

Report for IMPRESS DSMB: Prepared December 2010

Part A: Number of Patients Included and Excluded

There have been 66 patients enrolled in IMPRESS as of Dec 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 28 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. 35 patients were randomized to Treatment A and 31 to Treatment B. Of the 28 open fractures, 14 were randomized to Treatment A (50%) and 14 to Treatment B (50%). Of the 38 closed fractures, 21 were randomized to Treatment A (55.2%) and 17 to Treatment B (44.7%). 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 66 patients enrolled have exited the study early (18.18%). 11 patients have been lost to follow-up (16.67 %) and 1 patient died from injuries unrelated to the research study or device (1.5%). 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 Dec 1, 2010. There have been 12 reported Adverse Events in 10 subjects resulting in a 14.3 percent AE rate in Treatment A , and a 15.8 percent AE rate for Treatment B. Of all 12 events, 4 were definitely not related to the device, 6 were possibly related, and 1 was probably not related and 1 was unknown. 6 of the events were mild, 4 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

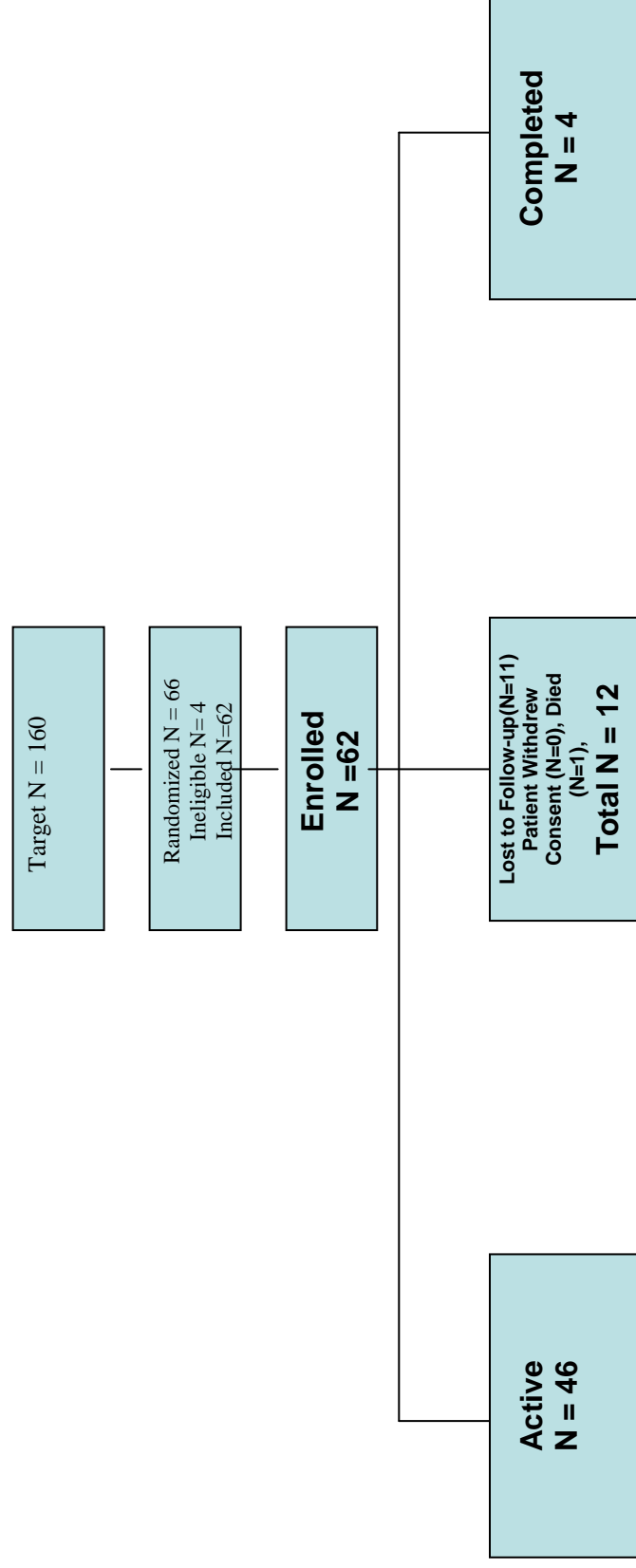


Figure 2: Cumulative enrollment by month:

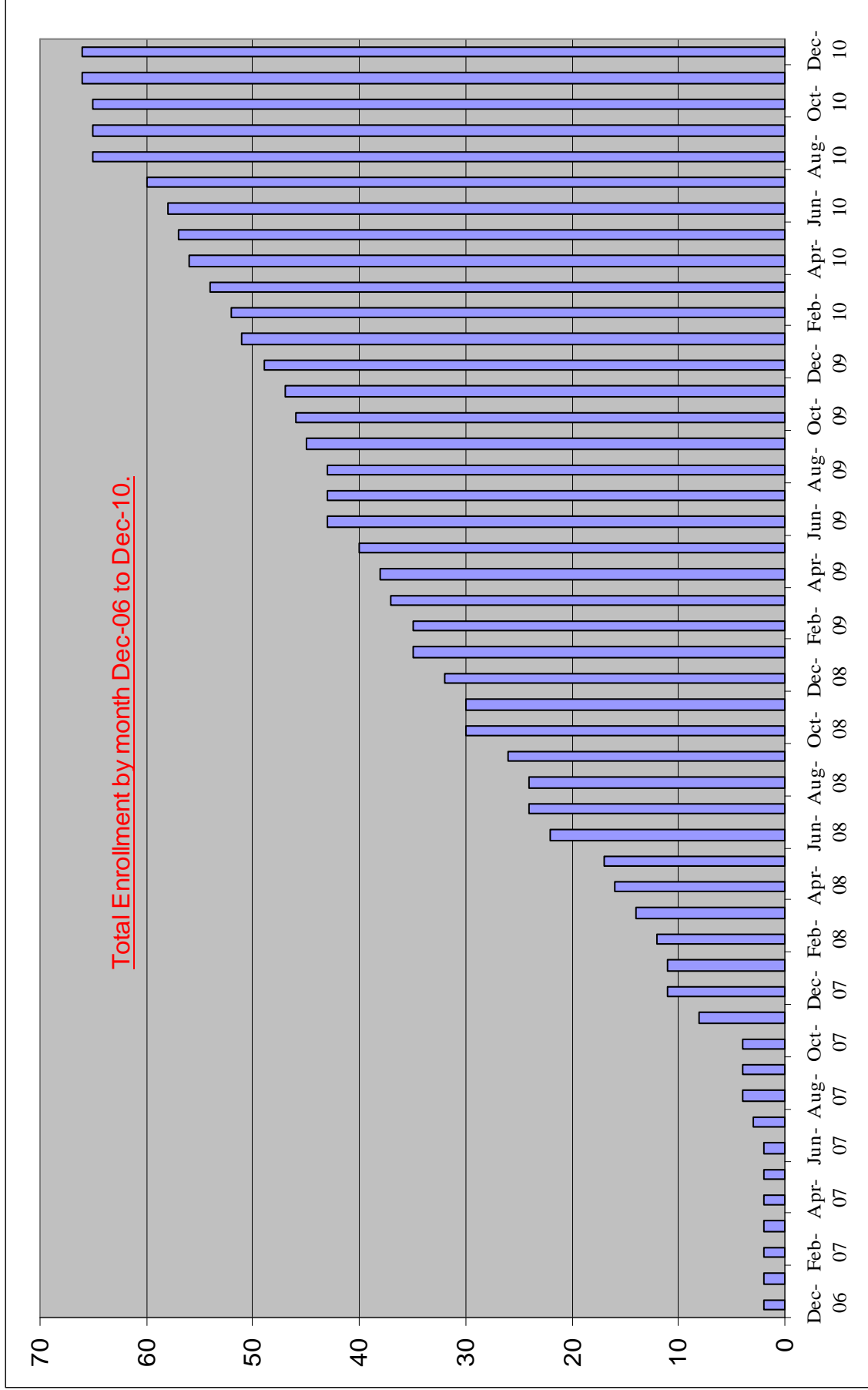


Table 1: Enrollment by Site, Dec. 2006 through November 2009:

Site #	IRB															
	Date	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	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	0	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	0	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	0	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	0	0	0	0	0	0	0	0
27	Jul-07	X	X	X	X	X	X	0	0	0	0	0	1	0	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	X	X	X
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	0	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	0	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	X	X	X	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	Jun-10	Jul-10	Aug-10
01	May-07	0	0	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	X	X	X	X	X	X	X	X	X
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	1	0	0	0	0	0	0	0	0	1
07	Mar-07	0	0	0	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	0	0	0
09	Apr-07	0	0	0	0	0	0	0	0	X	X	X	X	X	X	X
10	Nov-06	0	0	0	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	0	0	1
12	May-08	1	0	0	0	0	0	1	0	0	1	0	0	0	1	0
13	May-08	0	0	0	0	0	0	0	X	X	X	X	X	X	X	X
14	Jul-07	0	0	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	0	1	0	0	0	0
16	Feb-07	0	0	0	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	0	0	0
18	Mar-08	1	0	0	1	0	0	0	1	0	0	0	0	0	1	0
19	May-07	0	0	0	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	0	0	0
21	May-07	0	0	0	0	0	0	0	0	0	0	0	1	0	0	2
22	May-07	0	0	0	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	0	0	0
24	May-09	0	0	0	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	0	0	0
26	Apr-07	0	0	0	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	0	0	0
28	Nov-06	0	0	0	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	0	0	0
30	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
31	Dec-07	0	0	0	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	1	2	5
Cumulative		43	43	43	45	46	47	49	51	52	54	56	57	58	60	65
Total Sites		31	31	31	31	31	31	30	29	28	28	28	28	28	28	28

Table 1 Continued

Site #	IRB Date	Sep-10	Oct-10	Nov-10
01	May-07	0	0	0
02	Dec-06	0	0	0
03	Oct-06	0	0	0
04	May-07	X	X	X
05	May-07	0	0	0
06	Nov-06	0	0	0
07	Mar-07	0	0	0
08	Jun-07	0	0	0
09	Apr-07	X	X	X
10	Nov-06	0	0	0
11	Mar-08	0	0	0
12	May-08	0	0	0
13	May-08	X	X	X
14	Jul-07	0	0	0
15	Dec-06	0	0	0
16	Feb-07	0	0	0
17	Dec-06	0	0	0
18	Mar-08	0	0	0
19	May-07	0	0	0
20	Mar-07	0	0	0
21	May-07	0	0	0
22	May-07	0	0	0
23	Jun-08	0	0	0
24	May-09	0	0	0
25	Jun-07	0	0	0
26	Apr-07	0	0	0
27	Jul-07	0	0	0
28	Nov-06	0	0	0
29	Jan-09	0	0	0
30	Apr-07	0	0	1
31	Dec-07	0	0	0
Enrolled		0	0	1
Cumulative		65	65	66
Total Sites		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	2	2	0	1	1	0	3	3
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	4	4	0	7	7
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	2	2	4	4	3	7
19	0	0	0	0	0	0	0	0	0
20	0	1	1	0	0	0	0	1	1
21	2	2	4	1	0	1	3	2	5
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	2	1	3	1	0	1	3	1	4
31	0	0	0	0	0	0	0	0	0
TOTAL	14	21	35	14	17	31	28	38	66

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	8	6	35 (17.1)
Open	2	2	14 (14.3)
Closed	6	4	21 (19)
Treatment B	4	4	31 (12.9)
Open	2	2	14(14.3)
Closed	2	2	17 (11.8)
Total	12	10	66 (15.15)
Open	4	4	28 (14.3)
Closed	8	6	38 (15.8)

Table 4b: Adverse Event descriptions:

Site #	Patient ID	Treatment	Fx Type	AE Date	Related	Severity	Expected	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.
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
30	30-01	A	OPEN	10/28/2008	Def Not	Sev	NO	MULTITRAUMA/STROKE/I NTRACRANIAL HYPERTENSION
12	12-03	A	CLOSED	06/24/2010	Likely	Mild	NO	PAINFUL IMPLANT: SCREW
30	30-04	A	CLOSED	11/03/2010	Possibly	Mild	NO	Compartment Syndrome
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
26	26-03	B	OPEN	6/3/2009	Unknown	Mild	NO	INFECTION – SUPERFICIAL
18	18-07	B	OPEN	09/07/2010	Possibly	Mod	NO	Wound healing difficulty