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Horizon scanning prioritising summary

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**ArtAssist[®]: Intermittent pneumatic limb
compression device for lower limb
ischaemia and peripheral vascular disease
in patients with diabetes.**

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PRIORITISING SUMMARY

REGISTER ID: 000116

NAME OF TECHNOLOGY: ARTASSIST®

PURPOSE AND TARGET GROUP: INTERMITTENT PNEUMATIC LIMB COMPRESSION DEVICE FOR LOWER LIMB ISCHAEMIA AND PERIPHERAL VASCULAR DISEASE IN PATIENTS WITH DIABETES

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|--|---|
| <input type="checkbox"/> Yes | ARTG number |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not applicable |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Canada	✓		
United States	✓		

IMPACT SUMMARY:

ACI Medical provides ArtAssist® with the aim of treating patients with lower limb arterial blockages and/or leg and foot ulcers. The technology is not currently available in Australia. The ArtAssist® acquired approval for American Medicare funding in June 2004 (ACI Medical 2004).

BACKGROUND

The ArtAssist® is a portable device that applies compression to the foot, ankle and calf with the aim of increasing arterial blood flow (Figure 1). The device may be used at the user's home or in a clinic setting. The aim of the compression generated through the device is to simulate the effects of brisk walking and the manufacturer recommends it be used three hours daily throughout the treatment cycle (ACI Medical 2001). The ArtAssist® functions by first compressing the foot and ankle and then compressing the calf to facilitate blood flow to the lower limb. This compression can lead to an increase in the volume of biochemical factors, that enable blood circulation, released by cells that line the blood vessels (endothelium). There is evidence (level I) that intermittent pneumatic compression is useful in treating patients with severe Peripheral Vascular Disease (PVD) who are not eligible for surgical intervention (Labropoulos 2002).



Figure 1 ArtAssist® (Printed with permission: ACI Medical)

CLINICAL NEED AND BURDEN OF DISEASE

Diabetic patients are at increased risk of Peripheral Vascular Disease (PVD) due to reduced blood supply to the legs and feet. Severity may range from asymptomatic to pain at movement or rest. Peripheral Vascular Disease may result in leg and foot ulcers and, when severe, may lead to lower limb amputation. Diabetes accounts for almost half of all non-traumatic lower limb amputations in Australian hospitals and may also lead to further amputation as the remaining limb is at increased risk of poor circulation and ulceration (AIHW 2002a).

It is estimated that approximately one million people suffer from the three types of diabetes (Type-1, Type-2 and gestational diabetes) in Australia (AIHW 2002b).

The Australian National Diabetes Information Audit and Benchmarking (ANDIAB) data for 2000 reported a 3.0% prevalence of current foot ulcers among adult patients attending diabetes clinics (AIHW 2002). In addition, 6.2% of patients had a past history of foot ulcers. The majority (86.5%) of patients with a current foot ulcer had a past history of foot ulceration (NADC 2000). Also indicative of potential foot problems PVD were recorded in a total of 12.6% of persons with diabetes.

During 1999–00 a total of 3,404 amputations of lower extremities and/or limbs were performed for patients with diabetes (AIHW 2002, p68). Males with diabetes were more than twice as likely to have a lower extremity amputation than females. Hospitalisation for diabetes-related amputation increases with age. Patients hospitalised for lower extremity amputation tended to stay considerably longer than patients hospitalised for other diabetes-related conditions. The average length of stay in hospital for diabetes-related lower extremity amputation was 27.5 days (AIHW 2002, p68).

DIFFUSION

ArtAssist® is currently not available in Australia. However, given the high burden of disease from diabetes and other risk factors such as age, high blood pressure and obesity that contribute to the development of peripheral vascular disease, it is likely that the ArtAssist® may experience a rapid uptake in clinic and home settings as an adjunct or alternative to other treatments – particularly for those people with diabetes who are inactive.

COMPARATORS

Peripheral Vascular Disease is treated with anti-thrombotic medications and surgical procedures to open blocked blood vessels.

EFFECTIVENESS AND SAFETY ISSUES

The available studies describe the use of the ArtAssist® in patients with chronic lower limb ischaemia and pain at rest or tissue loss, and include both diabetic and non-diabetic patients (van Bemmelen et al 2001, Louridas et al 2002, van Bemmelen et al 2003). All of the studies found were of level IV evidence, with low numbers of participants.

In a case-series of thirteen patients who were not eligible for surgical intervention, ArtAssist[®] was used during a 3-month period and the main outcome measure was limb salvage (van Bemmelen et al 2001). Eight of the study participants were diabetic. Of the 14 critically ischaemic legs, the use of the ArtAssist[®] was associated with limb salvage in nine legs (70%) at maximum follow-up of 2.5 years.

The Louridas et al 2002 study of 33 legs in 25 patients assessed the ArtAssist[®] on pedal blood flow and amputation rate. At a mean follow-up of three months, 42% (14) legs were amputated and 58% (19) were saved and there was a significant improvement in toe pressure after treatment with ArtAssist[®] compared to baseline (p= 0.03).

COST IMPACT

According to the National Hospital Cost Data Collection in 2002-03 the estimated average cost per separation primarily for a lower limb amputation in a public hospital was approximately \$20,000. This amount includes treatment, recurrent and capital costs, and overhead (personal communication, AIHW). A total of 3,404 amputations of lower extremities and/or limbs were performed for a diagnosis of diabetes in 1999-2000 (AIHW 2002, p68).

The cost of the ArtAssist[®] device in the United States is \$US4900 (personal communication, ACI Medical representative). If studies of the ArtAssist[®] were to demonstrate a reduction in limb amputation, surgical treatment and/or a reduction in the use of drug therapy for pain relief it is likely that there would be significant cost savings.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were raised in any of the sources examined.

CONCLUSION:

Despite the high prevalence of diabetes and associated peripheral vascular disease, there is a need for more studies demonstrating the safety and effectiveness of the ArtAssist[®]

HEALTHPACT ACTION:

There are many other cheaper alternatives available this patient group. Therefore it is recommended the following this technology be archived.

SOURCES OF FURTHER INFORMATION:

AIHW (2002a). *Diabetes: Australian facts 2002* [Internet]. Australian Institute of Health and Welfare. Available from: <http://www.aihw.gov.au/publications/cvd/daf02/daf02-c04.pdf> [Accessed 5th August 2004].

AIHW (2002b). *Diabetes: Australian facts 2002, pge v* [Internet]. Australian Institute of Health and Welfare. Available from: <http://www.aihw.gov.au/publications/cvd/daf02/daf02.pdf> [Accessed 5th August 2004]

ACI Medical (2001). *ArtAssist[®] device description* [Internet]. Available from: <http://www.acimedical.com/> [Accessed 4th August, 2004].

Labropoulos, N., Wierks, C. & Suffoletto, B. (2002). 'Intermittent pneumatic compression for the treatment of lower extremity arterial disease: a systematic review', *Vasc Med*, 7 (2), 141-148.

Louridas, G., Saadia, R. et al (2002). 'The ArtAssist Device in chronic lower limb ischemia. A pilot study', *Int Angiol*, 21 (1), 28-35.

Montori, V. M., Kavros, S. J. et al (2002). 'Intermittent compression pump for nonhealing wounds in patients with limb ischemia. The Mayo Clinic experience (1998-2000)', *Int Angiol*, 21 (4), 360-366.

van Bemmelen, P., Char, D. et al (2003). 'Angiographic improvement after rapid intermittent compression treatment [ArtAssist] for small vessel obstruction', *Ann Vasc Surg*, 17 (2), 224-228.

van Bemmelen, P. S., Gitlitz, D. B. et al (2001). 'Limb salvage using high-pressure intermittent compression arterial assist device in cases unsuitable for surgical revascularization', *Arch Surg*, 136 (11), 1280-1285; discussion 1286.

SEARCH CRITERIA TO BE USED:

Ischemia/ complications/ physiopathology

Leg/ blood supply/ physiopathology

Leg Ulcer/ etiology/physiopathology/ therapy

Limb Salvage/ instrumentation

Peripheral Vascular Diseases/ complications/ physiopathology