What Do Osteoarthritis Health Outcome Instruments Measure? Impairment, Activity Limitation, or Participation Restriction?

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ABSTRACT. ***Objective.*** To explore whether commonly used osteoarthritis (OA) health outcome instruments (and items) are measuring single or multiple health outcomes using the International Classification of Functioning, Disability and Health (ICF) definitions.

Methods. Ten expert judges allocated 342 items from 13 instruments to one or more ICF construct, i.e., Impairment (I), Activity Limitation (A), and Participation Restriction (P). One-sample t tests were used to classify each item as measuring uniquely I, A, or P or some combination (i.e., IA, IP, AP, or IAP).

Results. Overall, 12 of the 13 instruments had items that measured a combination of outcome domains (i.e., IA, IP, AP, or IAP). Only the American Knee Society Score (AKS) had all items uniquely measuring either I or A. The instrument with the best representation of items for Impairment was the AKS, for Activity Limitation the WOMAC and Lequesne knee index, and for Participation Restriction the Disease Repercussion Profile.

Conclusion. All the existing OA outcome instruments, except one, had some items that were assessing more than one health outcome. Use of these instruments may either mask true treatment effects or make an effect difficult to attribute if the content is unclear. We determined which instruments were the best for measuring each health outcome. To improve the assessment of health outcomes in OA, new instruments that uniquely measure the 3 ICF constructs should be developed and all 3 should be included in relevant studies. (First Release Dec 15, 2005; J Rheumatol 2006;33:757–63)

Key Indexing Terms:
OUTCOME MEASURES OSTEOARTHRITIS
RELIABILITY VALIDITY OUTCOMES ASSESSMENT

Osteoarthritis (OA) of the hip and knee are common conditions for which new treatments are becoming available[1]. To assess the effectiveness of these and existing interventions we need reliable and valid outcome instruments. Many different instruments are used to assess health outcome in OA that may be measuring the same or different aspects of health outcomes. The WHO International Classification of Functioning, Disability and Health (ICF) model[2] defines 3 main health outcomes, based on consensus, Impairment (I), Activity Limitation (A), and Participation Restriction (P) (see Appendix for definitions). The ICF model and its predecessor (ICIDH[3]) have been the dominant models for exploring the consequences of a health condition.

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The ICF model has recently been used as the basis for exploring health instruments[4,5]. ICF core sets have been developed for a number of health conditions including OA[6]. The core sets identify which of over 1500 ICF categories should be included, as a minimum, for the assessment of functioning and health.

OA measures and their subscales may be measuring single or multiple ICF components. Even a single item may be measuring more than one outcome. For example, the Western Ontario and McMaster University OA Index (WOMAC)[7] item "How much pain do you have walking on a flat surface" may be measuring Impairment and Activity Limitation.

We suggest that all 3 main ICF components should be measured to fully assess the effect of a new treatment or drug. For example, a trial of 2 new analgesics may result in similar reductions in pain (impairment), but one may have a bigger influence on activity limitation than the other. This can only be assessed by a single instrument if it has clear subscales for each of the 3 main ICF components; alternatively, separate outcome instruments would have to be used. We suggest that we should use instruments (and subscales) that only have items measuring a single health outcome. An ideal instrument would either have all items uniquely meas-

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uring the same health outcome (e.g., all items only measuring I) or have subscales that each have items measuring the same health outcome (e.g., an instrument with 2 subscales: all items in one subscale measuring I and all items in the other subscale measuring A). With instruments of this type there is more chance of detecting a true effect of treatment, rather than the masking effect that may occur if instruments contain items that measure a mixture of outcomes. For example, a true effect on pain may not be detected if items also are measuring activity limitation; conversely, if an effect is found it is hard to attribute if the instruments have items that are measuring more than one construct. In addition, if instruments have items that measure more than one component, then observed relationships between components of the ICF model may be misleading due to, in effect, measuring the same thing twice[8].

We have proposed a new methodology for discriminant content validation using judges' ratings to explore the content of health outcome instruments[8]. This method allows evaluation of how well an instrument measures the construct it asserts to measure and not other constructs. Using this approach, each item can be classified as measuring either a single health outcome or more than one health outcome. We investigated the ICF health outcome or outcomes measured by commonly used health outcome instruments in hip and knee OA. (A parallel report deals with the theoretical and methodological aspects of the study[8].) The analyses were conducted at 3 levels — instrument, subscale, and item.

MATERIALS AND METHODS

Expert judges allocated items from OA hip and knee health outcome instruments to I, A, and P outcomes, and confidence ratings were used to classify items. Ten health service researchers and health professionals completed the task.

The judges were given the definitions of I, A, and P and asked to allocate each of 342 items from 13 outcome instruments to one or more of these domains. The judges were also asked to rate their "confidence" in each allocation between 0 and 10 (10 = extremely confident, 0 = not at all confident). For example, a judge could rate an item as A9 if they were very confident about an item being an Activity Limitation item, or A9/P7 if a judge was very confident about an item being Activity Limitation but also was reasonably confident the same item was also Participation Restriction.

The instruments chosen were health outcome assessments commonly used in assessment of hip and knee OA. As part of a review of interventions used for the treatment of OA[9], we examined the trials literature to assess which outcome measures were used most commonly, and selected these for the present study. Additionally, we included the London Handicap Scale[10], as it was a generic measure of handicap as defined by the earlier ICIDH model. This resulted in 8 disease-specific measures and 5 generic measures (Table 1).

Statistical analysis. All confidence ratings were transformed by adding 1 to all ratings and entering zero where the judge had not given a rating to a particular outcome (e.g., if rating was I7/A3 then I = 8, A = 4, and P = 0). One-sample one-tailed t tests were used to classify each item as either I, A, P, IA, IP, AP, or IAP. An item was classified to an outcome if its mean rating was significantly greater than zero ($p < 0.05$). An item was classified as unique if significantly greater than zero on only one of I, A, or P; or an item was classified as a mixed item if significantly greater than zero on more than one outcome (i.e., as IA, IP, AP, or IAP); or it was unclassified.

Table 1. Outcome instruments assessed in this study.

Disease-specific	American Knee Society Score (AKS)[11]
	Arthritis Impact Measurement Scale (AIMS)[12]
	Disease Repercussion Profile (DRP)[13]
	Harris Hip Score[14]
	Health Assessment Questionnaire (HAQ)[15]
	Lequesne Hip and Knee Indices[16]
	Oxford Hip and Knee Questionnaires[17,18]
	WOMAC OA Index (WOMAC)[7]
Generic	EuroQol[19]
	London Handicap Scale (LHS)[10]
	Medical Outcomes Study Short Form-36 (SF-36)[20]
	Sickness Impact Profile UK version[21] without work subscale (SIP-UK)
	WHOQol-BREF[22]

The items were explored and reported overall by instrument and by subscale.

Intraclass correlations (ICC)[23] were used to assess agreement between judges or interrater reliability applying a 2-way mixed model with measures of consistency. The ICC reported are for the mean of the ratings over judges for each instrument.

RESULTS

There was good agreement among the judges overall* (ICC = 0.93) and for each instrument [ICC for each instrument was > 0.90 except for the WHOQOL (0.85); see Table 2].

For ease of interpretation, the reporting of the unique impairment and activity items was then divided into 2 — (1) unique items directly related to hip/knee OA [I:H/K] and [A:H/K]; and (2) unique items not directly related to hip/knee OA [I:OTHER] (e.g., mental health, concentration, bowel function, and general health items) and [A:OTHER] (e.g., grip and eating items).

1. What do the items measure?

Overall, 42% of the 342 classified items from the 13 instruments measured were judged to include a mixture of outcome domains (i.e., IA, IP, AP, or IAP). Only the AKS did not have mixed items (Table 3). All items were classified.

2. What do the instruments measure?

The percentage of items, for each instrument, classified as either unique I [H/K and OTHER], A [H/K and OTHER], and P or mixed (IA or IP or AP or IAP) is shown in Table 3.

Only the AKS had items that were all unique; all the other instruments had mixed items (mean 41%, range 17%–67%).

The AKS was the only instrument with 50% or more of its items measuring I (67%), with all of this being relevant to hip/knee OA (Figure 1). The Harris Hip Score and Oxford hip and knee indices also had 25% or more Impairment items relevant to hip/knee OA (SF-36, AIMS, and EuroQol

*One judge was excluded as the ICC increased (indicating the excluded judge had poor fit with the other judges) when this judge was omitted. Therefore for the subsequent analyses this judge was omitted.

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Table 2. Judges' agreement (ICC) by instrument. See Table 1 for definitions.

Assessment	ICC
AKS	0.99
HAQ	0.97
AIMS	0.96
LHS	0.96
EUROQOL*	0.96
Lequesne knee	0.95
WOMAC	0.95
Lequesne hip	0.95
Oxford hip	0.95
Harris hip	0.95
SF-36	0.94
Oxford knee	0.94
DRP	0.91
SIP-UK*	0.88
WHOQOL	0.85

* Based on n = 8.

also had more than 25% Impairment, but many of these items were not relevant to hip/knee OA). The instruments developed by, and for use by, orthopedic surgeons (AKS, Harris, and Lequesne) have the highest proportion of Impairment items [I:H/K] (together with the Oxford hip and knee questionnaires). Two instruments had 50% or more of their items measuring A relevant to hip/knee OA, the WOMAC (50%) and the Lequesne knee (50%). The HAQ had 43%, while Lequesne hip, AKS, EuroQol, Harris, and Oxford hip also had 25% or more (Figure 2). Only the DRP had 50% or more of its items measuring participation (50%). The WHOQOL had 42%, with LHS having over a quarter (Figure 3).

The DRP and the SIP had at least 15% of items for each of I, A, and P, although this was only with I and A overall (e.g., [I:H/K] + [I:OTHER]).

3. What do the subscales measure?

There were 49 subscales (of more than one item) from 9 of the instruments. Three subscales measured only hip/knee Impairment [I:H/K] (knee score from the AKS, pain-AIMS, Stiffness-WOMAC), and 6 subscales contained only other Impairment items [I:OTHER]. Six subscales measured only hip/knee Activity Limitation (ADL-Lequesne knee), function-AKS, and HAQ-hygiene, dress, walk and arise, with one subscale (dexterity-AIMS) also containing only A items but both A:H/K and A:OTHER. There were only 2 subscales measuring only Participation Restriction (social activity-AIMS and social functioning-SF-36). All the other 31 subscales contained mixed items (Table 4).

The subscales of the AKS contained only unique items, with all the items in the Knee subscale being I and all items in the Function subscale being A. All the other instruments had some subscales that measured more than one outcome. The Lequesne hip, Harris, and WHOQOL had no subscales that measured a single outcome.

DISCUSSION

In order to accurately evaluate new treatments for OA we require instruments that adequately tap the full range of health outcomes. Using the ICF model this equates to, as a minimum, measuring Impairment (I), Activity Limitation (A), and Participation Restriction (P). In order not to mask any true effects of treatments, the instruments used should contain items that only measure a single health outcome, i.e., items not contaminated with other health outcomes. Using the ICF framework to define outcomes, it is clear that none of the currently used instruments give unique measures of all 3 ICF components. The AKS is the only instrument that has just unique items, and its subscales do give unique measures of Impairment and Activity Limitation. However, this instrument has had little validation and has been shown to have poor correlation between the items[24]. None of the other existing instruments can be used in their entirety to

Table 3. Percentage (number) of items in each outcome for each instrument.

Assessment	I:H/K	I:Other	A:H/K	A:Other	P	AP	IA	IP	IAP	N
AKS	67 (4)	0 (0)	33 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	6
SF-36	3 (1)	42 (15)	19 (7)	0 (0)	6 (2)	28 (10)	0 (0)	0 (0)	3 (1)	36
AIMS	9 (4)	27 (12)	13 (6)	9 (4)	9 (4)	33 (15)	0 (0)	0 (0)	0 (0)	45
Harris	33 (3)	0 (0)	33 (3)	0 (0)	0 (0)	11 (1)	22 (2)	0 (0)	0 (0)	9
EuroQol	17 (1)	17 (1)	33 (2)	0 (0)	0 (0)	17 (1)	17 (1)	0 (0)	0 (0)	6
Lequesne hip	20 (2)	0 (0)	40 (4)	0 (0)	0 (0)	10 (1)	30 (3)	0 (0)	0 (0)	10
Lequesne knee	20 (2)	0 (0)	50 (5)	0 (0)	0 (0)	0 (0)	30 (3)	0 (0)	0 (0)	10
HAQ	5 (1)	0 (0)	43 (9)	9 (2)	0 (0)	43 (9)	0 (0)	0 (0)	0 (0)	21
WOMAC	8 (2)	0 (0)	50 (12)	0 (0)	0 (0)	21 (5)	21 (5)	0 (0)	0 (0)	24
Oxford hip	25 (3)	0 (0)	25 (3)	0 (0)	0 (0)	25 (3)	25 (3)	0 (0)	0 (0)	12
Oxford knee	25 (3)	0 (0)	17 (2)	0 (0)	0 (0)	25 (3)	33 (4)	0 (0)	0 (0)	12
DRP	0 (0)	17 (1)	17 (1)	0 (0)	50 (3)	0 (0)	0 (0)	17 (1)	0 (0)	6
WHOQOL	0 (0)	15 (4)	0 (0)	0 (0)	42 (11)	19 (5)	4 (1)	11 (3)	8 (2)	26
LHS	0 (0)	0 (0)	0 (0)	0 (0)	33 (2)	50 (3)	0 (0)	17 (1)	0 (0)	6
SIP-UK	0 (0)	15 (19)	12 (15)	4 (5)	17 (22)	27 (34)	16 (21)	4 (5)	5 (6)	127

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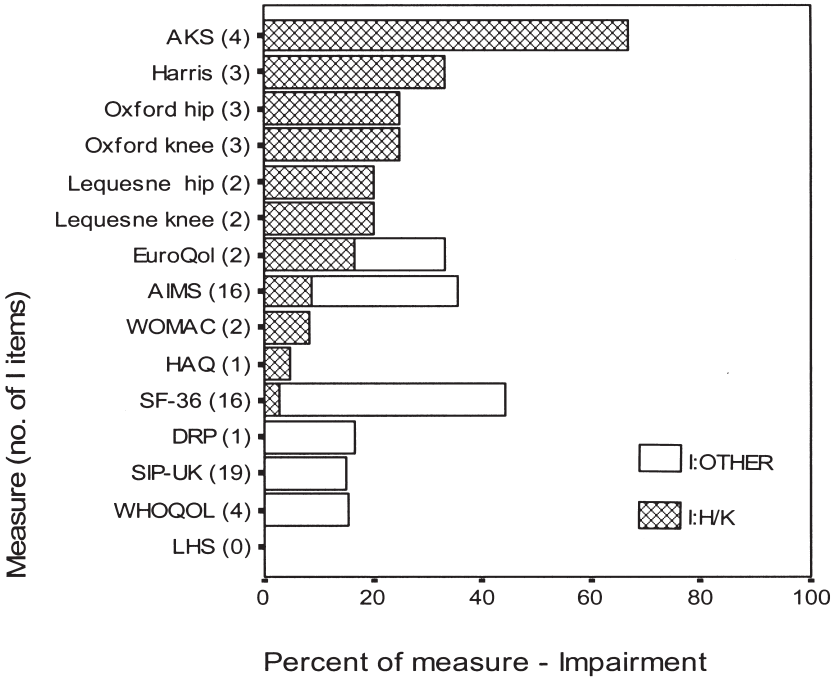

Figure 1. Percentage of Impairment items in each measure.

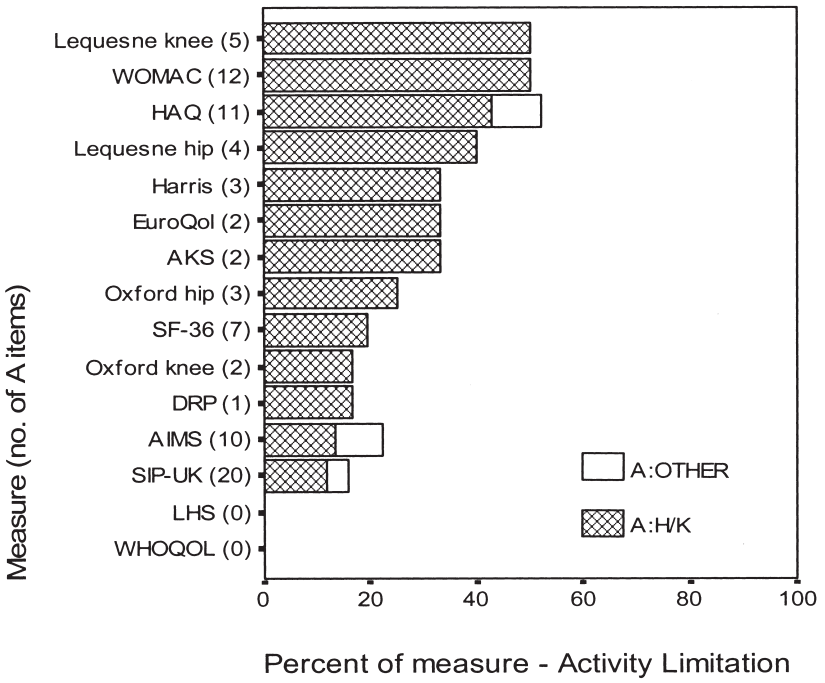

Figure 2. Percentage of Activity Limitation items in each measure.

measure the ICF components without contamination from other constructs.

The subscale analysis indicated that the subscales were more likely to reflect single health outcomes than were the instruments as a whole. These results suggest that the use of subscales allows for more uncontaminated measurement of the 3 specific ICF health outcomes. Thus, on the basis of this analysis, unique measures of hip/knee Impairment [I:H/K] are the knee joint score from the AKS, the pain subscale from the AIMS, and the stiffness subscale of the WOMAC;

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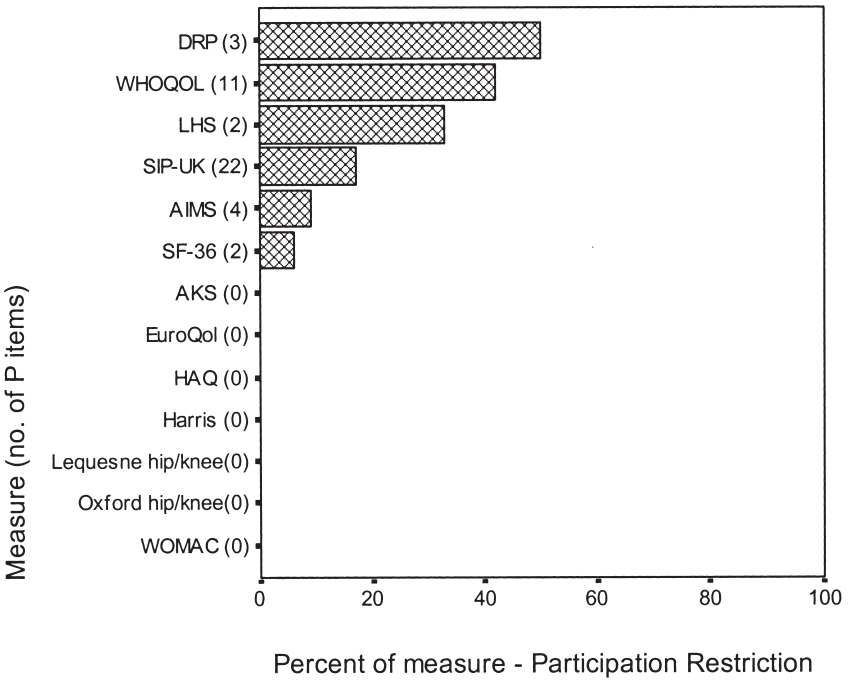

Figure 3. Percentage of Participation Restriction items in each measure.

for hip/knee Activity [A:H/K], the function subscale of the AKS, the subscales of arise, dressing, hygiene and walking from the HAQ, and for knee assessment the Lequesne ADL subscale; and for Participation, the social activity subscales from the AIMS and SF-36. While these subscales have a small number of items and only aim to tap part of the relevant ICF component, it may be informative to explore existing data using these divisions into I, A, and P.

Although not measuring only a single outcome, some instruments give better representations of the ICF components than others. Of the instruments that assessed impairments arising from hip and knee disease, the AKS has the best representation of items. For assessment of activity limitation arising from hip or knee disease, the WOMAC and Lequesne knee index appear to be the best, and for restricted participation the DRP. If we were to select both a generic and a disease-specific measure, as is the current general consensus for OA outcome studies, then one of the most commonly* used disease-specific instruments, the WOMAC, measures mainly activity limitation (50%). The most commonly used generic instrument, the SF-36 (said to be a quality of life measure), mainly (44%) measures Impairment; however, almost all of this is contained within mental health and general health items, and only one item is directly related to joint impairment (the pain item). Even instruments that purport to measure only a single health outcome (e.g., DRP and LHS assert that they measure participation) do, in fact, measure other health outcomes. In addition, instruments that aim to measure a broader range of health outcomes (e.g., the quality of life instruments WHOQOL and EuroQol) are measuring different proportions of each health outcome. Thus, comparison between studies using different instruments is problematic.

These results have implications for the selection of appropriate outcome instruments for the assessment of changes in health status in patients with OA. Instruments can clearly not be used interchangeably, and should be selected to at least have a strong component of the required outcome. Consideration should also be given to how well the content of each instrument covers the ICF OA "core set" domains[5,6,25].

We suggest that the above analyses are fundamental for clarifying what OA instruments are measuring, and for understanding what effects result from interventions. Only when the content of the instruments has been clarified should one proceed to assess how well they perform on psychometric assessment, and they may be found unsatisfactory at this stage.

In conclusion, results of studies may be more informative if the 3 main ICF components are measured rather than a mixture of outcomes. To improve outcome instruments we should ensure that items or subscales within them are only measuring a single construct and are not contaminated with other constructs. This would help to ensure that true effects of treatments detected by trials are not masked or misinterpreted. We have highlighted the difficulties in using existing OA instruments to uniquely measure the 3 main ICF con-

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Table 4. Percentage (number) of items in each subscale for each instrument.

Instrument	Subscale	I:H/K	I:Other	A:H/K	A:Other	P	Mixed	N
AKS	**Knee score**	**100 (4)**	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4
	Function	0 (0)	0 (0)	**100 (2)**	0 (0)	0 (0)	0 (0)	2
SF-36	General health	0 (0)	100 (5)	0 (0)	0 (0)	0 (0)	0 (0)	5
	Health transition	*0 (0)*	*100 (1)*	*0 (0)*	*0 (0)*	*0 (0)*	*0 (0)*	*1*
	Mental health	0 (0)	100 (5)	0 (0)	0 (0)	0 (0)	0 (0)	5
	Pain	50 (1)	0 (0)	0 (0)	0 (0)	0 (0)	50 (1)	2
	Physical	0 (0)	0 (0)	70 (7)	0 (0)	0 (0)	30 (3)	10
	Role emotional	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (3)	3
	Role physical	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (4)	4
	Social functioning	0 (0)	0 (0)	0 (0)	0 (0)	**100 (2)**	0 (0)	2
	Vitality	0 (0)	100 (4)	0 (0)	0 (0)	0 (0)	0 (0)	4
AIMS	Mobility	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (4)	4
	Physical activity	0 (0)	0 (0)	80 (4)	0 (0)	0 (0)	20 (1)	5
	Dexterity	0 (0)	0 (0)	20 (1)	80 (4)	0 (0)	0 (0)	5
	Household	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (7)	7
	Social activity	0 (0)	0 (0)	0 (0)	0 (0)	**100 (4)**	0 (0)	4
	ADL	0 (0)	0 (0)	25 (1)	0 (0)	0 (0)	75 (3)	4
	Pain	**100 (4)**	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4
	Depression	0 (0)	100 (6)	0 (0)	0 (0)	0 (0)	0 (0)	6
	Anxiety	0 (0)	100 (6)	0 (0)	0 (0)	0 (0)	0 (0)	6
Harris	Deformity	*100 (1)*	*0 (0)*	*0 (0)*	*0 (0)*	*0 (0)*	*0 (0)*	*1*
	Function	0 (0)	0 (0)	50 (3)	0 (0)	0 (0)	50 (3)	6
	Pain	*100 (1)*	*0 (0)*	*0 (0)*	*0 (0)*	*0 (0)*	*0 (0)*	*1*
	Range of motion	*100 (1)*	*0 (0)*	*0 (0)*	*0 (0)*	*0 (0)*	*0 (0)*	*1*
Lequesne	ADL							4
	Hip	0 (0)	0 (0)	75 (3)	0 (0)	0 (0)	25 (1)	
	Knee	0 (0)	0 (0)	**100 (4)**	0 (0)	0 (0)	0 (0)	
	Pain	40 (2)	0 (0)	0 (0)	0 (0)	0 (0)	60 (3)	5
	Walking	*0 (0)*	*0 (0)*	*100 (1)*	*0 (0)*	*0 (0)*	*0 (0)*	*1*
HAQ	Activity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (3)	3
	Arise	0 (0)	0 (0)	**100 (2)**	0 (0)	0 (0)	0 (0)	2
	Dress	0 (0)	0 (0)	**100 (2)**	0 (0)	0 (0)	0 (0)	2
	Eating	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (3)	3
	Grip	0 (0)	0 (0)	0 (0)	67 (2)	0 (0)	33 (1)	3
	Hygiene	0 (0)	0 (0)	**100 (3)**	0 (0)	0 (0)	0 (0)	3
	Reach	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (2)	2
	Walk	0 (0)	0 (0)	**100 (2)**	0 (0)	0 (0)	0 (0)	2
WOMAC	Pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (5)	5
	Physical	0 (0)	0 (0)	71 (12)	0 (0)	0 (0)	29 (5)	17
	Stiffness	**100 (2)**	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2
WHOQOL	Physical	0 (0)	0 (00	0 (0)	0 (0)	14 (1)	86 (6)	7
	Psychological	0 (0)	67 (4)	0 (0)	0 (0)	17 (1)	17 (1)	6
	Social	0 (0)	0 (0)	0 (0)	0 (0)	67 (2)	33 (1)	3
	Environment	0 (0)	0 (0)	0 (0)	0 (0)	88 (7)	12 (1)	8
SIP (UK)	Ambulation	0 (0)	0 (0)	50 (6)	0 (0)	0 (0)	50 (6)	12
	Body care	0 (0)	4 (1)	39 (9)	0 (0)	0 (0)	57 (13)	23
	Mobility	0 (0)	0 (0)	0 (0)	0 (0)	20 (2)	80 (8)	10
	Household	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (10)	10
	Recreation	0 (0)	0 (0)	0 (0)	0 (0)	50 (4)	50 (4)	8
	Social	0 (0)	0 (0)	0 (0)	0 (0)	80 (16)	20 (4)	20
	Emotion	0 (0)	100 (9)	0 (0)	0 (0)	0 (0)	0 (0)	9
	Alertness	0 (0)	60 (6)	0 (0)	0 (0)	0 (0)	40 (4)	10
	Sleep and rest	0 (0)	43 (3)	0 (0)	0 (0)	0 (0)	57 (4)	7
	Eating	0 (0)	0 (0)	0 (0)	44 (4)	0 (0)	56 (5)	9
	Communication	0 (0)	0 (0)	0 (0)	11 (1)	0 (0)	89 (8)	9

Bold type: subscales (of more than one item) with 100% unique H/K items; italic type: subscales with only one item. ADL: activities of daily living.

structs, although some of the subscales of the instruments did only measure one outcome. However, until unique measures have been developed, we have shown which of the commonly used OA instruments have the best representa-

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tion of each of the ICF components. We are currently developing a new unique OA instrument based on the results of this study. We would recommend that any study that aims to determine the influence of a treatment on health outcome should include a unique, separate measure of impairment, activity limitation, and participation restriction.

ACKNOWLEDGMENT

We thank the judges who took part in this study.

APPENDIX

Definitions of Impairment, Activity Limitations, and Participation Restrictions in the ICF[2].

In the context of health:

Impairments are problems in body function or structure such as a significant deviation or loss. Body functions are the physiological functions of the body systems (including psychological functions). Body structures are anatomical parts of the body such as organs, limbs, and their components.

Activity Limitations are difficulties an individual may have in executing activities. Activity is the execution of a task or action by an individual.

Participation Restrictions are problems an individual may experience in involvement in life situations. Participation is the involvement in a life situation.

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