

Report for SOLVED DSMB: Prepared JAN 2010

Part A: Number of Patients Included and Excluded

There have been 76 patients enrolled in SOLVED as of Jan 1, 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 23 centers who are participating in SOLVED study, 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. 40 patients were randomized to Treatment A (52.6%) and 36 were randomized to Treatment B (47.4%). There were 19 open fractures in total. 9 were randomized to Treatment A (47.4%) and 10 to Treatment B (52.6%). There were 57 closed fractures in total. 31 were randomized to Treatment A (54.4%) and 26 to Treatment B (45.6%).

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

Table 3 shows patients with early study exits. 12 of the 76 patients enrolled have exited the study early (15.8%). 9 patients have been lost to follow-up, 1 subject withdrew his consent and 2 patients were withdrawn by the study team due to ineligible fractures.

Part D: Summary of Adverse Events

Table 4a shows the event rates as of Jan 1, 2010. There have been 30 reported Adverse Events in 19 patients resulting in a 25.0 percent AE rate in Treatment A (N=40), and a 25 percent AE rate for Treatment B (N=36). No adverse events were considered serious. 14 events were definitely not related to the device, 2 were probably not related, 3 were possibly related, and 11 were definitely related. Descriptions of the reported Adverse Events are presented in **Table 4b**.

Figure 1: Overall study status

Overall Study Status

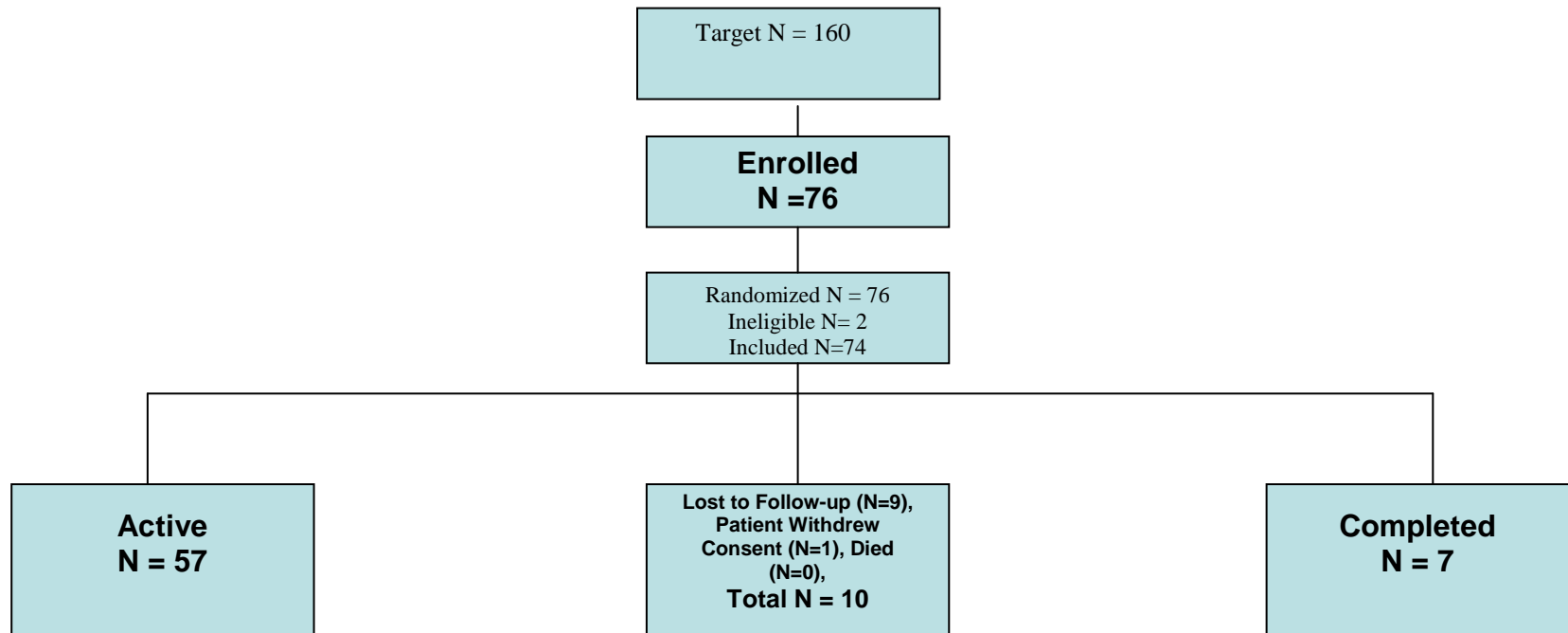


Figure 2: Cumulative enrollment by month:

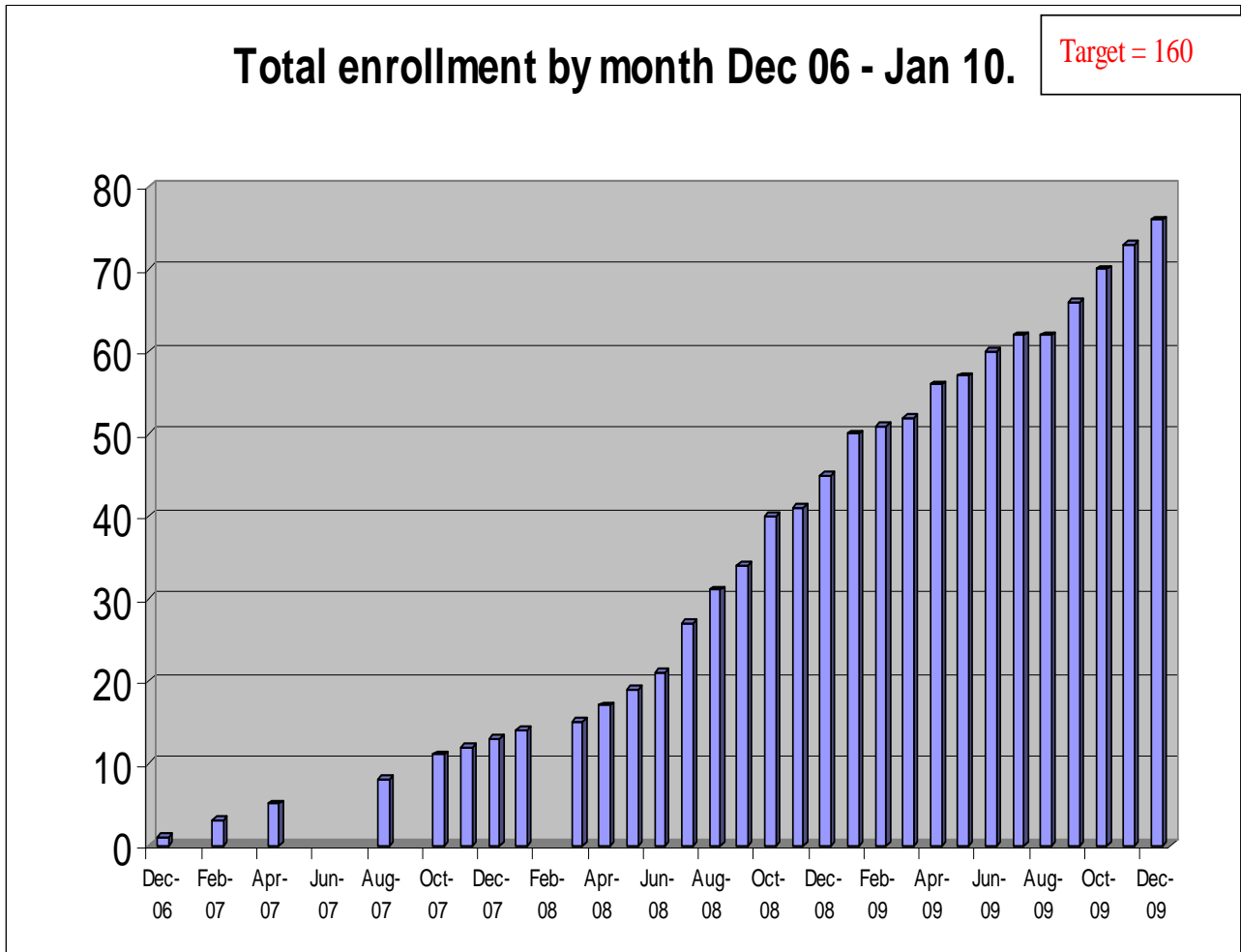


Table 1: Enrollment by Site. Dec. 2006 through June 2009:

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
06	Sep-06	0	0	0	0	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	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	Oct-07	X	X	X	X	X	X	X	X	X	X	0	0	0	0	0
29	Nov-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>		6	6	6	10	12	15	16	18	18	18	19	19	19	19	19

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	May09	Jun09
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
06	Sep-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
07	Jun-07	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0
08	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	X
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	X	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-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0	0
28	Oct-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	Nov-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	1	4	1	3
<i>Total Sites</i>		<i>19</i>	<i>20</i>	<i>21</i>	<i>22</i>	<i>23</i>	<i>22</i>	<i>22</i>	<i>22</i>	<i>22</i>	<i>22</i>	<i>22</i>	<i>22</i>	<i>22</i>	<i>22</i>	<i>23</i>	<i>23</i>

Table 1 continued:

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

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	2	2	0	4	4
03	0	4	4	0	3	3	0	7	7
04	1	1	2	0	0	0	1	1	2
05	2	2	4	3	1	4	5	3	8
07	1	3	4	0	0	0	1	3	4
08	0	0	0	0	0	0	0	0	0
09	0	2	2	0	2	2	0	4	4
11	0	0	0	0	1	1	0	1	1
12	3	1	4	4	1	5	7	2	9
13	0	0	0	0	1	1	0	1	1
14	1	5	6	1	6	7	2	11	13
15	1	5	6	1	5	6	2	10	12
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	1	1	0	1	1
28	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0
TOTAL	9	31	40	10	26	36	19	57	76

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

Pt ID	Reason
05-0002	Patient Incarcerated - lost to follow-up
05-0007	Patient Incarcerated - lost to follow-up
09-0004	Reason unknown - lost to follow-up
14-0001	Patient withdrawn due to non-compliance
12-0001	Patient moved - lost to follow-up
12-0004	Reason unknown - patient lost to follow-up
12-0007	Reason unknown - patient lost to follow-up
15-0005	Transportation issue - lost to follow-up
15-0008	Transportation issue - lost to follow-up
23-0002	Subject went to local orthopedist-lost to follow-up.
15-0004	Patient withdrawn(by the study team)
17-0002	Patient withdrawn(by the study team)

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

	Total Events	Patients	Total Enrolled	Rate
Treatment A	16	10	40	25.0 %
Open	3	2	9	22.2%
Closed	13	8	31	25.8%
Treatment B	14	9	36	25.0%
Open	3	2	10	20.0%
Closed	11	7	26	26.9%
Total	30	19	76	25.0%
Open	6	4	19	21.1%
Closed	24	15	57	26.3%

Table 4b: Adverse Event descriptions:

Pt #	FX Type	Treatment	Description	Related to Device?
3-0002	CLOSED	PLATE	Painful implant - plate	Definitely related
3-0002	CLOSED	PLATE	Hardware irritation	Definitely related
3-0004	CLOSED	PLATE	perforated bowel	Definitely not related
3-0004	CLOSED	PLATE	pulmonary embolism	Probably not related
3-0004	CLOSED	PLATE	Cardiovascular Arrhythmia	Definitely not related
3-0005	CLOSED	PLATE	Fractured implant plate	Definitely related
3-0006	CLOSED	NAIL	Painful Implant-Nail	Definitely related
3-0006	CLOSED	NAIL	Pulmonary Embolism	Definitely not related.
4-0001	OPEN	NAIL	Construct loosening - distal to femur	Definitely related
4-0001	OPEN	NAIL	Painful Implant Screw.	Definitely related
4-0002	CLOSED	NAIL	Decreased gastric motility	Definitely not related
4-0002	CLOSED	NAIL	Vitral hemorrhage	Definitely not related
5-0002	OPEN	NAIL	Painful implant - screw	Definitely related
5-0004	CLOSED	PLATE	Painful implant - plate	Definitely related
5-0005	CLOSED	NAIL	Leg Swelling	Definitely not related.
9-0001	CLOSED	PLATE	Neurological Deficit	Definitely not related
9-0001	CLOSED	PLATE	Urinary Tract Infection	Definitely not related
9-0002	CLOSED	NAIL	Left shoulder pain	Definitely not related
9-0002	CLOSED	NAIL	Abdominal hernia	Definitely not related
11-0001	CLOSED	PLATE	painful implant - screw & Arthrofibrosis	Definitely related
12-0001	OPEN	PLATE	Painful implant - plate, Arthrofibrosis	Possibly related
12-0001	OPEN	PLATE	Infection - deep, Non-union	Probably not related
15-0006	OPEN	PLATE	DVT	Definitely not related
15-0007	CLOSED	PLATE	DVT	Definitely not related
15-0009	CLOSED	NAIL	Open wound right heel, infected, retained suture	Definitely not related.
17-0001	CLOSED	NAIL	Contra lateral Knee TKA	Definitely not related
17-0001	CLOSED	NAIL	Painful implant - Nail	Definitely related
22-0001	CLOSED	NAIL	Painful implant - screw	Definitely related
23-0001	CLOSED	NAIL	Infection - deep	Possibly related
23-0001	CLOSED	NAIL	Infection - deep	Possibly related