A comparison between two types of osteosynthesis for distal radius fractures using validated Danish outcome measures

PhD dissertation

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2010

PhD dissertation by Jesper O. Schønnemann
Public defence: Thursday, 2 September 2010 at 13.00
Auditorium, Regional Hospital Holstebro.

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Preface

This dissertation was done during my employment as a research-fellow and doctor at the Department of Orthopaedics, Hospital Unit West, and is based on studies performed during the period 2007-20010. Studies were carried out at Regional Hospital Holstebro, Regional Hospital Herning and Regional Hospital Viborg.

I would like to thank the staff, doctors, nurses, secretaries and others, at the hospitals for their enthusiasm, tolerance, good spirits and support during my studies.

I am indebted to my supervisors, Kjeld Søballe and Torben Bæk Hansen, for their belief in me, and their support, advice and constructive criticism during the years. Sincere thanks to Torben Bæk Hansen for giving me the opportunity to carry out a PhD-study, in an excellent research and clinical environment and his never ending enthusiasm, his optimism and constant development of new ideas.

A sincere thanks to my fellow researchers Ole Gade Sørensen, Maiken Stilling, Flemming Jakobsen and Kristian Larsen for the many discussions and contributions to an interesting and constructive environment. A special thanks to Kristian Larsen, who with his astounding knowledge and helpfulness, has made invaluable contributions to my studies.

I am grateful for the advice I received from Hanne Thorsen and John Brodersen, and the assistance and help from Steen Olesen.

Finally, I wish to thank my patient and understanding family and friends, especially my beloved wife Tanja and my children Amalie, Elias and Augusta.

Financial support: The studies in this dissertation were supported by grants from the Danish Rheumatism Association and Ringkøbing Amts Forskningsfond.

This dissertation is based on the following papers:

I. Validation of the Danish Version of the Disabilities of Arm, Shoulder and Hand questionnaire.

II. Translation and validation of the Danish version of the Patient Rated Wrist Evaluation questionnaire.

III. Rasch analysis of the Danish versions of the Disabilities of Arm, Shoulder and Hand and Patient Rated Wrist Evaluation questionnaires.

IV. A randomized study of non-bridging external fixation versus intramedullary fixation of unstable distal radius fractures.

Abbreviations

AO	Arbeitsgemeinschaft für Osteosynthesefragen.
CI	Confidence interval.
DASH	Disabilities of Arm, Shoulder and Hand questionnaire.
DIF	Differential Item Functioning.
DRUJ	Distal radial ulnar joint.
ICC	Intra class correlation coefficient
NHP	Nottingham Health Profile questionnaire.
PRWE	Patient Rated Wrist Evaluation questionnaire.
RUMM2030	Rasch Unidimensional Measurement Model 2030.
SF-36	Short Form (36) Health Survey.

Contents

1. English summary

Introduction

The overall purpose of this dissertation was to compare two types of osteosynthesis for distal radius fractures, using two questionnaires relevant for wrist fractures, with both questionnaires being part of the outcome measures used. Firstly, the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire is a 30-item region specific questionnaire used to measure the effect of clinical treatment of the upper extremity. It exists in a Danish version, but reports about its reliability and validity were not available. Secondly, the Patient Rated Wrist Evaluation (PRWE), a wrist specific questionnaire that does not exist in Danish, but it would be of value if it did, since its high sensitivity towards measuring patients with distal radius fractures, has been established in other languages. As part of the validation process, the questionnaires would be tested for unidimensionality by using Rasch analysis and fitting from ordinal scale to interval scale. The dissertation encompasses four articles:

- A reliability and validity study of the DASH.
- A translation and cross cultural adaption of the PRWE, followed by a reliability and validity study.
- Rasch analysis of the DASH and PRWE investigating the questionnaires unidimensionality and conversion from an ordinal scoring scale to an interval scoring scale.

- A randomised prospective clinical trial comparing internal fixation (Micronail) and external fixation (Hoffmann II Compact non-bridging) for unstable distal radius fractures using the DASH and PRWE as outcome measures.

Material and methods

Studies I and II. Sixty patients with wrist fractures were included. The patients answered the DASH, PRWE and Nottingham Health Profile (NHP) questionnaires after 1 week and 6 weeks after start of treatment. We measured the time-to-complete the questionnaires and missing items. We investigated internal consistency and test-retest reliability. Furthermore we investigated convergent and divergent validity, content validity, concurrent validity, construct validity and responsiveness. The translations component of the PRWE consisted of translation by a group of experts that included cross-cultural adaptations with a feedback phase by a group of uninjured laymen and a group of patients.

Study III. Data drawn from studies I and II resulting in 120 questionnaires for both the DASH and PRWE. Rasch analysis was conducted using RUMM2030 software to assess person separation index, unidimensionality, misfit of items, differential item functioning (DIF) and a fitted model in order to convert ordinal scores to interval scores.

Study IV. Patients were included from the accident and emergency departments of the three participating hospitals. Inclusion criteria were Older type 2 and 3 fractures. External fixation was managed with Hoffmann II compact non-bridging. Internal fixation was managed with Micronail. Patients were followed for 12 weeks. Primary

outcome was the DASH. Secondary outcomes were PRWE, grip strength, satisfaction, radial length and volar tilt. Furthermore, complications were registered and an activity-based costing analysis was done.

Results

Study I. Time-to-complete the questionnaire was 11 minutes. Cronbach´s alpha was 0.96 and intraclass correlation coefficient 0.89. Difference of Mean was 4.60(CI: 0.477-8.720, P=0.030). Convergent validity at first and last control was high for pain, 0.40 and 0.45, respectively, and for physical mobility, 0.60 and 0.67, respectively. Construct validity was significant. No floor or ceiling effect was seen. Effect size was 0.53.

Study II. Translation was done by an expert panel followed by evaluation by a lay panel and a field test on 10 patients. Both the lay panel comments and the field test revealed issues not dealt with by the expert panel and resulted in a Danish questionnaire that included technically and culturally adapted changes. Time-to-complete the questionnaire was 7 minutes. Cronbach´s alpha: 0.94. Intraclass correlation coefficient: 0.88. Difference of Mean: 5.70 (CI: 1.12-10.37, P=0.017). Convergent validity at first and last control was for pain, 0.44 and 0.46, and physical mobility, 0.51 and 0.64, respectively. No significant floor or ceiling effect was seen. Concurrent validity was 0.84. Construct validity was significant. Effect size: 0.62.

Study III. Rasch analysis showed good person separation index for the DASH and PRWE, and both showed unidimensionality. There was no DIF for the time interval. There were indications of misfit of items, but these items displayed good content

validity and were within acceptable parameters. A nomogram for conversion from ordinal score to interval score could be made for both questionnaires.

Study IV. Thirty patients were randomized to external fixation and 31 patients to internal fixation. Internal fixation showed significantly better grip strength at 5 and 12 weeks. Apart from a shorter surgical time and minor differences in radiologic follow-up no other clinically relevant difference could be found. No significant result was found with the DASH and PRWE on either the ordinal and interval scale. An activity-based costing analysis showed a three times higher overall cost when using external fixation.

Conclusion.

Though concerns about reliability, studies I, II and III showed acceptable reliability and good validity and unidimensionality, and both questionnaires can be used in clinical and research settings. When comparing internal fixation and external fixation, in study IV, internal fixation had significantly greater grip strength, and a lower overall cost when compared to external fixation.

2. Danish summary

Introduktion

Formålet med dette PhD-studie var at sammenligne to typer af osteosyntese af distale radius frakturer, ved at bruge to håndleds-relevante spørgeskemaer. Først spørgeskemaet Disabilities of Arm, Shoulder and Hand (DASH), der er et 30-item overekstremitets spørgeskema der bl.a. bruges til at måle effekten af en behandling af

en skade på overekstremiteten. Det findes i en dansk version, men artikler om dets reliabilitet og validitet findes ikke. For det andet findes der et håndleds specifikt spørgeskema, Patient Rated Wrist Evaluation (PRWE), der ikke er oversat til dansk, men i udenlandske studier har vist stor følsomhed overfor at måle behandlingsresultater på patienter med distale radius frakturer, og derfor ville være et godt redskab at bruge i den danske klinik. Som en del af validiteten skal spørgeskemaerne også testes for unidimensionaliet ved hjælp af Rasch analyse. Afhandlingen omhandler fire videnskabelige artikler:

- Et reliabilitets- og validitets-studie af DASH.
- En oversættelse og tværkulturel tilpasning af PRWE, efterfulgt af et reliabilitets- og validitets-studie.
- Rasch analyse af DASH og PRWE der undersøger spørgeskemaernes unidimensinalitet og tilpasning fra ordinalskala til intervalskala.
- Et randomiseret prospektivt klinisk forsøg der sammenligner intern fiksation (Micronail) og ekstern fiksation (Hoffmann II Compact non-bridging) i behandlingen af ustabile distale radius frakturer med DASH og PRWE som en del af opfølgningen.

Materiale og metoder

Studie I og II. Tres patienter med håndledsbrud inkluderes. Patienterne besvarede DASH og PRWE og Nottingham Health Profile (NHP) efter en og seks uger efter opstart af behandling. Der tages tid på færdiggørelse af spørgeskemaer, antallet af manglende besvarede items optælles. Der undersøges internal consistency og test-

retest reliabilitet, og derudover convergent og divergent validity, content validity, concurrent validity, construct validity og responsiveness. PRWE oversættelsen indeholdt en ekspert oversættelse der inkluderede en tvær kulturel adaption, efterfulgt af en feedback fase fra en gruppe af lægfolk uden skader på håndleddet, der afsluttedes med test på en række håndledspatienter.

Studie III. Data blev samlet fra studie I og II, og resulterede i 120 spørgeskemaer fra hhv. DASH og PRWE. Der blev udført Rasch analyse vha. RUMM2030 software for at undersøge person separation index, unidimensionalitet, misfit af items, differential item functioning (DIF) og tilpasning af en ordinal score til intervalscore for hvert spørgeskema.

Studie IV. Patienter blev inkluderet fra skadestue og ambulatorium på de tre deltagende hospitaler. Inklusionskriterier var Older type 2 og 3 frakturer. Ekstern fiksation blev foretaget med Hoffmann II Compact non-bridging. Intern fiksation blev foretaget med Micronail. Opfølgningsperioden var 12 uger. Primære effektmål var DASH. Sekundære effektmål var PRWE, gribestyrke, tilfredshed, radial længde og volar vinkling. Derudover blev alle komplikationer registreret og der blev lavet en aktivitets baseret omkostnings analyse.

Resultater

Studie I. Tid til besvarelse var 11 minutter. Cronbach´s alpha var 0,96 og intra class correlation coefficient 0,89. Difference of mean var 4,60 (CI: 0,477-8,720, *P*=0,030). Convergent validitet ved første og sidste kontrol var høj for smerte, hhv. 0,40 og 0,45,

og for fysisk mobilitet, hhv. 0,60 og 0,67. Construct validitet var signifikant. Ingen gulv eller loft effekt var tilstede. Effect size var 0,53.

Studie II. Oversættelse blev lavet af et ekspert panel bestående af 5 personer, efterfulgt af evaluering af et lægmands panel og efterfølgende test på patienter. Både lægmands panel og felt test gav anledning til ændringer som ikke var gjort af ekspert panelet, resulterende i en dansk oversættelse af PRWE med tekniske og kulturelle ændringer. Tid til besvarelse var 7 minutter. Cronbach´s alpha var 0,94 og intra class correlation coefficient 0,88. Difference of mean var 5,70 (CI: 01,12-10,37, *P*=0,017). Convergent validitet ved første og sidste kontrol var høj for smerte, hhv. 0,40 og 0,46, og for fysisk mobilitet, hhv. 0,51 og 0,64. Concurrent validity var 0,84. Consctruct validitet var signifikant. Ingen gulv eller loft effekt var tilstede. Effect size var 0,62.

Studie III. Rasch analyse viste god person separation index for både DASH og PRWE, og begge spørgeskemaer var unidimensionelle. Der var ingen DIF for tidsperiode. Der var indikationer på misfit af items, men items var med god content validity og var indenfor de acceptable parametre. Et nomgram for konvertering fra ordinal skala til interval skala blev lavet for begge spørgeskemaer.

Studie IV. Tredive patienter blev randomiseret til ekstern fiksation og 31 patienter til intern fiksation. Intern fiksation viste signifikant bedre gribestyrke ved 5 og 12 uger. Fraset kortere operationstid og mindre ikke klinisk relevante forskelle i radiologiske parametre ved ekstern fiksation, var der ingen signifikante resultater. Både DASH og PRWE blev scoret på ordinal skala og interval skala uden signifikant forskel. Den

aktivitets baserede omkostnings analyse viste, overordnet set, en gennemsnitlig tre gange højere pris ved ekstern fiksation.

Konklusion

Trods usikkerhed omkring reliabliliteten viste studierne I, II og III acceptabel reliabilitet og god validitet og unidimensionalitet, og begge spørgeskemaer kan bruges i klinisk og forskningsmæssig sammenhæng. Ved sammenligning af intern og ekstern fiksation i studie IV, havde intern fiksation en signifikant bedre gribestyrke, og en overordnet set 3 gange lavere pris.

3. Introduction

Distal forearm fractures have been treated in several ways since antiquity. The ancient Egyptians used immobilisation with wood splints and cloth, and the ancient Greeks, according to Hippocrates, immobilised the fractures for 20 days with linen rolls. In the Middle Ages, the importance of reduction was realised and in 1814 Abraham Colles described the dorsally angulated distal radius fracture. During the last two decades, reports of different treatment options have been abundant (1), but still no consensus has been established about the treatment of the distal radius fracture. Fractures of the distal radius are common and account for approximately 1/6 of all fractures and 1/5 of all injuries to the hand in developed countries, and are likely to increase due to a rising number of elderly people (2;3). Although the fracture pattern shows a bimodal age distribution with peaks in early adolescence and again in older age, it is characteristically seen with an increasing incidence with increasing age. Females have an eight fold increased lifetime risk of sustaining a fracture compared to males, and the lifetime risk of sustaining a distal radius fracture in Northern Europe is estimated to 15-16% for women and 2-3% for men (4). Furthermore there is a seasonal variation with a higher incidence in the winter with snow(5), and also a higher incidence in areas with a high prevalence of osteoporosis (6-

11). Treatment methods vary from immobilisation, external fixation and internal fixation, with increasing focus on obtaining perfect radiology and early mobilisation (4;12-20). The fracture of the distal radius typically happens because of a fall on an outstretched hand. It occurs in the metaphysis of the distal radius within 2 cm of the distal end of the radius, is usually dorsally displaced and angulated, and can be accompanied by a fracture of the ulnar styloid. A Brazilian study among orthopaedic surgeons showed that the three main factors that determined what treatment was used were whether the fracture was intra-articular, the presence of shortening of the radius and the patient´s age (21). A recent study investigating the preferred treatment of distal radial fractures by younger American orthopaedic surgeons, documented a shift in treatment modality towards open reduction and internal fixation, from 42% in 1999 to 81 % in 2007(p<0.0001), despite the fact that no evidence based conclusion so far can be made that could justify such a shift in treatment modality (10). It is generally recognised that there are four factors to consider when choosing the correct treatment for patients with a distal radial fracture. A) The patient factor: lifestyle, compliance, medical co-morbidities and anticipated loading of the wrist postoperatively, which in some cases also coincide with the patients age. B) The fracture pattern: determine whether the fracture is intra or extra-articular and estimate radial inclination, radial length, dorsal tilt and articular incongruity. C) The fracture stability: an estimate of fracture stability can be made from the initial radiographs. Signs that indicate instability are

dorsal tilt greater than 15-20°, displacement greater than 1 cm, radial shortening more than 5 mm, radial inclination angle less than 15°, severe dorsal cortical comminution, intra-articular involvement and associated ulna fracture and redislocation after initial successful reduction. D) Associated injuries: for example open fractures, multiple injuries to the extremity and affection of the median nerve among others (15;22). Postoperative follow-up is typically characterised by a number of methods, e.g. clinical tests, radiology, objective findings, satisfaction, visual analogue scale, complications, pain medication and questionnaires. There is no consensus on which methods to use for postoperative follow-up, and most studies make use of both validated and non-validated methods (4;10;12;15;23-28), and these can be categorized into four groups of outcome measures, anatomical outcome, functional outcome, clinical outcome and resource use.

Demands for a safe and efficient method of treatment of distal radius fractures are also increasing, partly because elderly people today have higher demands for wrist function after a fracture than they did previously. They want a normal, painless function of the wrist after treatment, and also expect early mobilisation for a faster return to self-care, sports, work etc. (2;29). The elderly patient, the term lacks a well defined definition but is typically described as a patient with an age above 65 years, is a special concern, since the spectre of functionality is widespread, and because treatment with oestrogen, bisphosphonate etc. minimises bone loss, some authors have found a distinction between high-

demand and low-demand elders to be appropriate, in preference to the dichotomised model of under or over 65 years (30). Studies have shown that early mobilisation results in less pain, better movement and increased patient satisfaction, with no signs of increased deformity (31;32). Early mobilisation shows several benefits, such as increased cartilage repair, diminished stiffness and decreased osteopenia in the distal fragments (33;34). There are many different types of operative fixation, and several authors have published case series with promising results, but no final evidence has been published that could guide surgeons' choice of treatment based on evidence based knowledge. In addition, there are studies that suggest that 1 year after the fracture, good subjective end results, based upon patient reported outcome are achieved by following a treatment protocol based on primary radiological findings (35). These and other factors, e.g. patient and surgeon satisfaction with treatment (16), and the use of CT and three-dimensional reconstruction have enhanced the understanding of the injury (2;26;36) and has during the last decade contributed to a shift in treatment modality towards open reduction and internal fixation and early mobilisation (10;37;38).

The goal of any treatment has traditionally been to restore normal anatomy, and although this is disputed (29;39-42) there is an overall agreement that a stepoff of more than 2 mm in the radiocarpal joint is associated with arthritic changes, and more than 1 mm step-off can cause pain and decreased motion in the wrist(43). Fracture union with more than 10-15° dorsal tilt and/or under 15° of

radial inclination can cause problems with work and other activities, and extraarticular malunion causes deformity, decreased palmar flexion or distal ulnar radial joint (DRUJ) instability. (22;29;35;44-48). Until about 60 years ago, it was generally accepted that most fractures could be treated conservatively with a satisfactory outcome. It was then realised that healing with malunion results in lesser functionality, and historically loss of palmar tilt is correlated with a poor patient outcome (49). More recently it has been shown that intra-articular step-off and radial shortening corrected by surgery improved patient outcome (43;50;51). These problems are not as manifest in elderly people and low-demand patients (51;51-54) probably because of lower demands for functionality (51;55). In general anatomic reduction should be pursued in younger and high-demand elderly patients with extra-articular fracture or intra-articular fractures. In the high-demand elderly patient, internal fixation might be particularly indicated, since elderly people take a longer time to heal, and this procedure usually allows early mobility (30). Surgical treatment should also be chosen for low-demand elders with severely displaced intra-articular fracture or median nerve compression, but otherwise this group tolerates deformity well but there must be focus on joint movement (30;51). Metaphyseal defects can also be grafted, although not generally advocated in fresh fractures and good bone quality (11;26;44).

Non-displaced fractures are commonly treated conservatively with a cast or other forms of bracing. Reducible extra-articular fractures can also be treated

with casting if they are stabile. Non-stable reducible extra-articular fractures are commonly treated with reduction and often supplemented with extra- or intra-focal pinning. Non-bridging external fixation is a recommended choice of treatment for fractures with comminution, and in recent years devices for intramedullary fixation and biodegradable products have also become available (12;29;44;56;57). Extra-articular fractures that are irreducible, intraarticular fractures and fractures for demanding patients who require early mobilisation, are commonly treated with plating, and in recent years more often with palmar plating due to concerns about the disadvantages of dorsal plating, intramedullary fixation, external fixation or pinning (11;12;37;44). The correct indication and proper treatment are also valuable in order to avoid complications. Complications when treating distal radius fractures are frequent and include conditions like infection, loss of motion and strength, pain syndromes, arthritis as well as others (58). Most surgeons accept the fact that anatomical restoration is preferable, but the threshold for acceptable malunion and the long-term benefits of radiological reduction on functional outcome and patient satisfaction remain to be identifeid (11;29;59). Clarification of these questions will determine whether Dr. Abraham Colles statement from 1814 will be proven correct: "One consolation only remains, that the limb at some remote period again enjoy perfect freedom in all its motions, and be completely exempt from pain: the deformity, however, will remain undiminished through life".

Treatment options

Cast treatment

Treatment of undisplaced or reduced distal radius fractures with a cast has showed good results. Even with regard to displaced and intra-articular fractures among low-demand patients treated with a cast, good subjective outcome have been reported. Closed reduction and casting have historically been the treatment of choice. Loss of reduction and redisplacement are common, frequently in patients who initially required manipulation (60) and are sometimes an indicator for secondary reduction or osteosynthesis (61-63).

Percutaneous pinning

Percutaneous pinning is an effective method for certain fractures of the distal radius. It is mainly used in younger or high-demand patients with good bone quality and reducible extra- or intra-articular fractures. For this procedure fractures must be without any major shortening or volar comminution. In most cases in which percutaneous pinning is used, fractures have been unstable after primary closed reduction has been tried (64). It offers the advantage of a minimally invasive procedure and is often supplemented with cast-immobilisation for a longer period. Compared to cast-immobilisation percutaneous pinning reduces deformity and malunion, but no improvement of final outcome. Different methods of pinning are used and none are proven superior.

Bridging external fixation

Bridging external fixation uses a method of stable fixation proximal and distal to the fracture, thus spanning the fracture and off-loading the fracture fragments via the principle of ligamentotaxis by which tension is transmitted through radial and ulnar ligaments (65). It is an effective method for fixation of unstable distal radius fractures and has been used for more than 50 years. It is relatively easy to apply and is minimally invasive. The method is limited by the viscoelastic behaviour of the ligaments, which lose force, and thus the initial anatomical position of the reduction is lost, especially volar tilt. The method requires a long period of immobilisation and pin-related complications are frequent (15;66). Indications for use of this method are both temporary (open fractures with severe soft tissue loss and trauma patients requiring transfer to another location) and conditional (extra-articular unstable fractures and simple intra articular fractures with no or little displacement that need definitive care). There are studies that indicate that external fixation gives superior results in maintaining position and preventing late collapse and malunion compared to casting (14;67-70), but a recent Cochrane review documents that there is no overall evidence of this and no documentation of a superior clinical outcome with its use. It also concluded that external fixation is associated with a high frequency of complications, although many minor complications, some of which are avoidable by using a different surgical technique (18).

Non-bridging external fixation

Another variant of external fixation is non-bridging external fixation, which is used to directly fixate the distal and proximal fragments together. It is based on a closed reduction of the fracture followed by appliance of the external fixator. The non-bridging external fixator is indicated in extra-articular dorsally displaced fractures, especially if there is an increased risk of late fracture collapse such as in very comminuted fractures or in elderly patients. Attention should be brought to the fact that most surgeons require 1 cm of intact volar cortex in the distal fragment to ensure correct pin insertion (65). Two bicortically pins are inserted into the radius, and two bicortical pins are inserted into the distal fragment on either side of Lister´s tubercle, and the pins in the proximal fragment should be spread as widely as possible, with one pin as close to the fracture as possible and the second as far away as possible in order to achieve an even spread of forces. This method has the advantage that by reducing the fracture, it allows direct motion of the distal fragment by using the pins as a joystick. To achieve maximum stability, the external fixator can be frame-shaped preferentially by carbon-fibre bars that have the advantage of being radiolucent. Bars should be as close to the skin as possible to reduce bending forces and increase stability. A Cochrane review based on three small studies concerning bridging external fixation vs. non-bridging external fixation found no solid evidence in outcome scores to recommend one type of fixation (71). Although there were indications of better radiographic and functional outcome after non-bridging external fixation, no final conclusion is established due to a lack of

studies. In a study by M. M. McQueen it is argued that traditional casting is often not enough to maintain reduction especially in the elder population, and this results in a poor radiographic and functional outcome that is highly associated with loss of volar tilt (46). A randomised study comparing bridging external fixation with non-bridging external fixation in 60 patients (average age 62 years) allocated to treatment with the Pennig external fixator with 1 year follow-up showed that during the entire control period radiographic outcome and grip strength were statistic significantly better in the non-bridging group, as was range of movement, especially in the early postoperative period. Seven cases of pin infection were seen in the non-bridging group as well as two episodes of rupture of the extensor policis longus tendon. In the bridging group there were two episodes of pin infection and two cases of reflex sympathetic dystrophy (72). M. M. McQueen concludes that the non-bridging technique is a significantly better method of fixation for extra-articular fractures than is the bridging technique. A later study describes the use of the Hoffman II compact non-bridging external fixator as reliable (73). Another study describes the use of external fixation in the hands of the general orthopaedic surgeon, in contrast to the 1998 study by M. M. McQueen in which the author performed all the operations. This study also showed a statistically significant radiographic outcome in favour of the non-bridging technique in the hands of surgeons in training (74). Minor pin infection was statistically significant in the non-bridging group. There also were cases of both carpal tunnel syndrome and complex

regional pain syndrome in both groups. Both groups showed some loss of reduction after fixator removal, though more in the bridging group, which is consistent with studies showing that non-bridging fixation maintains reduction well after fixator removal(75). Other studies have shown similar outcomes(13;76;77) with no major complications reported, but minor complications, such as pin infection treated with oral antibiotics is reported in up to 19% of cases and signs of irritation of the superficial branch of the radial nerve, they have no influence on the final outcome. Another study comparing non-bridging and bridging osteosynthesis of complex intra articular distal radial fractures showed no significant differences in outcome. There were three cases of extensor pollicis longus tendon rupture in the non-bridging group and none in the bridging group, and the authors express concern about whether this complication is associated with the non-bridging technique, because other studies have shown similar findings (78). Atroshi et al. compared bridging and non-bridging in 38 patients who had both extra-articular and intra-articular fractures, and found no significant differences in outcomes, apart from less radial shortening in the non-bridging group at 52 weeks. Complications were minor in all groups (79). Atroshi et al.´s findings are in accordance with a retrospective study of non-bridging external fixation (75). In conclusion and in concordance with a Cochrane review, enough evidence has not yet been established to promote bridging over non-bridging technique, but there is

promising evidence to support the latter of the two techniques as being the better technique (16).

Plates

Open reduction and internal fixation have the advantage of being surgery under direct vision and should therefore promote exact anatomical reposition of the distal radial fracture. Dorsal plating was originally the mainstay of treatment, because, logically, dorsally angulated fractures would be served best with a dorsal technique, but studies have shown a high rate of complications with this technique, such as severe extensor tendon irritation or rupture, stiffness, prominent scarring and a high number of patients in need of hardware removal (80). With the development of low profile implants, there was a shift in treatment towards volar locking plates. The volar approach uses the advantage of a longer distance between tendon and cortex, and thus there is not as much contact between the tendons and the plate, and the surgeon has the possibility to cover the plate with m. pronator quadratus. Volar plates are typically volar buttress plates with or without screws, or fixed angle locking plates, which exhibit higher strength, especially to angular motion, than non-locking buttress plates. Volar plates facilitate a stable fixation in cases of bone defects and osteopenic bone, and are advantageous when there is need for early mobilisation. If the correct surgical procedure is used, these plates are associated with very few complications (81). Volar locking plates have been shown to facilitate similar rates of recovery in both young and elderly patients (82).

Theoretically, plate fixation enjoys a number of advantages like direct fracture reduction, short immobilisation period and stable fixation, but most implants are costly and they often require extensive and complex surgery (15). A meta-analysis by Margaliot et al (15) based on review of more than 46 retrospective studies of external (bridging) fixation and internal fixation devices that included more than 1500 patients, found no significant difference in outcome, whether clinical function, patient scores or radiographic outcomes. There were, however, significant differences in complications. There was a higher infection rate, failure of osteosynthesis and postoperative neuritis using external fixation, and using internal fixation there was a higher incidence of tendon rupture and tenosynovitis, and 80% of ruptures occurred on the extensor side. Similar there has been a development of low profile dorsal plates and retrospective studies examining dorsal plating found better results when using a low-profile dorsal plate than a normal plate, (83;84) indicating that with the correct type of osteosynthesis, complications associated with dorsal plating can decrease significantly. When comparing volar versus dorsal plating, studies indicate that the volar technique gives an equivalent or better functional outcome, better radiographic outcome, fewer complications and less fracture collapse (85-93).

Intra-medullary devices

Intra-medullary fixation has been used for several years, initially as intra-medullary pinning with results comparable to established treatments as pinning and external fixation, and in some cases at a lower cost (94;95). Recently, devices

have been developed that both enhance fracture stability and encompass a minimally invasive approach diminishing scaring and soft tissue damage, tendon irritation and allows early motion. One such device is the dorsal nail plate intended for extra-articular fractures and non-displaced intra-articular fractures (96). It is a hybrid between a distal dorsal plate and an intra-medullary proximal nail. Its inserted through an incision dorsally over the m. extensor pollicis longus, going through Lister´s tubercle for insertion. Even though more than 200 cases have been reported, real results have not been published and only comments like "complications are relatively infrequent with this method", have accompanied the descriptions. However, haematoma, implant removal due to discomfort, hypertrophic scarring and loss of fixation are mentioned. Another device is the Micronail. Indications are unstable fractures with no or minimal articular involvement. The Micronail is inserted through a cortical window in the radial styloid, between the first and second extensor compartment, taking care not to damage the radial sensory nerve. The nail is distally fixated using three fixed-angle locking buttress screws over the subchondral area and fixated proximally with two bicortically interlocking screws (97). V Tan et al conclude, based on 15 cases, that results are encouraging. Twenty-three patients in prospective cases showed satisfactory results with a grip strength of 40% compared to the uninjured side and a DASH score of 29 at 1 month postoperatively, and a grip strength of 80% of uninjured side and a DASH score of 8 at 6 months. The main problems with this device are

the avoidance of screw penetration to the distal radioulnar joint and intraoperative difficulty in visualising the sagittal view because of the device jig. Three of the reported patients had temporary radial sensory nerve affection, which resolved within 2 months (56;98). Another study involving 10 patients with an average follow-up of 21 months (12-28 months) found a grip strength of 91% compared to uninjured side and a DASH score of 8.1 (range 0-57). A high incidence of complications is described with two cases of transient neuritis of the radial sensory nerve and three cases of screw penetration to distal radioulnar joint (99). These authors recommend downsizing the screws and using fluoroscopy when inserting the screws. A cadaver study testing bending stiffness, ultimate load to failure and load needed to create 5 mm of displacement found no statistical difference between a volar locked plate, that exhibited the highest loads, and the Micronail (100). As has been mentioned only case series have yet been published, but in general, findings suggest that good functional and radiographic outcome can be achieved with intra-medullary fixation, when the potential pitfalls are respected and used only on correct indications.

Biodegradable devices

Biodegradable devices or bioresorbable devices are not yet widely used in orthopaedic traumatology, but have been used for some time in sports traumatology. Earlier reports have not been encouraging, and although satisfactory functional and anatomical results have been shown, complication

rates are high (101). Today, only a few devices exist for the treatment of distal radius fracture, and they only concern a limited number of patients.

Conclusion

Treatment methods are becoming increasingly advanced and more costly. One should keep in mind that to some extent the traditional methods of treatment have been proven efficient, and newer methods should be properly evaluated before they are integrated into the standard treatment of distal radius fractures. The fact remains that the treatment of unstable distal radius fractures is disputed, and the traditional striving for anatomical reduction is now also supplemented by the search for treatments that allow a swift return to daily activities with sufficient pain-free motion and a minimum risk of disability, degenerative changes and cosmetic scarring. The pros and cons of fixation methods have yet to be established, as have the best way to evaluate patient outcome with validated methods. Also to be determined is whether the outcome is improved by early mobilisation. Studies investigating patient satisfaction during treatment have not been reported since researchers primarily focus on the postoperative follow-up weeks, months or years later. Furthermore, there is a lack of cost studies to compare the different types of osteosynthesis (2;102).

Outcome measures

Patient-reported outcomes have become increasingly popular as a way to measure the patients´ own observations to the treatment given (2;40), and thus they are considered as a more sensitive way to measure the results of a given

treatment, often supplemented with objective and radiological findings (39;103;104). The potential benefits of using outcome measures are several: describing patient's needs, monitoring progression of a condition, monitoring response to treatment, setting goals for treatment and standardising contacts between clinicians and patients. Outcome measures also have to meet certain requirements if they are to be used. They have to be adapted to a busy clinical encounter, and have to be brief, easy to administer and to interpret. They have to be well targeted toward the condition and yield useful results with a minimum of extreme scores (floor and ceiling effect). Furthermore, they have to be reproducible for longitudinal measurement, and, finally, they have to display sensitivity to clinical change, by being adaptable to relevant validity parameters (105). A search in PubMed did not show publication of any validated Danish questionnaires regarding wrist disorders. There is a Danish version of the Disabilities of Arm, Shoulder and Hand questionnaire (DASH), but no articles have been published that describe the validation of the questionnaire. The DASH (106;107), which measures upper extremity function and pain in a 30-item questionnaire, is the most commonly used questionnaire for disorders of the hand and wrist and has been shown valid and reliable in follow-up after distal radius fracture (104). Although there are a minimum of 17 different questionnaires (108;109) being used for disorders of the wrist and hand, not all are validated for use with distal radius fractures, and not all are practical for use in an everyday clinic. The Patient Rated Wrist Evaluation (PRWE) is a 15-item

questionnaire measuring function and pain and validated for use with distal radius fractures (110;111). Most questionnaires are of either North-American or British origin, and it is generally accepted that in order to use a questionnaire in a population for which the original questionnaire was not designed, one has to ensure a proper translation and validation procedure (112-114), since an equivalent translation facilitates a comparison across languages and such a translation can include both cultural and linguistic adaptions. Validations of translations into other languages have also shown good results (115-117). The PRWE has typically been validated using a general health questionnaire such as the 36-item Short-Form Health Survey (SF-36) (118). Despite the SF-36 being available in a Danish version (119), no report is available concerning its use in Danish patients with wrist fractures. Another general health outcome measure, the Nottingham Health Profile (NHP) (120), is a self-administered generic health instrument measuring general health in six dimension, including physical function and pain. Because the Danish version of this questionnaire has been validated in Danish (121;122), and used in patients with wrist fractures (123), as well as used for validating other region-specific questionnaires (124), we chose the NHP as being the most appropriate for comparative purposes. Traditionally, translating questionnaires into other languages has been done by a forward/backward translation protocol. Recently, the method has become increasingly debated, the argument being that the method is more focused on translation than adapting the questionnaire (125;126), emphasising the content

of the questionnaire from the patient perspective rather than the correct word-to-word translation in an academic perspective. Besides estimating traditional reliability and validity parameters (intra class correlation coefficient (ICC), internal consistency, convergent validity, divergent validity, content validity, construct validity and responsiveness) recent developments in clinical psychometric analysis have also emphasised the need for modern psychometric evaluation, such as Rasch analysis, that display parameters like unidimensionality (127). Rasch analysis is a mathematical model against which an outcome measure is tested, to determine whether the outcome measure fits the model, that is, displays unidimensionality. Establishing unidimensionality assures that each answered item in the outcome measure is a result of both the patient's ability to answer the item (e.g. perform a certain task), and the difficulty of the item, without any form of bias or dependency from other items in the outcome measure. It is also important to determine whether items are biased in other categories (e.g. time period), thus displaying differential item functioning (DIF). Outcome measurement is based on the researchers' need to quantify their research. What is being measured is known as traits, but it is not possible to measure a trait directly, only indirectly by, for instance, using a weight to measure kilograms or by formalising questions that elucidate the trait. Therefore the term latent trait is often used. A questionnaire typically consists of several questions exploring latent traits related to a specific condition. These questions are called items and can have two or more response options, which

are then given a numeric value. The purpose of a questionnaire is to quantify latent traits by performing mathematic operations on the attained numeric values in order to measure them on a linear scale. Scales are divided into four categories, nominal, ordinal, interval and ratio scales (table 1). The responses on an ordinal scale exhibit a logical order, but the distance between responses on a linear scale may be different, whereas the responses on an interval scale exhibit both logical order and an equal distance between responses (figure 1) (128).

Scale	Characteristics	Examples
Nominal	Objects are classified and numbered. Whether the number is larger or smaller reflects only that the objects are different.	Car license plate numbers, number on the back of a soccer-team. Assigning "sex" with 0 = woman and 1 = man.
Ordinal	Objects are classified and numbered. Numbers reflect the amount of a given attribute, so that they can be ordered, but equal differences between the numbers does not imply equal differences in the amount of attribute	Military ranks. Grades in school.
Interval	Objects are classified and numbered. Objects can be ordered with equal differences between them, reflecting equal differences in the amount of attribute.	Calendar years. Temperature measured in degrees Celsius.
Ratio	Same properties as the interval scale, but there exists an absolute zero.	Height. Weight.

Table 1. Characteristics and examples of measurement scales.

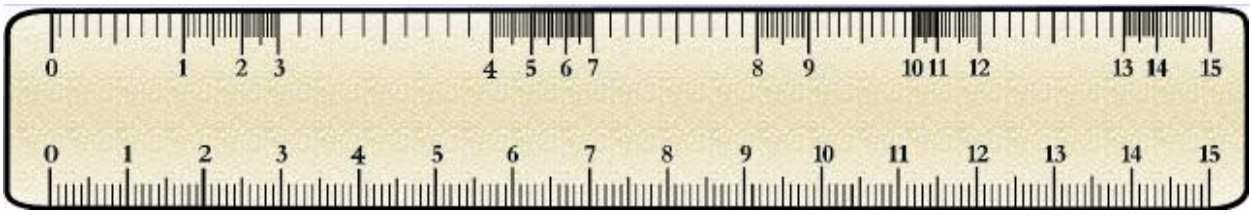


Figure 1. Example of ordinal scale (top line) and interval scale (bottom line).

The Rasch model is based on the assumption that a patient's probability of responding to an item is a logistic function of the distance between item difficulty (or item location) and patient ability (or patient location) on a linear scale, and in the case of an questionnaire there will be several items comprising a scale measuring a specific dimension of interest (129). In order to fit the Rasch model, the observed responses must coincide with the expected responses and thereby display unidimensionality (130;131). Because patients are usually scored with a sumscore reflecting the answers to a given set of related items in a questionnaire (132), and most clinical outcome measures are scored on an ordinal scale, including the DASH and PRWE, this makes the use of functions such as addition and subtraction impossible (133). Nevertheless, it is often assumed that the scale possess the properties of an interval scale. To perform arithmetic operations, the outcome measure must be measured on an interval scale such as that provided by Rasch analysis. Although classical test theory investigates reliability, validity, internal consistency and responsiveness, Rasch analysis is considered the most efficient method to establish a questionnaire's unidimensionality (127).

4. Aim of the dissertation

The overall aim of the dissertation was to compare two types of osteosynthesis for unstable distal radius fractures using validated Danish questionnaires for distal radius fractures in a randomised design.

No validated Danish questionnaires were available, so prior to the comparison we had to validate an upper extremity specific questionnaire available in Danish, and translate, culturally adapt and validate a wrist specific questionnaire, using classical and modern psychometric testing.

The studies in this dissertation had the following aims:

I. To investigate the reliability and validity parameters of the Danish version of the DASH in patients with wrist fractures.

II. To translate and cross culturally adapt the PRWE to Danish, and subsequently, to investigate the reliability and validity parameters of the PRWE in patients with wrist fractures.

III. To perform Rasch analysis on the Danish versions of the DASH and PRWE, in order to investigate whether the questionnaires are unidimensional, and to convert the ordinal scores of the questionnaires to interval scores.

IV. To perform a randomised study to compare two types of osteosynthesis, external fixation and internal fixation, used to treat unstable distal radius fractures, using the DASH and PRWE as outcome measures.

5. Design

I. Clinical measurement investigating reliability and validity parameters.

II. Clinical measurement performing translation and cross-cultural adaption followed by investigation of reliability and validity parameters.

III. Clinical measurement performing Rasch analysis to investigate unidimensionality.

IV. Prospective, randomised clinical trial with three months follow-up using the DASH as primary outcome.

6. Materials & methods

Ethical issues

Studies I, II and III required no approval by the Committee on Biomedical Research Ethics. The studies were registered with the Danish Data Protection Agency (J.nr. 2008-41-2636).

Study IV was approved by the Committee on Biomedical Research Ethics (J.nr. 20070043). The study was registered with the Danish Data Protection Agency (J.nr 2007-41-0951). The study was registered at ClinicalTrials.gov (study ID: JOS-1). Informed and written consent were obtained from all patients.

Patients and intervention

Study I

At the Fracture Clinic at Regional Hospital Holstebro 60 consecutive wrist-fracture patients were enrolled in the study over a 4 month period in 2009. Patients were excluded if they were under 18 years, mentally unfit to participate, unable to read or write Danish, had known disorders of the upper extremities or other disabling medical conditions, or declined to participate. Patients received either conservative or operative treatment prior to their first outpatient follow-up at 1 week, at which time they answered the PRWE, DASH, and the NHP and did so again at their last outpatient follow-up at 6 weeks. To calculate test-retest reliability, patients received

at the last follow-up a DASH-questionnaire with a postage-paid return envelope to be answered at home 3 days after the last follow-up. If items were missing, patients were contacted, either in the outpatient clinic or by phone, and the items completed. The study was conducted in accordance with the STARD statement, which is an initiative to improve the accuracy of studies investigating validity parameters. (http://www.stard-statement.org). Data for study I and study II were collected simultaneously.

Study II

Permission to translate and validate the questionnaire was attained from J. C. MacDermid. The study consisted of two major components, a translation component and a validation component. The translation component consisted of a translation by that included cross-cultural adaptations by a panel of experts, followed by a feedback phase in which the translation was evaluated by a group of uninjured laymen and a group of patients. The validation component consisted of measurement of psychometrics as described below.

Translation and cross-cultural adaption

The translation procedure was grouped into three phases. First, an expert panel was assembled consisting of five persons without wrist disorders who were bilingual in Danish and English, one member of which was the coordinator (author JOS) with knowledge of the questionnaires' background purpose and target group. The group had access to J. C. MacDermid´s articles describing the development and validation of the questionnaire. The expert panel was asked to focus on the content of the

questionnaire rather than a correct word-to-word translation. In situations in which the expert panel disagreed on a translation, they formulated several alternatives to be evaluated by the lay panel. The group consisted of five persons: two orthopedic registrars, one senior researcher with more than 10 years' experience with clinical research and validation, a senior researcher and MD with more than 20 years' experience in translation and validation of questionnaires and one retired specialist in internal medicine and current university lecturer in medical English, whose native language is American English, and who has resided in Denmark for more than 30 years, with recurring month-long visits to the native country over the years. Four were men, and the age range was 32-74 years. Prior to the groups´ meeting, the members were instructed to do their own translation of the questionnaire in order to facilitate the discussion of the translation and the translation was considered item for item. As a result of the meeting of the expert-panel, the coordinator made a contemporary paper version of the PRWE, based on the format received by J. C. MacDermid, and all considerations were written down, in order to be handed out to the lay panel. Second, a lay panel consisting of five persons not affiliated with healthcare or treatment and without wrist disorders was set up. Their task was to evaluate whether the translation completed by the expert panel represented plain and easy to understand Danish, but not to evaluate the contents of the questionnaire, and whether the items and response options were well correlated. The coordinator from the expert panel took part in their deliberations. If the expert panel had formulated several alternatives, the lay panel had to decide which alternative was the

most correct. The group consisted of two men and three women, with ages ranging from 33-64 years. None had more than a medium-length education. The coordinator wrote down any corrections the lay panel had. Third, a pilot study was performed in which the coordinator tested the PRWE in five consecutive out-patients with wrist fractures. The comments and suggestions from these five patients were evaluated, and if necessary, the content of the questionnaire was adjusted accordingly by the coordinator, and the adjusted questionnaire was then tested in an additional five out-patients. The interview comprised two parts, a think-aloud-test in which the patient read aloud the items and answers them accordingly. It was the task of the coordinator to be aware of any form of hesitation or other problems and ask why the patient experienced problems. This was followed by a cognitive debriefing, in which the coordinator reflected on each item with the patient and asked whether the items were relevant and were there relevant areas that were not covered by the questionnaire. Then, a final report was made, and the Danish version of the PRWE was made and presented to the expert panel.

Validation

Data were collected as described under study I. To calculate test-retest reliability, patients received a PRWE-questionnaire with a postage-paid return envelope at the last follow-up to be answered at home within 3 days.

Study III

Data for the DASH and PRWE were drawn from the data collected in studies I and II.

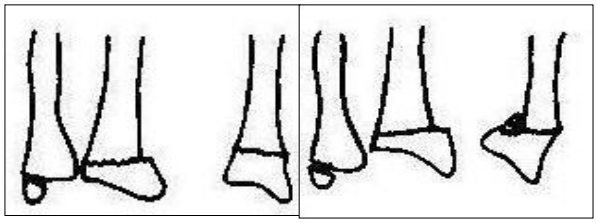


Figure 2. Older type 2 (left) and type 3 (right) fractures

Study IV

Patients were included from the accident and emergency departments of the three participating hospitals. Inclusion criteria were Older type 2 and 3 fractures (figure 2) with an intact volar cortex in the distal fragment of at least 1 cm. Exclusion criteria were fractures older than 3 weeks, pregnancy, unable to understand or read Danish, open fracture greater than Gustillo 1, previous fracture in the affected distal radius, age under 18, other injuries of the affected upper extremity, disabling conditions, and the inability to attend postoperative follow-ups at the participating hospitals. We made 66 envelopes for randomisation, 33 for internal fixation, and 33 for external fixation. A person not affiliated with the project mixed and numbered the envelopes in random order. Hereafter the envelopes were placed in chronological order. All attending surgeons were familiar with the two types of osteosynthesis. External fixation was managed with Hoffmann II compact non-bridging (figure 3). Through a dorsal incision two pins were placed in the distal fragment on both sides of Lister's tubercle and two pins through a dorsal incision in the radius proximal to the fracture. The fracture was then reduced under fluoroscopy and fixated. Internal fixation was managed with

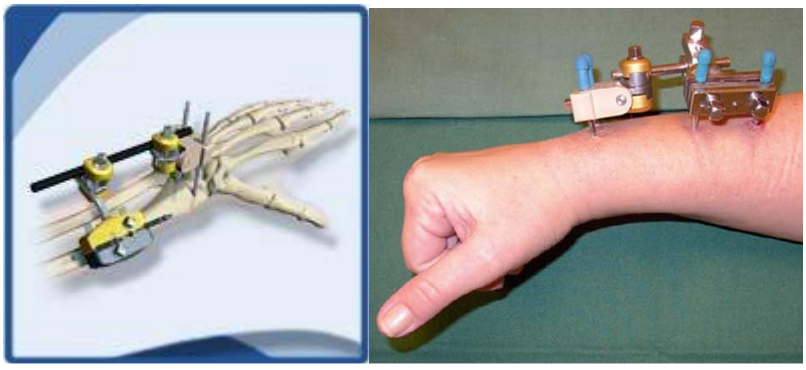


Figure 3. Hoffmann 2 Compact non-bridging.

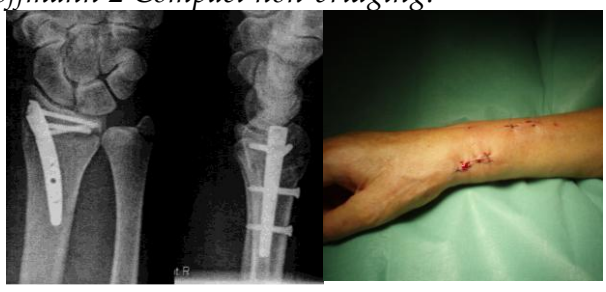


Figure 4. Micronail.

a Micronail (figure 4). The fracture was reduced to the correct anatomical position. An incision was made over the radial styloid followed by blunt dissection to the periosteum between the 1st and 2nd dorsal extensor compartments and a cortical window was opened to the medullary canal which was prepared with an awl and broach. A test-implant was inserted, and its correct position and size were verified with fluoroscopy. The implant was then inserted using a jig, the position of the nail determined with fluoroscopy, and the nail then fixated with three buttress screws. If, initially, a Kirschner-wire had been used to maintain the position of the fracture, it was now removed, and two interlocking screws were inserted into the proximal fragment using two dorsal incisions. Before discharge from the hospital post-operative X-rays were taken. Both groups were seen at postoperative follow-up at 1 week, 2 weeks, 5 weeks and 3 months. Patients with external fixation (Hoffmann II compact non-bridging) received pin site care during the entire fixation period and the fixator was tightened at 1 and 2 weeks follow-up. After 2 weeks, sutures were removed and patients were instructed to start unloaded wrist exercises. Patients with internal fixation (Micronail) had their casts removed at 2 weeks. At 5 weeks, external fixation was removed if heeling was satisfactory and the patients from both groups were instructed in exercises and referred to a physiotherapist for rehabilitation if necessary. The study was conducted in accordance with the CONSORT statement, which is a set of recommendations for reporting randomised clinical trials. (http://www.consort-statement.org/).

Outcomes and statistics

Studies 1 and 2 (Validation)

We used similar statistics in both studies 1 and 2.

Patient-burden and feasibility

We investigated patient-burden and feasibility expressed as time to complete the questionnaire (measured in 10 patients) and completeness (questionnaires with missing items were recorded prior to patient contact by phone or directly) at first follow-up at a time when none of the patients had completed the DASH and PRWE before.

Reliability

We estimated internal consistency, which describes homogeneity, by calculating Cronbach's alpha(134;135), where a value above 0.9 was considered excellent. Furthermore, we estimated test-retest reliability assessed by the intraclass correlation coefficient (ICC), which estimates the degree of concordance between results, and Bland Altman's 95% limits of agreement, in which a high concordance of results shows a small interval between results and mean difference, thus representing the bias (136-139) in a subsample of the study population who answered the last questionnaire within 3 days.

Convergent and divergent validity

Validity parameters were expressed by convergent validity (a higher correlation with the pain and physical domains of NHP being anticipated) expecting parameters to be greater than parameters displaying divergent validity (a lower correlation with

energy, sleep and emotional domains of NHP being expected). This is also described as criterion validity and describes the correlation with a gold standard

Content validity

Test results from patients with extreme scores in whom the questionnaire was unable to measure any meaningful improvement or deterioration in the condition were used to evaluate content validity (e.g. showing whether a questionnaire has enough items and covers the area of interest adequately), and to demonstrate the proportion scoring, the maximal (worst) and minimal (best) scores (floor and ceiling effects) at both follow-ups were used, a floor or ceiling effect below 15% being considered acceptable (105). A large proportion of extreme scores indicate a lack of sensitivity.

Concurrent validity

Concurrent validity was calculated by estimating the agreement between the PRWE and DASH in patients with wrist fractures.

Construct validity

Describes to what extent the questionnaire behaves as it is supposed to. That is, with a severe condition, the score is higher than with a less severe condition, or in this study that the severity diminishes over time.

Responsiveness

Responsiveness, the ability to measure sensitivity to change, was expressed as effect size, and calculated for both the PRWE and DASH. Responsiveness is expressed as the ratio of the mean change at the first and last follow-ups divided by the standard

deviation of the score at the first follow-up. An effect size of >0.5 is moderate and of >0.8 is large (140;141).

Statistical analyses were carried out using StataSE 11.0. *P* values < 0.05 were considered to be statistically significant.

Study II (translation and cross cultural adaption)

After conducting the three phases, a final report, and the Danish version of the PRWE were drawn up by the coordinator and presented to the expert panel. No statistics were used.

Study III

A total of 120 questionnaires were collected. This sample size gives stable estimates within ± 0.5 logit with α = 0.05. (http://www.rasch.org/rmt/rmt74m.htm). Statistical analysis was completed with SPSS and RUMM2030. Internal consistency is described by the Person separation index (equivalent to the Cronbach's alpha), but was calculated from the log score on a linear scale instead of the sum score, and it also expresses the homogeneity of the questionnaire (142). Furthermore, we consider item-person interaction: a mean of approximately 0 and standard deviations of approximately 1 indicate that the items and persons fit the model. A Bonferoni-adjusted non-significant chi square was done. This test is used to show good item-trait interaction and indicates whether the items in the questionnaire are constructed so that patients with low ability in a particular trait will answer it with a low response answer and patients with high ability will select a high response answer, that is whether the questionnaire fits the model. Furthermore, if a plot of the ordinal

score against the interval score demonstrated a non-linear configuration, this would indicate the possibility of making a nomogram, making it possible to measure data from the DASH and PRWE on an interval scale (143).

Study IV

The primary outcome was measured with the Danish version of the 30-item DASH questionnaire at final follow-up. Other measures of outcome used were the Danish version of the PRWE questionnaire at final follow-up, patient satisfaction was measured on a visual analogue-scale measured at 5 weeks and at final follow-up, grip strength was measured with a Saehan Dynamometer (average of three trials) at 5 weeks and at final follow-up, using a standardized protocol. Radial length and volar tilt were measured postoperatively and at final follow-up by one observer. Furthermore, one of the including hospitals supplied the patients with a diary upon discharge from the hospital. The purpose was to make a weekly registration of the extra expenses and costs the patients experienced for the first 5 weeks after surgery. We registered usage of prescription medication, non-prescription medication, time off from work or usual daily activities, number of visits from a community nurse, consultation with a medical practitioner, transportation costs related to their treatment, and other remedies or activities related to the treatment. A sample size calculation based on recent studies with the DASH as the outcome measure and a power of 0.80 and a 0.05 significance level indicated the need for 30 patients in each group. Student´s *t* test was used for significance.

7. Results

Patient characteristics

Studies I, II and III

In total, 60 patients were included in the study. Characteristics are shown in table 2.

No. of patients	**60**
F:M	44/16
Age	55(19-86)
Older fracture types 1:2:3:4	17:19:15:9
Injured side R:L	36/24
Osteosynthesis Yes:No	28:32

Table 2. Patient characteristics, studies I, II and III.

Study IV

In total, 61 patients were included in the study. Characteristics are shown in table 3.

	External fixation	Micronail	*P*-value
No. of patients	30	31	ns
F:M	26/4	25/6	ns
Age	64.2(35-88)	61.4(19-88)	ns
Older fracture types 2:3	3:27	9:22	ns
Injured dominant side	14	12	ns
Injured side R:L	15/15	19/12	ns
Final follow-up (days)	88(70-112)	92(79-129)	ns

Table 3. Patient characteristics, study IV.

Results study I

A total of 49 patients answered the DASH questionnaire 4.3 (2-14) days after the last follow-up. A total of 29 patients answered the questionnaire no later than 3 days after the last follow-up, and 10 patients at 5 days or later.

Patient-burden and feasibility

Time to complete the questionnaire was measured in the first 10 patients at first follow-up. None of the patients had completed the questionnaire before. The average time was 11 (6-17) minutes. At first follow-up 1-3 items were missing in nine patients (15%), and in two patients (3.3%), more than three items were missing. Except for item 21 (sexual activity), which was unanswered in 10 of the questionnaires, there was no specific pattern with regard to missing items.

Reliability

All scores were normally distributed (Figures 5 and 6).

Figure 5. DASH. First follow-up.

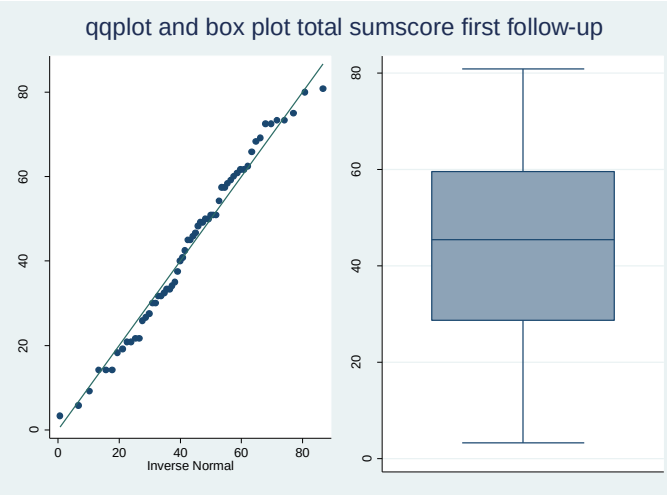
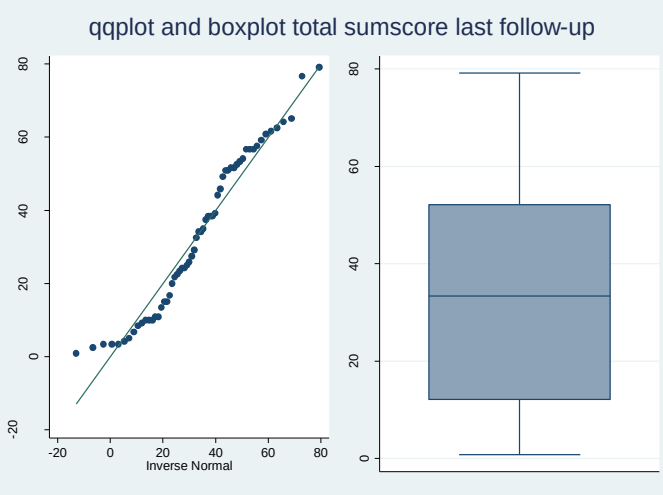


Figure 6. DASH. Last follow-up.



Internal consistency expressed as Cronbach's alpha was 0.96. Test-retest reliability was calculated in 29 patients who answered within 3 days after the last follow-up and demonstrated an ICC of 0.88. The 95% limits of agreement were ± 21.2 and the mean difference was 4.6 (CI: 0.477-8.720, *P*=0.030) (Figure 7).

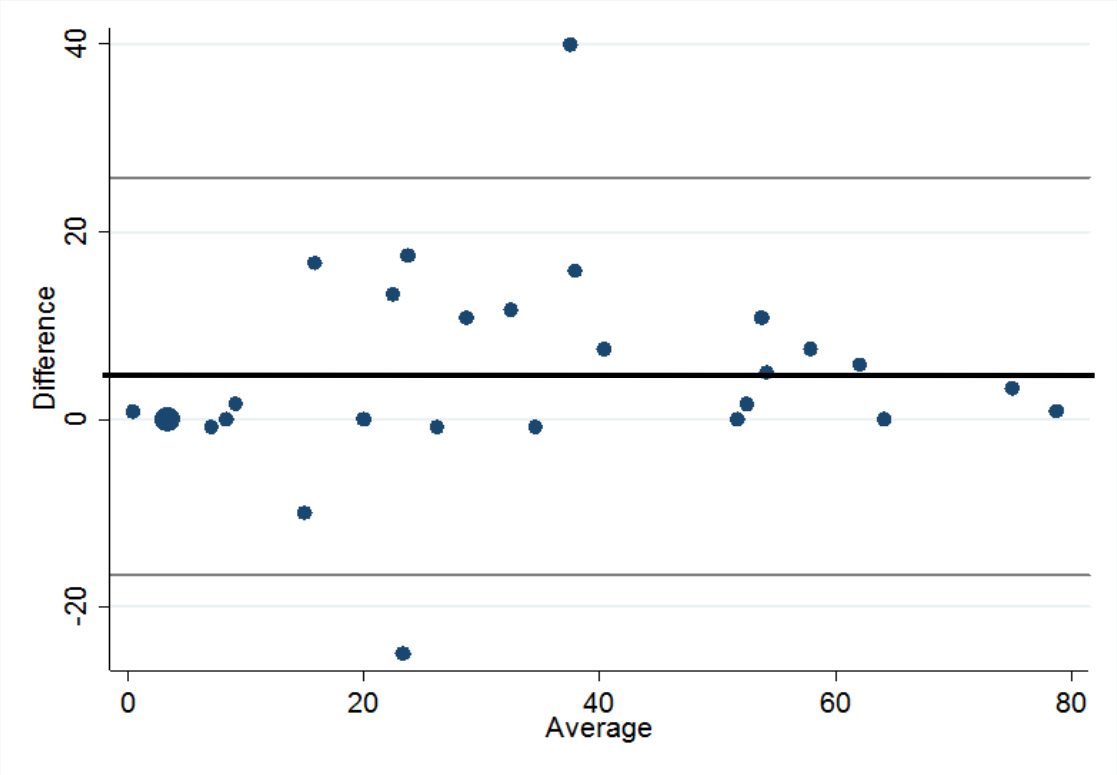


Figure 7. Bland Altman plot. X-axis: average of two measures, y-axis: difference between two measurements. Grey lines: 95% limits of agreement. Dark solid line: Bias from 0.

Convergent and divergent validity

Convergent and divergent validity were calculated for first and last follow-up (table 4).

Content validity

We found no extreme scores at either follow-up. No floor or ceiling effect was present.

NHP domain:	First control(P-value)	Last control(P-value)
Emotional reaction	0.32 (< 0.01)	0.28 (< 0.01)
Sleep	0.35 (<0.01)	0.25 (< 0.01)
Energy	0.39(< 0.01)	0.26 (< 0.01)
Pain	0.40 (< 0.01)	0.45 (< 0.01)
Physical mobility	0.60 (< 0.01)	0.67 (< 0.01)
Social isolation	0.26 (< 0.01)	0.34 (< 0.01)

Table 4: Pearson´s correlation coefficient of the DASH and Nottingham Health Profile.

Construct validity

Sum score first follow-up (mean): 43.7. Sum score last follow-up (mean): 33.2.

Sum scores at second follow-up were as expected lower than first follow-up at a significant level (*P*=0.001).

Responsiveness

Effect size was 0.53 for DASH.

Results study II

Study II (Translation and cross-cultural adaption)

The expert panel could agree on a translation but had two concerns. Item 6 ("turn a door knob using my affected hand") was a problem because the majority of doors in Denmark use door handles. We therefore suggested to J. C. MacDermid that we use the formulation "turn a key in a door with my affected hand", which was accepted as an alternative. We also found an alternative solution regarding item 7 ("cut meat

using a knife in my affected hand"). We debated whether this item meant cutting meat as in cutting a turkey or roast, or whether it meant using a knife with a fork during a meal. The first interpretation is not practiced regularly in Denmark by the majority, whereas the latter is a task done daily by most people in Denmark, and not only for cutting meat but also for vegetables, bread, etc. We therefore found that a formulation like "cutting with a knife with my affected hand" was more correct, since it is the ability to hold on to a knife and use it in a typical knife-cutting situation. We do not believe that it is important whether the focus of the item is meat, bread, vegetables etc., the focus is on the ability to hold on to the knife and use it. The lay panel had several remarks about the questionnaire. They found it confusing with the sample scales, and found that these could be misinterpreted as a question. Instead it was suggested that each response scale should be marked 0 and 10 with the appropriate marking, e.g. "no pain" and "worst ever". They also found that the almost identical instructions given at the beginning of each of the three sub-domains of the questionnaire were unnecessary and noted that one instruction at the beginning of the questionnaire would suffice. This was outside the focus of the lay panel, but the members where in strong consensus about this, so the coordinator chooses to include it in the final report and discuss it with the expert panel. Regarding item 3 ("When lifting a heavy object") and item 10 ("carry a 10 lb object in my affected hand"), the lay panel found them too abstract and also noted that to certain patients the task of lifting something heavy and lifting an object weighing 10lb (5 kilograms) could be the same challenge, and suggested supplementing the

items with examples. Item 3 could be exemplified with lifting heavier objects like a case of bottled beer (approximate weight 12 kilograms), a case of bottled soft drinks (approximate weight 8 kilograms) or a small child. These were examples that Danish patients were familiar with and would represent everyday functions they could relate to, remembering that the focus of the item is not being able to perform the task but estimating it on a response scale. Item 10 was suggested exemplified with lifting a bag with five 1-liter milk cartons, in which the same rationale as in item 3 was applied, an everyday task most Danish patients are familiar with. Item 8 ("fasten buttons on my shirt") was suggested changed to the formulation "fasten buttons on my shirt or blouse", since blouses are everyday garments, and perhaps used more often than shirts and can have buttons as well. The manner in which they are fastened are the same as in a shirt. All suggestions and concerns by the lay panel were presented to the expert panel which took note of the comments, and the questionnaire was revised accordingly. This was followed by a pilot study, interviewing 10 patients with wrist fractures, 9 were women and one man, average age 61 (range 19-85) average time for interview 41 minutes (range 26-48 minutes), and 9 patients had fractures of the dominant hand. After interviewing the first five patients, it became clear they found it difficult to estimate their average level of pain during the week with regard to items 1 to 4 and found it easier to give minimum or maximum level of pains. They all found that the questionnaire addressed issues that were relevant for them in their daily life and found that it covered their problems adequately, all though one patient missed an item about special abilities such as

playing the piano, but was satisfied with the questionnaire's possibility to comment on this.

The questionnaire was then altered, so that the maximum level of pain during the last week was asked for. The last five persons were then interviewed. All found the questionnaire relevant and with a good coverage of the problems they face with a wrist fracture. None found it difficult to estimate their maximum level of pain. One patient noted that the specific activities domain might be too detailed if patients were asked too early in their treatment, because at this time they probably could not perform any of the items addressed. A final report was made and submitted to the expert panel, describing each part of the translation process and the conducted alterations.

Study II (Validation)

As with the DASH a total of 49 patients answered the PRWE questionnaire 4.3 (2-14) days after the last follow-up. A total of 29 patients answered the questionnaire no later than 3 days after the last follow-up, and 10 patients at 5 days or later.

Patient-burden and feasibility

Time to complete the questionnaire was measured in the first 10 patients at first follow-up. None of the patients had completed the questionnaire before. The average time was 7 (3-16) minutes. At first follow-up, four patients (6.7%) had failed to answer certain items. Items seemed to be missing randomly, and no items were missing more than once.

Reliability

All scores were normally distributed (Figure 8 and 9).

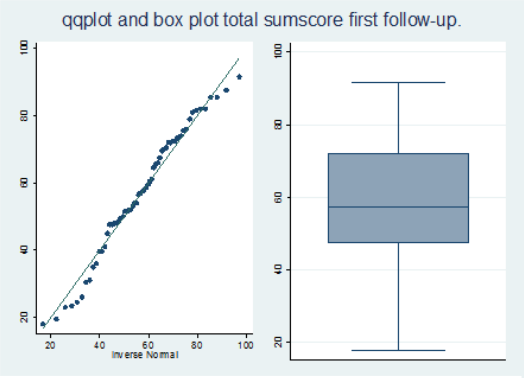


Figure 8. PRWE. First control.

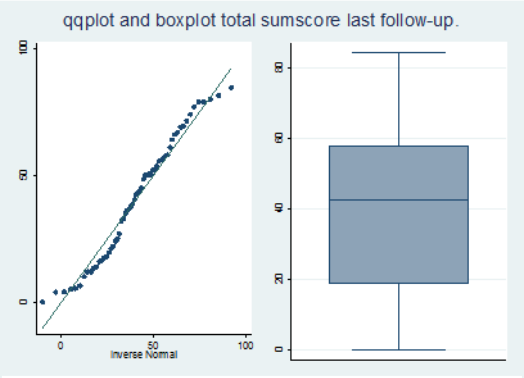


Figure 9. PRWE. Last control.

Internal consistency expressed as Cronbach's alpha is 0.94, and Cronbach's alpha for the three subsection's pain, specific activities and usual activities, were 0.87, 0.96, and 0.96, respectively.

Test-retest reliability was calculated in 29 patients who answered within 3 days after the last follow-up and demonstrated an ICC of 0.88. The 95% limits of agreement were ± 23.8 and the mean difference was 5.7 (CI: 1.12-10.37, *P*=0.017). (Figure 10)

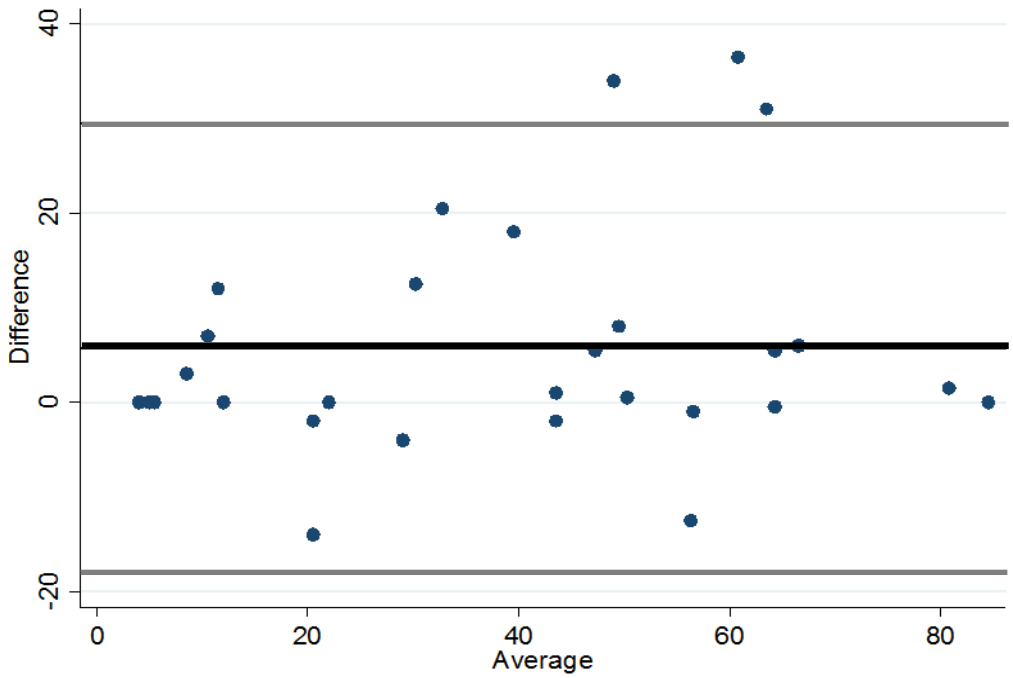


Figure 10: Bland-Altman plot: X-axis: average of two measures, y-axis: difference between two measurements. Grey lines: 95% limits of agreement. Dark solid line: Bias from 0.

Convergent and divergent validity

Convergent and divergent validity were calculated for first and last follow-up (table 5).

NHP domain:	First follow-up(*P*-value)	Last follow-up(*P*-value)
Emotional reaction	0.25(<0.01)	0.29(<0.01)
Sleep	0.21(<0.01)	0.21(<0.01)
Energy	0.39(<0.01)	0.16(<0.01)
Pain	0.44(<0.01)	0.46(<0.01)
Physical mobility	0.51(<0.01)	0.64(<0.01)
Social isolation	0.34(<0.01)	0.31(<0.01)

Table 5: Pearson´s correlation coefficient of the PRWE and Nottingham Health Profile.

Content validity

At the second follow-up one patient (1.7%) scored 0, indicating a high level of satisfaction and a slight ceiling effect, but within acceptable parameters.

Concurrent validity

Concurrent validity was calculated with Pearsons correlation coefficient 0.84 after 6 weeks.

Construct validity

Score	First follow-up	Last follow-up
Total PRWE sum (mean)	57.1	41.2
Pain subdomain (mean)	24.0	18.2
Function subdomain (mean)	33.1	23.0

Table 6. PRWE scores.

Sum scores at second follow-up were, as expected, lower than at first follow-up at a significant level (P=0.001).

Responsiveness

Effect size was 0.62 for the PRWE.

Results study III

Data were drawn from the questionnaires described in studies I and II, resulting in a total of 120 questionnaires for both the DASH and PRWE. SPSS analysis showed that both questionnaires scored in the same direction. Internal consistency, described by Person separation index was 0.96 for DASH and 0.94 for PRWE. The initial step in the analysis was to investigate thresholds. Ordered thresholds refer to the situation in which all responses within an item are used and patients with a high ability get a high score and vice versa. Disordered thresholds refer to the situation in which patients have difficulties discriminating between responses, making it uncertain whether a patient with a high ability would achieve a score reflecting the high ability. Regarding the DASH, a likelihood ratio test showed significant probability, which is why the unrestricted model in RUMM2030 was used. Disordered thresholds were found in 17 of 30 items. (Table 7: Analysis 1 & Figures 11a, 11b, 11c). Items were rescored resulting in ordered thresholds. (Table 7: Analysis 2). Residual correlation showed local dependency. All items were grouped into five domains, and the resulting subtest analysis showed no local dependency. The Bonferoni-adjusted final analysis confirms that the independent *t* test was significant (Table 7: Analysis 3). The analysis displayed no DIF for time interval. Initially, the 17 items were

individually rescored, but this did not result in unidimensionality, thus all 30 items were rescored into three responses, resulting in ordered thresholds and unidimensionality.

Analysis	Item fit residual		Person fit residual		Chi square interaction		Independent *t* test
	Mean	SD	Mean	SD	Total	Probability	
1	-0.08	1.75	-0.09	1.24	227.03	0.00	0.30
2	-0.21	1.69	-0.09	1.11	186.06	0.00	0.28
3	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	0.05	0.05

Table 7: DASH: Analysis summary. Due to regrouping, item and person residual statistics are not relevant in Analysis 3.

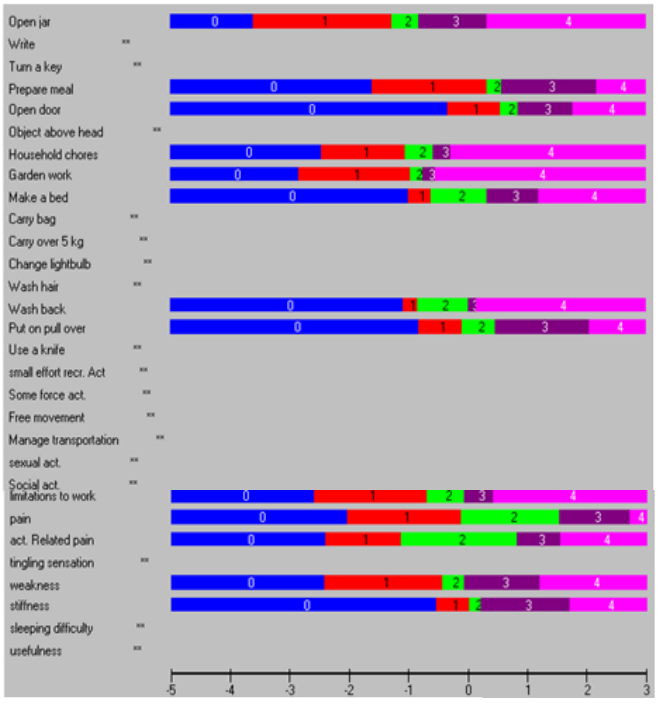


Figure 11a. DASH. Treshold map

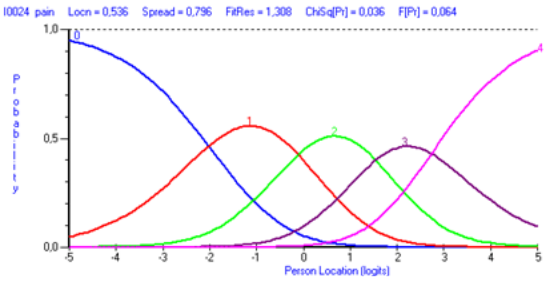


Figure 11b. DASH. Category probability curves for item 24 showing ordered tresholds.

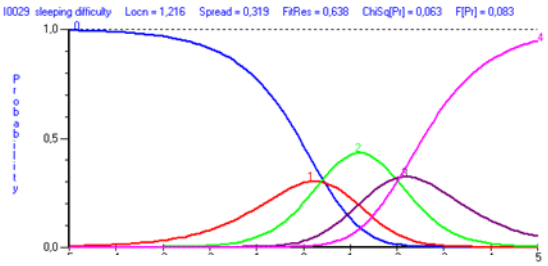


Figure 11c. DASH. Category probability curves for item 29 showing disordered thresholds.

Regarding PRWE, a likelihood ratio test showed significant probability, which is why the unrestricted model in RUMM2030 was used. Disordered thresholds were found in 14 of 15 items (Table 8: Analysis 1 & Figures 12a, 12b, 12c), which were then

rescored resulting in ordered thresholds. (Table 8: Analysis 2). Residual correlation showed local dependency. All items were grouped into three domains, and the resulting subtest analysis showed no local dependency. The Bonferoni-adjusted final analysis showed that the independent *t* test was significant (Table 8: Analysis 3). The analysis displayed no DIF for time interval. We made efforts to re-score items individually, but this did not result in unidimensionality. Therefore all items were rescored to four responses except item 11, which was rescored to three responses because disordered thresholds were still present with four responses to item 11, and by doing this we obtained the above-mentioned ordered thresholds.

Analysis	Item fit residual		Person fit residual		Chi square interaction		Independent *t* test
	Mean	SD	Mean	SD	Total	Probability	
1	-0.22	1.70	-0.30	1.21	67.11	0.00	0.23
2	-0.34	1.46	-0.37	1.32	76.25	0.00	0.23
3	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	0.09	0.03

Table 8: PRWE: Analysis summary. Due to regrouping, item and person residual statistics are not relevant in Analysis 3.

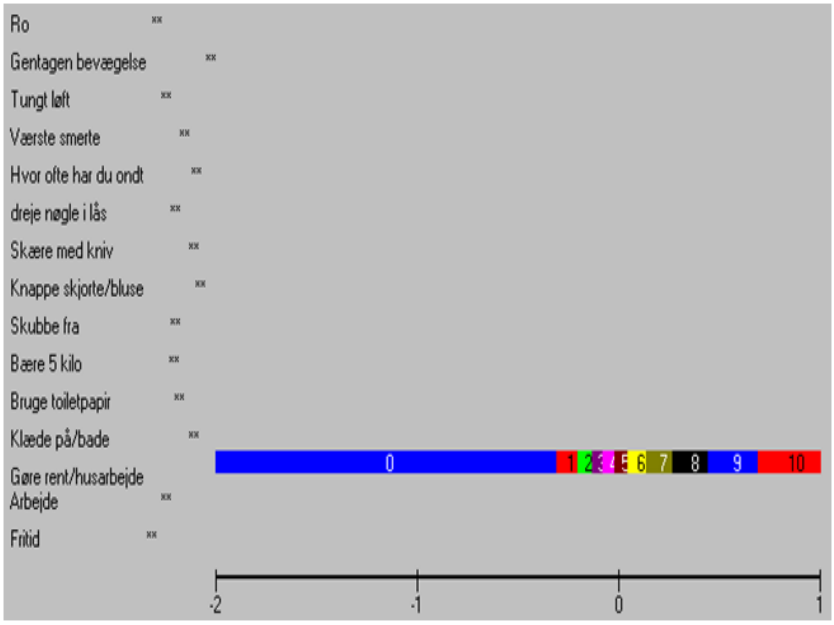


Figure 12a: PRWE. Treshold map.

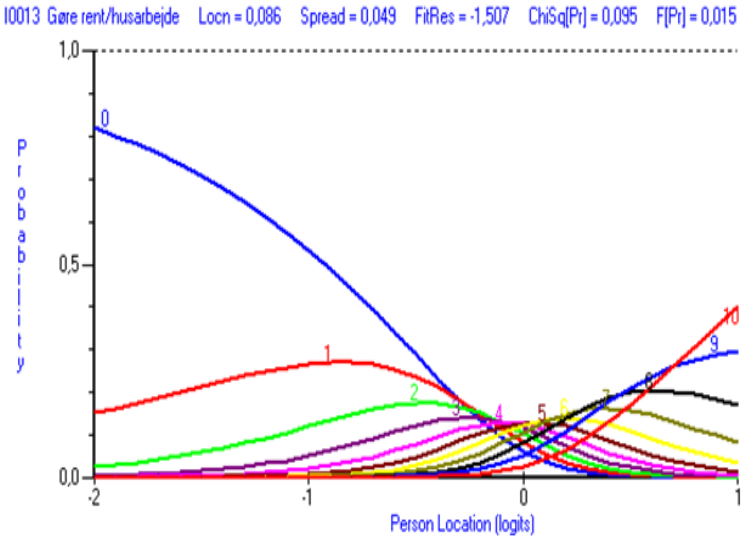


Figure 12b: PRWE. Category probability curves for item 13 showing ordered tresholds.

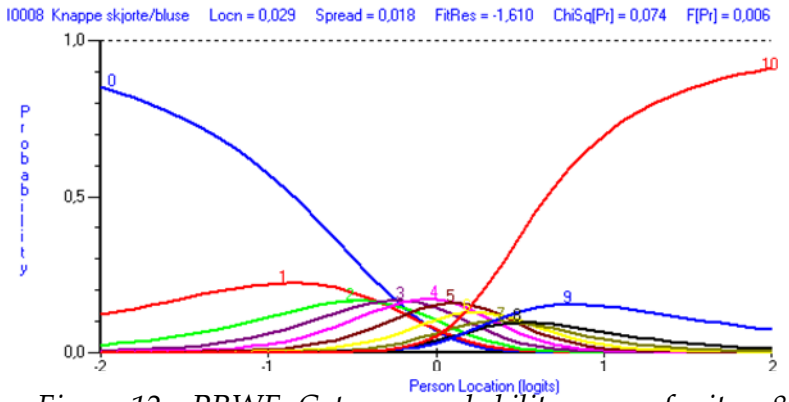


Figure 12c: PRWE. Category probability curves for item 8 showing disordered thresholds.

For both the DASH and PRWE not all values from 0 to 100 were represented for the ordinal scale or interval scale in our data. Both exhibited a non-linear property. For the DASH, we fitted a model from the observed data using fractional polynomial regression up to the sixth power. The best fit model was y = (ln(x) + 0.9 * 15.8) + (x^3 – 0.06 * 24.9) + (x^3 * ln(x) + 0.06 * -113.6) + 66.5, where x = (Ordinal score + 0.8 / 100) (Fig. 13). Model fit R-squared 0.98. Nomogram shown in table 9.

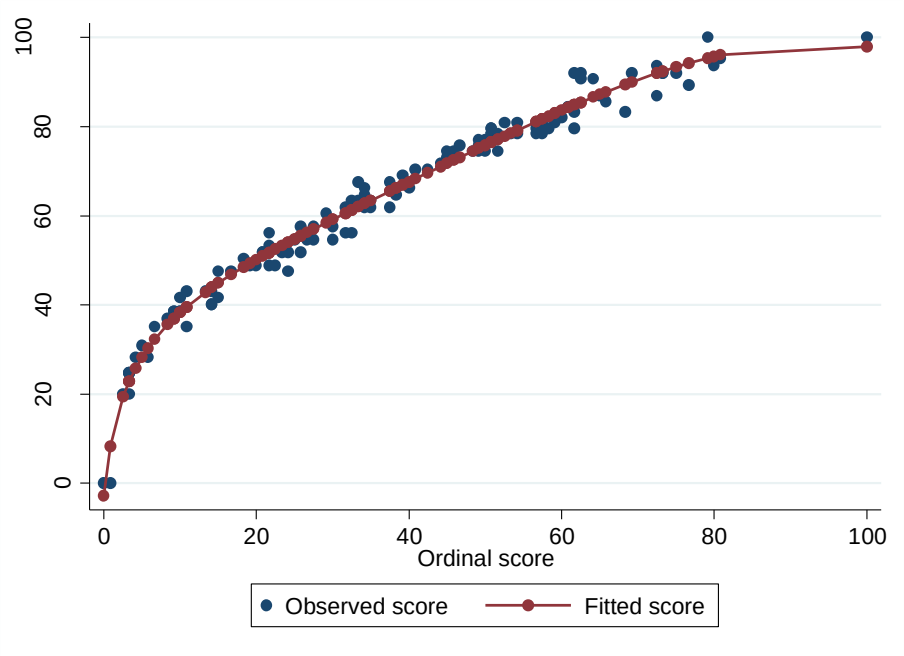


Figure 13. DASH. Best fit model for observed ordinal score and interval score data.

For PRWE we also fitted a model from the observed data using fractional polynomial regression up to the sixth power. The best fit model was y = x^0.5-0.7 * 299.9 + x^3-0.1 * -176,. + x^3*ln(x)+ 0.08 * 523.4 + x^3*ln(x)^2-0.06 * -1229.3 + x^3*ln(x)^3+0.04 * -916.2 + x^3*ln(x)^4-0.028 * -1202.3 + 52.96, where x = (Ordinal score + 0.5 / 100) (Fig. 14). Model fit R-squared 0.96. Nomogram shown in table 10

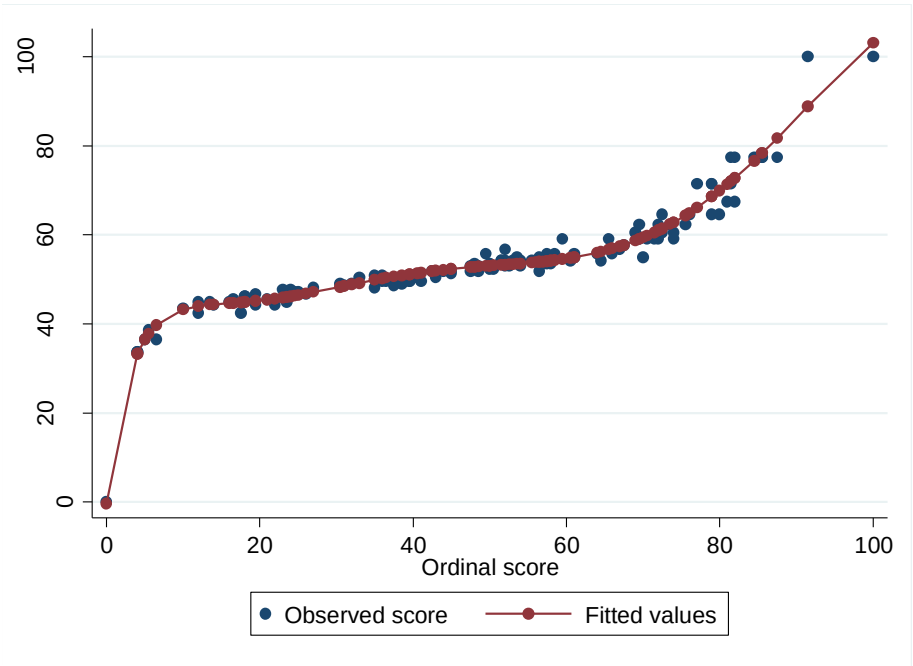


Figure 14. PRWE. Best fit model for observed ordinal score and interval score data.

Interval score	Ordinal score	Interval score (continued)	Ordinal score (continued)	Interval score (continued)	Ordinal score (continued)
0.0	0	62.6	34	89.2	68
9.8	1	63.4	35	89.9	69
16.7	2	64.3	36	90.5	70
21.5	3	65.1	37	91.1	71
25.2	4	65.9	38	91.7	72
28.2	5	66.8	39	92.3	73
30.8	6	67.6	40	92.8	74
33.0	7	68.4	41	93.4	75
34.9	8	69.3	42	93.9	76
36.7	9	70.1	43	94.4	77
38.3	10	70.9	44	94.9	78
39.8	11	71.8	45	95.3	79
41.2	12	72.6	46	95.8	80
42.5	13	73.4	47	96.2	81
43.7	14	74.2	48	96.5	82
44.9	15	75.0	49	96.9	83
46.0	16	75.8	50	97.2	84
47.1	17	76.9	51	97.5	85
48.2	18	77.4	52	97.8	86
49.2	19	78.2	53	98.0	87
50.2	20	79.0	54	98.2	88
51.1	21	79.8	55	98.4	89
52.1	22	80.6	56	98.5	90
53.0	23	81.4	57	98.6	91
53.9	24	82.1	58	98.7	92
54.8	25	82.9	59	98.7559	93
55.7	26	83.6	60	98.7560	94
56.6	27	84.4	61	99.0	95
56.6	28	85.1	62	99.2	96
58.3	29	85.8	63	99.4	97
59.2	30	86.5	64	99.6	98
60.0	31	87.2	65	99.8	99
61.7	32	87.9	66	100	100
62.6	33	88.6	67		

Table 9. DASH. Nomogram for converting ordinal scores to interval scores.

Interval score	Ordinal score	Interval score (continued)	Ordinal score (continued)	Interval score (continued)	Ordinal score (continued)
0.0	0	49.5	34	58.0	68
14.2	1	49.9	35	58.7	69
23.0	2	50.2	36	59.4	70
29.0	3	50.5	37	60.2	71
33.4	4	50.8	38	61.0	72
36.5	5	51.0	39	61.9	73
38.8	6	51.3	40	62.8	74
40.5	7	51.5	41	63.8	75
41.7	8	51.7	42	64.9	76
42.6	9	51.9	43	66.1	77
43.2	10	52.1	44	67.3	78
43.7	11	52.3	45	68.6	79
44.0	12	52.5	46	69.9	80
44.2	13	52.6	47	71.3	81
44.4	14	52.8	48	72.8	82
44.5	15	52.9	49	74.3	83
44.7	16	53.0	50	75.8	84
44.8	17	53.1	51	77.5	85
44.9	18	53.3	52	79.1	86
45.1	19	53.4	53	80.8	87
45.2	20	53.5	54	82.6	88
45.4	21	53.7	55	84.3	89
45.7	22	53.8	56	86.1	90
45.9	23	54.0	57	87.9	91
46.2	24	54.2	58	89.7	92
46.5	25	54.4	59	91.5	93
46.8	26	54.7	60	93.3	94
47.1	27	55.0	61	95.1	95
47.5	28	55.3	62	96.8	96
47.8	29	55.6	63	98.5	97
48.2	30	56.0	64	99.0	98
48.5	31	56.4	65	99.5	99
48.9	32	56.9	66	100	100
49.2	33	57.5	67		

Table 10. PRWE. Nomogram for converting ordinal scores to interval scores.

Results study IV

Sixty-six patients were initially included in the study. Five patients were lost during the follow-up period: two patients with a Micronail did not return for postoperative

follow-up, one patient randomised to external fixation had a volar fragment and was converted to another form of osteosynthesis, and two patients with external fixation fell within 2 weeks after surgery and sustained complicated refractures and loosening of the fixator and were converted to another form of osteosynthesis. This left 61 patients eligible for the study and the final follow-up control. All scores were normally distributed.

The three attending hospitals contributed 33, 23, and 5 patients. Forty-eight operations were performed by registrars, ten operations by senior registrars and three operations by consultant orthopaedic surgeons.

Outcome measures are given in tables 11 and 12.

	External fixation	Micronail	*P*-value
DASH	21.3(16.1)	22.9(18.5)	0.358
DASH interval score	48.5(19.6)	49.0(20.6)	0.462
PRWE	29.3(21.3)	26.2(23.8)	0.704
PRWE interval score	47.0(9.6)	43.2(14.6)	0.885
5-week satisfaction	7.9(1.9)	8.4(1.5)	0.121
Final control satisfaction	8.1(1.8)	8.2(2.3)	0.479
Postoperative radial length(mm)	-0.2(2.2)	0.9(1.4)	0.015
Postoperative volar tilt(°)	10.6(8.4)	2.2(6.6)	0.001
Final control radial length(mm)	-2.0(2.6)	0.2(1.5)	0.001
Final control volar tilt(°)	8.7(10.9)	0.03(9.8)	0.001
Change in radial length(mm)	1.8(1.9)	0.7(0.7)	0.999
Change in volar tilt(°)	1.9(7.4)	2.1(5.4)	0.563
5-week grip strength(kg)	3.8(2.8)	9.0(7.7)	0.001
Final control grip strength(kg)	11.8(5.7)	16.4(11.9)	0.031
Length of surgery(min)	41(11.2)	56(12.2)	0.001

Table 11: Outcome measures, mean (standard deviation).

		External fixation	Micronail
5-week follow-up			
	≥90%	0	0
	75-89%	0	1
	50-74%	0	7
	≤49%	30	23
Final control			
	≥90%	0	3
	75-89%	3	5
	50-74%	13	12
	≤49%	14	11

Table 12: Grip strength compared to unaffected opposite side.

Fourteen patients experienced complications during their treatment. One patient (Micronail) experienced pain in the DIP- and PIP-joints of 2nd to 5th fingers, which resolved within 6 months postoperatively. One patient (Micronail) was diagnosed with a regional pain syndrome which resolved within 6 months postoperatively, and one patient (Micronail) developed carpal tunnel syndrome and underwent surgery for the condition. Three patients (Micronail) experienced numbness in the area between the 1st and 2nd metacarpal bones. Whereas two patients only had transient numbness, one patient still had persistent symptoms 1 year postoperatively, no patients in the external fixation group had similar symptoms. Five patients (external fixation) developed pin-site infections which all resolved with antibiotics and one patient (external fixation) developed both pin-site infection and rupture of the extensor pollicis longus tendon. One patient (external fixation) experienced pain over the ulnar styloid after removal of the fixator and one patient (external fixation) had transient diminished feeling in all five fingertips. For both patients, symptoms were gone within 5 months after surgery. The weekly registration of a diary was

performed at the hospital that had included 33 patients. Twenty-one (11 internal fixation, 10 external fixation) patients returned the questionnaires after 5 weeks. Six internal fixation patients were retired and 8 of the external fixation patients were retired. All the non-retired patients were absent from work due to their fracture during the first 5 weeks. None of the patients had any use of prescription medication, and the use of non-prescription medication was the same in both groups for the first week, and after which there was a minimum of usage. There were no extraordinary transportation costs in either group, other than transportation to hospital in connection with postoperative follow-up, and these costs were covered by the hospital. No patients had consultations with their general practitioner. The external fixation group had an average of six (one patient four, one patient seven and eight patients six) weekly visits from a community nurse for pin-site care. No one in the internal fixation group had visits from the community nurse. The patients had similar courses during their hospital admission. The differences in hospital expenses were the cost of the osteosynthesis material, the prolonged operation time with internal fixation and the cost of sterilisation and packaging of the re-useable parts of the external fixator, the last two of which represent minor costs. An activity-based cost analysis(144) of important cost differences between the two groups is seen in table 13.

Activity:	Internal fixation	External fixation
Ostesynthesis material	5663 kr.(€ 761) (One nail, 3 buttress screws, 2 corticalis screws, 2 k-wires)	1500 kr.(€ 202) (Four standard Apex pins)
Community nurse	0 kr.(€ 0) (0 visits)	14850 kr.(€ 1996) (30 visits)
Total costs	5663 kr.(€ 761)	16350 kr.(€ 2197)

Table 13. Estimated costs pr. patient.

8. Discussion

Key findings and comparison with relevant findings from other studies

Study I

It took 11 minutes for the patients to answer the questionnaire in an out-patient setting, and none of the patients required help. Almost 20% of our patients initially failed to answer all the questions, and 3.3% of the questionnaires were unusable because of more than three missing items. Both time to complete questionnaire and unusable questionnaires correspond well to what others have reported (145). Except for item 21 (sexual activity), which was unanswered in 10 of the questionnaires, there was no specific pattern of missing items. Other reports have not mentioned that item 21 is often left unanswered. In our study it might be due to the age or gender of the patients, or they might not see the relevance of the item in conjunction with a wrist fracture.

Internal consistency showed excellent result with Cronbach´s alpha of 0.96 and this is similar to other studies (146;147)

Using Pearson´s test, we showed good convergent and divergent validity with regard to the Nottingham Health Profile, with convergent correlation to physical mobility domain and the pain domain. Although the pain domain was below 0.50, it still displayed a higher correlation than the divergent parameters. Other studies found even higher convergent validity using the SF-36 (146;147). We choose the NHP because it has previously been validated in Danish patients with wrist fractures, but the NHP is not region specific, so correlations would probably be higher if correlations were made to another validated wrist-specific questionnaire (106). Divergent validity was, as expected, low for the domains emotional reaction, sleep, energy and social isolation with a lower tendency for correlation at the final follow-up visit, although social isolation appeared to show fewer tendencies to a lower correlation than the other domains. Content validity demonstrated no floor or ceiling effect at first or last follow-up, showing good distribution of items. Responsiveness using effect size between first and last follow-up in this study was calculated to be 0.53. We consider this acceptable considering the short time period, and it would probably have been higher with a longer time period. Other studies describing results of wrist and hand patients show an effect size of 0.57 using a 12-week follow up (106). Test-retest reliability has in other studies with a longer follow up period shown acceptable results after 3 to 5 days (106). We found an ICC of a standard comparable to other studies, indicating a high degree of concordance of

results, but this could not be demonstrated with the Bland-Altman plot, which showed little concordance of results and a significant difference of mean. In this study, a better result could probably have been reached by excluding patients who mentioned a change in their situation. Furthermore our population was younger than in other studies and could have had a more rapid recovery, meaning that a 3-day period was too long for measuring test-retest reliability because the patients at this time were probably not in a stable period of recovery.

Study II

We used an elaborate approach in the translation process, both cultural and language specific differences being dealt with. The method we used for translation extends beyond mere translation. The first patients found it difficult to estimate average levels of pain, and indicated that it would be better to estimate minimum or maximum levels of pain. If we attempted to estimate the minimum level of pain, we would run the risk of underestimating the pain of the patients compared to the average level. By estimating the maximum level of pain we risk overestimating pain compared to the average level, but this would be a better choice than underestimating. Although there is a risk of getting a higher score in this item than the original questionnaire intended, we believe that it is an appropriate cultural adaption, and none of the following patients experienced problems answering this item. We also altered the instructions, so that only one instruction is shown at the beginning of the questionnaire, as well as marking each items response scale. These decisions were made by the expert panel after recommendation by the coordinator.

Our changes represented an alteration of the original questionnaire, but in our study we found some of the information to be redundant and potentially confusing for patients who answered the questionnaire. We believe that our alterations are in concordance with the method applied, because they extend beyond a mere translation and focuses on a true cultural adaption of the questionnaire, but acknowledge the fact that it is a modified version. We achieved experiential equivalence by replacing the term "door knob" with "a key in a door". We found no need to focus on idiomatic equivalence, since items did not include idioms. Semantic equivalence was obtained by changing the wording of item 7 about using a knife and supplementing item 8 with "using buttons on a blouse". Conceptual equivalence was made by describing items 3 and 10 with everyday examples of weight. The expert panel included only persons with a higher education, and this can seemingly be in contrast with Swaine-Verdier et al(125) who recommends use of people as ordinary as possible. Nevertheless we believe the expert panel to be well selected because three of the members had no daily contact with the patients who were to answer the questionnaire, one member was a native English speaker, and the panel was asked to keep the language as ordinary as possible.

The PRWE is known to have a high sensitivity for patients with wrist fractures, with responsiveness measured as effect size at 3.16 within the first 3 months after fracture (104;148). The reliability parameters of the original questionnaire showed excellent intraclass coefficient (ICC) above 0.90, in two groups with distal radius fractures, a total of 66 patients, and demonstrated good convergent validity with the bodily pain

and physical function domains of SF-36, 0.73 and 0.52 respectively, and good divergent validity of the mental domain of SF-36, which was 0.33 (111). Limit of agreements, difference of means, and internal consistency are not reported in the original development. Patient burden and feasibility were found at an acceptable level, with an average time of 7 minutes to answer the questionnaire in the clinic. No patients required help and 93.3 % questionnaires were with no missing items. Missing items seemed to appear randomly. Internal consistency showed good results, considering both total score and each of the three subdomains, which is similar to what has been reported in other studies (115;116). As expected, good convergent and divergent validity were shown by Pearson's correlation to the NHP, with highest convergent validity within the domains pain and physical mobility, which corresponds well to the original development of the questionnaire using SF-36 (111). No significant floor or ceiling effect was shown, demonstrating a good distribution of items. Concurrent validity was strong between the DASH and PRWE regarding wrist fracture, and on equivalent level with a Swedish study (0.86) and greater than demonstrated in a German study (0.62) (115;117). Responsiveness, calculated as effect size, was slightly larger for the PRWE than for DASH, indicating that the Danish PRWE is slightly more responsive at measuring change than the Danish DASH, although both were at a moderate level. A Swedish study (117) found an effect size of 1.3, but with a much longer time interval (7 weeks to 4-6 months), than presented in this study, which could explain the difference in effect size. Test-retest results were not satisfactory, even though demonstrating a high ICC at 0.88,

establishing a high concordance of results, which is comparable with other reports (111;115). By identifying three outliers in figure 10 and excluding them we found the 95% limits of agreement were ± 29.5 and the mean difference was 2.5 (CI: -0.6 - 5.6, *P*=0.111). This indicates that if we asked about a change in condition three days after last control, and excluded patients with a positive answer, we probably would have found satisfactory results in the Bland-Altman analysis.

Study III

The goal of this study was to perform Rasch analysis on the Danish versions of the DASH and PRWE. Both questionnaires display a unidimensional construct. We also fitted a model for conversion of ordinal scores to interval scores. Some considerations must be pointed out. The DASH displayed disordered thresholds in 17 of 30 items. Even though a considerable effort was made to rescore disordered items individually, this did not result in a significant end result. This was only achieved by rescoring all items, including items with ordered thresholds. Although this is allowed within the Rasch model, it is an alteration of items that are working properly, but it was the only way to achieve unidimensionality. This indicates that the DASH questionnaire could achieve a better construct with only three responses for each item. Analysis of the item fit residuals for the DASH showed that the standard deviation was at an elevated level, indicating a potential misfit of items. With regard to the item-person fit residual, items 7, 9 and 16 were below – 2.5 and 28 and 30 were above 2.5, indicating that the items were redundant. Looking at the DASH questionnaire, we found that these items were relevant for patients with distal

radius fractures and did display good content validity. The reason for this is probably because the DASH was developed as an upper extremity-specific questionnaire and was not designed specifically for patients with distal radius fractures. The PRWE is constructed with 11 responses within each item, so from the beginning it was suspected that the number of disordered thresholds would be substantial. It was, however, possible to rescore all items, achieve ordered thresholds and consistency in the questionnaire and show unidimensionality. The item fit residuals also show slightly elevated standard deviations. Examining the item-person fit residuals show probabilities below the Bonferoni adjustment for items 6 and 10, indicating redundancy. However, the content validity of the questionnaire is good, and the items are relevant for patients with distal radius fractures. We can further conclude that the pain domain of the PRWE, in which there were questions on the maximum level of pain, displayed no misfit of items.

Study IV

This randomised trial compared two types of osteosynthesis for unstable distal radius fractures. There was a significant difference in grip strength, with Micronail showing higher grip strength at both the 5 week control and at the final follow-up. This might have been the result of earlier mobilisation in patients treated with the Micronail and better radial length, the patients with non-bridging external fixation perhaps being impaired by the presence of the fixation on the forearm. There were significant differences between the two types of osteosynthesis regarding postoperative radiologic findings and final control radiologic outcome, although the

differences were minor and probably without any clinical importance. We did note, however, that the Micronail facilitated better radial length and prevented postoperative radial shortening better than did non-bridging external fixation. Non-bridging external fixation facilitated a better volar tilt than did the Micronail, probably due to direct manipulation of the distal fragment and the difficulty of getting a lateral view peroperatively with Micronail because of the insertion jig. Both patient-reported outcome measures, the DASH and PRWE, showed no significant differences at the final follow-up. In a study that included non-bridging fixated patients, the DASH score was 21 at 10 weeks follow-up (79), which is comparable to our result. No comparable studies have used the DASH for Micronail at 12 weeks. One study found a DASH score of 8.1 at 21 months after surgery (99). We also used the fitted data from study III to calculate a DASH and PRWE score on an interval scale, and found only minor non-significant differences. Patient satisfaction measured on a visual analogue scale at both 5 weeks and at final follow-up showed no significant differences and showed a high level of satisfaction. The activity-based costing analysis showed that the overall costs when using Hoffman II compact non-bridging, were approximately three times larger than those with the Micronail. It was also evident that the Micronail was approximately 4000 DKK (€ 540) more expensive for the hospital to use, but this was accompanied by a saving of 14850 DKK (€ 2000) in the municipality, responsible for the care in the postoperative period. We saw six complications in the Micronail group. Regional pain syndrome and carpal tunnel syndrome are both uncommon but known complications to osteosynthesis of the

distal radius as are nerve-related complications (58). Three patients who had received a Micronail showed symptoms of an affection of the superficial radial sensory nerve, which is a known complication related to the use of the Micronail (98;99). We saw no patients with screw penetration to the distal radioulnar joint, which was because all surgeons were familiar with the techniques and the use of fluoroscopy during the operation. Eight patients with non-bridging external fixation experienced complications. Five patients had pin-site infections, and one patient had both pin-site infection and rupture of the extensor pollicis longus tendon. No deep infections occurred. All are known complications and are of a magnitude comparable with other reports (58;72). Two patients with external fixation experienced atypical symptoms that resolved within 5 months. We found that the rate of complications was comparable to other reports; nevertheless, we must stress the fact that Micronail gives a potentially high risk of injury to the superficial radial sensory nerve.

Limitations

Study I

Despite the fact that we could not demonstrate satisfactory test-retest reliability in this study, we consider this a methodological problem and should not exclude use of the DASH in patients with wrist fractures, although this question is relevant to be addressed in future studies. Another limitation of this study is the small sample size, although this is in concordance with other studies validating the DASH (146;147;149). A larger sample size could increase the strength of our results. We only included

patients with wrist fractures, thus no conclusions can be made about patients with other upper extremity disorders. In this study no physical parameters of evaluation were used. Studies have described that parameters like range-of-motion, strength and movement are less responsive to measuring change than questionnaires administered during the first 3 months after a wrist fracture (148;149). Furthermore the use of physical objective parameters would also demand a description of the reliability and validity of each test to ensure a proper correlation, an issue, which is not addressed in many published validation studies. A longer time interval would strengthen the longitudinal results of the questionnaire.

Study II

Reliability was not demonstrated in the Bland-Altman plot, which showed little concordance of results and a significant difference of mean. We consider this to be due to a methodological error, since we estimated this approximately 6 weeks after fracture during a period in which patients' conditions were still improving, and at a time when the cast or other restrictions of loading and movement were just beginning to diminish. As in study I we have a relatively small sample size, although comparable with other studies (39;111;115;116), and as in study I, we choose not to investigate strength, movement, etc. and observed patients for a relatively short time period. We did alter the questionnaire, most conspicuous being a change in the instructions and the marking of the scales, and asking for the maximum level of pain instead of the average level. We do however believe that these changes are appropriate and on par with the method of translation we used, remembering that

our results are comparable to other studies, and that the Bland-Altman plot has never been used to describe reliability parameters in the PRWE before.

Study III

In this study, we also considered the DIF for the time interval between two responses to the questionnaires. We choose not to examine DIF for age because there is no overall agreement regarding an age-related cut off point for the treatment of distal radius fractures, and DIF is likely associated with the mental status of the patient, and mentally unfit patients were excluded from the study. We had a high proportion of women in our study, and with only 60 patients included we estimated that the proportion of men was not great enough to examine DIF for gender. In order to convert the ordinal score to interval score, we had to calculate a fitted model since not all values from 0 to 100 were represented in either the DASH or the PRWE. We had a high proportion of scores placed in the centre of our scales and few scores at both the ends of the scales. This increased the variance of data in the high and low ends of the scales, and we cannot exclude that a larger sample size and longer time interval could have increased the number of scores at either end of the scale, thus decreasing the variance. Nevertheless, we have a high R-squared in both fitted models which shows a low variance in the models overall. We have not found any other relevant studies with which to compare our results, and to our knowledge this is the first study examining the DASH and PRWE with Rasch analysis.

Study IV

The study has several limitations. There is a potential risk of type-2 error. We used the DASH as a primary outcome because it has been used to evaluate both types of osteosynthesis, but the DASH is an upper extremity-specific questionnaire, and it might have been advantageous to use a wrist-specific questionnaire such as the PRWE as the primary outcome measure. We only followed the patients for 3 months postoperatively, even though full recovery might take at least 2 years (149). In our study 48 patients were operated on by registrars and this might have influenced the results compared with those that would be obtained if a specialist in hand surgery had done all the operations; nevertheless, this reflects the daily activity in our departments. We did not estimate range of motion of the wrist for several reasons. First, it is a doubtful outcome measure during the first 3 months after surgery, because it is less responsive than other measures (149), and secondly, there is no consensus on how to measure range of motion (15;150). Albeit that many studies report range of motion, they fail to make a thorough description of the method and its reliability parameters. The activity-based cost analysis suffered from a lack of compliance by the patients invited to complete the diary. Only 21 out of 33 patients completed the diary, and none of these were patients experienced complications. Even though we believe the patients outlined the diary to the best of their ability, we did not check this. We do believe that the costs of a hospital stay are similar in the two groups. A proportion in each of the two groups answering the diary were not retired from work, although absent from their work due to their fracture. We did not

consider this in the cost analysis because it concerns very few patients. So overall we do find that the significant costs in this study are represented by the cost of the osteosynthesis material and postoperative care by the community nurse.

9. Conclusion

Study I

We conclude that the Danish version of the 30-item DASH is a valid and practical questionnaire for use with Danish patients with wrist fractures.

Study II

We conclude that the modified Danish version of the PRWE questionnaire is a valid and practical questionnaire for use in Danish patients with wrist fractures, and shows a higher responsiveness than the Danish version of the DASH.

Study III

We conclude that both the DASH and PRWE are unidimensional constructs that are useful in both clinical and research settings for distal radius fractures. Future clinical studies or clinicians using the Danish versions of the DASH and PRWE for wrist fracture patients, should report both the ordinal and interval scores of the questionnaires.

Study IV

We conclude that the Micronail facilitated a better radial length, but the volar tilt was better restored if non-bridging external fixation was used. Furthermore we found a significant difference in grip strength between the two types of osteosynthesis at 5 week and at 3 month follow-up, in that patients with Micronail displayed better grip

strength. We saw a high satisfaction with treatment in both groups. The cost of using Micronail involves a greater expense for the hospital, but this is followed by a considerable cost saving in the first 5 weeks after surgery due to less care needs. We could not show any significant difference between the two groups after scoring the DASH and PRWE on both ordinal and interval scales.

10. Perspectives and future research

For both the DASH and PRWE further studies are needed to demonstrate test-retest reliability expressed as difference of means and 95% limits of agreement, as well as longitudinal studies to establish long term sensitivity in Danish wrist fracture patients. Both questionnaires can also be used for other disorders of the upper extremity. The PRWE has been used for patients with scaphoid fractures and the carpal tunnel syndrome, and the DASH, as an upper extremity specific questionnaire, has been used for several conditions of the forearm, elbow and shoulder. Future studies are needed to estimate the reliability and validity in the Danish versions of the DASH and PRWE in these conditions, and these estimates should be accompanied by Rasch analysis to demonstrate unidimensionality and fitting of an ordinal scale to interval scale. In future studies in which Rasch analysis is used a larger proportion of patients should be included, thereby allowing for both assessment of DIF across other variables as well as a further examination of the misfit of items.

Future randomised studies investigating osteosynthesis of wrist fractures should use validated outcome measures and include wrist-specific questionnaires, and follow the patient for a time period of at least 1 year. Since the Micronail is a new device, it should be tested in a randomised setting and compared to some of the other frequently used types of osteosynthesis like Kirschner-wire fixation or volar plating using reliable and validated outcome measures. A cost analysis should be supplemented with a closer follow-up to increase compliance as well as ensure that a larger number of patients complete the diary.

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Appendices

1) DASH

DISABILITIES OF THE ARM, SHOULDER AND HAND
(HANDICAPS I ARM, SKULDER OG HAND)

DASH

VEJLEDNING

I dette spørgeskema stiller vi dig spørgsmål om dine symptomer og din evne til at udføre visse aktiviteter.

Vær venlig at svare på hvert eneste spørgsmål ved at sætte en cirkel om det tal, der passer bedst til din tilstand i den forløbne uge.

Hvis du ikke har haft lejlighed til at udføre en bestemt aktivitet i den forløbne uge, beder vi dig angive det svar, du mener ville dække bedst.

Det er uden betydning, hvilken hånd eller arm du anvender til at udføre aktiviteten; dit svar skal afspejle din evne til at udføre selve handlingen, uanset hvordan du gør det.

DISABILITIES OF THE ARM, SHOULDER AND HAND (HANDICAPS I ARM, SKULDER OG HAND)

Vurder venligst, hvordan din evne til at udføre følgende handlinger har været i den forløbne uge ved at sætte en cirkel om tallet under det svar, der passer bedst.

	Ikke vanskeligt	Lidt vanskeligt	Noget vanskeligt	Meget vanskeligt	Umuligt
1. Åbne et (marmelade)glas med strammt låg.	1	2	3	4	5
2. Skrive.	1	2	3	4	5
3. Dreje en nøgle i en lås.	1	2	3	4	5
4. Tilberede et måltid mad.	1	2	3	4	5
5. Skubbe en tung dør op.	1	2	3	4	5
6. Anbringe en genstand på en hylde over dit hoved.	1	2	3	4	5
7. Udføre tungt husarbejde (fx vaske vægge, vaske gulve).	1	2	3	4	5
8. Arbejde I haven.	1	2	3	4	5
9. Rede seng.	1	2	3	4	5
10. Bære en indkøbspose eller en mappe.	1	2	3	4	5
11. Bære en tung genstand (over 5 kg).	1	2	3	4	5
12. Skifte en elektrisk pære over hovedhøjde.	1	2	3	4	5
13. Vaske eller fønføre dit hår.	1	2	3	4	5
14. Vaske dig selv på ryggen.	1	2	3	4	5
15. Tage en sweater på.	1	2	3	4	5
16. Bruge en kniv til at skære mad ud.	1	2	3	4	5
17. Fritidsaktiviteter, der ikke er særlig anstrengende (fx kortspil, strikning, osv.).	1	2	3	4	5
18. Fritidsaktiviteter, som sender en vis kraft eller stød gennem din arm, skulder eller hånd (fx golf, slag med hammer, tennis, osv.).	1	2	3	4	5
19. Fritidsaktiviteter, som kræver fuld bevægelighed af din arm (fx frisbee, badminton, osv.).	1	2	3	4	5
20. Klare transport (komme fra et sted til et andet).	1	2	3	4	5
21. Dyrke sex.	1	2	3	4	5

DISABILITIES OF THE ARM, SHOULDER AND HAND (HANDICAPS I ARM, SKULDER OG HAND)

	SLET IKKE	LIDT	EN DEL	TEMMELIG MEGET	VIRKELIG MEGET
22. Hvor *vanskeligt* har det været for dig i den forløbne uge, at omgås familie, venner, naboer og grupper pga din arm, skulder eller hånd? (sæt cirkel om tallet)	1	2	3	4	5
	SLET IKKE HÆMMET	**LIDT HÆMMET**	**EN DEL HÆMMET**	**MEGET HÆMMET**	**UDE AF STAND TIL**
23. Har du i den forløbne uge været hæmmet i at udføre dit arbejde eller andre gøremål pga. din arm, skulder eller hånd?	1	2	3	4	5
Vær venlig at angive sværhedsgraden af følgende symptomer i den forløbne uge. (sæt cirkel om tallet)					
	INGEN	**LIDT**	**EN DEL**	**SVÆR**	**EKSTREM**
24. Smerte i din arm, skulder eller hånd.	1	2	3	4	5
25. Smerte i din arm, skulder eller hånd når du laver noget bestemt.	1	2	3	4	5
26. Prikken i din arm, skulder eller hånd.	1	2	3	4	5
27. Svaghed i din arm, skulder eller hånd.	1	2	3	4	5
28. Stivhed i din arm, skulder eller hånd.	1	2	3	4	5
	IKKE VANSKELIGT	**LIDT VANSKELIGT**	**NOGET VANSKELIGT**	**MEGET VANSKELIGT**	**SÅ VANSKELIGT AT DET FORHINDRER MIG I AT SOVE**
29. Hvor vanskeligt har det i den forløbne uge været for dig, at sove pga. smerter i din arm, skulder eller hånd? (sæt cirkel om tallet)	1	2	3	4	5
	HELT UENIG	**UENIG**	**HVERKEN ENIG ELLER UENIG**	**ENIG**	**HELT ENIG**
30. Jeg føler mig mindre effektiv, mindre sikker på mig selv, eller til mindre nytte pga. min arm, skulder eller hånd. (sæt cirkel om tallet)	1	2	3	4	5

DASH HANDICAP-/SYMPTOMSCORING= [((summen af n svar)/n) – 1] x 25, hvor n er lig med antallet af afgivne svar.
En DASH-scoring må ikke udregnes, hvis der er mere end 3 ubesvarede spørgsmål.

2) PRWE Danish version

Navn & cpr: _____. Dato:

Spørgeskema om smerter og bevægelser i håndled

(The Patient-Rated Wrist Evaluation (PRWE)[1])

Svarene på spørgsmålene vil hjælpe os til at forstå, hvor ondt du har haft og hvor meget besvær du har haft i den sidste uge i det håndled, som du har problemer med.
Tænk på dine problemer med håndleddet i løbet af den sidste uge.
Besvar venligst **alle** spørgsmålene.
Hvis du ikke - i den sidste uge - har udført det, der spørges om, skal du forestille dig den smerte eller det besvær, du ville have haft.
Hvis du **aldrig** tidligere har gjort det, der spørges om, skal du ikke besvare spørgsmålet.
Sæt en ring om det tal, som bedst beskriver smerten eller problemet.
0 *beskriver, at du ikke har haft smerte eller problemer, og* **10** *beskriver, at du har haft den værste smerte eller størst mulige problem,* **eller** *at du ikke har kunnet gøre det, der bliver spurgt om.*

1. Hvor ondt har du haft, når du har haft mest ondt - i den sidste uge	
Når du har holdt håndleddet i ro	0 1 2 3 4 5 6 7 8 9 10 Ingen smerte Værste smerte
Når du har gjort den samme bevægelse mange gange lige efter hinanden	0 1 2 3 4 5 6 7 8 9 10 Ingen smerte Værste smerte
Når du har løftet noget tungt (f.eks. en kasse øl eller vand eller et lille barn)	0 1 2 3 4 5 6 7 8 9 10 Ingen smerte Værste smerte
Når smerten har været værst	0 1 2 3 4 5 6 7 8 9 10 Ingen smerte Værste smerte

Hvor ofte har du ondt?	0 1 2 3 4 5 6 7 8 9 10 Aldrig Hele tiden

Næste side.....

B. Bevægelser
A. Særlige bevægelser
Hvor meget besvær har du i den sidste uge haft, når du skulle:

- dreje en nøgle i en lås med den syge hånd	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det
- skære med en kniv med den syge hånd	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det
- knappe en skjorte eller bluse	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det
- bruge den syge hånd til at skubbe fra, når du skulle rejse dig fra en stol	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det
- bære noget i den syge hånd, som vejer 5 kilo (f.eks. en pose med 5 liter mælk)	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det
- bruge toiletpapir med den syge hånd	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det

B. Daglige gøremål
Hvor meget besvær har du haft i den sidste uge med det, du gjorde, før du fik problemer med håndleddet:

Klæde dig på og/eller tage bad	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det
Gøre rent eller andet husarbejde	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det
Være på arbejde eller gøre det du plejer til daglig	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det
Gøre det, du plejer i din fritid	0 1 2 3 4 5 6 7 8 9 10 Intet besvær Kunne ikke gøre det
Du er velkommen til at skrive noget her, som du synes er vigtigt:	

3) PRWE Original version

Name: _____ Date:

PATIENT RATED WRIST EVALUATION

The questions below will help us understand how much difficulty you have had with your wrist in the past week. You will be describing your ***average*** *wrist symptoms* ***over the past week*** *on a scale of 0-10.* Please provide an answer for ALL questions. If you did not perform an activity, please **ESTIMATE** the pain or difficulty you would expect. If you have ***never*** performed the activity, you may leave it blank.

1. PAIN
Rate the average amount of pain in your wrist over the past week by circling the number that best describes your pain on a scale from 0-10. A zero (0) means that you did not have any pain and a ten (10) means that you had the worst pain you have ever experienced or that you could not do the activity because of pain. Sample scale ⌋ 0 1 2 3 4 5 6 7 8 9 10 No Pain Worst Ever

RATE YOUR PAIN:	
At rest	0 1 2 3 4 5 6 7 8 9 10
When doing a task with a repeated wrist movement	0 1 2 3 4 5 6 7 8 9 10
When lifting a heavy object	0 1 2 3 4 5 6 7 8 9 10
When it is at its worst	0 1 2 3 4 5 6 7 8 9 10

How often do you have pain?	0 1 2 3 4 5 6 7 8 9 10 Never Always

Please turn the page……

2. FUNCTION

A. SPECIFIC ACTIVITIES

*Rate the **amount of difficulty** you experienced performing each of the items listed below - over the past week, by circling the number that describes your difficulty on a scale of 0-10. A **zero** (0) means you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do it at all.*

Sample scale: 0 1 2 3 4 5 6 7 8 9 10 — No Difficulty … Unable To Do

Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Cut meat using a knife in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

B. USUAL ACTIVITIES

*Rate the **amount of difficulty** you experienced performing your usual activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities you performed **before** you started having a problem with your wrist. A **zero** (0) means that you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do any of your usual activities.*

Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

Comment/Interpretations:

4) Paper I

5) Paper II

6) Paper III

7) Paper IV