

# First Pass Recanalization Rates of Solitaire vs Trevo vs Primary Aspiration: The Kaiser Southern California Experience

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## ABSTRACT

**Context:** New stroke thrombectomy devices have significantly improved recanalization rates in patients with large vessel occlusion. The first pass effect, or complete or near complete recanalization after a single pass of a device, is associated with better outcome. However, it remains unclear whether one technique is superior to the others at first pass recanalization.

**Objective:** The successful recanalization rates of three common techniques: 1) Stent-retriever with the Solitaire or 2) Trevo device, or 3) primary aspiration (PA) with a distal aspiration catheter, were compared across three Kaiser Permanente Southern California Medical Centers over a 5-year period.

**Design:** Retrospective review of cases between October 2013 and May 2018.

**Main Outcome Measure:** Successful recanalization after a single pass of a device.

**Results:** Forty-five percent of Solitaire thrombectomies resulted in first pass success, compared with 31% of Trevo and 39% of PA, not statistically significant ( $p = 0.26$ ). Adjusted for age, gender, and National Institutes of Health Stroke Scale score, the odds of successful recanalization were  $1.90 \pm 0.72$  (CI 0.90-3.99,  $p = 0.09$ ) for Solitaire compared with Trevo, and  $1.41 \pm 0.50$  (CI 0.70-2.84,  $p = 0.33$ ) for aspiration compared with Trevo.

**Conclusion:** In this multi-center cohort, there was no statistical difference in successful first pass recanalization between Solitaire, Trevo, and PA. However, there was a trend towards improved efficacy with the Solitaire device compared to Trevo (OR 1.90,  $p = 0.09$ ). Additional data are needed to determine the conditions under which design differences may favor one technique over another.

trials suggesting clinical benefit<sup>3-5</sup> were countered with trials suggesting none.<sup>6-8</sup> It was not until 2015, when technological advances enabling rapid and complete revascularization coincided with timely randomized clinical trials, that the impressive clinical benefit of EST for large vessel cerebral occlusions was definitively demonstrated.<sup>9-14</sup> Today, EST is one of the most efficacious therapies in modern medicine, with a number needed to treat of 1 in 2.6 to decrease disability at 90 days, and 1 in 5 to achieve functional independence.<sup>14</sup> For patients with brain tissue starved of blood flow and at risk of infarction, it is becoming clear that rapid and complete revascularization is critical to improving functional neurological outcome.<sup>15-17</sup>

Over the past 10 years, there has been a proliferation of new devices designed for EST. The earliest of these retrieval devices was the Merci device (Concentric Medical, now part of Stryker Corporation, Kalamazoo, MI), a corkscrew-like coil of wire that was designed to integrate into clots and thereby allow their removal with antegrade blood flow arrest using a balloon.<sup>3,18</sup> Thrombectomy using this first-generation device was often a prolonged, pain-staking affair with moderate success rates.<sup>3</sup> Subsequently, non-detachable stent-retrievers were found to have superior ability to engage the clot and improved overall recanalization rates compared with Merci.<sup>4,5</sup> The Solitaire (Medtronic, Minneapolis, MN) and Trevo (Stryker Corporation, Kalamazoo, MI) devices were the first of these gaining Food and Drug Administration approval and remain the most used stent retrievers today. Concurrently, catheter technology improved, and new flexible, large-bore catheters were developed, which could be advanced directly to the site

## INTRODUCTION

In 1995, the landmark NINDS IV rTPA Stroke Study introduced the first evidence-based treatment for acute stroke within 3 hours of onset.<sup>1</sup> This led to an important paradigm shift in the minds of neurologists and emergency physicians, taking ischemic stroke from a disease where only supportive care could be offered to one where early emergent intervention could change the clinical course and improve functional outcome. Soon after the emergence of tissue plasminogen activator as a treatment for acute ischemic stroke, it was hypothesized that physically removing occlusions in the large vessels feeding the brain either pharmacologically or mechanically might benefit the patient.<sup>2</sup> In the intervening years, endovascular stroke therapy (EST)

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of occlusion to enable direct aspiration of the clot, making primary aspiration (PA) a viable alternative for EST.<sup>19,20</sup>

Despite the development of multiple devices designed to remove clots, the comparative success rates of recanalization between devices remains unclear. One small retrospective study found no significant difference between the two stent-retrievers<sup>21</sup> while another favored Trevo,<sup>22</sup> and two randomized trials comparing stent-retriever to PA have found no significant difference in clinical outcome between the two methods.<sup>19,20</sup> However, while recanalization of the occluded artery is clearly important, the speed at which recanalization occurs is also vital to the outcome of the patient.<sup>14</sup> The device-driven improvements in EST have led to a new metric, the first pass effect (FPE), which has been defined as complete or near complete recanalization with a single thrombectomy device pass.<sup>23</sup> Whether one device has a higher rate of FPE than the others is unknown.

The Kaiser medical system is one of the largest group hospital systems in the United States and, in total, performs more than 400 thrombectomies per year. We examined the Kaiser Southern California thrombectomy experience at three medical centers (Los Angeles, Fontana, and Anaheim) over a 5-year period from 2013 to 2018 to compare the efficacy of first pass recanalization using each of the two prototypical stent-retrievers (Solitaire and Trevo) or PA.

## METHODS

Approval was obtained from the Institutional Review Board of Kaiser Permanente Southern California. The study was designed as a retrospective cohort study to evaluate the rate of first pass recanalization given use of the Solitaire or Trevo device, or PA. Patients who underwent thrombectomy for stroke from October 2013 to May 2018 at Kaiser Los Angeles Medical Center, Fontana Medical Center, or Anaheim Medical Center were identified from patient logs maintained for Joint Commission certification. Data collection and analysis took place from June 2018 until October 2019. 271 patients who underwent thrombectomy for stroke were reviewed; 36 patients were excluded because the first pass attempt at thrombectomy was not performed using Solitaire, Trevo, or PA.

First pass success (FPS) was defined as procedures terminated after the first pull with modified Thrombolysis in Cerebral Infarction (TICI) grade 2b or better (antegrade reperfusion of more than 50% of the previously occluded target artery territory) recanalization. This differs from the official definition of FPE, which requires TICI 2c or better (complete or near complete reperfusion of the target artery territory). TICI 2b was chosen as the standard for successful recanalization because the goal for revascularization has increased over the years, and in earlier cases TICI 2b may have been the goal of thrombectomy. Earlier cases also

utilized the original TICI scoring system, where 2b represented a higher bar of antegrade perfusion of 2/3 or more of the target artery territory. Therefore, using a cutoff score of TICI 2b includes both original and modified TICI 2b cases. Also, the TICI category 2c (90% or greater, or near-complete reperfusion of the target artery territory) was proposed during the study time period but not consistently used.

The TICI score in most cases was determined by the attending neurointerventionalist performing the procedure and dictated in the procedure report. In cases ( $n = 3$ ) where a TICI score was not documented, the imaging was reviewed and scored by the first author (CWL). The sample size needed to find an effect was estimated at about 230, given the known results of FPE in the STRATIS (Solitaire) registry of 40%<sup>24</sup> and TRACK (Trevo) registry of 23%.<sup>25</sup> The recanalization rate using Solitaire, Trevo, or PA were compared with a Chi-square test. One-way ANOVA tests were used to determine differences in age, gender, and presenting National Institutes of Health Stroke Scale (NIHSS) between the three groups. Lastly, a multivariable logistic regression analysis was performed to evaluate the covarying roles of age, gender, and presenting NIHSS on the first pass recanalization rate. Statistical analyses were performed using the free online statistics program VassarStats ([vassarstats.net](http://vassarstats.net), Poughkeepsie, NY) and the commercially available Stata software, version 14 (StataCorp, College Station, TX).

## RESULTS

235 patients were ultimately included in the analysis. Eighty-four percent (197/235) of the cases were performed at Los Angeles Medical Center, 12% (28/235) at Fontana, and 4% (10/235) at Anaheim. No statistically significant difference was seen in the demographic categories of age ( $p = 0.36$ ), gender ( $p = 0.68$ ), or presenting NIHSS ( $p = 0.64$ ). The average age overall was  $68.8 \pm 14.6$ , 57% were male, and the median presenting NIHSS was 17 (Figure 1). Of the procedures performed on patients in this cohort, 31% utilized Solitaire as the first pass device compared with 23% with Trevo and 46% with PA. The overall rate of FPS was 39%, and successful recanalization at the end of the case was 89% (defined as TICI 2b or 3). The FPS with Solitaire was 45% (33/73), compared with 31% (17/55) for Trevo and 39% (42/107) for PA. In univariate analysis, there was no statistically significant difference between the three techniques ( $p = 0.26$ ). The number of cases meeting the higher standard of FPE (TICI 2c or better) was 30% (22/73) for Solitaire, 16% (9/55) for Trevo, and 26% (28/107) for PA, not statistically significant ( $p = 0.19$ ). The final recanalization rate as measured by TICI score was also not statistically significant ( $p = 0.40$ ), with successful recanalization occurring in 90% (66/73) of first device-Solitaire

	Total in cohort (n=235)	First pass Solitaire (n=73)	First pass Trevo (n=55)	First pass aspiration (n=107)	P
Age	68.8 ± 14.6	66.8 ± 14.1	69.6 ± 16.0	69.8 ± 14.2	0.36
Gender					0.68
Male	133 (57%)	40 (55%)	29 (53%)	64 (60%)	
Female	102 (43%)	33 (45%)	26 (47%)	43 (40%)	
Presenting NIHSS	17 ± 7	17 ± 7	18 ± 8	17 ± 8	0.64
<b>First pass success (TICI 2b+)</b>	<b>92 (39%)</b>	<b>33 (45%)</b>	<b>17 (31%)</b>	<b>42 (39%)</b>	<b>0.26</b>
“Official” first pass effect (TICI 2c+)	59 (25%)	22 (30%)	9 (16%)	28 (26%)	0.19
Final TICI					0.40
0-2a	27 (12%)	7 (10%)	5 (9%)	15 (14%)	
2b	97 (41%)	25 (34%)	26 (47%)	46 (43%)	
2c-3	111 (47%)	41 (56%)	24 (44%)	46 (43%)	
2b-3	208 (89%)	66 (90%)	50 (91%)	92 (86%)	

Figure 1. Demographic and success of thrombectomy data. (Continuous variables compared by one-way ANOVA, categorical variables by Chi-square analysis.)

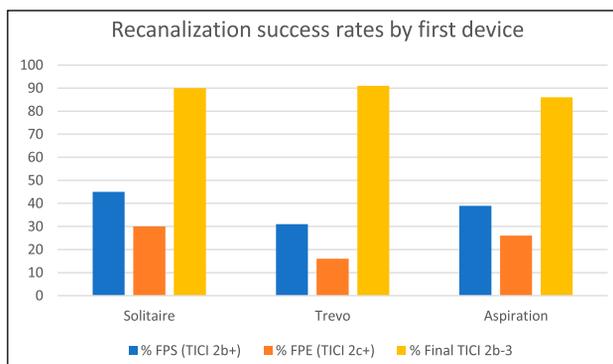


Figure 2. Recanalization success rates by first device used.

cases compared with 91% (50/55) first device-Trevo and 86% (92/107) first device-PA (Figures 1 and 2).

In regression analysis (Figure 3), there was again no statistically significant difference in FPS between the Solitaire, Trevo, and PA groups, although there was a trend towards statistical significance in Solitaire recanalization as compared to Trevo. Age ( $p = 0.09$ ), gender ( $p = 0.74$ ), and presenting NIHSS ( $p = 0.16$ ) were not significantly associated with FPS. Adjusted for these variables, the odds of

successful recanalization were  $1.90 \pm 0.72$  (CI 0.90-3.99,  $p = 0.09$ ) for Solitaire compared with Trevo, and  $1.41 \pm 0.50$  (CI 0.70-2.84,  $p = 0.33$ ) for aspiration compared with Trevo.

## DISCUSSION

EST has become the standard of care for patients with stroke from large vessel occlusion,<sup>26</sup> but the best method by which to perform thrombectomy remains uncertain. The major clinical trials that led to EST becoming first-line treatment were primarily stent-retriever studies.<sup>9-13</sup> Two subsequent randomized controlled trials have examined PA versus stent-retriever head to head without showing a clear difference.<sup>19,20</sup>

The stent-retrievers and aspiration catheters used in these studies tended to be referred to categorically, but in practice one device may not function as well as another. For example, there are significant differences in the construction of Solitaire and Trevo, the two stent-retrievers first introduced into the market, and even more differences when compared with newer generation devices such as the 3D Revascularization Device (Penumbra Inc, Alameda, CA), EmboTrap (Johnson and Johnson, New Brunswick, NJ),

	OR	P-value	95% CI
Treatment type			
Solitaire	1.90 ± 0.72	0.09	0.90-3.99
Aspiration	1.41 ± 0.50	0.33	0.70-2.84
Trevo	REFERENCE		
Age	1.02 ± 0.01	0.09	1.00-1.04
Gender	0.91 ± 0.25	0.74	0.53-1.57
NIHSS	0.97 ± 0.02	0.16	0.94-1.01

Figure 3. Multivariable regression analysis comparing independent variables versus dependent variable of FPS.

and others. Differences in stent-retrievers today primarily lie in the material construction of the device, the flexibility of the device, the location and configuration of the cells between the wires, and differences in how they expand when exiting the catheter and collapse when being pulled back into a catheter. Similarly, the Penumbra aspiration system was the first to market, but next generation competitor catheters from other companies have slightly different designs, which may convey advantages or disadvantages to aspiration thrombectomy performance. When viewed categorically, these tools may have roughly similar performance, as seen in the head-to-head studies performed for stent-retriever versus aspiration<sup>20,27,28</sup>; however, a small difference in design or improvement in performance may result in more rapid recanalization, improved recanalization rates, and/or better clinical outcomes. In this study, we found that the Solitaire device had a higher rate of FPS compared with Trevo, although this result was not statistically significant. Head to head comparisons between the devices are few, with one small study suggesting no difference<sup>21</sup> and another favoring Trevo.<sup>22</sup> One large network meta-analysis suggests that Solitaire and aspiration are better than Trevo,<sup>27</sup> while another suggests that stent-retriever usage (Solitaire and Trevo together) is better than aspiration.<sup>29</sup> The disparity of these results indicates that either the difference in effect is small, or that there still remain confounding variables not yet accounted for by these comparison studies.

Several limitations should be considered when interpreting the results of this study. First, the study was conducted with patient data over a relatively long period of time (2013-2018). Over that time period, multiple thrombectomy devices have come to market, and the techniques for thrombectomy have been incrementally improved upon with each new device. For example, at the beginning of the study, a balloon guide catheter was commonly used to occlude antegrade flow proximally in the neck, to prevent the clot from dislodging from the device while being removed, and the stent-retriever would then be pulled

completely into the guide catheter.<sup>30</sup> Later, new distal aspiration catheters allowed direct access to the face of the clot intracranially, and the clot might be pulled out with aspiration alone (“A Direct Aspiration first Pass Technique” technique),<sup>31</sup> with the stent retriever directly into these distal aspiration catheters (“Solumbra” technique),<sup>32</sup> or trapped between the stent-retriever and aspiration catheter to be pulled out of the guide catheter as a single unit (“TREvo Aspiration Proximal flow control” technique).<sup>33</sup> In these later cases, proximal balloon guides might or might not be used at the discretion of the neurointerventionalist. The many technical variations in how stent-retrievers are used may impact the efficacy of first pass recanalization, and case-specific characteristics, such as occlusion location, vessel tortuosity, underlying disease, or clot consistency may also play a role. At this time, it remains unclear which technique works best in which situation, and whether different techniques work better depending on the case scenario and which stent-retriever is used.

Secondly, this study uses the definition of FPS as TICI 2b or better, while the official definition of FPE has only recently been defined in 2018 as complete or near complete recanalization (TICI 2c or better) after the first pass.<sup>23</sup> It is becoming clear that more vascular recanalization is better,<sup>34</sup> and as devices and techniques have improved over the years, the goal of thrombectomy has evolved. Moreover, the TICI grading terminology has been in constant change, with variants, such as modified TICI, modified TICI with 2c (used in this study), expanded TICI, etc.<sup>35</sup> In the beginning of this study, it was common to stop additional attempts at thrombectomy if TICI 2b or better had been achieved, which initially meant 66% reperfusion to the downstream territory and was later modified to 50%. The category 2c was proposed in a later amendment and is not consistently used.<sup>36</sup> During chart review, it was not always clear which TICI scale was being used for grading. Therefore, for the purposes of this study, we used a definition of FPS as TICI 2b or better as defined by the operator, which was the

minimum goal of recanalization throughout the study period. Many neurointerventionalists now would not settle for 50% recanalization, and some early TICI 2b, FPS-positive cases in this dataset might today be first pass failures with the higher goal for revascularization in mind. Alternatively, some TICI 2c cases may have resulted in near complete revascularization but, at the discretion of the operator, were coded as TICI 2b. The “true FPE” calculated from the current dataset (TICI 2c or better) is likely lower than the FPS (overall 39%) and higher than the FPE (overall 25%) reported here.

This data also does not include clinical outcome, which is ultimately the *raison d'être* for achieving the FPE. It has been shown that FPE is associated with better outcomes,<sup>23</sup> but follow-up outside of a formal clinical trial can be challenging. Because reliable follow-up data was not available for all of the patients in the cohort, this study did not include the effect of FPS on clinical outcome. The Joint Commission's Comprehensive Stroke Center accreditation now requires obtaining this follow-up data, so the more recent patients in the cohort have reliable clinical follow-up. Regardless, from a procedural standpoint, achieving a successful FPE is an important goal that neurointerventionalists can keep in mind going into a case, knowing that it is likely associated with better clinical outcome.

Finally, being a retrospective study, this study is limited by selection bias and may be confounded by self-grading of the recanalization outcomes. Neurointerventionalists may naturally gravitate towards certain devices in certain situations, which may have the unintended consequence of selecting for better or worse performance. For example, if a physician is more comfortable with the Solitaire device, s/he may be more inclined to use that device first in certain clinical situations and have better results with it. To address this selection bias, true randomization is needed. Most of the patients in this study were also from a single center (84% from Los Angeles Medical Center), the only comprehensive stroke center among the Kaiser Southern California medical centers. Regarding confounding due to operator interpretation, in many clinical trials, TICI grading is performed by a central imaging core laboratory. Because this dataset is taken from the real world experience of the centers included, the recanalization score was determined by the physician performing the procedure. This type of scoring may introduce bias, where the clinician's scoring is influenced by his or her knowledge of the particular case and circumstances surrounding the thrombectomy.

Though the landscape of EST devices continues to evolve, determining which of these devices function the best in the real world will require large endovascular stroke datasets.

Future work leveraging the combined inter-regional Kaiser thrombectomy volume will allow for comparative evaluation of different EST devices and techniques, to determine the conditions under which each device gives the best performance and clinical outcomes.

## CONCLUSION

In this multi-center cohort, there was no significant difference between the successful first pass recanalization rates of the Solitaire or Trevo device or PA. However, there was a trend towards improved efficacy of the Solitaire device when compared with Trevo. Additional data are needed to determine whether a particular device or technique improves the FPE, which continues to be the primary goal of stroke thrombectomy for large vessel occlusion. Case-specific differences, such as occlusion location, vessel tortuosity, underlying disease, or clot consistency, may influence the odds of FPE depending on device design. ❖

## Disclosure Statement

*The authors have no conflicts of interest to disclose.*

## Authors' Contributions

Conrad Liang, MD, PhD, participated in the data collection, study design, data analysis, drafting, critical review, and submission of the final manuscript. Harjot Toor, DO and Evelin Martinez participated in data collection. Sunil Sheth, MD participated in data analysis and critical review. Kuo Chao, MD, Lei Feng, MD, PhD, Mazen Noufal, MD, Binh Nguyen, MD, Pankaj Mowji, MD, and Navdeep Sangha, MD participated in data collection and critical review. All authors have given final approval to the manuscript.

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