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Evaluation of the new questionnaire 'Forgotten Joint Score' in total hip arthroplasty with use of 'Oxford Hip Score' as reference standard

Degree Project in Medicine

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Programme in Medicine

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Abstract

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INTRODUCTION

Total hip arthroplasty (THA) is performed mainly because of pain in the hip joint. To evaluate the result after surgery, different questionnaires measuring the patient-reported outcome regarding quality of life are used. Forgotten Joint Score (FJS) is a questionnaire that was developed to find subtle differences between patients who report that their operated hip is "very good" or "excellent". The total score ranges from 0-100, where a high score is the best outcome. Oxford Hip Score (OHS) is a well-established tool to evaluate THA in clinical practice and scientific evaluations. This instrument ranges from 0-48, and focuses mainly on the pain from the artificial hip joint.

AIM

The aim of this study is to evaluate a new questionnaire called Forgotten Joint Score (FJS) to examine the reliability and assess whether it provides more information compared to already existing questionnaires; Oxford Hip Score (OHS) and EQ-5D-5L, regarding clinical results after hip prosthesis surgery.

METHOD

200 patients who underwent unilateral total hip arthroplasty in 2015 were included. The participants answered three questionnaires: Forgotten Joint Score, Oxford Hip Score and EQ-5D-5L.

RESULT

OHS ceiling effect (30.5 %) was higher compared to FJS (18.1%). Test-retest of the FJS revealed a good or excellent internal consistency (Cronbach's $\alpha = 0.91$). 20.7% of the patients had identical answers on both FJS questionnaires. The ceiling effect for EQ-5D was 37.5 % and 2 patients achieved a negative score.

CONCLUSION

OHS had a greater risk for ceiling effects, which could indicate that FJS is a more fine-tuned instrument to separate patients with good to excellent outcome after THA. The FJS has a good internal consistency.

Key words

Forgotten Joint Score, Total Hip Arthroplasty, Oxford Hip Score, EQ-5D-5L

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Background

The main indications for operation with total hip arthroplasty (THA) are pain and disability (1). In Sweden, more than 80% of the patients suffer from primary osteoarthritis. Other reasons are fractures, inflammatory joint disease and complications after childhood disease. In 2016 a total of 17 261 total hip replacements (THR) were performed in Sweden, which is an increase compared to earlier years. This is believed to depend on an increase in life expectancy as well as a higher share of elderly in the population. (2)

The aim with THA is to relive the pain in the patient as well as improving the joint mobility and the patient's physical ability and quality of life (1). Since the patient's expectations on the post-operative function has changed over the past 20 years (3) it is of great importance to find a validated method to measure the patient-reported outcome (PRO) after surgery (1). Questionnaires measuring PRO are used more widely, and should preferably be associated with ceiling and floor effects as small as possible. A ceiling effect means that a patient achieves the maximum score in a scale, which could make it difficult to study the development over time, since the true results and changes at follow up are concealed. Oxford Hip Score is a validated method that, above all, focuses on the pre-operative status. Forgotten Joint Score, on the other hand, is designed to chart the symptoms post-operatively.(4)

When doing a questionnaire study, it is of importance to use a questionnaire with high validity, i.e. using a questionnaire that measure what it is supposed to measure. A questionnaire should also be reliable, meaning that the answers provided by the patient are the same when repeating the questionnaire, provided that no change has emerged. Test-retest reliability is shown when the result is repeated the second time a questionnaire is answered. When sending out the second questionnaire, the time interval to the first distribution should

not be too short, since there might be a risk of patients remembering their previous answers, nor should it be too long, since the patients' health state might change. To avoid the risk of time related changes of test-retest reliability, internal consistency reliability could be used. Internal consistency reliability tests, for example Cronbach's α and intraclass correlation, describes the correlation between items in the questionnaire that are assessed to cover the same domain. (5)

When examining how good ability a scoring system has to detect clinical change, i.e. the sensitivity for change using an assessment technique, responsiveness is used (6). To be able to measure responsiveness, measurements both before and after surgery are required.

Forgotten Joint Score

The questionnaire called Forgotten Joint Score (FJS) was developed in 2012 (1) with the aim to measure PRO after THA (3). FJS is designed to measure the patients' ability to "forget" about their operated joint. Studies imply that older questionnaires do not provide a quite as variegated picture of the results, as they mostly differ between "good" and "bad". The authors, however, states that since FJS differ between "good", "very good" and "excellent" in a 5-grade Likert-scale ranging from "never" to "mostly", it could reduce the risk of ceiling effects. (1) As opposed to, for example Oxford Hip Score, FJS is a questionnaire that focus on the awareness, instead of the pain, of the affected joint (3). Four missing values are regarded as acceptable when the scores are summarized and transformed to a scale ranging from 0 to 100, where a high value indicate that the patient tends to be less aware of the affected joint when performing daily activities (1).

Oxford Hip Score

Oxford Hip Score (OHS), developed in 1996 (7), is a patient-centred, 12 item-questionnaire with questions concerning pain and physical ability in the patient experienced during the past four weeks (8). OHS originally used a scoring system ranging between 1-5 (worst-best) (7). Since 2007, OHS ranges from 0-4 where 4 is the best, which leads to a score ranging from 0-48, where 48 equals the best outcome (9) When interpreting the answers and calculating the overall score of OHS, a maximum of two missing values are accepted. If the patient fills in more than one answer per question, the worst response should be used when calculating the total score. (10)

Possible weaknesses of the Oxford Hip Score

The authors of a study performed at the Avon Orthopaedic Centre, learned about different weaknesses in the OHS questionnaire, e.g. that the patients experienced that some questions did not have a clear meaning. The patients also commented on the difficulty of answering according to their "average pain" during the past four weeks, since their pain sometimes fluctuated based on current medication and level of physical activity. Some of the questions in OHS are so called "double-barrelled questions", meaning there is more than one claim in each question. This could result in difficulty to interpret the answers, since some patients marked more than one of the possible answers at each question. (8) These findings indicate that a new, validated questionnaire with good responsiveness is needed, that is easy for the patients to understand.

EQ-5D-5L

EQ-5D-5L is a questionnaire consisting of five questions. In addition, a Visual Analog Scale (VAS 100) is presented, where the patients rank their experienced general health from 0-100.

EQ-5D-5L is an updated version of the EQ-5D-3L questionnaire and consists of questions covering five dimensions measuring the patient's mobility, self-care, usual activities, pain/discomfort and anxiety/depression, each question with five levels of possible answers. (11) Using five levels has shown an increase in sensitivity and reliability compared to using three levels (12).

Aim

The aim is to evaluate a new questionnaire, called Forgotten Joint Score, and examine the reliability of this instrument as well as examine if it gives more information compared to, or as a complement to, an already existing questionnaire (Oxford Hip Score) regarding the clinical results after total hip arthroplasty. EQ-5D-5L is used as reference regarding the patients' general health. Differences between men and women and the age groups are studied.

Materials and Methods

Sample/population

200 patients who underwent unilateral hip prosthesis surgery at the Department of Orthopaedics, Sahlgrenska University Hospital, Mölndal during 2015 were chosen consecutively with stratification for age and gender. Half of the participants were over 65 years old and the other half were 65 years old or younger. Half of the participants in each group were females (table 1). The patients were asked to fill out three questionnaires: Forgotten Joint Score, Oxford Hip Score and EQ-5D (See appendix 1-3), which were sent out in the beginning of September 2017. 10 to 14 days after return of the questionnaires, Forgotten Joint Score was sent out once again to evaluate its reproducibility (Fig. 1).

Table 1. Gender and age distribution of patients included in the study. The age of the patients is presented as the medians and range.

Age	Men		Women		Total		
	N	*Median*	*N*	*Median*	*N*	*Median*	*Range*
≤ 65	50	55	49	60	99	69	20-93
> 65	50	76	51	77	101	67.5	19-100

Loss to follow-up

Numbers included were calculated based on an estimated response rate of 75 %, i.e. 150 patients. Approximately one month after the first envelope was sent out, the patients who had not responded received a phone call reminder and an offer to receive a new set of questionnaires. If the patient declined participation or did not answer after two phone calls no further attempts to reach the patient were made.

Inclusion criteria

The patients included in the study were born between 1917 and 1997 and underwent unilateral THA 2015. All diagnoses (table 2), patients who previously had been operated in their opposite hip and those who had been revised after their index operation were included in the study. Thus, no selection based on these parameters were done because the instrument of interest (Forgotten Joint Score) should be generally applicable on all patients with a hip prosthesis.

Table 2. List of diagnoses of patients included in the study.

Diagnosis	Number of patients	Percentage (%)
Primary osteoarthritis	135	67.5
Inflammatory joint disease	1	0.5
Fracture	36	18
Complications after childhood disease	10	5
Idiopathic caput necrosis	18	9

Reason to no participation

Out of those patients receiving a reminder phone call, 30 did not answer the phone and were excluded. Table 3 shows reasons given by the patients to not participate. 15 patients accepted participation in the study, but did not send in their answers.

Table 3. Reasons to no participation given from patients when receiving a reminder phone call.

Reason to no participation	Number of patients
Not answering the phone	30
Missing valid phone number	6
Recent illness/hospitalized	5
On vacation	1
Dissatisfied with the surgery	2
Not registered in Elvis	1
Not interested	16
Accepted participation, but did not return questionnaires	15
Total	76

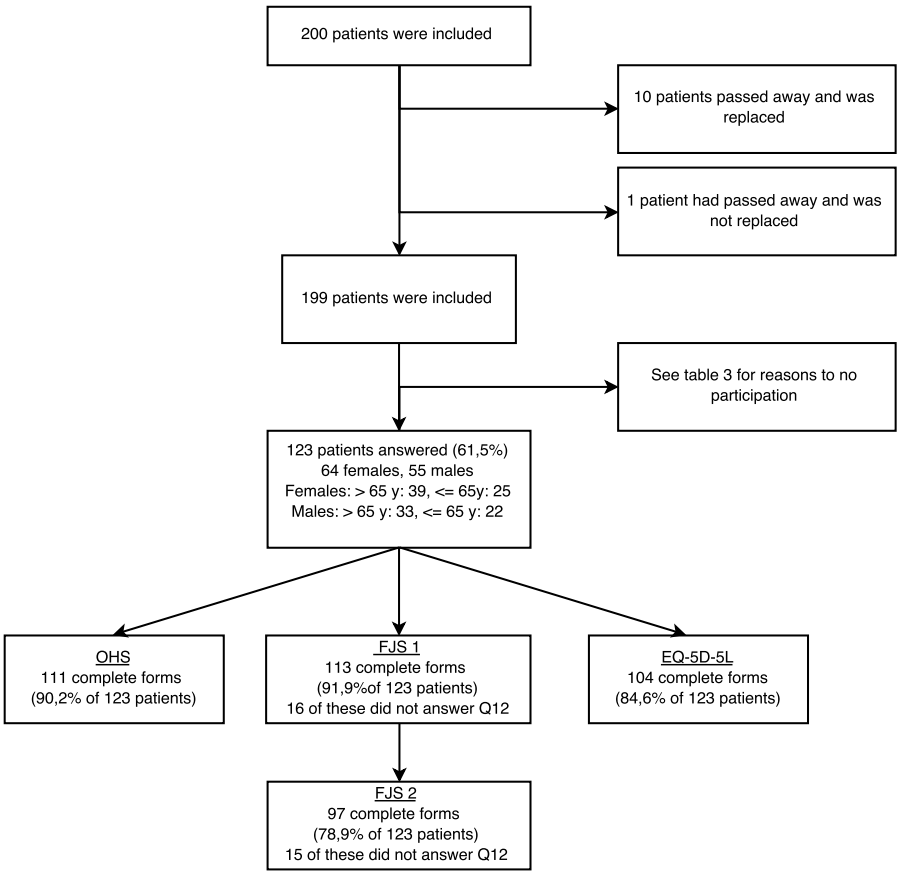

Figure 1. Flow-chart illustrating participation and answer frequency.

Statistics

Data collection procedures

All patients received an envelope with three questionnaires (Forgotten Joint Score, Oxford Hip Score and EQ-5D-5L) and a letter with information on the study and a form for written consent. Approximately two weeks after answering the questionnaires, a letter was sent out with a request to fill in the Forgotten Joint Score form once again. All data from the questionnaires and further information from the case records about patient demographics were entered into a database (IBM© SPSS© Statistics, 25.0).

Table 4 shows the seven questions with similar content that were assessed to correlate between FJS and OHS.

Table 4. The questions from OHS and FJS that were assessed to correlate.

Are you aware of your artificial joint…	During the past 4 weeks…
FJS 1: In bed at night?	OHS 12: Have you been troubled in bed at night by pain from your hip?
FJS 3: When you are walking for more than 15 minutes?	OHS 6: How long have you been able to walk before pain from your hip becomes severe?
FJS 4: When you are taking a bath/shower?	OHS 2: Have you had any trouble with washing and drying yourself (all over) because of your hip?
FJS 5: When you are traveling in a car?	OHS 3: Have you had any trouble getting in and out of a car or using public transportation because of your hip?
FJS 6: When you are climbing stairs?	OHS 7: Have you been able to use stairs?
FJS 8: When you are standing up from a low-sitting position?	OHS 8: How painful has it been for you to stand up from a chair because of your hip?
FJS 10: When you are doing housework or gardening?	OHS 11: How much has pain from your hip interfered with your usual work (including housework)?

Variables

Variables used were age at operation, gender and the answers to the questions from the questionnaires. We also included whether the questionnaire was complete or not and the reason to incomplete answers. Patient's year of birth and the date of answering the questionnaires were also recorded.

Statistical methods

Sample characteristics are presented as numbers and percentages, as well as means, standard deviations, medians and ranges of the different questionnaires and distribution related to age and gender. To compare the differences between FJS and OHS, the floor and ceiling effects were calculated. The patients obtaining the lowest score, i.e. patients who were the most satisfied, was counted as ceiling effect. The patients with the highest score, i.e. the patients that were the least satisfied, was considered floor effect, meaning that these patients might

have more problems than the instrument shows. If more than 15% of the participants achieved the maximum or minimum score, ceiling and floor effects was considered to be present. When comparing the correlating questions, intraclass correlation and Cronbach's α was used as well as interquartile range. Cronbach's α = 0.70-0.95 is considered good internal consistency. The Intraclass Correlation is a reliability coefficient with a ratio ranging from 0-1 and is considered good when ICC > 0.7. (6)

As mentioned above, FJS is transformed into a scale ranging from 0-100 and OHS ranges between 0-48. In this study, however, to be able to compare the questionnaires and since both FJS and OHS consists of 12 questions with 5 possible answers each, it was decided to use the answer options of 1-5, where 1 is best and 5 is worst. This results in a total score ranging from 12-60 for both questionnaires. Since neither of the questionnaires consists of weighted questions this was regarded to be an acceptable adjustment to facilitate the interpretation of the results. When calculating the score of EQ-5D-5L, the English value set for modelling results was used since no Swedish value set was available (13).

Ethics

This study includes 200 patients. Patient data were extracted from the records of prosthetic hip surgery collected at the Department of Orthopaedics, Sahlgrenska University Hospital, Mölndal. Approval was obtained from the Ethical Review Board (Etikprövningsnämnden, EPN) with Dnr/registration number 607-17. All the patients received a letter with information on the study and a form of written consent (see appendix 4), which is to be filled out by the patient and enclosed with the completed questionnaires. The participation in this study is voluntary and the patients can at any time decide to withdraw their data from the study results without giving any reason.

Results

Among the 123 patients (64 women, 55 men, 4 unknown) who answered the questionnaire, 72 were over 65 years and 47 were 65 years or younger (table 5). 105 of these patients had filled out both OHS and FJS completely.

Table 5. Showing the number of men and women in each age group. 4 patients did not fill out their date of birth and are therefore not included in this table.

	Age > 65	Age ≤ 65	Total
Women	39	25	64
Men	33	22	55
Total	72	47	119

There was an about equal distribution into age group and gender among those 119 patients who answered both questionnaires (Fisher's test, p=1). Neither did the distribution differ for these parameters concerning those who filled in the FJS 1 (likelihood ratio gender: X^2 (df=1) =2.1, p=0.16; age X^2 (df=34) = 43.9, p=0.12). The corresponding likelihood ratios for OHS were 21.8 (df=22, p=0.5) and 19.4 (df=22, p=0.6).

Mean and median values for OHS and FJS 1

The mean value of the total score of OHS was 18.2 (SD 8.5, median 15, IQR = 7.25, 52 males, 58 females). The mean value of the total score of FJS was 28.7 (SD 15.2, median 25, IQR = 23, 59 females, 52 males). These values were calculated on the number of questionnaires that were filled out correctly for both FJS and OHS, hence the difference in number of answers. FJS had a higher mean value than OHS, while the median value was approximately the same for all questions. The interquartile range showed that the answers of OHS were less scattered compared to FJS. Each question had an answer range between 1-5 and in some cases 1-4 (table 6).

Table 6. Mean and median values and interquartile range for the correlating questions of OHS and FJS respectively.

Question	N	Median	Mean	Std. Error	Std. Deviation	Minimum	Maximum	Interquartile range
FJS 1	114	2	2.02	0.12	1.33	1	5	1
OHS 12	114	1	1.48	0.10	1.08	1	5	0
FJS 3	112	1	2.30	0.15	1.55	1	5	3
OHS 6	112	1	1.63	0.11	1.15	1	5	1
FJS 4	116	1	1.79	0.12	1.30	1	5	1
OHS 2	116	1	1.35	0.06	0.68	1	4	0.75
FJS 5	114	1	2.07	0.12	1.32	1	5	2
OHS 3	114	1	1.53	0.08	0.84	1	4	1
FJS 6	115	2	2.37	0.14	1.52	1	5	3
OHS 7	115	1	1.63	0.09	0.95	1	5	1
FJS 8	115	2	2.64	0.14	1.53	1	5	3
OHS 8	115	1	1.51	0.10	1.05	1	5	1
FJS 10	115	2	2.52	0.13	1.42	1	5	3
FJS 11	115	1	1.63	0.10	1.07	1	5	1
FJS sum	91	25	26.87	1.48	14.14	12	60	22
OHS sum	91	14	17.45	0.85	8.13	12	52	7

* See table 4 for questions

Comparison of answers between FJS and OHS

In OHS, between 62.2 to 81.1% of the patients chose option 1 to each of the questions. The corresponding numbers for FJS were 35.4 to 65.5%. The answers for FJS were more scattered among the different options, and all answer options were chosen in all questions, which differs from OHS, where no patients chose option 5 on three questions (question number 2, 3 and 7) as well as for option 4 in question 12. (Fig. 2,3)

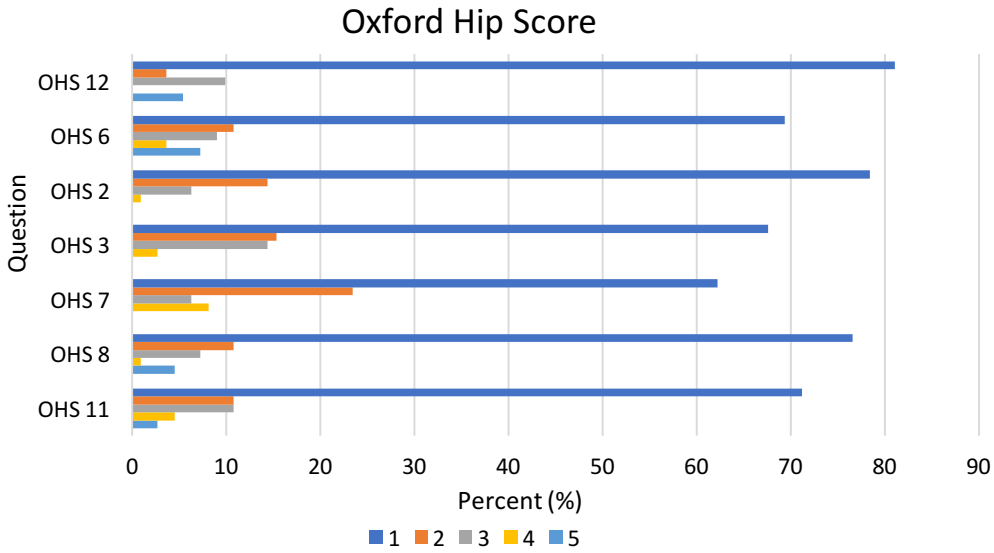

Figure 2. Oxford Hip Score – Result. The graph illustrates the number of patients (%) and how they answered the different questions of the questionnaire. See table 4 for the questions included in the graph.

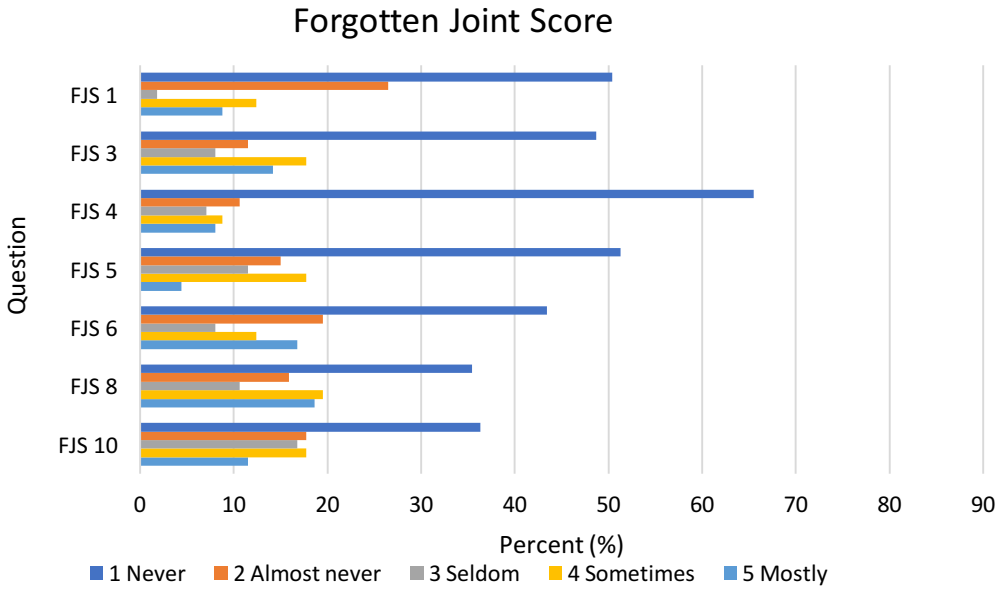

Figure 3. Forgotten Joint Score – Result. The graph illustrates the number of patients (%) and how they answered the different questions of questionnaire. See table 4 for the questions included in the graph.

Floor and ceiling effects of OHS and FJS

When answering the FJS, a total of 24 patients (19.5%) filled out the minimum score on all questions which summed up to 12 points. Two patients (1.6%), filled out the maximum score

to each question (60 points). 34 patients (27.6%) achieved the minimum score on OHS, which is a total of 12 points. No patient in the OHS group achieved the maximum score of 60 points. The highest score measured in OHS was 52 points and was filled out by one patient (0.8%).

When comparing the number of patients who chose option 1 (i.e. the best option) to each question, more than 50% of the patients in OHS had chosen option 1 to all questions (Fig. 4).

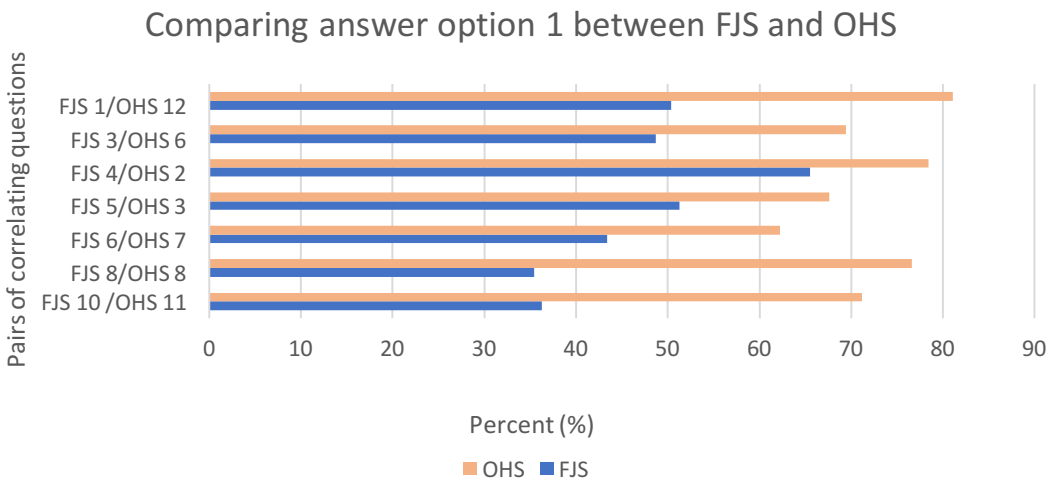

Figure 4. Number of patients who chose option 1 in OHS and FJS respectively. Illustrated in the graph, we can see that, when answering OHS, more than 60 % of the patients chose option 1 to all questions that were assessed to correlate with FJS.
See table 4 for exact questions.

105 patients had answered both questionnaires completely. Of these 105 patients, a total of 32 (30.5%) achieved the minimum score of 12 points in OHS. In these 32 patients, the corresponding median FJS score was 12 (range 12-32, mean 14.9; ICC-value = 0.0, 95% CI = -0.344-0.344) (Fig. 5). Thus, the FJS provided a more nuanced description of patients who reported the most optimum results according to the OHS.

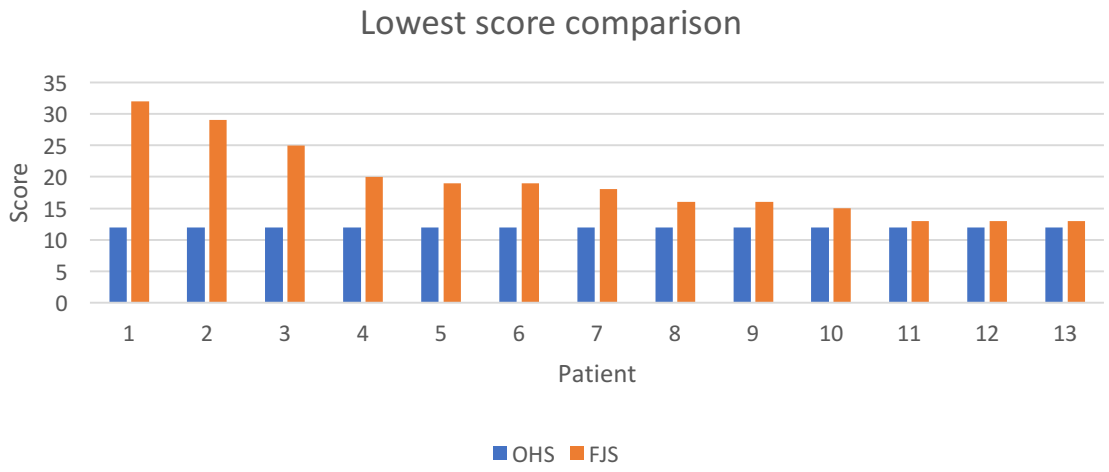

Figure 5. The patients who scored the lowest on OHS and FJS. 19 patients with a total score of 12 points in both questionnaires are not included in the graph.

In 17 patients (16.2%) who reported the highest FJS score (range 40-60, median 51, mean 50.4), the median OHS was 31 (range 13-52, mean 29.7). A comparison of the highest total score of FJS and the corresponding score of OHS resulted in an ICC value of 0.61 (CI 0.20-0.84, Cronbach's $\alpha = 0.76$) indicating a certain unanimity, but also with a more pronounced "floor-effect" for the FJS (Fig. 6).

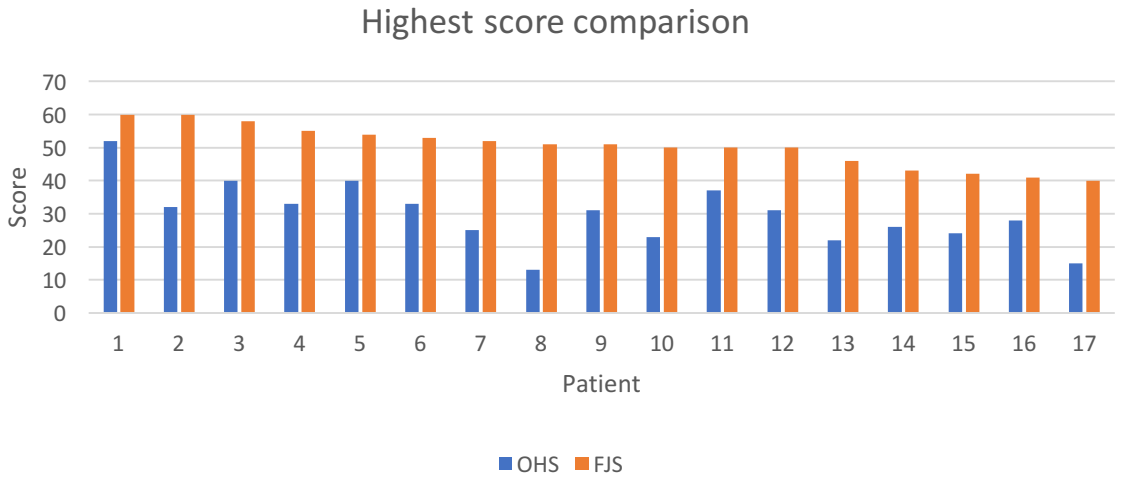

Figure 6. A comparison of the patients who scored the highest score on OHS and FJS respectively.

Intraclass Correlation (ICC) between FJS and OHS

When comparing the ICC between FJS and OHS, only one pair of questions got an ICC value over 0.7 (table 7).

*Table 7. Intraclass correlation and Cronbach's α between FJS and OHS correlating questions**

Questions	Valid cases	Cronbach's α	ICC single	CI lower	CI upper
FJS 1/OHS 12	114	0.85	0.73a	0.64	0.81
FJS 3/OHS 6	112	0.59	0.42a	0.26	0.56
FJS 4/OHS 2	116	0.64	0.47a	0.32	0.60
FJS 5/OHS 3	114	0.76	0.62a	0.49	0.72
FJS 6/OHS7	115	0.77	0.63a	0.51	0.73
FJS 8/OHS 8	115	0.73	0.58a	0.44	0.69
FJS 10/OHS 11	115	0.80	0.67a	0.56	0.76
FJS sum/OHS sum	106	0.83	0.71a	0.61	0.80

a The estimator is the same, whether the interaction effect is present or not.
* See table 4 for questions

Comparison between FJS 1 and FJS 2

In the second distribution of Forgotten Joint Score, 14 patients (14.4%) achieved the minimum score of 12 points. However, since the last question "are you aware of your artificial joint when you are doing your favourite sport?" was not answered by 15 patients' due to lack of favourite sport, 3 patients got a total of 11 points. One patient achieved the maximum of 60 points. The mean value for the total score was 28.7 (SD 15.2, median 25, IQR = 23) for FJS 1 and 28.8 (SD 15.1, median 26, IQR = 25, 54 females, 43 males) for FJS 2 (table 8).

Table 8. Median and mean values and interquartile range for FJS 1 and FJS 2 respectively.

Are you aware of your artificial joint…	FJS 1/2	Valid number	Median	Mean	Std. Error	Std. Deviation	IQR
In bed at night?	FJS 1	112	1	2.01	0.13	1.35	1
	FJS 2	97	1	1.99	0.13	1.29	2
When you are sitting on a chair for more than 1 hour?	FJS 1	112	2	2.30	0.14	1.48	3
	FJS 2	97	2	2.29	0.15	1.49	3
When you are walking for more than 15 minutes?	FJS 1	112	2	2.36	0.15	1.56	3
	FJS 2	97	2	2.36	0.15	1.48	3
When you are taking a bath/shower?	FJS 1	112	1	1.82	0.13	1.34	1
	FJS 2	97	1	1.91	0.14	1.33	1
When you are traveling in a car?	FJS 1	112	1	2.07	0.12	1.31	2
	FJS 2	97	1	2.01	0.14	1.39	2
When you are climbing stairs?	FJS 1	112	2	2.38	0.15	1.54	3
	FJS 2	97	2	2.45	0.15	1.51	3
When you are walking on uneven ground?	FJS 1	112	2	2.56	0.14	1.50	3
	FJS 2	97	2	2.54	0.15	1.50	3
When you are standing up from a low-sitting position?	FJS 1	112	2	2.69	0.15	1.57	3
	FJS 2	97	2	2.69	0.16	1.57	3
When you are standing for long periods of time?	FJS 1	112	2	2.56	0.14	1.48	3
	FJS 2	97	2	2.59	0.15	1.51	3
When you are doing housework or gardening?	FJS 1	112	2	2.49	0.13	1.43	3
	FJS 2	97	2	2.41	0.14	1.42	3
When you are taking a walk/hiking?	FJS 1	112	2	2.66	0.15	1.56	3
	FJS 2	97	2	2.63	0.16	1.53	3
When you are doing your favourite sport?	FJS 1	96	2	2.47	0.16	1.54	3
	FJS 2	82	2	2.35	0.16	1.45	3
Total	FJS 1 (- Q12)	96	25	27.17	1.48	14.54	23.5
	FJS 2 (- Q12)	82	24	26.89	1.55	14.01	21.5

FJS showed a good repeatability for the total score (ICC=0.84, CI 0.76-0.9, Cronbach's α=0.91). Ten questions had an ICC-value over 0.7 and all questions had a Cronbach's α value above 0.7 (table 9).

Table 9. ICC and Cronbach's α - comparing FJS 1 and FJS 2

FJS question	N	Cronbach's α	ICC	CI lower	CI upper
1	99	0.90	0.81a	0.73	0.87
2	98	0.90	0.82a	0.75	0.88
3	99	0.88	0.78a	0.69	0.85
4	100	0.84	0.73a	0.62	0.81
5	99	0.88	0.78a	0.69	0.85
6	100	0.86	0.76a	0.66	0.83
7	99	0.87	0.77a	0.67	0.84
8	100	0.81	0.68a	0.56	0.77
9	99	0.85	0.73a	0.63	0.81
10	99	0.86	0.75a	0.65	0.83
11	98	0.84	0.72a	0.61	0.80
12	76	0.75	0.60a	0.44	0.73

a The estimator is the same, whether the interaction effect is present or not.

92 patients had complete answers on both questionnaires. 19 patients (20.7%) had identical answers on FJS 1 and FJS 2. 53 patients (57.7%) had chosen different answers on 4 or more questions (Fig. 7).

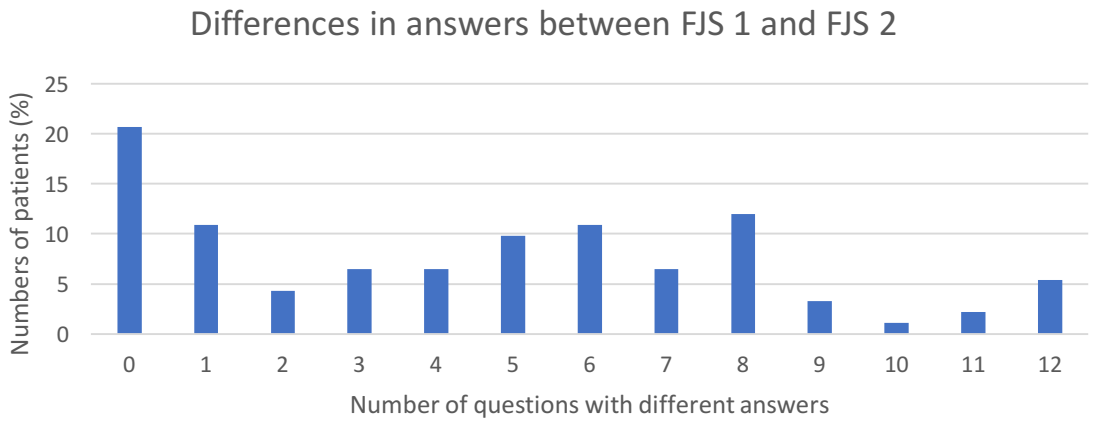

Figure 7. Comparing FJS 1 and FJS 2. The number of identical questionnaires and number of questions with different answers.

A comparison of each question in the FJS was made to examine the number of patients who achieved identical answers in both distributions of FJS (table 10).

Table 10. Comparing answers for each question in FJS 1 and FJS 2. The table illustrates the number of patients (%) who had identical answers in both distributions of FJS as well as the number of answers that differs in each question, with 1, 2 and more than 2 points.

Question	Identical answers	1 point difference	2-point difference	> 2-point difference
Q1	72.8%	21.7%	3.3%	2.2%
Q2	65.2%	25.0%	7.6%	2.2%
Q3	63.0%	23.9%	9.8%	3.3%
Q4	67.4%	22.8%	5.4%	4.3%
Q5	66.3%	25.0%	6,5%	2.2%
Q6	66.3%	17.4%	12.0%	4.3%
Q7	57.6%	29.3%	8.7%	4.3%
Q8	64.1%	20.7%	6.5%	8.7%
Q9	58.7%	29.3%	5.4%	6.5%
Q10	62.0%	26.1%	7.6%	4.3%
Q11	55.4%	26.1%	13.0%	5.4%
Q12	51.1%	22.8%	14.1%	12.0%

EQ-5D-5L and VAS 100

104 patients (53 women, 50 men, 1 unknown) filled out the EQ-5D-5L correctly, which was a total of 84.6% of the 123 patients who answered the questionnaires. 39 patients (37.5%) chose the best option to each question, achieving the highest score of 1. Two patients (1.9%) achieved a negative score (Fig. 8).

101 filled out the VAS-100. The mean value of the patients reported health state was 77.4 (median 80). 7.9% of the patients rated their total health below 50.

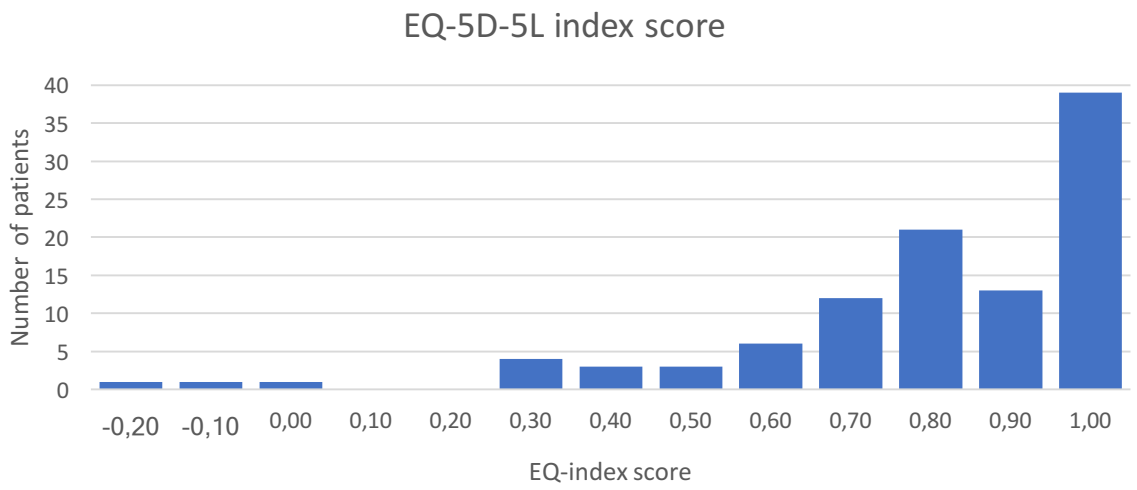

Figure 8. EQ-5D-5L Index score. 39 patients achieved the best possible score of 1, 2 patients achieved a negative score.

When comparing the result from EQ-5D-5L to FJS and OHS, patients with an EQ-5D score below 0.5 were chosen, which resulted in a population of 10 patients. The results from these 10 patients were compared to the results from FJS and OHS for the same patients (table 11).

Table 11. Comparing the lowest scores of EQ-5D with the corresponding total scores of FJS, OHS and VAS 100. Some of the questionnaires were not correctly filled out and are marked as "not complete" in the table.

Patient	EQ-5D score	VAS	FJS sum	OHS sum
1	-0.7	0	60	52
2	-0.16	2	54	40
3	0.2	15	51	42
4	0.33	45	51	31
5	0.36	70	57	Not complete
6	0.39	46	58	40
7	0.39	50	Not complete	18
8	0.41	20	54	40
9	0.48	50	54	Not complete
10	0.49	36	Not complete	33

Among the 39 patients (37.5%) with the highest score on EQ-5D-5L, the range, median and interquartile range were calculated for VAS-100, FJS and OHS (table 12).

Table 12. Median, range and interquartile range for VAS-100, FJS and OHS among the patients with the highest score on EQ-5D-5L.

	Median	Range	Interquartile range
VAS-100	95	75-100	15
FJS	13	12-51	13
OHS	12	12-19	1

Discussion

The main purpose of this study was to compare Forgotten Joint Score (FJS) to Oxford Hip Score (OHS) and examine whether FJS gives more information about factors associated to their previous THA or can function as a complement to OHS. In addition, the reproducibility of the FJS was studied. The patients were also asked to fill in EQ-5D-5L mainly to obtain information about their quality of life.

Floor and ceiling effects of FJS and OHS

When measuring the ceiling effects, the cut-off value was set at 40 points, resulting in 16.2% of the patients with the highest score on FJS to compare with OHS. Of the 17 patients (16.2%) who achieved the highest FJS score, 2 patients scored a maximum 60 points, the remaining 15 patients achieved a score ranging down to 40 points. Among these 17 patients, the highest score achieved on OHS was 52, ranging down to as low as 13 points. As many as 32 patients (30.5%) achieved the minimum score on OHS and the corresponding number of patients for FJS was 19 (18.1%). According to Terwee et al. a ceiling effect is present if more than 15 % of the participants got the “best” result, meaning in this study the minimum score (6). According to the conclusions of Terwee et al., the ceiling effect of OHS in this study is

30.5% and for FJS 18.1%. Neither of the two questionnaires reached 15% for floor effect, though 2 patients achieved the maximum score on FJS. Several of the patients answering the FJS achieved high total scores, which could be considered to be negative, since it could make it difficult to detect change at follow-up.

Hamilton et al. made a study where OHS and FJS were distributed twice between 6 and 12 months and the authors suggest that FJS is more responsive to change than OHS. The authors also noticed that the measured ceiling effect was nearly doubled for OHS compared to FJS (20.8% and 10.4% respectively.) (4).

The results from another study made by Hamilton et al. illustrates that the floor effects for FJS pre-operatively were explicit. 22.4% of the THA patients achieved the minimum score. These numbers differ from OHS, where no floor effects were shown pre-operatively. The ceiling effect, however, was approximately half for FJS 1 year post-operatively compared to OHS. (3)

Comparison of FJS 1 and FJS 2

When comparing the first and second distribution of Forgotten Joint Score, we can see that the mean and median values for each question correlates well, meaning that the patients chose the same answers on both questionnaires. One question that is hard to interpret is number 12, "Are you aware of your artificial joint when doing your favourite sport", since some of the patients (14.3% and 15.5% for FJS 1 and FJS 2 respectively) did not answer it because they did not have a favourite sport, either because of limited physical ability after surgery or due to age related physical inabilities. See table 13 and 14 for exact answer frequency to each question in the two distributions of FJS.

To examine the reproducibility of FJS, a comparison was made between the answers of FJS 1 and FJS 2. Fewer patients answered on the second distribution of FJS compared to the first, which resulted in an answer frequency of 112 and 97 patients on FJS 1 and FJS 2 respectively. 92 of these patients had complete answers on both questionnaires and 19 (20.7%) had identical answers on both FJS 1 and FJS 2. Since 4 missing values are acceptable when calculating the FJS, we chose 4 questions as the cut-off value. 53 patients (57.7%) had chosen different answers in 4 or more questions. The total score of FJS 1 and FJS 2 had a Cronbach's α value = 0.91 a ICC value = 0.84, which shows high internal consistency. A conclusion that can be drawn from this is that FJS has a good reliability, although the number of patients who returned the 2nd questionnaire were comparatively low to draw any clear conclusions on this point. Behrend et al. found that FJS had high internal consistency (Cronbach's α = 0.95) (1), which correlates well to the findings in our study.

EQ-5D results compared to FJS and OHS

When calculating the results of EQ-5D-5L, a tariff has been made that is used to transform the answers into a result where 1 is the best health possible and 0 is the worst imaginable health state. It is possible to achieve negative numbers, which is achieved by two patients in this study. Achieving negative numbers means that the patients experience a state of health which is to be interpreted as a state worse than death (14).

37.5% of the patients who answered EQ-5D-5L achieved the maximum score, i.e. the best possible outcome, which can be compared to OHS where 30.5% of the patients achieved the score for best possible outcome. The corresponding number for FJS is 20.7%. The range of answers for FJS in the patients with the highest score on EQ-5D-5L was 12-51 compared to 12-19 on OHS. One possible explanation to the wider range on FJS is that OHS measure the

level of pain the patient experience, while FJS measure awareness of the hip joint. These patients might not experience pain, only discomfort, which would result in a low score on OHS and a higher score on FJS. This could be one possible explanation to the higher ceiling effects on OHS.

When comparing the lowest scores for EQ-5D with OHS and FJS, the patients with the lowest score (cut-off value set at < 0.5 points) were chosen, resulting in a population of 10 patients. Their scores were compared to the correlating VAS-score and the total score for FJS and OHS. The three patients with the lowest score on EQ-5D had among the highest scores on FJS and OHS. The conclusion is that the EQ-5D results correlates well with FJS and OHS, with some exceptions which might be explained as a difficulty to interpret the questions for the patients.

Giesinger et al. compared different questionnaires, e.g. FJS and EQ-5D, measuring PRO after total knee arthroplasty (TKA). They showed that EQ-5D failed to detect change after short time follow-up as well as poor responsiveness due to high ceiling effects, and therefore other questionnaires, like FJS, are needed as a complement (15). Since these findings are about TKA, strict comparisons cannot be made between that study and ours, but we can assume that a complementary questionnaire to EQ-5D is needed for THA as well, since EQ-5D in our study achieved a ceiling effect of 37.5%.

Difference in answers and how age and gender affects the outcome

One aim of this study was to evaluate if the response rate differed between males and females or between age groups. No such bias could be documented neither for the FHS nor the OHS.

On the contrary, the distribution between genders and age groups was rather equal suggesting that out observations probably also are valid had the sample size been more comprehensive.

Strengths and limitations

Studies have compared OHS to FJS, but to our knowledge none of these studies have been performed in Sweden. A strength of our study is that since our study is performed on patients who underwent surgery in Sweden, the results could be applied to clinical practice in Sweden.

One possible limitation on this study is that a moderately sized population is included. The calculated participation level was 75%, i.e. 150 answers, and the actual participation level was 61.5%. The answer frequency probably would have been higher if the study took place over a longer period of time and more attempts could have been made to reach the patients who did not answer.

Yet another shortcoming of this study lies in the method. When calculating the results for FJS and OHS, the same scoring system for both questionnaires was used, i.e. 12-60 points, to facilitate interpretations of the results, instead of using the original scoring system (1, 9). One drawback with this approach is that it might be more difficult to compare the results with other studies on the same subject. On the FJS questionnaire, a line where the patients should fill in the date of answering the questions is provided. A limitation with this study is that several patients did not fill out the date, which makes it impossible to know exactly how long time that had passed between the two FJS distributions. This could mean that either too little or too long time had passed between the distributions, resulting in a risk of the patients remembering their previous answers or that their health state changed.

Recommendations

More studies on this subject is needed, and would preferably be performed on a larger study population. A question about the patients' expectations on the results of the operation and satisfaction with the results achieved, could, as well as a question about co-morbidity, be of interest to add to the study. It may also give valuable information if the patients included in the study were asked about which questionnaire they prefer between FJS and OHS.

When evaluating the results, it seems that FJS is easier to understand and is less time consuming to fill out, since it only consists of one page and the possible answers are the same for all questions. It seems as OHS is to be preferable in the pre-operative situation since this study, as well as other studies, show a greater risk for ceiling effects post-operatively (4). Another way of performing the study would be to do run it for a longer period of time and to evaluate the results with the Forgotten Joint Score and Oxford Hip Score pre-operatively and at repeated occasions after the operation. In this way, the floor and ceiling effects could be measured more accurately. A way to achieve a higher response rate is to do an online questionnaire instead of via mail, which can be more time consuming.

Conclusions and Implications

The answers on FJS are more scattered than on OHS, which could indicate that FJS provides a more variegated picture of the clinical results in this population. The risk of ceiling effects of FJS was almost half the risk of OHS, which provides valuable information, not least in a field where new implants with proposed superior performance are continuously introduced and patient expectations on the results tend to increase. The results from this study indicates that the reproducibility of FJS is good, with approximately 20% identical answers in both

distributions of FJS together and a Cronbach's α value of 0.91. The number of patients who returned the 2nd questionnaire was, however, limited (n=97) which is a cause of concern.

We think that the FJS could be used primarily as a complement to Oxford Hip Score. Further studies are needed to evaluate if the FJS can substitute this questionnaire. The observed floor effect of the FJS does not speak in favour of this alternative.

Populärvetenskaplig sammanfattning

Utvärdering av ett nytt uppföljningsformulär, Forgotten Joint Score, jämfört med Oxford Hip Score och EQ-5D-5L

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Handledare: Johan Kärrholm

En höftprotesoperation görs framförallt på grund av smärta, nedsatt funktion och påverkad livskvalitet. Orsaken är oftast primär artros (ledsvikt). Generellt sett är resultaten efter höftproteskirurgi mycket goda, speciellt om man jämför med patientens situation före operationen. Dock blir uppskattningsvis en tiondel av patienterna inte nöjda med ingreppet. Resultaten skiljer sig dessutom bland de patienter som klassificerar sig som nöjda. För att få en tydligare bild av resultaten har det utvecklats olika så kallade scoresystem, som i allmänhet består av olika typer av frågor som besvaras på olika skalor eller enkla frågor med ett flertal svarsalternativ som exempelvis Oxford Hip Score. Ofta finner man att dessa frågeformulär är allt för onyanserade. Exempelvis kan man i grupper med bästa tänkbara resultat fortfarande se skillnader som är värda att notera.

Syftet med denna studie är att undersöka om ett nytt formulär, Forgotten Joint Score (FJS), ger utökad information jämfört med, eller som tillägg till, Oxford Hip Score (OHS) och EQ-5D-5L gällande det kliniska resultatet efter en höftprotesoperation.

200 patienter, som höftprotesopererades under 2015, inkluderades i studien. De ombads att fylla i tre formulär (Forgotten Joint Score, Oxford Hip Score och EQ-5D-5L). Efter 10–14 dagar skickades Forgotten Joint Score ut ännu en gång för att validera svaren. Resultaten i denna studie visar att Forgotten Joint Score har en lägre risk för takeffekter jämfört med Oxford Hip Score, vilket innebär att fler patienter fyllt i bästa möjliga svar på frågorna och att det därmed blir svårare att följa utvecklingen av patientens tillstånd. Detta visade även att spridningen av svaren för FJS var större än spridningen för OHS. Resultatet visade även att median- och medelvärdena var ungefär lika stora för frågorna i båda formulären, men att medelvärden för totalpoängen var högre för FJS än för OHS (27,2 respektive 18,3). Vid jämförelse av de två utskicken av FJS kan vi se en statistisk samstämmighet mellan formulären. 20,7% av patienterna hade svarat identiskt på båda utskicken, vilket tillsammans med en hög samstämmighet innebär att reproducerbarheten för FJS kan betraktas som god. När resultaten från FJS och OHS jämförs med resultaten från EQ-5D-5L, kan vi se att de lägsta respektive högsta poängen i EQ-5D-5L stämmer väl överens med resultatet från FJS och OHS. Fler studier, förslagsvis med en större studiepopulation, behövs för att kunna dra några slutgiltiga slutsatser angående FJS.

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Figures and Tables

Table 13. First distribution of FJS – the number of patients (%) and how they answered each question.

Are you aware of your artificial joint…	1 Never	2 Almost never	3 Seldom	4 Sometimes	5 Mostly	6*	Total
In bed at night?	57 (50.9)	30 (26.8)	2 (1.8)	13 (11.6)	10 (8.9)		112
When you are sitting on a chair for more than 1 hour?	52 (46.4)	19 (17)	9 (8)	19 (17)	13 (11.6)		112
When you are walking for more than 15 minutes?	55 (49.1)	13 (11.6)	9 (8)	19 (17)	16 (14.3)		112
When you are taking a bath/shower?	74 (66.1)	12 (10.7)	7 (6.3)	10 (8.9)	9 (8)		112
When you are traveling in a car?	58 (51.8)	17 (15.2)	13 (11.6)	19 (17)	5 (4.5)		112
When you are climbing stairs?	49 (43.8)	22 (19.6)	9 (8)	13 (11.6)	19 (17)		112
When you are walking on uneven ground?	42 (37.5)	18 (16.1)	15(13.4)	21 (18.8)	16 (14.3)		112
When you are standing up from a low-sitting position?	40 (35.7)	18 (16.1)	12 (10.7)	21 (18.8)	21 (18.8)		112
When you are standing for long periods of time?	41 (36.6)	18 (16.1)	18 (16.1)	19 (17)	13 (11.6)		112
When you are doing housework or gardening?	41 (36.6)	20 (17.9)	19 (17)	19 (17)	13 (11.6)		112
When you are taking a walk/hiking?	42 (37.5)	16 (14.3)	11 (9.8)	24 (21.4)	19 (17)		112
When you are doing your favourite sport?	39 (34.8)	18 (16.1)	11 (9.8)	11 (9.8)	17 (15.2)	16 (14.3)	112
* Missing favourite sport a Answer given in number, percentage given in parenthesis (%)							

Table 14. Second distribution of FJS – the number of patients (%) and how they answered each question.

Are you aware of your artificial joint…	1 Never	2 Almost never	3 Seldom	4 Sometimes	5 Mostly	6*	Total
In bed at night?	50 (51.5)	22 (22.7)	8 (8.2)	10 (10.3)	7 (7.2)		97
When you are sitting on a chair for more than 1 hour?	45 (46.4)	17 (17.5)	10 (10.3)	12 (12.4)	13 (13.4)		97
When you are walking for more than 15 minutes?	40 (41.2)	22 (22.7)	9 (9.3)	12 (12.4)	14 (14.4)		97
When you are taking a bath/shower?	56 (57.7)	18 (18.6)	9 (9.3)	4 (4.1)	10 (10.3)		97
When you are traveling in a car?	54 (55.7)	17 (17.5)	6 (6.2)	11 (11.3)	9 (9.3)		97
When you are climbing stairs?	38 (37.1)	17 (17.5)	16 (16.5)	12 (12.4)	16 (16.5)		97
When you are walking on uneven ground?	36 (37.1)	17 (17.5)	16 (16.5)	12 (12.4)	16 (16.5)		97
When you are standing up from a low-sitting position?	33 (34)	20 (20.6)	7 (7.2)	18 (18.6)	19 (19.6)		97
When you are standing for long periods of time?	35 (36.1)	18 (18.6)	11 (11.3)	18 (18.6)	15 (15.5)		97
When you are doing housework or gardening?	37 (38.1)	21 (21.6)	11 (11.3)	18 (18.6)	10 (10.3)		97
When you are taking a walk/hiking?	34 (35.1)	18 (18.6)	12 (12.4)	16 (16.5)	17 (17.5)		97
When you are doing your favourite sport?	35 (36.1)	15 (15.5)	9 (9.3)	14 (14.4)	9 (9.3)	15 (15.5)	97

* Missing favourite sport

a Answer given in number, percentage given in parenthesis (%)

Appendices

Appendix 1

Frågeformulär om din opererade höftled (Poängskala för bortglömd led − 12)

Namn:_____ Datum: ___.___._____

Födelsenummer:

En frisk led är inte något man är medveten om i det dagliga livet. Men även minsta lilla besvär kan öka medvetenheten om en led. Det innebär att man tänker på leden eller att uppmärksamheten riktas mot den. Följande frågor gäller **hur ofta du är medveten om din berörda höftled i det dagliga livet.**

Välj det svar som passar bäst på varje fråga. **Är du medveten om din höftled …**

		Aldrig	**Nästan aldrig**	**Sällan**	**Ibland**	**För det mesta**
1.	… i sängen på natten?	O	O	O	O	O
2.	… när du sitter på en stol i över en timme?	O	O	O	O	O
3.	… när du går mer än 15 minuter?	O	O	O	O	O
4.	… när du badar/duschar?	O	O	O	O	O
5.	… när du åker bil?	O	O	O	O	O
6.	… när du går uppför en trappa?	O	O	O	O	O
7.	… när du går på ojämn mark?	O	O	O	O	O
8.	… när du reser dig upp från en låg sittande ställning?	O	O	O	O	O
9.	... när du står länge?	O	O	O	O	O
10.	… när du utför hushålls- eller trädgårdsarbete?	O	O	O	O	O
11.	… när du tar en promenad eller vandrar?	O	O	O	O	O
12.	… när du utövar din favoritsport?	O	O	O	O	O

Appendix 2

Höftscore (Oxford Hip Score)

Personnummer……

Namn……..

Frågorna avser eventuella problem som Du haft med din höft under de senaste 4 veckorna

1. Under de senaste 4 veckorna…

Hur vill du beskriva smärtan som du vanligtvis haft från din höft?

Ingen	Mycket lindrig	Lindrig	Måttlig	Svår
☐	☐	☐	☐	☐

2. Under de senaste 4 veckorna…

Har du haft några problem med att tvätta och torka dig själv (hela kroppen) **på grund av din höft**?

Inga problem	Mycket lindriga problem	Måttliga problem	Stora svårigheter	Omöjligt alls att utföra
☐	☐	☐	☐	☐

3. Under de senaste 4 veckorna…

Har du haft problem med att ta dig i och ur en bil eller haft problem att använda kollektivtrafik (det du brukar använda) **på grund av din höft**?

Inga problem	Mycket lindriga problem	Måttliga problem	Stora svårigheter	Omöjligt alls att utföra
☐	☐	☐	☐	☐

4. Under de senaste 4 veckorna…

Har du kunnat ta på dig strumpor, strumpbyxor eller ”tights”?

Ja med lätthet	Med viss svårighet	Med måttlig svårighet	Med stor svårighet	Nej, omöjligt
☐	☐	☐	☐	☐

5. Under de senaste 4 veckorna…

Har du kunnat handla till hushållet på egen hand?

Ja med lätthet	Med viss svårighet	Med måttlig svårighet	Med stor svårighet	Nej, omöjligt
☐	☐	☐	☐	☐

6. Under de senaste 4 veckorna…

Hur länge har du kunnat gå innan smärtan från höften blivit svår? (med eller utan krycka)

Ingen smärta Mer än 30 min	16-30 min	5-15 min	Endast inomhus	Inte alls, svår smärta vid gång
☐	☐	☐	☐	☐

7. Under de senaste 4 veckorna…

Har du klarat av att gå uppför en trappa?

Ja med lätthet	Med viss svårighet	Med måttlig svårighet	Med stor svårighet	Nej, omöjligt
☐	☐	☐	☐	☐

8. Under de senaste 4 veckorna…

Hur smärtsamt har det varit för dig att resa sig upp från en stol efter sittande måltid **på grund av din höft?**

Inte smärtsamt alls	Lite smärtsamt	Måttligt smärtsamt	Mycket smärtsamt	Outhärdligt
☐	☐	☐	☐	☐

9. Under de senaste 4 veckorna…

Har du haltat när du gått **på grund av din höft**?

Sällan/ aldrig	Ibland eller bara i början	Ofta, inte bara i början	Oftast	Alltid
☐	☐	☐	☐	☐

10. Under de senaste 4 veckorna…

Har du haft någon plötslig svår smärta – ”snabbt utstrålande”, ”huggande” eller ”krampartad” från **den påverkade höften**?

Inte alls	Bara 1-2 dagar	Några dagar	De flesta dagar	Varje dag
☐	☐	☐	☐	☐

11. Under de senaste 4 veckorna…

Hur mycket har **smärtan från din höft** stört dig i ditt vanliga arbete (inklusive hushållsarbete)?

Inte alls	Lite grann	Måttligt	I hög grad	Ständigt
☐	☐	☐	☐	☐

12. Under de senaste 4 veckorna…

Har **smärtan i din höft** varit ett problem för dig nattetid då du legat i sängen?

Inte alls	Bara 1-2 nätter	Några nätter	De flesta nätter	Varje natt
☐	☐	☐	☐	☐

Kryssa under varje rubrik i EN ruta som du tycker bäst beskriver hälsan för *(fyll i namnet på den person det gäller, t.ex. Herr Svensson eller Maria)* IDAG.

RÖRLIGHET

Inga svårigheter att gå omkring ❑
Lite svårigheter att gå omkring ❑
Måttliga svårigheter att gå omkring ❑
Stora svårigheter att gå omkring ❑
Kan inte gå omkring ❑

PERSONLIG VÅRD

Inga svårigheter att tvätta sig eller klä sig ❑
Lite svårigheter att tvätta sig eller klä sig ❑
Måttliga svårigheter att tvätta sig eller klä sig ❑
Stora svårigheter att tvätta sig eller klä sig ❑
Kan inte tvätta sig eller klä sig ❑

VANLIGA AKTIVITETER *(t ex arbete, studier, hushållssysslor, familje- eller fritidsaktiviteter)*

Inga svårigheter att utföra sina vanliga aktiviteter ❑
Lite svårigheter att utföra sina vanliga aktiviteter ❑
Måttliga svårigheter att utföra sina vanliga aktiviteter ❑
Stora svårigheter att utföra sina vanliga aktiviteter ❑
Kan inte utföra sina vanliga aktiviteter ❑

SMÄRTOR / BESVÄR

Inga smärtor eller besvär ❑
Lite smärtor eller besvär ❑
Måttliga smärtor eller besvär ❑
Svåra smärtor eller besvär ❑
Extrema smärtor eller besvär ❑

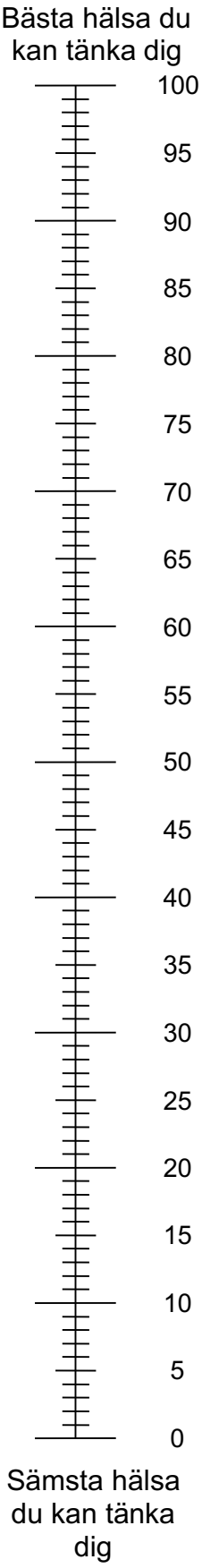
ORO / NEDSTÄMDHET

Är varken orolig eller nedstämd ❑
Är lite orolig eller nedstämd ❑
Är ganska orolig eller nedstämd ❑
Är mycket orolig eller nedstämd ❑
Är extremt orolig eller nedstämd ❑

VAS 100

- Vi vill veta hur bra eller dålig du anser att *(fyll i namnet på den person vars hälsa bedöms, t.ex. Herr Svenssons eller Marias)* hälsa är IDAG.
- Den här skalan är numrerad från 0 till 100.
- 100 är den bästa hälsa du kan tänka dig.
  0 är den sämsta hälsa du kan tänka dig.
- Markera med ett X på skalan för att visa hur bra eller dålig du tycker att *(fyll i namnet på den person vars hälsa bedöms, t.e.x. Herr Svenssons eller Marias)* hälsa är IDAG.
- Skriv nu i rutan nedan det nummer du har markerat på skalan.

PERSONENS HÄLSA IDAG ☐



Appendix 4

Du tillfrågas härmed om deltagande i en enkätstudie rörande utvärdering av ett nytt formulär som avser att mäta upplevd livskvalitet efter höftprotesoperation.

Bästa patient!

Vi avser att genomföra en enkätstudie för att jämföra tre formulär som bland annat mäter livskvalitet och funktion efter höftledsoperation. Syftet är att undersöka hur väl olika frågeformulär speglar olika personers livskvalitet och höftledsfunktion samt eventuella kvarvarande smärtor efter operationen. För att i framtiden kunna bedöma om till exempel en ny typ av protes eller operationsteknik ger önskat resultat är det viktigt att resultatet efter operationen bedöms så korrekt och rättvisande som möjligt. Ett sätt att bedöma om formulären är tillräckligt lätta att förstå och frågorna är korrekt ställda är att upprepa förfrågan med en tids mellanrum. Ett av formulären kommer därför att skickas ut två gånger för att svaren ska kunna jämföras med varandra. Observera att formulären är dubbelsidiga.

Orsaken till att Du tillfrågas är att Du under 2015 opererats med en höftprotes för första gången. Vi har valt detta år för att uppföljningstiden för de patienter som valts ut för denna undersökning skall vara mellan 1 och 3 år.
Den operation som avses genomfördes ……../…… 2015.

Vad är riskerna?
Studien innebär inte några specifika risker.

Finns det några fördelar?
Avsikten är att resultaten av denna undersökning skall underlätta framtida undersökningar med avseende på en bättre och mer nyanserad utvärdering av resultaten efter höftprotesoperation.

Hantering av data och sekretess
Dina uppgifter kommer att hanteras enligt personuppgiftslagen (1998:204) och dina data kommer att lagras genom kodning, där kodnyckel kommer att förvaras separat. Samtliga inlämnade uppgifter inklusive kodnycklar kommer att förvaras på servrar inom Sahlgrenska sjukhuset i lösenordskyddade program. Ingen obehörig har tillgång till data. Insamlade data lagras i sekretesskyddade databaser och kommer att sparas i åtminstone 15 år. Vissa uppgifter är även journalhandlingar, som också skyddas av sekretess. Personuppgiftsombud vid Sahlgrenska Universitetssjukhuset är Susan Lindahl, Kansli och juridik, Sahlgrenska Universitetssjukhuset, Röda stråket 8, plan 1, 413 45 Göteborg. Personuppgiftsansvarig är Utförarstyrelsen för Sahlgrenska Universitetssjukhuset.

Hur får jag information om studiens resultat?
Studien planeras pågå under ett halvår. Resultaten av Dina egna undersökningar lämnas ut på begäran. Resultatet av hela studien kommer att redovisas i form av en uppsats (examensarbete vid läkarutbildningen) och senare eventuellt skickas till vetenskaplig tidskrift, utan möjlighet att spåra enskilda patienter.

Försäkring, ersättning
Du omfattas av patientförsäkringen. Det utgår ingen ersättning om Du bestämmer Dig för att delta i studien.

Frivillighet
Vi vill med detta brev fråga om Din medverkan. Om Du väljer att medverka fyller Du i de tre formulär (Forgotten Joint Score, Oxford Hip Score och EQ-5D) som medföljer och skriver på dokumentet om samtycke. Samtliga formulär inklusive samtycke återsänds i medföljande kuvert. Din medverkan kommer att vara av värde för att vi på ett så korrekt sätt som möjligt skall kunna utvärdera resultatet efter höftprotesoperation.

Ditt namn eller andra uppgifter som kan identifiera Dig kommer **inte** att finnas med i studien. Medverkan är helt frivillig och Du kan närsomhelst avbryta Din medverkan utan att ge något skäl och utan att Din framtida vård påverkas på något sätt.

Ansvariga kontaktpersoner:
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Britt-Marie Efraimsson (Sekreterare) tel: 031-XXXXXX

Med Vänlig Hälsning

Amanda Larsson

_____

Jag godkänner härmed medverkan i denna enkätstudie

_____

Underskrift

_____

Namnförtydligande