Cross-cultural adaptation and validation of the French version of the rheumatoid and arthritis outcome score (RAOS)

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Abstract

Objectives

The Rheumatoid and Arthritis Outcome Score (RAOS) was recently developed to evaluate functional disability and quality of life in rheumatoid arthritis (RA) patients suffering from lower limb symptoms. The aims of this study were to cross-culturally adapt the RAOS into French and to assess its psychometric properties, in particular, responsiveness following intra-articular therapy.

Methods

The French RAOS was developed according to cross-cultural guidelines and was then evaluated in symptomatic RA patients with lower limb joint involvement. The psychometric properties assessed were – feasibility: percentage of missing data and floor and ceiling effects; reliability: intra-class correlation coefficients (ICC, and Bland and Altman representation; internal consistency: Cronbach's alpha; construct validity by correlation with the SF-36 and HAQ (Spearman's rank test); responsiveness to intra-articular corticosteroid injection (hip, knee, hindfoot) using standardised response mean (SRM) and effect size.

Results

Sixty patients were included (mean age 50.1±10.5 years). Neither floor nor ceiling effects were observed. Reliability was good with ICC for different RAOS subscales ranging from 0.76 to 0.91. Results for internal consistency (Cronbach's alpha ranging from 0.73 to 0.91) and construct validity were good. The responsiveness was moderate to large with SRMs ranging from 0.75 to 0.87 and effect sizes from 0.77 to 1.75 at two weeks following intra-articular corticosteroid injection.

Conclusion

The French version of the RAOS demonstrated good psychometric properties to capture functional disability and quality of life in RA. Moreover, the results suggest that the RAOS could be used as an outcome in trials evaluating single joint intra-articular injections.

Key words

rheumatoid arthritis, RAOS, cross-cultural adaptation, validity, reliability, responsiveness

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Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory disease affecting in particular weight-bearing joints, with significant pain and functional disability that severely impair patients' quality of life (1). In recent years, the treatment and prognosis of RA have been dramatically improved by new strategies and/or powerful agents, in particular, anti-tumour necrosis factors (TNF) and other biologics. However, some patients respond to systemically delivered therapies but complain of persistent pain and swelling of one or a few joints. In this context, the classical approach used by rheumatologists has been to administer an intra-articular corticosteroids injection (2, 3). In recent years, new approaches, such as intra-articular injections of cytokine antagonists, gene transfer agents that express cytokine antagonists, have been discussed (4-6). However, as pointed out recently by an OMERACT (Outcome Measures in Rheumatology) special interest group (7), while RA global activity, functional impairment and quality of life are assessed both in clinical research and day-to-day practice using validated generic or specific instruments (the Disease Activity Score (DAS), the Health Assessment Questionnaire (HAQ) or the Short Form Health Survey Questionnaire (SF-36)), there is a need to develop endpoints and outcomes specifically aimed at evaluating the efficacy of single joint, rather than systemic treatments (7, 8).

The Rheumatoid and Arthritis Outcome Score (RAOS) (9) is an adaptation of the Knee injury and Osteoarthritis Outcome Score (KOOS) (10). This self-administered questionnaire has been recently developed to specifically evaluate the impact of hip, knee or foot impairment on pain, function and quality of life in patients with chronic inflammatory rheumatic diseases. Therefore, it might be used as an outcome in trials evaluating intra-articular agents in RA, when delivered in a lower limb joint.

To evaluate a potential outcome measure, it is necessary to assess its psychometric properties, as defined by the OMERACT filter (11). The OMERACT filter checks that a potential outcome measure is (a) feasible, (b) truthful, *i.e.*, reflects what it is supposed to reflect (validity), (c) discriminant which includes reliability and sensitivity to change. The RAOS has been shown to be a valid, reliable and responsive instrument following general treatment, *i.e.*, physical therapy (9, 12).

Another property of an outcome, which does not appear in the OMERACT filter, is its generalisation. Since the number of large multicentre international studies is increasing, and since the results of epidemiologic and/or therapeutic studies must be clinically meaningful in every country, there is a need for cross-cultural adaptation and validation of health status measures (13). Such process requires not only translation, but also adjustment of cultural words, idioms, and colloquialisms (13-16). This process may involve substantial transformation of some items to fully capture the essence of the original concept (14, 15). To our knowledge, the RAOS is currently available in the Swedish (9), English (9), and Turkish (12) languages.

Thus, the aims of this study were to cross-culturally adapt the RAOS into French and to assess the psychometric properties of the adapted version, in particular responsiveness following lower limb intra-articular therapy in RA patients.

Methods

A two-step procedure was used:

Firstly, the instrument was translated and cross-culturally adapted into French.

Secondly, the psychometric properties of the adapted instrument were studied in a prospective study.

Translation and cross-cultural adaptation process

The translation and cross-cultural adaptation from the source English version was performed according to published international recommendations (13-17).

Preparation. The project manager contacted the developer (ER) to obtain permission to use and translate the instrument and to propose participation in the work.

Forward translation. Three persons (2 rheumatologists, including the project

manager, and one teacher of English) native in the target language translated independently the English version of RAOS into French.

Reconciliation. A final single version was obtained after a consensus meeting of the three translators.

Backward translation. The final consensus version was back translated literally into English by a bilingual native English speaker, blinded to the English original version.

Back translation review and harmonisation. The project manager reviewed the back translation against the source, in order to check for discrepancies. Then, a multidisciplinary consensus committee, including the three translators, another rheumatologist, an orthopaedic surgeon, and a rheumatologist and epidemiologist specialised in cross-cultural adaptation, was constituted. During a meeting, the committee checked that the translation was fully comprehensive, verified cross-cultural equivalence of the source and final versions, and by consensus produced a final version.

Cognitive debriefing and review. The final version was pre-tested among 15 French patients suffering from RA with characteristics comparable to those of the patients included in the second part of the study. They were asked whether they fully understood all items and whether they had problems with the formulation of the items of the French version.

Proof reading. In a final step, the project manager checked the final translation and corrected any errors.

Psychometric properties of the French version of RAOS

– Patients

Outpatients seen for RA at the Rheumatology Department of the Dijon University Hospital in France were included in this prospective study between July 2008 and July 2009.

The inclusion criteria were RA according to the ACR 1987 criteria (18) and the presence of symptomatic single-joint arthritis of the lower limbs (hindfoot, knee or hip). Patients had to be able to understand and complete the self-report questionnaires.

Patients with other significant rheumatic diseases, very active RA (DAS28 ≥5.1), recent joint surgery, intra-articular injection in the target joint or changes in RA treatment during the previous three months were excluded.

– Questionnaires

During the initial assessment, patients were asked to fill in the French version of the RAOS questionnaire, the SF-36 and the HAQ.

The RAOS (9) is a self-administered instrument and consists of 42 items assessing five separate patient-relevant dimensions: pain (9 items), other symptoms like stiffness, swelling, and range of motion (7 items); function in Activities of Daily Living (Function ADL) (17 items); function in sport and recreational activities (Function Sport and Recreation) (5 items); and lower limb related Quality of Life (QOL) (4 items). Five Likert boxes are used (no, mild, moderate, severe, extreme) to answer each question. Raw scores are then transformed to a 0-to-100, worst-to-best, scale. The mean scores for all five subscales can be plotted and connected with a line in an outcome profile. Missing data were treated according to RAOS guidelines (9), *i.e*. when more than two of the items of a domain were missing, the score was not calculated.

The SF-36 (19) is a widely used, self-administered, generic instrument for the evaluation of health status, and comprises eight subscales to assess physical and mental health to various degrees (Physical Function, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional and Mental Health). The SF36 has been validated in RA patients (20).

The HAQ (1) is a self-administered, RA disease-specific questionnaire. The HAQ contains 20 items and assesses the degree of difficulty experienced by the patient in performing activities of daily living during the previous week.

For the HAQ and the SF-36 questionnaires, when at least one item was missing, the score was not calculated.

– Feasibility

Feasibility was assessed at the baseline administration using the percentage of missing items and using the floor and ceiling effects of the baseline questionnaires. Floor and ceiling effects were considered present if more than 15% of the respondents achieved the highest or lowest possible RAOS scores (9).

– Reliability

Patients for whom RA treatment was not changed during the visit were included in the reliability assessment. For that purpose, they were given a second RAOS questionnaire and were instructed to complete and return by mail two weeks later, using a pre-stamped envelope. Evaluation of the reliability used the intra-class correlation coefficient (ICC) (two-way model, single measure), with a 95% confidence interval (CI). An ICC of more than 0.8 is usually considered to be indicative of excellent reliability (21). In addition, the Bland and Altman representations (22), in which the difference between the first and the second assessment (ordinate) is plotted against the mean of the two assessments (abscissa), were obtained. Such representations make it possible to describe the percentage of subjects and their distribution within the 95% limits of agreement along the range of the score scale. The smallest detectable difference (SDD) is then defined as 1.96 SD of the difference between measurements and provides an absolute estimate of measurement error (23).

– Internal consistency

Internal consistency was evaluated at the baseline administration using Cronbach's alpha coefficient (24). A Cronbach value >0.7 is generally regarded as satisfactory (25).

– Construct validity

Construct validity was determined by comparing the results of the baseline RAOS, SF-36 and HAQ questionnaires using Spearman's rank correlation. Coefficient correlations >0.5, 0.5–0.35, <0.35 were considered as strong, moderate, and weak, respectively (10, 26). *A priori* hypotheses were generated for convergent (moderate to strong correlation expected) and divergent (weak correlation expected) construct validity, according to the theoretical measurement of similar or divergent constructs and to

data from the literature. It was hypothesised that the RAOS pain, symptoms and function ADL subscales would strongly or moderately correlate with the SF-36 subscales assessing functional impairment and pain (role physical, bodily pain, physical function). Weak correlations were expected between all RAOS and SF-36 subscales assessing mental state (Role Emotional and Mental Health). Since the HAQ is a measure of QOL and functional disability in RA patients (20), it was expected to have moderate to strong correlations with the RAOS subscales function ADL, function Sport and Recreation and QOL.

– Responsiveness

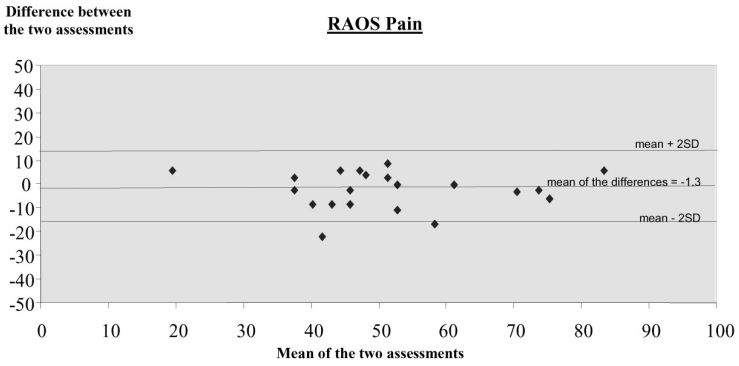
Responsiveness was assessed by comparing the results of the pre and two weeks post-corticosteroid injections (cortivazol) in patients for whom the rheumatologist indicated an intra-articular corticosteroid injection of a hip, a knee, or a hindfoot, without changing the systemically delivered therapy. The indication for intra-articular injection was a persistent single joint arthritis of the lower limb with a satisfactory overall control of global disease activity. For the hip, the presence of persistent synovitis was controlled using ultrasound (US) and the injection was US-guided. Regarding the hindfoot, the localisation of the synovitis was assessed using US. Then, patients eligible for responsiveness were given a second RAOS questionnaire which they were instructed to complete and return by mail two weeks later, using a pre-stamped envelope. The

Table I. Baseline characteristics of the patients included (n=60).

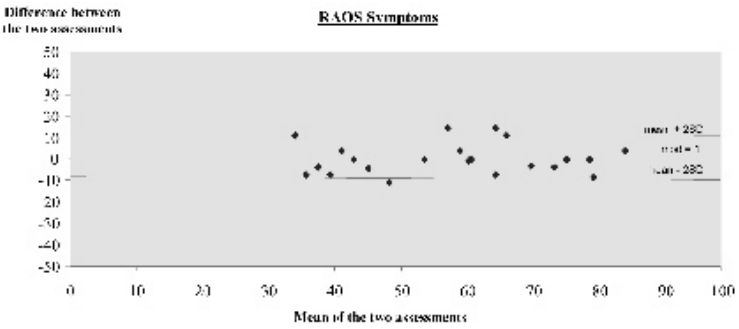
Number of patients	60
Age years mean (SD)	50 (10.5)
Gender % female	77.5
Disease duration years mean (SD)	12.4 (9.7)
DAS 28 at baseline mean (SD)	3.7 (1.8)
HAQ at baseline mean (SD)	1.47 (0.75)

DAS: Disease Activity Score; HAQ: Health Assessment Questionnaire.

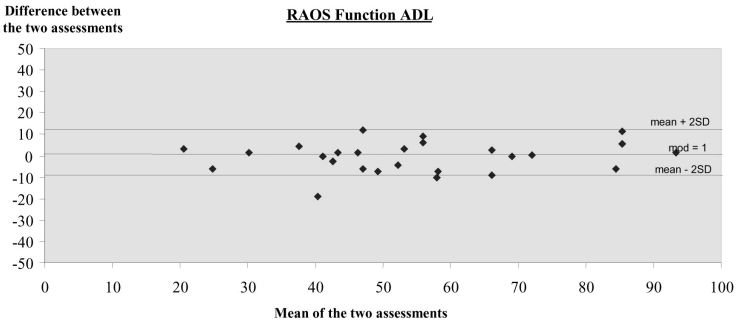
a. Pain subscale.



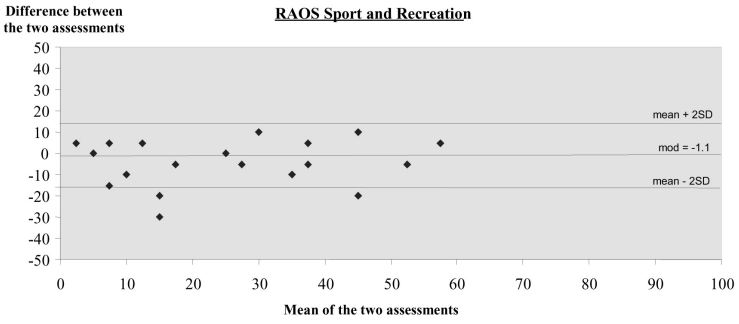
b. Symptoms subscale.



c. Function in Activity of daily living subscale.



d. Function in Sports and recreation subscale.



e. Quality of life subscale.

mod = mean of difference

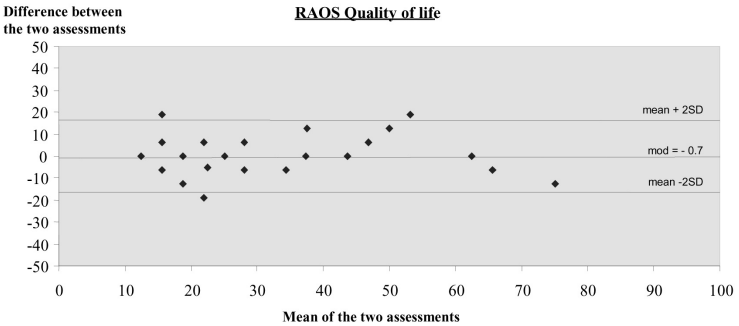


Fig. 1. Reliability of the French RAOS subscales presented as Bland and Altman representations. Two assessments were made, separated by a 2-week interval.
95% limits of agreement correspond to the mean difference between two measurements ± 1.96 SD.

Table II. Internal consistency (n=60) of RAOS subscales given as Cronbach's alpha coefficient and test-retest reliability (n=28) given as intra-class correlation coefficient (ICC) and smallest detectable difference (SDD).

RAOS subscales (number of items)	Mean RAOS score		ICC (95% CI)	SDD	Cronbach's alpha coefficient (95% IC)
	First assessment Mean (SD)	First assessment Mean (SD)			
Pain (9)	47.7 (17.1)	47.6 (19.6)	0.82 (0.62–0.91)	15.1	0.87 (0.79–0.93)
Symptoms (7)	56.3 (18.6)	54.0 (19.7)	0.86 (0.71–0.93)	10.5	0.73 (0.62–0.81)
Function ADL (17)	54.8 (19.4)	54.5 (18.6)	0.91 (0.82–0.96)	9.6	0.91 (0.83–0.96)
Function sport/ recreation (5)	22.8 (19.6)	23.3 (18.1)	0.76 (0.51–0.89)	15.5	0.84 (0.76–0.90)
QOL (4)	31.6 (18.3)	31.9 (18.4)	0.84 (0.67–0.92)	16.1	0.80 (0.74–0.85)

*The SDD is defined as 1.96 SD of the change between the first and second assessment (two-week interval) for each RAOS subscales. 0: worst to 100=best; CI: confidence interval; ADL: activities of daily living; QOL: quality of life.

Table III. Construct validity: correlations between French RAOS and the SF-36 and the HAQ questionnaires (n=46).

	RAOS subscales				
	Pain	Symp	ADL	Sport	QOL
SF-36 subscales					
Physical function	0.48*	0.43*	0.57*	0.35*	0.18
Role physical	0.38*	0.52*	0.32*	0.37*	0.31*
Bodily pain	0.56*	0.51*	0.55*	0.21	0.18
General health	0.17	0.22	0.21	-0.007	0.13
Vitality	0.14	0.31*	0.25	0.10	-0.001
Social functioning	0.05	0.29*	0.14	0.35*	0.15
Role emotional	0.23	0.33*	0.19	0.09	-0.06
Mental health	0.02	0.22	0.16	0.20	0.15
Physical component score	0.64*	0.57*	0.69*	0.30*	0.35*
Mental somponent score	0.007	0.26	0.07	0.16	0.001
HAQ	-0.32*	-0.43*	-0.58*	-0.39*	-0.42*

Spearman's correlation coefficient; *p-value <0.05; Symp: symptoms; ADL: activities of daily living; QOL: quality of life; HAQ: Health Assessment Questionnaire.

standardised response mean (SRM), *i.e.*, the mean change between baseline and 2 weeks after injection divided by the standard deviation of the mean change; and Cohen's effect size (ES) (27), *i.e.*, mean change between baseline and 2 weeks after injection divided by the standard deviation of the pre-injection values, were calculated. An SRM or ES >0.8 is considered large (27).

The Statistical Package for the Social Sciences (SPSS) version 14.0 was used for data management and statistical analyses. Statistical significance was defined as $p<0.05$.

Results

Translation process

Only slight differences were observed in the structure of the sentences between the original and back-translated versions. Before reaching a consensus, the committee discussed at length the adaptation of words to maintain concepts and the correct wording to allow the questionnaire to be fully understood by all patients. A large majority of RA patients felt that the questionnaire was clear and easy to complete.

Patient characteristics

A total of 60 subjects were included (77.5% women, mean age 50.1±10.5 years, disease duration 12.4±9.7 years). The mean values of the HAQ and DAS 28 were 1.47±0.75 and 3.7±1.8, respectively (Table I).

Internal consistency was evaluated using the first questionnaire filled in by all patients.

In 30 out of 60 patients, the treatment was not initially modified and intra-articular injection was not performed. These patients were included in the test-retest assessment of reliability. A large majority (28/30) returned their two-week questionnaire.

Forty-six patients answered the RAOS, the HAQ and the SF-36 questionnaires, which allowed the assessment of the construct validity.

In 48 patients (among whom 18 have also participated in the reliability study before), an intra-articular injection of the hip (2 patients), the knee (15 patients), or the hindfoot (31 patients) was performed. All but two returned their two-week questionnaire.

Evaluation of the psychometric properties

The RAOS was well understood by all patients. No floor or ceiling effect was observed for any subscale. Few individual items were missing (2.6%). The total score was always obtained for the Symptoms, Function Sport and Recreation and QOL subscales, and could not be calculated once for the pain and ADL subscales. The reliability was good to excellent, with ICC ranging from 0.76 to 0.91 (Table II). The SDD ranged from 9.6 (Function ADL) to 16.1 (QOL). The Bland and Altman graphic representations are shown in Figure 1. The internal consistency of the RAOS was good to excellent, with Cronbach's alpha ranging from 0.73 (Symptoms) to 0.91 (Function ADL) (Table II).

The results of convergent and divergent construct validity are shown in Table III. As expected, high or moderate correlations were found between domains of the RAOS and the SF-36 that intended to measure similar constructs: RAOS Pain and Symptoms and Function ADL correlated moderately to strongly with SF-36 Bodily pain, Physical Function, and Role Physical. As hypothesised, RAOS subscales correlated weakly with mental SF-36 subscales (Role Emotional and Mental Health). The HAQ questionnaire was correlated, as expected, with all RAOS subscales, particularly Symptoms, Function ADL and Quality of Life. In contrast, some unexpected results were

Table IV. Responsiveness of French RAOS subscales (n=46).

RAOS subscales (number items)	Foot n=31				Knee n=15				All joints n=46			
	Pre Mean (SD)	Post Mean (SD)	SRM	ES	Pre Mean (SD)	Post Mean (SD)	SRM	ES	Pre Mean (SD)	Post Mean (SD)	SRM	ES
Pain (9)	38.6 (11.2)	57.3 (26.2)	0.66	1.67	38.4 (11.9)	59.0 (18.0)	1.21	1.73	38.9 (11.4)	59.0 (23.8)	0.79	1.75
Symptoms (7)	47.8 (14.9)	62.7 (22.0)	0.66	0.99	43.5 (17.3)	66.2 (17.7)	1.89	1.31	47.4 (16.0)	64.8 (20.7)	0.87	1.09
Function ADL (17)	41.9 (15.1)	59.8 (23.8)	0.69	1.19	40.9 (15.6)	63.6 (22.3)	1.18	1.46	42.1 (15.7)	61.8 (22.8)	0.83	1.25
Function Sport/ recreation (5)	19.9 (12.5)	38.0 (26.2)	0.70	1.45	21.8 (17.2)	39.9 (33.0)	0.85	1.05	20.5 (13.7)	38.6 (27.6)	0.75	1.32
QOL (4)	28.6 (15.7)	41.1 (24.5)	0.69	0.80	40.0 (17.8)	54.3 (19.3)	1.05	0.80	31.6 (16.8)	44.5 (23.3)	0.79	0.77

Patients were evaluated prior to and 2 weeks after intra-articular corticosteroid injection.
0: worst to 100 = best; ADL: activities of daily living; QOL: quality of life; SRM: standardised response mean; ES: effect size.

observed: weak correlations were found between the RAOS QOL subscale and all SF-36 subscales.

The responsiveness was moderate to large for all domains, with SRM ranging from 0.75 (Function Sport and Recreation) to 0.87 (symptoms) and ES from 0.77 (QOL) to 1.75 (Pain) (Table IV). Additional analyses were performed for the knee alone and the hindfoot alone with again satisfactory responsiveness (Table IV). RAOS outcome profile for ultrasound guided hindfoot steroid injection is shown in Figure 2.

Discussion

In the present work, the English version of the RAOS questionnaire was cross-culturally adapted into French. The psychometric properties of the translated version were found to be satisfactory in RA patients with lower limb involvement and similar to previous versions (9, 12). Moreover, the responsiveness was good after intra-articular corticosteroid injection, suggesting that the RAOS might be used as an outcome in trials evaluating the effects of lower limb single joint intra-articular treatments in RA (7). The French version of the RAOS is not copyrighted and is freely available from the KOOS website (www.KOOS.nu) (28).

The findings from this study must be considered in light of their limitations: firstly, participating subjects might not be representative of the entire spectrum of RA patients as they were recruited from a University Hospital, and thus might have suffered from a more aggressive disease than the whole RA population. Secondly, the responsiveness of the RAOS was not evaluated following systemic treatments such as Disease Modifying Anti Rheumatic Drugs (DMARDs) or biologics. However, as stated above, the RAOS might be of particular interest in evaluating local intra-articular treatments (7, 8), in which validated outcomes are lacking, rather than systemically administered drugs, which can be evaluated using numerous validated outcomes. Thirdly, only two patients with hip synovitis were included, not allowing separate evaluation of responsiveness after injection of this joint. In addition, the number of patients who underwent a knee intra-articular injection was quite small. Thus, additional studies are needed for confirmation and generalisation.

The French version of the RAOS questionnaire seems to be a feasible self-administered instrument as demonstrated by the low proportion of missing data. The mean scores of the QOL and Sport and Recreation function subscales were notably lower than the scores of the other RAOS subscales, as previously reported (9). The test-retest reliability coefficients were high for all RAOS subscales, which is in keeping with previous studies (9, 12). According to the Bland and Altman representations (22), the difference between repeated measurements was not related to the mean of the measurements. The results for internal consistency were good for all subscales and comparable to those observed in other languages (9, 12), indicating a homogeneous questionnaire. In line with the original version (9), the highest

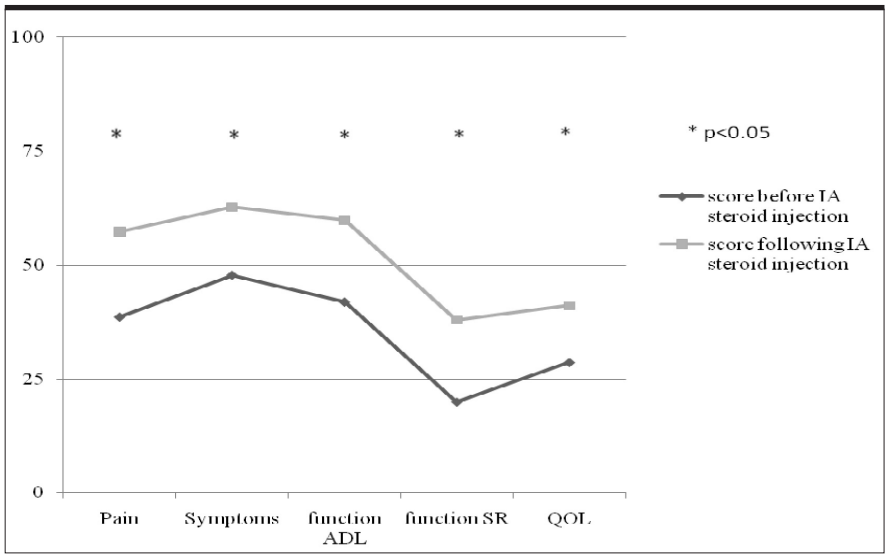


Fig. 2. Responsiveness of French RAOS subscales (outcome profile): RAOS subscales prior to and 2 weeks following ultrasound-guided corticosteroid injection of hindfoot (n=31).
This scale is 0–100, worst to best. ADL: activity of daily life; QOL: quality of life; IA: intra articular; Function SR: function in Sport and Recreation subscale.

Cronbach's alpha was found for the ADL subscale. Validated and commonly used instruments for assessing RA disability were chosen to evaluate construct validity of the RAOS. The results of the correlations support the idea that the French RAOS shows evidence of convergent and divergent construct validity. As expected, stronger correlations were found when the RAOS was compared with the SF-36 subscales of similar constructs (pain, physical activities and function), which is in agreement with previous studies (9, 12). However, the correlations between the RAOS QOL and SF36 subscales related to physical function were weak. This finding was not reported in the original study (9). Further studies are needed to shed light on this unexpected result. Responsiveness over time is a key psychometric property of a measurement instrument since high sensitivity to change makes it possible to reduce the number of subjects needed to demonstrate a significant difference between groups. To our knowledge, the RAOS responsiveness to intra-articular injection of pharmacological treatments had not yet been evaluated. While the original RAOS and the Turkish version (9, 12) have been shown to capture improvements induced by global exercise therapy, it was rewarding to discover that the questionnaire was able to assess interventions directed towards a single inflammatory joint. The present results are very encouraging since 1- all the RAOS subscales scores were markedly improved 14 days after intra-articular injection of corticosteroids, 2- the SRM and ES were moderate to large, ranging from 0.75 to 0.87 and from 0.77 to 1.75, respectively, 3- the analyses focused on knee and hindfoot subgroups were consistent with what was observed in the whole sample, with again good SRM and ES.

In conclusion, the French version of the RAOS is a feasible, reliable, valid and responsive instrument to capture specific aspects of functional disability affecting quality of life in RA patients suffering from disease in the lower limb joints. Moreover, the present results suggest that the RAOS could be used as an outcome in trials evaluating single joint intra-articular injections in RA.

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