pressed patients with headache, diplopia, and an invasive T2-hypointense sellar mass on imaging.

References


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Aspiration thrombectomy with off-label distal access catheters in the distal intracranial vasculature

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A B S T R A C T

Background: As neurointerventionalists aim to treat occlusions in the ever more distal vasculature, off-label catheters (OLCs) have been adapted for aspiration thrombectomy. This may not be without its attendant risks. Recently issued, a letter from the FDA cautioned providers against using OLCs as substitutes for FDA-cleared aspiration thrombectomy catheters, especially in the distal vasculature. In light of this, we evaluated the efficacy and safety of OLCs used for aspiration thrombectomy in the distal vasculature at our institution.

Methods: We retrospectively queried all patients who underwent thrombectomy at our institution between January 1, 2016 and March 1, 2017. Patients were screened for: (1) occlusion location in the distal vasculature (M2 or more distal) and (2) direct thrombus aspiration attempt with an OLC. Demographic, clinical, and procedural data were recorded.

Results: Eight patients were included for analysis (Table 1). The median admission NIHSS was 17 (IQR 13–23.3). Occlusion locations included left M2 (6/8), right M2 (1/8), and left M3 (1/8). The OLCs employed included the Stryker Catalyst 6 (5/8), Penumbra Velocity (2/8), and the MicroVention Sofia Plus (1/8). Direct thrombus aspiration was successful in 50% (4/8) of cases, though final TICI 2b-3 was achieved in all patients. There were no instances of symptomatic intracranial hemorrhage. Median NIHSS at discharge was 5 (IQR 0.8, 15).

Conclusions: Aspiration thrombectomy with OLCs may be safe and effective in the distal vasculature. In light of the recent FDA warning regarding their use, further evaluation of OLCs in this capacity is warranted.

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1. Introduction

Although large vessel occlusions of the distal vasculature are expected to involve a smaller vascular territory, the location of the infarction can cause significant morbidity and mortality [1]. Thrombolysis with intravenous tissue plasminogen activator (IV-tPA) is frequently ineffective, with recanalization rates of M2 occlusions reported at approximately 30%, and, as a result, endovascular intervention if often warranted [2]. Current guidelines recommend treating M2 occlusions with mechanical thrombectomy based on data from the STAR, SWIFT, and SWIFT PRIME studies [3,4]. Both stent retriever thrombectomy and manual aspiration thrombectomy have demonstrated effectiveness in the distal vasculature [4–8]. However, aspiration thrombectomy is of particular interest in these smaller vessels, as it may be associated with a lower rate of distal embolization and reduced vessel wall injury compared with stent retrievers [9–12].

As a result, neuroendovascular device manufacturers have continually developed improved catheter technologies to perform the procedure, including aspiration thrombectomy catheters (ATC), distal access catheters, and microwire catheters. These newer-generation devices, with superior trackability and safety profiles compared with previous generations, have allowed operators to treat occlusions more safely and effectively. The superior technology has also allowed operators to reach distal occlusions untreatable with previous technology.

Abbreviations: ATC, aspiration thrombectomy catheter; CT, computed tomography; CTA, computed tomography angiography; OLC, off-label catheter; FDA, Food and Drug Administration; IV-tPA, intravenous tissue plasminogen activator; NIHSS, National Institutes of Health Stroke Scale; TICI, thrombolysis in cerebral infarction.

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As neurointerventionalists aim to treat occlusions in vessels of smaller caliber and more distal location, they have turned to catheters with smaller diameters and improved trackability, including distal access catheters and microcatheters, to perform aspiration thrombectomy. Importantly, however, this adaptation of these catheters for aspiration thrombectomy is an off-label use. Unlike ATCs, which are FDA-cleared for aspiration thrombectomy, distal access catheters and microcatheters are only FDA-cleared for accessing the intracranial vasculature, and their adaptation to aspiration thrombectomy may not be without its attendant risks. These risks were recently emphasized in a letter to health care providers from the FDA cautioning operators that use of OLCs for direct aspiration thrombectomy may be associated with serious complications, especially in the distal vasculature [13]. They note that the design differences between OLCs and ATCs may lead them to perform differently and, thus, possess unique risk and safety profiles. In considering this FDA warning, we chose to retrospectively evaluate the performance and safety of OLCs for aspiration thrombectomy at our institution.

2. Methods

Institutional review board approval was obtained for this retrospective review. All patients with acute ischemic stroke who underwent mechanical thrombectomy between January 1, 2016 and March 1, 2017 were screened for inclusion from a prospectively acquired database. Only patients who had direct aspiration performed with an off-label distal access catheter in the distal vasculature (M2 or more distal) were included for analysis. The OLCs used at our institution included the Catalyst 6 distal access catheter (Stryker Neurovascular, Freemont, CA, USA), Sofia Plus distal access catheter (MicroVention, Tustin, CA, USA), and Velocity microcatheter (Penumbra, Alameda, CA, USA). Demographic data, occlusion location, catheter type, thrombectomy procedure details, postoperative complications, admission/discharge NIHSS scores, and final TICI revascularization scores were collected from the medical record. A successful revascularization attempt was defined as an improvement in TICI score as a result of the aspiration pass. Symptomatic intracerebral hemorrhage (sICH) was defined as a progression of parenchymal hematoma associated with neurologic deterioration, especially in the distal vasculature [13]. They note that the design differences between OLCs and ATCs may lead them to perform differently and, thus, possess unique risk and safety profiles. In considering this FDA warning, we chose to retrospectively evaluate the performance and safety of OLCs for aspiration thrombectomy at our institution.

3. Results

A total of 110 patients had thrombectomy within the study timeframe. Of these, 35 had occlusions located in the distal vasculature (M2 or more distal). Eight of these patients had aspiration thrombectomy performed with an OLC and, thus, met the inclusion criteria for the study (Table 1). The median age of the cohort was 71.5 years (IQR 60.8, 79.5), 6 (75%) were female, and median 123 admission NIHSS was 17 (IQR 13–23.3). There were 6 patients (75%) with left M2 occlusions, 1 (12.5%) with a right M2 occlusion, and 1 (12.5%) with a left M3 occlusion. The majority, 62.5% (5/8), were primary lesions, while the remaining 3 were distal embolizations that had occurred during a thrombectomy procedure. The Catalyst 6 (Stryker) was used in 5 cases, the Velocity (Penumbra) in 2 cases, and the Sofia Plus (MicroVention) in 1 case. Direct aspiration with these devices was successful in 50% (4/8) cases. All patients had a final reperfusion of TICI 2b-3. There were no instances of device complications during the direct aspiration attempt with any of these devices. No patients developed symptomatic intracranial hemorrhage (sICH), although a small intraparenchymal bleed was noted on routine postoperative imaging in one patient, who remained asymptomatic. All 8 patients had some degree of neurologic improvement and median NIHSS at discharge was 5 (IQR 0.8, 15).

4. Case illustrations

4.1. Patient 1

The patient is an 84-year-old female with a past medical history of paroxysmal atrial fibrillation off anticoagulation who was brought to the ED 4.5 h after the onset of difficulty speaking. On examination, she was found to be lethargic and not following commands (NIHSS 16). A CT head demonstrated subtle evidence of left frontal acute ischemic stroke (ASPECTS 9). Given symptom onset greater than 4.5 h, tPA was not administered. A CTA of the head and neck was performed, demonstrating a left M2 occlusion (Fig. 1). Given her examination, favorable ASPECTS, and left M2 occlusion on CTA, she was brought for mechanical thrombectomy. Angiography demonstrated a left superior division M2 occlusion (Fig. 2A & B). Given this location, the Catalyst 6 distal access catheter was chosen for aspiration thrombectomy. The Catalyst 6 tracked smoothly over a microcathewire to the proximal interface of the thrombus (Fig. 3). Suction was activated through the Catalyst 6 and the thrombus aspirated directly into the catheter. Subsequent angiography demonstrated full reperfusion (Fig. 2C & D). The patient was discharged home from the hospital on postprocedure day 3 with a NIHSS of 1.

4.2. Patient 3

The patient is an 86-year-old female with a past medical history of atrial fibrillation and prior left frontotemporal infarct who presented to the ED after collapsing on the floor of her apartment with altered mental status and right sided weakness. Upon arrival to the ED, her exam included right-sided hemiparesis, left gaze deviation, and altered mental status amounting to an NIHSS of 24. CT head demonstrated left frontotemporal encephalomalacia and hyperdensity in the left M2 segment while the CTA demonstrated excellent collaterals. Tissue plasminogen activator was administered and she was brought for mechanical thrombectomy.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient and Treatment Characteristics.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Admission NIHSS</td>
</tr>
<tr>
<td>1</td>
<td>16</td>
</tr>
<tr>
<td>2</td>
<td>18</td>
</tr>
<tr>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>4</td>
<td>23</td>
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<td>5</td>
<td>9</td>
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<td>6</td>
<td>14</td>
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<tr>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>25</td>
</tr>
</tbody>
</table>
Angiography demonstrated the left M2 occlusion (Fig. 4A & B). Given its location in a large M2 branch, the Catalyst 6 was chosen for aspiration thrombectomy. The Catalyst 6 catheter was advanced over a microguidewire until it abutted the proximal end of the thrombus (Fig. 5). Aspiration was activated and the thrombus was aspirated directly into the catheter. Subsequent angiography revealed that a single pass had achieved a TICI score of 3 (Fig. 4C & D). The patient was discharged to a subacute rehabilitation facility on postoperative day 6 with moderate aphasia and an NIHSS of 14.

5. Discussion

Here we report a series of patients who underwent aspiration thrombectomy with OLCs in the distal vasculature. Although OLCs are not FDA-cleared for direct aspiration thrombectomy, we observed good clinical and radiographic results. There were no instances of intraprocedural device complications or postoperative clinical complications, with the exception of an incidental, asymptomatic ICH in one patient. This retrospective series shows that, in our institution’s experience, aspiration thrombectomy with OLCs has a good safety record.

OLCs do not differ markedly from ATCs. Despite differences in FDA-cleared intended use, the catheters range similarly in their dimensions (Table 2). ATC inner diameters range from 0.035-inch to 0.068-inch, while OLCs used in the present study range from 0.025-inch to 0.070-inch. Where OLCs and ATCs likely differ the most is in their construction and design. These design differences may become more important in the distal vasculature, where vessels are smaller, less supported by surrounding tissue, and theoretically more susceptible to endothelial injury and the consequential flow limitation. These design differences may also manifest in the ability to reach the distal occlusion. There are, occasionally, occlusion locations reachable with an OLC that are infeasible for an ATC. Such a scenario was noted for one patient in our series; aspiration was first attempted with the ACE68 (Penumbra), but despite repeated attempts to deliver the ACE68 to the occlusion site, the vascular anatomy would not permit its advance. The Velocity (Penumbra), an OLC which had been employed in an attempt to facilitate delivery of the ACE68, was subsequently tried alone and was easily navigated to the site of distal occlusion on the first attempt and used for aspiration.

To date, the present study is the first with a dedicated focus on off-label aspiration thrombectomy with OLCs in the distal vasculature. The Sofia Plus (MicroVention) was previously investigated for aspiration thrombectomy in the proximal vasculature [14]. In a retrospective series of 9 patients, median NIHSS at admission was 18.
and improved to 4 at discharge. Of the 9 patients, 7 underwent direct aspiration with the Sofia Plus, while the other 2 patients were treated with a stent retriever. TICI 2b-3 was achieved in 8 of 9 patients and no device or postoperative clinical complications were encountered. There was a single case of distal occlusion in the cohort, in an M2 vessel, though treatment with direct aspiration was not specified for that specific case, nor was radiographic outcome.

While no reports of aspiration thrombectomy with OLCs in the distal vasculature currently exist in the literature, there have been several studies of aspiration thrombectomy with FDA-cleared ATCs in the distal vasculature (Table 3). In a retrospective series, Park and colleagues used the 4MAX (Penumbra) catheter to reach M2 occlusions in 32 patients [7]. They achieved TICI 2b-3 in 27 of these patients (84%) and at 90-day follow-up, 25 (78%) had a mRS ≤2. Routine imaging with postoperative CT revealed ICH in 3 patients (9%), though none were symptomatic. In another retrospective study, Vargas and co-authors performed aspiration thrombectomy in 35 patients with either isolated or tandem occlusions of the distal vasculature [15]. Aspiration with the 3MAX, 4MAX, 5MAX, or 5MAX ACE (Penumbra) catheter, achieved TICI 2b-3 in 26 patients (77.1%). Adjunctive use of a stent retriever provided added benefit, with 34 patients (97.1%) achieving a final TICI of 2b/3. Symptomatic postoperative ICH was reported in 1 patient (3%). Follow-up at 90 days was available in 32 patients and 59.2% had a mRS ≤2. In a subsequent comparative study of aspiration and stent retriever thrombectomy in the distal vasculature, Kim and colleagues used the 041 or 4MAX reperfusion catheter (Penumbra) in 25 patients [9]. Reperfusion of TICI 2b-3 was achieved in 16 patients (64%) with aspiration alone, and additional use of a stent retriever achieved this in another 2 patients. Follow-up at 90 days revealed a mRS ≤2 in 21 patients (84%). The authors reported postoperative symptomatic ICH in 1 patient and asymptomatic ICH in 3 others, which were found incidentally on routine postoperative imaging. Distal embolization was reported in 3 patients, though it was not noted whether this occurred in aspiration-only cases or those with adjunctive use of a stent retriever.

In the present study, aspiration attempts with OLCs were only successful in 4 out of 8 (50%) cases. However, aspiration attempt success is an outcome measure that is distinct from TICI reperfusion score, as unsuccessful aspiration in a TICI 2b or 2c scenario is still considered successful by conventional procedural standards. All of our patients achieved final TICI 2b-3 reperfusion, a slightly higher rate than in the M2 aspiration studies reviewed above, which range from 72% to 97%, though comparison with these is limited by the smaller sample size of the present study [7,9,15].
Fig. 5. Anterior-posterior and lateral fluoroscopic views demonstrate the location of the Catalyst 6 catheter prior to activating aspiration (arrows).

### Table 2

Aspiration thrombectomy catheter (ATC) and off-label catheter (OLC) specifications.

<table>
<thead>
<tr>
<th>Catheter type</th>
<th>Diameter, inches (mm)</th>
<th>Diameter, french (mm)</th>
<th>Working length (cm)</th>
<th>Additional characteristics</th>
</tr>
</thead>
</table>
| Penumbra ACE68 ATC | 0.068 (1.73) | 6 (2) | 132 | - coil winding geometry  
- flexible distal shaft  
- 16 transition zones  
- atraumatic tip  
- beveled tip  
- compatible with the Penumbra System for aspiration  
- 14 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- 12 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- kink-resistant nitinol-reinforced shaft  
- 15 transition zones  
- supportive stainless steel reinforced proximal shaft 14 cm flexible distal zone  
- hybrid braid and coil design  
- soft distal tip  
- steam shapeable tip  
- compatible with the Penumbra ACE catheter family, 5MAX, and 4MAX  
- compatible with the Penumbra System for aspiration |
| Penumbra ACE64 ATC | 0.064 (1.63) | 5.75 (1.92) | 132 | - 14 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- 12 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- atraumatic tip  
- soft distal tip  
- steam shapeable tip  
- compatible with the Penumbra System for aspiration |
| Penumbra ACE60 ATC | 0.06 (1.52) | 5.4 (1.8) | 132 | - 12 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- 10 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- atraumatic tip  
- soft distal tip  
- steam shapeable tip  
- compatible with the Penumbra System for aspiration |
| Penumbra 5MAX ATC | 0.054 (1.37) | 5.0 (1.67) | 132 | - 14 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- 12 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- atraumatic tip  
- soft distal tip  
- steam shapeable tip  
- compatible with the Penumbra System for aspiration |
| Penumbra 4MAX ATC | 0.041 (1.04) | 4.3 (1.43) | 139 | - 12 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- 10 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- atraumatic tip  
- soft distal tip  
- steam shapeable tip  
- compatible with the Penumbra System for aspiration |
| Penumbra 3MAX ATC | 0.035 (0.89) | 3.8 (1.27) | 153 | - 12 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- 10 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- atraumatic tip  
- soft distal tip  
- steam shapeable tip  
- compatible with the Penumbra System for aspiration |
| Stryker Catalyst 6 OLC | 0.06 (1.52) | 5.4 (1.8) | 132 | - 12 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- 10 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- atraumatic tip  
- soft distal tip  
- steam shapeable tip  
- compatible with the Penumbra System for aspiration |
| MicroVention Sofia Plus OLC | 0.07 (1.78) | 6.3 (2.1) | 125/131 | - 12 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- 10 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- atraumatic tip  
- soft distal tip  
- steam shapeable tip  
- compatible with the Penumbra System for aspiration |
| Penumbra Velocity OLC | 0.025 (0.64) | 2.6 (0.87) | 160 | - 12 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- 10 transition zones  
- nitinol reinforced distal lumen  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- tracking technology permits access over microguidewire only  
- compatible with the Penumbra System for aspiration  
- atraumatic tip  
- soft distal tip  
- steam shapeable tip  
- compatible with the Penumbra System for aspiration |

### Table 3

Previous studies of aspiration thrombectomy in the distal vasculature.

<table>
<thead>
<tr>
<th>First author</th>
<th>Year</th>
<th>N</th>
<th>NIHSS admission (IQR or SD)</th>
<th>Catheter type</th>
<th>Additional treatment method</th>
<th>Aspiration success rate</th>
<th>Final TICI 2B/3 rate</th>
<th>NIHSS discharge (IQR or SD)</th>
<th>Postoperative sICH</th>
<th>Postoperative aICH</th>
<th>Other complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Park</td>
<td>2016</td>
<td>32</td>
<td>10.9 (5.1)</td>
<td>Penumbra 4MAX</td>
<td>N/A</td>
<td>27/32 (84%)</td>
<td>27/32 (84%)</td>
<td>4.3 (4.0)</td>
<td>0/32 (0%)</td>
<td>3/32 (9%)</td>
<td>0/32 (0%)</td>
</tr>
<tr>
<td>Vargas</td>
<td>2016</td>
<td>35</td>
<td>14.1 (6.9)</td>
<td>Penumbra 3MAX, 4MAX, 5MAX, 5MAX ACE</td>
<td>7/35 (20%)</td>
<td>26/35 (77%)</td>
<td>34/35 (97%)</td>
<td>NR</td>
<td>1/35 (3%)</td>
<td>0/35 (0%)</td>
<td>1/35 (3%) (Dissection of ICA)</td>
</tr>
<tr>
<td>Kim</td>
<td>2016</td>
<td>25</td>
<td>15 (8–17)</td>
<td>Penumbra 041 or 4MAX</td>
<td>5/25 (20%)</td>
<td>16/25 (64%)</td>
<td>18/25 (72%)</td>
<td>2 (1–6)</td>
<td>1/25 (4%)</td>
<td>3/25 (12%)</td>
<td>3/25 (12%) (Distal embolization)</td>
</tr>
</tbody>
</table>
The complication rates in the present series fall within the expected range, according to previous thrombectomy investigations. The most commonly reported and formidable complication, symptomatic ICH, was not encountered in any of our patients, though rates range from 0% to 7.7% in the thrombectomy randomized controlled trials and 0–4% in the M2 aspiration literature reviewed above [7,9,15–20]. Asymptomatic ICH, defined as the presence of a postoperative bleed without clinical manifestation, is less commonly reported. One randomized controlled trial reported a rate of 16.5% in the thrombectomy group and 10.7% in the tPA group [20]. The previous M2 aspiration studies report rates that range from 0% to 12% [7,9,15]. In the present study, 1 patient (12.5%) was found to have asymptomatic ICH, which compares similarly to these previously reported rates.

This study has several limitations. Due to its retrospective study design, the results are subject to the limitations of electronic medical record review. The sample size of the study is small, however this series represents the first preliminary evidence for distal aspiration thrombectomy with OLCs, a topic that has yet to be studied in larger cohorts. Our experience is that of a single center, which limits its generalizability, however our medical center serves a large, diverse urban population and receives transfers from a wide catchment area.

6. Conclusions

Preliminary experience with direct aspiration thrombectomy using OLCs demonstrates that OLCs may be safe and effective in the distal vasculature. Aspiration thrombectomy with an OLC may be useful for cases in which navigation to the site of a distal occlusion cannot be achieved with an ATC. In light of the recent FDA warning regarding off-label use, a prospective multicenter study is necessary to further evaluate these catheters.

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Conflicts of interest statement

The authors have no conflicts of interest to declare.

Ethical approval

Institutional IRB approval was obtained for this retrospective review.

Previous Publication

This work has not been published previously and is not currently under consideration for publication elsewhere.

References
