Mechanical Thrombectomy Devices for the Treatment of Peripheral Arterial Occlusions

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The changing landscape of thrombolytic drugs used for treating peripheral occlusive disease has spurred increasing use of mechanical thrombectomy devices (MTDs). These devices comprise a variety of tools intended to remove, fragment, or disperse thrombus in veins, arteries, or bypass grafts. Although most devices are U.S. Food and Drug Administration approved for use in occluded hemodialysis access grafts, only one, the AngioJet device, is currently approved for use in peripheral arterial applications. Nevertheless, most devices have been used for this off-label application, and clinical centers have published their results. This article reviews the distinguishing features of current mechanical thrombectomy devices, as well as the currently available literature reporting on their use in peripheral arterial occlusions.
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Thrombus management forms a critical part of the care of vascular patients. It encompasses a wide range of indications, locations, and clot amounts, including intracranial vessel occlusions containing pea-sized clots, dialysis access grafts bearing approximately 3–6 cc of thrombus, ischemic lower extremities with native artery or bypass occlusions, and iliofemoral deep vein thromboses containing 100–200 cc of thrombus. The lytic landscape has changed with the growing familiarity with tissue plasminogen activators (rt-PAs), the market withdrawl and return of urokinase, and the advent of newer agents such as tenecteplase and plasmin-based products. With this

Table 1
Characteristics of an Ideal Mechanical Thrombectomy Device

Remove entire thrombus
Cause no injury to native vessel endothelium
Replace the need for a thrombolytic agent
Be effective in both acute and chronic organized clots
Cause no distal embolization
Cause minimal or no blood loss or hemolysis
Be effective in all vessel sizes
Be flexible and maneuverable
Have guidewire compatibility
Be easy to set up and operate
Have a low profile
Work rapidly
Be inexpensive

change, the longstanding dogma regarding the necessity for long infusion times, anticipated bleeding risks, and patient selection has been challenged. Rapid, safe removal of clots in order to restore patency of veins, arteries, or grafts is the goal, and increasingly, percutaneous mechanical thrombectomy devices (MTDs) have been used in this quest, either as stand-alone therapies or in combination with catheter-directed, chemical thrombolysis. These devices encompass a variety of tools intended to remove, fragment, or disperse thrombi through different means, including mechanical or vacuum-assisted mechanical fragmentation and aspiration, hydrodynamic recirculation, and ultrasound-generated cavitation.

When considering the rationale for using an MTD, "faster, cheaper, and safer" serves as a simple mantra. For example, an MTD that provides faster reperfusion of ischemic limbs might broaden use of catheter techniques to patients with ischemia previously too advanced to tolerate the time course of thrombolytic infusions. If MTD use shortened stays in intensive care units and reduced lytic drug costs, then economic arguments for routine use could be advanced. For example, the mean infusion of 7.5 million to 10 million units of urokinase for treatment of lower-extremity deep venous thromboses (DVT) requiring two or more days in an intensive care unit has arguably contributed to the lack of widespread use of DVT interventions.[1,2] Converting DVT therapy to a one-night stay could make its widespread application more palatable to patients and referrers. Many caveats exist, of course. For example, in contrast to the possible economic and clinical drivers for MTD use in DVT, those for MTD use in occluded dialysis grafts shifted dramatically with the release of 2-mg vials of rt-PA priced at approximately $50 and dissemination of "lyse and wait" techniques.[3,4] Lastly, MTDs could prove "safer" if they lead to fewer bleeding complications, because lytic drug doses could be reduced or the drug could be rendered unnecessary. This theoretic benefit would need to be balanced against device risks including distal embolization, hemolysis, vessel wall damage, etc.

In assessing the role of an MTD for a clinical application, it is worth considering the attributes of an ideal MTD (Table 1). Of course, no perfect device or therapy exists, but these characteristics provide a framework for device assessment and/or comparison with lytic or surgical tools.

Rapid, safe removal of clots is the goal, and increasingly, percutaneous MTDs have been used in this quest.

Classifications

Current devices may be classified according to a number of schemes. One approach is to divide devices into those that contact vessel walls (and often provide good clot-stripping efficacy with greater risk of endothelial denudation) versus those that create forces to produce clot fragmentation with or without clot removal (and tend to injure vessels less). Current devices can thus be classified as shown in Table 2.

Arguably, clot removal (rather than fragmentation or dispersal) is paramount in peripheral arterial or neurovascular applications where embolization of the microcirculation is anathema. A classification system based on this characteristic is shown in Table 3.

Arguably, clot removal (rather than fragmentation or dispersal) is paramount in peripheral arterial or neurovascular applications.

At present, all devices (except for the OmniSonics system) are approved for use in occluded hemodialysis access grafts (and native fistulae, in the case of the Arrow PTD). Dialysis grafts are an appealing initial route for human clinical applications and

Table 2
Classification of Mechanical Thrombectomy Devices Based on Mechanism of Action

Classification	Device	Manufacturer
Contact vessel wall	Arrow-Trerotola Percutaneous Thrombectomy Device	Arrow International, Reading, PA
	Cragg Brush	Micro Therapeutics, Irvine, CA
	Castaneda Over-the-Wire Brush	Micro Therapeutics, Irvine, CA
	Solera	Bacchus Vascular, Santa Clara, CA
Create clot fragmentation forces with or without removal	Hydrolyser	Cordis Endovascular, Warren, NJ
	Oasis	Boston Scientific/Medi-Tech, Natick, MA
	AngioJet/Xpeedior	Possis Medical, Minneapolis, MN
	Gelbfish Endovac	Neovascular Technologies, Brooklyn, NY
	Thrombex PMT	Edwards Lifesciences, Irvine, CA
	Amplatz Thrombectomy Device	Microvena, White Bear Lake, MN
	OmniSonics (investigational)	OmniSonics Medical Technologies, Wilmington, MA

regulatory approval, because device demands are far less stringent than for arterial applications. Patients with occluded hemodialysis grafts do not manifest critical arterial ischemia, carry a small clot burden, and tolerate particulate venous embolization with few side effects.[5] Compared with the trauma of repeated graft punctures, MTD injury to the polytetrafluoroethylene grafts is relatively insignificant. Lastly, device efficacy need not match the complete or near-complete dissolution required in arterial circulation because residual thrombus is generally fragmented and swept into the venous outflow during balloon angioplasty of underlying intragraft or anastomotic stenoses. Currently, only the AngioJet rheolytic thrombectomy system is approved for peripheral arterial (and coronary) applications. However, the unmet clinical need and the availability of multiple devices have resulted in experimental and off-label clinical use of MTDs in arterial systems.

AngioJet/Xpeedior

This over-the-wire rheolytic thrombectomy device uses the Venturi effect to create a hydrodynamic vortex that draws in and fragments the surrounding thrombus. The clot is evacuated through the exhaust lumen of the catheter. The system requires use of a specialized pump-drive system that creates very high pressures (8000–10,000 psi), almost 10 times those of contrast-injector–driven units. These high pressures allow the catheter to potentially extract more thrombus than other systems based on larger catheter profiles. The device is available in multiple sizes, including 4, 5, and 6 Fr. A microcatheter-sized device is in development for neurovascular applications. Chief disadvantages of the current device include the possibility of fluid overload and hemolysis. With heavy use, hemolysis is often seen, though it is rarely of clinical importance in appropriately selected patients. Patients with renal insufficiency, tenuous fluid status, or congestive heart failure may not tolerate extended runs of the device. Unexplained bradycardia and transient heart block have been described when using the device in central venous or pulmonary applications.

Sharafuddin and colleagues studied the effect of the 5-Fr AngioJet device in canine arteries compared with

Table 3
Classification of Mechanical Thrombectomy Devices Based on Clot Removal*

Classification	Device
Clot aspiration	AngioJet/Xpeedior
	Hydrolyser
	Oasis
	Gelbfish Endovac
	Thrombex PMT
	Solera
No clot aspiration	Amplatz Thrombectomy Device
	Arrow-Trerotola Percutaneous Thrombectomy Device
	Cragg Brush
	Castaneda Over-the-Wire Brush
	OmniSonics (investigational)

*Product manufacturer information shown in Table 1.

Fogarty-balloon thrombectomy and untreated controls.[6] The AngioJet group demonstrated significantly less endothelial denudation (12%) than the Fogarty-balloon group (42%), and no statistically significant difference from the untreated control group (10.3%). Transient hemolysis occurred, with plasma free-hemoglobin levels returning to normal in three days. Particulate embolization equal to approximately 12% of the initial clot volume was seen, with 99.8% of it smaller than 100 μm and none larger than 1000 μm. In 87 coronary-artery and vein-graft lesions treated in the Vein Graft AngioJet Study, the AngioJet reduced minimum lesion diameter by 0.81 mm to 1.7 mm and reduced the mean thrombus area from 79 mm^2 to 21 mm^2.[7,8]

Hydrolyser

This multi-lumen device uses the Venturi effect to fragment and remove the thrombus. It uses a standard angiographic injector to generate approximately 750 psi at a flow rate of 4 cc/min. It uses an eccentric opening, which, until the nozzle was redesigned, limited the uniformity of the circumferential vortex of the device. Extended use can potentially lead to fluid overload and hemolysis. Comparison of the device with Fogarty balloons and controls (intravascular ultrasound catheter alone) in goat arteries revealed significantly greater reactive intimal thickening with the Fogarty balloon than with the experimental or control groups.[9,10] When applied in vessels at least 3 mm in diameter, there was no significant difference in vessel wall reaction between the Hydrolyser and the control group. A comparison of the Hydrolyser and AngioJet in 7- and 20-mm diameter flow models indicated a clot removal advantage to the Hydrolyser in the 7-mm (arterial model); the devices proved equivalent when combined with guiding catheters. The Hydrolyser demonstrated a significantly higher particulate embolization rate than the AngioJet (4.8% vs 1.8%, respectively)[11] in this model.

Oasis

Once named the SET (shredding embolectomy thrombectomy) catheter, this over-the-wire device functions similarly to the Hydrolyser, in that it employs a conventional angiographic injector to generate a Venturi effect at its leading tip. Its exposed nozzle provides a more uniform vortex than does the original eccentric Hydrolyser nozzle. Its disadvantages include hemolysis and possible fluid overload. In comparing the Oasis, Hydrolyser, and AngioJet in vitro, Müller-Hülsbeck found that time to thrombectomy was fastest with the Hydrolyser (14.8 sec) compared with the Oasis (16.2 sec) and the AngioJet (37.7 sec).[12] Embolic weight was greatest with the Hydrolyser and least with the Oasis. The AngioJet and Hydrolyser performed isovolumetrically, unlike the Oasis, which withdrew more saline than was injected.

Gelbfish Endovac

This mechanical device depends upon the operator's rapid oscillation of a clot fragmenting "spoon" combined with clot aspiration into a syringe or evacuated container. It is not hydrodynamic. The device is most effective within a close space; once partial flow is restored, efficacy drops, though potential embolization risk remains. Current iterations do not traverse curves well and do not follow guidewires. This author is unaware of any data on peripheral arterial use.

Thrombex PMT

This over-the-wire device functions on the principle of an Archimedes screw. It contains a rotating helical screw that fragments the clot, which is then aspirated into an evacuated container. The device is potentially a wall-contact device, though its range is smaller than those of larger brush or basket-based devices. As a low-speed macerating device, it would be expected to potentially create embolic particles larger than deemed acceptable for peripheral arterial applications. No results of human peripheral arterial applications or in vitro clinical trials have been published.

The unmet clinical need and the availability of multiple devices have resulted in off-label clinical use of MTDs in arterial systems.

Amplatz Thrombectomy Device

The Clot Buster device is a compressed-gas–driven turbine that spins at greater than 100,000 rpm and creates a recirculating hydrodynamic vortex that draws in and macerates the clot. It does not aspirate the thrombus; rather, it disperses the fragments into the bloodstream. An in vitro human clot model demonstrated clot maceration in 99.8% of 10-day-old thrombus with embolic particles ranging from 13 to 1000 μm. Other flow models demonstrated similar results.[16] Hemolysis risk appears proportional to catheter activation time.[17] The current Helix design provides an estimated 24% increased efficacy in a 7-Fr platform.

Table 4
Literature Review of Mechanical Thrombectomy Devices (MTDs) Used for Peripheral Arterial Occlusion

Device	Author	N	Conduit, n (%)	Duration, n	MTD Success,* n (%)	Adjunctive Procedures	Primary Patency, %	Complications, %
Oasis	Hoepfner et al 1999[21]	51	Native: 44 (86) Grafts: 7 (14)	All acute	6 (11.8)	Lysis: 5 PTA: 20 PAT: 15 SA: 3	1 mo: 64 6 mo: 54	Hemorrhage: 8 Emboli: 4.8 Acute occlusion: 37 Amputation: 17.7 Mortality: 8
AngioJet	Müller-Hülsbeck et al 2000[28]	112	Native: 99 (86) Grafts: 16 (14)	All acute	79 (71)	Lysis: 20 PTA: 68 PAT: 11	6 mo: 68 2 y: 60 3 y: 58	Embolization: 9.8 Dissection: 8 Perforation: 3.6 Amputation: 1.8 Mortality: 7
	Kasirajan et al 2001[31]	83	Native: 52 (63) Grafts: 31 (37)	Acute: 62 Chronic: 21	Complete: 51 (61), Partial: 19 (23)	Lysis: 50 PTA: 47	3 mo: 90 6 mo: 78	Hemorrhage: 10.5 Emboli: 2.3 Dissection: 3.5 Perforation: 2.3 Amputation: 11.6 Mortality: 9.3
	Silva et al 1998[29]	22	Native: 13 (59) Grafts: 9 (41)	All acute	21 (95)	PTA: 21	NA	Hemorrhage: 10 Embolism: 9 Dissection: 5 Occlusion: 18 Amputation: 5 Mortality: 14
	Wagner et al 1997[30]	50	Native: 39 (78) Grafts: 11 (22)	All acute	26 (52)	Lysis: 15 PTA: 34 PAT: 9	1 yr: 69	Hemorrhage: 6 Emboli: 6 Dissection: 6 Perforation: 4 Amputation: 8 Mortality: 0
Hydrolyser	Reekers et al 1996[22]	28	Native: 11 (39) Grafts: 17 (61)	Acute: 23 Chronic: 5	23 (82)	Lysis: 11 PTA: 20 PAT: 2	1 mo: 50	Embolization: 18 Hemorrhage: 0 Acute occlusion: 10.7 Amputation: 11 Mortality: 0
	Henry et al 1998[23]	41	Native: 28 (68) Grafts: 8 (20) Other: 5	All acute	34 (83)	Lysis: 10 PTA: 29 PAT: 17	1 mo: 73	Acute occlusion: 12 Emboli: 2.4 Amputation: 0 Mortality: 0
Amplatz	Rilinger et al 1997[26]	40	All native	All acute	30 (75)	Lysis/PTA/SA: 9	NA	Hemorrhage: 2.5 Device failure: 7.5 Emboli: 0 Amputation: 5 Mortality: 0
	Tadavarthy et al 1994[24]	14	Native: 2 (14) Grafts: 10 (71) Other: 2	Acute: 9 Chronic: 5	10 (71)	Lysis: 4 PTA/SA: 11	6 mo: 43	Hemorrhage: 14.3 Emboli: 14 Device failure: 7 Amputation: 0 Mortality: 0
	Görich et al 1998[27]	18	All native	All acute	14 (78)	Lysis: 12 PAT: 9	NA	Hemorrhage: 6 Device failure: 6 Amputation: 6

*Definition of success varies among studies.
PTA, percutaneous transluminal angioplasty; PAT, percutaneous aspiration thrombectomy; SA, Simpson athrectomy; NA, not applicable.
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Arrow-Trerotola Percutaneous Thrombectomy Device

This device is based upon a self-expanding metal basket that is spun at approximately 3000 rpm using a battery-powered motor. An over-the-wire system is available. The device can generate embolic particles of 3 mm in diameter, though in one study, the majority was less than 1 mm in diameter.[13,14] An in vivo comparison of the device with Fogarty balloons in rabbit veins revealed similar, near-complete endothelial denudation with both devices. Its risks of large-clot-fragment embolization and vessel wall injury make its current iteration and method of action unsuited to peripheral arterial applications.[15]

Cragg and Castaneda Brushes

These devices are intended as adjuncts to chemical thrombolysis by macerating the clot and distributing lytic agents more uniformly throughout it. As nonaspirating wall-contact devices, they carry risks of endothelial damage and distal embolization. In one flow model, the Cragg thrombolytic brush removed only 60% of the thrombus, mandating its use with thrombolytic agents.[16] Testing within a canine femoropopliteal bypass graft model revealed distal emboli in two thirds of cases, with particles as large as 3 mm. Vessel damage was noted in 56% of proximal and 78% of distal graft anastomoses.[15,18] No human peripheral arterial trials are known to have been conducted.

OmniSonics

This investigational device functions similarly to a mini-lithotripter by using high-energy acoustic waves to ablate the clot. A hand-held transducer converts electrical signals into specific ultrasonic motion of the probe, resulting in cavitation along the active section of the device. Early in vitro and in vivo studies suggest that particulate size is small (10 μm) and vessel wall injury is low (Robert Rabiner, OmniSonics, personal communication, April 2002). This novel class of devices may prove useful as stand-alone tools or adjunctive tools with chemical thrombolysis.[19,20] Clinical trials in occluded hemodialysis grafts are under way. No results of peripheral arterial applications are known.

Clinical Applications of MTDs in Peripheral Arterial Occlusive Disease

As expected, most of these devices have been used and reported in off-label venous, pulmonary, or arterial applications. Most reports are of small case series or single cases. It is difficult to draw conclusions from these publications, as bias often promotes early publication of successful device use in small series rather than of complications or device limitations. Randomized trials evaluating MTD use with or without lytic agents or compared to surgery have not been performed. Important attributes of MTD use in off-label, peripheral arterial applications include minimal embolization, involving tiny particles; thrombus aspiration; and limited vessel wall damage. Accordingly, larger clinical trials have focused on non–wall-contact fragmentation devices with or without aspiration, such as the Oasis, Hydrolyser, AngioJet, and Amplatz Thrombectomy Device. The major peripheral arterial MTD trials are summarized in Table 4. When reading this literature, it is important to note that distal embolization is angiographically assessed in some series, and clinically determined in others. Clinical assessment is a cruder measure that may markedly underestimate its incidence. Furthermore, definitions of success vary among publications, ranging from complete clot extraction to less than 50% residual thrombus after MTD activation.

Hopfner and colleagues reported use of the Oasis catheter in 51 patients, with complete clot extraction achieved by the MTD used alone in 12% of cases.[21] Most remaining patients required chemical thrombolysis and/or balloon angioplasty. No significant change in serum creatinine was reported, suggesting minimal or subclinical hemolysis. Nineteen reocclusions occurred by 1 month; 6-month primary patency was 54%.

Reekers and colleagues reported use of the Hydrolyser in 11 native arteries and 17 grafts with success in 88% of grafts and 73% of native vessels.[22] Chemical thrombolysis was avoided in 58% of cases. Embolization was seen in five cases, managed by percutaneous aspiration or thrombolysis in all but one case. Henry and coworkers reported Hydrolyser use in 28 native arteries, eight grafts, and five venous applications.[23] They described success in 83% of cases, though technical success was defined as residual clot occupying less than 50% of lumen diameter. Thrombolysis was required in 10 cases, angioplasty in 29, and percutaneous thrombus aspiration in 17. One-month patency was 73%.

Several studies have reported results with the Amplatz thrombectomy device.[24-27] The largest, that of Rilinger and colleagues, reported its use in 40 native arterial acute occlusions.[26] Embolic occlusions were present in 80% of patients. Complete thrombus extraction was reported in 75% of cases. No clinically relevant distal embolization was seen, though angiographic evaluation was not performed. Chemical thrombolysis was used in 20% of cases.

Multiple studies have reported use

of the AngioJet in arterial applications with clot-removal success rates ranging from 52% to 95%, depending upon the definition of success.[28-31] Silva and coworkers reported device use in 22 limbs within 2 weeks of ischemia onset.[29] In 52% of their patients, thrombolysis was deemed contraindicated. They reported 1- and 6-month limb-salvage rates of 95% and 89%, respectively. Kasirajan described an initial success rate of 61% for use of the AngioJet as a stand-alone therapy in 52 native arterial occlusions and 31 bypass grafts.[31] In this series, 25% of patients had chronic occlusions. Chemical thrombolysis was used in 50 cases, and angioplasty in 47, yielding an overall primary patency of 90% at 3 months and 78% at 6 months. In the largest series to date, Müller-Hülsbeck and colleagues treated 99 native and 16 bypass-graft acute occlusions.[28] The mean device activation time was 280 ± 163 seconds. Overall success (defined as > 75% clot removal) was achieved in 88.4% of cases with 29% of these cases requiring adjunctive chemical thrombolysis. Distal embolization was reported in 9.8% of cases, dissection in 8%. Mean follow-up time was 14.8 months; primary patency, secondary patency, and amputation-free survival rates after 2 years were 60%, 84%, and 75%, respectively.

Certain principles should determine device choices for peripheral arterial occlusions, including minimization of endothelial damage and downstream embolization of the arterial microcirculation.

Conclusions

The tools available to vascular specialists treating acute peripheral arterial occlusions comprise a variety of new and old thrombolytic agents and mechanical thrombectomy devices. Choosing the best combination should be based upon empiric scientific evidence of safety and efficacy rather than on anecdotal experience. Comparative studies are needed to determine whether (and which) MTDs will prove faster, safer, and/or less expensive than chemical thrombolysis alone, and whether they allow treatment of patients with more advanced ischemia. Until then, certain principles should determine device choices for peripheral arterial occlusions, including minimization of endothelial damage and downstream embolization of the arterial microcirculation. At present, it is unrealistic to expect MTDs to replace chemical thrombolysis in peripheral arterial occlusions. One angioscopic study of dialysis grafts after use of a variety of MTDs revealed that many devices left moderate amounts of thrombus within the grafts, indicating that current efficacies were clearly less than those estimated with angiography.[32] Indeed, the expectation that purely mechanical thrombectomy will be successful may not be appropriate and may encourage excessive device application by physicians, leading to greater risks of residual thrombus, vessel dissection, perforation, or embolization. Rapid debulking of the thrombus alone is a useful goal, because partial restoration of flow in an acutely ischemic limb can dramatically reduce the depth of ischemia, allowing complete chemical thrombolysis to take place. This process will unmask the often-underlying culprit lesion or restore flow in the occluded downstream runoff vessel. Ultimately, whether combination therapies involving

Main Points

- The changing landscape of thrombolytic drugs used for treating peripheral arterial occlusive disease has spurred increasing use of mechanical thrombectomy devices (MTDs).
- Only the AngioJet rheolytic thrombectomy system is currently approved for peripheral arterial applications; however, most devices have been used for this off-label application.
- Comparative studies are needed to determine whether (and which) MTDs will prove faster, safer, and/or less expensive than chemical thrombolysis alone, and whether they allow treatment of patients with more advanced ischemia.
- Until then, certain principles should determine device choices for peripheral arterial occlusions, including minimization of endothelial damage and downstream embolization of the arterial microcirculation.
- At present, it is unrealistic to expect MTDs to replace chemical thrombolysis in peripheral arterial occlusions.
- Ultimately, whether combination therapies involving thrombolysis, MTD, and other pharmacologic agents will justify their costs by improving the speed, safety, and effectiveness of thrombus-management procedures remains to be shown.

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