Upper Extremity Outcome Instruments – My Experience

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Director, Orthopaedic Hand Fellowship
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Defining Outcome Metrics for Orthopaedic Devices
Overview

- Description and Personal Perspective
  - Disability of the Arm Shoulder and Hand (DASH)
  - Patient-Rated Wrist Evaluation (PRWE)
  - Michigan Hand Questionnaire (MHQ)
  - Modern Activity Subjective Survey of 2007 (MASS07)

- Discussion at Oxford – latest findings and Oxford tools
  - Key Components of Patient Reported Outcome Measures

- How the current Upper Extremity tools compare
DASH – Description

- Developed 1996 and intended for clinical and research assessment of upper extremity health
- Developed through collaboration
  - American Academy of Orthopedics (AAOS)
  - Institute for Work and Health (IWH)
  - the Upper Extremity Collaborative Group (UECG)
- Items generated from Literature Review, Clinician/Surgeon and Expert input
  - patients were involved in validity testing
- Validated through IWH through prospective trial of 109 patients
Key Components of Validation

- Internal Consistency
- Reliability/Test-Retest
- Validity – does it measure what it’s supposed to
  - Content Validity – asks about topics clearly
  - Construct Validity – produce anticipated relationships with other variables
- Sensitivity to Change
DASH – Description

- DASH consists of 2 sections for a total of 30 questions
- Measurement Concept - Overall Upper Extremity Health
- Two Domains
  - Symptoms
    - pain
    - weakness
    - tingling/numbness
    - stiffness
  - Function
    - physical
    - social
    - psychological
DASH – Scoring

- Score Calculated:
  - calculation normalizes scores from 0 - 100
  - lower scores = better function/symptoms
- MCID = 10
  - Gummesson, C. et al. (2003) *BMC Musculoskeletal Disorders*. Based on Shoulder Impingement and carpal tunnel surgery results
DASH – Experiences

- **Positive**
  - multi-centered/non-centered specific development and testing
  - overall assessment of upper extremity health
  - shown to be a good measure of any upper extremity problem

- **Drawbacks**
  - doesn’t look at handedness
  - non-wrist specific
  - patient evaluation only, excludes surgeon
  - no hand dominance
  - relatively long
QuickDASH - Description

- Developed through IWH to address relatively long DASH questionnaire
- QuickDASH consists of 11 questions
- Validated through NIH to correlate QuickDASH scores to full length DASH scores
Basal Joint Osteoarthritis of the Thumb: A Prospective Trial of Steroid Injection and Splinting

Charles S. Day, MD, Richard Gelberman, MD, Alpesh A. Patel, MD, St Louis, MO, Molly T. Vogt, MSc, Pittsburgh, PA, Konstantinos Ditsios, MD, Martin I. Boyer, MD, St Louis, MO
Low-Profile Dorsal Plating for Dorsally Angulated Distal Radius Fractures: An Outcomes Study

Atul F. Kamath, BA, David Zurakowski, PhD, Charles S. Day, MD

From the Department of Orthopaedic Surgery, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; and the Department of Orthopaedic Surgery, Children’s Hospital Boston, Boston, MA.
Low-profile Dorsal Plating for Dorsally Angulated Distal Radius Fractures

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Distal Radius Fractures
Prospective randomized trial comparing 2 surgical treatment options in DRFs
SCIENTIFIC ARTICLE

Complications of Low-Profile Dorsal Versus Volar Locking Plates in the Distal Radius: A Comparative Study

Yangyang R. Yu, BA, Melvin C. Makhni, BS, Shervin Tabrizi, BA, Tamara D. Rozental, MD, George Mundanthanam, MD, Charles S. Day, MD, MBA

- Comparing surgical complication rates in DRFs
Complications are worth the risk if there is improvement in functional outcome.

Literature supports anatomical reduction in younger patients.

But what about in the older population?
Older Patient Populations

- McQueen et al., *JBJS* 1988: “We conclude that malunion of a Colles’ fracture results in weak, deformed, stiff and probably painful wrist.”

- Board et al., *Injury* 1999: “There was a strong correlation between functional outcome and both dorsal angle and radial length at union [in patients over 55 years].”
Roumen et al., JBJS 1991: “…in patients over the age of 55 years…we found no correlation between final anatomical and functional outcome….”

Young et al., JHS 2000: “The radiographic outcome [in low-demand patients > 60 y/o] did not correlate with the functional outcome.”
Is the Difference based on the outcome instruments being used?
DOI 10.1007/s11999-008-0660-2

ORIGINAL ARTICLE

Distal Radius Fractures in Older Patients
Is Anatomic Reduction Necessary?

Andrew J. Synn BA, Eric C. Makhni BS,
Melvin C. Makhni BS, Tamara D. Rozental MD,
Charles S. Day MD, MBA

assessment of function
PRWE - Description

- Utilized for specific wrist problems
- Developed in 1998 for clinical assessment
  - Hand and Upper Limb Centre, St. Joseph Health Center (London, Canada)
  - Kinetex Innovative Assessment and Rehabilitation Centre (Waterloo, Canada)
- Surveyed 100 (66 responded) international wrist investigators (IWIW) to generate items
- Item generation from patient interviews
PRWE – Description

- Validated via Prospective study done with Distal Radius Fractures and Scaphoid Fractures in 101 patients
- 2 Sections for a total of 15 questions
- Measurement Concept – Wrist Function
- Consists of 2 domains for patients
  - pain
  - function
PRWE – Scoring

- Scoring
  - Functional score is out of 50
  - Pain score is out of 50
    - Average both sections
  - Add Function and Pain scores
    - normalizes to scale of 1 – 100
  - Less score = better outcome

- MCID = 12
PRWE – Experiences

- Started using PRWE to supplement DASH in order to focus on the wrist
- Positives
  - developed with patient interviews
  - region-specific (wrist) assessment
  - short, quick and reliable
- Drawbacks
  - validated / developed from fewer centers
  - region-specific
  - no hand dominance
MHQ - Description

- Initially developed by surgeons at University of Michigan Medical Center
- Developed through:
  - Evaluation of existing questionnaires
  - Any questions pertaining to the hand were incorporated into the MHQ
  - Hand patient panel developed additional items
- Evaluated through patient, surgeon, and therapist panel to categorize the scales
MHQ - Description

- Given to psychometricians to identify unclear and redundant items
- Factor analysis used to pare down questionnaire
- Validation was done by the same group of researchers
MHQ - Description

- 6 Sections (scales) for total of 65 Questions including demographics
- Overall Concept – Evaluation of the Hand
- Multiple Domains
  - Function
  - Active Daily Living activities
  - Pain
  - Work Performance
  - Aesthetics
  - Patient Satisfaction
MHQ - Scoring

<table>
<thead>
<tr>
<th>Scale</th>
<th>Recode†</th>
<th>Raw Score Range‡</th>
<th>Normalization§</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall hand function</td>
<td>None</td>
<td>5 to 25</td>
<td>-(raw score -25)/20*100</td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>None</td>
<td>5 to 25</td>
<td>-(raw score -25)/20*100</td>
</tr>
<tr>
<td>Work</td>
<td>None</td>
<td>5 to 25</td>
<td>-(raw score -35)/28*100</td>
</tr>
<tr>
<td>Pain</td>
<td>Question 2: (1 = 5) (2 = 4) (4 = 2) (5 = 1)</td>
<td>7 to 35 2-handed</td>
<td>(1-handed+2-handed)/2</td>
</tr>
<tr>
<td>Aesthetics</td>
<td>Question 1: (1 = 5) (2 = 4) (4 = 2) (5 = 1)</td>
<td>4 to 16</td>
<td>-(raw score -25)/20*100</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>None</td>
<td>6 to 30</td>
<td>-(raw score -30)/24*100</td>
</tr>
</tbody>
</table>

* The scoring algorithm is available from the authors in SAS program.
† The response categories for some of the questions are reversed and are recoded.
‡ Sum of the responses for each scale.

- MCID = depends on disease and domain of questionnaire, e.g. CTS can have 8, 13, or 23
MHQ – Experiences

- **Positives**
  - region-specific
  - detailed
  - hand dominance

- **Drawbacks**
  - doesn’t add any new clinical assessment wrt DASH and PRWE
  - scoring system confusing
  - time consuming to administer
  - burdens patients with 65 questions
Addressing a Common Problem

- How about modern activities?
  - Typing
  - Manipulating a Mouse
  - Cell Phones
  - Shooting digital photos
  - Taking money out of wallet/purse
  - Writing a check
  - Other small activities
<table>
<thead>
<tr>
<th>Functional Task</th>
<th>No Difficulty</th>
<th>Unable to Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Type on a keyboard</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
<tr>
<td>2. Use a computer mouse</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
<tr>
<td>3. Dial a cell phone / telephone</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
<tr>
<td>4. Take a photograph with a camera</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
<tr>
<td>5. Pull an item from a pocket/purse</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
<tr>
<td>6. Write a check</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
<tr>
<td>7. Take a dollar bill out of a wallet</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
<tr>
<td>8. Plug a cord into a power outlet</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
<tr>
<td>9. Do laundry / fold clothes</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
<tr>
<td>10. Type on a handheld device</td>
<td>N/A 012345678910</td>
<td></td>
</tr>
</tbody>
</table>
VALIDATION OF A MODERN ACTIVITY HAND SURVEY WITH RESPECT TO RELIABILITY, CONSTRUCT AND CRITERION VALIDITY

M. ALEXANDER, O. I. FRANKO, E. C. MAKHNI, D. ZURAKOWSKI and C. S. DAY

Department of Orthopedic Surgery, Beth Israel Deaconess Medical Center, Boston, MA, Harvard Medical School, Boston, MA and the Department of Orthopedic Surgery, Children’s Hospital Boston, Boston, MA, USA
MASS07 - Description

- Intended for clinical and research assessment
- Developed to address clinical need
  - Beth Israel Deaconess Medical Center
  - Harvard Medical School
  - assess more modern activities as compared to the DASH, PWRE, and MHQ
- Surgeons questioned for item generation
- Pilot tested with patients after initial development
MASS07 – Description

- Intention to produce short survey to evaluate wrist and hand function
- 10 Questions evaluating function and how injury affects daily activities
- Validated through 42 volunteer patients
MASS07 – Scoring

- Scoring
  - 10 questions from scale of 1-10
  - Sum each questions rating for overall score from 1 – 100

- MCID is unknown
MASS07 – Experiences

- **Positives**
  - addresses activities that impact quality of life and daily activities more
  - short and quick
  - scoring method is straightforward

- **Drawbacks**
  - May not be appropriate for all patient populations, i.e. older populations who might not use cell phone or hand held devices
  - no hand dominance
  - no patient input
MASS07 – Project Use

Functional Disability of the Wrist: Direct Correlation With Decreased Wrist Motion

Orrin I. Franko, BS, David Zurakowski, PhD, Charles S. Day, MD

- first, non-validated use of MASS07, concurrent with DASH and PRWE
- satisfaction with treatment
Bunnell Traveling Fellowship

Sterling Bunnell, M.D
“Father of Hand Surgery”
"The purpose of the Bunnell Fellowship is to sponsor a young Hand Surgeon in the development of national and international relationships which contribute to his/her pursuit of higher learning, and which foster the principles of scholarship of the American Society for Surgery of the Hand."
Bunnell Traveling Fellowship

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Bunnell – Themes and Objectives

- National Quality of Healthcare Initiative
- Global Innovations in Wrist Surgery
- Developing National and International Relationships
National Quality of Healthcare Initiative

The Dartmouth Institute
For Health Policy
& Clinical Practice

2011-2012 Sterling Bunnell Traveling Fellowship
James Weinstein, DO, MS
CEO and President of Dartmouth-Hitchcock
Founder
Spine Center at Dartmouth-Hitchcock
Co-founder
The Dartmouth Center for Health Care Delivery Science
National Quality of Healthcare Initiative

Cleveland Clinic
Michael Keith, MD

Chief, Orthopaedic Hand Service
MetroHealth Medical Center
Professor
Case Western Reserve University SOM

2011-2012 Sterling Bunnell Traveling Fellowship
National Quality of Healthcare Initiative
Washington D.C.

2011-2012 Sterling Bunnell Traveling Fellowship
Janet Corrigan
Former President and CEO
National Quality Forum

Three major quality goals:

1) Patient engagement in decision making
2) Patients are actually achieving the things that medical care is supposed to enable
3) Are we doing 1&2 in a cost-efficient manner?
Carolyn Clancy, M.D.
Director
Agency for Healthcare Research and Quality

• Under United States Department of Health and Human Services (HHS).
• Mission: improve the quality, safety, efficiency and effectiveness of healthcare
  • Funding people and projects for policy creation

Agency for Healthcare Research and Quality, Washington, D.C.
Faisal Mirza, M.D.

Medical Officer
Orthopaedic Device Evaluation, Regulation, and Research
U.S. Food and Drug Administration

U.S. Food and Drug Administration, Washington, D.C.
Professor Andrew Carr FRCS FMedSci
Nuffield Professor of Orthopaedic Surgery
University of Oxford
Head, Nuffield Department of Rheumatology & Orthopaedics
The Importance of PROs

- UK NHS system for coverage all citizens
- National Institute for Health and Clinical Excellence (NICE) –, i.e. functional outcomes
- Therefore, it is critical that functional outcome measurement tools, i.e. PROMs, be developed and validated appropriately
Jill Dawson, Ph.D.
Senior Research Scientist
Department of Public Health
Oxford University

Oxford, UK
Andrew Carr and Jill Dawson developed

- Oxford Shoulder Score (OSS)
- Oxford Shoulder Instability Score (OSIS)
- Oxford Elbow Score (OES)
- Oxford Knee Score (OKS)
- Oxford Foot Score (OFS)
- Oxford Hip Score (OHS)
Oxford Developed PROMs

- Multiple Specialties including Orthopedics
- Joint Collaboration
  - Health Services Research Unit of the Department of Public Health
  - Nuffield Orthopaedic Centre

- Purpose to create PROMs that were patient-centered and specific
Why did Oxford develop their own?

- Several key discrepancies led to Oxford scores
  - data depended on surgeon’s judgment which could lead to bias
  - no reliable shorter, more specific, simpler tools existed for region(s), e.g. shoulder
  - patient involvement was limited
Key Components to Consider

- **Key Development Components**
  - Specificity
  - Burden on Patients
  - **Patient involvement**
  - Scale of Development

- **Key Validation Components**
  - Reliability, Validity, Clinical Differences, Sensitivity to Change
  - Comparison to Other Tools
  - **Patient Involvement**
In Summary
<table>
<thead>
<tr>
<th>PROM</th>
<th>Item Generation &amp; Reduction</th>
<th># of ?s</th>
<th>MCID</th>
</tr>
</thead>
<tbody>
<tr>
<td>DASH (QuickDASH)</td>
<td>- Literature Review</td>
<td>30 (11)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>- Doctor &amp; Expert Input</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRWE</td>
<td>- Expert Survey</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>- Patient Interviews</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MHQ</td>
<td>- Other Surveys</td>
<td>65</td>
<td>Variable</td>
</tr>
<tr>
<td></td>
<td>- Patient Panel confirmation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MASS07</td>
<td>- Clinical Practice Observations</td>
<td>10</td>
<td>Unknown</td>
</tr>
</tbody>
</table>
# Upper Extremity PROM Comparison

<table>
<thead>
<tr>
<th>PROM</th>
<th>Validation Key Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>DASH</td>
<td>Standard Validation From above</td>
</tr>
<tr>
<td>PRWE</td>
<td>Standard Validation from above</td>
</tr>
<tr>
<td>MHQ</td>
<td>Psychometric Content Validity</td>
</tr>
<tr>
<td>MASS07</td>
<td>Standard Validation from above</td>
</tr>
</tbody>
</table>
# Upper Extremity PROM Comparison

<table>
<thead>
<tr>
<th>PROM</th>
<th>Positives</th>
<th>Negatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>DASH</td>
<td>- Scale of development</td>
<td>- Non-Region Specific</td>
</tr>
<tr>
<td></td>
<td>- Multi-centered tested</td>
<td>- Relatively Long</td>
</tr>
<tr>
<td>PRWE</td>
<td>- Region-Specific</td>
<td>- Region-Specific</td>
</tr>
<tr>
<td>MHQ</td>
<td>- Region-Specific</td>
<td>- Patient Burden</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Scoring Confusing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Region-Specific</td>
</tr>
<tr>
<td>MASS07</td>
<td>- Modern activities</td>
<td>- No patient involvement</td>
</tr>
<tr>
<td></td>
<td>- Short, quick, easy to use</td>
<td></td>
</tr>
</tbody>
</table>
Thank You

Beth Israel Deaconess Medical Center

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