

Report for IMPRESS DSMB: Prepared June 2009

Part A: Number of Patients Included and Excluded

There have been 40 patients enrolled in IMPRESS as of June 1, 2009. Target enrollment is 160 patients. No adjudication of patient eligibility has occurred.

Figure 1 presents the overall study status. **Figure 2** shows the cumulative enrollment of patients by month.

Table 1 presents the recruitment in the 27 centers who are participating in IMPRESS, and a month by month picture of the recruitment each center has achieved.

Part B: Summary of patient randomization

Table 2a presents the number of patients by fracture type and treatment assignment. 23 patients were randomized to Treatment A and 17 to Treatment B. There were 16 open fractures. 8 were randomized to Treatment A (50%) and 8 to Treatment B (50%). Of the 24 closed fractures, 15 were randomized to Treatment A (62.5%) and 9 to Treatment B (37.5%). **Table 2b** cross-references each patient's online randomization with the treatment present on the post-op x-rays. No patients were found to have crossed over from one treatment arm to the other.

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

Table 3 shows the patients with early study exits. So far, 13 of the 40 patients enrolled have exited the study early (32.5%). 9 patients have been lost to follow-up (22.5%), 3 patients enrolled were found to have ineligible fracture patterns and were removed from the study (7.5%), and 1 patient died from injuries unrelated to the research study or device (2.5%). No patients have withdrawn consent.

Part D: Summary of Adverse Events

Table 4a shows the event rates as of May 31, 2008. There have been 5 reported Adverse Events in 4 subjects resulting in a 13.0 percent AE rate in Treatment A (N=23), and a 5.9 percent AE rate for Treatment B (N=17). 2 of the adverse events were considered serious but were not related to the treatment. 3 events were definitely not related to the device, 1 was probably related, and 1 was definitely related. Descriptions of the reported Adverse Events are presented in **Table 4b**.

Figure 1: Overall study status

Overall Study Status

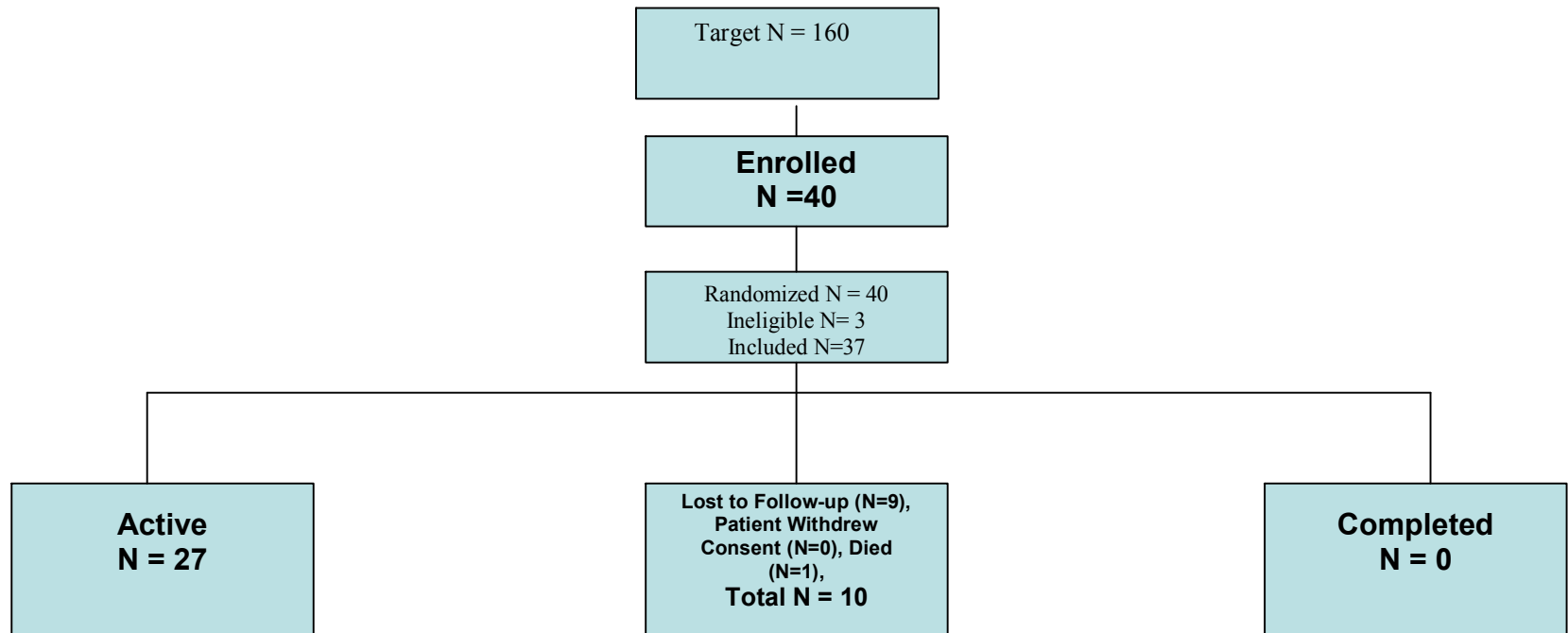
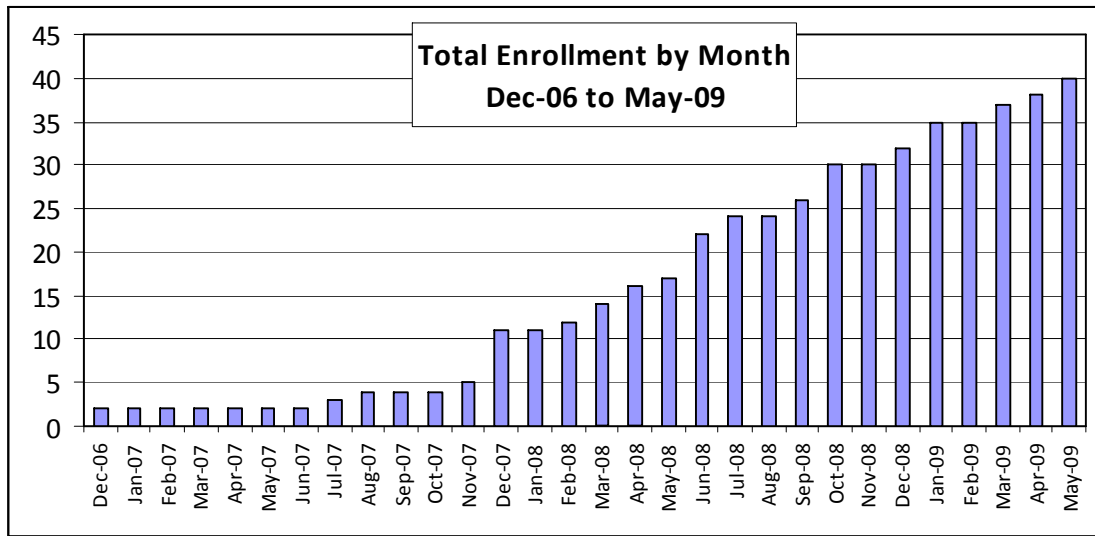


Figure 2: Cumulative enrollment by month:



Target = 160

Table 1: Enrollment by Site. Dec. 2006 through May 2009:

Site #	IRB Date	Enrollment															
		Dec-06	Jan-07	Feb-07	Mar-07	Apr-07	May-07	Jun-07	Jul-07	Aug-07	Sep-07	Oct-07	Nov-07	Dec-07	Jan-08	Feb-08	
01	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0	
02	Dec-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
03	Oct-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
04	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0	
05	Nov-06	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
06	Mar-07	X	X	X	X	0	0	0	0	0	0	0	0	0	0	0	
07	Jun-07	X	X	X	X	X	X	0	0	0	0	0	0	0	0	0	
08	Apr-07	X	X	X	X	0	0	0	0	0	0	0	0	0	0	0	
09	Apr-08	X	X	X	X	0	0	0	0	0	0	0	0	0	0	0	
10	May-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
11	Jul-07	X	X	X	X	X	X	X	0	0	0	0	0	0	0	0	
12	Mar-07	X	X	X	0	0	0	0	0	0	0	0	0	1	0	0	
13	Mar-07	X	X	X	0	0	0	0	0	1	0	0	0	0	0	0	
14	Dec-06	2	0	0	0	0	0	0	0	0	0	0	0	1	0	0	
15	May-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
16	Mar-07	X	X	X	0	0	0	0	0	0	0	0	0	0	0	0	
17	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0	
18	May-07	X	X	X	X	X	0	0	0	0	0	0	0	2	0	0	
19	Jun-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
20	Jun-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
21	Jun-07	X	X	X	X	X	X	0	0	0	0	0	0	0	0	0	
22	Apr-07	X	X	X	X	0	0	0	1	0	0	0	0	0	0	0	
23	Jul-07	X	X	X	X	X	X	X	0	0	0	0	0	2	0	0	
24	Mar-07	X	X	X	0	0	0	0	0	0	0	0	0	0	0	0	
25	May-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
26	Aug-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
27	Apr-07	X	X	X	X	0	0	0	0	0	0	0	0	0	0	0	
Enrolled		2	0	0	0	0	0	0	0	1	1	0	0	1	6	0	0
<i>Total Sites</i>		<i>4</i>	<i>4</i>	<i>4</i>	<i>8</i>	<i>13</i>	<i>17</i>	<i>19</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>

Table 1 continued:

Site #	IRB Date	Mar-08	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09	Apr-09	May-09
01	May-07	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
02	Dec-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
03	Oct-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
04	May-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
05	Nov-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
06	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
07	Jun-07	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
08	Apr-07	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
09	Apr-08	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	May-08	X	X	0	0	0	0	0	0	0	0	0	0	1	0	0
11	Jul-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
12	Mar-07	0	0	0	1	0	0	1	1	0	1	0	0	1	0	0
13	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	Dec-06	0	0	1	2	0	0	0	0	0	1	1	0	0	0	1
15	May-08	X	X	0	2	0	0	1	0	0	0	0	0	0	0	0
16	Mar-07	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
17	May-07	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0
18	May-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	Jun-08	X	X	X	0	0	0	0	0	0	0	0	0	0	0	0
20	May-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0
21	Jun-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	Apr-07	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
23	Jul-07	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
24	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	May-07	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0
26	Aug-08	X	X	X	X	X	0	0	1	0	0	0	0	0	0	0
27	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Enrollment		2	2	1	5	2	0	2	4	0	2	3	0	2	1	2
Total Sites		21	21	23	24	24	25	25	25	25	25	25	25	25	25	27

Table 2a: Randomization by Fracture Type and Treatment Assignment:

Site #	Treatment A			Treatment B			Total		
	Open	Closed	Total	Open	Closed	Total	Open	Closed	Total
01	0	1	1	0	1	1	0	2	2
02	0	0	0	0	0	0	0	0	0
03	0	0	0	0	0	0	0	0	0
04	0	0	0	0	0	0	0	0	0
05	0	1	1	0	0	0	0	1	1
06	0	0	0	0	0	0	0	0	0
07	1	0	1	1	0	1	2	0	2
08	0	1	1	0	0	0	0	1	1
09	0	0	0	0	0	0	0	0	0
10	0	1	1	0	0	0	0	1	1
11	0	0	0	0	1	1	0	1	1
12	2	1	3	2	1	3	4	2	6
13	0	1	1	0	0	0	0	1	1
14	0	3	3	2	4	6	2	7	9
15	1	1	2	1	0	1	2	1	3
16	0	1	1	0	0	0	0	1	1
17	1	1	2	0	0	0	1	1	2
18	0	0	0	1	1	2	1	1	2
19	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0
22	1	1	2	1	0	1	2	1	3
23	1	2	3	0	1	1	1	3	4
24	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0
26	1	0	1	0	0	0	1	0	1
27	0	0	0	0	0	0	0	0	0
TOTAL	8	15	23	8	9	17	16	24	40

Table 2b: Cross-reference of randomized treatment and x-ray

Site ID	PT ID	Randomization Assignment	X-Ray Adjudication
01	1-01	NAIL	NAIL
01	1-02	PLATE	PLATE
05	5-01	NAIL	NAIL
07	7-01	PLATE	PLATE
07	7-02	NAIL	NAIL
08	8-01	NAIL	***
10	10-01	NAIL	NAIL
11	11-01	PLATE	PLATE
12	12-01	NAIL	NAIL
12	12-02	PLATE	PLATE
12	12-03	PLATE	PLATE
12	12-04	PLATE	PLATE
12	12-05	NAIL	NAIL
12	12-06	NAIL	NAIL
13	13-01	NAIL	NAIL
14	14-01	NAIL	NAIL
14	14-02	PLATE	PLATE
14	14-03	PLATE	PLATE
14	14-04	NAIL	NAIL
14	14-05	PLATE	PLATE
14	14-06	PLATE	PLATE
14	14-07	NAIL	NAIL
14	14-08	PLATE	PLATE
14	14-09	PLATE	***
15	15-01	NAIL	NAIL
15	15-02	PLATE	PLATE
15	15-03	NAIL	NAIL
16	16-01	NAIL	screen fail
17	17-01	NAIL	screen fail
17	17-02	NAIL	NAIL
18	18-01	PLATE	PLATE
18	18-02	PLATE	PLATE
22	22-01	NAIL	NAIL
22	22-02	NAIL	screen fail
22	22-03	PLATE	PLATE
23	23-01	PLATE	PLATE
23	23-02	NAIL	NAIL
23	23-03	NAIL	NAIL
23	23-04	NAIL	NAIL
26	26-01	NAIL	***

*** data not entered into system at time of data extract

Table 3: Patients lost to follow-up, withdrew consent, ineligible:

Site#	Pt ID	Date of Enrollment	Date of Last Follow-up	Reason
22	22-01	7/11/2007	-	Reason unknown - patient lost to follow-up
14	14-03	11/3/2007	-	Patient moved away
05	5-01	11/5/2007	1/4/2008	Reason unknown - patient lost to follow-up
23	23-01	11/20/2007	1/3/2008	Reason unknown - patient lost to follow-up
23	23-02	12/28/2007	-	Reason unknown - patient lost to follow-up
23	23-03	2/10/2008	6/30/2008	Reason unknown - patient lost to follow-up
01	1-01	3/5/2008	5/23/2008	Patient moved away
23	23-04	4/6/2008	-	Reason unknown - patient lost to follow-up
12	12-02	6/6/2008	8/5/2008	Reason unknown - patient lost to follow-up
17	17-01	7/29/2008	-	Patient withdrawn (by study team)
23	23-01	10/20/2008	-	Patient deceased
16	16-01	10/23/2008	-	Patient withdrawn (by study team)
22	22-02	1/20/2009	-	Patient withdrawn (by study team)

Table 4a: Adverse Event rates by treatment and fracture type:

	Total Events	Total Patients w/ Events	Enrollment (Adverse Event Rate%)
Treatment A	4	3	23 (13.0)
Open	1	1	8 (12.5)
Closed	3	2	15 (13.3)
Treatment B	1	1	17 (5.9)
Open	0	0	8 (0.0)
Closed	1	1	9 (11.1)
Total	5	4	40 (10.0)
Open	1	1	16 (6.3)
Closed	4	3	24 (12.5)

Table 4b: Adverse Event descriptions:

Site	Subject-ID	Unexpected Event?	Related to Device?	Description of Event
14	14-01	NO	Definitely related	AE - painful implant - screw
01	01-02	NO	Definitely not related	SAE - Pneumonia, Aspiration
01	01-01	NO	Possibly related	AE - Loss of reduction (30° apex anterior angulation noted on xray- r tibia)
01	01-01	NO	Definitely not related	AE - Infection - deep
26	26-01	NO	Definitely not related	SAE - Multitrauma/ Stroke/ Intracranial Hypertension