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PIPELINE™ EMBOLIZATION DEVICE\*

**PEDESTRIAN Registry**  
Long-term outcomes from the  
**Pipeline™** Embolization Device  
for the treatment of Intracranial  
Aneurysms

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Pipeline™ 혈류전환 스텐트를 사용한 임상 논문 중 최근 2021 년에 발행된 PEDESTRIAN STUDY 를 소개  
드리고자 합니다. 해당 스터디는 자사의 혈류전환 스텐트인 Pipeline™ Classic version 부터 Pipeline™ flex with  
Shield Version 까지 사용하여 총 1,000 개의 Aneurysm 을 대상으로 13 년간 진행된 Study 입니다.

## PEDESTRIAN STUDY

**Background :** 전향적 연구로 디자인되었으며 두개강내 뇌동맥류를 대상으로 안전성과 효과성을 연구하기로  
하였습니다.

**Methods :** 데이터는 2006 년 3 월부터 2019 년 7 월까지 Pipeline™-Embolization Device 를 사용해 치료한 두개강내  
뇌동맥류를 가진 환자를 포함하였습니다. 이전 치료에 따른 해부학적 부적격 환자 및 또는 재발 환자는  
포함되고 급성 지주막하 출혈 환자는 제외되었습니다. Primary angiographic endpoint 은 완전한 폐색 및 장기적인  
안정성이었습니다. 임상 및 방사선 추적은 3-6 개월, 12 개월, 그리고 그 이후 매년 수행되었습니다.

**Results:** 총 835 명의 환자(평균 연령  $55.9 \pm 14.7$  세, 여성 80.0% )를 대상으로 1000 개의 동맥류를  
포함하였습니다. 뇌동맥류는 크기는 64.6%가 Small (10mm 이하), 25.6%가 Large (11-24mm), 9.8%가 Giant  
( $\geq 25$ mm 이하)이었습니다. 총 1,214 개의 PED 가 사용되었습니다. Angiography follow up 은 전체 Aneurysm  
중 85.1% 인 776 개 동맥류가  $24.6 \pm 25.0$  개월 (평균)에서 가능하였습니다.

**Primary End Point:** 동맥류의 완전폐색은, 12 개월 추적관찰에서 동맥류의 75.8%, 2~4 년의 추적관찰에서  
92.9%, 5 년 초과 추적관찰에서는 96.4%로 입증 되었습니다. 시술 후 환자의 96.2%에서 mRS 점수가  
안정적으로 유지되거나 개선되었으며, 5 년 이상 환자의 99.1%에서 안정적으로 유지 또는 개선되었습니다.  
전체 주요 이환율과 신경학적 사망률은 5.8%였습니다.

**Conclusion :** 이 연구는 장기간 추적관찰을 통해, 높은 두개강내 뇌동맥류의 폐색률을 보이고, 합병증 및  
사망률이 낮다는 것을 보여주었습니다. Pipeline™-Embolization Device 를 사용한 두개강내 뇌동맥류의 혈관 내  
치료는 장기간에 걸친 임상 및 혈관 조영 결과는 개선되었으며 안전하고 효과적이라는 것을 입증하였습니다.

# Pipeline Embolization Devices for the Treatment of Intracranial Aneurysms, Single-Center Registry: Long-Term Angiographic and Clinical Outcomes from 1000 Aneurysms

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**BACKGROUND:** Prospective studies have established the safety and efficacy of the Pipeline™ Embolization Device (PED; Medtronic) for treatment of intracranial aneurysms (IA).

**OBJECTIVE:** To investigate long-term outcomes from the Pipeline Embolization Devices for the Treatment of Intracranial Aneurysms (PEDESTRIAN) Registry.

**METHODS:** The PEDESTRIAN Registry data were retrospectively reviewed, which included patients (March 2006 to July 2019) with complex IAs treated with PED. Patients with unfavorable anatomy and/or recurrence following previous treatment were included and excluded those with acute subarachnoid hemorrhage. The primary angiographic endpoint was complete occlusion and long-term stability. Clinical and radiological follow-up was performed at 3 to 6 mo, 12 mo, and yearly thereafter.

**RESULTS:** A total of 835 patients (mean age  $55.9 \pm 14.7$  yr; 80.0% female) with 1000 aneurysms were included. Aneurysms varied in size: 64.6% were small ( $\leq 10$  mm), 25.6% were large (11–24 mm), and 9.8% were giant ( $\geq 25$  mm). A total of 1214 PEDs were deployed. Follow-up angiography was available for 85.1% of patients with 776 aneurysms at  $24.6 \pm 25.0$  mo (mean). Complete occlusion was demonstrated in 75.8% of aneurysms at 12 mo, 92.9% at 2 to 4 yr, and 96.4% at  $>5$  yr. During the postprocedural period, modified Rankin Scale scores remained stable or improved in 96.2% of patients, with stability or improvement in 99.1% of patients  $>5$  yr. The overall major morbidity and neurological mortality rate was 5.8%.

**CONCLUSION:** This study demonstrated high rates of long-term complete aneurysm occlusion, stable or improved functional outcomes, and low rates of complications and mortality. Clinical and angiographic outcomes improved over long-term follow-up, demonstrating that endovascular treatment of IA with PED is safe and effective.

**KEY WORDS:** Flow diverter, Follow-up studies, Intracranial aneurysm, Stroke, Subarachnoid hemorrhage, Pipeline Embolization Device

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[www.neurosurgery-online.com](http://www.neurosurgery-online.com)

또한 Sub-group analysis 를 통한 Pipeline™ Flex with Shield 사용 그룹과 Shield 기술이 적용되기 이전 버전의 Pipeline™ 사용 그룹 간의 Outcome 비교 결과는 다음과 같습니다.<sup>2</sup>

## Pipeline™ Shield Subgroup vs Overall PEDESTRIAN Results

- **Lower complication rate overall (M&M 2.4% vs 5.8%)** : Surface modification 이 되어 있는 Pipeline™ Flex with Shield 제품을 사용한 환자군에서, Mortality & Morbidity 는 2.4 %로 전 세대의 Pipeline™ Classic 및 Flex 버전이 사용된 환자군과 비교했을 시 안전성 측면에서 보다 개선됨을 알 수 있었습니다.
- **Similar Complete Occlusion rate ( 92.5% @ 2yrs vs 92.9% @ 2-4 yrs )** : 뇌동맥류 폐색률에서는 두 환자군 사이 큰 차이점을 보이지 않았습니다.

**Conclusion** : 해당 스터디의 결과를 미루어 본다면, 두개강내 뇌동맥류에서 Pipeline™ Embolization Device 의 안전성 및 효과성을 확인할 수 있었으며, 무엇보다도 SHIELD Surface modification 기술이 적용 된 Pipeline™ Flex with Shield 버전의 제품이 효과성 측면에서는 동등한 반면, 안전성 측면에서는 보다 뛰어난 Outcome 을 가지고 있음을 확인 하였습니다.

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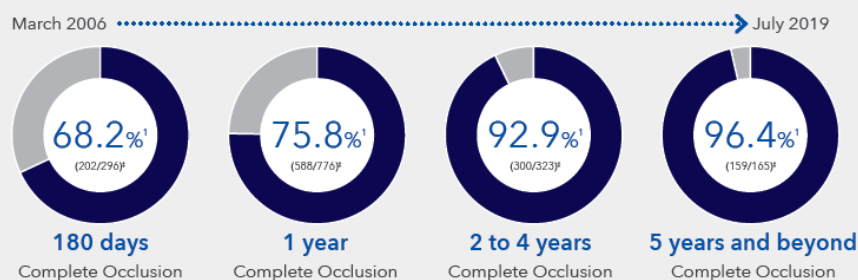
## PEDESTRIAN REGISTRY

Long-term outcomes from the Pipeline™ Embolization Device† for the treatment of Intracranial Aneurysms

PEDESTRIAN is the largest long-term study to date on Pipeline™, including 1,000 aneurysms treated.†  
This study demonstrated:

- High rates of long-term complete occlusion
- Stable or improved functional outcomes
- Low rates of complications and mortality

**Major Morbidity & Mortality (M&M):**  
5.8% over entire study period¹  
**Complete Occlusion**



### Pipeline™ Flex with Shield Technology™ subgroup showed:

(Pipeline™ Shield Subgroup⁵  
vs. Overall PEDESTRIAN Results)

- Lower complication rates overall (M&M: **2.4%** vs 5.8%)²
- Similar complete occlusion rates (92.5% @ 2yrs vs 92.9% @ 2-4yrs)²
- Trends towards less thromboembolic complications²

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† Includes Pipeline™ (Classic) Embolization Device (no longer commercially distributed), Pipeline™ Flex Embolization Device & Pipeline™ Flex Embolization Device with Shield Technology™

² Patient numbers at follow up

³ n=274 aneurysms (213 patients of which 80 patients were included in PEDESTRIAN)

## Subgroup showed: ²

(Pipeline™ Shield Subgroup\*\*\* vs. Overall PEDESTRIAN Results)

- ▶ Lower complication rates (M&M: 2.4% vs. 5.8%)
- ▶ Similar complete occlusion rates (92.5% @ 2yrs vs. 92.9% @ 2 to 4yrs)
- ▶ Trends towards less thromboembolic complications

<Reference>

1. Neurosurgery 0:1–7, 2021, <Pipeline Embolization Devices for the Treatment of Intracranial Aneurysms, Single-Center Registry: Long-Term Angiographic and Clinical Outcomes from 1000 Aneurysms>
2. Lylyk, I. Long-term outcomes from the Pipeline Embolization Device for the Treatment of Intracranial Aneurysms (PEDESTRIAN) registry with PED Shield Sub-analysis. Presented at Society of Neurointerventional Surgery Conference. Colorado Springs, CO, USA. July 2021.

메드트로닉([www.medtronic.com](http://www.medtronic.com))은 전세계 환자들의 고통 경감과 건강 회복, 그리고 수명 연장을 위한 의료 기술, 서비스 및 솔루션 부문의 글로벌 리더다. 160 여개국에 10 만명 이상의 임직원을 두고 있습니다. 메드트로닉은 세계 각지의 고객 및 이해관계자와의 협력을 통한 보건의료계의 발전을 추구합니다.

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