



**2009 OTA Annual Meeting**  
**Manchester Grand Hyatt**  
**San Diego, CA**

**Symposium I: Assessment of Fracture Healing**

**Elizabeth Ballroom, Level II**

**1:20pm – 2:35pm**  
**Thursday, October 8, 2009**

**Moderator: Emil H. Schemitsch, MD**

**Faculty: Mohit Bhandari, MD**  
**Michael D. McKee, MD**  
**Theodore Miclau, III, MD**  
**Marc F. Swiontkowski, MD**  
**Paul Tornetta, III, MD**

The material presented at this course has been made available by the Orthopaedic Trauma Association for educational purposes only. This material is not intended to represent the only, nor necessarily best, methods or procedures appropriate for the medical situations discussed, but rather is intended to present an approach, view statement or opinion of the faculty which may be helpful to others who face similar situations.

Disclosure: Faculty disclosure can be found starting on page 67 of the 2009 OTA Annual Meeting program.

## ***Fracture Healing Defined: Is There Consensus?***

Theodore Miclau, MD  
University of California, San Francisco  
Orthopaedic Trauma Institute  
San Francisco General Hospital

### **Outline**

#### **I. Introduction**

#### **II. Measures of healing**

#### **III. Current practice**

#### **IV. Future Directions**

#### **I. Introduction**

##### *Disease Burden:*

- 5.6 million fractures per year in the United States
- Price associated with limb trauma:
  - \$325 billion/year societal cost
  - \$26 billion lost work
  - 51% of workers do not return to work at 6 months
- 5-10% of fractures go onto non-union

##### *Common clinical dilemmas: Fracture Healing Continuum:*

- Why do we dichotomize?
  - Clinical decision making
  - Conclusions about treatment
- What is the risk?
  - Loss of information
  - Bias

#### **II. Measures of Healing:**

- *Radiographic*
- *Clinical / Quality of Life*

##### *Radiographic Measures:*

- Roentgenogram
- Computed Tomography
- Quantitative CT
- Bone Densitometry
- Ultrasound

##### Roentgenogram (X-ray):

- Advantages: Cost, availability, lower dose radiation
- Disadvantages: Qualitative, poor correlation with mechanical properties, location and fixation dependent appearance

- Properties: ~50% by mechanical gold standard  
Number of cortices bridged (Inter-observer K=0.75, 95% CI 0.61-0.89)

#### Computed Tomography (CT)

- Advantages: Higher resolution, compatible with implanted devices, useful for metaphyseal/periarticular locations
- Disadvantages: Radiation dose, cost
- Properties: Sensitivity=100%; Specificity=62%; K=0.67 (vs. x-ray 0.14)

#### Quantitative CT

- Advantages: Quantitative assessment of callus volume and density
- Disadvantages: Artifact from implants, high radiation doses
- Properties: Strongly associated with calcium content  
Predictor of torsional strength ( $R_2=0.72$ ) and stiffness ( $R_2=0.72$ ) in diaphyseal long bones

#### Bone Densitometry/Absorbtiometry

- Advantages: Cost, lower radiation dose (absorbtiion rates of photons directed at bone), internal fixation
- Disadvantages: No major disadvantages
- Properties: High resolution DEXA 100% sensitive (by 8 wks), 78% specific (by 16 wks) for nonunion diagnosis

#### Bone Scintigraphy

- Advantages: Low dose radiation (measures “early uptake” of Technitium<sup>99</sup> – MDP)
- Disadvantages: Medullary devices reduce accuracy
- Properties: Conservatively treated tibia fractures: 70% sensitivity, 90% specificity

#### Ultrasound

- Advantages: Can be used with medullary implants, inexpensive, low radiation dose
- Disadvantages: Requires operator expertise, soft tissue dependent
- Properties: Conservatively treated tibia fractures: 100% Sensitivity, 92% Specificity (by 6 – 9 wks) in predicting union

#### *Radiographic Measures: Summary*

- Cortical continuity most reliable X-ray finding
- QCT most accurately quantifies mechanical properties of bone but radiation intensive

- No evidence to suggest that bone densitometry or scintigraphy are better than routine clinical and plain-film management
- Ultrasound promising

*Clinical / Quality of Life:*

- Healing may mean different things to doctors and patients
- Patient-important outcomes emphasizing function and quality of life
- From *ad hoc* to SF-36

Instruments:

- General Instruments
- Disease or Body Region Specific Instruments
- Health Utility

General Instruments:

*Short Form - 36 (version 2)*

- Assesses general health
- Widely validated with extensive population normative data
- Self-administered in 5-10 minutes
- SF-12v2 (~2 minutes)

*Musculoskeletal Function Assessment (MFA):*

- Assesses musculoskeletal function
- Validated for patients with injury or arthritic conditions
- Self administered in 10 minutes (100 questions)

*SMFA (42 questions ~ 5 minutes)*

Disease/Region Specific Instruments:

*Disability of Arm, Shoulder and Hand (DASH)*

- Assess upper extremity function
- Validated for variety of upper extremity disorders
- Subscales: disability/symptoms; sports/music and work (optional)
- Self administered: 10 minutes (30 questions)
- Quick-DASH (11 items)

*Measures of Health Utility: EQ-5D*

- Generic measure of health
- Descriptive system of 5 dimensions: Mobility; Self-care; Usual activity; Pain/discomfort; and Anxiety/depression
- Index score (0-1)

– Self administered in 5 minutes

*Clinical Measurements: Summary*

- Advantages: Patient important; Useful regardless of treatment; and Results may be more comparable
- Disadvantages: May lack sensitivity; Functional scores influenced by of emotional factors (depression) Ring *JBJS-Am*, 2006; Even well healed fractures can continue to be the sources of pain and disability Dogra *JOT* 2002, Pollak *JBJS-Am* 2003, Butcher *J Trauma* 1996

### **III. Current practice**

- Clinician Survey
- Systematic Review of Literature

Clinician Survey: Bhandari et al. *JOT* 2002

- 444 members of OTA, AAOS, and European-AO International Trauma Centers to assess how they assessed tibial fracture healing
- Delayed Union: Mean=3.4mo (SD 1.4); Range=1 to 8 months
- Non-union: Mean=6.3mo (SD 2.1); Range=2 to 12 mo

Systematic Review:

“In studies assessing the impact of treatment of long-bone fractures, what definitions of healing/union were employed and what other outcomes were assessed?”

- Journals: *JBJS-Am*, *JBJS-Br*, *JOT*
- Time Period: January, 1996 through December, 2006
- Searches: Medline; Journal’s online computerized database; and Manual table of content search
- Assessments:
  - Type of Fracture Studied
  - Levels of Evidence
  - Definitions of Healing Used
  - Clinical Healing Definitions
  - Radiographic Healing Definitions
  - Who did the assessing?
  - Quality of Life / Function Instruments Used

### **IV. Future Directions**

- Where are we?
  - Trying to dichotomize complex biologic continuum
  - We rely on a large number of unreliable and potentially invalid endpoints
  - Lack of patient-important outcomes to date though this may be changing
  - While we know that the best of these measures go up with improving function, don’t know the threshold for a “clinically healed fracture”

- Use validated HRQoL instruments and report diagnostic properties of outcomes
- Developing/validating better instruments
- Adapt tests/endpoints for feasibility in the clinical setting

*Acknowledgments: Luis Corrales, Harry Genant, Saam Morshed*

# Measurement Error: Who Should Measure Healing in Clinical Research?

Paul Tornetta III, MD  
Boston University Medical Center

1. Definition
  - a. Clinical: Strong enough to support function without pain
  - b. Biomechanical: “Normal” strength
2. Measuring
  - a. We measure surrogates
  - b. Plain xrays
  - c. Ultrasound
  - d. Acoustic emissions
3. Healing is NOT dichotomous!!!
4. Who does the evaluation?
  - a. Standardized methodology
  - b. Training?
    - i. Radiologists: Blinded to clinical parameters
    - ii. Orthopaedists: ? Biased by clinical results?
  - c. Intra- and Inter- observer reliability
  - d. Accuracy (The real endpoint!)
5. Hammer ‘85
  - a. Radiologists
  - b. 44% of Stable fractures read as ununited
  - c. 55% of Unstable fractures read as united
6. Whelan ‘02
  - a. Specific readings better than overall assessment
  - b. Number of corticies bridged had higher Kappa value
7. Davis ‘04
  - a. Tibia, femur, forearm
  - b. Poor agreement, even with rank order
  - c. Suggested that radiographic healing is a poor endpoint
8. Kristiansen, Emami, Jones
  - a. All three studies
    - i. Radiologists are more conservative than surgeons
    - ii. Time to union
    - iii. Percent union
9. Conclusions
  - a. Radiographic “union” is a poor endoint
    - i. Not well defined
    - ii. Restricted to followup intervals
    - iii. Poor Kappa
    - iv. Clinical information irrelevant
  - b. Strongly support new endpoint of revision surgery

# *Symposium I: Assessment of Fracture Healing*

*Thursday October 8, 2009*

## Which radiographic measure should we use? Feasibility and relevance

Michael D. McKee

Professor, Division of Orthopaedic Surgery  
Department of Surgery, St. Michael's Hospital and the  
University of Toronto, Toronto, Canada

### **1. Introduction**

- **identification of the problem**
- **classification schemes**
- **qualitative versus quantitative**
- **clinical relevance**

### **2. Correlation to clinical parameters**

- **pain**
- **weight bearing**
- **stiffness**

### **3. Additional imaging studies**

- **CT**
- **MRI**
- **Ultrasound**

### **4. RUST score**

### **5. Is there a consensus in the literature?**

## **Assessment of Fracture Healing- OTA 2009 Symposium I**

### **What Outcomes Should We Measure? Beyond the Xray**

**Marc F. Swiontkowski, M.D.**  
**University of Minnesota**

- 1- We cannot omit the Xray!
  - OTA Standardized
  - Injury severity variable
  - Allows pooling of results
  
- 2- Relevant Clinical Outcomes
  - ROM
  - Strength
  - Limb Length
  - Cold Intolerance
  - Sensation
  - Alignment
  - Infection
  - Other complications
  
- 3- Functional Outcomes
  - Gait Analysis
  - Functional Testing (Jebsen-Taylor)
  - Pain
  - RTW
  - Functional Questionnaires
  
- 4- Functional Questionnaires must be validated
  - Appropriate item development
  - Face Validity
  - Criterion Validity
  - Construct Validity
  - Reliability testing
  - Responsiveness testing

5- Useful Questionnaires for fracture patients

- SF-36
- SIP
- QWB
- Euroqual
- MFA/SMFA
- DASH
- Condition Specific Measures

6- Need to be aware of (and document) major confounders

- Medical Co morbidity
- Age
- Education
- Social Support
- Other Injuries

7- So what is the ideal?

- Severity classification
- Report Clinical Outcomes
- Always report functional outcomes
- Ideally functional testing
- Use appropriately validated measures
- Don't forget to report confounders