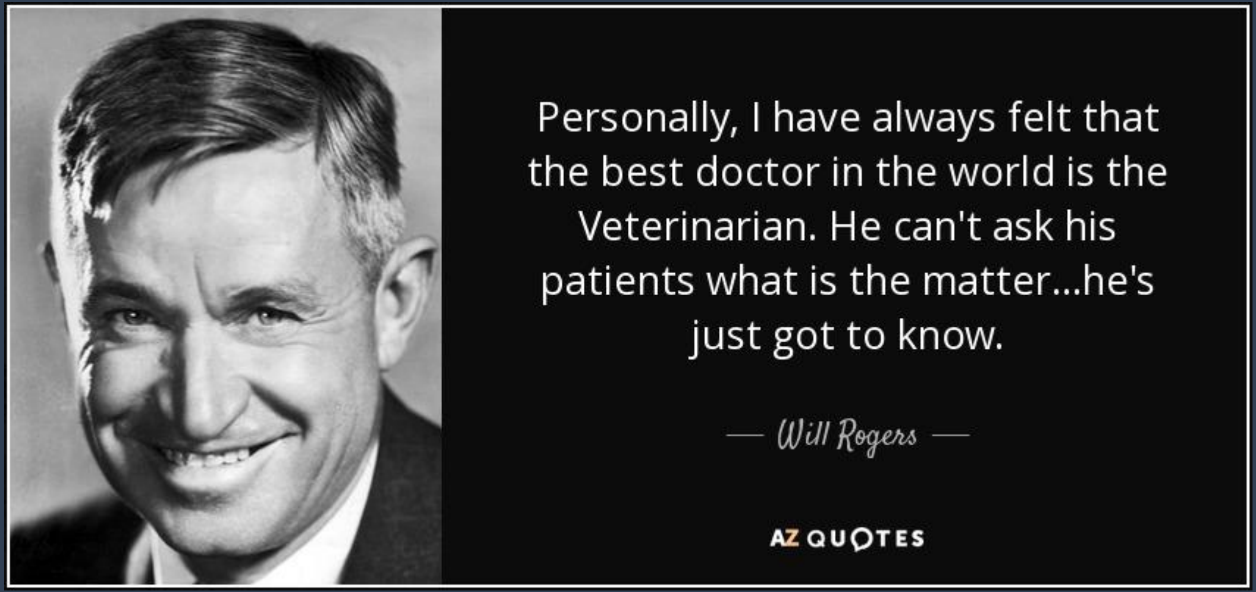
Choosing the best PROM in orthopaedic research

MD, PhD, Christian Fugl Hansen
Orthopaedic Resident

Department of Orthopaedics
Bispebjerg and Frederiksberg Hospital
Nordsjællands Hospital

KØBENHAVNS UNIVERSITET

WHY PROMs?


Personally, I have always felt that the best doctor in the world is the Veterinarian. He can't ask his patients what is the matter...he's just got to know.
— Will Rogers —
AZ QUOTES


"WE DID A FANTASTIC JOB."

"Add-on" to other measurements

KNEE

Functional performance tests, clinical measurements, and patient-reported outcome measures do not correlate as outcomes 1 year after anterior cruciate ligament reconstruction

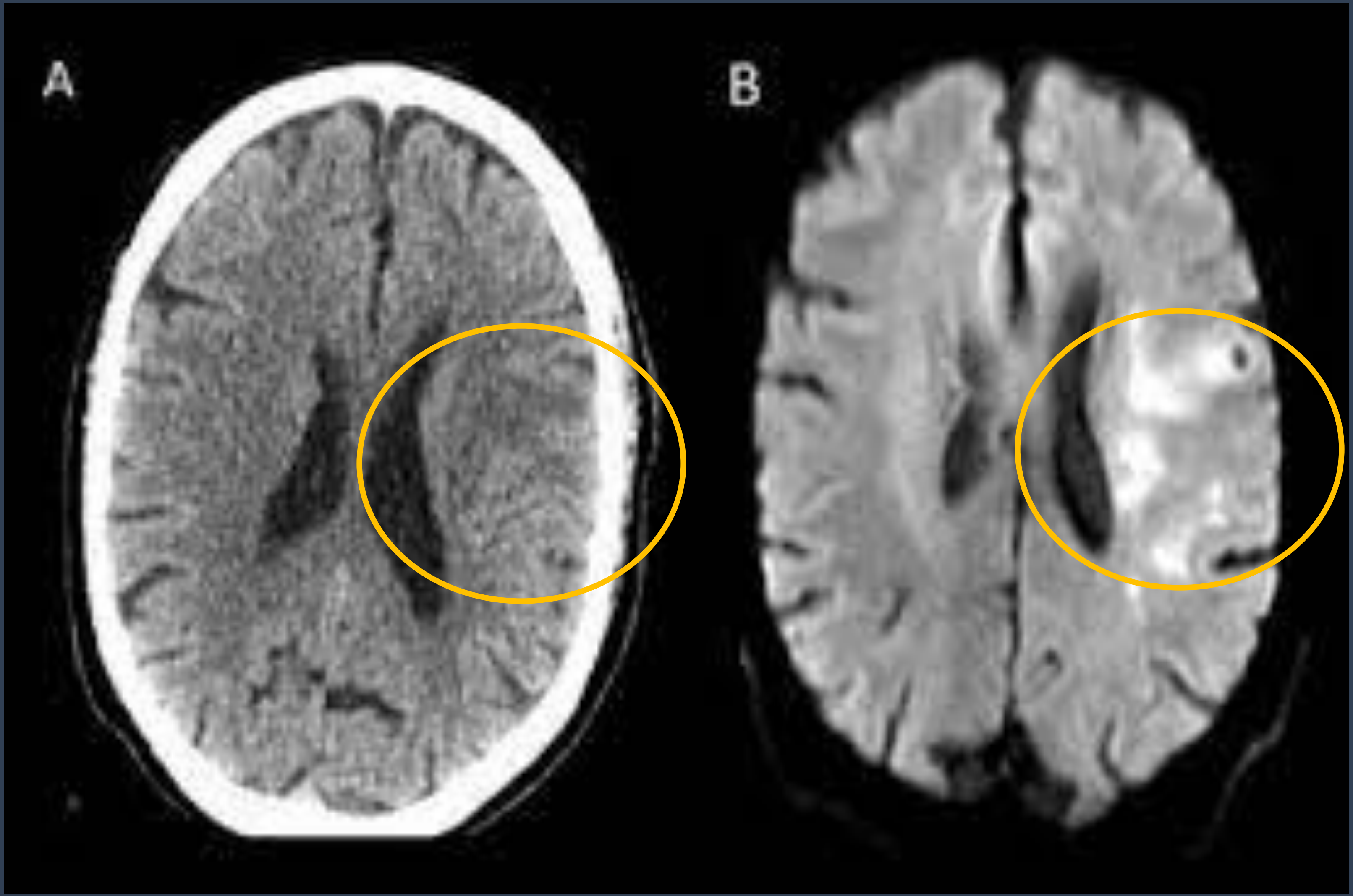
Mustafa Al-Gburi[1,2,3] · Jakob Bredahl Kristiansen[1,2,3] · Karl Bang Christensen[1,2,3] · Michael Rindom Krogsgaard[1,2,3]

Received: 5 May 2023 / Accepted: 24 October 2023

PROMs add something unique

Not just an ”add-on”? – It’s the primary outcome!

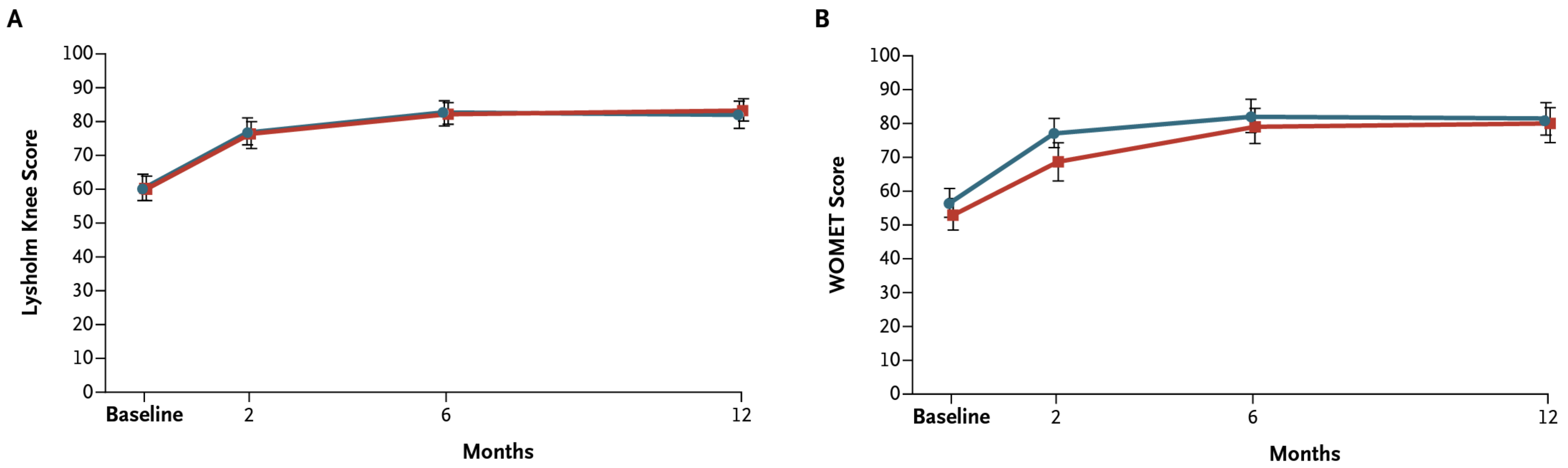
Surgery vs **Physioterapy**



CT

MRi

Acute stroke



The NEW ENGLAND JOURNAL of MEDICINE

Arthroscopic Partial Meniscectomy versus Sham Surgery for a Degenerative Meniscal Tear

Acute stroke

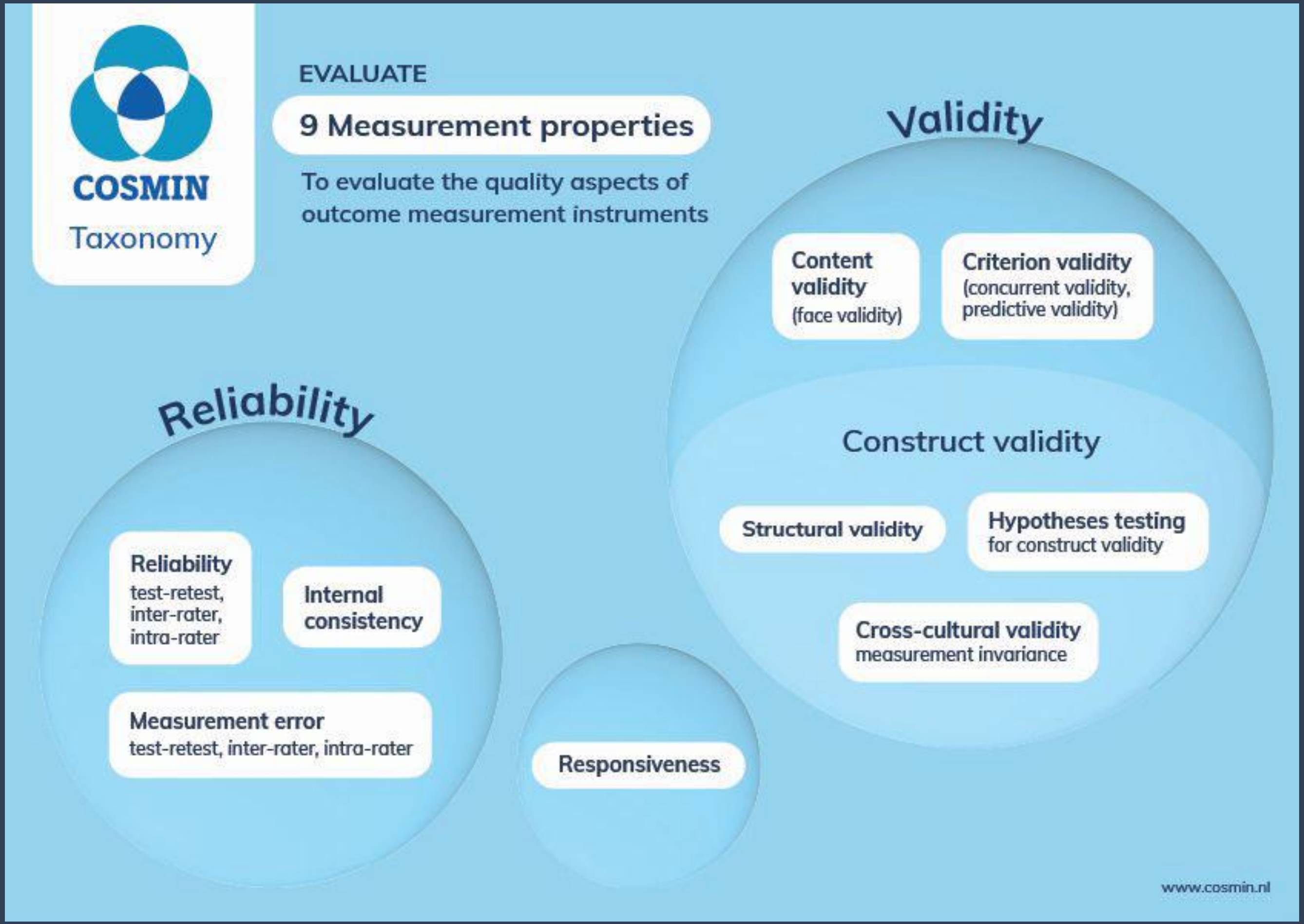
Better PROMs are more responsive

Knee Surgery, Sports Traumatology, Arthroscopy (2018) 26:2438–2446
https://doi.org/10.1007/s00167-018-4961-z

KNEE

KNEES-ACL has superior responsiveness compared to the most commonly used patient-reported outcome measures for anterior cruciate ligament injury

How to choose the best PROM



How to choose the best PROM

- Choose a PROM that was developed **through patient interviews**
- Choose a PROM that has been **validated with MTT models**
- Be inspired by our **catalogue!**

Table S12. Elbow PROMs validation

	Conditions validated (n)	Different phases	Normals validated (n)	IRT method	Comparision with other PROMs	Other methods	Domain aggregation	Test-retest reliability	Chronbach´ s α	Known groups validity	DIF	MID	Responsiveness	Floor/ceiling effect	Assessment
pASES-e *American Shoulder and Elbow Surgeons Elbow Questionnaire*															
English (MacDermid 2001) (195)	Elbow pathology (70)	Not disclosed	-	-	SF-36 PRTEE DASH	-	-	Yes	-	-	-	-	-	-	Elbow conditions in general: **
German (John et al. 2010) (196)	Elbow pathology (75)	11,2 y postop	-	-	SF-36 PRTEE DASH	-	-	Yes	Yes	-	-	-	-	Yes	Elbow conditions in general: ** Elbow prosthesis patients: ***

How to choose the best PROM

What do we measure?

Order of importance

1. **Content validity** – relevance, coverage, understandability
2. **Structural validity (MTT models!)**
3. Reliability, criterion validity, hypotheses testing construct validity, responsiveness

Can we measure it?

Is it accurate?

Research | Open access | Published: 25 May 2003

Knee injury and Osteoarthritis Outcome Score (KOOS) – validation and comparison to the WOMAC in total knee replacement

Conclusion

The Knee injury and Osteoarthritis Outcome Score (KOOS) is a valid, reliable, and responsive outcome measure in total joint replacement. In comparison to the WOMAC, the KOOS

3. Reliability, criterion validity, hypotheses testing construct validity, responsiveness

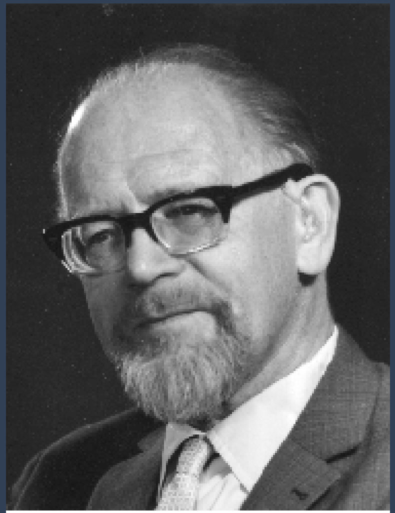
Is it accurate?

Analysis of 61 musculoskeletal PROMs

- **80 of 624** validity studies used adequate statistics (MTT models) - 13%

What's the deal with those MTT models?

Rasch analyse



Georg Rasch (1901-1980)

items (questions)

Easiest

Most difficult

Less ablility

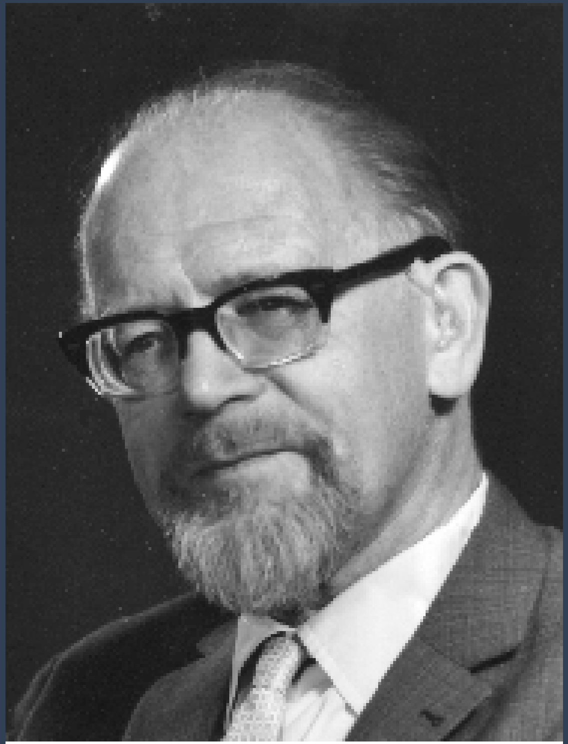
persons

Top of class

	2	5	4	6	1	3	10	9	7	8
H	1	0	0	0	0	0	0	0	0	0
C	1	0	1	0	0	0	0	0	0	0
J	1	1	0	1	0	0	0	0	0	0
E	1	1	0	1	1	0	0	0	0	0
D	1	0	1	1	1	1	0	0	0	0
F	1	1	1	1	0	1	0	0	1	0
G	1	1	1	1	1	1	1	0	0	0
A	1	1	1	1	1	1	1	0	1	0
B	1	1	1	1	1	1	0	1	1	1
I	1	1	1	1	1	1	1	1	1	1

Rasch analysis

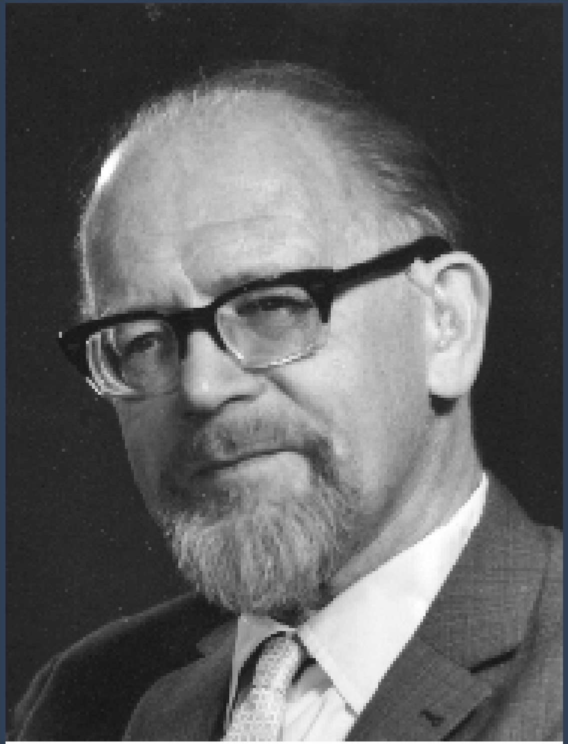
- Local dependence
- Unidimensionalitet
- Transition from ordinal scales to interval scales



Georg Rasch (1901-1980)

Rasch analysis

- **Local dependence**
- Unidimensionalitet
- Transition from ordinal scales to interval scales



Georg Rasch (1901-1980)


ADL
1. Walk on even ground
2. Walk on uneven ground
3. Walking stairs
4. Squat
5. Crossing legs
6. Biking
7. Sitting on knees
8. Sit in a squat
9. Dance
10. Run
11. Sleep

Rasch analysis

- Local dependence
- **Unidimensionalitet**
- Transition from ordinal scales to interval scales

Rasch analysis

The structural validity of the Danish version of the Oxford Knee Score is not substantiated using Rasch analysis and confirmatory factor analysis

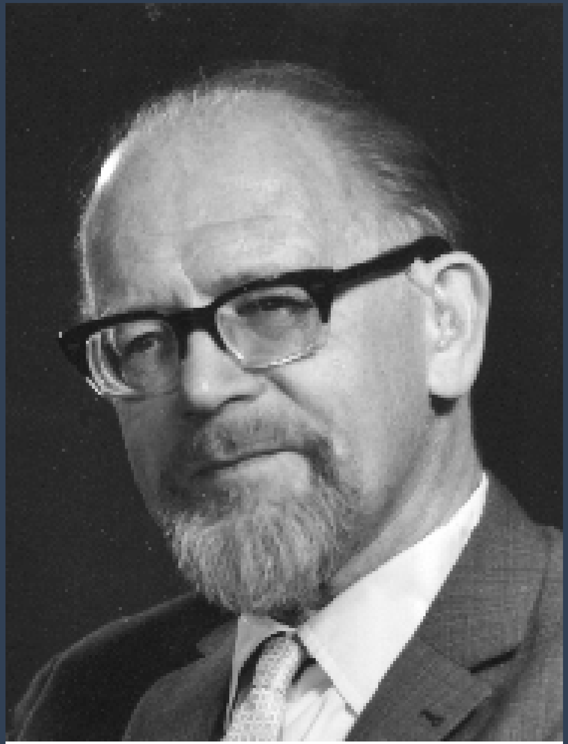
C. F. Hansen,[1] A. Mørup-Petersen,[2] A. Odgaard,[3,4] M. R. Krogsgaard,[3,5,6] K. B. Christensen[7]

Results

OKS data did not fit the original unidimensional model of one total score. Reporting OKS data as the two subscales “pain" and “function” improved CFA fit, but model fit was still inadequate. Results were consistent across subsamples.

Rasch analysis

- Local dependence
- Unidimensionality
- **Transition from ordinal scales to interval scales**



Georg Rasch (1901-1980)

Rasch analysis

Ordinal level scale - observations

Interval level scale

Mineral	Mohs Hardness	Image
Talc	1	
Gypsum	2	
Calcite	3	
Fluorite	4	
Apatite	5	
Feldspar	6	
Quartz	7	
Topaz	8	
Corundum	9	
Diamond	10	

Ordinal level scale

1	Talc	$Mg_3Si_4O_{10}(OH)_2$	1	
2	Gypsum	$CaSO_4{\cdot}2H_2O$	2	
3	Calcite	$CaCO_3$	14	
4	Fluorite	CaF_2	21	
5	Apatite	$Ca_5(PO_4)_3(OH,Cl,F)$	48	
6	Orthoclase feldspar	$KAlSi_3O_8$	72	
7	Quartz	SiO_2	100	
8	Topaz	$Al_2SiO_4(OH,F)_2$	200	
9	Corundum	Al_2O_3	400	
10	Diamond	C	1500	

Interval level scale

"Observations are Always Ordinal;Measurements, however, Must be Interval"

B. D. Wright

Rasch analysis

- Local dependence
- Unidimensionality
- Transition from ordinal scales to interval scales

	2	5	4	6	1	3	10	9	7	8
H	1	0	0	0	0	0	0	0	0	0
C	1	0	1	0	0	0	0	0	0	0
J	1	1	0	1	0	0	0	0	0	0
E	1	1	0	1	1	0	0	0	0	0
D	1	0	1	1	1	1	0	0	0	0
F	1	1	1	1	0	1	0	0	1	0
G	1	1	1	1	1	1	1	0	0	0
A	1	1	1	1	1	1	1	0	1	0
B	1	1	1	1	1	1	0	1	1	1
I	1	1	1	1	1	1	1	1	1	1

How to choose the best PROM

- Choose a PROM that was developed **through patient interviews**
- Choose a PROM that has been **validated with MTT models**

Table S12. Elbow PROMs validation

	Conditions validated (n)	Different phases	Normals validated (n)	IRT method	Comparision with other PROMs	Other methods	Domain aggregation	Test-retest reliability	Chronbach´ s α	Known groups validity	DIF	MID	Responsiveness	Floor/ceiling effect	Assessment
pASES-e *American Shoulder and Elbow Surgeons Elbow Questionnaire*															
English (MacDermid 2001) (195)	Elbow pathology (70)	Not disclosed	-	-	SF-36 PRTEE DASH	-	-	Yes	-	-	-	-	-	-	Elbow conditions in general: **
German (John et al. 2010) (196)	Elbow pathology (75)	11,2 y postop	-	-	SF-36 PRTEE DASH	-	-	Yes	Yes	-	-	-	-	Yes	Elbow conditions in general: ** Elbow prosthesis patients: ***

I've identified the best PROM. It's not very good

Surgery
Protocol

Is arthroplaSty bEtter than interNal fixation for undiSplaced femoral nEck fracture? A national pragmatic RCT: the SENSE trial

Bjarke Viberg [1,2], Søren Kold [3], Ole Brink [4], Morten Schultz Larsen [2], Kristoffer Borbjerg Hare [5,6,7], Henrik Palm [8]
SENSE collaborators
Correspondence to Dr Bjarke Viberg; bjarke.viberg@rsyd.dk

Primary:
New mobility score

Secondary:
OHS

Study protocol | Open access | Published: 12 May 2020

Individualized treatment for acute Achilles tendon rupture based on the Copenhagen Achilles Rupture Treatment Algorithm (CARTA): a study protocol for a multicenter randomized controlled trial

Maria Swennergren Hansen, Marianne Toft Vestermark, Per Hölmich, Morten Tange Kristensen & Kristoffer Weisskirchner Barfod

Primary:
Heel-rise work test

Secondary:
Achilles' tendon rupture score

I’ve identified the best PROM. It’s not very good

1. Is the PROM able to answer the research question? **Should it be secondary outcome?**
2. Consider the use of an **anchor question** as primary outcome
3. Consider and **describe** the limitations of the PROM already in the protocol
4. Consider developing **a new PROM** for your study
5. Consider a **validity study** using MTT

Men hvad viste PROMen??

Summarized

- **Content validity is the most important property –** patients, not clinicians, decide relevance, coverage, and comprehensibility
- **Adequate structure is key to accurate measurement**
  - Evaluating by MTT models
- **Choose a PROM where patients were involved**
- **Choose a PROM validated with MTT models**
  - Local dependence
  - Unidimensionality
  - Confirms accurate transition from ordinal to interval level scale
- **Consider all outcomes!**

MD, PhD, Christian Fugl Hansen
Orthopaedic resident
Department of Orthopaedics

Bispebjerg and Frederiksberg Hospital
Nordsjællands Hospital Hillerød

MCID
Minimal clinically important difference

Udfordringerne ved MCID

- Varierer imellem patientgrupper
- Varierer over tid - MCID ved 3 mdr. ≠ MCID ved 12 mdr.
- Varierer ift. hvad man scorer på skalaen – lidt eller meget udfordret
- Varierer imellem metoder (fra 1,8 til 25,9 i nyligt studie, på samme kohorte)
- **Kræver at PROMen er en interval-level-scale!**

> Arch Phys Med Rehabil. 1989 Nov;70(12):857-60.

Observations are always ordinal; measurements, however, must be interval

B D Wright[1], J M Linacre

Further perspectives

For the researcher	Economical and human resources
For patients	Miss out on the best treatment
For society	Skewing of whole research fields → wrong use of resources