SOLVED
MEMORANDUM

To all,

This is an amendment for the multicenter trial SOLVED. After interviewing site investigators and coordinators, the steering committees decided to make amendments to the protocol. Attached to this letter are screening forms to help each center offer entry to all potential study candidates. We are asking all centers to screen ALL distal femur fractures.

We are pleased to announce that the Synergos Online Randomizer is ready. Each PI will be supplied with a login and user-id for the randomizer once review board approved. Patients who meet the inclusion/exclusion criteria will be randomized. Screening forms of patients who are not eligible will be saved. All portions of the system are HIPAA compliant.

Study Amendments:

I. Inclusion/Exclusion Criteria:

1. Multiple-trauma patients will now be eligible for the study. Surgery timing should be done according to standard of care. The inclusion of these patients posses no additional risk as they will need surgery regardless of participation.

2. Periprosthetic fractures will now be eligible for the study. Supracondylar fractures above TKA will be eligible providing that they have a retaining design. There is no additional risk to these patients as their injury will require operation by IM nail or plate regardless of their participation in the study.

II. Online Randomization and Data Capture

3. The study will no longer use envelopes for randomization. PIs and designees will randomize patients through a secure website. The coordinator at Boston Medical Center will provide the website address, password, and login upon approval of this amendment.

4. As of Jan. 1, 2008 forms and radiographs will be completed and submitted electronically through a web-based data capture system. You will access the site using a unique user-id and password different from randomizer. Please continue to submit data forms via fax to Boston Medical Center until the system is ready.

III. Screening

5. Screen all patients presenting with a distal femur fracture. This can be done through the online randomizer or on paper.

Please refer to the tables below for detailed changes to study forms and the protocol

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Protocol Changes: A Study of Locked Plates versus Intramedullary Nails in Distal Femur Fractures: A Multicenter Randomized Trial Comparing IM Nails and Plate Fixation (S.O.L.V.E.D)

Old Version: **2-21-07**
New Version: **10-15-07**

Changes:

Pg	Para-graph	Heading	Change	Reason
3	3	**Inclusion Criteria**	Added, "and with or without a TKA" to criteria #2	TKA amenable by IM nail or plate is now eligible (see Periprosthetic change below)
3	3	**Exclusion Criteria**	Edited #9 to: Contralateral distal femur fractures (bilateral injury) or ipsilateral lower extremity injury that would compromise function of the knee	Clarification of what type of injury would be excluded under this criteria.
3	3	**Exclusion Criteria**	Removed exclusion criteria, "Multiple traumatic injuries of the ipsilateral lower extremity (hip, femur, tibia) that would compromise outcome assessment"	Multiple trauma patients will not be excluded. There is no additional risk to these patients as these patients will need operation by either an IM Nail or plate regardless of their participation in the study. The timing of the surgery will be done according to standard of care at each investigator site.
3	3	**Exclusion Criteria**	Removed exclusion criteria, "Periprosthetic fracture"	Periprosthetic fractures will not be excluded. Supracondylar fractures above TKA will be eligible providing that they have a retaining design. There is no additional risk to these patients as their injury will require operation by IM nail or plate regardless of their participation in the study.
4	2	**Patient Enrollment**	Removed reference to envelope randomization. The study will no longer use envelopes for randomization. Investigators and designees will randomize patients through a secure website. The coordinator at Boston Medical Center will provide the website address, password, and login upon approval of this amendment.	To ensure concealed treatment allocation (i.e., to eliminate the possibility of investigators to determine treatment of the next enrolled patient), a centralized randomization system that is available 24/7 is optimal.
4	4	**Patient Randomization**	Same as above	Same as above
11	2	**Data management**	Same as above	Same as above

11	3	**Data Entry**	Data forms will be entered and submitted via a HIPAA compliant online electronic data capture system (avail. 1/1/08). Until then, forms should still be faxed to BMC.	To eliminate faxing forms to BMC. The site coordinator, PI, and the central coordinating site (BMC) will be able to access data. No co-investigators will have access. The EDC will significantly improve our ability for patient tracking, data monitoring, and statistical analysis.

Steering Committee Requested Form Changes:

Old Form: Inclusion/Exclusion Criteria [ver.022107]
New Form: Inclusion/Exclusion Screening Criteria [ver.101507]

Heading	Change	Reason
Inclusion Criteria	Added, "and with or without a TKA" to criteria #2	TKA amenable by IM nail or plate is now eligible (see Periprosthetic change below)
Exclusion Criteria	Edited #12 to: Contralateral distal femur fractures (bilateral injury) or ipsilateral lower extremity injury that would compromise function of the knee	Clarification of what type of injury would be excluded under this criteria.
Exclusion Criteria	Removed, "Multiple traumatic injuries of the ipsilateral lower extremity (distal tibia, femur, ankle or patella) that would compromise outcome assessment"	Multiple trauma patients will not be excluded. There is no additional risk to these patients as these patients will need operation by either an IM Nail or plate regardless of their participation in the study. The timing of the surgery will be done according to standard of care at each investigator site.
Exclusion Criteria	Removed, "Periprosthetic fracture"	Periprosthetic fractures will not be excluded. Supracondylar fractures above TKA will be eligible providing that they have a retaining design. There is no additional risk to these patients as their injury will require operation by IM nail or plate regardless of their participation in the study.
Inclusion Criteria	Added space to document any reasons for exclusion	The screening form will help determine the number of patients with distal femur fractures that did not qualify for the study. It will also document the reasons for exclusion. No PHI will be gathered on the form.
Exclusion Criteria	Added space to document any reasons for exclusion	Same as above
Post Screening Data Capture	Added question, "Was this patient randomized"	Same as above
Post Screening Data Capture	Added question, "Why did the eligible patient choose NOT to participate in the study?	Same as above