

Report for SOLVED DSMB: Prepared July 2009

Part A: Number of Patients Included and Excluded

There have been 62 patients enrolled in SOLVED as of July 1, 2009. 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 23 centers who are participating in SOLVED, 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. 34 patients were randomized to Treatment A (54.8%) and 28 were randomized to Treatment B (45.2%). There were 15 open fractures in total. 7 were randomized to Treatment A (46.7%) and 8 to Treatment B (53.3%). There were 47 closed fractures in total. 27 were randomized to Treatment A (57.4%) and 20 to Treatment B (42.6%).

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

Table 3 shows patients with early study exits. 15 of the 62 patients enrolled have exited the study early (24.2%). 11 patients have been lost to follow-up and 4 patients were withdrawn by the study team due to ineligible fractures. No study subjects voluntarily withdrew consent.

Part D: Summary of Adverse Events

Table 4a shows the event rates as of July 1, 2008. There have been 23 reported Adverse Events in 15 patients resulting in a 20.6 percent AE rate in Treatment A (N=34), and a 28.6 percent AE rate for Treatment B (N=28). No adverse events were considered serious. 10 events were definitely not related to the device, 2 were probably not related, 3 were possibly related, and 8 were definitely related. Descriptions of the reported Adverse Events are presented in **Table 4b**.

Figure 1: Overall study status

Overall Study Status

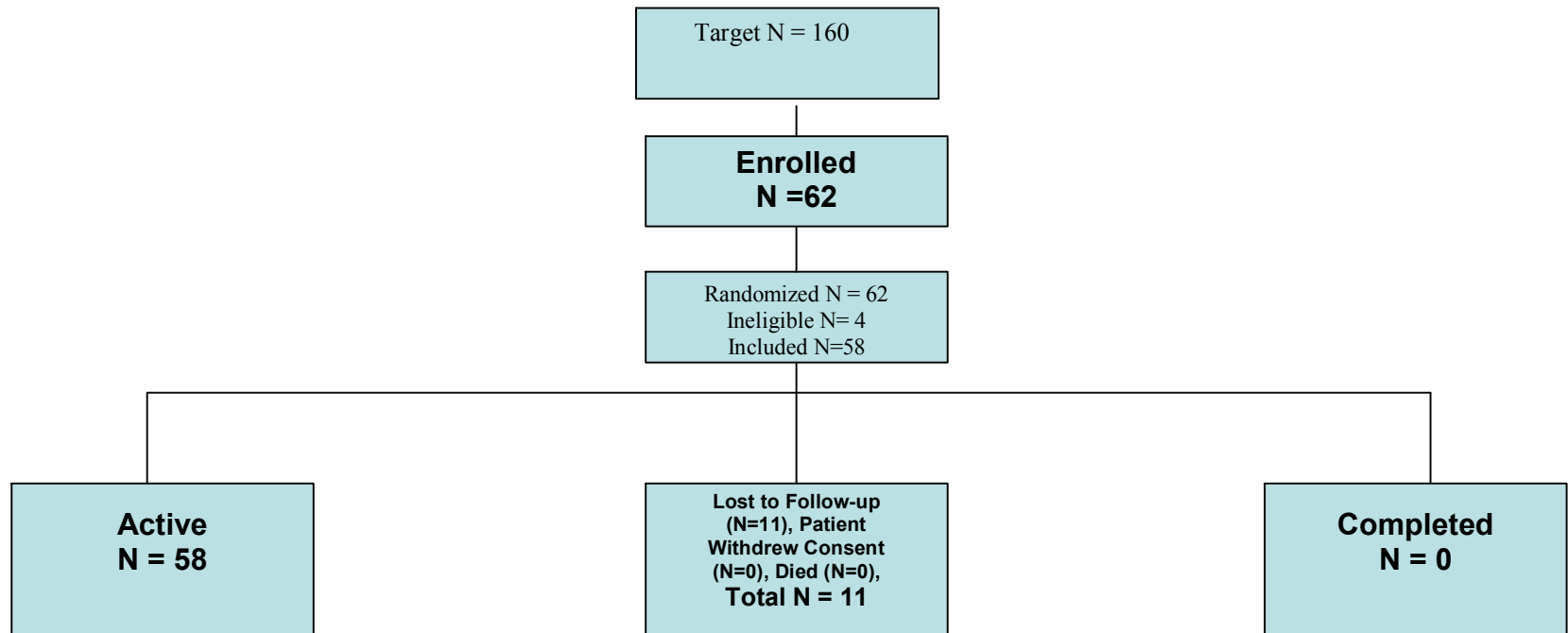


Figure 2: Cumulative enrollment by month:

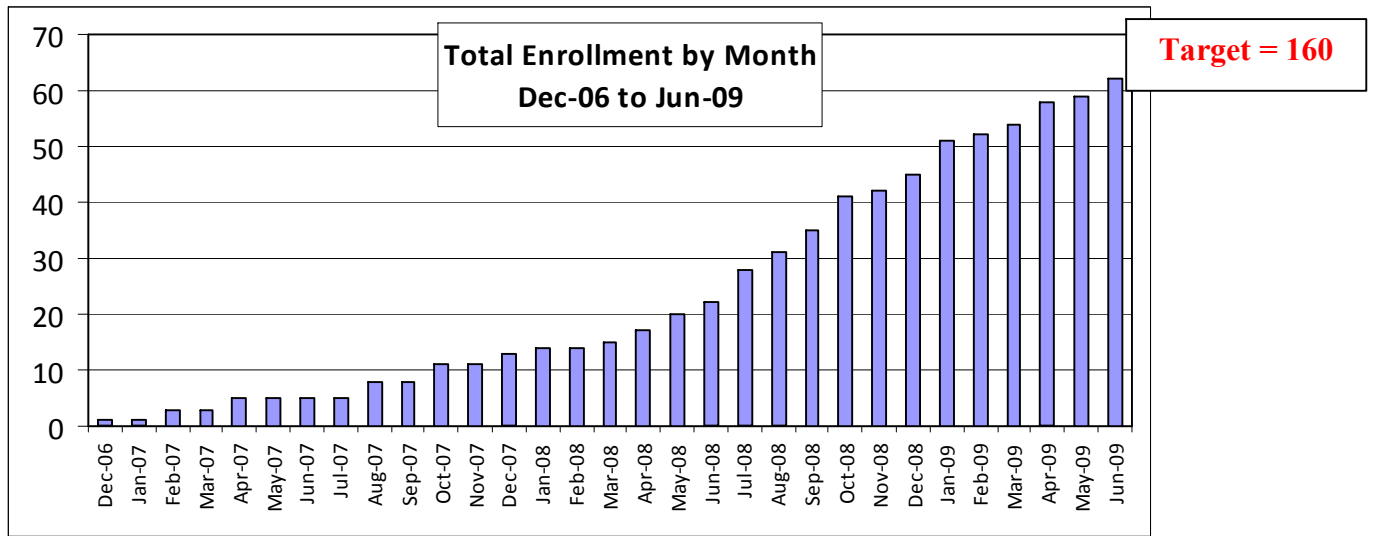


Table 1: Enrollment by Site. Dec. 2006 through June 2009:

Site #	IRB Approval	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
02	Dec-06	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
03	Oct-06	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
04	May-07	X	X	X	X	X	0	0	0	1	0	0	0	0	0	0
05	Nov-06	0	0	0	0	0	0	0	0	0	0	1	0	1	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	X	X	X	X	X	X	X	X	X	X	X
11	Jul-07	X	X	X	X	X	X	X	0	0	0	1	0	0	0	0
12	Mar-07	X	X	X	0	1	0	0	0	0	0	0	0	1	0	0
13	Mar-07	X	X	X	0	1	0	0	0	0	0	0	0	0	0	0
14	Dec-06	1	0	2	0	0	0	0	0	0	0	0	0	0	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	1	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	0	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
22	Apr-07	X	X	X	X	0	0	0	0	1	0	0	0	0	0	0
23	Jul-07	X	X	X	X	X	X	X	0	0	0	0	0	0	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
28	Apr-07	X	X	X	X	0	0	0	0	0	0	0	0	0	0	0
29	Sep-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Enrollment		1	0	2	0	2	0	0	0	3	0	3	0	2	1	0
<i>Total Sites</i>		5	5	5	9	12	15	16	18	18	18	18	18	18	18	18

Table 1 continued:

Site #	Approval 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	Jun-09
02	Dec-06	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
03	Oct-06	1	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0
04	May-07	0	1	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	2	0	0	0	0	0	1
07	Jun-07	0	0	1	1	1	1	0	0	0	0	0	0	1	0	0	0
08	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
09	Apr-08	X	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
11	Jul-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	Mar-07	0	0	1	0	1	0	1	0	0	0	1	1	0	1	0	0
13	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	Dec-06	0	0	1	0	1	0	1	2	0	0	2	0	0	2	0	0
15	May-08	X	X	0	1	1	0	0	2	0	1	2	0	0	0	1	1
16	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
17	May-07	0	0	0	0	0	1	0	0	0	0	1	0	1	0	0	0
18	May-07	0	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	1
20	Jun-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0	0
22	Apr-07	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
23	Jul-07	0	1	0	0	0	0	1	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	0
25	May-07	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0	0
28	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	Sep-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Enrollment		1	2	3	2	6	3	4	6	1	3	6	1	2	4	1	3
<i>Total Sites</i>		<i>18</i>	<i>19</i>	<i>20</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>	<i>21</i>	<i>21</i>	<i>23</i>	<i>23</i>

Table 2: Randomization by Fracture Type and Treatment Assignment:

Site #	Treatment A			Treatment B			Total		
	Open	Closed	Total	Open	Closed	Total	Open	Closed	Total
02	0	2	2	0	1	1	0	3	3
03	0	2	2	0	2	2	0	4	4
04	1	1	2	0	0	0	1	1	2
05	1	2	3	1	1	2	2	3	5
07	1	3	4	0	1	1	1	4	5
08	0	0	0	0	0	0	0	0	0
09	0	1	1	0	1	1	0	2	2
11	0	0	0	0	1	1	0	1	1
12	2	1	3	4	1	5	6	2	8
13	0	0	0	0	1	1	0	1	1
14	1	5	6	1	5	6	2	10	12
15	1	4	5	1	3	4	2	7	9
16	0	1	1	0	1	1	0	2	2
17	0	2	2	1	0	1	1	2	3
18	0	0	0	0	0	0	0	0	0
19	0	0	0	0	1	1	0	1	1
20	0	0	0	0	0	0	0	0	0
22	0	2	2	0	0	0	0	2	2
23	0	1	1	0	1	1	0	2	2
24	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0
TOTAL	7	25	32	8	19	27	15	44	59

Table 3: Patients lost to follow-up & withdrawn from study:

Pt ID	Reason
2-01	Patient moved - lost to follow-up
2-02	Reason unknown - patient lost to follow-up
2-03	Patient moved - lost to follow-up
7-04	Patient withdrawn (by study team)
12-01	Reason unknown - patient lost to follow-up
12-03	Reason unknown - patient lost to follow-up
12-04	Reason unknown - patient lost to follow-up
12-05	Reason unknown - patient lost to follow-up
14-01	Reason unknown - patient lost to follow-up
15-04	Patient withdrawn (by study team)
15-05	Patient moved - lost to follow-up
17-02	Patient withdrawn (by study team)
22-02	Patient withdrawn (by study team)
23-01	Reason unknown - patient lost to follow-up
23-02	Patient moved - lost to follow-up

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

	Total Events	Patients	Total Enrolled	Rate
Treatment A	11	7	34	20.6%
Open	2	2	7	28.6%
Closed	9	5	27	18.5%
Treatment B	12	8	28	28.6%
Open	3	2	8	25.0%
Closed	9	6	20	30.0%
Total	23	15	62	24.2%
Open	5	4	15	26.7%
Closed	18	11	47	23.4%

Table 4b: Adverse Event descriptions:

Pt #	FX Type	Treatment	Description	Related to Device?
3-02	CLOSED	PLATE	Painful implant - plate	Definitely related
3-02	CLOSED	PLATE	Hardware irritation	Definitely related
3-04	CLOSED	PLATE	perforated bowel	Definitely not related
3-04	CLOSED	PLATE	pulmonary embolism	Probably not related
4-01	OPEN	NAIL	Construct loosening - distal to femur	definitely related
4-02	CLOSED	NAIL	DECEASED GASTRIC MOTILITY	Definitely not related
4-02	CLOSED	NAIL	VITRAL HEMORRHAGE	Definitely not related
5-02	OPEN	NAIL	Painful implant - screw	Definitely related
5-04	CLOSED	PLATE	Painful implant - plate	Definitely related
9-01	CLOSED	PLATE	Neurological Deficit	Definitely not related
9-01	CLOSED	PLATE	Urinary Tract Infection	Definitely not related
9-02	CLOSED	NAIL	LEFT SHOULDER PAIN	Definitely not related
9-02	CLOSED	NAIL	ABDOMINAL HERNIA	Definitely not related
11-01	CLOSED	PLATE	painful implant - screw & arthrofibrosis	Definitely related
12-01	OPEN	PLATE	Painful implant - plate, Arthrofibrosis	Possibly related
12-01	OPEN	PLATE	Infection - deep, Non-union	Probably not related
15-06	OPEN	PLATE	DVT	Definitely not related
15-07	CLOSED	PLATE	DVT	Definitely not related
17-01	CLOSED	NAIL	CONTRALATERAL KNEE TKA	Definitely not related
17-01	CLOSED	NAIL	Painful implant - Nail	Definitely related
22-01	CLOSED	NAIL	Painful implant - screw	definitely related
23-01	CLOSED	NAIL	Infection - deep	Possibly related
23-01	CLOSED	NAIL	Infection - deep	Possibly related