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ORIGINAL STUDY

Only limited correlations between patient-reported outcomes and objectively monitored physical activity 10-years after THA

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In orthopaedics, patient reported outcomes (PROMs) are designed to quantify changes in pain and to assess physical function, most often after joint arthroplasty. However, PROMs have some disadvantages, most important is their subjective nature. The aim was to investigate how patient-self-reported-outcomes of general health, disease-specific outcome and physical function, joint-awareness and self-perceived activity-levels are correlated with objectively-measured physical-activity (PA) parameters derived from wearable activity-monitors (AM) in subjects with a hip-arthroplasty. A prospective cohort study was conducted in a group of 32 patients, with a mean follow-up of 10 years after total hip arthroplasty. To assess different domains, the SF-36 (general health), HOOS-PS (pain/functional outcome), FJS-12 (joint awareness) and SQUASH (physical activity) were chosen. Activity-monitoring was performed using a 3-axis accelerometer, gyroscope and magnetometer. No significant correlations between PA-parameters and the FJS-12 and SQUASH were found. The HOOS-PS was significant correlated with BMI, the daily time walking and total-time active and the amount of daily steps. The physical functioning-subscale of the SF-36 was significant negative correlated with BMI and time sitting, but significant positive correlated with time walking, total-time active and the amount of daily steps. Considering the value of PA for maintaining general health, the value of using sensor-based AMs to assess efficacy of treatments in this health related dimension or use it as a tool for patient education, awareness and communication, seems very high.

Keywords: hip arthroplasty; patient reported outcomes (PROMs); physical activity; physical activity monitoring; wearables.

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INTRODUCTION

Physical activity (PA) is recognised as an important factor for health benefits. The World Health Organization (WHO) has developed public health-oriented PA guidelines because physical inactivity is a risk factor for chronic diseases and premature mortality *(1)*. To quantify PA, multiple techniques are used that can be divided into direct methods (e.g. accerelometers) and indirect methods including questionnaires retrospectively collecting patient perceptions of an outcome dimension *(2)*. Patient Reported Outcome Measures (PROMs) are used to quantify a disease state or interventional outcome as perceived by the patient, potentially improving care *(3)*. PROMs are available to measure pain, satisfaction, psychological dimensions such as kinesophobia or awareness and also PA. In orthopaedics, PROMs are designed to quantify changes in pain and to assess physical function (PF), most often after joint arthroplasty *(4,5)*. The International Society of Arthroplasty Registries (ISAR) stated that PROMs are the best objective tool currently available to evaluate patient-centered outcomes *(6)*. While commonly used, PROMs can suffer from their subjective nature, recall bias, ceiling effects, time consuming methodology, low response and completion rate or transcription errors *(7-10)*.

Objective function can be assessed by performance tests such as the 'Timed-Up and Go-test (TUG)' or gait analysis in a biomechanic laboratory, but also by activity monitoring in daily life capturing PA behaviour (e.g. number of steps) and qualitative aspects of PA (e.g. steps per minute). Self-reported PF and objectively measured function after total hip (THA) or knee arthroplasty (TKA) are increasingly reported in the literature before and at various time points after surgery, but also shows the limitations of PROMs *(11)*. Within the first 3-weeks after THA or TKA patients report improved PF (HOOS & KOOS), but this was not correlated with objectively assessed PF (paced-walk, chairstand, stair-climb tests) *(12)*. Also, at 4-months follow-up self-reported PF (HOOS & KOOS) improved significantly whereas performance-based function (30-second chair stand-test) improved only slightly *(13)*. HOOS scores one year after THA were not in line with objectively measured improvements in performance-based function and gait *(14)*.

Wearable activity-monitors (AMs) are able to differentiate between different PA types in the free living environment (e.g. stand, walk, sit). The major purpose and patient expectation of THA is the reduction in pain and restoration of function. It is unknown if and how PROMs after THA reflect levels or qualitative aspects of PA in daily life as captured with wearable AMs. The aim of this study was to investigate how PROMs of various dimensions, general health, disease specific outcome and in particular PF, joint awareness and self-perceived activity levels are correlated with objectively measured PA parameters derived from wearable AMs in subjects with a hip arthroplasty.

MATERIALS AND METHODS

A prospective cohort study was conducted between August 2017 and June 2018. First, patients with a primary unilateral hip resurfacing arthroplasty (HRA) at 10 ± 1 years were included. A total of 40 patients were eligible, but 24 were excluded, among them 9 revisions and 8 declines in follow-up/research. The other group of patients received an unilateral stemmed THA with a small diameter femoral head (28mm) on conventional polyethyelene with osteoarthritis as indication for surgery. This group was matched with the HRA-group for sex, age at surgery, follow-up since surgery (8-12 years) and BMI. The groups were initially included for another study, the methods of which are described in detail elsewhere *(15)*. For the current study all data were merged. This study was conducted in accordance with the Good Clinical Practice (GCP)-guidelines and performed in compliance with the 1975 Declaration of Helsinki, as revised in 2013. The study was approved by the IRB (METC-Z, Heerlen, The Netherlands, IRB: 10N72 + amendment). All included patients signed informed consent.

Activity monitoring was performed and PROMs were collected at one moment in follow-up, close to 10-years follow-up (8-12 years). A 3-axis accelerometer, gyroscope and magnetometer (HAM-IMU+

alt, Gulf Coast Data Concepts LLC, Waveland Missipi, United States) was used. The AM was applied on the lateral side of the affected upper-leg using skin-friendly tape. Patient's habitual PA patterns can be representatively characterized by measuring activity for 3-4 days *(16,17)*. PA was measured during waking hours for four consecutive days in daily living with a minimum of 8h per day. The raw signal received with this AM was analysed using published algorithms in MATLAB (MATLAB R2017a, The Mathworks Inc., Natick, Massachusetts, United States). This approach has been previously described and validated in a semi-free setting and achieved an excellent accuracy (>97%) in determining PA levels in healthy subjects and subjects after unilateral total joint arthroplasty *(18,19)*.

The PROMs used in the current study were chosen to assess different domains and thus to study their respective correlation with objective levels and qualitative aspects of PA: general health (SF-36), pain and functional outcome (HOOS-PS), joint awareness and satisfaction (FJS-12) and physical activity (SQUASH). The 36-item short-form (SF-36) was constructed to survey health status and designed to use in clinical practice and research. It includes eight health concepts: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health. For all subscales 100 is the best score and 0 the least. Only the subscale physical functioning (PF) was used *(20)*. The disability and Osteoarthritis Outcome Score - Physical Function Short Form (HOOS-PS) is a validated measure of physical function. The score ranges from extreme difficulties (0) to no difficulties (100) in physical function *(21,22)*. The 12-item Forgotten Joint Score (FJS-12) was designed to evaluate the patients' ability to forget about a joint as a result of a successful treatment. It consists of 12 questions about awareness of an artificial joint with five answer possibilities ranging from never to mostly. The FJS-12 is validated and was shown to have a high internal consistency and a low ceiling effect *(23)*. The score ranges from 0 (worst) to 100 (best). The Short Questionnaire to Assess Health-enhancing physical activity (SQUASH) is a questionnaire to measure PA. The domain scores were calculated by multiplying the number of minutes per week with an intensity score (range 1-9) which is based on the reported intensity combined with the classification according to Ainsworth's Compendium of Physical Activities *(24,25)*. The sum of the scores per domain is the total activity score, which was used for this study. In order to reach sufficient content validity, van Poppel et al. recommended that at least duration and frequency should be determined by a questionnaire assessing total PA and should also cover PA in all settings during daily life *(26)*. This is in accordance with the FITT components established by the WHO (frequency, intensity, type and time). In light of this recommendation, the SQUASH was the only questionnaire in the current study to specifically assess PA and able to determine if patients meet recommendations for PA *(27)*. No funding was obtained.

Parameters of PA and results of the PROMs were averaged for the whole cohort and reported as mean ± standard deviation (SD) [range] or with numbers and proportions (%). Pearson's correlation coefficient (r) was computed to quantify the correlation between parameters of PA and results of PROMs. Correlations of 0.20-0.39 were considered 'weak', 0.40-0.59 'moderate' and 0.60-0.79 'strong' *(28)*. No multivariate analyses was performed because the goal was to show the degree of linear relationship between two continuous measures (e.g. PROMs and PA). For all analyses, a p-value was considered to be statistically significant at $P \leq 0.05$. IBM SPSS Statistics 22 (International Business Machines Corporation, Armonk, New York, United States) was used for statistical analysis.

RESULTS

A total of 32 subjects with 32 hip arthroplasties were included. Baseline characteristics (e.g. BMI, age) and follow-up time are summarized in Table 1. The results of the PROMs and parameters of PA monitoring, all showing large value ranges, are shown in Table 2 and 3. Correlation coefficients were computed for PROMs with baseline characteristics and PA parameters. No significant correlations were found for the FJS-12. The HOOS-

Table 1. — Baseline Characteristics

Sex	24 M (75%) - 8 F (25%)
Age at Surgery (years)	57.8 ± 5.7 [43.0-68.0]
Follow-Up (years)	9.9 ± 0.9 [8.5-11.8]
BMI (Kg/M²)	28.2 ± 4.9 [20.4-39.8]

Table 2. — Results of PROMs

SF-36 PF (n=32)	70 ± 22 [25-100]
HOOS-PS (n=25)	77 ± 19 [49-100]
FJS-12 (n=31)	56 ± 31 [2-100]
SQUASH (n=29)	5744 ± 4103 [1050-18480]

Table 3. —Parameters of Physical Activity Monitoring

AM wearing days	3.6 ± 0.7 [2-4]
Total measured time (hours)	13.1 ± 1.8 [10.5-16.2]
Time sitting (hours)	8.4 ± 2.2 [3.8-12.7]
Time standing (hours)	3.3 ± 1.3 [1.6-6.2]
Time walking (hours)	1.2 ± 0.5 [0.4-2.2]
Time cycling (hours)	0.2 ± 0.3 [0.0-1.2]
Total time active (%)	10.4 ± 4.4 [3.4-20.0]
Sit-Stand Transfers (number)	40 ± 13 [21-74]
Steps (number)	5434 ± 2566 [1567-11749]
Cadence (steps/min)	98 ± 10 [80-112]
Intensity Peaks <2.0g (number)	27135 ± 20741 [2442-85974]
Intensity Peaks >2.0g (number)	886 ± 1670 [0-8097]

*Daily values except AM wearing days and cadence

PS was statistically significant correlated with BMI (negative correlation), the daily time walking, the daily total time active and the amount of daily steps. The SQUASH was only statistically significant negative correlated with the age at surgery, but not with any of the objectively measured PA parameters. The PF-subscale of the SF-36 was statistically significant negative correlated with BMI and the time sitting, but statistically significant positive correlated with the time walking, the total time active and the amount of daily steps (Table 4).

DISCUSSION

The aim of this study was to investigate the correlation between PROMs of different outcome dimensions and objectively measured PA in daily life with the use of a wearable AM in subjects 10-years after unilateral hip arthroplasty. The main finding of this study was that objectively measured PA levels (time walking, total time active, amount of steps) does not show a correlation with the FJS-12 and SQUASH, but does show a significant correlation with the HOOS-PS and PF-subscale of the SF-36 for which also sedentary time was correlated, though negatively as can be expected. The correlations found however were of moderate strength.

Table 4. —Pearson's R correlation

	HOOS-PS	SQUASH	FJS-12	SF-36 PF
Age at surgery	-.031	**-.592****	.226	-.310
BMI	**-.590****	-.041	-.358	**-.537****
Time sitting	-.395	-.208	-.034	**-.407***
Time standing	.267	.211	.021	.327
Time walking	**.498***	.273	.260	**.500****
Time cycling	-.042	-.006	.030	.144
Total time active	**.447***	.247	.229	**.524****
Sit-Stand Transfers	-.065	-.333	.063	-.081
Steps	**.408***	.199	.209	**.445***
Cadence	.172	.198	.134	.345
Intensity Peaks <2.0g	.149	-.050	.228	.165
Intensity Peaks >2.0g	.142	-.031	.265	.118

* Correlation is significant at the 0.05 level (2-tailed). ** Correlation is significant at the 0.01 level (2-tailed)

The SQUASH is a patient self-report of PA levels and thus is supposed to directly and most closely capture the dimensions assessed by the sensor-based PA. However, even for the same construct, the current study could not identify a correlation. Previous studies in orthopaedic populations investigating a correlation between the SQASH and objective PA measures from accelerometry could find some, mostly weak correlations. Patients after THA with unknown follow-up worn the ActiGraph accelerometer on a belt on the waist during a two-week period. Outcome, expressed in counts (the sum of accelerations measured during a time interval), was statistically significant correlated ($r_{spearman}$ 0.67, p = 0.01) with the total activity score of the SQUASH *(29)*. This was higher than found in the study by Wendel-Vos et al. who reported a Spearman correlation coefficient of 0.45 in healthy adults with the use of the Computer Science and Applications (CSA) Activity Monitor *(24)*. The ActiGraph generation used in these studies was an uniaxial accelerometer which is relative insensitive to PA that requires little vertical movements like cycling. In these studies, PA was not classified in activities but summarized in an intensity count related overall metric. The AM used in the current study does not have this limitation. Terwee et al. stated that a questionnaire assessing PA should be correlated to an accelerometer by at least 0.50 *(30)*. Unexpected, no correlations were found between the SQUASH and the time walked and total time active, not achieving the 0.50 limit stated by Terwee et al.

Analysis of AM parameters showed that the total time active, time walked and number of steps were all statistically significant positive correlated with the HOOS-PS. The HOOS-PS reports for PA during daily life, though not reporting for duration and frequency of PA as recommended by van Poppel et al., but by registering the prevalence and level of difficulties experienced during specific activities of daily life *(26)*. Apparently such difficulties experienced during descending stairs, getting in/out bath or shower, sitting, running and twisting/pivoting on a loaded leg are more closely related with the ability of being active in daily life as represented by the total time active, time walked and number of steps performed. Nevertheless, the correlation is only moderate, which means that general and health related PA levels such as walking, daily steps taken and non-sedentary time are and can be achieved in THA patients with or without such self-reported difficulties. The investigation of such discrepancies may reveal valuable insights into THA patient outcomes and potential interventions beyond orthopaedics.

This study is the first in current literature correlating the FJS-12 with objectively measured PA. No correlations were found. The FJS-12 was designed to evaluate the patients‘ ability to forget about their operated joint in everyday life as a result of a successful arthroplasty. Subjects are asked for the awareness of an artificial joint during twelve different activities including physically demanding activities such as walking for more than 15 minutes, climbing stairs and when doing their favourite sport. In theory a high score and thus often forgotten joint during various activities shall facilitate and lead to higher and more intense PA in daily live. Subanalysis on the different questions were not performed, because the goal was to correlate the complete questionnaire with the objectively measured PA. The mean FJS-12 in the current study was low. Rosinsky et al. stated a threshold for success after THA with FJS-12 scores of 73.96 and 69.79 at 1- and 2-years follow-up respectively *(31)*. The current study reported the FJS-12 at almost 10-years follow-up and was highly influenced by three subjects with scores <5. In addition, a recent longitudinal study in TKA with a mean follow-up of 8.1 years (range 7.3-9.4) showed that PROMs and objective outcome measures drop over time *(32)*. Correlation testing also showed no statistically significant correlation between the FJS-12 and the SQUASH ($r_{pearson}$ .099, p = .616). It seems that daily life PA is not influenced by the degree of forgetting to have a hip replacement, both in self-report and objectively measured, but is influenced by other factors.

The present study does have limitations. At first, the SQUASH (91%) and FJS-12 (97%) were completed by a sufficient amount of subjects. However the analysis of the HOOS-PS was limited by a lower response and completion rate of 25 (78%)

subjects submitting fully completed questionnaires, which seems more a limitation of the PROM itself. The 'running-difficulties' question was the main question not completed. Presumably because these subjects never tried to run and thus were not able to answer how much difficulties they experienced during running. Although one may think that 'extreme difficulties' is the appropriate answer for these subjects, the HOOS-PS requires five answers to calculate a total score. In comparison, in the current study the AM was worn for the appropriate 3 or 4 days by 88% of the subjects for a mean 13.1 ± 1.8 hours per day and all data were available for analysis. PROMs remain inherently subjective, prone to an individual's interpretation and perception of joint functioning. Patients can have difficulties in keeping other negative conditions or illnesses out of consideration that might have impaired mobility, general condition or quality of life. The used PROMs don't take in to account for negative conditions or illnesses *(33)*. The fact that subjectively reported PA levels and objectively measured PA levels do not correlate may hint at the fact, that it is inherently difficult to recall in detail PA durations and frequencies without bias questioning this approach for individual or group outcome studies but limiting it maybe to large population based research where sensor-based assessment is not yet possible. A combination of PROMs and AM displays a patient's perception on physical functioning and the practitioner/researchers view on objectively determined PA of THA patients.

CONCLUSION

In conclusion, this study shows that PROMs are hardly affected by or do hardly capture levels and differences in objectively measured PA, a supposedly patient centred outcome and a goal of THA. Considering the value of PA for maintaining general health, and the restoration of PA via surgery such as THA, the value of using sensor based AMs to assess efficacy of treatments in this health related dimension or use it as a tool for patient education, awareness and communication, seems very high. Future studies should focus on the changes in health status as measured by PROMs and the correlation with objectively measured PA, for example pre and post total joint arthroplasty.

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