

## Mechanical Thrombectomy of Occluded Haemodialysis Grafts and Native Vessel Fistulas

a report by

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Dr András Kónya is an Associate Professor of Diagnostic Radiology at the University of Texas MD Anderson Cancer Center. His research interests include interventional radiology and catheter ablation, and the primary focus of his research activity is developing new interventional radiologic devices and techniques. Recently, he conducted studies with colleagues to test a mixture of ethanol and iodised lymphographic contrast material (ethiodised oil) for transcatheter ablation of renal tumours. They have developed a new two-phase technique consisting of capillary embolisation using the mixture in combination with arterial occlusion and are currently investigating its efficacy in the laboratory.

More than 260,000 patients are undergoing haemodialysis in the US and each year the number of new patients with end-stage renal disease is approaching 100,000.<sup>1</sup> In this patient population, the leading cause for hospital admission is a problem related to the life-sustaining access. More than 80% of this patient population has a polytetrafluoroethylene (PTFE) graft access, which provides an average patency of 20 months after placement. Outside the US, native vessel arteriovenous fistula accesses have been preferred to synthetic graft accesses and are utilised extensively.

Shunt thrombosis is a frequent complication in haemodialysis shunts, particularly in synthetic grafts, but it may also be found in autologous fistulas. An underlying stenosis or aneurysmal vein causing flow irregularities are predisposing factors for thrombosis, and venous stenosis in particular is found in the vast majority of cases. Venous stenosis in grafts is typically located at the venous graft anastomosis, whereas in native fistulas, stenoses are more frequently located distally close to the arteriovenous anastomosis.<sup>2</sup> Early intervention to dilate an underlying stenosis, which may be efficacious for dysfunctional autogenous haemodialysis fistulas in particular, may prevent thrombosis.<sup>3</sup>

Typically, the arterial and venous anatomy is sufficient to support three upper extremity grafts or fistulas; therefore, permanent access availability from the upper extremities is limited. If a renal transplant does not become available, many patients will need to resort to peritoneal dialysis or a less preferable haemodialysis access, such as a lower extremity graft or a haemodialysis catheter. Therefore, efforts to maintain each available permanent haemodialysis access have become a matter of paramount importance.

The type and management of the haemodialysis access greatly influence survival and quality of life for patients undergoing haemodialysis. The Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines for vascular access recommend primary placement of native or autogenous haemodialysis

fistulas in preference to PTFE grafts and central venous catheters because the former form of access has fewer complications and longer durability.<sup>4</sup> With the introduction of these guidelines, there has been a shift in clinical practice. Collins et al. have noted increased placement of these fistulas in patients in the North American haemodialysis population.<sup>5</sup>

Compared with prosthetic grafts, clotted native fistulas pose a wider range of technical difficulties:

- The thin venous wall is difficult to palpate and is transfixated without resistance.
- The venous anatomy is extremely variable.
- The underlying stenosis can be located anywhere from the subclavian artery to the central veins.
- Stenosis is much tighter than in grafts and can be impossible to traverse.
- The presence of side branches can be deceptive.
- The volume of thrombus can be very high.
- Aneurysmal segments, which are bigger and longer than in grafts, can contain thick, old mural thrombi.
- Acute thrombosis of the feeding artery commonly occurs in cases of end-to-end anastomosis.<sup>6</sup>

### Percutaneous Thrombectomy

There are three primary interventional radiology methods for percutaneous thrombolysis for both synthetic grafts and native arteriovenous fistula accesses:

- pharmacological thrombolysis;
- pulse-spray pharmacomechanical thrombolysis; and
- pure mechanical thrombolysis or thrombectomy.

Several articles have recently reported excellent results in the percutaneous declotting of synthetic

grafts and native fistulas for haemodialysis.<sup>6–14</sup>

These articles report on using different pharmacomechanical and/or mechanical thrombectomy methods and devices including thrombus aspiration;<sup>6,12,13</sup> Fogarty balloon thrombectomy; rotating mini pig-tail catheter;<sup>9</sup> bolus urokinase infusion;<sup>11</sup> rheolytic (hydrodynamic) devices such as the Cordis hydrolyser,<sup>12,14</sup> Boston Scientific Oasis<sup>2</sup> and Possis AngioJet<sup>21</sup>, which all utilise the Venturi effect; and vortex-based devices without aspiration such as Amplatz ClotBuster.<sup>8,18</sup> The wall contact devices like the Cragg Brush,<sup>14</sup> Casteñada Brush and the Arrow-Trerotola percutaneous thrombectomy device (PTD)<sup>15</sup> are clot-macerators and form a sub-category within the mechanical thrombectomy devices; they are equipped with a motor drive (3,000rpm) and have been used mostly for declotting synthetic graft accesses. There is only one report in the literature on utilising the Arrow-Trerotola PTD for mechanical declotting of thrombosed haemodialysis native fistulas.<sup>10</sup>

Reports have been published finding that all these devices can restore flow (high technical success) but all can produce distal emboli, endothelial denudation due to contact surfaces or high-pressure exerted by the jet or turbulence, and different degrees of haemolysis. All the devices that aspirate (Oasis, AngioJet, Hydrolyser) can produce both considerable blood loss and fluid overload.

### Devices

The Arrow-Trerotola PTD (Arrow International), with a 5F rotating nitinol basket fragmentation cage, requires only a minute or two to restore the flow. It is unique among the current family of devices for two reasons. First, the wires of the basket contact the conduit wall directly. This is supposed to be more effective in disrupting adherent clot than any fluid-driven product. In addition, the PTD is the only device that reliably removes the platelet-rich arterial plug.<sup>16</sup> The over-the-wire (OTW) PTD works on a 7F platform with a 0.025-inch guidewire.

The Amplatz mechanical thrombectomy device (Clot Buster) and its new version (Helix Catheter) (ev3) are 6F and 7F devices, respectively, neither with guidewire compatibility, consisting of a gas-driven, high-speed (150,000rpm) cam that pulverises the clot. The mechanical components of the catheter never actually contact the wall. The active component is the fluid stream. Residual thrombus may occur with the device and it cannot be used to treat the arterial plug.

The Edwards thrombex percutaneous mechanical

thrombectomy device (PMT) has a 6F size. The device is equipped with an auger screw housed by the tip. As the screw rotates, engaging thrombus, it enters the tip housing where it is sheared and aspirated actively.

Among the fluid-driven devices, both the 6F Cordis Hydrolyser and the 6F Meditech Oasis catheter use the Venturi effect to achieve mechanical thrombolysis. Both create suction by forcing a single high volume (3cc/sec) from a small tube either positioned across from an eccentric open gap (Hydrolyser) or positioned opposite to the catheter's end-hole (Oasis). Both catheters are driven by a conventional angiographic injector. One concern with these devices is the amount of blood aspirated during the procedure (50–150mL per pass), which could be problematic for these chronically anaemic patients. The AngioJet (Possis Medical) has a costly dedicated drive unit. The design is more versatile than other similar devices, and approved for peripheral vascular, native coronary and arteriovenous access applications. The disposable catheter costs extra.

Among the simpler devices, the Fogarty balloon catheter is probably the best for removing the arterial clot because of its low cost and durability, but the original device is not guidewire-compatible. Recently, guidewire-compatible Fogarty balloons have been made available. Other OTW alternatives include occlusion balloons and percutaneous transluminal angioplasty (PTA) balloons to macerate the clots.

### Disadvantages

Despite many advantages, mechanical thrombolytic devices have some significant drawbacks. Residual adherent clot is a significant problem with devices that do not get into contact with the wall of the graft during the procedure. Some devices do not remove the macerated clot and it is embolized into the lungs. The use of the devices with suction may result in significant blood loss, and inadvertent fluid overload is a possible complication.

### Efficacy

The excellent technical success rate (>90% average) achievable with almost all mechanical thrombectomy devices could not be translated into long-term patency rate (see *Table 1*). The three-month average primary patency rate for graft declotting remains very disappointing (approximately 40%). One of the possible reasons for this failure may be residual adherent clots, which are not sufficiently addressed even by the wall contact devices. Angioscopic

**Table 1: Reported Results using Mechanical Thrombectomy Devices to Treat Thrombosed Haemodialysis Grafts**

Device	Tech Success	One Month	Three Months	Six Months
ATD <sup>18</sup>	89	47		
AngioJet <sup>21</sup>	73	32	15	
PTD <sup>15</sup>	95	39	20	
Hydrolyser <sup>18</sup>	84	57	48	37
Cragg brush <sup>14</sup>	93	37		
Oasis <sup>2</sup>	95	69	40	

ATD = Amplatz thrombectomy device.<sup>17</sup>

observations reveal that wall-contact thrombectomy devices (Cragg Brush, Arrow-Trerotola PTD) leave less residual thrombus than hydrodynamic devices, aspiration devices, or the 'lyse and wait' technique.<sup>24</sup>

The declotting of an autologous (native) arteriovenous fistula poses extra challenges compared with the synthetic graft.<sup>6</sup> Rocek et al. reported a 90% clinical success rate with use of the PTD in a short series of 10 fistulas, but there was significant residual thrombus in three cases.<sup>10</sup> In all 10 fistulas (seven forearm, three upper arm), the thrombosed segment was more than 10cm long and the diameter was greater than 6mm.

There is a need for a rapid, effective, safe, easily performed and minimally invasive out-patient procedure that will restore function to a thrombosed graft. Theoretically, a simple multi-function device for mechanical thrombolysis would be ideal for this purpose. The treatment consists of two parts: restore the flow in the venous side eliminating the outflow venous stenosis(es); and restore the flow within the graft/fistula. The stenoses at the venous anastomosis, along with possible more proximal stenoses located in the central veins, should be treated first with angioplasty. The second step is clot maceration in the graft/fistula (especially in the venous limb), as well as the removal of intragraft thromboses and the arterial plug. Ideally, methods requiring the least consumable devices should be preferred.

An ideal mechanical thrombectomy device is able to remove both acute and chronic organised thrombus completely without using thrombolytic agents. It does not cause injury to the native vessel and blood loss and/or haemolysis. Such a device is easily operable, effective in all vessel sizes, flexible and manoeuvrable, guidewire-compatible with a low profile, and works rapidly. Ideally, all of these features are offered by an inexpensive design.<sup>23</sup> Treatment of a thrombosed haemodialysis graft is an ideal application for a mechanical thrombectomy device. The soft, acute thrombus contained within the graft can be quickly macerated and removed with minimal risk of damaging native vascular endothelium.<sup>17</sup> n

### AKónya Eliminator Plus™

#### A Non-rotational Guidewire-compatible Mechanical Thrombectomy Device with Torque Control

The directional ability of the currently available mechanical thrombectomy devices (MTD) is poor ('in-axis' designs):

- lack of guidewire compatibility requires the use of large guiding catheters;
- non-adjustable wall-contact devices with motor drive do not offer controlled operation and cause endothelial damage;
- MTDs are costly and some require expensive equipment;
- no devices are available for large diameter vessels; and
- their use in chronic and adherent thrombi is inefficient.

The AKónya Eliminator Plus™ (AKE-P), however, offers distinct advantages to overcome market shortcomings. The AKE-P is a hand-operated, low-profile design featuring a 6F woven mesh basket and a 4F flexible shaft. AKE-P is guidewire-compatible (0.018-inch) and allows for fluid administration. The length/diameter of the mesh basket are continuously adjustable between minimal profile and maximum expansion (10mm).

The AKE-P has a soft rubber tip that is complemented by the soft tip of the guidewire, minimising the likelihood of injury. The mesh basket exerts lateral force to vessel/graft walls, which aids in facilitating maceration and removal of firmly adhered clots. The adjustable mesh basket adapts the entire circumference of its wire mesh to the vessel/graft wall.

Experimentally, histology revealed that the acute, subchronic and chronic damages caused by the AKE-P basket adjusted to the diameter of the swine arteries were acceptably low (grade 1) with no lumen compromise as opposed to those lesions caused by the PTD (grade 3) (poster presentation, ISET 2005). Experimental studies also verified that the AKE-P has excellent torque control and high manoeuvrability.

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