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ORIGINAL STUDY

Adjustments in 2011 KSS increase the clinical suitability

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The 2011 KSS is a valid clinical TKA questionnaire, but with a low completion rate (42%). Adjustments, focusing on optimizing scale features, are required to improve its clinical use. The low completion rates, non-optimal scale features, lacking rules or a combination of these factors where addressed, leading to the development of the adjusted 2011 KSS (2011 KSS-A). Four-hundred-ninety-nine primary TKA patients were addressed pre- and postoperative by mail. Clinimetric quality was evaluated. Seventy percent responded and 90% completed the scale. Internal consistency proved excellent with Cronbach's Alpha ≥ 0.79 for all subscales. Strong correlations were found between the Functional Activity subscales and KOOS-PS (r = -0.63 to -0.87). All subscales improved significantly after intervention (r-range 14-33%, effect size 0.50-2.85). Postoperatively, ceiling effects were found in the subscales Symptoms (16%) and Walking & Standing (26%). Adjustments led to a shortened and simplified questionnaire while maintaining its clinimetric quality.

Keywords : Patient-reported outcome measure ; 2011 knee society score ; functional outcome ; adjustments.

INTRODUCTION

Recently, the 2011 Knee Society Scoring System (KSS) has been developed and promoted by The Knee Society in order to better monitor the outcome of the younger and more demanding total knee arthoplasty (TKA) patients (*12,19*). The 2011 KSS is an adjusted version of the 1989 KSS which has been the most popular method of reporting outcomes after TKA worldwide (*3,9,11,12,19*). The 2011 KSS consists of 34 questions and assesses four different domains including the Objective Knee Score (e.g. pain and range of knee motion), Satisfaction, Expectation and Functional Activity, which is subdivided in four subscales of Walking & Standing, Standard Activities, Advanced Activities and Discretionary Activities (*5,12,19,24*).

The clinimetric quality of the 2011 KSS has recently been evaluated by Dinjens *et al* (2014) in a large group of Dutch TKA patients. This study showed that the 2011 KSS is a reliable (intraclass correlation coefficients ≥ 0.79), internal consistent (Cronbach's Alpha ≥ 0.76), construct valid (high correlations (r-range -0.74 to -0.83) with other questionnaires) and responsive (effect sizes 0.57-2.17)

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questionnaire (*5*). Similar results were found by Van Der Straeten *et al* (2013). Besides the high clinimetric quality, Dinjens *et al* (2014) reported high response rates (96%). However more than 50% of the returned questionnaires could not be scored due to incompleteness (30%) and limitations of the questionnaire (e.g. missing rules for calculating scores, answer options not related to a score (32%)), which makes the 2011 KSS less usable for patient evaluations (*5*). This is in contrast to other patient reported outcome measures (PROMs) such as the Knee injury and Osteoarthritis Outcome Score - Physical Function (KOOS), KOOS-Short Form (KOOS-PS) and the Western Ontario McMaster University Osteoarthritis Index (WOMAC), which showed completion rates of 75% and higher (*5,10,14*). Thus although the 2011 KSS is of high clinimetric quality, adjustments in the questionnaire are required, focusing on optimizing scale features and increasing completion rates, in order to make the 2011 KSS feasible for clinical use.

Several limitations of 2011 KSS were proposed by Dinjens *et al* (2014) which caused that the 2011 KSS could not be scored ; a lacking "not applicable" option resulting in unanswered questions, answer options without a related score and the complexity of the layout (especially for the subscale Functional Activity-Discretionary Activity. In addition, the questionnaire is extensive (34 questions), including redundant and irrelevant questions (*25*). This makes the 2011 KSS time consuming (10-30 min.), which may contribute to the low completion rate (*5*). Adjusting the 2011 KSS by dealing with these factors may increase the clinical suitability of the 2011 KSS.

This study aimed to optimize the clinical suitability of the 2011 KSS by adapting the limitations of the 2011 KSS causing the high rate of unusable questionnaires. This led to the adjusted 2011 KSS (2011 KSS-A). The clinimetric quality (e.g. the practice of assessing or describing symptoms and signs by means of scales, indices and other quantitative instruments) of the 2011 KSS-A is then investigated in a large group of TKA patients. For this purpose, the response- and completion rate, the internal consistency, construct validity and responsiveness of the 2011 KSS-A are evaluated.

METHODS

The adjusted 2011 KSS (2011 KSS-A)

Fifty-seven percent (227 of 398) of the returned 2011 KSS questionnaires could not be scored in the study of Dinjens *et al* (2014) due to low completion rates, non-optimal scale features, lacking rules or a combination of these factors. Dinjens *et al* (2014) reported that with 21%, 38% and 32% respectively the subscales Standard Activities, Advanced Activities and Discretionary Activities showed most problems when completing the scale. The lacking answers could be due to too demanding activities, too many questions, the missing answer option 'I never do this' and for the Discretionary Activity subscale the complex lay out. The Discretionary Activity subscale first demands to select three discretional activities which are of most importance for the patient and subsequently to rank it. The 2011 KSS-A has dealt with these aspects aiming at improving the completion rate : A "not applicable/I never do this" answer option, which is associated with the worst possible score (zero), is added in the (sub)scales Satisfaction, Standard Activities and Advanced Activities of the 2011 KSS-A. In addition, the Discretionary Activity subscale has been replaced by one question concerning hobbies, which is added to the subscale Advanced Activities. This can be justified as hobbies reflect activities which are of importance for individuals. To reduce the length of the questionnaire, irrelevant questions which are not part of the (sub)score calculation (e.g. Can you walk without any aids ?) are removed in the 2011 KSS-A. Moreover, questions which are considered less important for TKA patients as shown by Weiss *et al* (2002), (e.g. "turning your knee", "getting in and out of a car") were replaced by three questions which are successfully used in the KOOS-PS and considered important as daily activities for TKA patients ("putting on or off your socks/shoes", "bending or grabbing something from the floor" and "domestic activities") (*1,4,15*).

The lack of a rule for calculating a score based on one or two missing answers and the fact that 32% of the questions in the 2011 KSS have an answer option 'I never do this' which has no related score (non-optimal scale feature), caused that 32% of the 2011 KSS (sub)scores could not be calculated in the study of Dinjens *et al* (2014). Additional analysis showed that the percentage of usable scales increased to 72% by introducing the "1998 rule for missing answers advised for the KOOS" (www.koos.nu) and by linking the answer option "I never do this" with the worst score (zero). Due to these promising results, the

2011 KSS-A includes a rule for missing answers which is conform the KOOS rule, stating that the average of the completed questions within a specific subscale needs to be used when one question is missing in a three item subscale or when two or less questions are missing in a subscale consisting of more than 3 items. In addition in the 2011 KSS-A all answer options 'I never do this' are associated with the worst possible score.

Finally the pain-related questions "Pain with level walking" and "Pain with stairs or inclines", which are originally part of the subscale Objective Knee Score completed by a clinician, are distracted from this scale as they are PROM related. These two questions are re-integrated as a PROM scale called "Symptoms". To strengthen this new scale, an additional question is added : "How often do you experience pain in your knee" (answer options : "never" (5 points), "sometimes" (4 points), "weekly" (3 points), "daily" (2 points) or "always" (1 point)).

Based on these adjustments, the 2011 KSS-A was developed, consisting of five clinician-administered questions (subscale Objective Knee Score, not further evaluated in this study because it is similar to the 1989 and 2011 KSS) and 20 PROM-questions, divided into the scales Symptoms (three items ; 25 points), Satisfaction (four items ; 32 points), Expectation (two items ; 10 points) and Functional Activity (11 items ; 70 points) (Fig. 1). The Functional Activity subscale is further divided into Standing & Walking (three items ; 30 points), Standard (four items ; 20 points) and Advanced Activities (four items ; 20 points)). To improve the interpretation and the comparability of the KSS 2011-A, the (sub) scales are reported as percentages, ranging from 0% (worst) to 100% (excellent). Comparable to the 2011 KSS, the 2011 KSS-A consists of a pre- and postoperative version, which only differs in the formulation of questions in the subscale Expectation.

Patients & Questionnaires

A total of 494 primary TKA patients (avg. 69 ± 9 years, 284♀:210♂, 33 pre and 461 postoperative with a follow-up of six weeks to > 5 years)) were approached by mail. Every patient, independent of their follow-up time, received an envelop containing an explanatory letter, the 2011 KSS-A and the KOOS-PS including a stamped returning envelop with a pre-printed address of the out-patient clinic. All patients were asked once to complete both outcome scales and to return it by mail. Patients who underwent a hemi-knee prosthesis or revision surgery were excluded. All scores were collected six weeks after they were sent.

Knee injury and Osteoarthritis Outcome Score - Physical Function Short Form (KOOS-PS)

The KOOS-PS is a short version of the long-form KOOS and consists of seven questions (*15*). It assesses people's opinions about inconveniences experienced during daily activities due to problems with their knee and has proven to be cross culturally valid (*1,4,13,17*). All items (e.g. rising from bed, putting on socks/stockings, rising from sitting, bending to floor, twisting/pivoting on your injured knee, kneeling and squatting) are rated from 0 to 4 points, with 0 representing no complaints (Perruccio *et al* 2008). The KOOS-PS is calculated by summing the raw response (range 0-28) and using a nomogram were the raw score is converted to a true interval score from 0 (no difficulty) to 100 (extreme difficulty) (*15*).

Statistical analysis

Response and completion rate

The response rate was calculated as the amount of questionnaires (% of send questionnaires) that were returned to the outpatient clinic. From the returned questionnaires, the completion rate was calculated, defined as the number of patients who completely filled in the questionnaire. Only completely filled in questionnaires were included for the analysis.

Internal consistency

To investigate the homogeneity of the items in the (sub)scale, internal consistency was measured using Cronbach's Alpha, with Alpha > 0.70 indicating good homogeneity (*18,21,22*).

Construct validity

A subgroup of 266 postoperative TKA patients (follow-up 6 weeks to > 5 years, avg. 70 ± 9 years, 145♀:121♂) was used to investigate correlations between the subscale Functional activity of the 2011 KSS-A score and the KOOS-PS (16, 18, 22). Evaluation of the construct validity was examined by using Pearson's correlations, with $r \geq 0.70$ indicating a strong correlation and $r < 0.50$ a low correlation (*21*).

More correlations between (sub)scales were investigated, like the correlations between the subscale Symptoms and KOOS-PS and patient satisfaction and function as measured by the 2011 KSS-A and KOOS-PS.

Symptoms subscale (25 points)
1. Pain when walking on a even underground ? (10 points = severe pain)
2. Pain during intensive activities (e.g. climbing stairs, cycling, sports etc.) ? (10 points)

Answer options : 1-10

3. How often do you experience pain in your knee ? (5 points = never)
4. Answer options : always, daily, weekly, sometimes, never

Satisfaction subscale (32 points)

How satisfied are you with the pain level of your knee while...

1. sitting ? (8 points = very satisfied)
2. lying in bed ? (8 points)
3. getting out of bed ? (8 points)
4. performing light household duties ? (8 points)

Answer options : not applicable, very dissatisfied, dissatisfied, neutral, satisfied, very satisfied

Expectation subscale (10 points)

My expectations for...

1. pain relief were… (5 points = yes a lot)
2. being able to do my normal activities of daily living were… (5 points)

Answer options : no not at all, yes a little, yes somewhat, yes moderate, yes a lot

Functional Activity subscale (70 points)

Walking & Standing (30 points)

1. Which of the following aid(s) do you use ? (-10 = wheelchair, 0 = none)

Answer options : none, brace/bandage, one cane, two canes, crutches/walker, wheelchair

2. For how long can you stand... (15 points = > 1 hour)
3. How long can you walk... (15 points = > 1 hour)
   ...(with or without aid) before stopping as a result of knee discomfort ?

Answer options : cannot stand/walk, 0-5, 6-15, 16-30, 31-60 minutes, > 1 hour

Standard Activities (20 points)

How much does your knee bother you during each of the following activities ?

1. Walking on a uneven underground (5 points = no bother)
2. Putting on or taking of socks/shoes (5 points)
3. Climbing up or down a flight of stairs (5 points)
4. Getting up from a low couch or a chair without arms (5 points)

Answer options : no bother, slight, moderate, severe, very severe, impossible, not applicable

Advanced Activities (20 points)

How much does your knee bother you during each of the following activities ?

1. Bending down or picking something up from the floor (5 points)
2. Domestic activities (5 points)
3. Hobbies (e.g. distance walking, gardening, cycling, swimming etc.) (5 points)
4. Kneeling (5 points)

Answer options : no bother, slight, moderate, severe, very severe, impossible, not applicable

Fig. 1. — Questions for the patients in the 2011 KSS-A

Responsiveness

To investigate the responsiveness, the sensitivity of the 2011 KSS-A to changes over time was evaluated. The 2011 KSS-A was completed preoperatively and 6 to 12 weeks postoperative in a subgroup of 33 TKA patients (avg. 66 ± 10 years, 15♀:18♂) (*18,22*). The paired-samples t-test and effect size (mean score change divided by the standard deviation of the preoperative score, score > 0.8 is considered large effect) was used (*16*). The responsiveness of the KOOS-PS was examined in the same population subgroup using the same statistics. In addition, for both pre and postoperative scales, floor and ceiling effects were evaluated for all subscales of the 2011 KSS-A. Floor and ceiling effects refer to specific limitations encountered in questionnaires when measuring

Table I. — Internal consistency of the 2011 KSS-A subscales, expressed by Cronbach's Alpha

2011 KSS-A subscales	Cronbach's Alpha n = 288
Symptoms	0.83
Satisfaction	0.92
Expectation	0.89
Function : Walking & Standing	0.83
Function : Standard Activities	0.87
Function : Advanced Activities	0.79

clinical outcome. A floor effect means that a patient scores at or near the minimum possible score. Ceiling effects occur when the maximum possible score is reached and no further improvement can occur. Changes in health status are an important outcome and floor and ceiling effects can influence the results. It can affect the ability of the questionnaire to detect changes over time. A ceiling and floor effect is present if > 15% of the patients achieved respectively the highest or lowest possible score (*22*).

Data were analyzed using SPSS statistical software (version 19.0). The level of significance was set at a p-value ≤ 0.05 for all statistical procedures.

RESULTS

Response and Completion rate

Seventy percent of the 2011 KSS-A and KOOS-PS were returned, of which respectively 90% and 92% was filled out completely. This resulted in 288 completed 2011 KSS-A scores which are available for analysis (avg. 70 ± 10 years, 162♀:126♂). The scale takes approximately five minutes to complete.

Internal consistency

A Cronbach's Alpha ≥ 0.83 was found for all subscales in the 2011 KSS-A with exception of the subscale Advanced activity which showed a Cronbach's Alpha of 0.79. This indicates good internal consistency of all items within one subscale (Table I). No redundancy (Cronbach's Alpha ≥ 0.95) was found between the items of a subscale.

Table II. — Construct validity of the 2011 KSS-A, expressed by Pearson's correlations between 2011 KSS-A subscales and KOOS-PS

2011 KSS-A subscales	KOOS-PS n = 139
Symptoms	-0.60*
Satisfaction	-0.68*
Expectation	-0.51*
Function : Walking & Standing	-0.63*
Function : Standard Activities	-0.87*
Function : Advanced Activities	-0.86*
Function Total	-0.82*

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

Construct validity

Strong correlations (r-range -0.83 to -0.87) were found between the KOOS-PS and the Functional Activity subscales Standard and Advanced Activities of the 2011 KSS-A, indicating good construct validity (Fig. 3, Table IV). A moderate correlation (r-range -0.63) was found between the KOOS-PS and the Functional Activity subscale Walking & Standing (Table II).

Moderate correlations (respectively -0.60 and -0.53 to -0.68 r-range) were also found between the subscale Symptoms and KOOS-PS and subscale Satisfaction of the 2011 KSS-A and respectively the Functional Activity subscales of the 2011 KSS-A and KOOS-PS (Fig. 2, Table II).

Responsiveness

All subscales showed significant changes after surgery, showing improvements ranging from 14-33% (range effect size 0.50 - 2.85) (Table III, Fig. 3). Similar improvements were found in KOOS-PS (range 24%, effect size 1.28) (Table III, Fig. 3). The Symptom subscale was the most responsive subscale showing an effect size of 2.85 and the subscale Walking & Standing was least responsive (effect size 0.50) (Table III).

No floor or ceiling effects were found preoperatively (Table IV). Postoperatively, ceiling effects of 16% and 26% were found for respectively the sub-

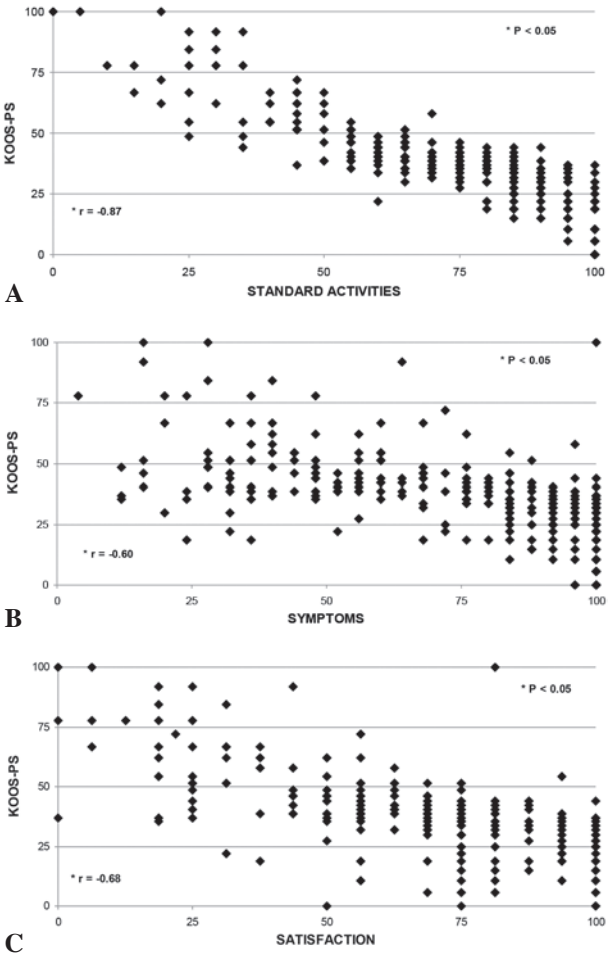


Fig. 2. — Correlation between function subscales of the 2011 KSS-A and the KOOS-PS.

scales Symptoms and Walking & Standing. No floor effects were encountered (Table IV).

A remarkable finding was that 61% of all pre-operative patients reached the highest possible score in the subscale Expectation, indicating that these patients expected maximum benefits from TKA.

DISCUSSION

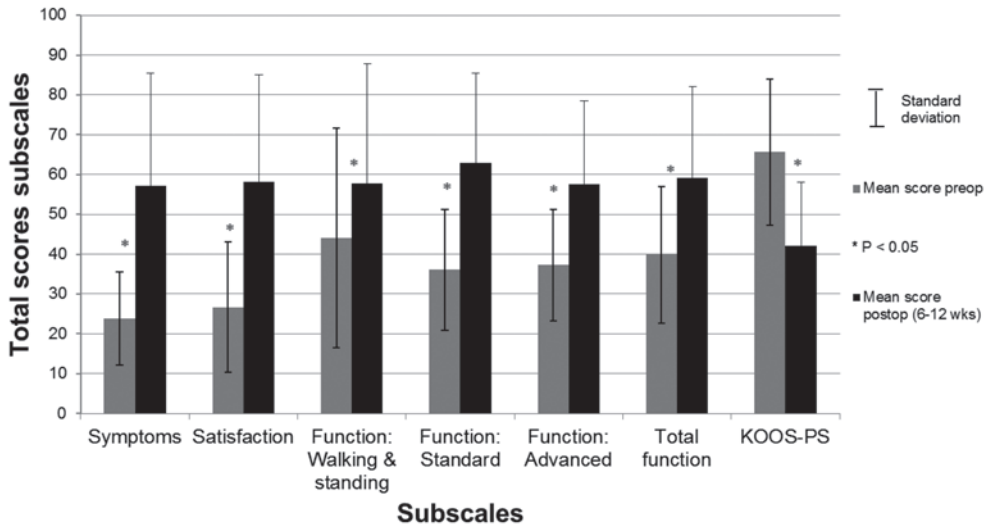
This study aimed to optimize the clinical suitability of the 2011 KSS by adapting limitations of the 2011 KSS causing the high rate of unusable questionnaires (e.g. low completion rate, lacking rules, non-optimal scale features) found in the recent study of Dinjens *et al* (2014). The clinimetric quality of the adjusted 2011 KSS (2011 KSS-A) was then evaluated in a large group of TKA patients.

Table III. — Effect sizes of the 2011 KSS-A

2011 KSS-A subscales	Effect Size n = 33
Symptoms	2.85
Satisfaction	1.92
Function : Walking & Standing	0.50
Function : Standard Activities	1.77
Function : Advanced Activities	1.45
Function Total	1.13
KOOS-PS	1.28

The 2011 KSS-A had a response rate of 70% which is lower than that reported for 2011 KSS by Dinjens *et al* (2014) (96%), but comparable to those reported for other PROMs (KOOS : 68%, WOMAC : 77%) (*10,14*). However the adjustments in 2011 KSS resulted in huge improvements in completion rate. The 2011 KSS-A showed a completion rate of 90% which is more than double as high as the completion rate of the 2011 KSS (43%) as reported by Dinjens *et al* (2014). Comparable completion rates were found for the KOOS-PS in this study (92%) and for TKA outcome related PROMs in previous studies (KOOS 95%, WOMAC 94%) (*10,14*). The high completion rate of the 2011 KSS-A indicates that it is more feasible for clinical use, e.g. for the follow up of patients, than the 2011 KSS.

In addition high clinimetric quality was found for the 2011 KSS-A showing comparable internal consistency, construct validity and responsiveness as reported for the 2011 KSS (*5,24*). Every subscale of the 2011 KSS-A showed good internal consistency (Cronbach's Alpha ≥ 0.83). The Functional Activity subscale Advanced Activities displayed slightly lower, but still acceptable, values (Cronbach's Alpha 0.79). Comparable internal consistency was reported in previous studies for the KOOS, (Cronbach's Alpha ≥ 0.71), KOOS-PS (Cronbach's Alpha 0.89), IKDC Subjective Knee Form (Cronbach's Alpha 0.92) and Oxford 12-item knee questionnaire (Cronbach's Alpha 0.94) (*2,6,7,8*).



KOOS-PS : score 100 = extreme difficulty, score 0 = no complaints.
Subscales 2011 KSS-A : score 100 = no difficulty, score 0 = extreme difficulty.

Fig. 3. — Average subscores pre and postoperative showing the responsiveness of the 2011 KSS-A.

Table IV. — Floor and ceiling effects of the subscales of the 2011 KSS-A ; percentage of patients displaying worst possible (floor effect)/best possible score (ceiling effect)

2011 KSS-A subscales	Pre-op n = 33	Post-op n = 288
Symptoms	3/0	0/16
Satisfaction	9/0	1/15
Expectation	0/61	9/16
Function : Walking & Standing	0/3	3/26
Function : Standard Activities	0/0	0/11
Function : Advanced Activities	0/0	1/3
Function Total	0/0	0/2

These results showed that the 2011 KSS-A is internal consistent, indicating good homogeneity between the items of a subscale. In addition, the Functional Activity subscale of the 2011 KSS-A is construct valid, as is shown by moderate to high correlations with the KOOS-PS ($r \geq 0.62$). These results are in line with the construct validity published for the KOOS-PS ($r = 0.73$), IKDC Subjective Knee Form (r-range -0.62 to -0.77) and Oxford 12-item knee questionnaire (r-range 0.48-0.81) (*4,7, 8*). This shows that the 2011 KSS-A is construct valid which indicates that it measures what it is intended to measure. Moreover, all subscales of the 2011 KSS-A were sensitive to changes over time, which indicates that the questionnaire is responsiveness. The subscale Symptoms, where pain is assessed, proved to be most responsive (effect size 2.85), which is not surprising as the main goal of TKA is pain relief. The Functional Activity subscale Walking & Standing was the least responsive (effect size 0.50). This can be attributed to the fact that walking and standing are low demanding activities. The preoperative patients of today are not very limited in walking as they are able to walk a substantial distance before surgery. This leads to only small postoperative improvements, explaining the small effect size. Similar to the 2011 KSS, the 2011 KSS-A showed a ceiling effect of 26% postoperative in the Functional Activity subscale Walking & Standing which stands in line with the small effect size found in this subscale (*5*). This indicates that maximum scores are reached so that no further improvement can be measured. The subscale Symptoms showed also a ceiling effect (16%). This is

comparable to the ceiling effects found in the KOOS, e.g. in the subscale pain (15-28%)) (*6,16*). Despite the reported ceiling effects in the subscales Symptoms and Walking & Standing, they are important clinical outcomes because pain relief is one of the main outcomes after TKA and because walking is the most basic way of locomotion for individuals. The fact that the 2011 KSS-A shows good internal consistency, construct validity and responsiveness, which is in addition comparable to that of the 2011 KSS, indicates that the 2011 KSS is successfully adjusted, making 2011 KSS-A suitable for clinical use.

This study also showed that mailing questionnaires to patients at home with a stamped returning envelop is an effective, easy and relatively cheap method to monitor patients at a distance (a small burden for both patient and clinician). The amount of patients that respond by mail is satisfying. However the response rate can still be improved, as 30% of the patients did not respond in the current study. A reminder sent by mail or calling patients at home could further increase the response rate in future studies.

If the above named adjustments give a definite solution for improving the 2011 KSS and making it therefore fully clinical applicable, a couple of issues need to be addressed. Future studies should investigate the test-retest reliability of the 2011 KSS-A, as reliability is an additional aspect contributing to the clinimetric quality of a questionnaire. However, a comparable reliability as reported for the 2011 KSS is expected as other studies show comparable ratings concerning test-retest reliability when analyzing a shortened version of an outcome scale (*4,13,15*). In addition, future studies could evaluate the 2011 KSS-A in a longitudinal study. In this way it can be investigated whether the 2011 KSS-A is able to deal with the new generation of younger and more physically active TKA patients and their rising demands. Final, to determine the added value and discriminative power of 2011 KSS-A, future studies could investigate correlations with objective outcomes such as performance tests (e.g. Get-up and Go test), objective motion analysis (e.g. acceleration based motion analysis) or sensor based activity monitoring (*20,23*).

CONCLUSION

Adjustments in 2011 KSS improved the completion to excellent scores, while remaining the clinimetric quality. The 2011 KSS-A shows high response and completion rate, and is internal consistent, construct valid and responsive. This shows that the 2011 KSS is successfully adjusted and indicates that the 2011 KSS-A suitable for routine clinical use.

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