23.0)	*90.6 (20.5)
RE	33.6 (41.0)	43.8 (44.3)	63.3 (40.7)	*86.3 (29.2)	56.8 (44.0)	*83.6 (32.0)
MH	68.3 (19.8)	71.6 (23.8)	80.2 (19.3)	*87.3 (15.7)	76.5 (19.8)	*83.4 (20.1)

* = $p < 0.05$ hybrid vs. cemented THR for each observation time. PF-physical function, RP-role physical, BP-bodily pain, GH-general health, VT-vitality, SF-social function, RE-role emotional, MH-mental health. The scale is 0–100, worst to best.

Table 2: WOMAC before, and at one year and 3.6 years (26–65 months) after THR for OA. Mean scores and (standard deviations) of the three WOMAC subscales for all patients investigated and operated on with cemented total hip replacement and hybrid total hip replacement. The scale is 0–100, worst to best.

WOMAC subscale	Preop Cemented (N = 65)	Preop Hybrid (N = 29)	1 year Postop Cemented (N = 90)	1 year Postop Hybrid (N = 42)	3.6 years Postop Cemented (N = 139)	3.6 years Postop Hybrid (N = 57)
Pain	45.3 (17.9)	44.8 (15.9)	84.4 (17.1)	84.1 (18.1)	81.0 (20.1)	84.2 (21.0)
Stiffness	37.7 (16.6)	42.0 (15.7)	75.8 (20.5)	81.8 (16.6)	76.1 (22.0)	80.7 (22.3)
Function	37.1 (15.5)	41.8 (12.5)	75.4 (18.0)	83.0 (16.1)	71.3 (21.7)	*81.2 (20.4)

* = $p < 0.05$ hybrid vs. cemented THR for each observation time.

Table 3: Univariate and multivariate logistic regression analysis comparing follow-up data (26–54 months) for SF-36 PF (physical function) and WOMAC function in patients operated on with hybrid or cemented technique (dependent variables) adjusted for age, sex, follow-up time and baseline values (explanatory variables) in the multivariate analysis.

variable	N	Univariate OR	95% CI	p-value
Age	198	*0.62	0.53–0.72	<0.01
Sex	198	0.52	0.28–0.97	0.04
Follow-up time	198	0.99	0.96–1.02	0.49
SF-36 PF baseline	196	1.00	0.98–1.02	0.98
SF-36 PF follow-up	196	*1.02	1.00–1.03	<0.01
WOMAC function baseline	196	1.02	0.99–1.05	0.16
WOMAC function follow-up	94	*1.02	1.00–1.04	<0.01

*per one year or scale unit increase. OR less than 1 means that with increasing age there is a less probability of being operated with hybrid technique. OR = odds ratio, 95% CI = 95% confidence interval

Table 4: Univariate and multivariate logistic regression analysis comparing follow-up data (26–54 months) for SF-36 PF (physical function) and WOMAC function in patients operated on with hybrid or cemented technique (dependent variables) adjusted for age, sex, follow-up time and baseline values (explanatory variables) in the multivariate analysis.

variable	N	Multivariate OR	95% CI	p-value
Age	198	*0.57	0.48–0.69	<0.01
Sex	198	0.29	0.08–1.06	0.06
Follow-up time	198	0.96	0.90–0.16	0.16
SF-36 PF baseline	196	*0.95	0.91–0.99	<0.01
SF-36 PF follow-up	196	1.03	0.98–1.06	0.07

*per one year or scale unit increase. OR less than 1 means that with increasing age there is a less probability of being operated with hybrid technique. OR = odds ratio, 95% CI = 95% confidence interval

A limitation of the study is the variable follow-up time. Thus, the patients with the longest follow-up time have reached a higher age than the patients with a shorter follow-up time. On the other hand, these patients have had longer time for rehabilitation and recovery. However, there was no difference between the surgical procedures when adjusted for follow-up time.

We have in this study described outcomes after THR for unilateral OA in an orthopaedic department at a general hospital. Patient mix and selection varies between different hospitals, which may influence outcome [28]. The patient groups compared in this study were of limited size. However, with the high responsiveness of the outcome measures SF-36 and WOMAC after THR [29,30] only a small sample size is required for statistical calculations. A power analysis of the present study thus resulted in a power of 75–94% to detect a difference of 10 points, assuming a standard-deviation of 15 and a significance level of 0.05. The reason for the choice of an absolute

Table 5: Univariate and multivariate logistic regression analysis comparing follow-up data (26–54 months) for SF-36 PF (physical function) and WOMAC function in patients operated on with hybrid or cemented technique (dependent variables) adjusted for age, sex, follow-up time and baseline values (explanatory variables) in the multivariate analysis.

variable	N	Multivariate OR	95% CI	p-value
Age	198	*0.59	0.46–0.76	<0.01
Sex	198	0.23	0.04–1.43	0.12
Follow-up time	198	0.90	0.79–1.02	0.10
WOMAC function baseline	196	1.00	0.95–1.06	0.90
WOMAC function follow-up	94	1.02	0.97–1.09	0.37

*per one year or scale unit increase. OR less than 1 means that with increasing age there is a less probability of being operated with hybrid technique. OR = odds ratio, 95% CI = 95% confidence interval

change of 10 score units is the knowledge that in clinical trials of rehabilitation intervention and medical treatment of OA the smallest clinically significant improvement in WOMAC function and pain is 9–12 score units [31,32]. We have not found any published randomized studies comparing cemented and hybrid THR, using patient-relevant outcome measures. Had we found differences between the two study groups in the present open study, this would have provided a rationale for a blinded, randomized study. The absence of difference between the study groups in this prospective, open cohort study comparing hybrid and cemented THR suggests that any difference in patient-relevant outcome and health-related quality of life between these two techniques will be small, and require a large randomized trial to prove. However, recently introduced techniques such as hybrid THR should continue to be monitored to determine long-term patient-relevant outcome, including health-related quality of life, as well as implant survival.

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