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Dimensionality and clinical importance of pain and disability in hand osteoarthritis: Development of the Australian/Canadian (AUSCAN) Osteoarthritis Hand Index

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Summary

Objective: To develop a reliable, valid, and responsive self-administered questionnaire to probe pain, stiffness and physical disability in patients with osteoarthritis (OA) of the hand.

Design: In order to assess the dimensionality of the symptomatology of hand OA, a self-administered questionnaire was developed to probe various aspects of pain (10 items), stiffness (two items), and physical function (83 items). The question inventory was generated from eight existing health status measures and an interactive process involving four rheumatologists, two physiotherapists, and an orthopaedic surgeon.

Results: Face-to-face interviews were conducted with 50 OA hand patients; 39 females and 11 males with mean age 62.8 years and mean disease duration 9.4 years. Items retained were those which fulfilled specified selection criteria: prevalence ≥60% and mean importance score approximating or exceeding 2.0 Item exclusion criteria included low prevalence, gender-based, ambiguous, duplicates or similarities, alternatives, composite items, and items that were too restrictive. This process resulted in five pain, one stiffness and nine function items which have been proposed for incorporation in the AUSCAN Index .

Conclusions: Using a traditional development strategy, we have constructed a self-administered multi-dimensional outcome measure for assessing hand OA. The next stage includes reliability, validity and responsiveness testing of the 15-item questionnaire.

Key words: Osteoarthritis, Hand disability index, Outcome assessment, Clinical trials.

Introduction

Osteoarthritis (OA) commonly involves the DIP, PIP and first CMC joints of the hand (less frequently involving the MCP and wrist articulations)[1]. Involvement often results in pain and physical disability requiring the use of analgesics, non-steroidal antiinflammatory drugs, physiotherapy, local corticosteroid injections, and, occasionally, orthopaedic surgical intervention. Over the past few years, two international workshops have been held on hand OA; the first in Marbella, Spain in 1994 with the proceedings published in a supplement of Revue du Rhumatisme[2], and the second in Boston, United States in 1999 with the proceedings published in a supplement of this Journal[3]. While there are many scales described which can adequately assess pain severity in musculoskeletal disorders, and functional indices to assess the entire musculoskeletal system (e.g., AIMS, HAQ) or specific areas (e.g., WOMAC, Lequesne Indices)[4], there are few instruments available to evaluate patients with digital OA[5–7]. The Functional Index for Hand Osteoarthritis (FIHOA), developed by Dreiser, is an investigator-administered questionnaire[8–10]. Its development was based on 10 questions selected by clinicians as most appropriate for assessing the functional impact of active digital OA. It has been validated, has shown good interrater reliability[8,9], and its sensitivity to change over 6 months has been assessed[10]. The Cochin (Duruöz) Hand Functional Disability Scale, developed for rheumatoid hands, is an 18-item questionnaire rated by the patient's doctor[11,12]. Recently, its performance has been evaluated in OA hand patients[13,14]. A 23-item questionnaire (SACRAH—Score for the Assessment and Quantitation of Chronic Rheumatic Affections of the Hands) has also been established to quantitate disease activity and impairment in

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both rheumatoid arthritis and OA[15]. A self-assessment clinical scoring system to assess patients with hand OA has been reported by Maheu and Dewailly[16]. Four severity indices, based on examination findings only, have been created to assess the impact of hand OA independent of function[17]. In addition, the Disabilities of the Arm, Shoulder and Hand (DASH) scale was developed as a regional outcome measure that could be used for the evaluation of any joint or condition of the upper extremity[18].

The development of a self-administered questionnaire usually follows a series of steps: (1) index characterization, (2) item generation, (3) item rationalization, (4) questionnaire construction, (5) pre-test questionnaire, and (6) validation study which results in determination of reliability, validity, responsiveness and parameters for future sample size calculation. Thus, the process begins with the development of an item pool and ends with one or more validation studies establishing test–retest reliability, internal consistency, construct validity and responsiveness, and relevant parameters for future sample size calculation.

We have previously used these procedures in the successful development of the WOMAC Osteoarthritis Index[19]. WOMAC is a valid, reliable and responsive self-administered questionnaire for assessing outcomes in clinical trials in OA hip and knee patients. It has been recommended as a standard measure for clinical trials of slow-acting, disease-modifying drugs in OA trials and is cited in OARSI Guidelines[20]. The development of the hand index followed almost identical procedures to those used in the development and validation of WOMAC[21].

Our goal was to develop a reliable, valid, and responsive self-administered questionnaire to probe pain, stiffness and physical disability in patients with OA of the hand.

Subjects and methods

SUBJECTS

Fifty, consecutive outpatients with OA of the hand were selected for study at two centers: The University of Western Ontario, London, Canada and Cabrini Hospital, Melbourne, Australia. To be eligible patients had to meet the following criteria: age 30–80 years, fluent in the English language, fulfill the American College of Rheumatology clinical criteria for OA hand[22], have symptomatic (i.e. pain or disability) OA of the hand (DIP and/or PIP and/or CMC±MCP and/or wrist involvement), and be willing to provide informed consent. Any patient who had prior orthopaedic surgery on the hand joints, psoriasis or rheumatoid arthritis was excluded. Ethics approval was obtained from the Review Board for Health Sciences Research Involving Human Subjects, The University of Western Ontario and the Ethics Committee on Research, The Royal Melbourne Hospital.

QUESTIONNAIRE DEVELOPMENT

Item generation

The method adopted for item generation capitalized on the experience of both clinical investigators and patients with hand OA. Clinical trials in OA from 1968 to 1995 were reviewed. Predefined areas of disability were culled from eight existing questionnaires: AIMS[23], HAQ[24], Functional Status Index[25], Jebsen Index[26], Independent Measure of Functional Capacity[27], Lee Index[28], Convery Index[29], and the McMaster Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR)[30]. Opinions of four rheumatologists (NB, MD, BH, KM), an orthopaedic surgeon (JR), and two physiotherapists (KH, JM) were solicited in the generation of closed-ended questions for use in patient interviews to generate the item inventory.

Thereafter, patients with hand OA were questioned first with the aforementioned closed-ended questions that probed the clinical importance and characteristics of pain, stiffness and physical dysfunction. Once responses to those questions were exhausted, an open-ended question, which elicited any additional sources of pain, stiffness and physical disability, was used to complete the assessment of each dimension and quantitate any sources of discomfort or disability elicited.

The following data were recorded in response to the aforementioned closed-ended and open-ended questions: (1) the presence or absence of each of several types of discomfort and disability, (2) the frequency with which each type of discomfort or disability occurred (daily, weekly, fortnightly or monthly or less), (3) the importance of the discomfort or disability to the patient rated on a five-point adjectival scale (none, slight, moderate, very, extreme), and (4) the extent to which the discomfort or disability was due to left, right or both hands. The end result of the selection process was a large pool of items covering the disability dimension and containing items which varied in their prevalence rate of occurrence, clinical importance and attribution to hand(s).

Item rationalization

The necessity for item reduction was driven by the feasibility of carrying a large number of redundant items through the subsequent validation study. It was intended to present the patient with two alternate scaling forms of the same AUSCAN questions (i.e., Likert and visual analogue scaling) followed by presentation of several other health status questionnaires. Based on our prior experience in questionnaire construction, we thought that approximately 80 questions could be posed. Therefore, given the duplication necessary to compare the two forms of responses, it was thought that approximately 40 individual items could be posed. In order to reduce the number of items, the following exclusion rules were applied: (1) gender based items, (2) ambiguous items, (3) low prevalence items (e.g. <50%), (4) composite items, (5) items that may be considered too restrictive, (6) elimination of alternatives (e.g. do/undo or fasten/unfasten), and (7) elimination of duplicates or similarities. The end result of the process of item rationalization was to be a pool of a maximum of 40 items of known frequency, clinical importance and rate of recurrence. In general, the McMaster University guide to questionnaire construction and question writing was used to generate the hand index questionnaire[31].

SAMPLE SIZE ESTIMATION AND DATA ANALYSIS

The sample size of 50 patient interviews was based on two considerations: (1) our experience in the development of the WOMAC Index, where interview of the first 50 subjects provided almost all necessary information for the development of the test item inventory, and (2) with 50 patients, the confidence interval around a symptom frequency of 50% would be about 15%, i.e., the true frequency would be between 35% and 65% in 95% of situations in which a frequency of 50% was obtained[32].

Table I
Pain rank ordered by prevalence

Item	Prevalence	Daily or weekly frequency*	Mean importance score (MIS)†
Candidate items			
When turning objects with your hands	0.80	89	2.30
At rest (i.e. when not using your hands)	0.78	85	1.95
When gripping objects with your hands	0.76	91	2.34
When squeezing objects with your hands	0.72	100	2.36
When lifting objects with your hands	0.70	91	2.47
Reserve items			
With repetitive activity	0.86	86	2.61
With heavy activity	0.86	88	2.56
With light activity	0.78	90	2.18
When shaking hands with another person	0.58	66	1.97
During the night (i.e. wakes you from sleep)	0.42	91	2.48

*Percentage of patients reporting pain daily or weekly.
†MIS=sum of the individual importance scores given by *N* affected patients divided by *N*.

Following completion of the 50 interviews, the data were summarized using descriptive statistics to provide the following values: (1) prevalence of each type of discomfort or disability (P), (2) mean importance (MI) score (MI=the sum of the individual importance scores given by *N* affected individuals divided by *N*)[21], and (3) the percentage of symptomatic patients experiencing daily or weekly symptoms (DW%=high frequency). The individual items were then ranked within each dimension in order of their prevalence. In this study, prevalence was defined as the proportion of patients in the 'at risk' population who were concerned by ongoing symptomatology on a given variable. From this process, questions that were gender specific, ambiguous, or replicated were discarded from the item inventory, and from the remaining items, questions that met the prevalence criteria of ≥50% were retained. Thereafter, based on a statistico-judgemental process, two sets of items were created from this item pool, the first fulfilling selection criteria as 'candidate' items for inclusion in the final AUSCAN Index, which were to be carried forward for clinimetric evaluation, and a second set of 'reserve' items that we retained for a separate investigation of the comparative effects of late vs early item reduction in index construction. In other words, we deliberately retained items destined to be discarded in order to study their clinimetric properties and, in a separate publication, report our experience for the information of other index constructors. The aforementioned statistico-judgemental process took into consideration three statistical parameters (MI score, DW%, prevalence), and three clinically based judgements (item potential for gender bias, ambiguity, or duplication), as explained in succeeding paragraphs. To be included, items required to fulfill both statistical and clinical judgement criteria.

Results

SUBJECTS

Fifty patients (39 females, 11 males) were interviewed face-to-face at three sites; 32 at London Health Sciences Centre, Victoria Campus, 11 at Cabrini Hospital, and seven at St Joseph's Health Care. The mean age was 62.8 years (standard deviation 9.3, range=46 to 79) and mean disease duration (i.e. symptomatic) 9.4 years (standard deviation 9.9, range=1 to 35 years). Thirty-nine patients were right-handed and 11 were left-handed. All patients were symptomatic at the time of assessment. Radiographs from participating patients showed wide diversity in the number (one to several) and distribution (first CMC alone vs IP alone, vs both first CMC and IP) of joints involved, and in the extent of joint space narrowing (JSN) (mild to severe), osteophyte formation (mild to advanced), sclerosis and cystic changes (present vs absent), indicating inclusion of patients from a broad spectrum of disease severity.

PAIN

Pain was disaggregated into pain occurring during 10 types of activity (Table I). The interviewer asked the patient the following question: 'When does arthritis cause pain in your hands?' The prevalence of different sources of pain varied from 42 to 86%, pain with repetitive and heavy activity being the most prevalent. Nine of the 10 items were reported with a prevalence ≥58%. Pain during the night was the least prevalent (42%). Mean importance (MI) scores for pain varied from 1.95 to 2.61. All 10 items were reported with daily or weekly frequency ≥66%.

STIFFNESS

The interviewer read to the patient the following preamble, 'The following questions are concerned with joint stiffness. That is the sensation that the ease with which you move your joints is being restricted or slowed.' The interviewer then posed the question, 'Do you suffer from joint stiffness in your hands?' Seventy-six percent of patients reported that they suffered from joint stiffness in their hands. The interviewer then posed the question, 'When do you experience stiffness in your hands?' Two closed-ended questions were asked. The presence or absence of (a) morning stiffness, and (b) stiffness later in the day following inactivity were recorded, and in those with stiffness, the duration (in minutes) was estimated by the patient. Seventy

Table II
Physical function rank ordered by prevalence

Item	Prevalence	Daily or weekly frequency*	Mean importance score (MIS)†
Candidate items			
Opening a new jar	0.92	67	2.43
Carrying a full pot[1]	0.80	95	2.43
Picking up large heavy objects	0.80	63	2.43
Fastening jewelry (i.e., wrist watch, bracelet)	0.78	74	1.97
Turning taps/faucets on	0.76	87	2.05
Doing up buttons	0.72	92	2.33
Wringing out washcloths	0.68	100	2.50
Peeling vegetables	0.66	94	2.48
Gripping and turning a round doorknob or handle	0.60	97	1.97
Reserve items			
Unfastening jewelry[2]	0.76	74	1.92
Carrying a 10 lb (4.5 kg) object	0.70	63	2.26
Carrying a 2 lb (1 kg) bag of sugar in one hand	0.68	50	2.06
Doing up shirt or blouse	0.64	84	2.25
Using scissors	0.64	59	1.97
Using a can opener	0.62	84	2.29
Turning taps/faucets off[3]	0.62	94	2.23
Squeezing a sponge	0.62	90	2.23
Picking up change from a flat surface	0.62	94	1.77
Writing a letter with a pencil or ordinary pen	0.58	55	2.38
Carrying a hard cover book in one hand	0.58	66	1.90
Opening/closing a safety pin[4]	0.56	50	1.93
Peeling fruit[5]	0.56	86	1.89
Grabbing a full bottle and raising it[6]	0.56	71	1.82
Gripping and turning a key in a lock	0.54	85	2.07
Using a screwdriver, wrench or hammer[7]	0.52	54	2.15
Opening a new carton of milk or fruit juice pack	0.52	96	2.08
Holding a full plate of food	0.52	89	2.04
Cutting a piece of paper with scissors	0.52	54	2.00
Tying up shoelaces	0.50	88	2.12
Gripping a pen or pencil	0.50	88	2.00
Discarded items			
Opening a jar that has previously been opened	0.48	96	2.38
Picking up a full mug of tea/coffee to your mouth	0.48	96	2.21
Doing up fasteners	0.48	71	2.08
Opening a car door	0.48	92	2.00
Dressing lower body	0.46	100	2.65
Threading a needle	0.46	39	2.04
Sewing	0.46	43	2.00
Dressing upper body	0.44	100	2.23
Turning lamps/light switches on	0.44	95	2.14
Turning lamps/light switches off	0.44	95	2.14
Using your hands to push up from a chair (or bathtub)	0.42	91	2.33
Cutting meat with a knife	0.42	86	2.24
Washing and drying your body	0.42	100	2.05
Holding a bowl	0.42	81	2.05
Tying a knot in a rope or piece of string	0.42	67	1.95
Clipping your nails	0.40	60	2.25
Winding a watch or changing the time	0.40	30	2.25
Gripping and turning the steering wheel of a car	0.40	85	2.10
Squeezing a new tube of toothpaste	0.40	80	1.95
Holding an open umbrella with one hand	0.38	26	2.47
Doing up belts and/or buckles	0.38	79	1.89
Shuffling a deck of cards	0.36	44	2.28
Turning the ignition key in a car	0.36	94	2.22
Pouring liquid from a bottle into a glass	0.36	94	2.06
Washing and shampooing your hair	0.36	94	1.83
Tying ties and/or scarves	0.34	53	2.29
Knitting or crocheting	0.34	53	2.29
Writing a short sentence with a pencil or ordinary pen	0.34	94	1.94
Stacking small items (i.e., plates or coins)	0.34	71	1.59

Table II *continued*
Physical function rank ordered by prevalence

Item	Prevalence	Daily or weekly frequency*	Mean importance score (MIS)†
Squeezing a tube of toothpaste	0.32	100	1.94
Picking up large light objects	0.32	81	1.81
Opening and closing drawers with your hands	0.32	100	1.69
Toileting	0.30	100	2.40
Counting money in a coin purse	0.30	80	2.07
Turning over a piece of paper (i.e., page of a book)	0.26	100	1.92
Doing up zippers	0.26	77	1.92
Shaving or applying cosmetics	0.26	100	1.54
Combing your hair	0.24	100	2.25
Typing or keyboarding	0.22	91	2.27
Folding a letter and putting it in an envelope	0.22	55	1.64
Gripping a golf club, racquet or bowling ball	0.20	60	1.70
Pricking things well with a fork	0.18	89	1.78
Flossing your teeth	0.18	100	1.56
Using a television remote control	0.18	89	1.00
Walking the dog	0.16	88	2.50
Brushing your teeth	0.16	100	2.00
Using a camera	0.16	13	1.88
Playing a musical instrument	0.12	67	1.83
Spreading butter on bread	0.12	100	1.67
Operating a touch tone telephone (i.e., push button)	0.12	100	1.34
Operating a microwave oven	0.10	100	2.40
Dialling a telephone	0.08	100	2.25
Using the instabank machine	0.08	100	0.75

*Percentage of patients reporting difficulty daily or weekly.
†MIS=sum of the individual importance scores given by *N* affected patients divided by *N*.
[1]Disaggregated into one vs two hands.
[2]Alternative of fastening.
[3]Alternative of on.
[4]Too restrictive.
[5]Combined with vegetables.
[6]Disaggregated into one vs two hands.
[7]Gender biased.

percent (35/50) of all patients reported experiencing morning stiffness, while only 52% (26/50) reported later in the day stiffness. Mean importance scores were 2.06 and 2.12, respectively. Stiffness occurred on a daily basis in almost all affected individuals (86% morning, 85% later in the day). The mean duration of morning stiffness was 38.1 minutes with two patients reporting that it lasted all day. The mean duration of stiffness later in the day was 19.3 minutes with four patients reporting that it lasted for the rest of the day.

PHYSICAL FUNCTION

Physical function was disaggregated into disability occurring during 83 types of activity (Table II). The interviewer read the following preamble to the patient, 'The following questions are concerned with your physical function. By this we mean your ability to use your hands to perform a variety of tasks in day to day living. We would like to know how arthritis in your hands has affected your physical function.' The interviewer posed the following question, 'What physical difficulties do you have as a result of arthritis in your hands?' The prevalence of physical disability on individual items varied from 8 to 92%. Opening a new jar, carrying a full pot, picking up large heavy objects, fastening jewelry, and turning taps/faucets on were the most prevalent forms of disability. Walking the dog, spreading butter on bread, operating a microwave oven, and dialing a telephone were infrequent causes of disability. Thirty of the 83 items were reported with a prevalence ≥50%. Mean importance scores varied from 0.75 to 2.65.

At the end of each of the three sections of the interview patients were prompted to identify any additional items. This process did elicit a few extra items, but they were neither consistent nor frequent and were therefore excluded from further consideration.

By this process a total of 10 pain, two stiffness and 30 physical function items were identified. With further item rationalization the number of function items was reduced to 27. Amongst these items, five pain, one stiffness and nine physical function items were selected for evaluation as 'candidate' items for the AUSCAN Index, the remaining five pain, one stiffness and 18 function items being designated as 'reserve' items for separate evaluation. 'Candidate' items were characterized by prevalence ≥60%, MI score approximating or exceeding 2.0 and frequency (DW%) ≥63%. In contrast 'reserve' items, had a prevalence ≥50%, but were items about which we had residual concerns regarding one or more of the following: (a) low MI score, (b) low DW%, (c) prevalence <60%, or (d) residual concerns regarding gender bias, ambiguity, or duplication. Items deleted from further consideration were all items having a prevalence of <50%.

Discussion

Clinical tools that can be used for assessing symptomatic hand OA in clinical research have recently been reviewed[5]. Tools exist for assessment of pain, function, performance, mobility, stiffness, inflammation and deformity, and core outcome measures have been proposed for clinical trials in hand OA. Existing instruments available to assess hand OA have limitations. Both the FIHOA and the Cochin Hand Functional Disability Scale are administered by interviewers, which could possibly result in bias due to interviewer–respondent interaction. Furthermore, neither instrument assesses pain or stiffness, necessitating the employment of additional instruments to measure these two domains. The capability of assessing pain is particularly important since pain is one of the core set measures for OA clinical trials[20]. In the Women's Health and Aging Study, trained nurse examiners scored each DIP, PIP and first CMC on two severity indices, resulting in a score which is based on examination findings alone. Although three categories of disease activity (function, pain and stiffness) are covered by the SACRAH, the rationale for selection of the 23 items included is unclear from the abstract report. The DASH is a broad upper extremity outcome measure not specifically targeting the hand joints of OA patients. Finally, the tool developed by Maheu and Dewailly[16] measures only pain flow over time. Its general applicability as an outcome measure for clinical trials purposes remains to be established. In view of the limitations of currently available instruments, there remains a need for a multidimensional, disease-specific, patient-reported outcome measure for OA hand studies. As a consequence, we have developed the item inventory for a patient-relevant, self-administered questionnaire.

The necessity for conducting 50 patient interviews was based, in part, on prior experience with the development of the WOMAC OA Index item inventory[21], and was considered adequate to generate the test item inventory for the AUSCAN Index. In that prior experience with the WOMAC Index, only one additional item was generated by one individual, the vast majority of retained items being contributed by the first 50 patients. The predominance of female subjects in the item generation sample was comparable to the approximate 2–3:1 ratio in reported OA hand clinical trials. Hand dominance (left vs right vs ambidextrous), hand involvement (unilateral vs bilateral), the configuration of hand joint involvement (IP alone vs first CMC alone vs both IP and first CMC), and the number of joints involved (one vs several) in OA can be quite variable, creating a large number of possible permutations. From the standpoint of item generation, the inclusion of right-handed, as well as left-handed patients, and the inclusion of patients with several different configurations of hand joint involvement provided opportunity to address issues of variability in disease expression and hand dominance. The performance of the final index in several of the aforementioned subgroups, will be the subject of future study.

The AUSCAN Index is intended as an evaluative instrument for the measurement of clinically meaningful outcomes in clinical trials in OA of the hand. The principal advantages of a self-administered questionnaire are: (1) observer variation is eliminated, (2) administration costs are substantially reduced, (3) the format can be standardized, is readily portable, and (4) the index can be translated into different languages. We contend that in symptomatic disease states, it is the patient who should define the clinical importance of change in health status. In evaluation, we are interested in change, and in this context, a clinically important difference in health status at two points in time can be defined as 'any change, for the better or worse, which the patient, himself/herself, can appreciate'. Measures, such as range of movement and grip strength, elude this definition since the clinical consequence to the patient of a performance detriment cannot be readily appreciated. The clinically meaningful outcome, which this index will attempt to measure, is disability.

The object of the process of item generation is to define the various components of a disease state for the subsequent purposes of measurement. An item pool may be generated from one of three sources: (1) medical literature, (2) physicians and other health care providers, and (3) patients (or disease-free members of the general public). The medical literature provides a convenient source of items and capitalizes on the experience of other investigators who have pondered similar questions. However, while this approach provides a base on which to build, it cannot be considered entirely satisfactory, since it fails to consider items which may be peculiar to OA of the hands and assumes that no differences exist with other conditions. In general, physicians and other health care providers can make a significant contribution to index development. However, the most important source of information is the patient who is in the reference condition, and who has personally experienced the various manifestations of that condition. Since there are interindividual differences in the disease experience, it is important to interview sufficient subjects, to gain an adequate appreciation of the dimensionality of the condition.

The five pain items retained as candidate items were focused on pain situations (rest, gripping, turning etc.), while those relegated to 'reserve' item status focused on pain during differing degrees of severity of effort (light activity, heavy activity, repetitive activity). Although pain during the night did not meet the 50% prevalence selection criteria, we elected to carry it on to the next stage, as a 'reserve' item because of the potential importance of nocturnal pain in disturbing sleep.

The morning stiffness item was retained as a candidate item on the basis of its higher prevalence. Following discussions within the development group, the stiffness later in the day question was relegated to 'reserve' item status.

Of the 30 physical function items that fulfilled the prevalence criterion, five were excluded: (1) unfastening jewelry since it is an alternative of fastening jewelry, (2) turning taps/faucets off is an alternative of turning taps/faucets on, (3) peeling fruit was combined with peeling vegetables to eliminate duplication, (4) opening/closing a safety pin was considered as being too restrictive, and (5) using a screwdriver, wrench or hammer could be gender biased. Several changes were made to the original wording of the items. Using a can opener was reworded to using a manual can opener to avoid confusion with an electric can opener. Carrying a full pot was disaggregated into two questions, one addressing difficulty with one hand, the other querying difficulty with two hands. Similarly, grabbing a full bottle and raising it was split into two questions, again addressing difficulty of using one vs two hands. We also added 'one litre' to the wording to clarify bottle size. Two composite items, gripping and turning a key in a lock and gripping and turning a round doorknob or handle, were simplified to

turning. These modifications resulted in 27 physical function items being carried forward, nine designated as candidate items, and 18 as 'reserve' items, to the next stage of development.

The potential advantages of the AUSCAN Index at the item generation stage of the development are conceptual and operational. Compared with the FIHOA and Cochin Indices, the AUSCAN Index contains two additional subscales (pain and joint stiffness), and is patient self-completed, rather than being interviewer administered. In addition, the AUSCAN item content was generated through a series of interviews with symptomatic and OA patients.

In conclusion, we have developed a 15-item patient relevant questionnaire that assesses pain, stiffness and physical disability in patients with OA of the hand. While the resulting index may find application in various forms of hand OA, our goal is to develop the item inventory for a patient, self-reported, health status questionnaire applicable to clinical trials in primary hand OA. The reliability, validity and responsiveness of this questionnaire will be investigated in the next step in the development of this index[33]. These 15 items capture a combination of OA hand symptoms that are common, frequently recurring and of general importance to OA hand patients. The 'reserve' items will be separately evaluated to progress our understanding of the consequences of early vs late item reduction in index construction, but they are not directly relevant to the subsequent evaluation of the clinimetric properties of the AUSCAN Osteoarthritis Hand Index.

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References

1. Flatt AE. Correction of arthritic deformities of the hand. In: McCarty DJ, Koopman WJ, Eds. Arthritis and Allied Conditions—A Textbook of Rheumatology, 12th ed. Philadelphia: Lea & Febiger 1993:919–38.
2. Lequesne M, Maheu E, (Eds). Special Issue: Osteoarthritis of the Hand: New Data and Prospective. Proceedings of an International Seminar, Marbella, Spain, 14–15 October, 1994. Revue de Rhumatisme [English ed.] 1995;62, No. 6(Suppl 1).
3. Maheu E, Pelletier J-P, Lequesne M (Eds). Proceedings of the Second International Workshop on Hand Osteoarthritis, Boston, USA, 21–22 May 1999. Osteoarthritis Cart 2000;8(Supplement A).
4. Bellamy N. Musculosketal Clinical Metrology. Dordrecht: Kluwer Academic Publishers 1993.
5. Hochberg MC, Vignon E, Maheu E. Session 2: Clinical aspects. Clinical assessment of hand OA. Osteoarthritis Cart 2000;8(Suppl A):S38–40. doi:10.1053/joca.2000.0335.
6. Lequesne MG, Maheu E. Methodology of clinical trials in hand osteoarthritis: conventional and proposed tools. Osteoarthritis Cart 2000;8(Suppl A):S64–9. doi:10.1053/joca.1999.0340.
7. Chevalier X, Mejjad O, Babin S. Session 4: Methodology for the assessment of treatments of hand osteoarthritis. Osteoarthritis Cart 2000;8(Suppl A):S70–2. doi:10.1053/joca.2000.0341.
8. Dreiser RL, Maheu E, Guillou GB, Caspard H, Grouin JM. Validation of an algofunctional index for osteoarthritis of the hand. Rev Rheum (English ed.) 1995;62(Suppl 1):43S–53S.
9. Dreiser RL, Maheu E. Inter-rater reproducibility of a functional index for hand osteoarthritis (HOA). (Abstract). Osteoarthritis Cart 1997;5(Suppl A):57.
10. Dreiser RL, Maheu E, Guillou GB. Sensitivity to change of the functional index for hand osteoarthritis. Osteoarthritis Cart 2000;8(Suppl A):S25–8. doi:10.1053/joca.2000.0332.
11. Duruöz MT, Poiraudeau S, Fermanian J, Menkes C, Amor B, Dougados M, *et al*. Development and validation of a rheumatoid hand functional disability scale that assesses functional handicap. J Rheumatol 1996;23:1167–72.
12. Poiraudeau S, Lefevre-Colau MM, Fermanian J, Revel M. The ability of the Cochin rheumatoid arthritis hand functional scale to detect change during the course of disease. Arthritis Care Res 2000;13:296–303.
13. Cerrahoglu L, Dinçer F, Ünlü Z, Oguz AK, Duruöz MT. Validation of the Duruöz's Hand Index (DHI) for osteoarthritis (OA) of the hand (Abstract). Ann Rheum Dis 2000;59(Suppl 1).
14. Poiraudeau S, Chevalier X, Conrozier T, Flippo R-M, Liote F, Noël E, *et al*. Reliability, validity, and sensitivity to change of the Cochin hand functional disability scale in hand osteoarthritis. Osteoarthritis Cart 2001;9:570–7.
15. Sautner J, Rintelen B, Wolf J, Leeb BF. SACRAH (Score for the Assessment and Quantitation of Chronic Rheumatic Affections of the Hands) (Abstract). Arthritis Rheum 2000;43(9)(Suppl):S223.
16. Maheu E, Dewailly J. Weekly self-assessment of painful joints in hand osteoarthritis (HOA): a new assessment tool. Preliminary validation study (Abstract). Arthritis Rheum 1997;40(9)(Suppl):S236.
17. Hirsch R, Guralnik JM, Leveille S, Smonsick E, Ling SM, Bandeen-Roche K, *et al*. Assessing the impact of hand osteoarthritis: new indices to measure severity independent of function (Abstract). Arthritis Rheum 1997;40(9)(Suppl):S236.
18. Hudak P, Amadio PC, Bombardier C, and the Upper Extremity Collaborative Group (UECG). Development of an upper extremity outcome measure: The DASH (Disabilities of the Arm, Shoulder, and Hand). Am J Ind Med 1996;29:602–8.
19. Bellamy N. WOMAC Osteoarthritis Index—User's Guide III. 1998, 27 pp.
20. Altman R, Brandt K, Hochberg M, Moskowitz R and the Task Force of the Osteoarthritis Research Society. Design and conduct of clinical trials in patients with osteoarthritis: recommendations from a task force of the Osteoarthritis Research Society. Osteoarthritis Cart 1996;4:217–43.
21. Bellamy N, Buchanan WW. A preliminary evaluation of the dimensionality and clinical importance of pain and disability in osteoarthritis of the hip and knee. Clin Rheumatol 1986;5(2):231–41.
22. Altman RD. Criteria for classification of clinical osteoarthritis. J Rheumatol 1991;18(Suppl.27):10–12.

23. Meenan RF, Gurtman PM, Mason JH. Measuring health status in arthritis: the Arthritis Impact Measurement Scales. Arthritis Rheum 1980;23(2):146–52.
24. Fries JF, Spitz P, Kraines RG, Holman HR. Measurement of patient outcome in arthritis. Arthritis Rheum 1980;23:137–45.
25. Liang MH, Jette AM. Measuring functional ability in chronic arthritis: a critical review. Arthritis Rheum 1981;24:80–6.
26. Jebsen RH, Taylor N, Trieschmann RB, Trotter MJ, Howard LA. An objective and standardized test of hand function. Arch Phys Med Rehabil 1969;50:311–19.
27. Smythe HA, Helewa A, Goldsmith CH. 'Independent Assessor' and 'Pooled Index' as techniques for measuring treatment effects in rheumatoid arthritis. J Rheumatol 1977;4:144–52.
28. Lee P, Jasani MK, Dick WC, Buchanan WW. Evaluation of a functional index in rheumatoid arthritis. Scand J Rheumatol 1973;2:71–7.
29. Convery FR, Minteer MA, Amiel D, Connett KL. Polyarticular disability: a functional assessment. Arch Phys Med Rehabil 1977;58:494–9.
30. Tugwell P, Bombardier C, Buchanan WW, Goldsmith CH, Grace E, Hanna B. The MACTAR patient preference disability questionnaire—an individualized functional priority approach for assessing improvement in physical disability in clinical trials in rheumatoid arthritis. J Rheumatol 1987;14:446–51.
31. Woodward CA, Chambers LW. Guide to Questionnaire Construction and Question Writing. Ottawa: Canadian Public Health Association 1983.
32. Guyatt GH, Bombardier C, Tugwell PX. Measuring disease-specific quality of life in clinical trials. CMAJ 1986;134:889–95.
33. Bellamy N, Campbell J, Haraoui B, Gerecz-Simon E, Buchbinder R, Hobby K, *et al*. Clinimetric properties of the AUSCAN Osteoarthritis Hand Index: An evaluation of reliability, validity and responsiveness. Osteoarthritis Cart 2000;11:863–869.