



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

Fracture Healing Defined: Is There Consensus?

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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 Technitium⁹⁹ – 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
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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

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Which radiographic measure should we use? Feasibility and relevance

Michael D. McKee

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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