Major trial for world-first limb saving Australian device gets go-ahead

- Sydney hospitals to perform 40 operations

MEDIA INFORMATION
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A 40-patient clinical trial of a surgical technique, using a world-first Australian invention, has been registered by the Therapeutic Goods Administration (TGA) having been recently approved by the of Northern Sydney Central Coast Area Health Ethics Committee.

Led by Professor of Vascular Research at Macquarie University Rodney Lane, the Sydney-based clinical trial involving seven surgeons, will be commencing at Dalcross Private Hospital in Killara and expanding to multiple sites across Sydney and is expected to take up to 18 months.

The duration of the trial is required to allow an appropriate period of time to assess the success of the operation and treatment – with the ultimate positive result being the retention of a limb that would otherwise have been amputated.

The clinical trial follows on from a pilot trial by Professor Lane that began four years ago. Seven patients treated over a two-year period have retained their limbs, despite initially requiring imminent amputation and thereby avoiding the need for major rehabilitation accompanying the loss of a limb.

Current medical science is such that amputation of an affected limb is the only way to prevent the untimely death of most people with advanced peripheral vascular disease (PVD)

Waiting in the wings to launch the technique along with the use of the Australian developed device is Advanced Surgical Design and Manufacture (ASDM), the publicly listed medical products specialist manufacturer, which over 16 years has launched a range of medical devices worldwide.

The procedure – H.E.L.P (Hypertensive Extracorporeal Limb Perfusion) can be performed by any skilled vascular surgeon.

It involves the use of a blood pump, along with the Peripheral Access Device (PAD), which was developed by ASDM with Professor Lane. ASDM has exclusive worldwide manufacturing rights for the PAD invention. *(TGA has approved the class IIA device for use in other applications – such as repeatable precision targeting of cancer in particular parts of the body)*

The HELP procedure is being used in cases where the patient has a threatened limb and has no other options to avoid amputation

The ground breaking treatment regime uses the patient's own blood to generate high pressure being pumped into their diseased limb to stimulate collateral growth and increase flow to the peripheral vessels.

The perfusion process involves inserting two PAD devices into an artery to take blood from the patient, pass it through a pump creating a high pressure and flow back into the leg above the diseased area of the limb. This occurs for approximately 24 hours; then a 24-hour rest period before another 24 hour pressure pumping session is repeated. And that, in most cases, is it.

The almost immediate physical impact of the treatment is that the affected leg can be seen to brighten to a healthy pink colour, indicating that the blood flow has returned to the limb's extremities. The surgeon in consultation with the patient's own doctors will recommend a recovery regime including light exercise such as walking and leg massage.

Over the following weeks it is expected the limb will continue to improve and the typical obvious symptoms of poor blood flow such as pain and early-stage gangrenous sores will resolve.

The treatment is not suitable for everyone with vascular issues, so the surgical protocols call for a screening process enabling people with PVD to be assessed. On being considered a likely patient, a visit to a surgeon will be arranged for further assessment and upon agreement by the assessment panel for the trial the procedure will be carried out.

Essentially, people to undergo the operation during the trial period will have been diagnosed as needing an amputation within eight weeks because there is no other alternative to treating the diseased limb.

FURTHER MEDIA INFORMATION: Norman Fay 0418 99 44 35

normanfay @ mediaaffairs. com. au