



# ORTHOPAEDIC TRAUMA RESEARCH CONSORTIUM

(WWW.ORTHOTRAUMARESEARCH.COM)



## Investigators Meeting Minutes

October 13, 2011

San Antonio, Texas

Thank you everyone for the time and effort you each gave to make the OTRC Investigators Meeting a priority during the OTA Meeting. The meeting was a success due in large measure to the excellence of the PI's and RC's involved. In addition to current studies we were able to brain storm some new study ideas that are detailed below. The meeting also marked the successful completion of one of the OTRC studies giving us a solid foundation of success.

### I ATTENDANCE

Andrew Schmidt  
Darin Friess  
Mir Hassan  
Kelly Trask  
Leslie Hill  
Paul Tornetta  
Sue Engerman  
William Ricci

Brian Mullis  
David Teague  
Jodi Seigel  
Laura Phieffer  
Ojas Joshi  
Ross Leighton  
Tahnee Groat  
Karl Shively

Dan Chan  
Deb Sietsema  
Julie Agel  
Lisa Cannada  
Paul Ertl  
Shelly Macdonald  
Tigist Belaye  
Samir Mehta

### II STUDIES CURRENTLY ACTIVE

#### 1. ANKLE (Lateral vs. Posterolateral Plating)

The Ankle Fracture study has been the most successful OTRC study to date. Target enrollment of 249 subjects has been achieved marking the first successfully enrolled trial for the OTRC. Congratulations! to all investigators. Research coordinators please mark that you will not be able to randomize any more subjects in the data capture system. ***NOTE: We still need to get all followup data on the most recent patients and cannot publish until we have it!!! So please be vigilant!***

It was also noted that since we have significant subject population of ANKLE fractures more studies can be designed in this area. The collected data from this study will be analyzed after the last enrolled subject finishes his final follow up (May 2012). If any investigator has interest in using this data for any other analysis/comparison please let us know. **Also, the payment for subjects participating in this study will be reimbursed after May 2012 based on the final followup. Other re-imburement will be on a prorated basis after those followed for the year.**



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**2. SOLVED (Distal Femur fxs)**

We currently have 137 Subjects enrolled at 22 sites, top enrollment being done by NYU hospital (Dr. Kenneth Egol). With current enrollment, it is most likely that we will achieve our target of 160 subjects by Mar 2012. Again, sites are requested to actively follow up with the enrolled subjects. Please keep looking for new patients as well!!

**3. IMPRESS (Proximal Tibia fxs)**

Currently, there are 81 patients enrolled in the IMPRESS study at 27 sites. Top enrollment for this study has been done by NYU hospital (Dr. Kenneth Egol).

Enrollment has been slow for this study and we have just 16 patients enrolled since last year. Issues associated with this slow enrollment were discussed. With target enrollment of 160 subjects sites are requested to actively screen for potential subjects. Please try hard to get patients as this is a funded study and an important one to finish!

**4. SACRAL(Sacral Fractures)**

The Sacral study has currently 71 subjects enrolled from 14 participating sites, top enrollment being from Indiana University (Dr. Brian Mullis). This study was submitted for OTA funding however it did not receive the award for this year (2011-2012). Additional sites are encouraged to participate in this study as it takes just a couple of minutes to fill out the CRF involved.

It was also noted that this study has higher rate of lost to follow up patients. Ideally, the fracture heals in 3-4 months time frame and the patients don't show up for the one year follow up so we will accept phone followup. Other funding sources will be sought out. Anyone with any suggestions please let us know!

**5. SCAPULA (Scapula Fractures)**

We have currently 11 sites participating in this study with total subject enrollment of 40 subjects. Top subject contributor for this study has been from Indiana University (Dr. Brian Mullis).

Again, this fracture heals quickly and followup is difficult to achieve. A final phone follow up was again recommended.

Various approaches to increase the recruitment for this study were discussed. Dr. Tornetta suggested removing of CT scan requirement which was agreed upon by all. The CT scan will be removed as a requirement, but should be filled out if obtained. An update will be prepared for your IRB's changing the inclusion criteria.



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### III NEW STUDY:

#### 1. OPERATIVE VERSUS NON OPERATIVE TREATMENT OF ISOLATED HUMERUS FRACTURES: A PROSPECTIVE COHORT COMPARISON STUDY.

INCLUSION CRITERIA: SUBJECTS BETWEEN 18-65 DIAGNOSED WITH A CLOSED, HUMERAL SHAFT FRACTURE.

EXCLUSION CRITERIA: HUMERAL SHAFT FRACTURES THAT EXTEND INTO THE ARTICULAR SURFACE, ADDITIONAL LONG BONE INJURIES OF UPPER OR LOWER EXTREMITY THAT WOULD COMPROMISE OUTCOME ASSESSMENT, PRISONERS, PREGNANT OR LACTATING FEMALE.

→ PLEASE DOWNLOAD ALL STUDY MATERIAL FROM [WWW.ORTHOTRAUMARESEARCH.COM](http://WWW.ORTHOTRAUMARESEARCH.COM)

### IV NEW STUDY IDEAS\*

1. SYNDESMOTIC SCREW REMOVAL VS SYNDESMOTIC SCREW RETENTION
2. RETROSPECTIVE HUMERUS NON UNION OUTCOME STUDY

**\*PLEASE COMPLETE THE STUDY INTEREST SURVEY SENT OUT TO LET US KNOW YOUR STUDY INTERESTS. ALSO, IF YOU HAVE ANY STUDY IDEAS OR ARE INTERESTED IN A PARTICULAR RESEARCH QUESTION DO LET US KNOW.**



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### **V Next Meeting**

Mark your calendars. The next proposed OTRC investigator's meeting is scheduled in **FEBRUARY 2012** during the AAOS annual meeting in San Francisco. We would be sending you the details shortly.

### **ACTION ITEMS**

- Please contact Leslie Hill (lhill17@slu.edu) if you are interested in participating in the Isolated Acute Humerus Fracture study. All the study material involved in this study can be downloaded from our website [www.orthotraumaresearch.com](http://www.orthotraumaresearch.com)
- The CT scan requirement is removed from the SCAPULA study. A new data collection grid would be sent out shortly to the participating sites. An amendment for your IRB will be sent as well.
- Please complete the STUDY INTEREST SURVEY sent out by Ojas by Nov 04, 2011 to plan for future studies.
- Please continue to enter all CRFs and radiographs for the IMPRESS, SOLVED, and ANKLE studies into the online data capture system.
- If there are any other studies you would like to propose, please write in immediately!