# In Vitro Testing of a New Aspiration Thrombus Device

Gillian Pearce, BM, BCh, PhD,* Rev Neil D. Perkinson,† Julian Wong, FRCS,‡ Christine Roffe, FRCP,§ Lee Brooker, BSc, MSc,* Kay Jones,// Michael Dodd,// Julian Spence, BSc,* Mahendra Rai,* and Paul Brookfield, BSc*

*Background:* Mechanical thrombectomy can restore blood flow to the brain after acute ischemic stroke, but may be associated with risks, such as breakage of moving parts and clot fragmentation. The aim of this study was to evaluate a new aspiration thrombus device (ATD), the GP ATD, which has no moving parts and extracts clots by suction in a vortex flow pattern. *Methods:* The GP ATD is used to extract porcine blood clots inserted into the middle cerebral artery (MCA) of a model of the circle of Willis, and from porcine aorta. *Results:* The GP ATD is navigable around the acute angles of the circle of Willis model and successfully extracts clots that cause complete occlusion of the MCA. There is a strong correlation between the pressure required for clot extraction (mean 31.8, range 30-34 kPa) and its mass (mean 0.08, range 0.03-0.13 g). Complete clot extraction can be demonstrated by computed tomography scanning. Lysis of a 0.15-g thrombus using alteplase at a concentration of 3.4 μg/mL was more effective when delivered and extracted via the GP ATD than via a catheter without the GP ATD or delivered systemically in our circle of Willis model and extracted without suction (clot mass after extraction 0.07, 0.09, and 0.11 g, respectively). Histologic examination does not show evidence of damage of the arterial wall caused by clot extraction at suction pressures of up to 30 kPa via the GP ATD. *Conclusion:* The GP ATD appears to effectively extract blood clots from models of the MCA without significant clot fragmentation and damage to the arterial wall. Further experiments using arteries in situ are required to confirm these findings. **Key Words:** Aspiration thrombus device—GP device—blood clot.


There are only a few interventions that have been shown to have an impact on the outcome of acute stroke. These include treatment of the patient on a specialist stroke department, early administration of aspirin, and intravenous thrombolysis with alteplase.[1] Thrombolysis within 3 hours of stroke onset is the most effective intervention, but is associated with a significant risk of bleeding, both intracranial and in other vascular beds. It is contraindicated in pregnancy and postnatally, after trauma, postoperatively, and in other conditions associated with an increased bleeding risk.[2] It can therefore only be given to a small proportion of patients with stroke. Therapeutic thrombolysis restores blood flow to the affected area of the brain, and can, if given early enough, prevent development of a cerebral infarct, or limit its size.

Intraarterial thrombolysis delivers the thrombolytic agent into or close to the thrombus causing the stroke, and has been investigated by Arnold et al.[3] Although still associated with intracranial and systemic bleeding, risk of hemorrhage appears to be lower than with intravenous treatment.

From the *Wolverhampton University, United Kingdom; †Community Church, Whangamata, New Zealand; ‡Departments of Surgery, //Radiology, University Hospital of North Staffordshire, United Kingdom; and §Stroke Service, University Hospital of North Staffordshire and Keele University, United Kingdom.

Received February 19, 2009; revision received March 23, 2009; accepted March 26, 2009.

Supported by a grant from Mercia Spinners to patent and develop a prototype of the GP device.

Address correspondence to Gillian Pearce, Wolverhampton University, Wulfruna Street, Wolverhampton, West Midlands, WV1 1SB United Kingdom. E-mail: g.pearce@googlemail.com.

1052-3057/$—see front matter

doi:10.1016/j.jstrokecerebrovasdis.2009.03.017

Mechanical thrombectomy devices (MTDs) can restore blood flow. Devices approved by the Food and Drug Administration for use in the cerebral circulation include the MERCI clot retriever,[4] and the penumbral device.[5] MTDs engage and remove the clot by different methods.[6,7] These include suction using an unadapted angiography catheter,[8-12] rheolytic catheters (Angiojet),[13] traction with the device entering the clot using a corkscrew-like device (MERCI device model L5 and X6),[14] or the traction acting distal of the clot (basket type devices)[15-17] and microsnare.[18-20] Thrombectomy may have associated risks, which include breakage of moving parts, penetration of the arterial wall, and downstream embolization due to clot fragmentation.[21,22] Mechanical embolectomy works well on large volume proximal occlusions, for which there was previously no effective treatment.[23] Aspiration during clot retrieval is considered important to reduce the risk of distal embolization.[24]

The GP ATD (Fig 1)[25] avoids many of these potential problems. It has the potential to be used in relatively small arteries. The GP ATD has no moving parts that can break off, does not cause significant fragmentation of the clot, and allows aspiration during clot retrieval. Thrombectomy is achieved by suction through a catheter tip with the internal surface designed to create a vortex flow. This flow pattern is associated with low forces at the periphery of the device reducing the risk of arterial collapse with higher suction pressures.[26-34] In addition to mechanical thrombectomy, the device also allows delivery of thrombolytic agents to the clot. This could further improve efficiency of clot removal.

The aim of this study is to examine the performance of the GP ATD during clot removal in vitro. We will describe the relationship between clot weight and pressure required for clot extraction, demonstrate clot removal radiographically, compare the effectiveness of mechanical clot removal via the GP ATD or simple suction in the presence of alteplase, and show the effects of the GP ATD on the vessel wall.

The GP device has a uniquely designed internal surface. The action of the vortex is to create maximum forces along the central axis of the device with minimum forces on its periphery (thus reducing the risk of arterial collapse). The gradation in forces across the orifice of the device enables gentle removal of the clot as the pressure of suction is gradually increased. Applying a previously developed technique[35] to the GP device, we define the pressure and velocity values to be a multivector-valued function and the radius of the device as an independent variable. Using this mathematical technique, we can calculate, for example, values required for suction pressure in clot extraction for a chosen radius of GP ATD. Such values have been computed for a range of different diameters of GP devices,[36] and have been found to compare favorably with values obtained experimentally.

## Methods

### *Experiment 1: Relationship Between Clot Weight and Pressure Required for Clot Extraction*

Materials needed are porcine blood clots (Gill's Abbatoir, Wolverhampton, West Midlands, United Kingdom), water, plastic circle of Willis model, GP ATD with an internal diameter of 0.1 mm at the tip (GP ATD, Kimal PLC, UK) (Fig 2), and a suction pump with a pressure range of 0 to 100 kPa (Welch model number 2622C-02, Gardner Denver, Sheboygan, WI).

Eleven porcine blood clots of increasing mass (0.03-1.13 g in steps of 0.01 g) were prepared by cutting the clot using a scalpel until the desired weight was achieved and weighed to an accuracy of $\pm 0.01$ g using electronic scales (Mettler A.E. PE 1600, Waymatic Ltd, unit 15 Bridgewater way Windsor, Berks, United Kingdom). The clot was then inserted into the middle cerebral artery (MCA) of the plastic tube model of the circle of Willis causing 100% occlusion (confirmed by visual inspection through the transparent plastic tube) by maneuvering it into position using 1 mm–diameter plastic tubing. Water was injected slowly into the tubes on either side of the clot filling the whole circle of Willis. The GP device was inserted into the MCA via the internal carotid artery with its tip positioned 3 mm proximally from the clot. Suction was applied (via the vacuum pump) to the carotid artery leading to the occluded MCA and the pressure was gradually increased until clot capture occurred (e.g., the clot was sucked onto the tip of the GP ATD). The pressure

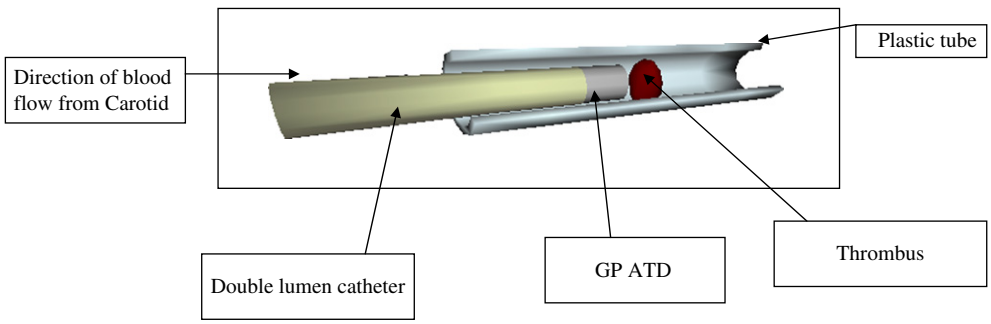


**Figure 1.** *Three-dimensional schematic view of GP ATD.*