



ORTHOPAEDIC TRAUMA RESEARCH CONSORTIUM
Investigators Meeting Minutes
October 14, 2010
Baltimore, Maryland



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 the progress of each OTRC study during the meeting.

I ATTENDANCE

Matt Rudloff	Robert Ostrum	Ted Miclau
Bob Marburger	Brian Mullis	Tigist Belaye
Deb Seitsema	Darin Friess	Kenneth Egol
Zach Roberts	Tahnee Groat	Utku Kandemir
David Teague	Laura Phieffer	Paul Tornetta
Lisa Cannada	Leslie Hill	Ojas Joshi
Barb Steverson	Jim Goulet	Dave Templemen
Andy Schmidt	Julie Agel	Jodi Seigel

II STUDIES CURRENTLY ENROLLING

1. ANKLE (Ankle Fractures)

Presented by: Dr. Laura Phieffer (Ohio State University)

The Ankle Fracture study has been the most successful OTRC study to date. Currently, 235 patients have been randomized at 10 sites led by the Orthopaedic Associates of Michigan (Dr. Cliff Jones). The target enrollment was shifted from 144 to 249 due to higher rate of subject drop out (47%). Payment for this study would be initiated once the last enrolled subject completes his final follow up visit. Sites are requested to continue enrollment/follow up until then.

2. SACRAL(Sacral Fractures)

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

The Sacral study has currently 41 subjects enrolled from 15 sites, the top enrollment being from Boston Medical Center (Dr. Paul Tornetta). This study at present has no funding and various approaches were proposed to raise funds. One approach was to submit the study to other sponsors since we did not receive OTA funding for this year. Another option was to approach METRC group and check if they would be willing to support this project. At present, it was decided to continue enrollment and apply for OTA funding next year. Dr. Tornetta had conversation with the research committee to try to shape this the way they want it.



It was also noted that sites enrolling subjects for this study are missing VAS outcome for the pre-op visit. This outcome is an important tool for the study analysis and sites were requested to take care of this for future enrollments.

Additionally, there have been small changes in the study:

1. Deletion of Mini-Mental status exam.
2. Patient information form divided into Patient information and Patient injury form.
3. VAS moved to patient form.

All the sites currently approved for this study are requested to submit amendment to the study. New Case report forms (CRF) can be downloaded from www.orthotraumaresearch.com

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

Presented by Dr. Andrew Schmidt (Minneapolis, MN)

Currently, there are 65 patients enrolled in the IMPRESS study at 30 sites. Top enrollment for this study has been done by NYU hospital (Dr. Kenneth Egol).

Enrollment has been slow for this study and the reasons behind this were discussed.

Dr. Tornetta suggested that the exclusion criteria of Tibial shaft fracture not amenable to Intramedullary nailing (i.e. fracture is less than 4 cm from joint surface) is restricting his contribution of subjects and proposed if this exclusion criteria should be removed. A steering committee call will be arranged to discuss this issue.

Another option was to include Spanish/Chinese population in the study and the cost analysis for this inclusion was decided to be worked out. All sites would be notified if these amendments are made.

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

Presented by Dr. Andrew Schmidt (Minneapolis, MN)

The enrollment for SOLVED study has really picked up and we have 110 Subjects enrolled at 22 sites, top enrollment being done by NYU hospital (Dr. Kenneth Egol). With current enrollment, it is most likely that we would achieve our target of 169 subjects in a year and a half.

It was suggested that reports detailing the number of patient excluded from each site and the reasons for their exclusion should be sent out to all the sites periodically. This would help in understanding top reasons for subject exclusion.



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Hence, going forward Ojas will request this information from the research coordinators and would send out the final report to all sites.

5. SCAPULA (Scapula Fractures)

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

We have currently 10 sites participating in this study with total subject enrollment of 26 subjects. Top subject contributor for this study has been from Boston Medical Center (Dr. Paul Tornetta).

The importance of patient outcomes for pre-injury and 2 week follow up was emphasized during the discussion.

One of the difficulties encountered in this study was patient retention; because patients do not return once they felt better. Phone/Mail follow up for the subjects will be allowed.

To increase the recruitment for this study, removing of CT scan requirement from the inclusion criteria was proposed by Dr.Tornetta. An amendment will be sent out shortly.

The target for this study being 150, Sites were requested to contribute more subjects for this study.

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)
OTC	Ankle fractures	\$50,000 (\$/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.

**cost per patient for ANKLE study would be decided when we finish the final follow up of the last enrolled subject.*



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VI Next Meeting

Mark your calendars. The next proposed OTRC investigator's meeting is scheduled on **SATURDAY, FEBRUARY 19, 2011 SAN DIEGO CONVENTION CENTER** during the OTA Specialty day in San Diego. We would be sending you the details shortly.

ACTION ITEMS

- Please contact Paul Tornetta or Ojas Joshi if you are interested in participating in any of the OTRC studies.
- Please download the new CRF for SACRAL and SCAPULA study from www.orthotraumaresearch.com and submit it to your IRB.
- Any changes with the IMPRESS and SCAPULA will be communicated to all sites.
- Please continue to enter all CRFs and radiographs for the IMPRESS, SOLVED, and Ankle studies into the online data capture system.