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# Novel outcome measures for patients with "impingement" symptoms



The Western Ontario Rotator Cuff (WORC) score in rotator cuff disease patients - A comprehensive reliability and responsiveness validation study -

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# Abstract

**Background:** The Western Ontario Rotator Cuff index (WORC) is an increasingly applied condition-specific outcome measure for rotator cuff (RC) pathologies. However, in most WORC validation studies only a limited number of psychometric properties are studied in indistinct patient groups.

**Purpose:** Assess psychometric properties of the WORC according to the Scientific Advisory Committee quality criteria for health questionnaires in three patient groups with distinct RC conditions.

Study design: Descriptive Epidemiology Study.

**Methods:** The WORC (range 0-100, 21 items, 5 domains) was administered twice (T1, T2) in 92 patients (35 RC tear, 35 calcific tendinitis, 22 impingement). Additionally, the Constant Score (CS) and the Disabilities of the Arm, Shoulder and Hand score (DASH) were recorded. Calcific tendinitis patients were re-assessed 6 weeks after treatment with needling and lavage or a subacromial injection with corticosteroids (T3).

We assessed floor/ceiling effects, internal consistency, test-retest reliability, precision, construct validity, minimal detectable change, and responsiveness in subgroups and the total group.

**Results:** Mean age was 55.0 years (SD=8.7) and 49/92 (53%) were female. Mean baseline WORC was 46.8 (SD=20.4), CS 63.9 (SD=15.4) and DASH 40.9 (SD=18.6). Significant differences were found for CS and DASH between RC tear patients (severe symptoms) and the other patients, but not for the WORC. There were no relevant floor and ceiling effects. Internal consistency was high: Cronbach's Alpha coefficient was 0.95. The Intraclass Correlation Coefficient (ICC) of 0.89 and Standard Error of Measurement of 6.9 indicated high reproducibility. Pearson's correlations of the WORC with CS and DASH were 0.56 and -0.65 (both p<0.001). At T3, total WORC improved significantly (mean change 18.8, 95%-CI: 11.3-26.2). Correlations of the WORC change scores with CS and DASH changes were 0.61 and -0.84 (both p<0.001). Effect Size was 0.96, with a Standardized Response Mean of 0.91, indicating good responsiveness.

**Conclusions:** Applied to a variety of RC patients, the WORC had high internal consistency, moderate to good construct validity, high test-retest reliability and good sensitivity to change. These findings support the use of the WORC as a condition-specific self-reported outcome measure in RC patients, but its validity in patients with severe symptoms needs further investigation.

**Keywords:** Rotator Cuff; WORC; Quality of Life; Reliability; Responsiveness; Validity; Shoulder; Questionnaire

# 1. Introduction

Shoulder problems, rotator cuff conditions in particular, are common musculos keletal disorders with a high socioeconomic impact. The incidence of shoulder complaints in general practice is 22 per 1000 patients per year.<sup>1</sup> Rotator cuff conditions cover over 44-65% of these shoulder complaints,<sup>2</sup> with subacromial impingement syndrome, rotator cuff tendon tears and calcific tendinitis as its most frequently diagnosed forms. Young sportive individuals and active participants of society are often affected.<sup>3, 4</sup> Despite high incidence rates and the ensuing high number of ongoing rotator cuff research projects worldwide, there are currently few validated outcome measures focusing on rotator cuff pathologies. For accurate patient assessment however, it is advisable to combine a general health outcome measure, a general regional outcome measure and a condition specific outcome measure.<sup>5</sup> In 2003, Kirkley et al. introduced the English language version of the Western Ontario Rotator Cuff index (WORC): a condition specific self-reported instrument to assess guality of life (QOL) of patients with shoulder complaints as a consequence of rotator cuff disease.<sup>6</sup> It comprises 21 visual analogue score (VAS) items in 5 domains: physical symptoms, sports/recreation, work, lifestyle and emotions. All items represent quality of life aspects that can particularly be influenced by rotator cuff pathology. The domains are based on the World Health Organization definition of health.

The WORC is an increasingly applied outcome measure for rotator cuff conditions,<sup>7-21</sup> and has been translated and validated in several languages, including Dutch, Brazilian, Norwegian, Persian, Turkish and German.<sup>22-28</sup> However, most studies describing the psychometric properties of either the original or translated WORC versions have some limitations: patient groups are small, not well defined, or include only patients with the same rotator cuff condition and similar symptoms. Furthermore, in most validation studies only a limited set of psychometric properties is taken into account. Hence, the goal of this study was to evaluate a comprehensive combination of the most relevant psychometric properties of the WORC, according to the proposed Scientific Advisory Committee (SAC) quality criteria for psychometric properties of health questionnaires,<sup>29, 30</sup> by comparing outcome scores at several follow-up moments in a heterogeneous but strictly defined group of patients with a broad spectrum of rotator cuff conditions of varying severity, including the subacromial impingement syndrome, rotator cuff tendon tears and calcific tendinitis.

# 2. Materials and Methods

# 2.1 Study design

From April 2010, all consecutive patients referred by primary health care for treatment of shoulder pain with arm abduction were assessed for participation in one of three rotator cuff disease research projects, depending on their underlying diagnosis after usual care investigations. Study 1 (Trial registry no.: NTR1545) was a crosssectional study on muscle activation patterns in patients with a full thickness rotator cuff tear vs. healthy controls.<sup>31</sup> Study 2 (NTR2283) was a cross-sectional study on the etiologic mechanisms of the subacromial impingement syndrome with the use of questionnaires on shoulder function, radiographs, Magnetic Resonance Imaging (MRI) and biomechanical methods.<sup>32</sup> Study 3 (NTR2282) was an intervention study on the effectiveness of ultrasound-guided needle puncture, aspiration, lavage and a subacromial injection with corticosteroids in patients with rotator cuff calcific tendinitis. In all three studies the WORC, Disabilities of the Arm, Shoulder and Hand score (DASH)<sup>33</sup> and Constant Score (CS)<sup>34</sup> were used in combination with various other study specific outcome measures. Other than with regard to the current WORC assessments, the three studies were independent and there was no overlap in included patients between the studies. Data of all patients included in the three research projects until July 2011 were used in the current WORC study.

The Medical Ethics Committee approved all three study protocols and written informed consent was obtained from all participants.

#### 2.2 Patients

Each of the three rotator cuff condition research projects had its specific inclusion and exclusion criteria, partially overlapping, with the general selection of patients based on usual care history taking, physical examination and standard shoulder radiographs (anteroposterior in both external and internal rotation).<sup>31, 32</sup> For all studies, patients had one or more of the following criteria present, apart from a positive Neer impingement test, a positive Hawkins test and diffuse unilateral shoulder pain for >3 months: pain during activities with arm abduction, extension and/or internal rotation (e.g. closing the door, putting on jacket, overhead activities); pain at night or incapable of lying on the shoulder; diffuse pain at palpation of the greater tuberosity; disturbed scapulohumeral rhythm; classic painful arc; positive Yocum test<sup>35</sup>; positive full or empty can test.

For all three studies, patients were excluded in case of insufficient language skills or no informed consent, any form of inflammatory arthritis of the shoulder, glenohumeral or acromioclavicular osteoarthritis, a history of surgical interventions of the affected shoulder, clinical signs of cervical radiculopathy, glenohumeral

instability and frozen shoulder syndrome (<90 degrees of passive abduction and external rotation).

With respect to study specific inclusion and exclusion criteria, patients had to be aged 18-75 years for study 1, 35-65 years for study 2, and 18-65 years for study 3. Moreover, patients in study groups 1 and 2 had a MRI arthrogram for usual care diagnostic purposes, that was also used for assessing eligibility criteria of the concerning studies. In study 1, all patients had a symptomatic full thickness rotator cuff tear that was non-responsive to conservative treatment. Patients with an intact rotator cuff or a partial tear could be included in study 2. Furthermore, for both studies 1 and 2, patients were excluded in case of calcific tendinitis or alternative diagnoses on MRI, including intra-articular and bony lesions (Hill Sachs, (old) fractures, tumors), labrum abnormalities, capsular or ligamentous tears/avulsions, superior labral tear from anterior to posterior (SLAP lesion), pulley lesion, Biceps tendinitis or tear, os acromiale, cartilage lesions and bony cysts. As calcific tendinitis can be demonstrated on standard radiographs, it can be distinguished from most other causes of shoulder pain without MRI. Therefore, in study 3, patients underwent radiographs and ultrasound-guided evaluation of the shoulder and were excluded in case of other pathologies, including cuff tendon tears and Biceps tendinitis.

#### 2.3 Assessments

Patients were assessed at three time points: T1 (within 2 weeks before the scheduled outpatient visit); T2 (at the scheduled outpatient visit); and T3 (6 weeks after treatment; only for patients included in study 3).

At T1, the WORC and the Disabilities of the Arm, Shoulder and Hand score (DASH) were administered. These were sent to patients by regular mail, 7-14 days before the scheduled outpatient visit. Patients were requested, over the phone and by regular mail, to complete the questionnaires at least three days before the visit. Patients received written instructions to the questionnaires and did not receive any help with filling them out. At T2 patient characteristics (age, gender, arm dominance, affected arm and duration of symptoms) were recorded and clinical measures (including Constant Score) were obtained at the outpatient clinic of the Department of Orthopaedics by the investigating researcher. Moreover, the WORC was again administered at T2 for test-retest evaluation.

In the calcific tendinitis study, the WORC, DASH and CS were recorded once more at 6 weeks after treatment: WORC and DASH were sent by regular mail before the scheduled outpatient clinic visit. CS was recorded at the outpatient clinic by the investigating researcher. These T3 data were used for responsiveness evaluation.

# 2.3.1 Western Ontario Rotator Cuff index (WORC)

The WORC is a self-reported disease-specific QOL measure, comprising 21 items in five domains: physical symptoms (6 items), sports and recreation (4 items), work (4 items), lifestyle (4 items) and emotions (3 items).<sup>6</sup> Each item is scored on a 0-10 cm visual analog scale (the higher the rating, the higher the negative impact on quality of life), summing up to a minimum total score of 0 and a maximum total score of 2100 (worst possible). In a more clinical comprehensible format, the maximum score can be expressed as a percentage score by subtracting the total score from 2100, dividing by 2100 and multiplying by 100%, leading to total outcomes ranging from 0 (worst possible) to 100 (best possible).<sup>6</sup> In case of one missing value in a domain, the domain score can be calculated using the average of the other items in the domain. In case of more than two missing items in a domain, the concerning WORC questionnaire is considered incomplete, and must be excluded from analyses. In this study, we used the Dutch translation of the WORC. Permission was granted from both the developers of the original WORC questionnaire and the translators.<sup>6</sup>, 18, 28

# 2.3.2 Constant Score (CS)

The CS is filled out by the physician and combines objective physical examination tests and subjective patient assessments.<sup>34</sup> 35 Points are allocated for patient-reported items on pain (15) and activities of daily living (20), 40 points are available for 4 physical examination items focused at (painless) range of motion, and 25 points are available for abduction strength evaluation. Consequently, the total maximum score is 100 points.

Arm strength was measured using a handheld dynamometer (MicroFET 2, Biometrics, Almere, the Netherlands).

#### 2.3.3 Disabilities of the Arm, Shoulder and Hand score (DASH)

The DASH score is a self-reported questionnaire to measure disability and symptoms in patients with any or several musculoskeletal disorders of the upper arm.<sup>33</sup> The score contains a total of 30 items; 21 items relate to physical function, 5 to clinical symptoms, and 4 to social and work-related activities. Each item is scored on a 5 point scale, ranging from no difficulty (1 point) to unable (5 points). The total score can be calculated with a formula of the designers, and ranges from 0 (best score) to 100 (worst score).

#### 2.4 Statistical Analysis

Normally distributed values were expressed using mean values and standard deviations (SD) and eventual skewed data were expressed using medians and

ranges. The baseline sociodemographics and clinical characteristics of patients in the three diagnostic study groups were compared with one-way ANOVA analyses or Chi-squared tests where appropriate.

Floor and ceiling effects of the total WORC score, WORC domain scores and individual WORC items at T1 were assessed by calculating the proportion of subjects scoring the minimal or maximal scores, relative to the total number of subjects. For maximal scores we applied percentage scores of 90-100 and similarly we used 0-10 percentage scores for the minimal scores. A percentage value of >15% of the subjects scoring maximal or minimal scores was considered a relevant floor or ceiling effect.

Internal consistency of the items comprising the total WORC score and the WORC domain scores was examined by computing Cronbach's alpha coefficients at T1. This coefficient assesses whether items within each domain or within the total WORC produce similar/correlating scores, contributing to and correlating with the domain and total WORC score, respectively.<sup>21</sup> Cronbach's alpha ranges from 0.0 for poor correlation to 1.0 for best correlation. However, high values are not necessarily desirable, as this might indicate redundancy of questionnaire items.

Reliability was determined by comparing the test-retest WORC scores (T1, T2) by means of paired t-tests, or Wilcoxon signed rank tests in case of non-parametric data. An instrument is considered reliable if it gives similar outcomes over time for each subject, provided that there are no changes in the measured items over time. Additionally, the Intraclass Correlation Coefficient (ICC) was applied. The ICC ranges from 0 to 1.00, with 0.00 to 0.39 for poor, 0.40 to 0.59 for fair, 0.60 to 0.74 for good, and 0.75 to 1.00 for excellent reliability. In this study a two-way random effects model for agreement ICC (2,1) for single measure reliability was used for each domain.<sup>36</sup> This model includes potential systematic differences in its analyses. Furthermore, the precision of the WORC was expressed in Standard Error of Measurement (SEM), which can be estimated by the formula, Eq 1:

$$SEM = SD \times \sqrt{1 - ICC}$$
(1)

where SD is the pooled standard deviation of the test and retest measurements of all subjects. The SEM gives an absolute measure of reliability within subjects. In contrast, the ICC gives a relative measure of reliability within subjects, and depends on the population it is calculated from.<sup>37</sup> Furthermore, the SEM can be used to can be used to determine the minimally detectable change (MDC),<sup>38</sup> also reported as minimum difference (MD) to be considered real<sup>37</sup> or smallest real difference (SRD),<sup>39</sup> Eq 2:

$$MDC = SEM \times 1.96 \times \sqrt{2}$$
 (2)

Validity of the WORC was assessed using construct validity, as there is no gold standard for a subject's status of rotator cuff related QOL. Pearson's correlation coefficients (or Spearman's rank correlation coefficients in case of non-parametric data) were computed between total and domain scores of the WORC score at T1 and the DASH (T1) and the CS (T2). In this study, positive correlations were defined as r: 0 to 0.25 being poor, 0.25 to 0.5 as fair to moderate, 0.5 to 0.75 as moderate to good correlation, and 0.75 as good to excellent correlation. Negative correlations were defined in a similar way. The calculation of the correlation of the WORC and the CS was repeated using the T2 WORC.

Lastly, responsiveness of the WORC was assessed, by comparing WORC scores before and 6 weeks after treatment in the calcific tendinitis group. The magnitudes of the changes in total and domain WORC scores were expressed as Effect Size (ES: mean test-retest difference, divided by the SD of the test mean) and Standardized Response Mean (SRM: mean test-retest difference, divided by the SD of the mean change in score).<sup>40,41</sup> Both outcomes can be interpreted as follows: 0.2 is small, 0.5 moderate, 0.8 or higher is a large effect. Additionally, the correlation coefficients between changes over time in the WORC with respect to changes in CS and DASH were calculated. Furthermore, the proportion of patients with the previously defined minimal clinically important difference of the WORC (MCID, 11.7 percentage points)<sup>42</sup> was assessed.

All analyses were performed for the total group, as well as for each of the three study groups separately. For all tests, p-values < 0.05 were considered statistically significant. Analyses were processed using SPSS 16.0 software (SPSS Inc., Chicago, Illinois).

# 3. Results

#### 3.1 Patient characteristics

Of 94 patients included in the three projects until July 2011, 2 were excluded from the calcific tendinitis study group after filling out the first WORC because of cancelling of the treatment due to contraindications, as judged by the treating orthopaedic surgeon. In addition, one patient in the calcific tendinitis study group did not complete the third assessment 6 weeks after treatment.

Of all included participants, 7 patients left 1 item unanswered in one of the WORCs. Two patients left more than 1 item unanswered. Of these two patients, the corresponding WORC scores were not included in the analyses. 10 Patients did not complete either the first (n=4) or the second WORC. Their results were not included in the reproducibility analyses. In case of a missing T1 WORC, data of the T2 WORC

were used as baseline WORC data for comparison with CS, DASH and T3 scores. The final study group comprised 92 patients with a mean age of 55.0 years: 35 with a rotator cuff tear (study 1), 22 with subacromial impingement (study 2), and 35 with calcific tendinitis (study 3).(Table 1) On average, rotator cuff tear patients were significantly older than patients in the other two diagnostic groups. Cuff tear patients had a significantly lower CS and higher DASH compared to impingement and calcific tendinitis patients. There were no statistically significant differences for the CS and DASH between the latter study groups.

#### 3.2 Psychometric properties of the baseline WORC questionnaire

The mean total WORC score at (T1) was 1112.2 (SD=428.3, range: 208.5 – 1859.2). Expressed in percentage score, mean total WORC was 46.8 (SD=20.4, range: 10.0-90.0). The WORC total and domain scores were normally distributed in all groups and the total group. The mean total WORC score was significantly lower in group 3, compared to group 2. In contrast to the differences between cuff tear patients and impingement and calcific tendinitis patients in DASH and CS, there was no statistically significant difference between cuff tear patients and the other study groups for the WORC.(Table 1)

For all items, the domain scores and the total scores, less than 15% of the patients obtained the maximum or minimum score, implying there were no floor and ceiling effects of the WORC. In the physical symptoms domain, 0 patients scored between 0 and 10 and 3 patients (3.1%) had scores between 90 and 100. In the sports domain 5 patients (5.2%) obtained minimal scores and 2 (2.1%) the maximum scores. For the work domain, there were 7 patients (7.2) in the 0-10 score range and 1 (1%) in the maximal score range. In the life style domain, 4 (4.1%) patients had the lowest scores and 4 had scores in the 90-100 range. Lastly, in the emotions domain there were 6 (6.2%) and 13 (13.4) patients in the minimal and maximal score ranges, respectively. For the total WORC score, both score ranges contained 1 patient (1%).

#### 3.3 Internal consistency

Internal consistency, as calculated with Cronbach's Alpha, was high for all WORC domain scores. Internal consistency for all items with respect to the total WORC was high as well, with a Cronbach's alpha of 0.95 for the total WORC. (Table 2) For the three diagnostic groups, Cronbach's alpha coefficients of the total WORC scores were 0.96, 0.91 and 0.95 for rotator cuff tear, impingement and calcific tendinitis patients, respectively.

# 3.4 Test-retest Reliability

Table 3 shows that there were no statistically significant differences between the test and retest WORC total score and domain scores, except for the Work domain in the total group, where the WORC score was higher at T2 (mean change 3.0, 95%-CI: 0.1-6.0). Pearson's correlation coefficients between the test and retest scores was 0.90 (p<0.001) for the total WORC score. Expressed in ICCs, test-retest reliability of the WORC domain scores ranged from 0.81 (p<0.0001) to 0.89 (p<0.0001), and was 0.89 (p<0.0001) for the total WORC score. Corresponding SEM was 6.9 for the total WORC score can be estimated by: observed score  $\pm$  1.96 x 6.9 = observed score  $\pm$  13.5. The minimum detectable change MDC (Eq. 2) was 19.1.

For the three study groups, ICCs were 0.94 (p<0.0001), 0.82 (p<0.0001) and 0.84 (p<0.0001) for rotator cuff tear, impingement and calcific tendinitis patients, respectively.

# 3.5 Validity

Table 2 shows Pearson correlation coefficients between the WORC, CS and DASH. Except for the Emotions domain in impingement patients, there were significant correlations between the domain and total WORC scores with the CS and the DASH. Pearson's correlations of the total WORC were 0.56 (p<0.001) for the CS and -0.65 (p<0.0001) for the DASH, as high percentage WORC scores mean less symptoms, where high DASH scores indicate worse symptoms. Correlations with the DASH were highest for impingement and calcific tendinitis patients: -0.77 (p<0.001) and -0.82 (p<0.001) respectively, in contrast to -0.49 (p<0.05) in cuff tear patients.(Table 2)

Correlation of the WORC at T2 instead of the WORC at T1 with the CS (T2) showed a correlation of similar magnitude: 0.63 (p<0.0001).

#### 3.6 Responsiveness (sensitivity to change)

Table 4 shows that, on average, the mean WORC total and domain scores, the CS and DASH scores improved significantly 6 weeks after treatment for calcific tendinitis. 16 Patients (47%) had an improvement larger than the MCID: 11.7 percentage points, as reported by Kirkley et al.<sup>42</sup> With a value of 18.8, mean WORC improvement was higher than the MCID.

Overall, the ES and SRM of the WORC total and domain scores indicated good responsiveness. Except for the WORC sports and emotions domains, the ES and SRM of the WORC were larger than those of the DASH and in the same range (ES) or slightly lower (SRM) than those of the CS.

Table 5 shows significant and moderate to good correlations between changes over time of the WORC total and domain scores and the CS and DASH. For the CS, changes in time correlated best with changes in the WORC Lifestyle, Physical symptoms and Sports domains. The changes in DASH correlated moderate to good to changes in all WORC domains.

# 4. Discussion

The results of our study show that the WORC is a reliable, valid and responsive measure of health related quality of life in patients with rotator cuff lesions of various origins. WORC total and domain scores correlate moderate to good with the CS and DASH.

With respect to internal consistency, the Cronbach's Alpha of 0.95 observed in the present study is in line with the results of previous studies reporting a Cronbach's Alpha of 0.93 for the original translation and ranging from 0.92 to 0.97 for translated versions.<sup>24-27,43</sup> This implies that the domains and items within the WORC contribute to and correlate with each other and the total WORC score.<sup>21</sup>

We found good test-retest reliability, with test-retest correlation coefficients of the total WORC score ranging from 0.82 to 0.94 in the three diagnostic groups. This is in concordance with Huber et al. who reported a test-retest correlation coefficient of 0.96, using the German WORC in 21 patients.<sup>26</sup> Intraclass correlations (ICC=0.89 for the total WORC) were comparable to those in literature, with 0.96 for the WORC designers in 55 patients<sup>6</sup> and values ranging from 0.88 to 0.98 for translated versions.<sup>23-27</sup> To the best of our knowledge, there is only one study reporting the Standard Error of Measurement (SEM) of the WORC: Lopes et al. reported mean SEM's ranging from 3.0 to 5.2, which is of the same order as the 6.9 we observed.<sup>24</sup>

Concerning construct validity, the WORC correlated moderate to good with the DASH (-0.65) and CS (0.56). The latter predominantly contains objective items and lacks emotional or lifestyle factors that are included in the WORC. Others have reported similar correlations of the WORC with the SF-36, ASES or UCLA score, often superior than correlations with the Constant Score.<sup>6, 24-27, 44-46</sup> Moderate to good correlation coefficients, as found for the WORC, are desirable as high or excellent correlation coefficients with other scores would mean the WORC is not of additional value to existing measures. To a further extent, this makes combining the WORC with other outcome measures, including the Constant Score, applicable and even advisable. However, the WORC appeared less discriminative than the DASH and CS in case of severe symptoms: differences were found for CS and DASH between cuff tear patients (severe symptoms on average) and the impingement and calcific tendinitis groups, but not for the WORC.

In our study, the WORC was also compared to the Constant Score and DASH to assess its responsiveness after treatment. Evaluating change score correlations, our results were moderate to good: -0.84 for the DASH and 0.61 for the CS. Holtby et al. published higher correlations for change scores: 0.77 for the CS and 0.85 for the ASES in a group of 50 surgically treated impingement and cuff tear patients.<sup>18</sup> Possibly, the WORC correlates better with change scores of e.g. CS, ASES and DASH in case of rigorous interventions in patients with severe symptoms, i.e. when large changes in scores over time can be expected. This can be the case with surgical treatment of rotator cuff problems, as shown by Holtby et al.<sup>18</sup> However, in the current study interventions were less invasive: patients were treated with an injection or ultrasound guided needling and lavage for calcific tendinitis.

A limited number of studies assessed the responsiveness of the WORC expressed in Standardized Response mean (SRM) or Effect Size (ES).<sup>22, 45, 47, 48</sup> Reported SRM's of the total WORC score range between 0.8 and 2.0, often comparable or superior to other scores, including the CS, DASH and Oxford Shoulder Scale, but are mostly based on subgroups of patients who are defined as "responsive to treatment". In our study, mean SRM was 0.91 for patients responsive and non-responsive 6 weeks after treatment of calcific tendinitis: better than the DASH and in the same range as the CS. Data on Effect Size of the WORC is scarce. An ES of 0.92 for the Brazilian WORC has been reported; comparable to the 0.96 in our study.<sup>22</sup> In both studies, ES of the WORC was superior to the DASH.

Hence, comparing with published validation studies of both original and translated WORC versions, our results are similar.<sup>23-27, 43-48</sup> However, our study provides some new and important information. Firstly, with regard to psychometric properties of the WORC, in most publications only internal consistency measures, test-retest assessments and/or responsiveness are reported. In our study a comprehensive combination of the most relevant measurement properties is assessed in one population, as advised by e.g. the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust and Terwee et al.<sup>29,30</sup> Secondly, patient groups in many publications are guite homogeneous, small, or selected with unclear eligibility criteria.<sup>23-27, 43, 44, 47</sup> In contrast, we studied a consecutive patient group composed of patients with one of three diagnoses and with a broad spectrum of severity of symptoms, using strict inclusion and exclusion criteria and advanced imaging technologies. Therefore, this study assessed a comprehensive combination of relevant psychometric outcome measures in a large, and heterogeneous but well-defined cohort, indicating high external validity of our results. Thirdly, we found potential discriminative problems of the WORC in patients with severe symptoms (in the lower score ranges in patients with cuff tears). To the best of our knowledge, this has not been reported earlier and has to be taken into account when using the WORC in similar patients.

Over the past two decades, there has been an increasing emphasis on the use of self-reported outcome measures in orthopaedic practice, including the WORC.<sup>49</sup> Conventional musculoskeletal instruments are mainly based on objective quantities that do not necessarily correlate with outcomes that are most relevant to patients, such as activities of daily life, mental health, or other QOL aspects. For broad and accurate patient assessment, it is advisable to combine objective and self-reported general health scores, general regional (e.g. shoulder) measures, and condition-specific measures.<sup>5, 50</sup> The results of the current study and previous publications demonstrate that the WORC, one of few available condition-specific HRQOL measures for the rotator cuff, can be used in the assessment of cuff patients.

There are some limitations of our study that need to be taken into account when interpreting our results. Firstly, the investigating researcher was not blinded for the diagnostic study groups and treatment, leading to potential bias towards improvement with regard to the Constant Score. Secondly, within the study period, there was only an intervention and WORC assessment of longitudinal responsiveness in the calcific tendinitis patients. It is a possibility however, that results for longitudinal responsiveness in the calcific tendinitis group cannot necessarily be extrapolated to other rotator cuff conditions. Thirdly, all patients in this study were referred to our medical center for treatment by general practitioners. Therefore, this patient group might not be representative of all patients with rotator cuff conditions. Fourthly, the test-retest time-interval was relatively short: near 3-7 days in many patients. Yet, earlier validation studies for the WORC reported a substantial number of included patients to be considered clinically unstable over a two week's period.<sup>23, 24</sup> and even a 2-3 day period for WORC test-retest assessments is not uncommon.<sup>25, 27</sup> Fifthly, for practical reasons the DASH (T1) and CS (T2) were not administered at the same occasion, whereas both were compared with the baseline (T1) WORC. Given the insignificant T1-T2 differences of the WORC and high T1-T2 correlation coefficients, we believe this does not influence our results. Comparing the T2 WORC to the CS (T2) gave a similar correlation coefficient. Lastly, we used the Dutch version of the WORC and therefore it cannot be guaranteed that our results are generalizable to the original or other translated versions. However, the Dutch translation we used was made by another and independent institution using international translation guidelines.<sup>28</sup> Furthermore, the results obtained in each of the diagnostic groups are comparable to previously (but separately) published average scores,<sup>23</sup> SD's,<sup>14,</sup> <sup>23, 51-53</sup> Cronbach's Alpha,<sup>23, 43</sup> correlations with CS<sup>43, 44, 51</sup> and DASH,<sup>6, 43</sup> and ICC<sup>6, 23</sup> of the original WORC in patient groups with similar diagnoses. Therefore, we think this study can be considered to be the first study extensively assessing the validity of the WORC according to the CAS guidelines in a strictly defined patient group covering a broad spectrum of rotator cuff conditions. Nevertheless, repeating this

comprehensive combination of analyses for the original WORC in a similarly broad spectrum of RC condition patients is recommendable.

Concluding, our results suggest the WORC is applicable in research and clinical practice as a self-reported disease-specific Health Related Qualitative of Life outcome measure for rotator cuff patients. It is advisable to use this disease-specific measure in combination with a regional and a general health outcome measure. The WORC is potentially less discriminative between subjects with severe complaints, compared to other outcome measures. This needs to be studied further and has to be taken into account when using the WORC in assessing patients with severe symptoms.

					Differences between	
		Rotator Cuff tear	Impingement	Calc. Tendinitis	study groups	All patients
		(n=35)	(n=22)	(n=35)	p-value	(n=92)
Age (yrs)		60.6 (8.6)	51.1 (6.5)	52.4 (7.6)	< 0.001 1,2,3	55.0 (8.7)
Gender	Male (n)	19 [54%]	9 [41%]	15 [43%]	0.52	43 [47%]
	Female (n)	16 [46%]	13 [59%]	20 [57%]		49 [53%]
Duration (months)	of symptoms	NA	33.1 (58.7)	42.5 (41.6)	0.56	39.6 (47.0)
Dominan	t side affected (n)	16 [40%]	12 [55%]	20 [57%]	0.78	32 [56%]
Constant	Score	53.4 (14.8)	74.7 (10.7)	67.3 (12.3)	< 0.001 1,3	63.9 (15.4)
DASH		50.9 (18.4)	28.7 (13.5)	38.6 (16.3)	< 0.001 1,3	40.9 (18.6)
WORC	Total score	1159.3 (461.9)	906.1 (334.0)	1194.7 (414.7)	0.03 <sup>2</sup>	1112.2 (428.3)
	Percentage score	44.3 (22.0)	56.8 (15.8)	43.0 (19.7)	0.03 <sup>2</sup>	46.8 (20.4)

# Legend

Table 1. Demographic and baseline characteristics of 92 included patients with a rotator cuff tear, subacromial impingement syndrome, or calcific tendinitis.

1) Statistically significant difference between study groups 1 and 2; 2) Statistically significant difference between study groups 2 and 3; 3) Statistically significant difference between study groups 1 and 3) ((SD), Standard Deviation; DASH, Disabilities of arm, Shoulder and Hand score; WORC, Western Ontario Rotator Cuff Index)

	Cronbach		Cor	relation	s of WORC with	Constant	Score and I	DASH	
	Alpha		Constar	it Score			D	ASH	
		RC#	SIS	Calc	All patients	RC#	SIS	Calc	All patients
Total WORC (n=92)	0.95	0.59**	0.65*	0.55*	0.56**	-0.49*	-0.77**	-0.82**	-0.65**
Physical Symptoms	0.85	0.51*	0.61*	0.49*	0.50**	-0.41*	-0.58*	-0.73**	-0.56**
Sports/recreation	0.76	0.52*	0.50*	0.51*	0.50**	-0.41*	-0.76**	-0.72**	-0.57*
Work	0.84	0.47*	0.56*	0.55*	0.51**	-0.51*	-0.73**	-0.80**	-0.65**
Lifestyle	0.82	0.66**	0.60*	0.45*	0.52**	-0.51*	-0.37	-0.66**	-0.52**
Emotions	0.86	0.53*	0.20	0.43*	0.49**	-0.48*	-0.69**	-0.72**	-0.63**
Table 2. Internal & Const	ruct Validity of 1	the WORC in	all patien	ts (n=92)					

Cronbach's Alpha for internal validity and Pearson correlation coefficients of the WORC with the DASH and CS. DASH score: 0 is best, to 100 for worst. WORC and Constant Score: 0 is worst and 100 is best.

(DASH, Disabilities of arm, Shoulder and Hand score; RC#, rotator cuff tendon tear (n=35); SIS, subacromial impingement syndrome

(n=25); Calc, calcific tendinitis (n=35))

(\*p<0.05, \*\*p<0.001)

	:						
	Baseline mean	Retest mean	Mean difference	p-value	Pearson's r		SEM
	(SD)	(SD)	(95% CI)			(95% CI)	
Total WORC (n = 83)	46.3 (20.2)	47.9 (21.3)	1.6(-0.5 - 3.7)	0.13	0.90**	0.89 (0.84 - 0.93)	6.9
Physical symptoms	52.2 (21.6)	54.3 (22.5)	2.0 (-0.4 - 4.4)	0.10	0.88**	0.87 (0.81 - 0.92)	8.0
Sports/recreation	43.3 (21.6)	44.6 (21.6)	1.3 (-1.7 - 4.3 )	0.41	0.81**	0.81 (0.72 - 0.87)	9.4
Work	37.3 (22.6)	40.4 (23.8)	3.0 (0.1 - 6.0)	0.04	0.83**	0.83 (0.74 - 0.88)	9.6
Lifestyle	44.6 (24.2)	44.6 (24.2)	0.4 (-2.3 - 3.1)	0.78	0.86**	0.86 (0.80 - 0.91)	9.1
Emotions	58.0 (28.3)	59.3 (28.3)	1.2(-2.4 - 4.9)	0.50	0.83**	0.83 (0.75 - 0.89)	11.7
Table 3. Reproducibility	y of the WORC.						

Test-retest reproducibility was assessed by comparing the differences between test and retest examination within 3-14 days, expressed in percentage scores, with paired t-test and Pearson's correlations. Reliability was estimated with Intraclass Correlation Coefficients. (SD, Standard Deviation; 95% CI, 95% confidence interval; SEM, standard error of measurement; WORC, Western Ontario Rotator Cuff Index)

(\* p<0.01, \*\* p<0.001)

	Baseline mean	Follow-up mean	Change	p-value	ES	SRM
	(SD)	6 wks (SD)	(95% Cl)			
Constant Score (n=34) DASH (n=34)	67.1 (12.4) 38.6 (16.5)	78.2 (16.8) 28.6 (22.9)	11.1 (7.8 - 14.4) -9.9 (-15.14.8)	<0.001 <0.001	-0.89 0.61	-1.16 0.68
Total WORC (n=34) Physical symptoms	42.9 (19.6) 48.3 (21.1)	61.7 (26.7) 67.3 (24.3)	18.8 (11.3 - 26.2) 19.0 (11.4 - 26.7)	<0.001 <0.001	-0.96 -0.90	-0.91 -0.86
Sport Work	41.6 (19.6)	56.9 (27.7) 56.8 (29.4)	15.3 (7.2 - 23.4) 21 9 (13 9 - 29 9)	0.001	-0.78 -1.04	-0.67 -0.97
Lifestyle	39.0 (23.7)	61.9 (31.9)	22.9 (14.4 - 31.5)	< 0.001	-0.97	-0.96
Emotions	54.6 (29.2)	67.1 (29.0)	12.5 (4.6 - 20.4)	0.003	-0.44	-0.56

Table 4. Baseline and 6-weeks follow-up data in 34 patients treated with ultrasound guided needling and lavage or a subacromial injection with corticosteroids in the calcific tendinitis group. For ES and SRM: 0.2 is small, 0.5 moderate, 0.8 or higher is large effect (idem for negative values). (SD, Standard Deviation; 95% CI, 95% confidence interval; WORC, Western Ontario Rotator Cuff Index; DASH, Disabilities of arm, Shoulder and Hand score; ES, effect size; SRM, standardized response mean)

		Correlations of ch	nanges (0 to 6 week	(s)
	Consta	nt Score	DAS	Н
	Pearson	p-value	Pearson	p-value
Total WORC (n=34)	0.61	< 0.001	-0.84	<0.001
Physical Symptoms	0.55	0.001	-0.65	<0.001
Sports/recreation	0.60	<0.001	-0.77	< 0.001
Work	0.52	0.002	-0.78	<0.001
Lifestyle	0.66	<0.001	-0.77	<0.001
Emotions	0.38	0.03	-0.72	< 0.001

Table 5. Longitudinal responsiveness.

Correlations of changes in WORC scores with changes in the Constant Score and DASH, from baseline to 6-weeks after treatment in the calcific tendinitis group.

(WORC, Western Ontario Rotator Cuff Index; DASH, Disabilities of arm, Shoulder and Hand score)

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Chapter