Evidence and Outcomes Based Practice: Is it Possible?

Michael Suk, MD JD MPH FACS
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Disclosures

Other financial or material support from a company or supplier

- Stryker (Education Consultant)
- Synthes (Education Consultant / Institutional Support)
- CarboFx (Consultant)

Medical/Orthopaedic publications editorial/governing board

- American Journal of Orthopaedics
- Geriatric Orthopaedic Surgery & Rehabilitation
- Journal of Trauma Management and Outcomes
- Military Medicine

Board member/committee appointments for a society

- AOA Critical Issues Committee
- International Geriatric Fracture Society (Immediate Past President)
Evidence-based medicine was recently noted as one of the top 15 most important medical discoveries of the past 160 years.
Paradigm Shift

EMINENCE Based Practice

EVIDENCE Based Practice
Evidence Based Practice is...

“...the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient."

It means integrating individual clinical expertise with the best available external clinical evidence from systematic research."
The Evidence Pyramid

- **RCT**
  - Gold-standard

- **Observational Studies**
  - Cohort and case-control studies

- **Case Series**
  - Necessary before comparison studies can be performed

- **Expert opinion**
  - Ideas and innovations
RCTs and meta analyses

Expert opinion and clinical observations
EBM Evolution

Best available published evidence

Emphasis on patient values and expected outcomes
We must be familiar/critical with the literature...

Because your patients are (or think they are)!

Because one in six papers may contain manipulated, fraudulent, or fabricated data!

Locating the best available research (RCTs and meta-analyses)

Time to access and read full-text published research papers

Critically appraise the available evidence
In 2010, there were about 3000 articles listed in PubMed on orthopedic fracture treatment.

If a physician read for 1 hour/day - 20 min/article, 

At the end of the year, he/she would be 4 years worth of reading behind!
## Table. Deficient Abstracts*  

<table>
<thead>
<tr>
<th>Journal</th>
<th>% Deficient (95% CI)</th>
<th>Inconsistency</th>
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*Number of abstracts examined was 44 from each journal. CI indicates confidence interval. \( \chi^2 = 31.3; P < .001 \).
The Reporting of Functional Outcome Instruments in the *Journal of Orthopaedic Trauma* Over a 5-Year Period

Daniel S. Horwitz, MD, Raveesh D. Richard, MD, and Michael Suk, MD

5 years of JOT articles reviewed (n=497)

Use of validated functional outcome instrument 56%

Use of *appropriate* validated instrument 23%
When looking for evidence, start with the END in mind ... Think OUTCOMES
Current Challenges

Over 500 different musculoskeletal outcomes instruments for the extremities

Lack of standardization in the measurement of outcomes
Evaluating an Instrument

Content – What is the purpose of the instrument?

• Type – PRO versus CBO
• Scale – Questions and scoring
• Interpretation – Higher scores indicate better outcome?

Methodology

• Validity – Does it measure what it is supposed to measure?
• Reliability - Repeatability
• Responsiveness – Sensitivity to change

Clinical Utility

• Patient friendly?
• Clinician friendly
Higher scores = better outcome?

**4. Harris hip score (1969)**

**Content**

**Type**  Clinician based outcome

**Scale**  4 subscales (13 items):

- Pain (44 points)
- Function (47 points)
- Deformity (4 points)
- Range of motion (5 points)

**Interpretation**

- Excellent: 90–100 points
- Good: 80–89 points
- Fair: 70–79 points
- Poor: < 70 points

**Clinician Based**

**Patient Reported**

**How is the instrument scored?**

**Validation studies:**


### Methodological evaluation

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<th>Points</th>
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**Subtotal** 5

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1. **Does it measure what it is supposed to measure?**
2. **Does it measure the same way twice?**
3. **Ability of the instrument to change as the patient status changes**
Types of Outcome Instruments

- Physiological Outcomes
- Patient Reported Outcomes
- Clinician Based Outcomes
Physiological Outcomes

<table>
<thead>
<tr>
<th>Considered to be “objective”</th>
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<tbody>
<tr>
<td>Often not tested for reliability or validity</td>
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Examples

<table>
<thead>
<tr>
<th>Fracture union</th>
<th>Joint motion</th>
<th>Strength</th>
<th>Alignment</th>
<th>Osteoarthritis</th>
</tr>
</thead>
</table>

RCT comparing cast immobilization to percutaneous cannulated screw fixation of non-displaced scaphoid fractures

<table>
<thead>
<tr>
<th>Time to union</th>
<th>Grip strength</th>
<th>Wrist range of motion</th>
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</table>
Clinician Based Outcomes

Combination of signs and symptoms

Assessed by clinician sometimes in combination with the patient
Often summarized into a single rating of "excellent, good, fair, poor"

“Simple reamed nailing of humeral non-union is insufficient”

Retrospective case-series evaluating reamed nailing in humeral non-union

- 58% healing rate after first procedure (Poor)
- Mean 1.9 procedures/patient necessary
- Mean Neer Shoulder Score = 91 points (Excellent)

I. Classification and evaluation. 

Content

Type: Clinician based outcome 
Scale: 4 subscales (18 items):

- Pain (35 points)
- Function (30 points)
- Range of motion (25 points)
- Anatomy (10 points)

Interpretation
Excellent: 90–100 points  
Satisfactory: 80–89 points  
Unsatisfactory: 70–79 points  
Failure: < 70 points

Validation

No validation studies were identified.

<table>
<thead>
<tr>
<th>Patient population tested in</th>
<th>Validity</th>
<th>Reliability</th>
<th>Responsiveness</th>
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<tbody>
<tr>
<td>Not applicable</td>
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Patient Reported Outcomes

Concerned with the patient's perception of their symptoms, functional ability, and quality of life.

Historically considered “soft” or “subjective”

Examples

Functional ability with daily activities  Health-related quality of life  Pain and symptoms  Can be very specific (sports or ADLs)

Multi-center RCT comparing operative to nonoperative management of displaced intraarticular calcaneal fractures in women.

The SF-36 was used as a primary outcome to show that operatively managed patients (standard lateral approach) demonstrated better outcomes (p=0.04).
3. Short Form 36 health survey questionnaire (SF-36)* (1992)


Other versions available: SF-12, SF-8
Both shorter versions measure the same 8 subscales with fewer items.

**Content**

**Type**  Generic patient reported outcome

**Scale**  8 subscales measuring physical and mental health (36 items):
- Physical functioning (10 items)
- Role limitations due to physical health problems; (physical role functioning) (4 items)
- Bodily pain (2 items)
- General health (5 items)
- Vitality (4 items)
- Social functioning (2 items)
- Role limitations due to emotional problems (emotional role functioning) (3 items)
- Mental health (5 items)

Reported health transition (1 item) is used to measure changes in health status. It is not included in any of the subscales and is administered as a supplemental question.

**Interpretation**

The questionnaire provides 8 subscale scores but not a total score.

For each subscale:
Minimum score: 0 points; maximum score: 100 points

The higher the score, the higher the function.

Norm-based scoring (NBS) can be used to score all 3 SF surveys. Through NBS, scale and summary scores are standardized to a mean of 50 and a standard deviation of 10 in the general US population, allowing scores to be compared within and across the different SF surveys.

* The SF-36 and SF-12 are available in original (SF-36 and SF-12) and updated (SF-36v2 and SF-12v2) versions, while the SF-8 is available in one version only. Versions 2.0 are very similar to versions 1.0; however, they offer a number of improvements, including increased range and precision for the role-functioning scales, improved item wording, and an easier-to-use format.
60 year old female RA

SF-36 (126% of Norm)

Is this a “good” result?
DASH 50
(57.9% of Norm)

Is this a 
“good” result?
Impossible Task?

When did we stop caring about fracture union or ROM?

When did a surgical opinion on outcome cease to matter?

By limiting the number of PROs in use are we affecting our ability to innovate?

Does the PRO for $$ movement make sense - is it for the patient or for the surgeon?

When we measure PROs post hoc – is there anything we can do to make it better?
Patient Expectations?

Patients often go from young and healthy to severe disability after trauma.

Patient expectations are often high.

Surgeon expectations are often less than the patient.
Expectations

Patients rarely achieve their baseline status!
Expectations

![Graph showing hypothetical outcomes score over time.](Image)

**Hypothetical Outcomes Score**

- Patient expectations
- Surgeon expectations
- Outcome score
- Case example

**Timepoints:**
- Injury
- Post-op
- 3 mos
- 6 mos
- 12 mos

**Legend:**
- Blue line: Patient expectations
- Pink line: Surgeon expectations
- Yellow line: Outcome score
- Cyan line: Case example
Trauma Expectation Factor (TEF)
• Administered preoperatively
• Assesses patient expectations for their outcome at one-year post surgery

Trauma Outcome Measure (TOM)
• Administered postoperatively
• Assesses the degree to which the surgical outcome fulfils their expectations

TEFTOM: A Promising General Trauma Expectation/Outcome Measure—Results of a Validation Study on Pan-American Ankle and Distal Tibia Trauma Patients

Michael Suk,¹ Monica Daigl,² Richard E. Buckley,³ Cleber A. J. Paccola,⁴ Dean G. Lorich,⁵ David L. Helfet,⁶ and Beate Hanson²
### Trauma Expectation Factor (TEF)

1. One year (12 months) after surgery, how painful do you **expect** your injury to be?

<table>
<thead>
<tr>
<th></th>
<th>No Pain</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Unbearable Pain</th>
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2. One year (12 months) after surgery, how much do you **expect** your injury to interfere with your normal/usual necessary activity (including prolonged standing, walking, stairs, car driving, and sleeping)?

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<tr>
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3. One year (12 months) after surgery, how much do you **expect** your injury to interfere with your normal/usual physical activity (including work, housework, school, recreation/sports activities)?

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4. One year (12 months) after surgery, how much do you **expect** your injury to interfere with your normal/usual activities of daily living (including eating, dressing, putting on shoe wear)?

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5. One year (12 months) after surgery, how much do you **expect** your injury to interfere with your normal/usual relationships (including family, friends, co-workers)?

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6. Necessary activities (you **have** to do these)

One year (12 months) after surgery, how much do you **expect** to cut down on the physical activities you **HAVE** to do (including work, housework, school, etc)?

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7. Optional activities (you **enjoy** to do these)

One year (12 months) after surgery, how much do you **expect** to cut down on the physical activities you **ENJOY** doing (including sports, recreation, gardening, etc)?

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8. One year (12 months) after surgery, how satisfied do you **expect** to be with your pain, physical function, and disability?

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<th>Not Satisfied</th>
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9. One year (12 months) after surgery, how satisfied do you **expect** to be with the appearance of your injury?

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<tr>
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10. One year (12 months) after surgery, how satisfied do you **expect** to be with your overall well-being?

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</table>
1. How painful is your injury today?

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2. How much does your injury currently interfere with your normal/usual necessary activity (including prolonged standing, walking, stairs, car driving, and sleeping)?

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3. How much does your injury currently interfere with your normal/usual physical activity (including work, housework, school, recreational/sports activities)?

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4. How much does your injury currently interfere with your normal/usual activities of daily living (including eating, dressing, putting on shoe wear)?

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5. How much does your injury currently interfere with your normal/usual relationships (including family, friends, co-workers)?

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6. Necessary activities (you have to do these)

How much do you currently cut down on the physical activities you HAVE to do (including work, housework, school, etc)?

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7. Optional activities (you enjoy to do these)

How much do you currently cut down on the physical activities you ENJOY doing (including sports, recreation, gardening, etc)?

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</table>

8. How satisfied are you with your current level of pain, physical function, and disability?

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9. How satisfied are you with the current appearance of your injury?

<table>
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10. How satisfied are you with your current overall well-being?

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TEFTOM Project

Validation study creates outcome benchmark

New patients complete TEF to correlate with benchmark TOM

Scale
• Did not meet expectations
• Met expectations
• Exceeded expectations

Satisfaction?
94.5% of surgeon and 90.3% of patient satisfied at 1 year.

Discordance due to patient dissatisfaction-surgeon satisfaction.

- The strongest predictors were unmet patient expectations and the presence of complications.
63% reported that their expectations had been fulfilled or exceeded 3 years postoperatively.

37% did not meet expectations.

• However, they did not exhibit a lower postoperative functioning than those who were satisfied.
What determines patient satisfaction with surgery? A prospective cohort study of 4709 patients following total joint replacement

Overall patient satisfaction was predicted by:

• meeting preoperative expectations
• satisfaction with pain relief
• satisfaction with the hospital experience
• Oxford scores carried little weight in the algorithm.

How we deliver healthcare may be of key importance

Capturing Outcomes in Realtime

01. Patient
02. Wearable Technology
03. Realtime Data
04. Realtime Feedback
05. Intervention
06. Analytics
07. Navigation
08. Satisfaction

Capturing Outcomes in Realtime
Evidence-based medicine is founded on the “integration of clinical expertise with the best available clinical evidence and patients’ values.”

As we continue to explore its application to orthopedics, understanding the anatomy of outcomes measures and future directions in the integration of patient expectations will bring us to greater acceptance in clinical practice.

The promise of evidence-based orthopedics is great and realization of that promise seems just on the horizon.
THANK YOU