

## **Report for ANKLE DSMB: Prepared March 2009**

There have been 130 patients randomized online as of March 31, 2009. Of those, 1 patient was removed after randomization due to an ineligible fracture pattern and 2 patients withdrew consent prior to surgery bringing the total enrollment to 127. Target enrollment is 144 patients.

### **Summary of Randomization**

	Randomized	Withdrew	Ineligible	<b>Total</b>
Treatment A	65	1	0	<b>64</b>
Treatment B	65	1	1	<b>63</b>

**Figure 1** presents the overall study status. **Figure 2** shows the total number of enrolled patients by month.

### **Part A: Number of Patients Included and Excluded**

**Table 1a** presents the number of patients by fracture type and treatment assignment. 64 patients have been randomized to Treatment A (50.4%) and 63 to Treatment B (49.6%). **Table 1b** presents the starting dates of recruitment of the 9 centers in the study, and a month-by-month picture of the recruitment each center has achieved.

### **Part B: Patients lost to follow-up, withdrew consent, ineligible**

**Table 2a** presents the patients that were lost to follow-up, withdrew consent, or were removed due to an ineligible fracture. **Table 2b-d** shows the number of patients by center and fracture type that were lost to follow-up, withdrew consent, and were declared ineligible. There have been 4 patients lost to follow-up. 2 patients withdrew consent after randomization, and 1 patient was removed due to an ineligible fracture pattern leaving a total active enrollment of 123.

### **Part C: Patients lost to follow-up, withdrew consent, ineligible**

**Table 3a-b** cross-references each patient's online randomization with the treatment indicated on the Surgical Summary form. Of the 127 patients enrolled, 3 (2.3%) crossed treatments.

### **Part D: Summary of Adverse Events**

**Table 4a** shows the event rates as of May 31, 2008. There have been 12 reported Adverse Events in 5 study patients, resulting in a 6.3 percent AE rate in Treatment A (N=63), and a 1.6 percent AE rate for Treatment B (N=64). No Serious Adverse Events have been reported. Descriptions of the reported Adverse Events are presented in **Table 4b**.

Figure 1: Overall study status

## Overall Study Status

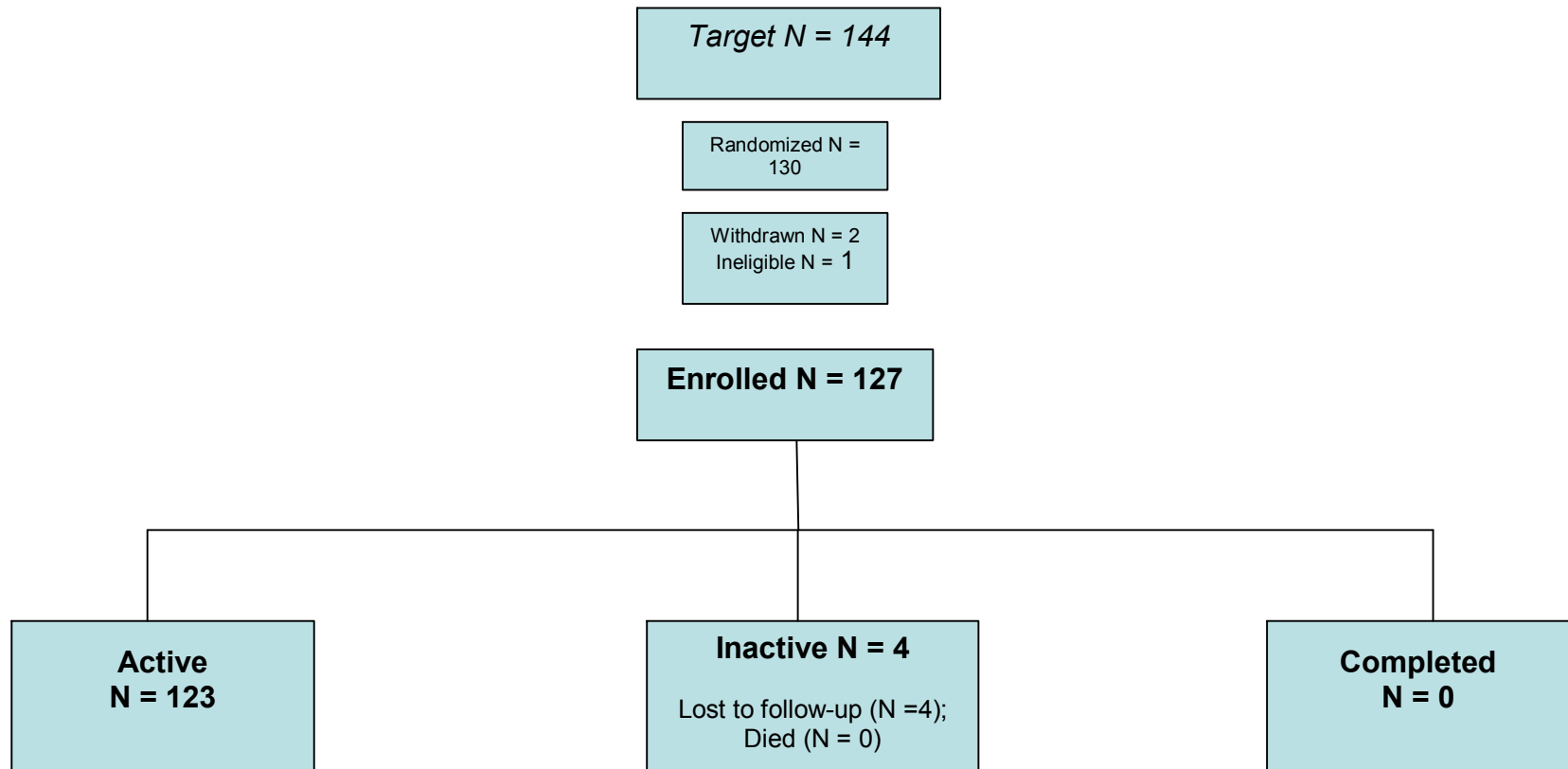
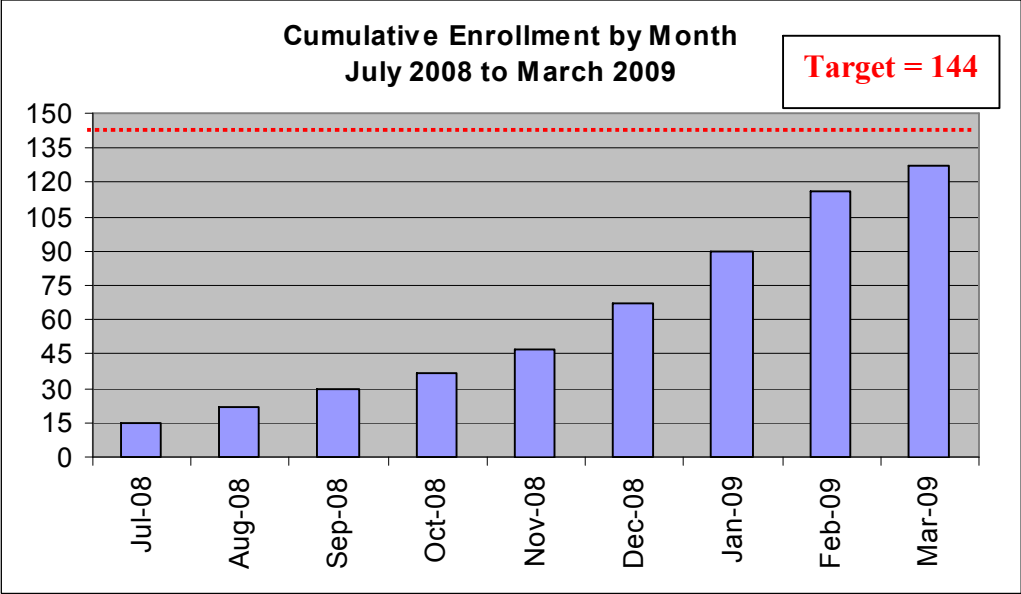


Figure 2: Cumulative enrollment by month



**Table 1a: Enrollment by Fracture Type and Treatment Assignment**

<b>CenterID</b>	<b>Treatment A</b>	<b>Treatment B</b>	<b>Total</b>
<b>01</b>	10	11	21
<b>02</b>	9	7	16
<b>03</b>	0	1	1
<b>04</b>	0	0	0
<b>05</b>	13	15	28
<b>06</b>	5	3	8
<b>07</b>	26	24	50
<b>08</b>	0	0	0
<b>09</b>	1	2	3
<b>TOTAL</b>	<b>64</b>	<b>63</b>	<b>127</b>

**Table 1b: Enrollment July 2008 through March 2009**

<b>CenterID</b>	<b>Approval Date</b>	<b>Jul-08</b>	<b>Aug-08</b>	<b>Sep-08</b>	<b>Oct-08</b>	<b>Nov-08</b>	<b>Dec-08</b>	<b>Jan-09</b>	<b>Feb-09</b>	<b>Mar-09</b>
01	10-Sep-08	-	-	2	1	4	3	5	5	1
02	27-Mar-08	5	1	0	1	1	4	2	1	1
03	6-Jun-08	0	0	0	0	0	0	0	1	0
04	26-Sep-08	-	-	-	0	0	0	0	0	0
05	26-May-08	4	4	3	3	1	3	6	1	3
06	08-Jan-09	-	-	-	-	-	-	0	6	2
07	03-Jun-08	6	2	3	2	4	10	8	11	4
08	01-Feb-09	-	-	-	-	-	-	-	0	0
09	27-May-08	0	0	0	0	0	0	2	1	0
<b>Total Sites</b>		<b>5</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>7</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>9</b>
<b>Monthly Enrollment</b>		<b>15</b>	<b>7</b>	<b>8</b>	<b>7</b>	<b>10</b>	<b>20</b>	<b>23</b>	<b>26</b>	<b>11</b>
<b>Cumulative Enrollment</b>		<b>15</b>	<b>22</b>	<b>30</b>	<b>37</b>	<b>47</b>	<b>67</b>	<b>90</b>	<b>116</b>	<b>127</b>

**Table 2a: Patients lost to follow-up, withdrew consent, ineligible**

Subject-ID	Center-ID	Date of Enrollment	Date of Last Follow-up	Reason
03-***-0001	02	01-Jul-08	12-Aug-08	Lost to follow-up
03-***-0005	02	31-Jul-08	19-Aug-08	Lost to follow-up
03-***-0012	05	15-Aug-08	N/A	Withdrew consent
03-***-0007	07	11-Aug-08	No f/u	Lost to follow-up
03-***-0015	07	02-Nov-08	No f/u	Lost to follow-up
03-***-0025	07	18-Dec-08	N/A	Withdrew consent
03-***-0038	07	02-Feb-08	N/A	Ineligible

**Table 2b: Ineligible Patients by Fracture Type and Treatment Assignment**

CenterID	Treatment A	Treatment B	Total
01	0	0	0
02	0	0	0
03	0	0	0
04	0	0	0
05	0	0	0
06	0	0	0
07	0	1	1
08	0	0	0
09	0	0	0
<b>TOTAL</b>	<b>0</b>	<b>1</b>	<b>0</b>

**Table 2c: Withdrawn Patients by Fracture Type and Treatment Assignment**

CenterID	Treatment A	Treatment B	Total
01	0	0	0
02	0	0	0
03	0	0	0
04	0	0	0
05	1	0	1
06	0	0	0
07	0	1	1
08	0	0	0
09	0	0	0
<b>TOTAL</b>	<b>1</b>	<b>1</b>	<b>2</b>

**Table 2d: Patients Lost to Follow-up by Fracture Type and Treatment Assignment**

CenterID	Treatment A	Treatment B	Total
01	0	0	0
02	1	1	2
03	0	0	0
04	0	0	0
05	0	0	0
06	0	0	0
07	1	1	2
08	0	0	0
09	0	0	0
<b>TOTAL</b>	<b>2</b>	<b>2</b>	<b>4</b>

**Table 3a: Patients with different randomized treatment than indicated on surgical summary**

<b>Subject ID</b>	<b>Site</b>	<b>Randomized Treatment</b>	<b>Surgical Summary</b>
03-***-0016	02	A	B
03-***-0003	05	A	B
03-***-0008	05	B	A

**Table 3b: Summary of patients that crossed treatment groups by Center**

<b>Center</b>	<b>Number of Patients Enrolled</b>	<b>Crossed from A to B</b>	<b>Crossed from B to A</b>
<b>01</b>	21	0	0
<b>02</b>	16	1	0
<b>03</b>	1	0	0
<b>04</b>	0	0	0
<b>05</b>	28	1	1
<b>06</b>	8	0	0
<b>07</b>	50	0	0
<b>08</b>	0	0	0
<b>09</b>	3	0	0
<b>TOTAL</b>	<b>127</b>	<b>2</b>	<b>1</b>

**Table 4a: Adverse Event rates by treatment**

	<b># Patients with Events</b>	<b>Total Patients (Rate%)</b>
Treatment A	4	63 (6.3)
Treatment B	1	64 (1.6)
<b>Total</b>	<b>5</b>	<b>127 (3.9)</b>

**Table 4b: Adverse Event descriptions**

*Total Events = 12*

<b>Subject-ID</b>	<b>Center ID</b>	<b>Date</b>	<b>Description of Event</b>	<b>Severity of Event</b>	<b>Device Related?</b>
03-***-0009	02	17-Feb-09	NECROSIS/WOUND SLOUGH	MILD	POSSIBLY RELATED
03-***-0006	05	9-Sep-08	SUPERFICIAL INFECTION	MILD	POSSIBLY RELATED
03-***-0006	05	30-Sep-08	DEEP INFECTION	MILD	POSSIBLY RELATED
03-***-0006	05	6-Oct-08	DEEP INFECTION	MODERATE	POSSIBLY RELATED
03-***-0006	05	30-Oct-08	SUPERFICIAL INFECTION	MILD	POSSIBLY RELATED
03-***-0001	07	9-Jul-08	INFECTED SUPERFICIAL WOUND (not at surgical site)	MILD	DEFINITELY NOT RELATED
03-***-0001	07	11-Jul-08	DVT	MODERATE	POSSIBLY RELATED
03-***-0001	07	31-Jul-08	DVT	MODERATE	POSSIBLY RELATED
03-***-0002	07	4-Nov-08	INFECTED SUPERFICIAL WOUND (not at surgical site)	MILD	DEFINITELY NOT RELATED
03-***-0010	07	13-Sep-08	MAYOCARDIAL INFARCTION	MODERATE	DEFINITELY NOT RELATED
03-***-0010	07	20-Nov-08	FRACTURED OTHER ANKLE (RIGHT)	MODERATE	DEFINITELY NOT RELATED
03-***-0010	07	19-Feb-09	Non-Union	SEVERE	POSSIBLY RELATED