

# MERCI Clinical Investigation

(Mechanical Embolus Removal in Cerebral Ischemia)

## Summary of Clinical Results to Date

### Panel Packet

**TABLE OF CONTENTS**

1	Regulatory History .....	3
2	Definitions .....	3
3	MERC Clinical Summary Overview .....	4
4	MERC Investigational Sites .....	5
5	MERC Clinical Results .....	7
5.1	Patient Demographics .....	8
5.2	Primary Endpoint .....	10
5.3	Secondary Endpoints .....	11
5.3.1	NIH Stroke Scale Score – 30 & 90 Days .....	14
5.3.2	Modified Rankin Score – 30 & 90 Days .....	15
6	Summary of Primary and Secondary Endpoints by Territory Treated .....	16
6.1	Middle Cerebral Artery .....	17
6.2	Internal Carotid Artery and Posterior Circulation Occlusions .....	17
7	Patient Screening/Enrollment .....	19
7.1	Patient Enrolled/Not Treated .....	20
7.2	Revascularization and Outcomes by Investigational Site .....	21
7.3	Device/Procedure-Related Serious Adverse Events .....	21
7.3.1	Device-Related Serious Adverse Events .....	21
7.3.2	Procedure-Related Adverse Events .....	22
7.3.3	Symptomatic Intracranial Hemorrhages .....	23
8	Anticipated and Unanticipated Serious Adverse Events .....	23
8.1	Anticipated Serious Adverse Events Leading to Death .....	24
8.2	Other Anticipated Serious Adverse Events .....	37
8.3	Unanticipated Adverse Events .....	41
9	Protocol Deviations .....	41
10	Device Complaints .....	42
11	Device Shipments .....	50
12	Risk/Benefit Analysis .....	50

**1 Regulatory History**

**Table 1** details the submission history for the Concentric MERCI Retriever. IDE G010059 was the original IDE and [REDACTED]. IDE G020163 was submitted specifically for [REDACTED]. During the September 2002 FDA meeting, FDA instructed Concentric to reference all supplements to G020163.

Table 1 Regulatory Submission History		
Submission	Reason	Approval Date
IDE G010059	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
IDE G020163	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]

**2 Definitions**

*Revascularization:* Restoration of blood flow to an area previously occluded.

*TIMI Flow:* Thrombolysis In Myocardial Infarction. A grading scale used to calculate percentage of revascularization. The following TIMI grading scale was used to assess blood flow:

- Grade 0: No perfusion.
- Grade I: Penetration with minimal perfusion.
- Grade II: Partial perfusion of the artery and its main branches (IIa < 50%; IIb ≥ 50%).
- Grade III: Complete perfusion of the artery and its main branches.

*Treatment Success:* Per the MERCI protocol, treatment success was defined as the achievement of revascularization in all of the major cerebral vessels immediately post MERCI Retriever treatment while minimizing the occurrence of serious device-related adverse events.

*Major Cerebral Vessels:* Per the MERCI protocol, these include the internal carotid artery, the middle cerebral artery (M1 and M2 segments), the basilar artery and the vertebral artery.

*Serious Device-Related Adverse Events:* Per the MERCI protocol, these are defined as target vessel perforation, target vessel intramural dissection, or significant embolization in a previously uninvolved arterial territory.

*Serious Adverse Event:* Any adverse event that met one of the following criteria was categorized as a “serious” adverse event.

1. Death
2. Life-threatening events resulting in extended hospitalization or death
3. Events which result in a permanent impairment of a body function or permanent damage to body structure
4. Events which necessitate medical or surgical intervention by a health care professional:
  - o to preclude permanent impairment of a body function or permanent damage to body structure;
  - o to relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure.

*NIH Stroke Scale (NIHSS):* A grading scale used to evaluate patients who have suffered a stroke. This scale measures the patients’ motor and neurological abilities.

*Modified Rankin Scale:* A quality of life scale used to evaluate patients who have suffered a stroke. This scale measures the patients’ ability to carry out daily tasks of living.

*Enrolled Patient:* In the MERCI Phase II protocol, a patient was considered enrolled in the trial when the Balloon Guide Catheter was inserted into the subject.

*Treated Patient:* A patient is considered treated when the Retriever is deployed into the target vessel.

*Device Complaint:* Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

### **3 MERCI Clinical Summary Overview**

The primary objective of this investigation was to determine whether the MERCI Retriever when used to retrieve neurovascular thrombus poses any additional risks to the patient as compared to other catheter-based interventions including foreign body retrieval with the predicate device, the Concentric Retriever. Specifically, the investigation examined whether the MERCI Retriever could safely access the treatment site, cross the thrombotic occlusion, retrieve the occlusive thrombus, and restore blood flow. The resulting primary endpoint for the study was as follows:

- Achievement of revascularization in all of the major cerebral vessels immediately post MERCI Retriever treatment while minimizing the occurrence of serious device-related adverse events. Serious device-related adverse events are defined as target vessel perforation, target vessel intramural dissection, or significant embolization in a previously uninvolved arterial territory.

The secondary endpoints for the study were as follows:

- Assessment of patient's neurological condition and functional state using the NIHSS score and Modified Rankin at 30 and 90 days post-procedure.
- A composite of major adverse events at 30 and 90 days post-procedure. Major adverse events are defined as death, stroke and myocardial infarction.

As of November 18, 2003, one hundred and forty four (144) patients have been enrolled in the MERCI investigational trial and one hundred and thirty seven patients (137) have been treated with the MERCI Retriever.

#### 4 MERCI Investigational Sites

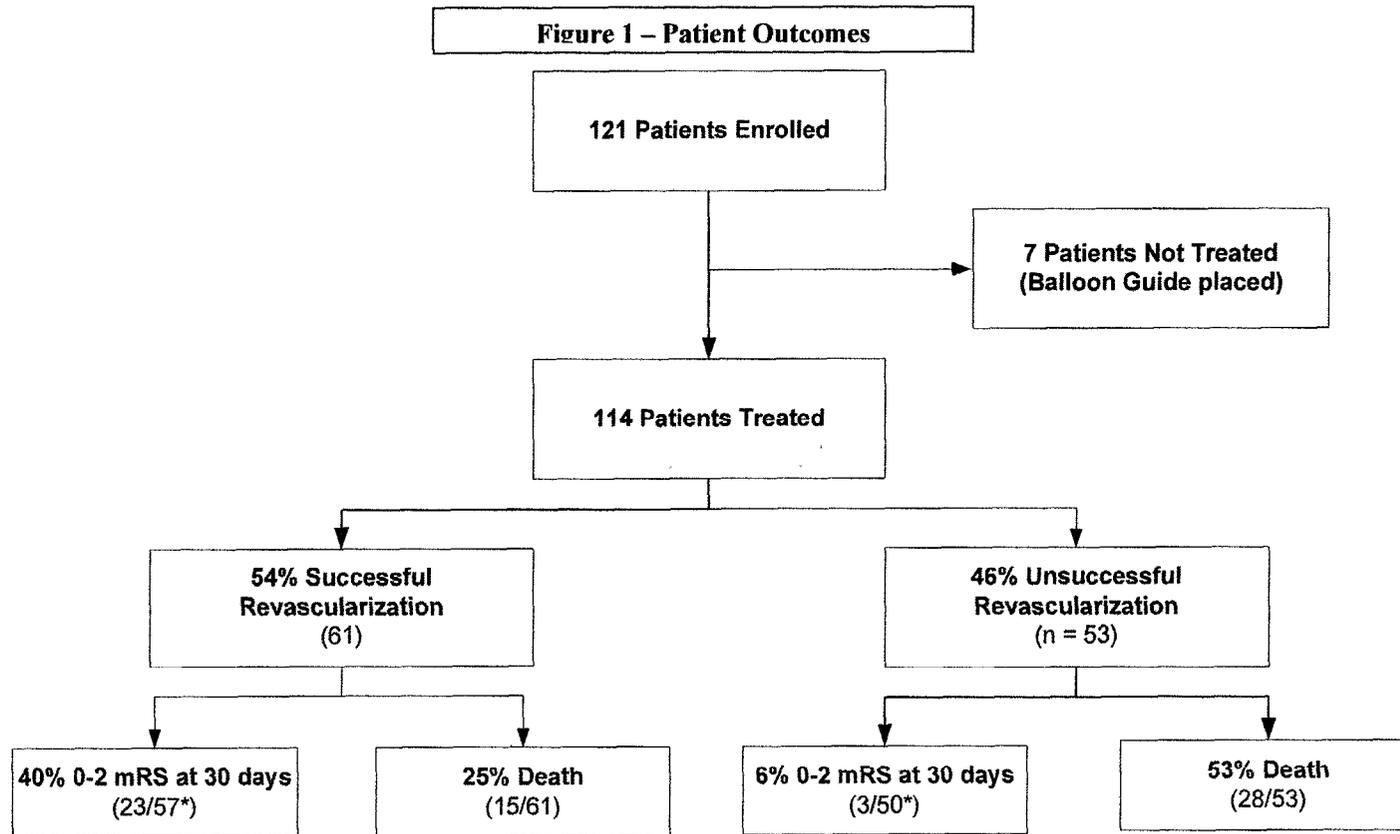
The MERCI investigational sites are listed in **Table 2**. With the exception of UCLA Medical Center, the following investigational sites have institutional review board approval and are eligible to enroll under the MERCI Phase II protocol. Patient enrollment at UCLA was discontinued after they reached the 25 patient pre-determined enrollment limits.

<b>Table 2</b> <b>Principal Investigator/Site</b>	
<b>Dr. Sidney Starkman</b> UCLA Medical Center 924 Westwood Blvd., Suite #300 Los Angeles, CA 90024	<b>Dr. Morgan Campbell</b> University of Texas, Houston 643 Fannin St., MSB 7.044 Houston TX 77030
<b>Dr. Randall Higashida</b> UCSF Medical Center 505 Parnassus Ave, L352 San Francisco, CA 94143	<b>Dr. Helmi Lutsep</b> University of Oregon 3191 SW Jackson Park Road, L104 Portland OR 97201
<b>Dr. Sten Solander</b> University of North Carolina— Chapel Hill Dept. of Neurology 3114 Bioinformatics Building Chapel Hill, NC 27516	<b>Dr. L. Nelson Hopkins</b> State University of New York at Buffalo Department of Neurosurgery 3 Gates Circle Buffalo NY 14209
<b>Dr. Alan Segal</b> Associate Professor of Neurology NY Presbyterian Hospital – Cornell 525 E 68th St F610 New York, NY 10021	<b>Dr. Claudio Schonholz</b> Louisiana State University at Shreveport 1501 Kings Highway, Rm. 6-331 Shreveport, LA 71103
<b>Dr. Thomas Grobelny</b> Saint Luke's Hospital 4401 Wornall Road Kansas City, MO 64111	<b>Dr. John Jacobs</b> Latter-Day Saints Hospital Department of Cardiology 8 <sup>th</sup> Ave and C-Street Salt Lake City, UT 84143

<b>Table 2</b>	
<b>Principal Investigator/Site</b>	
<b>Walter Koroshetz, MD</b> Mass General Hospital/Brigham & Women's Hospital Gray / Bigelow 289 55 Fruit Street Boston, MA 02114	<b>Dr. Ronald Budzik</b> Riverside Methodist Hospital 3535 Olentangy River Road, Suite 2050 Columbus OH 43214
<b>Dr. Michael Marks</b> Stanford Medical Center Dept. of Radiology, Room S-047 Stanford, CA 94305-5105	<b>Dr. Joseph Bernard</b> Carolina Neurosurgery & Spine 1010 Edgehill Road North Charlotte NC 28207
<b>Dr. Vance Watson</b> Georgetown University 3800 Reservoir Road, Rm. C-G201 Washington DC 20007	<b>Dr. Frank Huang-Hellinger</b> Florida Hospital Neuroscience Institute 2501 North Orange Avenue Orlando, FL 32804
<b>Dr. Albert Alexander</b> Baton Rouge General Hospital 7373 Perkins Road Baton Rouge, LA 70808	<b>Dr. Paul Katz</b> Washoe Medical Center 77 Pringle Way Reno, NV 89502
<b>Dr. Isaac Silverman</b> Hartford Hospital 85 Seymour St., Suite 800 Hartford, CT 06106	<b>Dr. John Pile-Spellman</b> NY Presbyterian Cornell & Columbia 177 Fort Washington Ave. Milstein, Bldg 8-SK New York, NY 10032
<b>Dr. James Frey</b> Barrow Neurological Institute 222 West Thomas St., Suite 404 Phoenix AZ 85013	<b>Dr. David Liebeskind</b> University of Pennsylvania Department of Neurology 3 West Geates Building 3400 Spruce Street Philadelphia, PA 19104
<b>Dr. Joanne Stallmeyer</b> University of Maryland Dept. of Diagnostic Radiology 22 South Greene St. Baltimore MD 21201	<b>Dr. John Barr</b> Baptist Memorial Clinical Research Center 6025 Walnut Grove Rd Ste 100 Memphis, TN 38120

**5 MERCI Clinical Results**

The data presented herein reflects a total of 114 patients with acute data, 107 patients with 30-day follow-up and 70 patients with 90-day follow-up. The remaining patients were enrolled recently and the complete data sets are not yet available. Seven (7) patients were excluded from the data analysis, as the MERCI Retriever was not deployed in the target vessel. Circumstances for non-treatment are detailed in the Patient Enrollment section. Details of patient outcomes following treatment with the MERCI Retriever are provided in **Figure 1**.



\* mRS scores available on 107 of 114 patients treated

**Table 3** provides an overview of the primary and secondary endpoint results for the MERCI patient cohort.

Successful Revascularization	54% (61/114)
Serious Device-Related Adverse Events	3.5% (4/114)
Major Adverse Events (MI, Stroke, Death)	46% (52/114)
≥ 10 point Improvement in NIHSS at 30 days	37% (38/102)
≥ 10 point Improvement in NIHSS at 90 days	24% (15/62)
Modified Rankin ≤ 2 at 30 days	24% (26/107)
Modified Rankin ≤ 2 at 90 days	24% (17/70)
Overall Mortality Rate	38% (43/114)
Post procedure through 30 days	37% (42/114)

In seventeen patients where the MERCI Retriever was unsuccessful in restoring flow, ten (10) patients were successfully treated with another therapy increasing the procedural success rate from 54% (61/114) to 62% (71/114). Eight (8) patients were revascularized with intra-arterial thrombolysis and two (2) were revascularized with mechanical embolectomy.

### 5.1 Patient Demographics

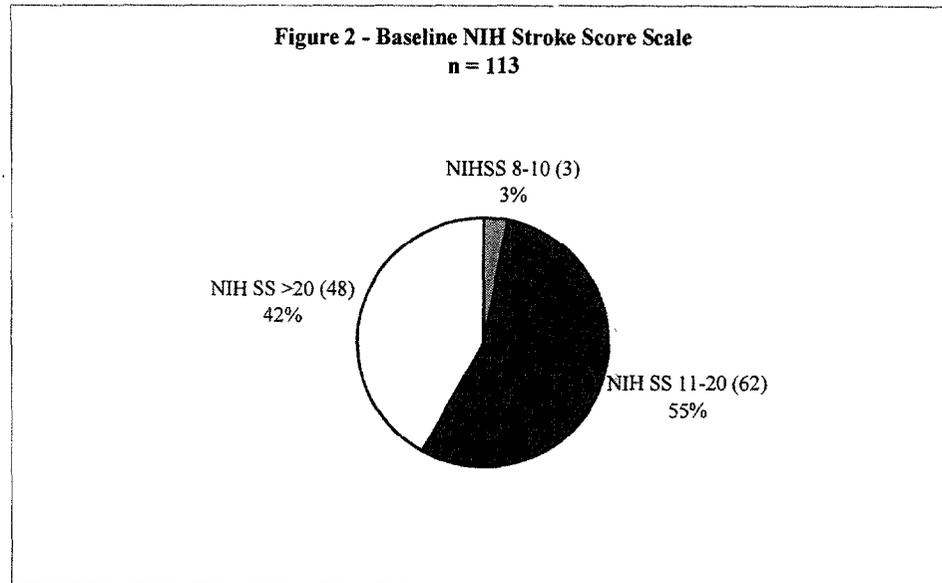
During pretreatment assessment, medical history and history of stroke were recorded. Per the MERCI clinical protocol, patients presenting within 8 hours of symptom onset were eligible for treatment. Patients presenting within 3 hours of symptom onset could be enrolled if they were contraindicated for IV thrombolysis (t-PA). **Table 4** summarizes the demographics and time to treatment for the MERCI patient cohort.

<b>Table 4</b>		
<b>Patient Demographics (n=114)</b>		
<i>Characteristic</i>		
Female		46% (52)
Age	Median	70
	Range	28 – 93
Baseline NIHSS Score*	Median	19
	Range	9 – 40
Time to Treatment		
Symptom onset to groin puncture	Median:	4.0 hours
	Range:	20 minutes – 9.5 hours
Symptom onset to final angiogram	Median:	6.1 hours
	Range:	2.0 – 16.4 hours
	Median procedure time	1.8 hours

\*Pre-NIHSS was not reported in one patient

In one patient the MERCI Retriever procedure was initiated within 8 hours and treatment was completed beyond 8 hours. One additional patient presented beyond the 8 hours but MR diffusion/perfusion weighted imaging showed a significant mismatch between the infarct territory and the penumbra and, in the physician's opinion, was a good candidate for treatment. This patient is detailed in the Protocol Deviation section.

**Figure 2** details the distribution of patients based on the presenting NIH Stroke Scale Score. Baseline NIH Stroke Scale data are available on 113 patients. In one patient the presenting NIH Stroke Scale Score was not recorded on the CRF. For all patients, the NIHSS Score met the 8-point minimum requirement established in the MERCI Phase II protocol.



## 5.2 Primary Endpoint

The primary endpoint for the study was as follows:

- Achievement of revascularization in all of the major cerebral vessels immediately post MERCİ Retriever treatment while minimizing the occurrence of serious device-related adverse events. Serious device-related adverse events are defined as target vessel perforation, target vessel intramural dissection, or significant embolization in a previously uninvolved arterial territory.

Achievement of revascularization (successful revascularization) was based on data recorded on the vessel patency case report form and the TIMI Score recorded by the operating physician. In order for a procedure to be successful, flow had to be restored with the MERCİ Retriever alone in all of the major cerebral vessels within the target territory (i.e., anterior circulation: ICA, MCA – M1/M2 segments; posterior circulation: basilar and vertebral). Serious device-related adverse events were defined as intramural dissection, vessel perforation or embolization of a previous uninvolved territory. Each serious device-related adverse event was reviewed and adjudicated by the Data Safety Monitoring Board (DSMB).

The MERCİ Phase II protocol states that the successful revascularization rate for the MERCİ Retriever must be statistically different than the 18% revascularization rate experienced by the placebo group in the PROACT II study. Restoration of flow in all of the major vessels was achieved in 54% (61/114) of the patients treated. The probability (i.e., p-value) for a study with 114 patients having 61 or more "successes" given the underlying probability of an 18% success rate is < 0.0001<sup>1</sup>.

In addition, the MERCİ Phase II protocol states that the data must show a minimum revascularization rate of 30% as stated in the MERCİ protocol. The probability (i.e., p-value) for a study with 114 patients having 61 or more "successes" given the underlying probability of a 30% success rate is < 0.0001<sup>1</sup>.

<sup>1</sup> Exact Binomial Test

In seventeen patients where the MERCI Retriever was unsuccessful in restoring flow, ten (10) patients were successfully treated with another therapy increasing the procedural success rate from 54% (61/114) to 62% (71/114). Eight (8) patients were revascularized with intra-arterial thrombolysis and two (2) were revascularized with mechanical embolectomy.

### 5.3 Secondary Endpoints

The secondary endpoints for the Phase II study were patient outcomes, specifically major adverse events and neurological status at 30 days and 90 days. Per the MERCI protocol, patients were followed for 30 and 90 days post treatment and patient neurological condition was assessed using the Modified Rankin and the NIH Stroke Scale Score (NIHSS). The MERCI Phase I protocol did not require patients to be followed beyond 30 days post treatment. The majority of the Phase I investigational sites have obtained patient status for those patients surviving beyond the 30 day follow-up. Patients who died prior to their follow up assessment were given a modified Rankin Score of 6 and NIH Stroke Scale Score of 42.

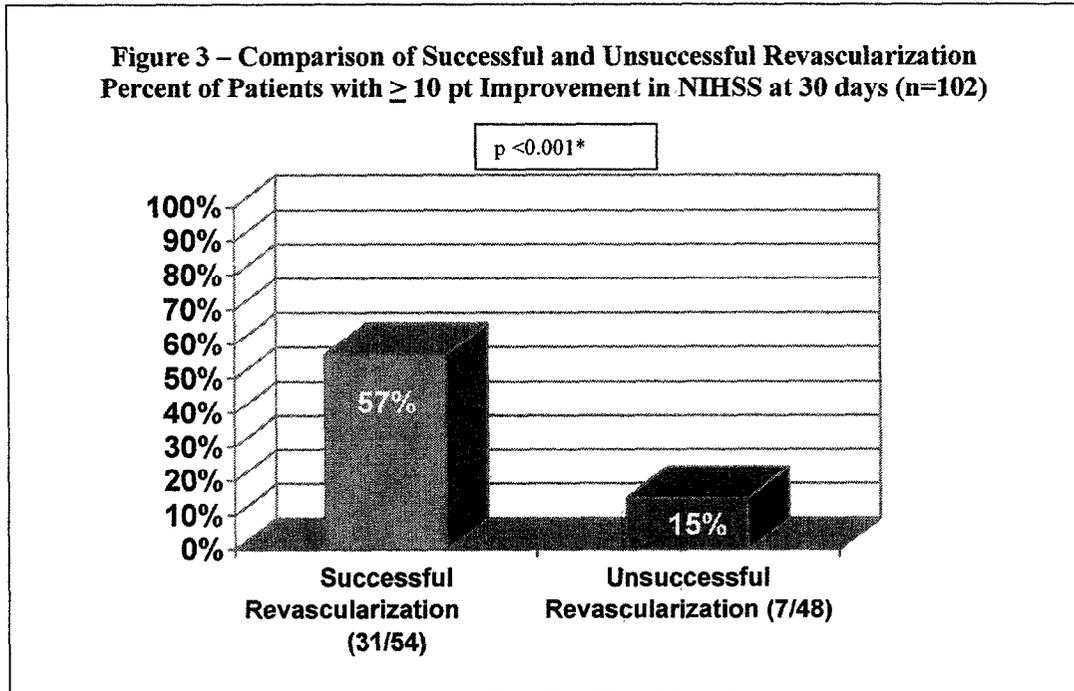
At 30 days, NIH Stroke Scale data are available on 103 patients and Modified Rankin data are available on 107 patients. In 112 patients assessed at 30 days at least one neurological test was available. Seventy (70) patients reached the 90-day follow up interval and were reported. NIH Stroke Scale data are available on 63 patients and Modified Rankin data are available on 70 patients at 90 days. **Table 5** compares the neurological outcome of successfully revascularized patients to unsuccessfully revascularized patients.

Table 5 Patient Outcome Secondary Endpoints at 30 & 90 days		
Secondary Endpoint	Successfully Revascularized Patients†	Unsuccessfully Revascularized Patients±
<u>30 day:</u> ≥10 pt. improvement in NIHSS	57% (31/54)	15% (7/48)
Modified Rankin Score ≤2	40% (23/57)	6% (3/50)
<u>90 day:</u> ≥10 pt. improvement in NIHSS	44% (12/27)	9% (3/35)
Modified Rankin Score ≤2	52% (16/31)	3% (1/39)
Overall Mortality Rate (through 90 days)	25% (15/61)	53% (28/53)

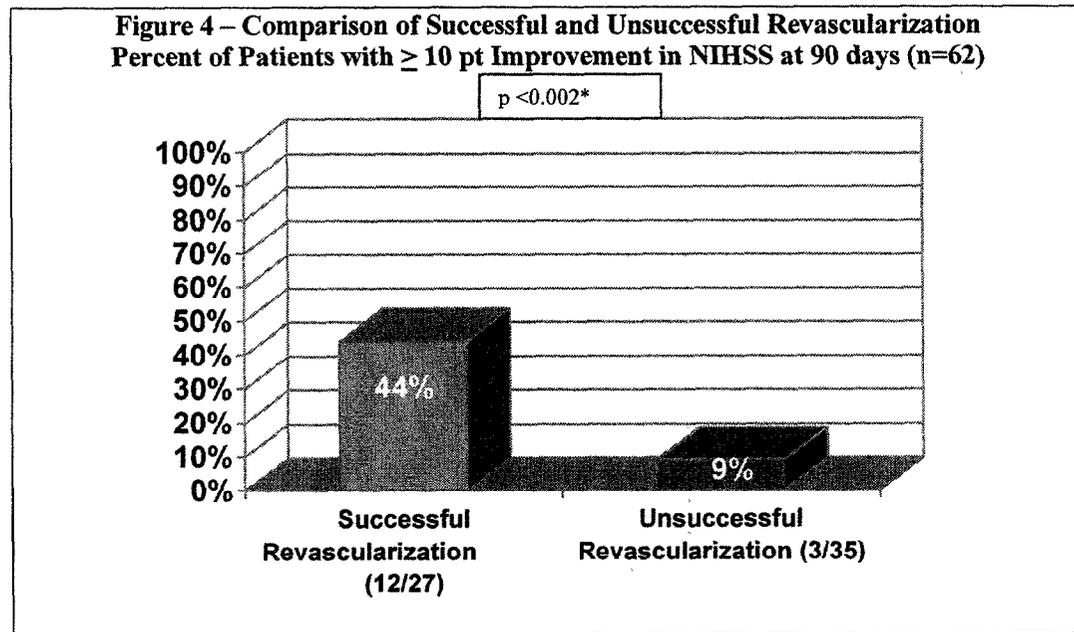
†Includes patients who received some thrombolysis post successful treatment with Retriever.

± Includes patients successfully revascularized with adjunctive therapy following failed treatment with Retriever.

**Figure 3** and **Figure 4** compares the NIH Stroke Scale Scores of patients who were successfully revascularized to patients who were not revascularized. Specific p-values have been provided for each group.



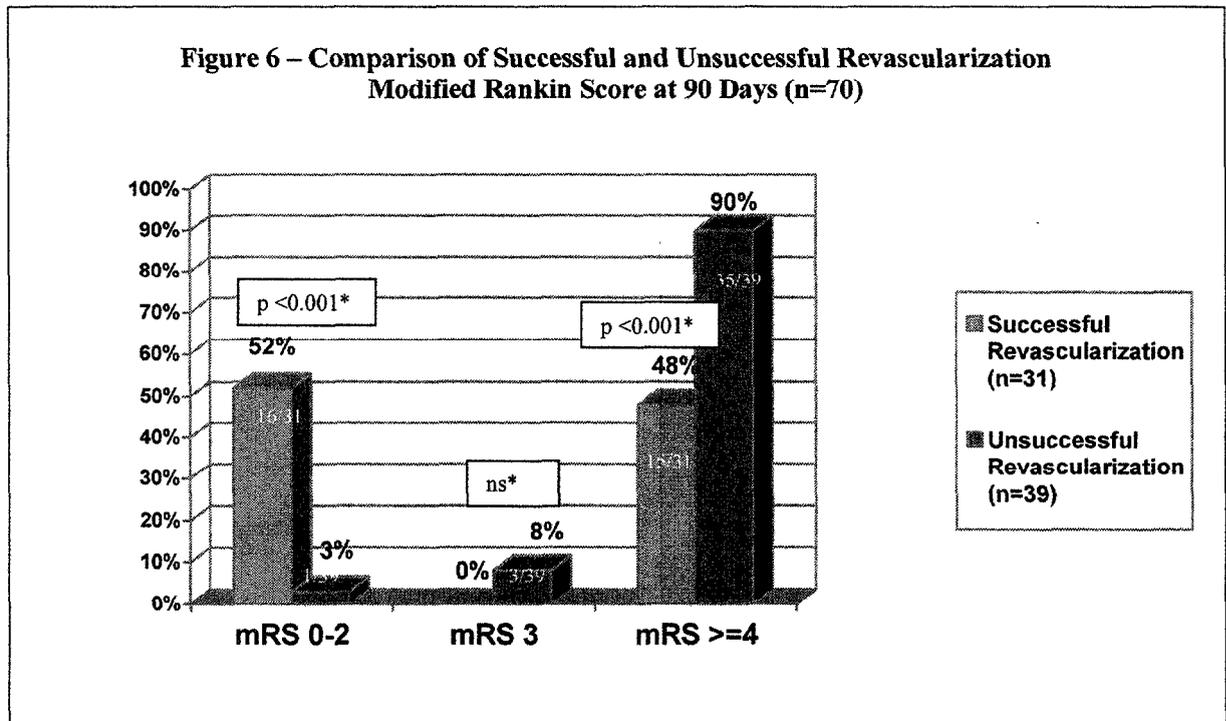
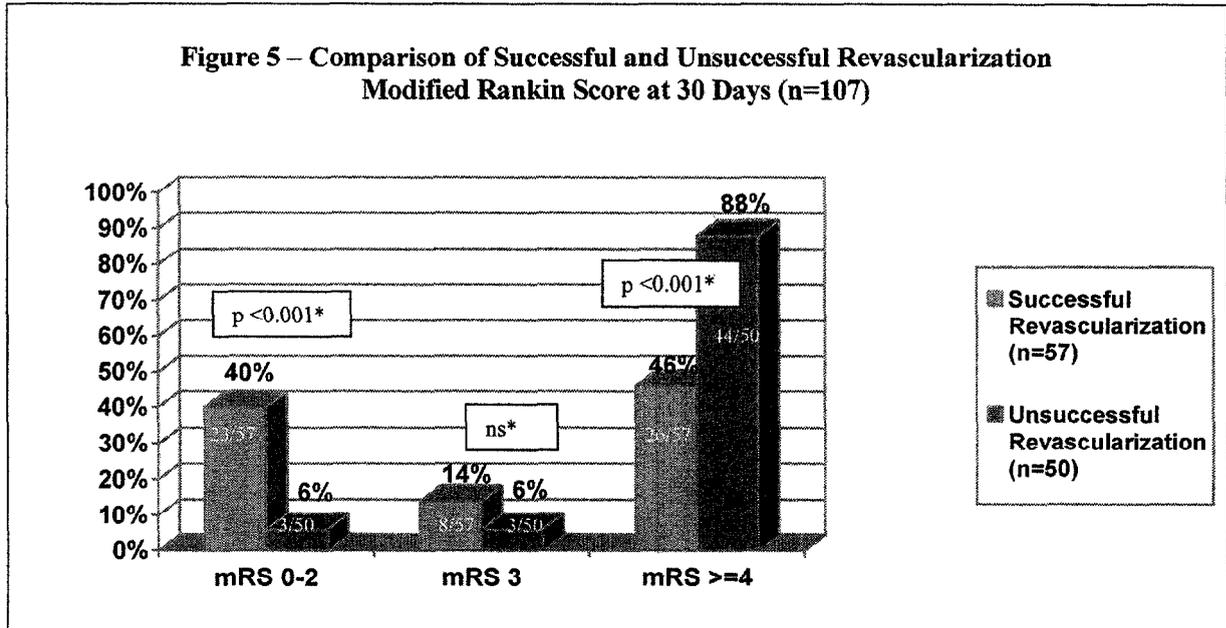
\* Fisher's Exact Test.



\* Fisher's Exact Test.

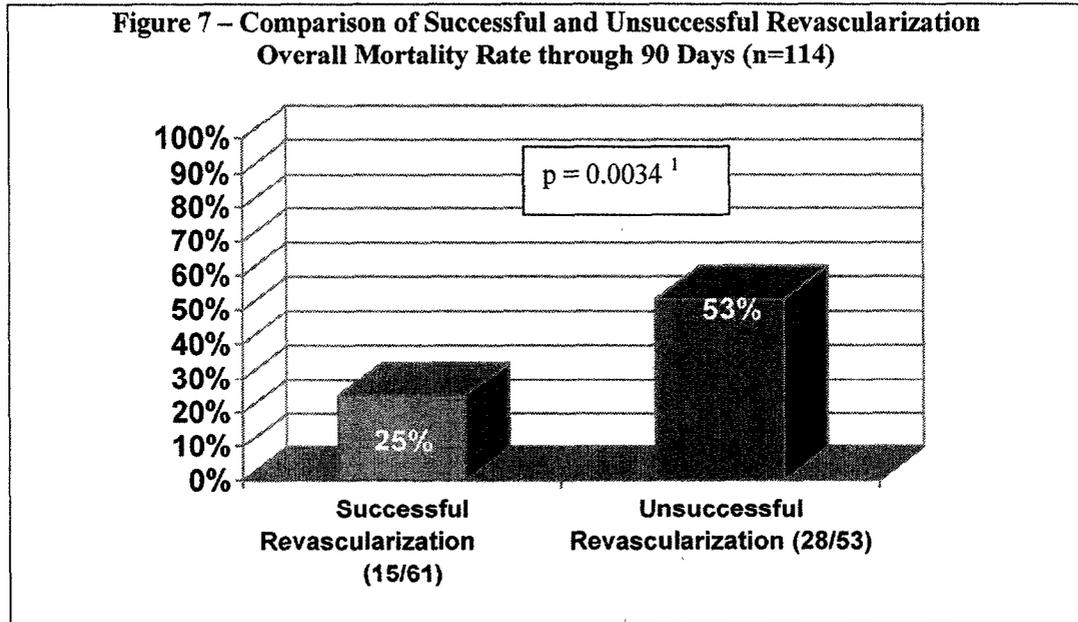
At both 30 and 90 day follow up intervals, the clinical data demonstrate that revascularized patients experienced a statistically significant difference in NIH Stroke Scale Score improvement when compared to patients who were not successfully revascularized with the MERCI Retriever.

Similarly, at 30 and 90 days there is a statistically significant difference in Modified Rankin Scores when comparing patients who were successfully revascularized to those patients who were not. Refer to **Figure 5** and **Figure 6** for graphical representations and specific p values.



In patients where the MERCi Retriever was successful in restoring TIMI II/III blood flow, the mortality rate was statistically less than those patients where restoration of flow was not

achieved. **Figure 7** compares the mortality rate through 90 days in patients who were successfully revascularized with the Retriever alone and patients who were not revascularized.



At both the 30 and 90 day follow up intervals, the clinical data demonstrate that revascularized patients experienced a statistically significant difference in clinical outcomes (NIHSS Score, Modified Rankin, and mortality) when compared to patients who were not successfully revascularized with the MERCI Retriever.

5.3.1 NIH Stroke Scale Score – 30 & 90 Days

**Table 6** and **Table 7** compare revascularized patients and non-revascularized patients by pre-treatment NIH Stroke Scale Score at 30 and 90 days. For the 30 day follow up, 103 patients had NIH Stroke Scale Scores available. One patient was excluded from the following analysis as the baseline NIHSS score was not recorded.

Baseline NIHSS	Successfully Revascularized† (n = 54)		Unsuccessfully Revascularized± (n = 48)	
	Number of Patients	≥ 10pt improvement over Pre-NIHSS	Number of Patients	≥ 10pt improvement over Pre-NIHSS
8-10	2	100% (2)	0	0%
11-20	29	52% (15)	27	15% (4)
>20	23	61% (14)	21	14% (3)

Baseline NIHSS	Successfully Revascularized† (n = 27)		Unsuccessfully Revascularized± (n = 35)	
	Number of Patients	≥ 10pt improvement over Pre-NIHSS	Number of Patients	≥ 10pt improvement over Pre-NIHSS
8-10	1	100% (1)	-	-
11-20	14	43% (6)	17	6% (1)
>20	12	42% (5)	18	11% (2)

†Includes patients who received some thrombolysis post successful treatment with Retriever.

± Includes patients successfully revascularized with adjunctive therapy following failed treatment with Retriever.

### 5.3.2 Modified Rankin Score – 30 & 90 Days

An overview of Modified Rankin Score for all patients treated with Retriever is provided in **Table 8**. The 30 and 90-day data include all reported patient deaths. Patient deaths were recorded as “Modified Rankin Score 6.” Modified Rankin Scores are available on 107 patients at 30 days and 70 patients at 90 days.

Modified Rankin Score	30 Days (n=107)	90 Days (n=70)
0 – 2	24% (26)	24% (17)
3	10% (11)	4% (3)
≥4	65% (70)	71% (50)

When the Retriever was successful in restoring TIMI II or TIMI III blood flow, 40% of the patients achieved a Modified Rankin score of less than or equal to 2 at 30 days.

In patients where the Retriever was unsuccessful in achieving at least TIMI II Flow, 6% of the patients achieved a Modified Rankin Score of less than or equal to 2 at 30 days. In patients where successful revascularization with the Retriever was not achieved, a statistically significant number of patients (90% versus 48%,  $p < 0.001$ ) had a poor outcome ( $mRS \geq 4$ ) at 90 days – refer to Figures 5 and 6.

**Table 9** and **Table 10** compare patient outcomes at 30 (106) and 90 days (69) by stroke severity and whether the patient was successfully treated with the Retriever. The baseline NIHSS Score was not reported on one patient. Patients who were not successfully revascularized with the Retriever and continued on to adjunctive therapy were included in the “Unsuccessfully Revascularized” group.

<b>Table 9</b> <b>Modified Rankin Score at 30 Days</b> <b>Stroke Severity vs. Successful Revascularization</b>				
<b>Baseline NIHSS</b>	<b>Successfully Revascularized† (n=56)</b>		<b>Unsuccessfully Revascularized± (n=50)</b>	
	<b>Number of Patients</b>	<b>mRS<sub>≤2</sub></b>	<b>Number of Patients</b>	<b>mRS<sub>≤2</sub></b>
8-10	2	100% (2)	-	-
11-20	31	48% (15)	27	11% (3)
>20	23	26% (6)	23	0% (0)

<b>Table 10</b> <b>Modified Rankin Score at 90 Days</b> <b>Stroke Severity vs. Successful Revascularization</b>				
<b>Baseline NIHSS</b>	<b>Successfully Revascularized† (n=30)</b>		<b>Unsuccessfully Revascularized± (n=39)</b>	
	<b>Number of Patients</b>	<b>mRS<sub>≤2</sub></b>	<b>Number of Patients</b>	<b>mRS<sub>≤2</sub></b>
8-10	2	100%(2)	1	0%(0)
11-20	16	56% (9)	18	6% (1)
>20	12	42% (5)	20	0% (0)

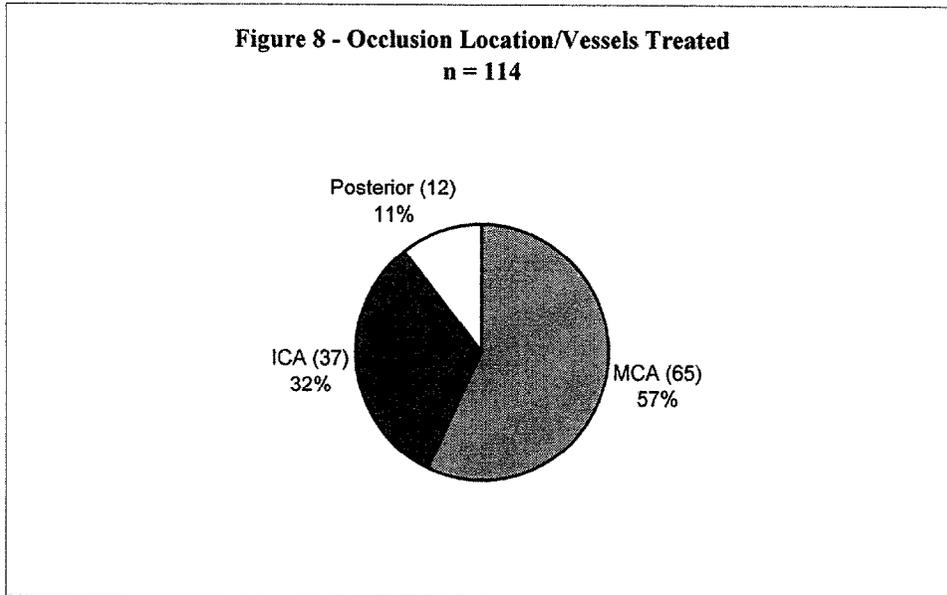
†Includes patients who received some thrombolysis post successful treatment with Retriever.

± Includes patients successfully revascularized with adjunctive therapy following failed treatment with Retriever.

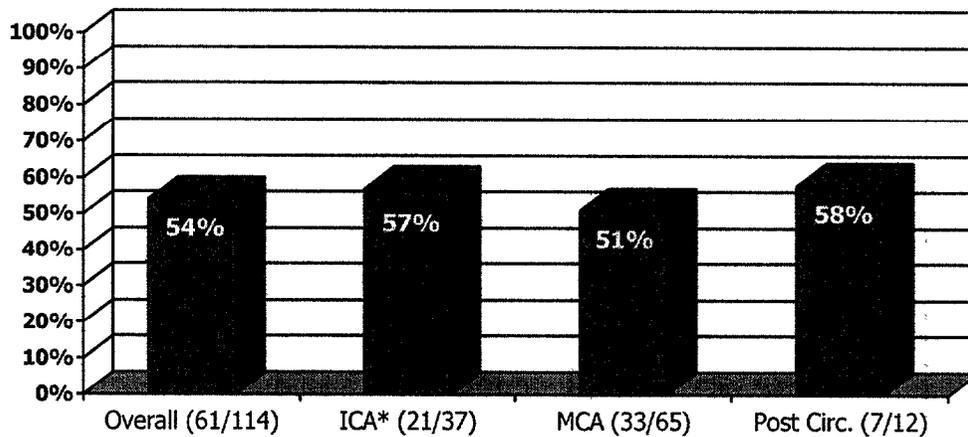
## 6 Summary of Primary and Secondary Endpoints by Territory Treated

The treatable vessels per the MERCI Phase II protocol included the middle cerebral artery (M1/M2 segments), the internal carotid artery, basilar, and vertebral artery. The following data detail the performance of the MERCI Retriever and compare the patient outcomes by vessel treated.

**Figure 8** shows the breakdown of vessels treated under the MERCI protocol. **Figure 9** details the rate of revascularization with the MERCI Retriever alone by neurovascular territory.



**Figure 9 – Successful Revascularization Rate with the Retriever Alone by Territory (n = 114)**



\* ICA and ICA T (ICA/MCA) occlusions were combined into the ICA group.

**6.1 Middle Cerebral Artery**

The acute data presented herein reflect a total of 65 patients presenting with occlusion of the M1 and/or M2 segment of the Middle Cerebral Artery (MCA). Thirty-day NIH Stroke Scale (NIHSS) follow up is available on fifty-seven (57) patients and 90-day NIHSS follow up is available on thirty-one (31) patients. Thirty-day Modified Rankin follow up is available on fifty-eight (58) patients and 90-day Modified Rankin follow up is available on thirty-five (35) patients. Overall the procedural success rate with the MERCI Retriever alone in Middle Cerebral Artery occlusions was 51% (33/65). **Table 11** provides an overview of the patient demographics by vessel treated.

**6.2 Internal Carotid Artery and Posterior Circulation Occlusions**

In the MERCI Trial, 37 patients presented with occlusion of the Internal Carotid Artery or ICA “T” which includes occlusion of both the ICA and MCA. Acute data is available on all 37

patients. Thirty day NIH Stroke Scale (NIHSS) follow up is available on thirty-four (34) patients and 90-day NIHSS follow-up is available on twenty six (26) patients.

Overall the procedural success rate with the MERCİ Retriever alone in Internal Carotid Artery occlusions was 57% (21/37) and in Posterior Artery occlusions was 58% (7/12). **Table 11** provides an overview of the demographics of patients by vessel treated.

<i>Characteristic</i>	ICA/ICA T (n=37)	Basilar/Vertebral (n=12)	Middle Cerebral (n=65)
Female	46% (17)	17% (2)	51% (33)
Age:			
Median	73	55	72
Range	32 to 93	31 to 86	28-91
Baseline NIHSS Score			
Median	19	29	19
Range	12 to 26	10 to 39	9 – 40
Time to Treatment:			
Symptom onset to groin puncture			
Median:	4.0 hours	4.2 hours	4.0 hours
Range:	1.0 – 9.5 hours	0.3 – 6.0 hours	1.0 – 7.5
Symptom onset to final angiogram			
Median:	6.0 hrs	5.8 hrs	6.1 hours
Range:	2.9 – 9.6 hours	2.6 – 8.9 hours	2.0 – 9.6 hours
Median procedure time	2.1 hours	1.5 hours	1.6 hours

**Table 12** provides an overview of safety and effectiveness of the MERCİ Retriever in occlusions located in the middle cerebral artery, internal carotid artery and posterior circulation.

	ICA	Posterior	MCA
Successful Revascularization	57% (21/37)	58% (7/12)	51% (33/65)
Serious Device-Related Adverse Events	3% (1/37)	0% (0/12)	5% (3/65)
Symptomatic Hemorrhage within 24 hours	14% (5/37)	0% (0/12)	6% (4/65)
Mortality Rate through 90 days	46% (17/37)	42% (5/12)	32% (21/65)

	<b>ICA</b>	<b>Posterior</b>	<b>MCA</b>
≥ 10 point Improvement in NIHSS at 30 days	32% (11/34)	55% (6/11)	37% (21/57)
Modified Rankin ≤ 2 at 30 days	27% (10/37)	17% (2/12)	24% (14/58)

**7 Patient Screening/Enrollment**

**Table 13** provides an overview of the number of patients screened, enrolled, and treated at each investigational site.

<b>Site</b>	<b>Patients Screened</b>	<b>Patients Treated</b>
A	■	■
B	■	■
C	■	■
D	■	■
E	■	■
F	■	■
G	■	■
H	■	■
I	■	■
J	■	■
K	■	■
L	■	■
M	■	■
N	■	■
O	■	■
P	■	■
Q	■	■
R	■	■
S	■	■
T	■	■
U	■	■
V	■	■
W	■	■

Table 13 Patient Enrollment by Investigational Site		
Site	Patients Screened	Patients Treated
X	■	■
Y	■	■
Total	■	■

**7.1 Patient Enrolled/Not Treated**

A patient is considered “Treated” only when the MERCI Retriever has been advanced through the microcatheter and deployed into the target vessel. A patient was considered enrolled when the Balloon Guide Catheter was inserted into the patient. **Table 14** details the reason for exclusion for each patient enrolled/not treated.

Table 14 Patients Enrolled/Not Treated	
Unable to access occlusion with guidewire/microcatheter	■
Unable to place Balloon Guide	■
Unable to advance Retriever through microcatheter	■
Vessel spontaneously recanalized	■
Occlusion located in a non treatable vessel	■
Total	■

During the September 2003 FDA/Concentric Meeting, FDA inquired about the number of patients who met the clinical enrollment criteria and were excluded at the time of angiography. This information was collected on the patient-screening log and has been provided in **Table 15**.

Table 15 Patients Excluded at Time of Angiogram	
Occlusion located in a non treatable vessel	■
Too tortuous anatomy	■
Proximal stenosis	■
Vessel spontaneously recanalized	■
Total	■

The performance by individual investigational site that treated at least one patient is detailed in **Table 16**.

**7.2 Revascularization and Outcomes by Investigational Site**

**Table 16**  
**Successful Revascularization/Mortality by Investigational Site**

Site	Patients Treated	Successful Revascularization	Mortality Through 30 Days
A	■	■■■■■	■■■■■
B	■	■■■■■	■■■■■
C	■	■	■
D	■	■■■■■	■■■■■
E	■	■■■■■	■■■■■
F	■	■■■■■	■■■■■
G	■	■■■■■	■■■■■
H	■	■	■
I	■	■■■■■	■■■■■
J	■	■■■■■	■■■■■
K	■	■	■■■■■
L	■	■■■■■	■
M	■	■■■■■	■■■■■
N	■	■	■
O	■	■■■■■	■
P	■	■■■■■	■
Q	■	■■■■■	■■■■■

**7.3 Device/Procedure-Related Serious Adverse Events**

**7.3.1 Device-Related Serious Adverse Events**

Per the MERCI Phase II protocol, the investigator categorized all serious adverse events as: “Definitely Device-related”; “Probably Device-related”; “Possibly Device-related”; “Unlikely Related to the Device”.

In this data set, there have been four device-related adverse events. Two patients (02-003, 04-015) experienced hemorrhage categorized by the investigator as “possibly” related to the device and two patients (04-008, 05-020) had embolization in a previously uninvolved territory.

During the procedure for patient 02-003, the physician deployed the MERCI Retriever X5 around a firmly impacted thrombus in the M1 segment of the middle cerebral artery. Upon system withdrawal, he felt significant resistance followed by no resistance. Angiography confirmed the tip of the Retriever had detached. The physician was successful at retrieving the tip of the device after several attempts with different devices. The physician then dilated

the segment using an angioplasty catheter to improve flow. The post-treatment CT showed contrast extravasations in the MCA region, most likely a result of the multiple devices introduced into the vessel to retrieve the broken tip. The physician categorized the event as possibly related to the device. The Data Safety Monitoring Board concurred with the investigator's findings and recommended that no other mechanical devices be used in conjunction with the MERCI Retriever.

During the procedure for patient 04-015, the physician made the first two passes in the ICA to retrieve the large occlusion. The angiogram performed after the second pass revealed a patent ICA with an occluded MCA. The third pass was performed into the MCA using the same X6 device. The physician engaged the clot and felt significant resistance when he tried to pull back on the MERCI Retriever. He attempted to re-sheath the Retriever with the microcatheter, but was unable to pass the microcatheter beyond the proximal loop of the MERCI Retriever. The physician pulled on the device, and the tip detached. He re-crossed the clot with the microcatheter/guidewire with the intent to retrieve the device tip. He removed the guidewire and performed a dye injection. The dye injection revealed a small amount of contrast extravasation, indicative of a small dissection in the vessel. The physician decided to stop all interventions at this point and left the tip of the device in the patient. The patient's post procedure condition was the same as the pre-procedure condition. The post procedure hospital course and death has been detailed in **Table 17**.

Two patients experienced embolization of a previously uninvolved territory. Both patients presented with an occlusion of the M1 segment of the MCA territory. Patient 04-008 had thrombus embolized into a previously uninvolved territory. During the procedure, the MERCI Retriever was successfully deployed as per the protocol and was successful at removing a large amount of intraluminal thrombus within the left MCA. During the retrieval of thrombus, an embolus to the ipsilateral anterior cerebral artery was experienced, with subsequent occlusion in the A2 segment and distal branches. Thrombolysis using tPA was performed within the ACA distribution in an attempt to restore flow, but this was unsuccessful.

Patient 05020 was treated initially with the MERCI Retriever X6 without success. After three passes with the MERCI Retriever X6, the physician deployed 2 MERCI Retrievers simultaneously in the MCA segment and succeeded in achieving TIMI III Flow. During the final angiogram, flow to the A2 segment of the Anterior Cerebral Artery had been reduced to TIMI IIB flow and on subsequent filming the A2 segment was occluded. Approximately 24 hours post treatment, the patient experienced a petechial hemorrhage in the right basal ganglia/caudate. No significant mass effect from the hemorrhage was observed and the hemorrhage was categorized by the DSMB as asymptomatic. During this timeframe the patient did experience an increase in NIH Stroke Scale Score from 13 to 20. By day 5, the patient's neurological status improved to an NIH Stroke Scale Score of 16. At 30 days, the patient's NIH Stroke Scale Score was 15.

The Data Safety Monitoring Board determined the event was procedure related because the complication could have happened with any type of interventional procedure and is not specifically related to the MERCI Retriever. However, because embolization in a previously uninvolved territory is delineated in the MERCI Phase II protocol as being a device-related adverse event, both events are categorized as such.

### *7.3.2 Procedure-Related Adverse Events*

Per the DSMB, to date there have been thirteen (13) procedure-related adverse events. Eleven (11) of the thirteen events were categorized as "Severe" or "Life Threatening"

Adverse Events.” The remaining 2 procedure-related adverse events were categorized as “mild” or “moderate”.

Two (2) patients (04-007, 06-006) experienced vessel dissection potentially involving the balloon guide catheter. Patient 04-007 had severely tortuous anatomy, which the physician identified as the root cause of the complication. Patient 06-006 experienced vessel spasm during the procedure, which the physician identified as the most likely cause of the complication. An investigation was performed on the one device that was returned to the Sponsor (patient 06-006) and it was found to meet established specifications. Both patients are detailed in **Table 17** and **Table 18**.

Five (5) patients (01-015, 04-012, 05-011, 05-019, 06-001) experienced hematomas post-procedure. Patients 04-012, 05-019 and 06-001 were characterized by the investigator as “Severe” and are detailed in **Table 17** and **Table 18**. Patient 01-015 had a moderate hematoma, which was successfully treated by evacuation. Patient 05-011 had a mild hematoma and was given acetaminophen for the pain and the hematoma resolved prior to discharge.

Four (4) patients (02-006, 04-010, 05-010, 08-001) experienced symptomatic intracranial hemorrhages within 24 hours that were adjudicated by the Data Safety Monitoring Board (DSMB) as procedure related. In three of these patients, adjunctive therapy had been used following unsuccessful revascularization with the Retriever.

Two (2) patients (02-004, 06-005) experienced asymptomatic hemorrhages that were adjudicated by the DSMB as “Procedure-Related.” Both patients were unsuccessfully treated with the MERCİ Retriever and received intra-arterial thrombolytic therapy. The DSMB adjudicated both adverse events as “Procedure Related”. Patient 02-004 has been detailed in **Table 17** and patient 06-005 has been detailed in **Table 18**.

### 7.3.3 Symptomatic Intracranial Hemorrhages

Overall, nine patients (8%) experienced a symptomatic (“Major”) intracranial hemorrhage within 24 hours of the procedure (02-006, 04-010, 05-010, 08-001, 02-003, 04-015, 05-008, 11-001, 11-002). As previously stated, two (2) were adjudicated by the DSMB as device related, four (4) were adjudicated as procedure related. The additional 3 patients were adjudicated as related to the initial stroke. All patients experiencing a symptomatic hemorrhage have been detailed in **Table 17** and **Table 18**.

## 8 Anticipated and Unanticipated Serious Adverse Events

Per the MERCİ Protocol, adverse events were categorized by the investigator as unlikely related, possibly related, probably related or definitely related to the study device. Any adverse event that met one of the following criteria was categorized as a “serious” adverse event.

1. Death
2. Life-threatening events resulting in extended hospitalization or death
3. Events which result in a permanent impairment of a body function or permanent damage to body structure
4. Events which necessitate medical or surgical intervention by a health care professional:
  - o to preclude permanent impairment of a body function or permanent damage to body structure;

- to relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure.

The principal investigator at each site reviewed all clinical adverse events and determined the severity and relationship to the device. The Data Safety Monitoring Board reviewed and adjudicated each reported serious adverse events. For cerebral hemorrhages, the Chair of the DSMB and an independent radiologist reviewed all Computer Tomography scans where a cerebral bleed was detected. Each bleed was categorized as “Symptomatic”, “Asymptomatic” based on this review and a change in NIH Stroke Scale Score.

### **8.1 Anticipated Serious Adverse Events Leading to Death**

A chronology of serious adverse events leading to patient death, categorized by the investigator as “Major” or “Severe” on the case report forms, has been summarized in **Table 17**.

<b>Table 17</b>				
<b>Anticipated Serious Adverse Events Leading to Death</b>				
<b>(n = 43)</b>				
<b>Pt. ID</b>	<b>Event</b>	<b>Severity</b>	<b>Relationship to Device (Adjudicated by DSMB)</b>	<b>Patient Course</b>
01002	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
01005	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
01014	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<b>Table 17</b>				
<b>Anticipated Serious Adverse Events Leading to Death</b>				
<b>(n = 43)</b>				
<b>Pt. ID</b>	<b>Event</b>	<b>Severity</b>	<b>Relationship to Device (Adjudicated by DSMB)</b>	<b>Patient Course</b>
01021	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
01022	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
02003	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<p align="center"><b>Table 17</b>  <b>Anticipated Serious Adverse Events Leading to Death</b>  <b>(n = 43)</b></p>				
Pt. ID	Event	Severity	Relationship to Device (Adjudicated by DSMB)	Patient Course
02004	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
02005	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
02006	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**Table 17**  
**Anticipated Serious Adverse Events Leading to Death**  
**(n = 43)**

Pt. ID	Event	Severity	Relationship to Device (Adjudicated by DSMB)	Patient Course
04001	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
04004	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
04005	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<p align="center"><b>Table 17</b>  <b>Anticipated Serious Adverse Events Leading to Death</b>  <b>(n = 43)</b></p>				
<b>Pt. ID</b>	<b>Event</b>	<b>Severity</b>	<b>Relationship to Device (Adjudicated by DSMB)</b>	<b>Patient Course</b>
04007	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
04009	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**Table 17**  
**Anticipated Serious Adverse Events Leading to Death**  
**(n = 43)**

Pt. ID	Event	Severity	Relationship to Device (Adjudicated by DSMB)	Patient Course
04010	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
04011	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
04013	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**Table 17**  
**Anticipated Serious Adverse Events Leading to Death**  
**(n = 43)**

Pt. ID	Event	Severity	Relationship to Device (Adjudicated by DSMB)	Patient Course
04015	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05003	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05004	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05005	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**Table 17**  
**Anticipated Serious Adverse Events Leading to Death**  
**(n = 43)**

Pt. ID	Event	Severity	Relationship to Device (Adjudicated by DSMB)	Patient Course
05006	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05008	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05010	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05016	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05017	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<b>Table 17</b>				
<b>Anticipated Serious Adverse Events Leading to Death</b>				
<b>(n = 43)</b>				
<b>Pt. ID</b>	<b>Event</b>	<b>Severity</b>	<b>Relationship to Device (Adjudicated by DSMB)</b>	<b>Patient Course</b>
05021	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
06003	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
06007	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
06009	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<b>Table 17</b>				
<b>Anticipated Serious Adverse Events Leading to Death</b>				
<b>(n = 43)</b>				
<b>Pt. ID</b>	<b>Event</b>	<b>Severity</b>	<b>Relationship to Device (Adjudicated by DSMB)</b>	<b>Patient Course</b>
06010	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
07001	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
07005	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
11001	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<b>Table 17</b>				
<b>Anticipated Serious Adverse Events Leading to Death</b>				
<b>(n = 43)</b>				
<b>Pt. ID</b>	<b>Event</b>	<b>Severity</b>	<b>Relationship to Device (Adjudicated by DSMB)</b>	<b>Patient Course</b>
11002	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
11003	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
14001	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
14005	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
14007	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
14010	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<p align="center"><b>Table 17</b>  <b>Anticipated Serious Adverse Events Leading to Death</b>  <b>(n = 43)</b></p>				
Pt. ID	Event	Severity	Relationship to Device (Adjudicated by DSMB)	Patient Course
15001	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
17002	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
21001	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**8.2 Other Anticipated Serious Adverse Events**

A chronology of serious adverse events not leading to patient death, categorized by the investigator as “Major” and “Severe” on the case report forms, has been summarized in **Table 18**.

<b>Table 18</b>				
<b>Other Anticipated Serious Adverse Events</b>				
<b>Pt. ID</b>	<b>Event</b>	<b>Severity</b>	<b>Relationship to Device (Adjudicated by DSMB)</b>	<b>Patient Outcome</b>
01011	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
01022	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
02004	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
04007	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<b>Table 18</b>				
<b>Other Anticipated Serious Adverse Events</b>				
<b>Pt. ID</b>	<b>Event</b>	<b>Severity</b>	<b>Relationship to Device (Adjudicated by DSMB)</b>	<b>Patient Outcome</b>
04008	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
04012	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05001	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05005	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05009	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05019	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
05020	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<b>Table 18</b>				
<b>Other Anticipated Serious Adverse Events</b>				
<b>Pt. ID</b>	<b>Event</b>	<b>Severity</b>	<b>Relationship to Device (Adjudicated by DSMB)</b>	<b>Patient Outcome</b>
05021	[REDACTED]	+	-	[REDACTED]
06001	[REDACTED]	-	[REDACTED]	[REDACTED]
06005	[REDACTED]	-	[REDACTED]	[REDACTED]
06006	[REDACTED]	-	[REDACTED]	[REDACTED]
08001	[REDACTED]	-	[REDACTED]	[REDACTED]
14010	[REDACTED]	+	-	[REDACTED]
16001	[REDACTED]	-	[REDACTED]	[REDACTED]

Table 18 Other Anticipated Serious Adverse Events				
Pt. ID	Event	Severity	Relationship to Device (Adjudicated by DSMB)	Patient Outcome
19003	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
20003	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**8.3 Unanticipated Adverse Events**

To date, there have been no reported unanticipated adverse events.

**9 Protocol Deviations**

Nine patients deviated from the MERCI Inclusion/Exclusion protocol requirements. The respective institutional review boards were notified of the deviations. No other deviations to the protocol have been reported.

Patient ID#	Deviation from protocol
201-002	[REDACTED]
201-008	[REDACTED]
201-015	[REDACTED]
202-005	[REDACTED]
204-015	[REDACTED]
207-001	[REDACTED]
211-001	[REDACTED]
217-001	[REDACTED]
220-003	[REDACTED]

**10 Device Complaints**

For the 114 patient cohort, there have been sixteen (16) complaints associated with the MERCI Retriever and/or the accessories. **Table 19** below details the complaints.

<b>Table 19</b> <b>Device Complaints</b> <b>n = 16</b>				
Pt. ID	Complaint	Patient Outcome	Failure Investigation	Corrective/Preventive Action
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<p align="center"><b>Table 19</b>  <b>Device Complaints</b>  <b>n = 16</b></p>				
Pt. ID	Complaint	Patient Outcome	Failure Investigation	Corrective/Preventive Action
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<b>Table 19</b> <b>Device Complaints</b> <b>n = 16</b>				
Pt. ID	Complaint	Patient Outcome	Failure Investigation	Corrective/Preventive Action
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<b>Table 19</b>				
<b>Device Complaints</b>				
<b>n = 16</b>				
<b>Pt. ID</b>	<b>Complaint</b>	<b>Patient Outcome</b>	<b>Failure Investigation</b>	<b>Corrective/Preventive Action</b>
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<p align="center"><b>Table 19</b>  <b>Device Complaints</b>  <b>n = 16</b></p>				
<b>Pt. ID</b>	<b>Complaint</b>	<b>Patient Outcome</b>	<b>Failure Investigation</b>	<b>Corrective/Preventive Action</b>
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<p align="center"><b>Table 19</b>  <b>Device Complaints</b>  <b>n = 16</b></p>				
<b>Pt. ID</b>	<b>Complaint</b>	<b>Patient Outcome</b>	<b>Failure Investigation</b>	<b>Corrective/Preventive Action</b>
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<p align="center"><b>Table 19</b>  <b>Device Complaints</b>  <b>n = 16</b></p>				
<b>Pt. ID</b>	<b>Complaint</b>	<b>Patient Outcome</b>	<b>Failure Investigation</b>	<b>Corrective/Preventive Action</b>
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

<b>Table 19</b> <b>Device Complaints</b> <b>n = 16</b>				
<b>Pt. ID</b>	<b>Complaint</b>	<b>Patient Outcome</b>	<b>Failure Investigation</b>	<b>Corrective/Preventive Action</b>
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**11 Device Shipments**

A total of [REDACTED] devices have been shipped throughout the course of the MERCİ study. Of the quantity shipped, [REDACTED] were MERCİ Retriever X4; [REDACTED] were MERCİ Retriever X5 and [REDACTED] were MERCİ Retriever X6. A total of [REDACTED] devices were used to treat the 114 patient cohort. Of the devices used, [REDACTED] were MERCİ Retriever X4; [REDACTED] were MERCİ Retriever X5 and [REDACTED] were MERCİ Retriever X6.

**12 Risk/Benefit Analysis**

The successful revascularization rate and low incidence of serious device-related adverse events achieved in the MERCİ Clinical Trial support the benefits of using the MERCİ Retriever for the removal of neurovascular thrombus in patients experiencing ischemic stroke. Effectiveness data presented within the MERCİ Clinical Summary further demonstrate that successful revascularization correlates to improved patient outcomes. As a result, the risk of vessel perforation, dissection, and embolization while removing thrombus with the MERCİ Retriever are appropriate in light of the demonstrated clinical benefit. Furthermore, these risks are comparable to those of the predicate device in removing a foreign body from the neurovasculature.

In conclusion, the clinical performance data demonstrate that the MERCİ Retriever is safe and effective for its intended use and is substantially equivalent to marketed devices.

