



ORTHOPAEDIC TRAUMA RESEARCH CONSORTIUM



Investigators Meeting Minutes

February 25, 2009

Las Vegas, NV

Thank you everyone for the time and effort you each gave to make the OTRC Investigators Meeting a priority during the Academy Meeting. The meeting was a success due in large measure to the excellence of the PI's and RC's involved. We were able to review each OTRC study in depth and had an extended discussion on future funding and direction of the OTRC. Again, I thank you and look forward to seeing you in San Diego at the OTA.

I ATTENDANCE

Paul Tornetta	Abducca Hawsauri	Deb Sietsema
Julie Agel	Brad Henley	Sheila Sprague
Charles Ball	Emily Hui	Dick Tarr
Tigist Belaye	Ryan Khan	Dave Teague
Michael Bosse	Paula Mckay	Dave Templeman
Lisa Cannada	Rob Molnar	Christina Tiezler
Bob Dunbar	Karyn Moon	Kelly Trask
Ken Egol	Brian Mullis	Mary Zadnik
Joshua Elson	H.C. Pape	Mark Zocchi
Mike Gardner	Ed Perez	Mauri Zomar
Jim Goulet	Roy Sanders	
Jonathan Gross	Andy Schmidt	

II STUDIES CURRENTLY ENROLLING

1. SE Ankle Fractures

Presented by: Dr. Ken Egol (New York, NY)

The SE Ankle Fracture study has been the most successful OTRC study to date. Currently, 121 patients have been enrolled at 7 sites led by the Orthopaedic Associates of Michigan (Dr. Cliff Jones). As of November, 2008 all sites are entering data through the online Data Capture System. The attendees indicated no problems with IRB approvals or patient enrollment. With a target sample size of 144 patients, study enrollment is close to complete.

2. Sacral Fractures

Presented by: Dr. Paul Tornetta, III (Boston, MA)

The group addressed several issues with the new sacral fracture study. While there is considerable interest in the topic, enrollment has been low and the logistics of recruiting 1000 patients necessary for adequate study power has proven to be problematic. Bilateral, head, high energy, and AP injuries were cited as common reasons for exclusion.

As the protocol is currently written, there are a considerable number of data collection points. To increase buy-in for this unfunded study, the group decided that it would be a good idea to eliminate some of the data collection points. The steering committee will review all data



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collection points and only keep the ones most critical to answering the study's primary question (e.g. 3, 6, and 12 month follow-ups only).

The timing of administering the VAS was addressed as well as the concern that all visits need to fall within standard of care. When patients have reached union, it is acceptable to administer the VAS over the phone or via mail to study patients. Clearer directions will be included with the next study amendment.

The OTA rejected the initial study submission and aforementioned revisions will need to be made for the next funding cycle. The main

The action plan going forward is as follows:

- 1) Have the steering committee reduce the data collection burden
- 2) Rework the study design and shoot for 200-250 total patients
- 3) Submit new preproposal to OTA for April 1, 2009.
- 4) Have a fully revised protocol ready for IRB submissions in 2-3 months
- 5) Resubmit to OTA for full funding in July 1, 2009

3. **IMPRESS (proximal tibia fx)**

Presented by Dr. Andrew Schmidt (Minneapolis, MN)

Currently, there are 35 patients enrolled in the IMPRESS study at 14 sites. In total, 26 sites have IRB approval and 4 more are pending approval. Although enrollment has improved with more sites involved, most sites are having difficulties finding eligible patients. Common reasons for exclusion are fractures not being amendable to both IM nail and plate or the fracture line coming too close to the proximal tibial articular surface (< 4cm). Many patients suffer additional injuries that make prohibit inclusion into the study. Some in the group also felt that there were a lot of posterior fractures that could be nailed but fell outside the inclusion parameters.

In order to increase enrollment, multi-trauma patients will be now included. A protocol amendment will be sent to each site participating in the study. All sites should continue to screen patients rigorously to ensure all eligible fractures are being screened for possible inclusion.

4. **SOLVED (distal femur fx)**

The enrollment in SOLVED is up to 52 patients at 15 sites. In total, 21 sites have IRB approval and 5 more sites are pending approval. Enrollment has been picking up since April of 2008 and no one in attendance expressed any concerns with the study design or recruitment. Like IMPRESS, the study is OTA funded and sites will be paid for all patients who follow up for at least 1 year.

Common reasons for exclusion were reviewed. Like IMPRESS, the most common reason for exclusion was a fracture not amenable to both IM nail and plate. Other common reasons for exclusion included head injuries, intraarticular comminution, and symptomatic knee arthritis.

5. **Scapula Fractures**



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Presented by: Dr. Paul Tornetta (Boston, MA)

The scapula fracture is an unfunded study currently being run at 7 sites. Additional sites are invited to join the study, but it was agreed that this study would be pulled out of the regular multicenter group discussions.

6. rhBMP-2 vs Autograft

Presented by: Dr. Lisa Cannada (St. Louis, MO)

The rhBMP-2 vs Autograft study is an OTA funded that has recently received full IDE approval from the FDA. The study will recruit 50 patients with open tibia fractures with critical size defects to be randomized to receive either rhBMP-2 or iliac crest bone graft. Sites interested in participating in the study should begin the IRB approval process using the protocol and CRFs available on the OTRC website (www.orthotraumaresearch.com).

Once IRB approved, sites will receive randomization envelopes and two rhBMP-2 kits donated by Medtronic. Upon successful enrollment and follow-up, each sites will receive \$1,000 per patient from the OTA grant. The grant money will be distributed through St. Louis Medical Center. Subcontract will be sent to approved sites to have signed by the PI and a contracts administer.

III NEW BUSINESS

New Study Ideas:

Mike Gardner, MD of Indiana University proposed a prospective observational cohort of posterior malleolous fractures. Dr. Gardner will write a simple protocol to be distributed to the group for comment.

Funding Issues:

Smith and Nephew put up the starting funds the data capture system. However, due to new Department of Justice regulations, money for new studies will be difficult to secure through industry sponsors. New funding sources for the central coordinating system will be necessary going forward. A few ideas were discussed at the meeting:

- 1) Seek funds through AO- North America.
- 2) Create an working group through the OTA. Smith and Nephew could donate money to the OTA for specific outcome studies and then the working group (the OTRC) would submit bids for those studies.
- 3) Transition the OTRC into a multi-center research committee through the OTA. The focus of the committee would be multi-center outcome studies similar to the studies being currently run by the OTRC.
- 4) Apply for a NIH program grant. A good amount of funds are available, but it is hard to receive unless a major clinical issue is being addressed.
- 5) Create a non-profit organization that is funded by industry. Downside is that there are many different non-profits all competing for the same industry funds.



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- 6) Fold the OTRC, Southeast Fracture Group, and the LEAP study group into a DoD funded group. There is between 12 and 16 million dollars available with a good potential to go to U.S. trauma centers. The focus of this program grant would be on extremity trauma and outcomes. At its onset, 12 trauma centers would be identified as the core of the group with other centers receiving money from the core centers on a per-patient enrolled basis.

IV GRANT SUBMISSIONS AND AWARDS

Current OTRC grants:

<u>Agency</u>	<u>Study</u>	<u>Amount Awarded</u>
OTA	IMPRESS**	\$80,000 (\$500/pt for 1-year follow-up)
OTA	SOLVED**	\$80,000 (\$500/pt for 1-year follow-up)
OTA	rhBMP-2	\$63,000 (\$1,000/pt for 1-year follow-up)
FOT	Sacral fractures	\$30,000 (for database development)
OTC	Ankle fractures	\$50,000 (\$344/pt for 1-year follow-up)

V OTRC WEBSITE

The website is up and running. Paul provided a brief overview of the OTRC website. The website houses all current OTRC research information including: specific study information, grant and funding details, patient education information, meeting minutes, contact information and more.

The website is easily accessible at www.orthotraumaresearch.com.

VI Next Meeting

Mark your calendars. The next proposed OTRC investigator’s meeting is scheduled for the week of October 8-10, 2009 during the OTA Annual Meeting in San Diego.

Please look for meeting notices, via email and the OTRC website, in the late summer with a specific date, time, and location.

ACTION ITEMS

- Please contact Paul Tornetta or Mark Zocchi if you are interested in participating in any of the OTRC studies
- Please continue to enter all CRFs and radiographs for the IMPRESS, SOLVED, and Ankle studies into the online data capture system.



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- If you are participating in the IMPRESS study you will need to submit a protocol amendment to their IRB to allow the inclusion of multi-trauma patients. A memo detailing this change along with and updated protocol will be sent to your site.
- Sites interested in the rhBMP-2 study should begin submission to their IRB. Please contact Mark Zocchi to receive study materials or downloaded them from the study page on the OTRC website (www.orthotraumaresearch.com).
- The Sacral Fracture Steering Committee will revise the data collection forms and protocol. All interested sites will receive a copy of the revised forms and protocol for review.