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SilverHawk™ Peripheral Plaque Excision System: Percutaneous peripheral atherectomy for patients with peripheral vascular disease.

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PRIORITISING SUMMARY

REGISTER ID: **000174**

NAME OF TECHNOLOGY: **SILVERHAWK™ PERIPHERAL PLAQUE EXCISION SYSTEM**

PURPOSE AND TARGET GROUP: **PERCUTANEOUS PERIPHERAL ATHERECTOMY FOR PATIENTS WITH PERIPHERAL VASCULAR DISEASE**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number
☒	No	

The SilverHawk™ System is not currently available in Australia and is not listed on the Australian Register of Therapeutic Goods. The device received FDA approval in 2003 with the original model of the device and further approval in February 2005 for the current device.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		
Germany	✓		
Italy	✓		
Switzerland	✓		

IMPACT SUMMARY:

FoxHollow Technologies has developed the SilverHawk™ Peripheral Plaque Excision System with the aim of treating atherosclerotic lesions in patients with peripheral vascular disease.

BACKGROUND

Peripheral vascular disease refers to the narrowing of the lumen of arteries in the legs, causing a reduction in circulation to the legs and feet. The most common cause of peripheral vascular disease is atherosclerosis. Atherosclerosis is characterised by the accumulation of cells, matrix fibres, lipids and tissue debris in the arterial lumen. The build-up of atherosclerotic plaque may lead to ulceration, embolisation and thrombosis (Rutherford 2000).

There are several surgical and non-surgical options for the removal of atherosclerotic plaque from arterial walls. The Silverhawk™ is designed to perform atherectomy, a procedure that cuts off plaque from arterial walls. There are several established techniques for performing atherectomy within blood vessels. Some of these techniques are used in both peripheral and coronary vasculature. *Rotational atherectomy* to remove plaque involves pulverising plaque with a rotablator and flushing the microparticles out in the bloodstream. *Directional atherectomy* involves inflating a balloon to push the blade toward the plaque, cutting the plaque with the rotablator, storing it within the catheter device. The plaque is removed when the catheter is withdrawn. A percutaneous transluminal extraction uses a catheter with a rotablator and a hollow tube that allows for the plaque to be sucked through it and expelled from the body.[1]

An atherectomy may be performed either instead of, or in addition to, the more traditional balloon angioplasty when plaque has become exceptionally hard (due to calcification) or presents other challenges. A rigid artery may prevent a stent from expanding properly to hold the vessel open, which may lead to re-narrowing (restenosis) or blockage altogether.

The SilverHawk™ Peripheral Plaque Excision System is intended for the atherectomy of the peripheral vasculature including femoral-popliteal and tibial-peroneal vessels and is not approved for use in the coronary or carotid vasculature (United States Food and Drug Administration, 2005).

The SilverHawk™ System is approved in Europe for the treatment of both coronary and peripheral arterial disease. In the coronary arteries, plaque excision with the SilverHawk™ has been used to treat bifurcation lesions, ostial lesions, long lesions and in-stent restenosis. In the peripheral arteries, it is most commonly used to treat the femoral-popliteal and tibial-peroneal arteries in the legs (FoxHollow Technologies 2005).

The SilverHawk™ Peripheral Plaque Excision System consists of two major components used together during the atherectomy procedure, the SilverHawk™ Peripheral Catheter and SilverHawk Cutter Driver (United States Food and Drug Administration, 2005). The plaque excision procedure is performed by inserting the SilverHawk™ Peripheral Catheter through a puncture in the leg or arm and advancing to the blocked or narrowed area of the vein/artery. Once the catheter is at the site of the blockage a small rotating blade is activated, shaving plaque off the artery walls. The plaque is collected in the tip of the catheter and then removed with the catheter (FoxHollow Technologies 2005). This technique is a modified directional atherectomy procedure, as it does not employ a balloon to move the blade towards the plaque.

CLINICAL NEED AND BURDEN OF DISEASE

Peripheral Vascular Disease (PVD) is associated with a significant increase in cardiovascular morbidity and mortality. Patients with PVD are approximately 5 times more likely to have an acute myocardial infarction (AMI) and two to three times more likely to have a stroke (Treat-Jacobsen and Walsh 2003) than patients without PVD. The mortality in patients with claudication is 30% at 5 years, 50% at 10 years, and 70% at 15 years, and mortality increases with disease severity (Treat-Jacobsen and Walsh 2003; Leng et al 1996). The major preventable risk factors

[1] Percutaneous transluminal coronary rotational atherectomy (PTCRA) was approved by MSAC in 2002 for the revascularisation of complex and heavily calcified coronary artery lesions as an adjunct to percutaneous transluminal coronary angioplasty (PTCA) or when previous PTCA attempts have not been successful; and for revascularisation of complex and heavily calcified coronary artery stenoses where coronary artery bypass graft (CABG) surgery is contra-indicated (MSAC 2005).

for PVD include diabetes, tobacco smoking, high blood cholesterol, high blood pressure and overweight and obesity (Treat-Jacobsen and Walsh 2003).

No national data are available on the prevalence of PVD in Australia (AIHW 2001). In 2001–02, there were 24,288 hospitalisations where PVD was the principal diagnosis, representing 0.4% of all hospitalisations in Australia (AIHW 2004). Of the hospitalisations for heart, stroke and vascular diseases, PVD accounted for 5.5%. Atherosclerosis of the peripheral arteries accounted for over half (13,564) of these hospitalisations (AIHW 2004).

Among those hospitalised for at least one night with PVD, the average length of stay was 11.5 days (AIHW 2004). On average, those hospitalised for PVD tended to stay almost twice as long as those hospitalised for coronary heart disease.

In 2002 there were 1,347 and 1,234 deaths in males and females respectively from PVD (AIHW 2004).

DIFFUSION

It is likely that the device would diffuse into clinical practice either as a stand-alone procedure or as an adjunctive therapy if it demonstrates effectiveness in addressing the reported limitations of stenting and balloon angioplasty.

COMPARATORS

The treatment options for removal of atherosclerotic plaque depend on the severity and type of occlusions. In mild forms, lifestyle modifications (smoking cessation, diet, physical activity) and pharmacological therapy (anti-platelet agents, manage hypertension, cholesterol and diabetes) are employed (Burns et al 2003).

More invasive alternatives involve open surgical techniques to bypass or replace the diseased vessel and other percutaneous endovascular techniques such as stenting and balloon angioplasty. The endovascular techniques increase arterial luminal diameter by stretching the vessel whereas atherectomy removes atherosclerotic plaque.

EFFECTIVENESS AND SAFETY ISSUES

At the time of writing there were limited published studies of the SilverHawk™ reporting clinical effectiveness and safety outcomes in a total of 63 patients (Zeller et al 2004a; Pershad and Stevenson 2005; Ikeno et al 2004). All identified studies provided low evidence (level IV intervention) with maximum follow-up periods of six months.

In a study of 52 patients with a total of 71 lesions the SilverHawk™ was used to extract plaque from the common femoral (n=2), superficial femoral (n=52) and the popliteal (n=17) arteries, (Zeller et al 2004). In eight patients (15%) more than one lesion was treated. The average lesion length was 48 ± 64mm (range 10-300). All procedures were performed without complications. One lesion required predilation (the authors do not report how this was carried out) prior to atherectomy. After the Silverhawk™ procedure, residual stenosis was ≤30% in 54 (76%) lesions and ≤50% in 68 (98%) lesions. Following atherectomy with the SilverHawk™, the study reports 41 (58%) lesions were balloon dilated to smooth the contour of the lesion and that a stent was implanted in 4 (6%) lesions.

Atherectomy results post-intervention are included in Table 1 below. Duration of the procedure, number of device insertions and number of lesions passes was significantly higher in the in-stent-restenosis group because of the doubled lesion length in this group.

The average diameter stenosis (DS) after atherectomy was reduced from 84 ± 10% (range 70-100%) to 27 ± 23% (range 0-100%) and the minimal lumen diameter was increased from 0.88±0.70 to 3.69 ± 0.90mm (Zeller et al, 2004).

The study reports one patient died at two months post-atherectomy from a myocardial infarction (Zeller et al, 2004). At six months, restenosis rates were not significantly lower in the primary lesion (27%) compared to the other groups (41% for restenoses and 36% for in-stent restenoses). Reintervention rates were lowest in the primary lesions. The average ankle-brachial index (ABI) in the entire study group increased from 0.62 ± 0.24 to 0.87 ± 0.27 after treatment, 0.84 ± 0.24 after three months and 0.72±0.21 after six months (Table 2).

Table 1 Acute Atherectomy Results

	Primary Lesion (n=30)	Restenotic Lesion (n=27)	In-Stent Restentosis (n=14)	P value
Lesion passes	7.1±2.9	6.8±3.6	99.9±3.2	0.02
Device insertions	2.0±1.2	2.0±1.1	3.5±1.7	0.01
Duration of atherectomy, min	11±8	11±4	20±14	0.04
MLD post-atherectomy, mm	3.6±1.0	3.8±0.7	3.3±1.2	NS
DS post-atherectomy, %	29±18	22±15	31±23	NS
MLD final, mm	4.4±0.7	4.4±0.7	4.2±0.5	NS
DS final, %	15±9	8±9	14±8	0.01
Balloon angioplasty	17 (57%)	16 (59%)	8 (57%)	NS
Stenting	1 (3%)	2 (8%)	1 (7%)	NS
ABI before discharge	0.84±0.019	0.77±0.15	0.85±0.12	NS

MLD: minimal lumen diameter, ABI: ankle brachial index, DS: diameter stenosis
Source: Zeller et al, 2004

Table 2 Atherectomy Results at 3 and 6 months

	Primary Lesion (n=30)	Restenotic Lesion (n=27)	In-Stent Restentosis (n=14)	P value
Three months				
Restenosis %	2 (7%)	8 (30%)	3 (21%)	NS
Reintervention %	1 (3%)	8 (30%)	3 (21%)	0.02
ABI	0.84 ±0.19	0.77±0.15	0.86±0.12	0.049
Six months				
Restenosis %	8 (27%)	11 (41%)	5 (36%)	NS
Reintervention %	6 (20%)	10 (37%)	4 (29%)	NS
ABI	0.72±0.2	0.64±0.16	0.72±0.27	NS
Primary patency %	80	63	71	NS
Assisted primary patency %	100	96	79	NS
Secondary patency %	100	96	93	NS

Source: Zeller et al, 2004

Ten patients underwent atherectomy with the Silverhawk™ on a total of 12 lesions located in the left anterior descending artery (n=four), right coronary artery (n=five), left circumflex coronary artery (n=one), a diagonal branch and in one saphenous vein graft (Ikeno et al 2004). There were four bifurcations, six in-stent restenoses and one de novo lesion. The SilverHawk™ catheter was successfully inserted in 11 of 12 lesions (92%) without complications. The catheter in the diagonal branch failed to cross. In the 11 treated lesions, an average of 9.9 ± 5.0 cutting passes was made in 3.1±0.8 insertions. The total excised tissue per lesion was 15.2 ± 7.8 mg. Eight of the lesions (73%) had adjunctive therapy with either balloon angioplasty or stent placement.

The manufacturer's website lists seven abstracts presented at the Transcatheter Cardiovascular Therapeutics Symposium 2004 of single-centre data in an estimated 635 patients (Fox Hollow 2005)[2]. An abstract presented at the Society of Vascular Surgery Annual Vascular Meeting 2005 includes data (level 1V intervention evidence) collected from a registry of centres using the Silverhawk™, and reports on clinical outcomes at six months in 505 patients (Ramaiah et al 2005). Endpoints include immediate procedural and angiographic outcomes and target lesion revascularization (TLR) at 6 and 12 months. Plaque excision was performed in 505 patients, 617 limbs and 1047 lesions. A total of 88.3% of the lesions were de novo and 11.7% were restenotic. Chronic total occlusions (CTO) accounted for 27.8% of lesions. Stand alone plaque excision was performed in 74.3% of patients, with an adjunctive stent placement rate of 5.3%. Angiographic outcomes in stand alone SilverHawk™ cases showed a greater than 75% reduction in the average diameter stenosis (pre-SilverHawk 85.7% vs. post-SilverHawk 10.1%).

The presentation included data available for 317 lesions from patients who had reached the 6 month follow-up point. Revascularisation occurred in 35/317 (11%) lesions. The TLR rate in patients with a single lesion treated was 3/65 (4.6%). The TLR rate was 7/85 (8.2%) of CTO lesions (Ramaiah et al 2005).

[2] One abstract (Allie et al 2004) states number of lesions treated but not the number of patients.

COST IMPACT

At the time of writing this summary there were no available data on the cost impact of using the SilverHawk™ as a stand alone or an adjunct to other procedures for the removal of atherosclerotic plaque. Costings of the SilverHawk™ device and of the procedure were not made available by the manufacturer at the time of preparing this summary.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

No issues were identified/raised in the sources examined.

CONCLUSION:

Cardiovascular disease is Australia's leading cause of morbidity and mortality and represents a significant economic burden on public health funding. There is currently limited, low-level evidence available that demonstrates that the SilverHawk™ may decrease the health and economic burden associated with peripheral vascular disease in the long-term. Furthermore, there are no studies comparing the device with other endovascular therapies.

HEALTHPACT ACTION:

Until randomised studies are conducted that compare the SilverHawk™ with other directional arethectomy procedures and/or other endovascular therapies, it is recommended that this technology be monitored.

LIST OF STUDIES INCLUDED	TOTAL
Total number of studies	
Level IV intervention evidence	4
Level IV intervention evidence (abstract)	1

SOURCES OF FURTHER INFORMATION:

Australian Institute of Health and Welfare (2001). Heart, stroke and vascular diseases -Australian facts 2001. AIHW Cat. No. CVD 13. Canberra: AIHW, National Heart Foundation of Australia, National Stroke Foundation of Australia (Cardiovascular Disease Series No. 14).

Australian Institute of Health and Welfare (2004). Heart, stroke and vascular diseases -Australian facts 2004. AIHW Cat. No. CVD 27. Canberra:

AIHW and National Heart Foundation of Australia (Cardiovascular Disease Series No. 22).

Burns, P., Gough, S. & Bradbury, A. W. (2003). 'Management of peripheral arterial disease in primary care', *BMJ*, 326 (7389), 584-588.

Das, T. (2004). 'Optimal therapeutic approaches to femoropopliteal artery intervention', *Catheter Cardiovasc Interv*, 63 (1), 21-30.

FoxHollow Technologies (2005) Available from: http://www.foxhollowtech.com/index.php/silverhawk_eu.html [Accessed 14th July 2005].

Ikeno, F., Hinohara, T. et al (2004). 'Early experience with a novel plaque excision system for the treatment of complex coronary lesions', *Catheter Cardiovasc Interv*, 61 (1), 35-43.

Leng, G. C., Lee, A. J. et al (1996). 'Incidence, natural history and cardiovascular events in symptomatic and asymptomatic peripheral arterial disease in the general population', *Int J Epidemiol*, 25 (6), 1172-1181.

Medical Services Advisory Committee 2005. *Percutaneous transluminal coronary rotational atherectomy for lesions of the coronary arteries Assessment report - May 2002* [Internet] Available from: http://www.msac.gov.au/reports.htm [Accessed 13th July, 2005]

Pershad, A. & Stevenson, J. (2004). 'Directional atherectomy with the SilverHawk plaque excision device in the treatment of a proximal subclavian-vertebral artery stenosis in coronary-subclavian steal syndrome (CSSS)', *J Invasive Cardiol*, 16 (12), 723-724.

Ramaiah, V., Gammon, R. et al (2005) *'Mid-Term Results From TALON: A Prospective, Multi-Center Registry on Infrainguinal Plaque Excision'* [Internet] conference presentation, Vascular Annual Meeting June 16, 2005, Available from: http://svs.vascularweb.org/_CONTRIBUTION_PAGES/Annual_Meeting/Program/2005/page-print_layout_1_16308_16308.html [Accessed 6th July, 2005].

Rutherford R (2000). Arterial diseases In *Vascular surgery*, Vol. 1 (Ed, Rutherford R). W.B. Saunders Company, Philadelphia.

Sacks, D., Marinelli, D. L. et al (2003). 'Reporting standards for clinical evaluation of new peripheral arterial revascularization devices', *J Vasc Interv Radiol*, 14 (9 Pt 2), S395-404.

Treat-Jacobson, D. & Walsh, M. E. (2003). 'Treating patients with peripheral arterial disease and claudication', *J Vasc Nurs*, 21 (1), 5-14; quiz 15-16.

Zeller, T., Rastan, A. et al (2004a). 'Percutaneous peripheral atherectomy of femoropopliteal stenoses using a new-generation device: six-month results from a single-center experience', *J Endovasc Ther*, 11 (6), 676-685.

Zeller, T., Rastan, A. et al (2004b). 'Midterm results after atherectomy-assisted angioplasty of below-knee arteries with use of the Silverhawk device', *J Vasc Interv Radiol*, 15 (12), 1391-1397.

SEARCH CRITERIA TO BE USED:

Arterial Occlusive Diseases/radiography/ surgery
Atherectomy/instrumentation/methods
Femoral Artery/ surgery
Peripheral Vascular Diseases/diagnosis/epidemiology/ nursing/therapy
Popliteal Artery/ surgery
Vascular Patency/physiology