

THUNDER STUDY

IDE TRIAL SUMMARY

Penumbra

THUNDERBOLT™ for Acute Ischemic Stroke

Powered by Penumbra ENGINE™

The latest Penumbra™ ***CAVT***™ platform, THUNDERBOLT, is the first and only cleared technology to utilize Modulated Aspiration for stroke thrombectomy



THE THUNDER STUDY: IDE TRIAL SUMMARY

SITES ENROLLED:
29 U.S. Sites

INDIVIDUAL INVESTIGATORS:
119

ENROLLMENT PERIOD:
August 2022 – September 2024

TOTAL ENROLLMENT:
216

INTRODUCTION: The THUNDERBOLT Computer Assisted Vacuum Thrombectomy (CAVT) System is the first FDA-cleared stroke technology designed to fatigue and remove clot at the site of the occlusion using Modulated Aspiration. The THUNDER Study is the first in-human study to record clot ingestion rates. **Complete Clot Ingestion (CCI) is an emerging area of interest in stroke thrombectomy as it may be associated with a reduction in clot fragmentation, increased first-pass success rates, and reduced procedure times.**[1,a]

STUDY DESIGN: A prospective, single-arm, multicenter, core-lab adjudicated, Investigational Device Exemption (IDE) study evaluating the safety and efficacy of CAVT using the Penumbra System™ with THUNDERBOLT in patients with LVO.

BASELINE PATIENT CHARACTERISTICS:

Occlusion Location	%, (n/N*)
ICA/Carotid T	**9.3%** (20/215)
M1	**59.5%** (128/215)
M2	**27.4%** (59/215)
Basilar	**2.8%** (6/215)
Other	**1%** (2/215)

*** For N=215, one patient was not treated with THUNDERBOLT and procedural information was not available.**

NIHSS at Baseline	N=216
Median (Interquartile Range = IQR)	**15.0** (9.0, 20.0)
ASPECTS	**N=205**
Median (IQR)	**10** (8.0, 10.0)

PRIMARY EFFECTIVENESS ENDPOINT:

Post-THUNDERBOLT successful revascularization (TICI 2b–3) before the use of any additional therapy or adjunctive devices. Pre-defined performance goal of 71.5% was exceeded.

mTICI 2b–3	%, (n/N)	(95% CI)	p-value
ITT Population*	87.5% (189/216)	(82.3%, 91.6%)	<.001
Per Protocol[d]	89.1% (179/201)	(83.9%, 93.0%)	<.001

SECONDARY SAFETY ENDPOINTS:

Outcome	%, (n/N)
Device or Procedure-related SAE within 24 hours[b]	**2.8%** (6/216)
sICH	**0.9%** (2/216)
ENT	**0.5%** (1/216)
Intracranial Vascular Injury	**2.3%** (5/216)
All-Cause Mortality at 90 days[c]	**11.7%** (24/205)

*** Intent-to-treat (ITT) = Patients not treated with THUNDERBOLT, as well as those with intracranial stenosis/atherosclerosis (ICAD) who underwent stenting or angioplasty at target vessel occlusion prior to achieving ≥mTICI 2b were analyzed as primary effectiveness endpoint failures.**

a. Defined as complete ingestion of thrombus into a reperfusion catheter or canister with no remnants remaining at the tip.
b. Attributed as 'Related' when classified as 'Probable' or 'Definite,' per CEC. Of these, none were evaluated by site investigators as related to THUNDERBOLT System. Patients may have experienced more than one event.
c. Denominator is for patients with completed 90-day follow-up visit or reported deceased.
d. Per Protocol (PP) population included ITT patients who received treatment with the THUNDERBOLT System and met eligibility criteria.
1. Arslanian RA, Marosfoi M, Caroff J, et al. Complete clot ingestion with cyclical ADAPT increases first-pass recanalization and reduces distal embolization. *J Neurointerv Surg.* 2019 Sep;11(9):931–936. doi:10.1136/neurintsurg-2018-014625.

SECONDARY ENDPOINTS AND ADDITIONAL OUTCOMES:

Revascularization Outcomes	%, (n/N)
First Pass mTICI 2b–3	**64.8%** (140/216)
Post-THUNDERBOLT mTICI 2c–3	**70.4%** (152/216)
Functional Outcomes	**%, (n/N)**
mRS 0–2 at 90 days[e]	**55.4%** (112/202)
Procedure Time	**Minutes**
Time-to-revascularization[f]	**20** (N=214)
Final Radiographic Outcomes	**%, (n/N)**
Final mTICI 2b–3	**96.3%** (206/214)
Final mTICI 2c–3	**78.5%** (168/214)
Complete Clot Ingestion (CCI) per PI	**%, (n/N)**
Visualized after final pass	**79.9%** (171/214)
CCI[g]	**83.0%** (142/171)
Retained[e]	**17.0%** (29/171)

SUMMARY & DISCUSSION:
THUNDERBOLT exceeded the pre-defined performance goal for efficacy and demonstrated a considerably high first-pass success rate. It should be noted that the success of THUNDERBOLT in these key performance indicators is substantially impacted by correct assembly and usage of the system, which differs from traditional aspiration systems.

In cases where clot was observed, a high rate of CCI was recorded, **strongly indicating robust device performance.**

MODULATED-ONLY EXPLORATORY ANALYSIS

SUMMARY: A post-hoc exploratory analysis was performed for 150 patients from the ITT population who underwent all thrombectomy passes exclusively using Modulated Aspiration without any additional therapies and/or adjunctive devices.[h] The analysis included the same outcomes evaluated in the primary populations.

Safety and Efficacy Outcomes	%, (n/N)
Post-THUNDERBOLT mTICI 2b–3	**98.0%** (147/150)
Post-THUNDERBOLT mTICI 2c–3	**87.3%** (131/150)
Device or Procedure-related SAE within 24 hours[b]	**1.3%** (2/150)
sICH	**0.7%** (1/150)
ENT	**0.0%** (0/150)
Intracranial Vascular Injury	**1.3%** (2/150)
All-Cause Mortality at 90 days[c]	**9.0%** (13/145)

First-Pass Effect (FPE)	%, (n/N)
First-Pass mTICI 2b–3	**76.0%** (114/150)
Functional Outcomes	**%, (n/N)**
mRS 0–2 at 90 days[e]	**61.3%** (87/142)
Procedure Time	**Minutes**
Time-to-revascularization[f]	**18** (N=150)
Complete Clot Ingestion (CCI) per PI	**%, (n/N)**
Visualized after final pass	**83.3%** (125/150)
CCI[g]	**82.4%** (103/125)
Retained[i]	**17.6%** (22/125)

e. Denominator is for patients with completed mRS 90-day assessment or reported dead.
f. Defined as time from arterial puncture to mTICI 2b–3 first reached else final angiogram. N is based on available assessment of mTICI.
g. Defined as clot visualized in the canister, tubing or catheter, and/or guide sheath, rotating hemostatic valve (RHV) or syringe; multiple responses were allowed for each participant.
h. Modulated-only mode includes static/continuous mode only when the device automatically initiates it either after 60 seconds or after clot is ingested. If static/continuous aspiration mode is manually initiated, it is not considered modulated-only.
i. Defined as clot visualized as "corked" at the tip of the catheter.

ANALYSIS: REPORTED FPE IN THUNDER AND OTHER PUBLISHED IDE STUDIES

SUMMARY: A key point of interest for THUNDERBOLT is FPE. THUNDERBOLT was analyzed alongside published IDE studies evaluating the effectiveness of various aspiration systems.[j] THUNDERBOLT achieved an exceptionally high rate of FPE in both the ITT population and those treated with modulated-only mode.



j. The forest plot represents first-pass referfusion (mTICI 2b–3) rates in the THUNDER Study alongside results reported in the Penumbra System including 3D Revascularization Device (COMPLETE Study) and other recent prospective IDE studies, including the Zoom Reperfusion System (Imperative Trial) and the HiPoint Reperfusion System/Vecta Aspiration System (Summit MAX RCT). Values are shown as percentages with corresponding 95% confidence intervals (CI). Published n/N were used to calculate the rates and 95% CI; see the original publications for source data. For informative purposes only. Details of eligibility criteria, devices used, and definitions can be found in published studies.



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