

Report for IMPRESS DSMB: Prepared June 2010

Part A: Number of Patients Included and Excluded

There have been 57 patients enrolled in IMPRESS as of June 01, 2010. Target enrollment is 160 patients.

Figure 1 presents the overall study status.

Figure 2 shows the cumulative enrollment of patients by month.

Table 1 presents the recruitment in the 31 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 2 presents the number of patients by fracture type and treatment assignment. 31 patients were randomized to Treatment A and 26 to Treatment B. Of the 23 open fractures, 12 were randomized to Treatment A (52%) and 11 to Treatment B (48%). Of the 34 closed fractures, 19 were randomized to Treatment A (59%) and 15 to Treatment B (41%). 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, 12 of the 57 patients enrolled have exited the study early (21.0%). 11 patients have been lost to follow-up (19.3%) and 1 patient died from injuries unrelated to the research study or device (1.8%). No patients voluntarily withdrew consent. 3 patients were randomized but were not enrolled due to discovery of an ineligible fracture patterns and were removed from the study. 1 subject was not enrolled after randomization as he was mentally impaired.

Part D: Summary of Adverse Events

Table 4a shows the event rates as of June 1, 2010. There have been 9 reported Adverse Events in 7 subjects resulting in a 12.9 percent AE rate in Treatment A, and a 11.5 percent AE rate for Treatment B. Of all 9 events, 3 were definitely not related to the device, 4 were possibly related, and 1 was probably not related and 1 was unknown. 4 of the events were mild, 3 events were moderate, and 2 of the events were considered serious. Of the serious events, 1 was definitely not related to the treatment and the other was probably not related to the treatment.

Table 4b contains the descriptions of the reported Adverse Events

Figure 1: Overall study status

Overall Study Status

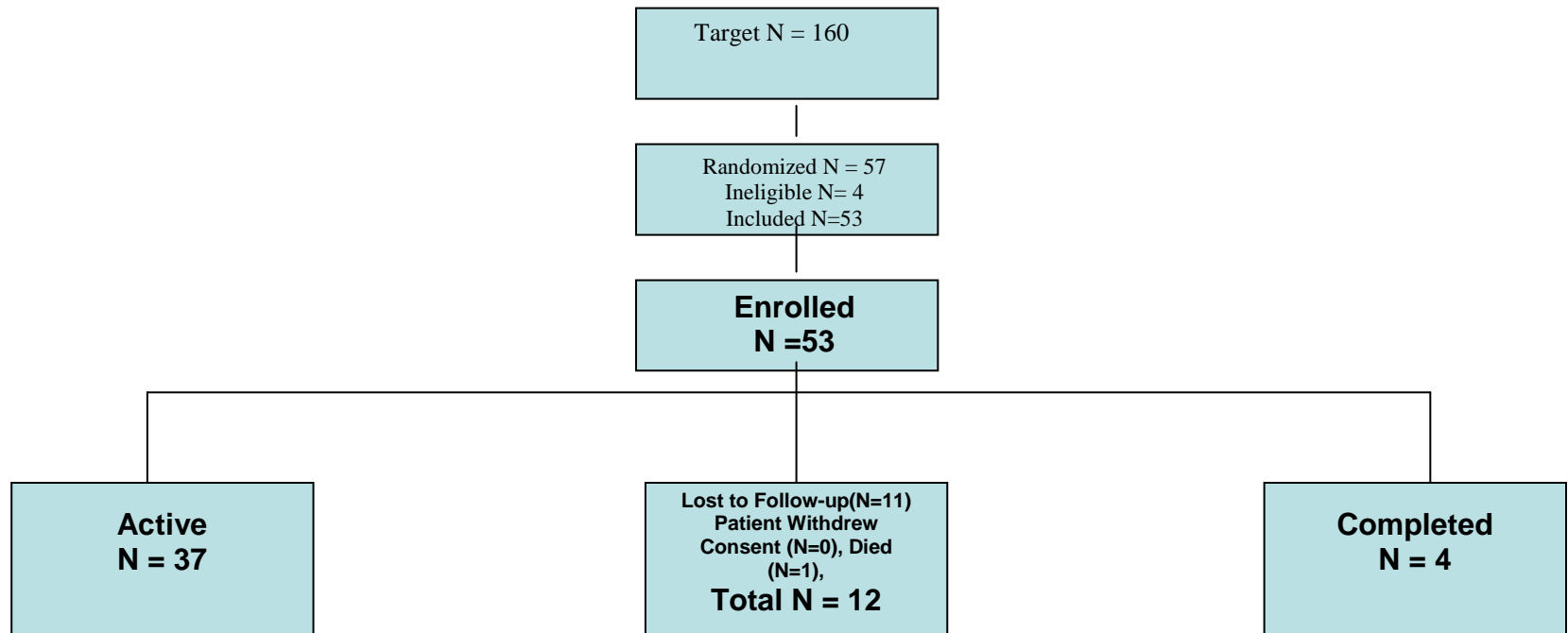


Figure 2: Cumulative enrollment by month:

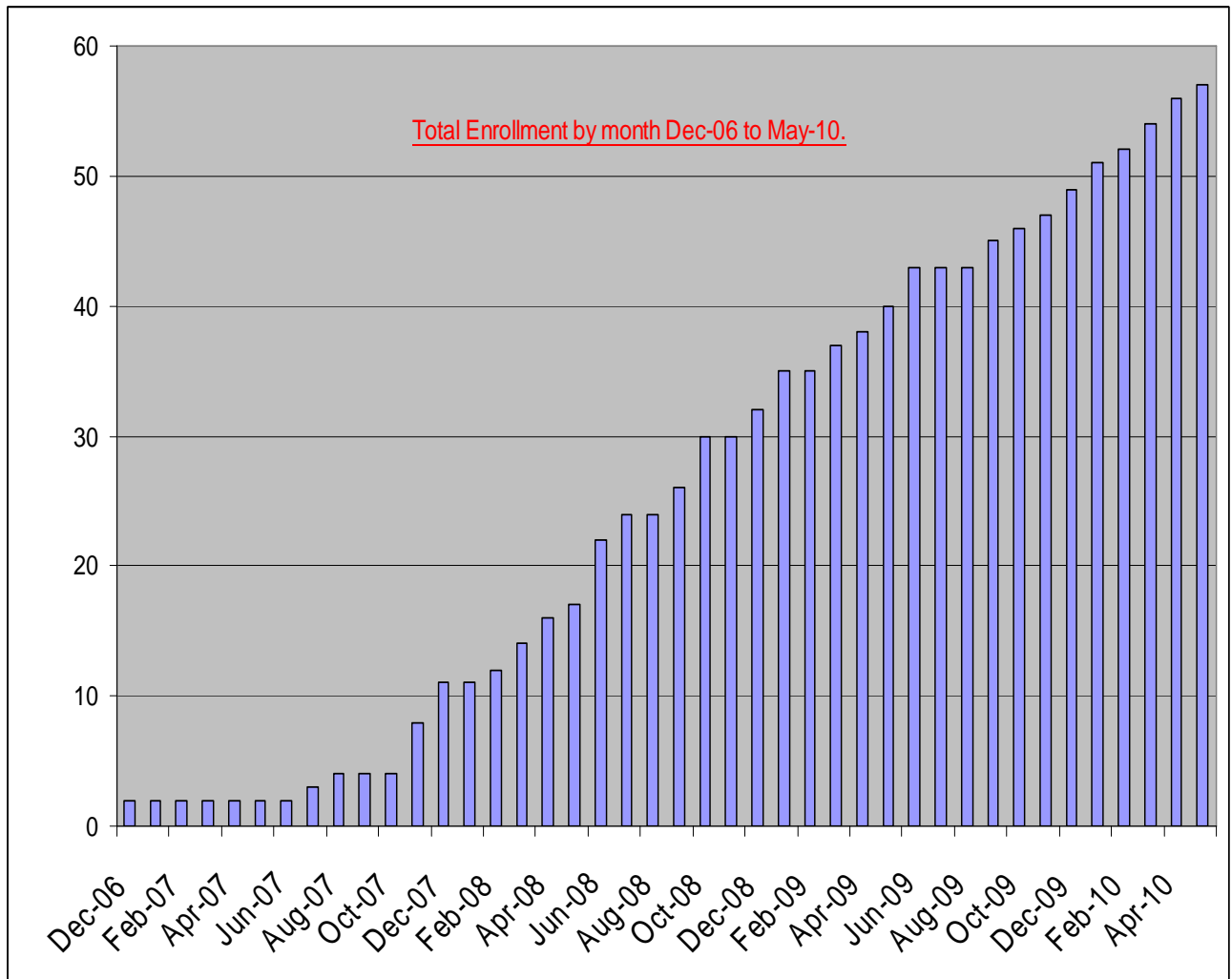


Table 1: Enrollment by Site. Dec. 2006 through November 2009:

Site #	IRB	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
	Date															
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	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0
06	Nov-06	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
07	Mar-07	X	X	X	0	0	0	0	0	0	0	0	0	0	0	0
08	Jun-07	X	X	X	X	X	X	0	0	0	0	0	0	0	0	0
09	Apr-07	X	X	X	X	0	0	0	0	0	0	0	0	0	0	0
10	Nov-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	Mar-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
12	May-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
13	May-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14	Jul-07	X	X	X	X	X	X	X	0	0	0	0	0	0	0	0
15	Dec-06	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
16	Feb-07	X	X	0	0	0	0	0	0	1	0	0	0	0	0	0
17	Dec-06	2	0	0	0	0	0	0	0	0	0	0	1	0	0	0
18	Mar-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
19	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0
20	Mar-07	X	X	X	0	0	0	0	0	0	0	0	0	0	0	0
21	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0
22	May-07	X	X	X	X	X	0	0	0	0	0	0	1	1	0	0
23	Jun-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
24	May-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
25	Jun-07	X	X	X	X	X	X	0	0	0	0	0	0	0	0	0
26	Apr-07	X	X	X	X	0	0	0	1	0	0	0	0	0	0	0
27	Jul-07	X	X	X	X	X	X	X	0	0	0	0	1	1	0	1
28	Nov-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	Jan-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
30	Apr-07	X	X	X	X	0	0	0	0	0	0	0	0	0	0	0
31	Dec-07	X	X	X	X	X	X	X	X	X	X	X	X	0	0	0
Enrolled		2	0	0	0	0	0	0	1	1	0	0	4	3	0	1
Cumulative		2	2	2	2	2	2	2	3	4	4	4	8	11	11	12
<i>Total Sites</i>		7	7	7	8	13	18	21	23	23	23	23	23	24	24	24

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	May-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
06	Nov-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
07	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
08	Jun-07	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
09	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	Nov-06	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
11	Mar-08	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	May-08	X	X	0	0	0	0	0	0	0	0	0	0	1	0	0
13	May-08	X	X	0	0	0	0	0	0	0	0	0	0	0	0	0
14	Jul-07	X	X	0	0	0	0	0	0	0	0	0	0	0	0	0
15	Dec-06	0	0	0	1	0	0	1	1	0	1	0	0	1	0	1
16	Feb-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	Dec-06	0	0	0	2	0	0	0	0	0	1	1	0	0	0	0
18	Mar-08	0	0	0	2	0	0	1	0	0	0	0	0	0	0	1
19	May-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	May-07	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
21	May-07	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0
22	May-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23	Jun-08	X	X	0	0	0	0	0	0	0	0	0	0	0	0	0
24	May-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0
25	Jun-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	Apr-07	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0
27	Jul-07	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
28	Nov-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	Jan-09	X	X	X	X	X	X	X	X	X	X	0	0	0	0	0
30	Apr-07	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
31	Dec-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Enrolled		2	2	1	5	2	0	2	4	0	2	3	0	2	1	2
Cumulative		14	16	17	22	24	24	26	30	30	32	35	35	37	38	40
Total Sites		27	27	29	29	29	29	29	29	29	29	30	30	30	30	31

Table 1 Continued

Site #	IRB Date	Jun-09	Jul-09	Aug-09	Sep-09	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10	Apr-10	May-10
01	May-07	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
03	Oct-06	0	0	0	0	0	0	0	0	0	0	0	0
04	May-07	0	0	0	0	0	0	X	X	X	X	X	X
05	May-07	0	0	0	0	0	0	0	0	0	0	0	0
06	Nov-06	0	0	0	0	0	1	0	0	0	0	0	0
07	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0
08	Jun-07	0	0	0	0	0	0	0	0	0	1	0	0
09	Apr-07	0	0	0	0	0	0	0	0	X	X	X	X
10	Nov-06	0	0	0	0	0	0	0	0	0	0	0	0
11	Mar-08	0	0	0	0	0	0	0	0	0	0	0	0
12	May-08	1	0	0	0	0	0	1	0	0	1	1	0
13	May-08	0	0	0	0	0	0	0	X	X	X	X	X
14	Jul-07	0	0	0	0	0	0	0	0	0	0	0	0
15	Dec-06	0	0	0	1	0	0	1	1	0	0	1	0
16	Feb-07	0	0	0	0	0	0	0	0	0	0	0	0
17	Dec-06	1	0	0	0	1	0	0	0	0	0	0	0
18	Mar-08	1	0	0	1	0	0	0	1	0	0	0	0
19	May-07	0	0	0	0	0	0	0	0	0	0	0	0
20	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0
21	May-07	0	0	0	0	0	0	0	0	0	0	0	1
22	May-07	0	0	0	0	0	0	0	0	0	0	0	0
23	Jun-08	0	0	0	0	0	0	0	0	1	0	0	0
24	May-09	0	0	0	0	0	0	0	0	0	0	0	0
25	Jun-07	0	0	0	0	0	0	0	0	0	0	0	0
26	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0
27	Jul-07	0	0	0	0	0	0	0	0	0	0	0	0
28	Nov-06	0	0	0	0	0	0	0	0	0	0	0	0
29	Jan-09	0	0	0	0	0	0	0	0	0	0	0	0
30	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0
31	Dec-07	0	0	0	0	0	0	0	0	0	0	0	0
Enrolled		3	0	0	2	1	1	2	2	1	2	2	1
Cumulative		43	43	43	45	46	47	49	51	52	54	56	57
Total Sites		31	31	31	31	31	31	30	29	28	28	28	28

Part B: Summary of patient randomization

Table 2: Enrollment by Fracture Type and Treatment Assignment:

Site #	Treatment A			Treatment B			Total		
	Open	Closed	Total	Open	Closed	Total	Open	Closed	Total
1	0	1	1	0	1	1	0	2	2
2	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0
6	0	1	1	0	1	1	0	2	2
7	0	0	0	0	0	0	0	0	0
8	2	0	2	1	0	1	3	0	3
9	0	0	0	0	0	0	0	0	0
10	0	1	1	0	0	0	0	1	1
11	0	0	0	0	0	0	0	0	0
12	0	3	3	0	2	2	0	5	5
13	0	0	0	0	0	0	0	0	0
14	0	0	0	0	1	1	0	1	1
15	3	1	4	4	2	6	7	3	10
16	0	1	1	0	0	0	0	1	1
17	1	4	5	2	4	6	3	8	11
18	2	1	3	1	2	3	3	3	6
19	0	0	0	0	0	0	0	0	0
20	0	1	1	0	0	0	0	1	1
21	1	2	3	0	0	0	1	2	3
22	0	0	0	1	1	2	1	1	2
23	0	0	0	1	0	1	1	0	1
24	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0
26	1	1	2	1	0	1	2	1	3
27	1	2	3	0	1	1	1	3	4
28	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0
30	1	0	1	0	0	0	1	0	1
31	0	0	0	0	0	0	0	0	0
TOTAL	12	19	31	11	15	26	23	34	57

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

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

Site #	Pt ID	Date of Enrollment	Date of Last Follow-up	Reason
01	1-01	3/5/2008	5/23/2008	Patient moved away
06	6-01	11/5/2007	1/4/2008	Reason unknown - patient lost to follow-up
10	10-01	1/5/2009	no follow-up	Patient is mentally Impaired and has not been able to comply with F/Us
15	15-02	6/6/2008	8/5/2008	Reason unknown - patient lost to follow-up
15	15-04	10/31/2008	No follow-up	Reason unknown-patient lost to follow-up.
17	17-03	11/3/2007	no follow-up	Patient moved away
18	18-03	09/21/08	01/08/2009	Homeless and unreachable.
20	20-01	10/23/2008	-	Patient withdrawn (by study team)
21	21-01	7/29/2008	-	Patient withdrawn (by study team)
26	26-01	7/11/2007	no follow-up	Reason unknown - patient lost to follow-up
26	26-02	1/20/2009	-	Patient withdrawn (by study team)
27	27-01	11/20/2007	1/3/2008	Reason unknown - patient lost to follow-up
27	27-02	12/28/2007	no follow-up	Reason unknown - patient lost to follow-up
27	27-03	2/10/2008	6/30/2008	Reason unknown - patient lost to follow-up
27	27-04	4/6/2008	no follow-up	Reason unknown - patient lost to follow-up
30	30-01	10/20/2008	-	Patient deceased

Part D: Summary of Adverse Events

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

	Total Events	Total Patients w/ Events	Enrollment (Adverse Event Rate%)
Treatment A	6	4	31 (12.9)
Open	2	2	12 (16.6)
Closed	4	2	19 (10.5)
Treatment B	3	3	26 (11.5)
Open	1	1	11(9.0)
Closed	2	2	15 (13.3)
Total	9	7	57 (12.3)
Open	3	3	23 (13.0)
Closed	6	4	34 (11.8)

Table 4b: Adverse Event descriptions:

Site #	Patient ID	Treatment	Fx Type	AE Date	Related	Severity	Unexpected	Description
01	1-01	A	CLOSED	5/23/2008	Possibly	Mod	NO	30 DEGREE APEX ANTERIOR ANGULATION NOTED ON XRAY - R TIBIA
01	1-01	A	CLOSED	9/15/2008	Def Not	Mod	NO	INFECTION - DEEP
01	1-01	A	CLOSED	6/23/2009	Def Not	Mod	NO	WOUND BREAKDOWN RIGHT PROXIMAL TIBIA SURGICAL SITE.
01	1-02	B	CLOSED	4/19/2008	Def Not	Sev	NO	ASPIRATION PNEUMONIA
15	15-03	B	CLOSED	3/24/2009	Possibly	Mild	NO	NON-UNION
17	17-01	A	CLOSED	11/6/2007	Possibly	Mild	NO	PAINFUL IMPLANT - SCREW
18	18-05	A	OPEN	04/08/10	Possibly	Mild	NO	NON-UNION
26	26-03	B	OPEN	6/3/2009	Unknown	Mild	NO	INFECTION – SUPERFICIAL
30	30-01	A	OPEN	10/28/2008	Def Not	Sev	NO	MULTITRAUMA/STROKE/I NTRACRANIAL HYPERTENSION