The Oxford Shoulder Score: Cross-cultural adaptation and translational validation into Afrikaans

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'Listen to your patient, he is telling you the diagnosis'

- William Osler

Declaration

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Abstract

Purpose: The Oxford Shoulder Score (OSS) is a robust and universally utilised shoulder score that has been translated for use in Western and Asian countries. This study aimed to translate, cross-culturally adapt and psychometrically validate the Afrikaans version of the OSS for use in Africa.

Methods: Translation and cross-cultural adaptation was performed in accordance with guidelines in the literature. 108 consecutive patients with either degenerative or inflammatory pain of the shoulder were prospectively enrolled. Patients were evaluated by completing the Afrikaans OSS, Constant-Murley, quickDASH, and the Subjective Shoulder Value (SSV) scores. Comprehensibility and acceptance, as well as any floor or ceiling effects, were calculated. Reliability was assessed through reproducibility. Internal consistency was assessed using Cronbach's alpha. Validity was determined using a Pearson Correlation Co-efficient between the Afrikaans OSS and the other validated shoulder scores.

Results: Comprehensibility and acceptance were excellent, and no floor or ceiling effects were observed. Reproducibility ($r = 0.99$) and internal consistency (Cronbach's alpha = 0.93) were both excellent. Correlation of the Afrikaans OSS with the Constant-Murley and quickDASH was excellent ($r = 0.84$; $r = 0.81$ respectively), and very good with the SSV and VAS pain score ($r = 0.73$; $r = 0.66$).

Conclusion: The Afrikaans OSS proved understandable, acceptable, reliable and valid. It is an appropriate instrument for use in Afrikaans speaking patients with shoulder pain from degenerative or inflammatory origin.

Level of evidence: 3

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Abbreviations

ASTM	- American Society for Testing and Materials
COSMIN	- Consensus-based Standards for the selection of health Measurement Instruments
HRQoL	- Health Related Quality of Life
MDT	- Multidisciplinary Team
MOS sf-36	- Medical Outcome Short form 36
OSS	- Oxford Shoulder Score
PCORI	- Patient-Centered Outcomes Research Institute
PROM	- Patient Reported Outcome Measure
PROMIS	- Patient-Reported Outcomes Measurement Information System
quickDASH	- Short form for the Disability of the Arm, Shoulder and Hand
SAC	- Scientific Advisory Committee
SSV	- Simple Shoulder Value
VAS	- Visual Analogue Scale

Chapter one

1. Research synopsis

1.1 Context

Surgeons have moved away from purely clinically based assessment scores. Patient reported outcome measures (PROMS) provide a more accurate reflection of the impact of disease or injury for the patient within their context [1]. The Oxford Shoulder Score (OSS) is one such outcome measure that was developed in conjunction with patients and underwent rigorous and robust validation [2]. It is designed to assess patient perceptions about their shoulder problems and is intended for use as an outcome measure of specialist intervention in shoulder pathology. It was originally only created in English, but has been transcribed into European and Asian languages [3,4]. It is yet to be expanded into any African language.

One of the greatest challenges facing local clinicians is the cross-cultural and cross-lingual barrier that hampers effective, efficient information transfer and understanding between patient and surgeon. Besides English, the predominant language in the Western Cape is Afrikaans. The English OSS cannot be used in these patients, as cultural and language appropriateness is crucial to the understanding, interpretation and validity of the score. Hence there is the need for accurate translation and validation thereof to enable utilisation in the local context.

1.2 Study design

Prospective clinical cohort validation study

1.3 Study objectives

1. To formulate a robust translation of the OSS into Afrikaans.
2. To cross-culturally validate the translated OSS in a cohort of patients against other validated shoulder outcome measures.

1.4 Setting and recruitment

All research participants were recruited on a voluntary basis from the D6 upper limb clinic at Groote Schuur Hospital. This is a public service that provides tertiary and quaternary upper limb care for the majority of the Cape Metropole low to middle income socioeconomic groups.

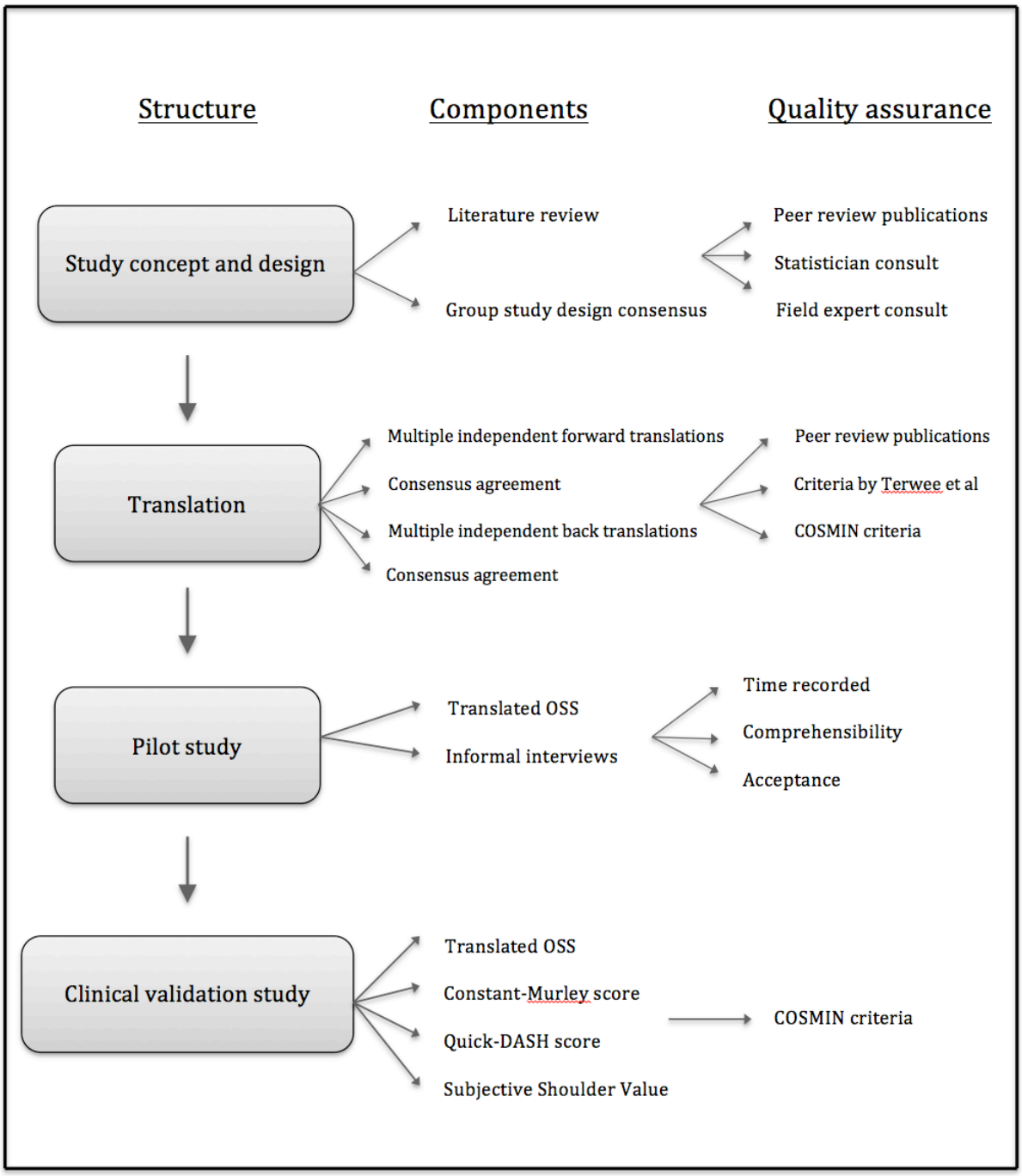
1.5 Research methodology

The OSS translation was performed in accordance with guidelines suggested by Huber et al 2004 [3]. These were later supported by the original developers of the OSS [5]. They were also reviewed for adherence to the COSMIN checklist for assessment of cross-cultural validation [6].

First, three bilingual people, all with health care experience, provided three independent translations of the Oxford Shoulder Score. Due to the rich nature of Afrikaans and the variability of local dialects, emphasis on simple and precise wording was requested. Focus on comprehension of concept and not on grammatical correctness was given priority [7]. Then, at conference, a consensus was reached providing an initial copy. Subsequently, three separate bilingual people, all also with healthcare experience, independently back-translated this copy. No translator knew anything about the score, nor were they involved in the validation process. Each of these copies was assessed for uniformity on consensus review by a final panel, generating the final translated score.

This version underwent a pilot study to test comprehensibility, acceptance and patient burden in 10 people with shoulder problems. In order to ensure consistency, the same consent form was used for the pilot comprehensibility study as the main study. Once developed as above, more than 100 patients' (as defined by an a priori power calculation) were prospectively recruited. (Figure 1-1).

Figure 1-1: Diagrammatic algorithm of the study stucture, components and quality criteria.



1.5.1 Inclusion and exclusion criteria

Inclusion criteria

- Patients with shoulder pain from either degenerative or inflammatory (either traumatic or atraumatic) origin
- Patients older than 18 years

- Patients able to both speak, read and write in basic English and Afrikaans
- No previous surgery to the afflicted shoulder

Exclusion criteria

- Patients with shoulder instability
- Illiterate patients or patients with language difficulties

1.5.2 Data analysis

Data was analysed in accordance with the COSMIN checklist for evaluation of methodological quality [6]. The analysis involved assessment of time needed, comprehensibility, acceptance, floor and ceiling effects, reliability and validity.

Time, comprehensibility and acceptance.

Time was recorded as the time required to complete the questionnaire. Comprehensibility and acceptance were assessed by compliance, ie the number of questions answered or omitted. No more than two questions for the OSS may be omitted for it to be valid, and if there were two or more answers recorded for a question, by convention, the worst score was recorded [5].

Floor and ceiling effects

Floor or ceiling effects are said to be present if more than 15% of the respondents choose either the highest or the lowest score [8]. This may introduce bias, as discrimination is lost at the extremes of scores, limiting the content validity.

Reliability

Reliability includes both a measure of reproducibility and internal consistency (test-retest reliability). Reproducibility was tested using Pearsons correlation coefficient (r) in a group of 40 stable patients. Verbal permission was obtained to contact each patient telephonically in 24-48 hours following their initial visit to repeat the translated score. Internal consistency was assessed using Cronbach's alpha. It defines the correlation between all the items within a scale[3]. Values may range from 0 to 1, with 0.90 – 0.95 optimal for clinical application [9]. Values above 0.95 indicate items are too similar and may be redundant.

To best assess the measurement error, a Bland Altman plot of the difference in scores relative to their mean, across the range of scores was computed [10].

Validity

Construct validity was determined using the Pearson correlation co-efficient to compare the Afrikaans OSS to three previously validated shoulder assessment scores, one of which included a Visual Analogue Scale (VAS) pain score. The scores used were the Constant-Murley shoulder assessment [11], the quickDASH shoulder scoring system [12] (which included the VAS pain score) and the Subjective Shoulder Value [13].

1.8 Consent and confidentiality

A comprehensive consent form addressing all concerns related to treatment if included in the study, and explaining the protection of confidential data was designed and is included as appendix 2. Each patient was asked to read and complete the consent form, with any queries settled in consult with the primary researcher. In terms of data protection, all patient data were anonymised prior to any statistical analysis. Patient data were kept on a password-protected database, with access only available to the study investigators.

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Chapter two

2. Literature Review

2.1 Objectives of literature review

To discuss:

i. Patient Reported Outcome Measures (PROM's) in the context of evidence based medicine
ii. Quality control and define criteria for the assessment of PROM's
iii. Shoulder specific PROM's and the relevance of the Oxford Shoulder Score
iv. Methods of translating PROM's to ensure cultural validity and appropriateness
v. Present OSS translations into European and Asian languages
vi. PROM implementation and barriers to clinical incorporation of PROMs
vii. Relevance to our clinical setting and define the context and rationale for this study

2.2 Literature research strategy

A literature review was conducted using PubMed, Scopus and Google scholar. The Scopus search repository was utilised to rank articles according to importance based on citation number. The keyword search included the terms "Patient reported outcome measure", "PROM", "Oxford shoulder score", "translation", "cross-cultural validation", "Shoulder arthroscopy", "Rotator cuff disease", "Constant Murley", "Subjective shoulder value", "quickDASH" and "Afrikaans". Items were searched both individually and in different combinations to generate results. Only peer-reviewed publications where the original article was available for inspection were included. Besides specific measurement instruments or criteria generated earlier, articles were limited to those from the last 10 years to ensure current evidence. All articles were written in English, or had an English translation accompanying the original article. Where significant articles central to this thesis had references quoted that conveyed a pertinent message, the original article was accessed, assessed and quoted.

2.3 Introduction

The goal of medical intervention is to cure the patient to their complete satisfaction from disease or affliction. Central to achieving this is an understanding of patient perception about their

problem and its effect on their life, coupled with their expectation of the surgical intervention. Both of these principles need to be adequately addressed. To this end, Health Related Quality of Life (HRQoL) measures have been created in an attempt to incorporate the effect of cognitive, emotional, social, societal, work, religious, financial and other influences on patient wellness. This creates a measureable health score that is valid, consistent and able to assess the degree of impairment at multiple time points during the treatment process. These data points monitor patient progress in an evidence-based approach.

Patient Reported Outcome Measures (PROM's) form the backbone of HRQoL's, and are either generic general health assessment questionnaires or limb- or pathology-specific assessment questionnaires. The general health assessment questionnaire covers most domains of health, including activities of daily living and psychological effects of the disease [1,2]. The limb or pathology specific assessment questionnaires cover aspects of symptoms and function related to the afflicted limb or disease.

PROM's are now long established as the benchmark in ascertaining patient's views with regard to their symptoms and functional status, as well as their quality of life [3]. Their implementation in research trials and clinical practice is on the rise [4,5]. This is not surprising as, due to their proven utility, both governments and professional organisations have invested heavily in the establishment of centres like the National Institute of Health sponsored Patient-Reported Outcomes Measurement Information System (PROMIS) [6] and the Patient-Centered Outcomes Research Institute (PCORI) [7]. These centers serve as hubs for the 'development of rigorous standards for research generation guided by patient input and reflective of patient-directed health outcomes' [4,8].

2.4 Measurement instrument quality control

It is imperative for clinicians to choose a measurement instrument that measures what it purports to in a reliable, valid and responsive way. As such, an evaluation of the psychometric properties need to be made for the chosen measurement instrument, dealing with the theory and technique of psychological measurement [9]. Improper use of measurement instruments or unpublished measurement instruments may lead to inappropriate decisions on individual patient care or worse, health policy alterations with the potential to affect millions of people.

In 1994 the Medical Outcomes Trust created a Scientific Advisory Committee (SAC) that defined a set of characteristics and standards to develop measurement instruments, and against which those measurement instruments need to be measured for validity, reliability and responsiveness

[10,11]. Terwee et al in 2007 then comprehensively defined all these measurement properties and outlined detailed quality criteria for each measurement property (Table 2-1) [12].

Table 2-1: Quality criteria for measurement properties of health status questionnaires [12].

Table 1
Quality criteria for measurement properties of health status questionnaires

Property	Definition	Quality criteria[a,b]
1. Content validity	The extent to which the domain of interest is comprehensively sampled by the items in the questionnaire	+A clear description is provided of the measurement aim, the target population, the concepts that are being measured, and the item selection AND target population and (investigators OR experts) were involved in item selection; ?A clear description of above-mentioned aspects is lacking OR only target population involved OR doubtful design or method; −No target population involvement; 0No information found on target population involvement.
2. Internal consistency	The extent to which items in a (sub)scale are intercorrelated, thus measuring the same construct	+Factor analyses performed on adequate sample size (7 * # items and ⩾100) AND Cronbach's alpha(s) calculated per dimension AND Cronbach's alpha(s) between 0.70 and 0.95; ?No factor analysis OR doubtful design or method; −Cronbach's alpha(s) <0.70 or >0.95, despite adequate design and method; 0No information found on internal consistency.
3. Criterion validity	The extent to which scores on a particular questionnaire relate to a gold standard	+Convincing arguments that gold standard is "gold" AND correlation with gold standard ⩾0.70; ?No convincing arguments that gold standard is "gold" OR doubtful design or method; −Correlation with gold standard <0.70, despite adequate design and method; 0No information found on criterion validity.
4. Construct validity	The extent to which scores on a particular questionnaire relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured	+Specific hypotheses were formulated AND at least 75% of the results are in accordance with these hypotheses; ?Doubtful design or method (e.g., no hypotheses); −Less than 75% of hypotheses were confirmed, despite adequate design and methods; 0No information found on construct validity.
5. Reproducibility		
5.1. Agreement	The extent to which the scores on repeated measures are close to each other (absolute measurement error)	+MIC < SDC OR MIC outside the LOA OR convincing arguments that agreement is acceptable; ?Doubtful design or method OR (MIC not defined AND no convincing arguments that agreement is acceptable); −MIC ⩾ SDC OR MIC equals or inside LOA, despite adequate design and method; 0No information found on agreement.
5.2. Reliability	The extent to which patients can be distinguished from each other, despite measurement errors (relative measurement error)	+ICC or weighted Kappa ⩾ 0.70; ?Doubtful design or method (e.g., time interval not mentioned); −ICC or weighted Kappa < 0.70, despite adequate design and method; 0No information found on reliability.
6. Responsiveness	The ability of a questionnaire to detect clinically important changes over time	+SDC or SDC < MIC OR MIC outside the LOA OR RR > 1.96 OR AUC ⩾ 0.70; ?Doubtful design or method; −SDC or SDC ⩾ MIC OR MIC equals or inside LOA OR RR ⩽ 1.96 OR AUC < 0.70, despite adequate design and methods; 0No information found on responsiveness.
7. Floor and ceiling effects	The number of respondents who achieved the lowest or highest possible score	+⩽15% of the respondents achieved the highest or lowest possible scores; ?Doubtful design or method; −>15% of the respondents achieved the highest or lowest possible scores, despite adequate design and methods; 0No information found on interpretation.
8. Interpretatability	The degree to which one can assign qualitative meaning to quantitative scores	+Mean and SD scores presented of at least four relevant subgroups of patients and MIC defined; ?Doubtful design or method OR less than four subgroups OR no MIC defined; 0No information found on interpretation.

MIC = minimal important change; SDC = smallest detectable change; LOA = limits of agreement; ICC = Intraclass correlation; SD, standard deviation.
[a] + = positive rating; ? = indeterminate rating; − = negative rating; 0 = no information available.
[b] Doubtful design or method = lacking of a clear description of the design or methods of the study, sample size smaller than 50 subjects (should be at least 50 in every (subgroup) analysis), or any important methodological weakness in the design or execution of the study.

Finally, in 2010 the Consensus-based Standards for the selection of health Measurement INstruments (COSMIN) initiative built on this work by Terwee et al and the SAC to 'create a standardised assessment of the content and measurement properties of measurement instruments, with the aim to provide tools for evidence-based instrument selection' [13].

They conducted a four-round Delphi study with 57 international experts in psychology, epidemiology, statistics and medicine. Each completed four rounds of questionnaires relating to the psychometric properties to be included, and consensus standard was reached by 67% majority selecting either 'agree' or 'strongly agree'. They defined 10 discrete but interconnected domains for assessment of the measurement tool known as the COSMIN taxonomy (Figure 2-1) [13].

Figure 2-1: The COSMIN taxonomy [13].

A fundamental part of the COSMIN taxonomy development included the creation of a checklist with 10 domains A-J (Table 2-2). Each domain then has a box set of questions relevant to that theme, to elucidate the strengths and weaknesses of the instrument or study. This allows formal appraisal of the properties of the measurement instrument by both authors and reviewers, serving as a check-rein in ensuring that only high quality valid instruments are used in studies.

Table 2-2: The COSMIN checklist of 10 measurement properties to assess the quality of an instrument [13].

Box	**Measurement property**	**Check**
A	Internal consistency	
B	Reliability	
C	Measurement error	
D	Content validity	
E	Structural validity	
F	Hypothesis testing	
G	Cross-cultural validity	
H	Criterion validity	
I	Responsiveness	
J	Interpretability	

This COSMIN checklist is in itself a measurement instrument and has been validated [13]. It is the yardstick for assessment of measurement instruments and their psychometric properties. Its contents formed the criterion standard to be met in the study design of this investigation.

2.5 Selecting a shoulder pain measurement instrument

Selecting the appropriate measurement instrument for shoulder pain is important for the patient, but also for the surgeon. Clinicians working in South Africa have very limited patient contact time, due primarily to the co-burden of a high patient load and limited resources [14,15]. This makes the adoption of PROM's difficult, as, despite their benefits, there is already clinician reluctance to implement PROM's due to fear of them increasing their workload [16]. Adopting an instrument that the patient may fill in prior to the consultation is thus necessary. This allows a directed assessment of points raised in the questionnaire, actually saving on contact time.

There are at least 39 measurement instruments for assessing shoulder pain arising from rotator cuff disease alone [17]. Many shoulder scores are used inappropriately and most often in case series or other low levels of evidence, leading to flawed conclusions [5]. In accordance with the criterion standard defined above, the Oxford Shoulder Score is an appropriate measure to implement.

2.5.1 The Oxford Shoulder Score

The OSS is a validated outcome score consisting of a 12-item questionnaire, each with five options graded in a Likert scale system [18]. Revised in 2009 to a more intuitive scoring system [19], it consists of four questions covering aspects of pain intensity and frequency, and eight questions probing activities of daily living where shoulder movements are central to function. It has been assessed independently and found to be a highly reliable and responsive scoring system for surgery of the shoulder [20-22]. It is one of only two scores recommended by the American Academy of Orthopaedic Surgeons for assessment of shoulder pain. Critically, it fully represents the patient's perspective due to the incorporation of interviews in the development of the instrument. It is easy to administer, places very little burden on the patient and is continually being assessed for improvement and sensitivity to clinically significant changes [19].

2.6 Translation and cross-cultural adaptation of an orthopaedic outcome measure

A multitude of validated scores covering the full spectrum of shoulder pathology are available. Each has been validated to a greater or lesser degree in the process of instrument development, but few utilise a universal criterion standard to which the process of validation has been held. Further, some reviews of studies incorporating outcome measures point to the lack of statistically rigorous, high-level evidence available to draw appropriate conclusions [23,24]. This is primarily due to low patient numbers. In order to achieve these numbers it is imperative that existing scores be culturally adapted and translationally validated to compare global orthopaedic disease burden [15,25,26].

Countries vary broadly in language, culture, heritage, religion, socio-economics and perceptions about disease, all of which influence patterns in health seeking behaviour and expression of illness or pathology [27]. Direct application of an English questionnaire where English is not the native language is ill advised, for the potential for misinterpretation of culturally derived references or norms is great. This would likely result in skewed data, compromising the integrity of the study and hence validity of the conclusions [28,29].

2.6.1 Cross-cultural validation and translation criteria

The COSMIN initiative defined robust criteria for cross-cultural validation, and these quality criteria are central in outlining the translation processes to follow. These recommendations (included overleaf in Table 2-3) are congruent with the opinion of the OSS developers [19], and favour both a forward and back translation process, with discrepancies mediated by consensus agreement, and an assessment of the translated score's measurement properties as originally described in the German translation of the OSS [30]. It is these criteria that structured this study's methodology.

Table 2-3: The COSMIN initiative design requirements defined for cross-cultural validation [13].

Box G. Cross-cultural validity				
Design requirements		**yes**	**no**	**?**
1	Was the percentage of missing items given?	☐	☐	
2	Was there a description of how missing items were handled?	☐	☐	
3	Was the sample size included in the analysis adequate?	☐	☐	☐
4	Were both the original language in which the HR-PRO instrument was developed, and the language in which the HR-PRO instrument was translated described?	☐	☐	
5	Was the expertise of the people involved in the translation process adequately described? e.g. expertise in the disease(s) involved, expertise in the construct to be measured, expertise in both languages	☐	☐	
6	Did the translators work independently from each other?	☐	☐	☐
7	Were items translated forward and backward?	☐	☐	☐
8	Was there an adequate description of how differences between the original and translated versions were resolved?	☐	☐	
9	Was the translation reviewed by a committee (e.g. original developers)?	☐	☐	
10	Was the HR-PRO instrument pre-tested (e.g. cognitive interviews) to check interpretation, cultural relevance of the translation, and ease of comprehension?	☐	☐	
11	Was the sample used in the pre-test adequately described?	☐	☐	
12	Were the samples similar for all characteristics except language and/or cultural background?	☐	☐	☐
13	Were there any important flaws in the design or methods of the study?	☐	☐	
Statistical methods		**yes**	**no**	**NA**
14	for CTT: Was confirmatory factor analysis performed?	☐	☐	☐
15	for IRT: Was differential item function (DIF) between language groups assessed?	☐	☐	☐

2.7 Translation and cross-cultural validation of the Oxford Shoulder Score

2.7.1 Oxford Shoulder Score translation into European languages

Translation of the OSS was first described into German in 2004 by Huber et al [30]. Recognising the perils of applying an English questionnaire to a non-native English community, they duly independently forward and back translated the English version, with discrepancies settled by panel consensus. This was then trialled in a pilot study, and definitively compared to the validated Constant Murley shoulder score, the UCLA shoulder score and the Medical Outcome Short form 36 (MOS sf-36) in a prospective cohort of 102 patients. The MOS sf-36 is a comprehensive general health questionnaire which assesses the impact of any impairment on eight subscales: physical function, social function, limitations caused by physical symptoms, limitations caused by emotional problems, general mental health, vitality, pain, and perception of general health [1].

Although the COSMIN checklist was only formally developed six years later, Huber et al's method of psychometric testing followed the majority of the recommendations (as these were based on the SAC's criteria which were already in existence), with an adequate assessment of internal consistency, reproducibility and validity, and incorporation of time required, comprehensibility and acceptance [30].

A criticism of their methodology is that no assessment of floor or ceiling effects were made, potentially skewing the data if patients scored consistently high or low for a particular question. Further, no assessment of the minimal clinically important change in the score was made. Subsequently from 2008 to 2012, the Norwegian [31], Italian [32], Dutch [33], Danish [34] and Turkish [35] versions of the OSS were produced, each with varying degrees of methodological rigour.

The Norwegian OSS group were the only group to document a subjective measure of stability assessment in the reproducibility analysis, asking each patient included in the test-retest statistic whether their shoulder condition had changed in the preceding week, and excluding those who said it had [31]. The remainder of the studies simply shortened the time interval to between 24 and 72 hours and assumed no change in clinical condition of the shoulder in their cohorts.

The psychometric properties of all the translations were similar, with all studies concluding that their respective translations were suitable and appropriate for use in their respective populations. All were published in peer review journals. The Danish version of the OSS is

however less vigorous, as it was only validated against the Constant Murley score. Besides this, the humourous double entendre of "Data were collected by three bachelor students in rehabilitation." [34] exemplifies the difficulty in communicating in a language that is not your native language, even in scientific, published, peer reviewed writing.

2.7.2 Oxford Shoulder Score translation into Asian languages

In 2012 Roh et al translated and validated the Korean OSS [36]. This was the first OSS translation to appear in the East. The Chinese version of the OSS was then published in 2015 [37]. For both the Korean and Chinese versions, the translation and validation processes were statistically thorough, and a detailed description and assessment of the psychometric properties given.

As compared to the western patient populations, the eastern populations were similar in age and heterogenous with respect to gender distribution. Also, as appropriately defined by the OSS, most patients included were similar with respect to pathology, predominantly afflicted with either degenerative or inflammatory conditions of the shoulder [30,32-37].

2.7.3 Most recent Oxford Shoulder Score translations

The OSS's use continues to expand with translation and validation into French as recently as September 2016 [38]. It is now also available in Brazil, having been validated in a population of Rheumatoid arthritis patients with inflammatory shoulder pathology [39]. To date, it has not been translated into any African language.

2.8 Present PROM utilisation and its effects

There is some reticence to PROM utilisation in the clinical setting and generally there is conflicting evidence about the utility of PROMs in routine patient care [40]. This likely stems from confusion about the exact indication and specific application of the PROM, as they may be used for multiple purposes [41]:

1. Screening tools
2. Monitoring tools
3. Method of promoting patient-centred care
4. Decision aid
5. Method of facilitating communication amongst multidisciplinary teams (MDTs)
6. Monitoring the quality of patient care

Their use is further expanding to quality of care studies, 'feeding back information on patients' health, health-related quality of life and other health-related constructs in an attempt to improve patient care' [40]. Although not originally designed for this purpose, the theoretical basis for this is sound. At an individual level, feedback on patient health may alter clinical decision-making in the form of further investigations, sub-specialist opinion on difficult cases or altered medication or treatment. At a patient population level the results may be collated and distributed, used for performance monitoring and to encourage clinical audit [40].

The positive knock-on effects of PROM incorporation cannot be overstated: They are at the epicentre of a patient centred approach to healthcare. Santana and Feeny in 2014 highlighted this by outlining a framework for the cascade of effects their incorporation would result in (Table 2-4 overleaf). Facilitating communication was the core element, resulting in improved patient engagement/activation, shared decision-making, patient management and satisfaction, clinician satisfaction and patient adherence and outcome [42].

Table 2-4: Description of the positive effects of PROM incorporation into clinical practice [42].

Framework components	Description
Communication	Clinician–clinician
	Patient–clinician
	Patient–relative
	Clinician–relative
Patient engagement/ activation	Individual better understands their role in the care process and has the knowledge, skill, and confidence to carry it out
	Patients who are activated are ENGAGED in more preventive behaviors, healthy behaviors, self-management behaviors
Shared decision making	Process by which patients and clinicians discuss patient preferences and outcome probabilities to agree mutually on a plan for care
Patient management	Patient self-management of chronic disease
	Clinician management of patient with chronic disease
Patient satisfaction	Enhanced communication positively affects patient satisfaction
	Actively engaged patients are more satisfied with their treatment and have better outcomes
Clinician satisfaction	Enhanced communication positively affects clinician satisfaction
	Clinician satisfaction affects positively the management of patient with chronic disease
Patient adherence	Actively engaged patients involved in the decision-making process tend to adhere to treatment advice
Patient outcome	*Reduction*
	Adverse outcomes
	Medical mismanagement
	Readmission rates
	Length of stay in hospital
	Improvement
	Overall health status and health-related quality of life
	Survival rates

2.9 Knowledge gaps and rationale for this study

South Africa is in stark contrast with developed countries that have electronic databases and touch screen technology available to patients enabling instant data capturing and recording. Resource allocation is rightly heavily weighted in favour of public health provision and effective service delivery to an overwhelmingly poor population, but this leaves very little for evidence-based research. Add to this that South Africa also has a very diverse population, with a total of eleven official languages each representing at least one (but many have more) ethnographic

groups. To gather accurate patient reported outcome data across this diversity is extremely difficult, and it's this combination of factors that is partly responsible for the dearth of evidence for surgical disease in South Africa.

Despite these challenges, it is essential that accurate patient outcomes for shoulder pain be recorded in our population, as the burden of musculoskeletal disease does not escape the low to middle income countries [43]. Further, due to the relatively higher proportion of our population that rely on manual labour for income, it could be argued that it is even more important in this socio-economic group, as this work places individuals at high risk for the development of shoulder pathology [44].

Afrikaans is the most spoken language in the western half of South Africa, with 50% of the Western Cape population speaking it as a first language, and the total number speaking it totalling almost seven million people [15,45]. With increased emphasis on randomised controlled trials to provide adequate answers to clinical questions [26], and the difficulty in acquiring sufficient patient numbers without multicentre international collaboration [25], the aim of this study was to translate and cross-culturally validate the OSS into Afrikaans to enable appropriate assessment of our patient populations' shoulder pain, and generate a body of evidence to aid forming guidelines which are applicable in South Africa.

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Chapter three

3. Manuscript in publication-ready format

This manuscript has been submitted to the Journal of Quality of Life Research and, as such, adheres to their submission guidelines. Specifically to ensure consistency, the same referencing style has been applied throughout this thesis. A copy of the guidelines is included in appendix 5.

3.1 Title page

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3.2 Abstract

Purpose: The Oxford Shoulder Score (OSS) is a robust and universally utilised shoulder score that has been translated for use in Western and Asian countries. This study aimed to translate, cross-culturally adapt and psychometrically validate the Afrikaans version of the OSS for use in Africa.

Methods: Translation and cross-cultural adaptation was performed in accordance with guidelines in the literature. 108 consecutive patients with either degenerative or inflammatory pain of the shoulder were prospectively enrolled. Patients were evaluated by completing the Afrikaans OSS, Constant-Murley, quickDASH, and the Subjective Shoulder Value (SSV) scores. Comprehensibility and acceptance, as well as any floor or ceiling effects, were calculated. Reliability was assessed through reproducibility. Internal consistency was assessed using Cronbach's alpha. Validity was determined using a Pearson Correlation Co-efficient between the Afrikaans OSS and the other validated shoulder scores.

Results: Comprehensibility and acceptance were excellent, and no floor or ceiling effects were observed. Reproducibility (r = 0.99) and internal consistency (Cronbach's alpha = 0.93) were both excellent. Correlation of the Afrikaans OSS with the Constant-Murley and quickDASH was excellent (r = 0.84; r = 0.81 respectively), and very good with the SSV and VAS pain score (r = 0.73; r = 0.66).

Conclusion: The Afrikaans OSS proved understandable, acceptable, reliable and valid. It is an appropriate instrument for use in Afrikaans speaking patients with shoulder pain from degenerative or inflammatory origin.

Keywords: Patient Reported Outcome Measure (PROM); Oxford Shoulder Score (OSS); Shoulder pain; Afrikaans; Questionnaire; Cross-cultural; Quality of Life; Psychometrics; Rotator cuff disease.

3.3 Manuscript

3.3.1 Introduction

Shoulder pain from inflammatory or arthritic disease is a disabling condition, with an incidence of 7% in the general population rising to about 20% in the elderly [1,2]. Most studies on shoulder pain have been conducted in developed countries [3], but the burden of musculoskeletal disease does not escape low to middle income countries [4]. Here manual labour predominates to generate income, involving repetitive work, working with hands above shoulder height, carrying heavy loads and operating vibrating tools; all of which increase the risk for shoulder pathology [4-7].

The Oxford Shoulder Score (OSS) is a joint specific patient reported outcome measure (PROM) created to assess patient perception about their shoulder pain and its affect on their quality of life. It has been translated and validated into numerous European and Asian languages [5,6,8-13], reflecting its robustness and universal acceptability. It is however yet to be translated and validated into any African language.

Afrikaans is the most spoken language in the western half of South Africa, with 50% of the Western Cape population speaking it as a first language, and the total number speaking it totalling almost seven million people [14,15]. There is increasing emphasis on randomised controlled trials to provide adequate answers to clinical questions [16], but difficulty in acquiring sufficient patient numbers without multicentre international collaboration [17]. The aim of this study was thus to translate and cross-culturally validate the OSS into Afrikaans to enable appropriate assessment of our patient populations' shoulder pain, and increase patient recruitment for multicentre international trials.

3.3.2 Methods

The study was conducted in three distinct phases. The first phase involved translation of the OSS, followed by a pilot study, run to assess comprehension and suitability of the translated questionnaire. Lastly a definitive prospective trial was undertaken.

Translation and pilot study

Translation was performed in accordance with guidelines in the literature [16,18,19]. Due to the wide variety of dialects spoken among the various ethnic groups, emphasis on understanding and simplicity of concept over grammatical correctness was requested.

Three bilingual speakers independently translated the OSS into Afrikaans. Each person had a medical background and at least a university level degree of education. A single translated version was then agreed upon by consensus decision. Three different translators then back translated this version into English. Following this, a final version was agreed upon, again at consensus, which matched the original version of the OSS. The translated OSS was piloted on ten consecutive bilingual patients presenting to the upper limb outpatient clinic with shoulder pain. Comprehensibility for 11 of the 12 questions was perfect. One question required adjustment of one word to a more colloquial form to facilitate easier understanding. All patients completed the questionnaire in less than six minutes and none described the test as difficult or onerous.

Validation study

108 consecutive patients were prospectively recruited via the upper limb outpatient clinic of a tertiary care hospital in Cape Town, from July to November 2015. Patients were included if they were over 18 years old, able to read, write and speak both English and Afrikaans, and had shoulder pain arising from inflammatory, degenerative or post-traumatic causes. Patients with shoulder pain from instability, as well as literacy and language difficulties were excluded.

Each patient first completed the translated OSS, followed by the quickDASH [20] (which had a VAS pain score included), Subjective Shoulder Value [21] and Constant Murley Shoulder Assessment [22]. The clinical assessment of the Constant Murley Score was administered by a single researcher, under the guidance of and following a training session with the head of the Shoulder Unit.

<u>Patient Specific Outcome Scores</u>

Oxford Shoulder Score

The OSS is a shoulder specific PROM devised for use in patients with degenerative or inflammatory conditions thereof. It elucidates both the degree and frequency of pain, and its impact on shoulder related activities of daily living (ADL's). There are 12 questions, graded in the original paper on a Likert scale from 1 to 5, with a range from 60 (worst) to 12 (best)

score[2]. This was later revised to a more intuitive 0 to 4 scale, with a range from 0 (worst) to 48 (best) [23]. It is simple to administer, valid, consistent, sensitive to clinical changes and reliable [2,23-25].

QuickDASH -11 Score

The quickDASH score consists of 11 questions each graded 1 to 5. For each question one selection is made, representing the score as felt by the patient over the last week. The scores are then summed, and mathematically manipulated to a score out of 100 [20]. This abbreviated version of the more comprehensive DASH score is reliable, valid and responsive to change [26,27].

A Visual Analogue Scale (VAS) score, rating pain level with activity, but not specifying the duration, was also recorded with the quickDASH. The scale was from 0 (no pain) to 10 (worst pain).

Subjective Shoulder Value

The Subjective Shoulder Value (SSV) is a patient estimation of the function in their afflicted shoulder, relative to their completely normal shoulder, expressed as a percentage [21].

Constant-Murley Score

This shoulder scoring system is a combination of subjective (patient reported - 3 questions) and objective (clinician based - 5 measurements) assessment, adding to a total out of 100. Of the subjective questions, one examines the pain severity and two determine affect on ADL's (max 35 points). The objective measurements involve four questions assessing range of shoulder motion (max 40 points) and a last question evaluating abduction force as measured in pounds by a spring scale [22].

Statistical analysis

Sample size calculation

An a priori power calculation, setting α at 0.05 and the power at 80%, defined a need for at least 44 patients. This assumed a population mean of 24.9 for the OSS (Std Dev 9.0) [23], a minimal clinically important difference of half the standard deviation [28], and a postulate sample mean to be within 2 points of the population mean. Despite an acceptable power with only 44 patients,

most other studies, in accordance with Terwee et al's recommendations [25], included more than 100 patients when translating and validating the OSS into their native language [5,8,10,9].

Comprehensibility, acceptance and time

Comprehensibility and acceptance were assessed by compliance through the number of questions answered or omitted. No more than two questions may be omitted for the questionnaire to be valid, and if any single question had two or more answers, we adhered to the convention of adopting the worse score for recording [23]. The time taken for the patient to complete the OSS was recorded.

Floor and ceiling effects

Floor and ceiling effects were also determined to assess whether there was any bias introduced at the extremes of the scores [19]. If more than 15% of the respondents achieve either the highest or lowest score, these effects are present [29]. This limits content validity, as discrimination is lost at the limits of the scale.

Reliability

Reliability is a measure of stability of a test [8]. It consists of a measure of both *reproducibility* and *internal consistency*. The American Society for Testing and Materials (ATSM) recommends both a qualitative statement of the test set up and a quantitative statement of precision when assessing the reliability of a measurement tool where the accepted reference values are not known or exactingly defined for the population [30,31].

This precision in questionnaires involves test-retest reproducibility. It was measured by contacting the first 40 patients telephonically between 24-48 hours of their consult, to again complete the Afrikaans OSS. A Pearson correlation coefficient (r) was used to determine the correlation between these overall test scores. Pearson correlation coefficients may range from -1 (inverse correlation) to 1 (perfect correlation), with values nearing 0 indicating very poor correlation [9,10]. Further, a Bland Altman plot was calculated to determine the test-retest score consistency relative to the overall mean, across the range of scores [32].

Internal consistency was determined by calculating Cronbach's alpha. It defines the correlation between all the items within a scale[8]. Values may range from 0 to 1, with 0.90 – 0.95 optimal for clinical application [33]. Values above 0.95 indicate items are too similar and may be redundant.

Validity

Validity is a qualitative characteristic that may be described according to face, content, criterion and construct [34]. Validity of face exists in that the OSS is ostensibly a questionnaire developed to assess patient's perceptions about their shoulder problems. Content validity was established in the original derivation of the OSS through exploratory interviews with patients, without 'imposing clinical assumptions' and ensuring complete understanding prior to questionnaire finalisation [2].

Criterion validity cannot truly be determined as there is no universally accepted benchmark PROM for shoulder pain. Validity of construct was assessed by calculating the Pearson correlation between the Afrikaans OSS and the quickDASH, the VAS pain score, the Subjective Shoulder Value and the Constant-Murley score. The correlation was interpreted as poor, fair, moderate, very good and excellent when r = |0.00-0.20|, r = |0.21-0.40|, r = |0.41-0.60|, r = |0.61-0.80| and r = |0.80-1.00|, respectively [35].

3.3.3 Results

Translation

No major discrepancies were noted between translators in either the forward or backward translation of the OSS. Consensus agreement was reached easily.

Patient and questionnaire characteristics

All 108 patients who met the inclusion criteria participated and completed the questionnaires. Demographic data and pathology were recorded and are outlined in Table 1.

Table 1 Demographic data and diagnosis for the study population.

39 patients were pending planned surgery, 40 patients post surgery (not within 6 weeks postoperatively) and 29 patients were being managed conservatively with no scheduled surgery.

Comprehensibility, acceptance and time

No patients reported any difficulty with comprehension. Acceptance was excellent with all patients answering all the questions for the OSS, and only one patient omitting one question for the quickDASH. The mean time (min:sec) to complete the OSS was 4:09 (Standard Deviation {SD} ± 1:12). Overall absolute values, mean scores and the ranges are given in Table 2.

Table 2 Mean ± SD and ranges for the scores of all the outcomes measures used.

Floor and ceiling effects

In the OSS dataset, the lowest possible score is 0 and the highest possible score is 48. Seven respondents achieved the lowest and only one achieved the highest, totalling 7.4% of all respondents. No floor or ceiling effects were thus present.

Reliability

The test-retest reproducibility for the 40 patients was very high (r = 0.99). The mean difference between the questionnaires was 0.2 points. (95% CI -0.31 to 0.43). The internal consistency was also high (Cronbach's α = 0.93). Single question elimination did not drop the value significantly, with all items correlating (Item Total Correlation ≥ 0.65) (Table 3).

Table 3 Mean scores and SD's for each question of the Afrikaans OSS, along with each Item Total Correlation and measure of internal consistency.

A Bland Altman plot was calculated to indicate the differences between the test-retest scores, as plotted against the overall mean and across the range of scores. (Figure 1) There were only two outliers, with no trends observed across the range of scores.

Figure 1 A Bland Altman plot of the differences between the 40 test-retest scores, plotted against the overall mean, across the range of scores achieved

Validity

Pearson correlation co-efficients calculated between the Afrikaans OSS and the Constant-Murley and quickDASH were excellent (r = 0.84 and 0.81 respectively), and very good for the SSV and the VAS pain score (0.73 and 0.66 respectively)

3.3.4 Discussion

Afrikaans was originally derived from Dutch and is now the first language for approximately seven million people in Southern Africa [15]. It is a diverse language with multiple dialects and expressions within each dialect, which creates the potential for misunderstanding of questions. This was borne out in our study in the pilot phase, with one question requiring revision of a word "kruideniersware" meaning "groceries", to the more colloquial and direct translation of "huishoudelike inkopies", meaning "household shopping". This was rectified for the definitive study, and the results indicate excellent acceptance and understanding, for all patients answered all questions, skipping none. This overall response rate of 100% was similarly high in comparison to other studies [8-12].

The mean age of 55 was approximately the same as that reported for other OSS translation study populations [8-12]. There was a slight female preponderance in our study (Male – female, 49 – 59), which was similar to the Turkish [11] and Chinese [12] findings. The Dutch [5] and German [8] population had approximately equal numbers, with the Italian [9] and Korean [10] population had a strong male prevalence. This probably reflects the heterogeneity of shoulder pain from inflammatory or degenerative disease, without a specific gender associated risk [36,37].

The mean time taken to complete the OSS (4min9sec) was slightly longer than in other translations [8-10,12]. This may reflect the patient population that we serve, for although the inclusion criteria mandated that patients were bilingual in both Afrikaans and English, many only had access to a basic education possibly resulting in more time to read and complete the questionnaire.

The psychometric properties of the Afrikaans OSS were excellent across all measurements and compared favourably with other validation studies. The test-retest reproducibility was very high ($r = 0.99$), and the internal consistency was excellent (Cronbach's alpha = 0.93) indicating the translated OSS is reliable (Table 4).

Table 4 Overall mean values and standard deviations of the OSS for different translation studies[2,5,8-12].

By correlating the translated OSS with the Constant Murley, the quickDASH, the Subjective Shoulder Value and a VAS pain score, construct validity was determined. All the comparative outcome scores are reliable and widely accepted, and correlations between each were either

"very good" or "excellent", demonstrating good construct validity. The Bland Altman plot of the differences against their means indicated no systematic bias across the range of scores.

The English (data from original paper), German, Italian, Dutch and Korean translations used the older OSS scoring system, while the Chinese and Turkish have adopted the newer, more intuitive scoring system. Absolute values for the scores give an indication of the severity of the patient's perception of their shoulder problem. With simple mathematical conversion, the standardised scores for comparison are given below (Table 5).

Table 5 Standardised mean scores for the OSS for each language (Range 0-48).

The mean score for the Afrikaans patients is at least 4.6 points below the mean of the lowest scoring population group compared. This is equal to a minimal clinically important difference for the OSS [23]. Reasons for this difference are likely due to disparate health care access and our patient population. Low-income populations generally have inferior access to health care services. Patients often only seek help when it is direly needed due to the prohibitive transport cost and long waiting times. This may result in perceived and 'real' differences in their shoulder pain, both from patient desperation for assistance with their shoulder and disease progression.

There are some limitations that merit discussion. Firstly, our patient cohort is from a single centre, and although our drainage area is broad and encompasses a wide spectrum of Afrikaans dialects, it will not have included them all. Secondly, unlike other studies that translated the OSS into their native languages [5,8,9,11,12], we chose not to use a generalised health assessment questionnaire when assessing construct validity. Although shoulder specific pathology may not necessarily have direct impact on overall patient function and wellness [5,10], this would not reflect in our study. Lastly, we did not include a measure of sensitivity to change within the questionnaire, which would have aided assessment of responsiveness.

3.3.5 Conclusion

The Oxford Shoulder Score has been translated, cross-culturally adapted and validated into Afrikaans in this study. The questionnaire was easily comprehended and completed by all patients. Measures of stability and validity were robust in statistical analysis, with excellent internal consistency and construct validity in comparison to other shoulder outcome scores. It is appropriate for use in Afrikaans speaking patients with shoulder pain from degenerative or inflammatory origin.

Compliance with Ethical Standards

This research required no funding.

Conflict of interest: All authors declare that they have no conflict of interest.

Ethical approval: All procedures performed in this study were in accordance with the ethical standards of the Human Research Ethics Committee (HREC) of the University of Cape Town. (HREC study approval number: 457/2014) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study. A copy of the form is included as Appendix 2.

3.3.6 References

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3.4 List of tables

Table 1 Demographic data and diagnosis for the study population.

Patients (n)	108
Mean age - years (±SD)	55 (13)
Age range - years	18 - 84
Male - Female	49 - 59
Right - Left handed	105 - 3
Right - Left shoulder	69 - 39
Dominant shoulder	70
Diagnoses (%)	***n (%)***
• Impingement syndrome with rotator cuff tear	27 (25)
• Impingement syndrome without rotator cuff tear	17 (15.7)
• Primary or secondary OA (Glenohumeral or Acromioclavicular)	33 (30.6)
• Adhesive capsulitis	13 (12)
• Calcified deposits in rotator cuff	3 (2.8)
• Other diagnoses	15 (13.9)
○ Proximal humerus fracture or non-union	3 (2.8)
○ Chronic elbow dislocation with shoulder pain	3 (2.8)
○ Acute R/C tear and clavicle fracture	2 (1.9)
○ Traumatic suprascapular nerve palsy	2 (1.9)
○ ACJ dislocation with pain	1 (0.9)
○ Tuberculosis of the shoulder	1 (0.9)
○ No diagnosis	3 (2.8)

Table 2 Mean ± SD and ranges for the scores of all the outcomes measures used.

	Scores	
	Mean ± SD	Range
OSS	18.03 ± 11.99	0-48
quickDASH	65.00 ± 23.85	0-100
quickDASH pain VAS	7.03 ± 2.39	0-10
Constant-Murley	35.26 ± 21.48	0-96
SSV (%)	41.29 ± 23.34	2-95

Table 3 Mean scores and SD's for each question of the Afrikaans OSS, along with each Item Total Correlation and measure of internal consistency.

Question	Mean score (±SD)	Item Total Correlation	Cronbach's α (1 item removed)
1	1,036 ± 0.976	0.678	0.924
2	1.772 ± 1.359	0.777	0.920
3	2.455 ± 1.418	0.700	0.924
4	2.200 ± 1.543	0.770	0.921
5	1.682 ± 1.433	0.771	0.921
6	1.818 ± 1.546	0.676	0.926
7	1.364 ± 1.393	0.793	0.919
8	1.255 ± 1.112	0.760	0.921
9	1.200 ± 1.387	0.800	0.919
10	1.536 ± 1.488	0.851	0.916
11	1.091 ± 1.130	0.784	0.920
12	0.836 ± 1.129	0.646	0.926

Table 4 Overall mean values and standard deviations of the OSS for different translation studies[2,5,8-12].

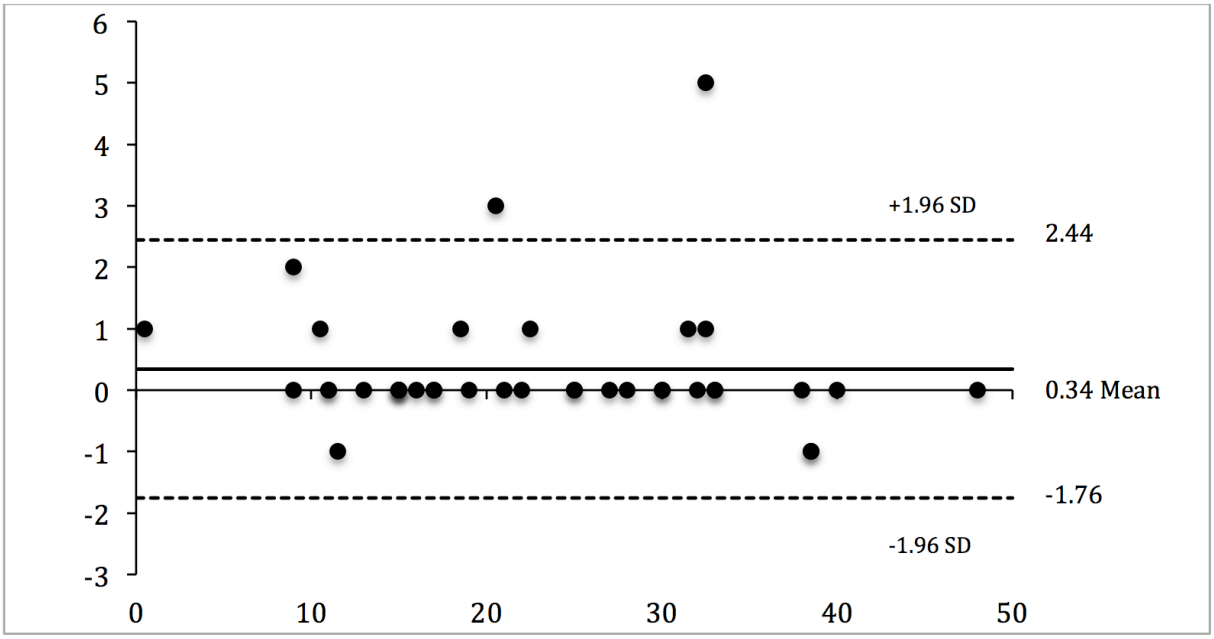
	Afrikaans (n = 108)	Chinese (n = 121)	English (n = 111)	Dutch (n = 103)	German (n = 102)	Italian (n = 140)	Turkish (n = 84)	Korean (n = 105)
OSS (Mean & SD)	18.03 ± 11.99	Not stated	36.3	32.5 ± 9.5	27.34 ± 10.42	36.05 ± 13.95	22.58 ± 9.88	25.6 ± 7.3
Reliability								
Cronbach's Alpha	0.93	0.92	0.89-0.92	0.92	0.94	0.95	0.92	0.91
ICC (95% CI)/*Pearson correlation coefficient*	0.99	0.97 (0.94-0.98)	N/A	0.98	*0.98*	*0.97*	*0.99*	0.95 (0.91-0.98)
Construct Validity								
Constant Murley	0.84	0.66	0.74	0.64	0.60	0.73	N/A	0.3<r<0.6
quickDASH/DASH	0.81	N/A	N/A	N/A	N/A	N/A	N/A	>0.6
VAS (pain activity)	0.66	0.70	N/A	N/A	N/A	N/A	N/A	0.34-0.45

Table 5 Standardised mean scores for the OSS for each language (Range 0-48).

	Afrikaans (n = 108)	Chinese (n = 121)	English (n = 111)	Dutch (n = 103)	German (n = 102)	Italian (n = 140)	Turkish (n = 84)	Korean (n = 105)
OSS (Mean)	18.0	Not stated	23.7	27.5	32.7	24.0	22.6	34.4

3.5 List of figures

Figure 1 A Bland Altman plot of the differences between the 40 test-retest scores, plotted against the overall mean, across the range of scores achieved



Appendices

Appendix 1: Afrikaans OSS questionnaire

Oxford Shoulder Score

(Afrikaans translation)

PROBLEME MET U SKOUER

Merk slegs een blokkie vir elke vraag (✓).

1. Gedurende die afgelope 4 weke…				
Hoe sal u die **ergste** pyn van u skouer beskryf?				
Geen	Gering	Matig	Erg	Onuithoudbaar
☐	☐	☐	☐	☐

2. Gedurende die afgelope 4 weke…				
Het u enige probleme gehad om u self klere uit/aan te trek weens u skouer?				
Geen probleme	Effens moeilik	Moeilik	Baie moeilik	Onmoontlik
☐	☐	☐	☐	☐

3. Gedurende die afgelope 4 weke				
Het u enige problem gehad om in en uit motors te klim, of van publieke vervoer te gebruik weens u skouer?				
Geen probleme	Effens moeilik	Moeilik	Baie moeilik	Onmoontlik
☐	☐	☐	☐	☐

4. Gedurende die afgelope 4 weke…				
Was dit vir u moontlik om 'n mes en vurk gelyktydig te gebruik?				
Ja, maklik	Met bietjie moeite	Met moeite	Met baie moeite	Nee, onmoontlik
☐	☐	☐	☐	☐

5. Gedurende die afgelope 4 weke

Kon u die huishoudelike inkopies op u eie gaan koop?

Ja, maklik	Met bietjie moeite	Met moeite	Met baie moeite	Nee, onmoontlik
☐	☐	☐	☐	☐

6. Gedurende die afgelope 4 weke…

Kon u 'n skinkbord met 'n bord kos daarop deur 'n kamer dra?

Ja, maklik	Met bietjie moeite	Met moeite	Met baie moeite	Nee, onmoontlik
☐	☐	☐	☐	☐

7. Gedurende die afgelope 4 weke…

Was dit moontlik om u hare te kam/borsel met die seer arm?

Ja, maklik	Met bietjie moeite	Met moeite	Met baie moeite	Nee, onmoontlik
☐	☐	☐	☐	☐

8. Gedurende die afgelope 4 weke…

Hoe sal u die pyn wat u gewoonlik in u skouer ervaar het, beskryf?

Geen	Gering	Matig	Erg	Onuithoudbaar
☐	☐	☐	☐	☐

9. Gedurende die afgelope 4 weke…

Was dit moonlik vir u om u klere in die kas op te hang met die seer skouer/arm?

Ja, maklik	Met bietjie moeite	Met moeite	Met baie moeite	Nee, onmoontlik
☐	☐	☐	☐	☐

10. Gedurende die afgelope 4 weke…
Was dit vir u moontlik om onder albei arms te was en af te droog?

Ja, maklik	Met bietjie moeite	Met moeite	Met baie moeite	Nee, onmoontlik
☐	☐	☐	☐	☐

11. Gedurende die afgelope 4 weke…
Tot watter mate het u skouer pyn/ongemak met u daaglikse werk (insluitend tuiswerk) u ingekort?

Glad nie	Klein bietjie	Matig	Grootliks	Heeltemal
☐	☐	☐	☐	☐

12. Gedurende die afgelope 4 weke…
Pla u skouerpyn u snags as u slaap?

Nee, geen aande	Slegs een of twee aande	Sommige aande	Meeste aande	Elke aand
☐	☐	☐	☐	☐

Maak asseblief seker u het elke vraag beantwoord.

Baie dankie.

Appendix 2: Consent form

INFORMATION FOR STUDY:
PATIENT REPORTED OUTCOME SCORES IN ORTHOPAEDICS – TRANSLATED INTO AFRICAN LANGUAGES

Institution	Individuals
Groote Schuur Hospital	DR. HELD, DR. KRUGER, DR. ROCHE

THE INFORMATION BELOW WILL BE SUPPLIED TO ALL PARTICIPANTS TAKING PART IN THIS STUDY.

What is this study about?
We are carrying out medical research to find better ways of assessing the outcome of orthopaedic illnesses and injuries. We want to ask you questions to find out how you cope in your daily life. We would like to use this data to come up with an assessment score, which will help us compare patients with each other and direct our treatment in a more structured and scientific way. We wish to translate a validated shoulder outcome score into Xhosa and Afrikaans, to make future assessment of the score easier for people who cannot understand or read English as well. You will be asked to complete the translated score first and then some other scores so we can compare these with the translated score. We would also want to ask for your permission to phone you within 3 days to ask you the same questions in the translated score to see if your answers match the score you have given us today.

What will it involve for me?
You will be treated no differently to anyone who does not take part in this study. It will involve a 15 min interview in which we will go over the questions with you.

Are there any risks or disadvantages for me taking part?
You will have exactly the same risks as someone with your condition not taking part in this study.

Are there any benefits for me?
There are no additional benefits for you and you will not be paid.

What happens if I refuse to participate?
All participation in research is voluntary. You are free to decide if you want to take part. If you do agree you can change your mind at any time and withdraw from the research. This will not affect your care now or in the future.

Who will have access to information about me in this research?
All data will be registered to a study identification code. Only the local investigators have access to the key of the coding, so identifiable data will not leave the participating centres. Any additional staff involved (Research assistance, statisticians) with the research project will see your data WITHOUT your personal details.
The data will be stored for 10 years.

Who has allowed this research to take place?
Our departmental research committee and the local ethics committee have looked carefully at this work and agreed, that the research will be conducted properly and participants' safety and rights have been respected.

What if I have any questions?
You may ask any of our staff questions at any time. Your contact person for this study is:
Dr. Steve Roche
Division of Orthopaedic Surgery, Shoulder Service
Secretaries: University of Cape Town, Mrs Priest, tel. 021 404 5108

If you want to ask someone independent anything about this research:
If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Chairperson of the Human Research Ethics Committee, Prof Blockman: 021 406 6492.

I understand the above information and agree to take part in this study

_____ _____ _____
(Initial and Name or sticker of participant) (Date) (Signature)

Appendix 3: OSS translation data collection sheet

PATIENT 1					
Name		Time to complete OSS			
Folder number		Time to record OSS			
Age		Number of questions answered (OSS)			
Gender					
Handedness		Time to complete quickDASH			
Shoulder affected		Time to record quickDASH			
Contact number		Number of questions answered (quickDASH)			
Preop/Postop					
Diagnosis	Impingement syndrome with rotator cuff tear				
	Impingement syndrome without rotator cuff tear				
	Calcified deposits in rotator cuff				
	Primary or secondary OA				
	Adhesive capsulitis/frozen shoulder				
	Other diagnosis				
	No diagnosis				

OSS		**QuickDASH**			**Constant-Murley**
Question	Score (Range 0-4)	Question	Score (Range 1-5)	Score	
1		1		Subjective (max 35)	
2		2		Objective (max 65)	
3		3		TOTAL SCORE	
4		4			
5		5			**SSV (%)**
6		6			
7		7			
8		8			
9		9			
10		10			
11		11			
12		TOTAL SCORE			
TOTAL SCORE					

Appendix 4: Human Research Ethics Committee confirmation letter

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)			
☐ Approved	☐ Type of review: Expedited	☐ Full committee	
This serves as notification that all changes and documentation described below are approved.			
Signature Chairperson of the HREC		Date	13/11/2014

Note: All amendments should include a Synopsis justifying the changes for the amendment (please see notice dated 23 April 2012)

Principal Investigator to complete the following:

1. Protocol information

Date form submitted	27.10.14
HREC REF Number	457/2014
Protocol title	Reliability of orthopaedic patient based outcome scores converted to an "image only" outcome measure
Protocol number (if applicable)	
Principal Investigator	Dr. Michael Held
Department / Office Internal Mail Address	Orthopaedic Department, H49 OMB, Groote Schuur Hospital

1.1 Is this a major or a minor amendment? (see FHS006hlp)	☐ Major	x Minor
1.2 Does this protocol receive US Federal funding?	☐ Yes	x No
1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval?	☐ Yes	x No

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval.
This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.

1. Translation of Patient Based Outcome Scores into African languages.

RESEARCH ETHICS COMMITTEE
2014 -11- 11
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

3. Protocol status (tick ✓)

x	Open to enrolment
☐	No participants have been enrolled
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only

4. Proposed changes will affect: (tick ✓ all the categories that apply)

	Protocol
☐	Study objectives, design (including investigator's brochure, clinical activities, study length)
x	Study instruments, questionnaires, interview schedules
☐	Sample size
☐	Recruitment methods
☐	Eligibility criteria (inclusion and exclusion criteria)
☐	Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information)
☐	Data collection/ analysis
☐	Principal Investigator. (Please attach revised conflict of interest and PI declaration statements. Refer: sections 7 and 8.4 in the New Protocol Application Form FHS013)
☐	Consent form and information sheet
☐	Recruitment materials (e.g. advertisements)
☐	Administrative (e.g. change in sponsor's name, change in contact information)
☐	Other. Please specify:

4.1 In your opinion, will there be any **increase** in risk, discomfort or inconvenience to participants?	☐ Yes	x No
If yes, please provide a detailed justification/explanation:		

4.2 What follow-up action do you propose for participants who are already enrolled in the study?

☐	Inform current participants as soon as possible
☐	Re-consent current participants with revised consent/assent forms (append)
x	No action required
☐	Other. Please describe:

5. Detailed description of the change(s)

Please attach, for each amendment, a summary of all changes which clearly indicates:

i. Old wording (e.g. ~~strikethrough~~ text, CHANGED FROM and CHANGED TO)

ii. New wording (e.g. *italicized*, **bold**, tracked)

iii. Detailed rationale/ justification/ explanation for each change

6. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC.

Signature of PI	Urihal Hall	Date	27.10.2014

Justification of the amended changes:

We would like to avoid bias introduced by testing "Image only" scores against English scores in patients who have poor or no English language skills. For this reason we would like to validate the original English score against translated scores.

Summery of Amendment into study design:

The Patient reported Outcome Measure (PROM) will be translated into Xhosa and Africaans (and any additional African language) before testing them against images in patients who cannot speak English. The translation will be done by a bilingual health care provider and/or non-medical translator. Bilingual patients with at least basic level education will be asked to complete the translated score and at least one other English PROM. Their age, level of education and first language will be recorded. The added score as well as the scores for the individual questions will be compared to each other and reliability will be assessed.

Each of the translated scores will be tested on an additional 100 adult patients (not included in the "image only" study cohort) under the care of members of the orthopaedic department/department of occupational therapy/department of physiotherapy at Groote Schuur Hospital or any of the teaching hospitals of the University of Cape Town. If needed for the validation, the scores will be tested in other hospitals in South Africa and Africa where certain African languages are predominant.

Appendix 5: Quality of Life Research Journal manuscript submission guidelines

Article types

Quality of Life Research welcomes scientific articles in the following categories:

- Full-Length Original Articles (must include a 250-word structured abstract, maximum word limit of 4,000 words exclusive of abstract, tables, figures, and references)
- Brief Communications (maximum word limit of 1,500 words, exclusive of structured abstract, tables, figures, and references). See section below on Brief Communications.

Full-Length Original Articles

Original articles are a maximum of 4,000 words, exclusive of a 250-word structured abstract, figures, tables, and references. We are particularly interested in studies that utilize patient-reported outcomes, focusing on clinical and policy applications of quality-of-life research; showcasing quantitative and qualitative methodological advances; and / or describing instrument development.

Brief Communications

Brief communications are a maximum of 1,500 words, exclusive of a 200-word structured abstract, up to 2 figures, up to 3 tables, and 25 references. Any topic can be submitted as a brief communication, but all manuscripts that report cross-cultural adaptations of existing measures will only be considered for publication as brief communications in Quality of Life Research. If a paper of this type provides substantially new methodological and/or substantive knowledge (e.g., a superior method of cross cultural adaptation, more thorough evaluation of the original instrument being adapted, multi-language or multi-country comparisons, etc.), authors should include a letter with their submission justifying the need for a full length report. All cross-cultural translation articles should include information in the abstract and manuscript text that summarize how psychometric characteristics of the new translation compares to the original tool.

Other Types of Articles

The journal also publishes commentaries and editorials; reviews of the literature; reviews of recent books and software advances; and abstracts presented at the annual meeting of the International Society of Quality of Life Research conference. These articles should be as long as needed to convey the desired information, and no more than 4,000 words in length. To the extent that it is possible, a structured abstract is appreciated.

Language

We appreciate any efforts that you make to ensure that the language usage is corrected before submission using standard United States or United Kingdom English. This will greatly improve the legibility of your paper if English is not your first language.

Manuscript Submission

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

Permissions

Authors wishing to include figures, tables, or text passages that have already been published elsewhere are required to obtain permission from the copyright owner(s) for both the print and online format and to include evidence that such permission has been granted when submitting their papers. Any material received without such evidence will be assumed to originate from the authors.

Online Submission

Please follow the hyperlink "Submit online" on the right and upload all of your manuscript files following the instructions given on the screen.

Title page

Title Page

The title page should include:

The name(s) of the author(s)
A concise and informative title
The affiliation(s) and address(es) of the author(s)
The e-mail address, telephone and fax numbers of the corresponding author

Abstract

Please provide a structured abstract of 150 to 250 words which should be divided into the following sections:

Purpose (stating the main purposes and research question)
Methods
Results
Conclusions

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

Text

Text Formatting

Manuscripts should be submitted in Word.

Use a normal, plain font (e.g., 10-point Times Roman) for text.
Use italics for emphasis.
Use the automatic page numbering function to number the pages.*

> ** Please note: in order to comply with Mmed regulations the overall font and page numbering was adjusted to continue the sequence in this dissertation and keep a uniform style. For actual journal submission the page numbers were adjusted accordingly.*

Do not use field functions.
Use tab stops or other commands for indents, not the space bar.
Use the table function, not spreadsheets, to make tables.
Use the equation editor or MathType for equations.Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).
Manuscripts with mathematical content can also be submitted in LaTeX.
LaTeX macro package (zip, 182 kB)

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

Scientific style

Please always use internationally accepted signs and symbols for units (SI units).

Generic names of drugs and pesticides are preferred; if trade names are used, the generic name should be given at first mention.

References

Citation

Reference citations in the text should be identified by numbers in square brackets. Some examples:

1. Negotiation research spans many disciplines [3].

2. This result was later contradicted by Becker and Seligman [5].

3. This effect has been widely studied [1-3, 7].

Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text. Do not use footnotes or endnotes as a substitute for a reference list.

The entries in the list should be numbered consecutively.

Journal article

Harris, M., Karper, E., Stacks, G., Hoffman, D., DeNiro, R., Cruz, P., et al. (2001). Writing labs and the Hollywood connection. Journal of Film Writing, 44(3), 213–245.

Article by DOI

Kreger, M., Brindis, C.D., Manuel, D.M., & Sassoubre, L. (2007). Lessons learned in systems change initiatives: benchmarks and indicators. American Journal of Community Psychology. doi:10.1007/s10464-007-9108-14.

Book

Calfee, R. C., & Valencia, R. R. (1991). APA guide to preparing manuscripts for journal publication. Washington, DC: American Psychological Association.

Book chapter

O'Neil, J. M., & Egan, J. (1992). Men's and women's gender role journeys: Metaphor for healing, transition, and transformation. In B. R. Wainrib (Ed.), Gender issues across the life cycle (pp. 107–123). New York: Springer.

Online document

Abou-Allaban, Y., Dell, M. L., Greenberg, W., Lomax, J., Peteet, J., Torres, M., & Cowell, V. (2006). Religious/spiritual commitments and psychiatric practice. Resource document. American Psychiatric Association. http://www.psych.org/edu/other_res/lib_archives/archives/200604.pdf. Accessed 25 June 2007.

Journal names and book titles should be italicized.

For authors using EndNote, Springer provides an output style that supports the formatting of in-text citations and reference list.

EndNote style (zip, 3 kB)

Tables

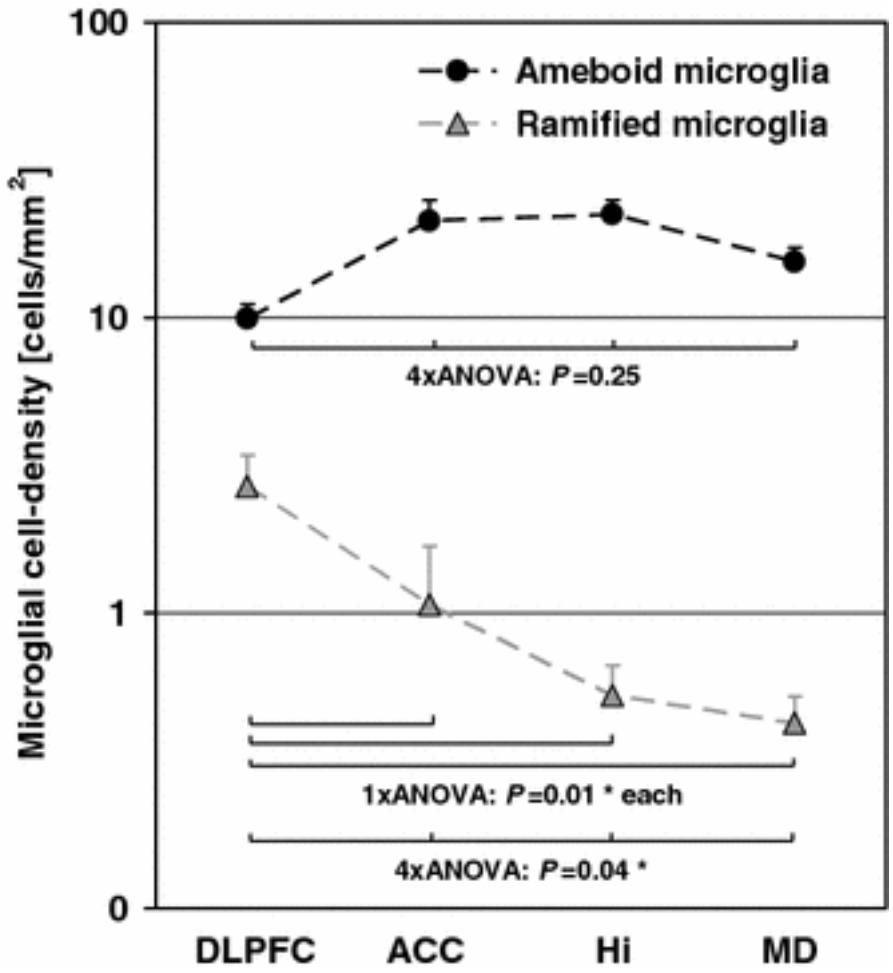
All tables are to be numbered using Arabic numerals.
Tables should always be cited in text in consecutive numerical order.
For each table, please supply a table caption (title) explaining the components of the table.
Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.
Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

Artwork and Illustrations Guidelines

Electronic Figure Submission

Supply all figures electronically.
Indicate what graphics program was used to create the artwork.
For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.
Vector graphics containing fonts must have the fonts embedded in the files.
Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

Line Art



Definition: Black and white graphic with no shading.

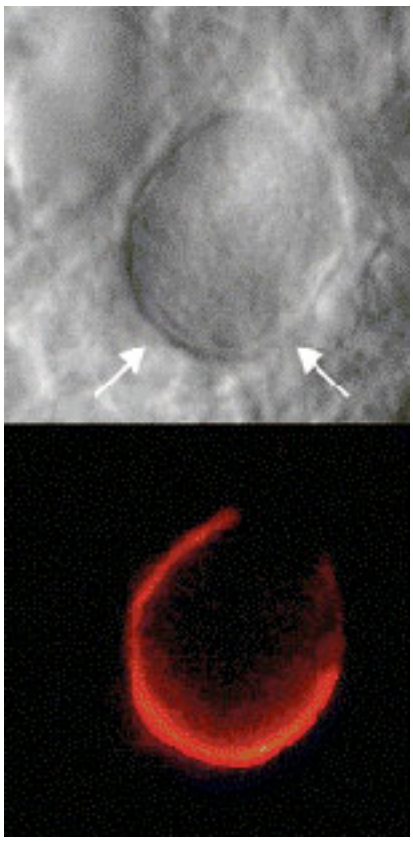
Do not use faint lines and/or lettering and check that all lines and lettering within the figures are legible at final size.

All lines should be at least 0.1 mm (0.3 pt) wide.

Scanned line drawings and line drawings in bitmap format should have a minimum resolution of 1200 dpi.

Vector graphics containing fonts must have the fonts embedded in the files.

Halftone Art

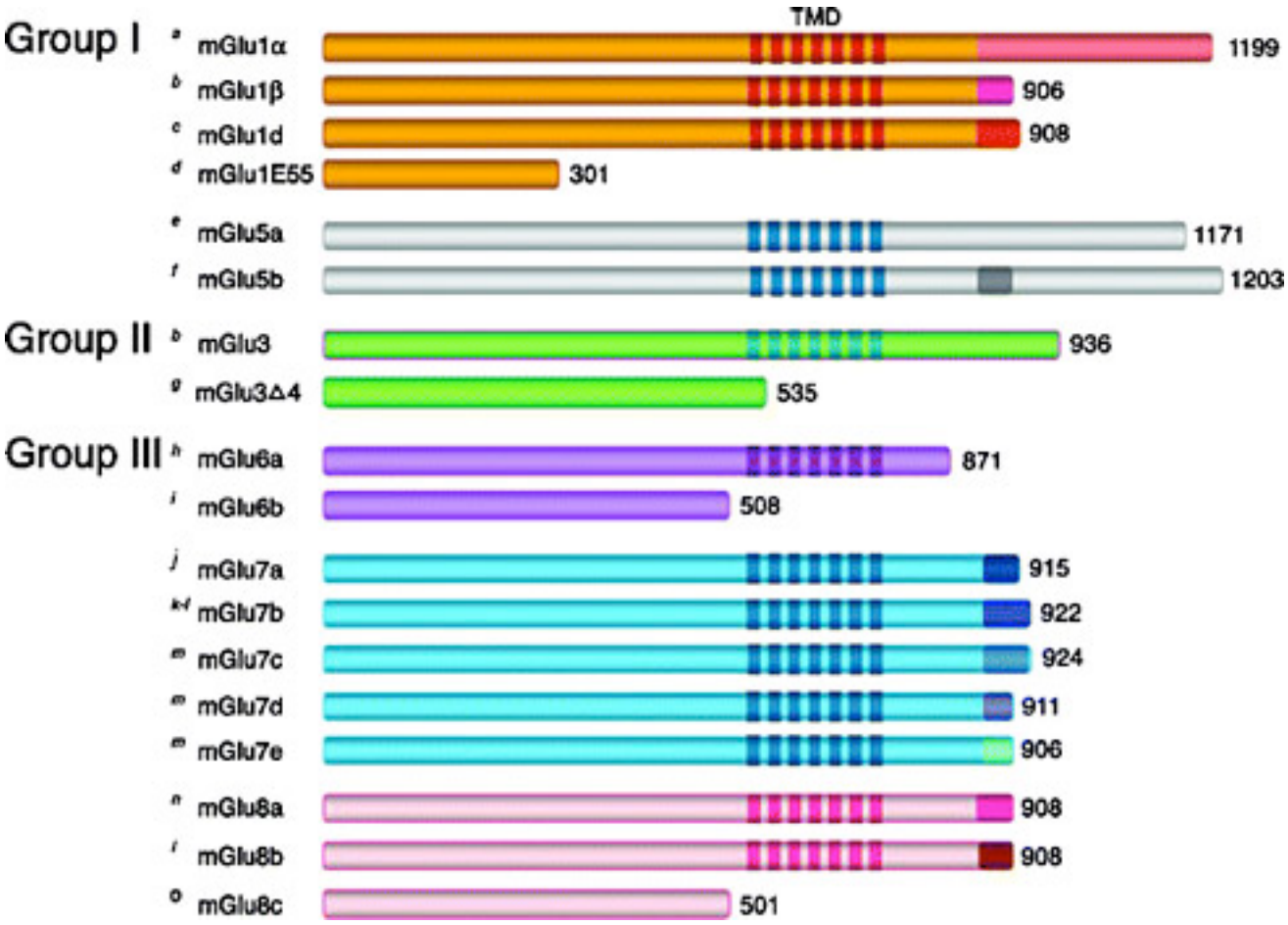


Definition: Photographs, drawings, or paintings with fine shading, etc.

If any magnification is used in the photographs, indicate this by using scale bars within the figures themselves.

Halftones should have a minimum resolution of 300 dpi.

Combination Art



Definition: a combination of halftone and line art, e.g., halftones containing line drawing, extensive lettering, color diagrams, etc.

Combination artwork should have a minimum resolution of 600 dpi.

Color Art

Color art is free of charge for online publication.

If black and white will be shown in the print version, make sure that the main information will still be visible. Many colors are not distinguishable from one another when converted to black and white. A simple way to check this is to make a xerographic copy to see if the necessary distinctions between the different colors are still apparent.

If the figures will be printed in black and white, do not refer to color in the captions.

Color illustrations should be submitted as RGB (8 bits per channel).

Figure Lettering

To add lettering, it is best to use Helvetica or Arial (sans serif fonts).

Keep lettering consistently sized throughout your final-sized artwork, usually about 2–3 mm (8–12 pt).

Variance of type size within an illustration should be minimal, e.g., do not use 8-pt type on an axis and 20-pt type for the axis label.

Avoid effects such as shading, outline letters, etc.

Do not include titles or captions within your illustrations.

Figure Numbering

All figures are to be numbered using Arabic numerals.

Figures should always be cited in text in consecutive numerical order.

Figure parts should be denoted by lowercase letters (a, b, c, etc.).

If an appendix appears in your article and it contains one or more figures, continue the consecutive numbering of the main text. Do not number the appendix figures, "A1, A2, A3, etc." Figures in online appendices (Electronic Supplementary Material) should, however, be numbered separately.

Figure Captions

Each figure should have a concise caption describing accurately what the figure depicts. Include the captions in the text file of the manuscript, not in the figure file.

Figure captions begin with the term Fig. in bold type, followed by the figure number, also in bold type.

No punctuation is to be included after the number, nor is any punctuation to be placed at the end of the caption.

Identify all elements found in the figure in the figure caption; and use boxes, circles, etc., as coordinate points in graphs.

Identify previously published material by giving the original source in the form of a reference citation at the end of the figure caption.

Figure Placement and Size

Figures should be submitted separately from the text, if possible.

When preparing your figures, size figures to fit in the column width.

For most journals the figures should be 39 mm, 84 mm, 129 mm, or 174 mm wide and not higher than 234 mm.

For books and book-sized journals, the figures should be 80 mm or 122 mm wide and not higher than 198 mm.

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Accessibility

In order to give people of all abilities and disabilities access to the content of your figures, please make sure that

All figures have descriptive captions (blind users could then use a text-to-speech software or a text-to-Braille hardware)

Patterns are used instead of or in addition to colors for conveying information (colorblind users would then be able to distinguish the visual elements)

Any figure lettering has a contrast ratio of at least 4.5:1

Electronic Supplementary Material

Springer accepts electronic multimedia files (animations, movies, audio, etc.) and other supplementary files to be published online along with an article or a book chapter. This feature can add dimension to the author's article, as certain information cannot be printed or is more convenient in electronic form.

Before submitting research datasets as electronic supplementary material, authors should read the journal's Research data policy. We encourage research data to be archived in data repositories wherever possible.

Submission

Supply all supplementary material in standard file formats.

Please include in each file the following information: article title, journal name, author names; affiliation and e-mail address of the corresponding author.

To accommodate user downloads, please keep in mind that larger-sized files may require very long download times and that some users may experience other problems during downloading.

Audio, Video, and Animations

Aspect ratio: 16:9 or 4:3

Maximum file size: 25 GB

Minimum video duration: 1 sec

Supported file formats: avi, wmv, mp4, mov, m2p, mp2, mpg, mpeg, flv, mxf, mts, m4v, 3gp

Text and Presentations

Submit your material in PDF format; .doc or .ppt files are not suitable for long-term viability.

A collection of figures may also be combined in a PDF file.

Spreadsheets

Spreadsheets should be converted to PDF if no interaction with the data is intended.

If the readers should be encouraged to make their own calculations, spreadsheets should be submitted as .xls files (MS Excel).

Specialized Formats

Specialized format such as .pdb (chemical), .wrl (VRML), .nb (Mathematica notebook), and .tex can also be supplied.

Collecting Multiple Files

It is possible to collect multiple files in a .zip or .gz file.

Numbering

If supplying any supplementary material, the text must make specific mention of the material as a citation, similar to that of figures and tables.

Refer to the supplementary files as “Online Resource”, e.g., "... as shown in the animation (Online Resource 3)", “... additional data are given in Online Resource 4”.

Name the files consecutively, e.g. “ESM_3.mpg”, “ESM_4.pdf”.

Captions

For each supplementary material, please supply a concise caption describing the content of the file.

Processing of supplementary files

Electronic supplementary material will be published as received from the author without any conversion, editing, or reformatting.

Accessibility

In order to give people of all abilities and disabilities access to the content of your supplementary files, please make sure that:

The manuscript contains a descriptive caption for each supplementary material

Video files do not contain anything that flashes more than three times per second (so that users prone to seizures caused by such effects are not put at risk)

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理文□□

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- The manuscript has not been submitted to more than one journal for simultaneous consideration.
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- A single study is not split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. "salami-publishing").
- No data have been fabricated or manipulated (including images) to support your conclusions
- No data, text, or theories by others are presented as if they were the author's own ("plagiarism"). Proper acknowledgements to other works must be given (this includes material that is closely copied (near verbatim), summarized and/or paraphrased), quotation marks are used for verbatim copying of material, and permissions are secured for material that is copyrighted. Important note: the journal may use software to screen for plagiarism.
- Consent to submit has been received explicitly from all co-authors, as well as from the responsible authorities - tacitly or explicitly - at the institute/organization where the work has been carried out, before the work is submitted.
- Authors whose names appear on the submission have contributed sufficiently to the scientific work and therefore share collective responsibility and accountability for the results.

In addition:

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If the article is still under consideration, it may be rejected and returned to the author.
If the article has already been published online, depending on the nature and severity of the infraction, either an erratum will be placed with the article or in severe cases complete retraction of the article will occur. The reason must be given in the published erratum or retraction note.
The author's institution may be informed.

Compliance with Ethical Standards

To ensure objectivity and transparency in research and to ensure that accepted principles of ethical and professional conduct have been followed, authors should include information regarding sources of funding, potential conflicts of interest (financial or non-financial), informed consent if the research involved human participants, and a statement on welfare of animals if the research involved animals.

Authors should include the following statements (if applicable) in a separate section entitled "Compliance with Ethical Standards" when submitting a paper:

Disclosure of potential conflicts of interest
Research involving Human Participants and/or Animals
Informed consent

Please note that standards could vary slightly per journal dependent on their peer review policies (i.e. single or double blind peer review) as well as per journal subject discipline. Before submitting your article check the instructions following this section carefully.
The corresponding author should be prepared to collect documentation of compliance with ethical standards and send if requested during peer review or after publication.
The Editors reserve the right to reject manuscripts that do not comply with the above-mentioned guidelines. The author will be held responsible for false statements or failure to fulfill the above-mentioned guidelines.

Disclosure of potential conflicts of interest

Authors must disclose all relationships or interests that could have direct or potential influence or impart bias on the work. Although an author may not feel there is any conflict, disclosure of relationships and interests provides a more complete and transparent process, leading to an accurate and objective assessment of the work. Awareness of a real or perceived conflicts of interest is a perspective to which the readers are entitled. This is not meant to imply that a financial relationship with an organization that sponsored the research or compensation received for consultancy work is inappropriate. Examples of potential conflicts of interests that are directly or indirectly related to the research may include but are not limited to the following:

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- Financial support for attending symposia
- Financial support for educational programs
- Employment or consultation
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- Multiple affiliations
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The corresponding author collects the conflict of interest disclosure forms from all authors. In author collaborations where formal agreements for representation allow it, it is sufficient for the corresponding author to sign the disclosure form on behalf of all authors. Examples of forms can be found here:

The corresponding author will include a summary statement in the text of the manuscript in a separate section before the reference list, that reflects what is recorded in the potential conflict of interest disclosure form(s).

See below examples of disclosures:

Funding: This study was funded by X (grant number X).

Conflict of Interest: Author A has received research grants from Company A. Author B has received a speaker honorarium from Company X and owns stock in Company Y. Author C is a member of committee Z.

If no conflict exists, the authors should state:

Conflict of Interest: The authors declare that they have no conflict of interest.

Research involving human participants and/or animals

1) Statement of human rights

When reporting studies that involve human participants, authors should include a statement that the studies have been approved by the appropriate institutional and/or national research ethics committee and have been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

If doubt exists whether the research was conducted in accordance with the 1964 Helsinki Declaration or comparable standards, the authors must explain the reasons for their approach, and demonstrate that the independent ethics committee or institutional review board explicitly approved the doubtful aspects of the study.

The following statements should be included in the text before the References section:

Ethical approval: "All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards."

For retrospective studies, please add the following sentence:

"For this type of study formal consent is not required."

2) Statement on the welfare of animals

The welfare of animals used for research must be respected. When reporting experiments on animals, authors should indicate whether the international, national, and/or institutional guidelines for the care and use of animals have been followed, and that the studies have been approved by a research ethics committee at the institution or practice at which the studies were conducted (where such a committee exists).

For studies with animals, the following statement should be included in the text before the References section:

Ethical approval: "All applicable international, national, and/or institutional guidelines for the care and use of animals were followed."

If applicable (where such a committee exists): “All procedures performed in studies involving animals were in accordance with the ethical standards of the institution or practice at which the studies were conducted.”

If articles do not contain studies with human participants or animals by any of the authors, please select one of the following statements:

“This article does not contain any studies with human participants performed by any of the authors.”

“This article does not contain any studies with animals performed by any of the authors.”

“This article does not contain any studies with human participants or animals performed by any of the authors.”

Informed consent

All individuals have individual rights that are not to be infringed. Individual participants in studies have, for example, the right to decide what happens to the (identifiable) personal data gathered, to what they have said during a study or an interview, as well as to any photograph that was taken. Hence it is important that all participants gave their informed consent in writing prior to inclusion in the study. Identifying details (names, dates of birth, identity numbers and other information) of the participants that were studied should not be published in written descriptions, photographs, and genetic profiles unless the information is essential for scientific purposes and the participant (or parent or guardian if the participant is incapable) gave written informed consent for publication. Complete anonymity is difficult to achieve in some cases, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of participants is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic profiles, authors should provide assurance that alterations do not distort scientific meaning.

The following statement should be included:

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If identifying information about participants is available in the article, the following statement should be included:

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