

## Clinical and haemodynamic evolution of lesions treated by means of atherectomy with SilverHawk in the femoropopliteal sector

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### ARTICLE INFO

#### Article history:

Received 15 November 2010

Accepted 4 January 2011

#### Keywords:

Atherectomy  
Haemodynamic  
Femoropopliteal  
SilverHawk

### ABSTRACT

The objective of the work is to study the clinical and haemodynamic evolution, over 1 year, in patients with femoropopliteal arterial pathology treated by means of atherectomy with the SilverHawk device. *Materials and methods:* Nineteen (19) patients were treated between December 2008 and May 2009, collecting data on sex, age, comorbidity and clinical degree, with prospective monitoring over 12 months of clinical symptoms, physical examination and ecodoppler, obtaining results on diameter and peak systolic velocity at different arterial levels.

*Results:* Of the 19 patients, 14 were men and 5 women, with a mean age of 70 years, hypertensive (73%), diabetic (63%) and smokers (63%). Six (6) presented disabling claudication and 13 critical ischemia with advanced distal trophic lesions in 5. A good arteriographic result was obtained in 12 cases, a stent was placed on the superficial femoral artery in 5 due to suboptimal outcome. Contrast extravasation was observed in 2, with femoropopliteal bypass performed and one exclusion with endoprosthesis for repair. In the ecodoppler after 1, 3, 6 and 12 months, a progressive reduction in lumen diameter and peak intraarterial systolic velocity was observed, particularly on the distal superficial femoral artery. After one year, 7 patients (36.8%) were symptom-free, 5 (26.3%) presented mild or moderate intermittent claudication and 1 patient (5.3%) presented localised distal trophic lesion. Four (4) major amputations were performed, in 2 the knee was preserved, there were 3 thromboses due to the procedure, a secondary endovascular procedure was performed in one case and a femoropopliteal bypass in another, and there were 2 non procedure-related deaths.

*Discussion:* atherectomy with SilverHawk achieves an improvement in clinical degree, with a good rate of extremity salvage in patients with critical ischemia. In the first year, the ecodoppler shows evolution of the arteriopathy, without this necessarily meaning a clinical worsening.

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### 1. Introduction

The increase in the population's life expectancy is giving rise to an increase in the prevalence of peripheral obstructive arteriopathy, significantly affecting patient quality of life.

Up until several years ago, the surgical treatment of arteriopathy at infrainguinal level by means of bypass was regarded as the "gold standard" [1]. In recent years, different devices for the performance of endoluminal treatment of infrainguinal lesions have been developed and perfected, such as balloon angioplasty with or with-

out stent, cryoplasty, directional atherectomy, laser atherectomy, remote endarterectomy [2].

The endoluminal treatment of peripheral arteriopathy provides lower morbidity and mortality, with good permeability results with regard to bypass revascularisation [3], hence in many centres it has become the first option in the treatment of infrainguinal lesions.

In 1987, a directional atherectomy was introduced, namely the Simpson device, with a complex mechanism whose results were poorer than expected [4]. In 2003, the Food and Drug Administration (FDA) approved a new, easy-to-manage infrainguinal directional atherectomy device, the SilverHawk Plaque Excision System (Fox Hollow Technologies, Redwood City, CA), which features a carbide blade that eliminates material from the damaged arterial wall, and unlike balloon angioplasty and stent placement, which expand the arterial lumen mechanically, this device does not use a balloon, thus reducing barotrauma, minimising vessel wall trauma [5–11]. Several works describe

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the SilverHawk atherectomy device and the results it presents [12–22].

The objective of our work is to study clinical and haemodynamic evolution over 12 months, with measurements performed by ecodoppler of femoropopliteal arterial pathology treated with atherectomy with SilverHawk device.

## 2. Materials and methods

A prospective study was performed over 12 months with 19 patients with femoropopliteal arterial lesions treated by atherectomy between December 2008 and May 2009. The SilverHawk device (Fox Hollow Technologies, Redwood City, CA) was used for the atherectomy. Data were collected on age, gender, cardiovascular risk factors, comorbidity and clinical degree according to the classification described by Rutherford et al. [23].

All the patients were studied preoperatively by means of arteriography, the lesions were classified according to the TASC criteria [1], the number of distal aperture vessels was considered, and whether it was stenosis or arterial occlusion.

The atherectomies were performed in the operating theatre by a vascular surgeon by means of anterograde homolateral femoral access. Data were obtained on the device, and different-sized devices – MS, LL or LX – were used, according to the diameter of the vessel to be treated; and the use of the distal filter, the criteria for the use of the filter were on plaques that were more susceptible to emboly and when the patient presented poor distal aperture. A balloon angioplasty and/or stent placement was performed in the same operation when significant residual stenosis was observed (>30%).

Technical success was regarded as a final arteriographic image with correct arterial rechannelling, residual stenosis <30% and the absence of contrast extravasation; clinical success was the improvement of clinical degree, healing of distal lesions and when major amputation of the extremity was not required.

These patients were monitored after 1, 3, 6 and 12 months, evaluating clinical symptoms, physical examination, ankle-arm index, antiaggregant and/or anticoagulant treatment and an exploration was performed by means of an ecodoppler of the infrainguinal arterial axis of the operated extremity, the data on peak systolic velocity and diameter of the intraarterial lumen at different levels were collected: the common femoral artery, the superficial femoral in its proximal segment, the superficial femoral artery before Hunter's canal and the popliteal infragenicular artery before the anterior tibial origin. A Philips Envisor C HD ecodoppler with a multifrequency probe of 3–12 MHz was used for the study. The ecodoppler was performed by the same explorer.

Primary permeability was defined as the absence of thrombosis of the treated arterial segment by means of ecodoppler study in monitoring, and salvage of an extremity through not having to perform a major amputation, either at supracondylar or infrapatellar level.

The statistical analysis was performed with the SPSS program version 16.0, the Student's *t* was used to analyse the quantitative variables and the Chi-square test to study the qualitative variables. The Kaplan–Meier method was used for survival analysis. A *p* < 0.05 was regarded as a statistically significant difference.

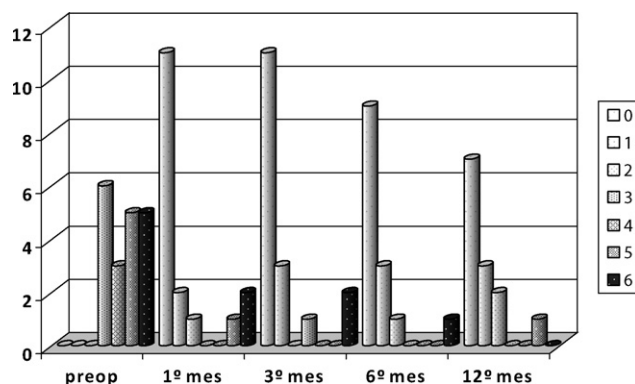
## 3. Results

Of the 19 patients studied, 14 (73.7%) were men and 5 (26.3%) women, with a mean age of 70 years (range 50–89). They presented the following cardiovascular risk factors: 73.7% hypertension, 63.2% with diabetes, 63.2% smokers and 31.6% with dyslipemia, with a record of ischemic heart disease in 31.6%,

**Table 1**  
Demography and comorbidity (n, %).

Men	14 (73.7%)
Women	5 (26.3%)
Age	70 years (50–89)
Hypertension	14 (73.7%)
Diabetes	12 (63.2%)
Smokers	12 (63.2%)
Dyslipemia	6 (31.6%)
Heart disease	6 (31.6%)
Bronchitis	3 (15.8%)
CKD	3 (15.8%)

CKD: chronic kidney disease.



**Fig. 1.** Clinical evolution of patients according to the Rutherford category in the preoperative phase, 1st, 3rd, 6th and 12th month.

chronic bronchitis in 15.8% and chronic renal failure in 15.8% (Table 1).

The preoperative clinical symptoms presented by the patients were 6 with severe intermittent claudication (degree 3), 3 with pain at rest (degree 4), 5 with trophic lesion or localised gangrene (degree 5) and 5 with advanced gangrene (degree 6) and with a mean ankle-arm index of 0.36.

The arteriographic lesions treated according to the TASC classification were 9 type A (47.4%), 8 type B (42.1%) and 2 type C (10.5%); 12 were lesions that produced stenosis and 7 occlusions; the superficial femoral artery was affected in 14 cases, the popliteal artery in 2 and both in 3. In 2 patients, distal runoff was to 3 vessels, to 2 vessels in 3, to 1 vessel in 8 and in 6 patients there was severe distal involvement with divergent collateral circulation.

The MS device was used in 12 cases, LS in 6 and LX in 1; the distal filter was used in 6 cases and a nithinol stent was placed in 5. Contrast extravasation arose as a complication in 2 patients, requiring the implantation of a covered stent and the performance of a femoropopliteal bypass in each one of the cases for arterial repair. Postoperative treatment in 13 patients was with clopidogrel, oral anticoagulation in 3, in one case it was combined with 100 mg adiro and in another with clopidogrel, with adiro at a dose of 300 mg in one and with triflusal in one.

The clinical evolution presented by patients in the controls after 1, 3, 6 and 12 months is presented in Fig. 1. After 1 year, 7 patients (36.8%) were symptom-free, 2 of them required amputation below the knee and another one presented thrombosis of the superficial femoral artery on the ecodoppler, 5 (26.3%) mild-moderate intermittent claudication (Rutherford degree 1–2) and 1 patient (5.3%) localised distal trophic lesion (degree 5).

The mean preoperative ankle-arm index was 0.36, which increased in the exploration after the 1st month to 0.76, the mean index after one year was still above preoperative level (0.58), and comparing the preoperative mean to the mean after one year there

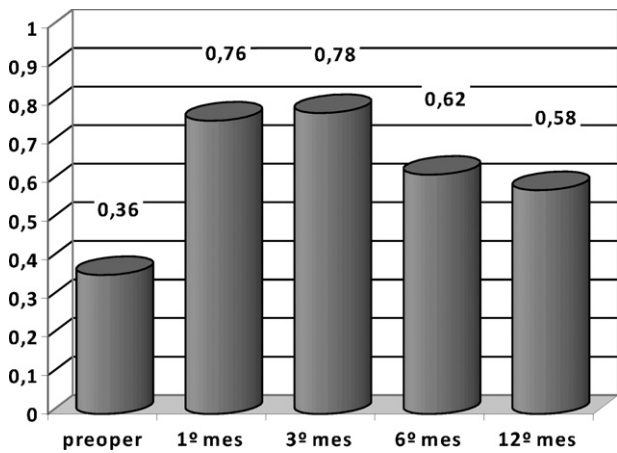


Fig. 2. Evolution of the mean ankle-arm index.

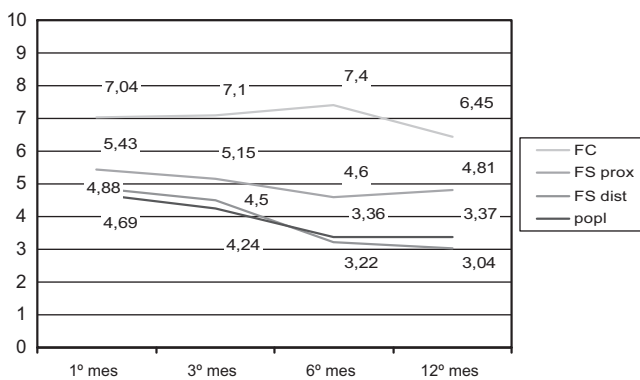


Fig. 3. Evolution of mean arterial lumen diameter (mm).

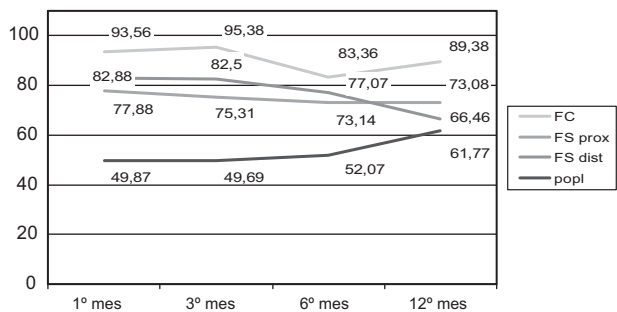


Fig. 4. Evolution of mean peak systolic velocity (cm/s).

is an increase of 0.22 in the index. The evolution of the mean index is represented in Fig. 2.

The mean diameter of the arterial lumen is expressed in millimetres (mm), at the level of common femoral artery, proximal and distal femoral superficial and infragenicular popliteal artery, which were found after 1, 3, 6 and 12 months in the study by means of ecodoppler are reflected in Fig. 3. It was observed that in the course of the controls, there is a tendency towards a reduction in the arterial lumen at all the arterial levels monitored, this reduction is more important at distal superficial and infragenicular popliteal level.

The mean peak systolic velocity is expressed in cm/seg at the level of common femoral artery, proximal superficial femoral and distal superficial and infragenicular popliteal artery, which were found after 1, 3, 6 and 12 months in the study by means of ecodoppler are reflected in Fig. 4. The means of intraarterial systolic peak velocities were observed, there being a marked reduction in

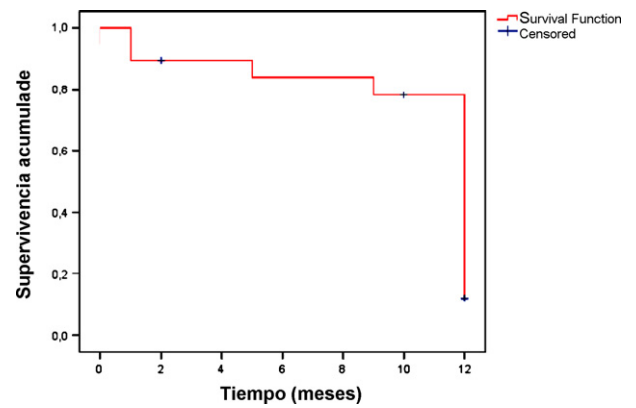


Fig. 5. Kaplan-Meier extremity salvage table.

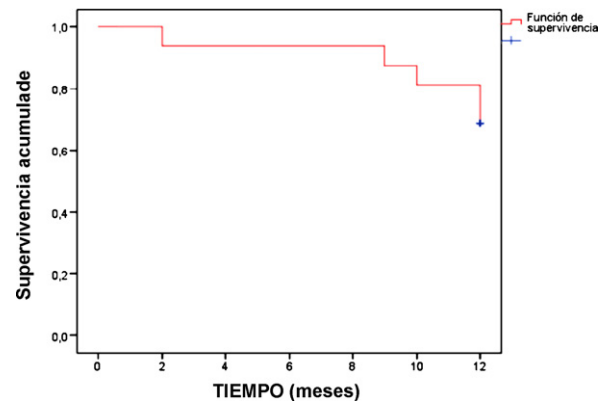


Fig. 6. Kaplan-Meier primary permeability table.

mean velocity at distal femoral artery level and an increase in mean velocity in the infragenicular popliteal artery.

An extremity salvage rate of 79% after one year was obtained (Fig. 5), four major amputations were performed, a more distal amputation was performed in 2 of them, preserving the knee, thanks to the good outcome of the atherectomy of the superficial femoral artery; and a primary permeability of 58% after one year (Fig. 6). Monitoring with ecodoppler showed occlusion of the superficial femoral artery in 3 patients, 2 of them in the control after 12 months, one case was resolved with balloon angioplasty, and the other did not require surgical treatment as the patient remained symptom-free, and the third occurred 9 months after the operation, requiring revascularisation by means of femoropopliteal bypass, obtaining secondary permeability of 62% after one year.

In the follow-up there were two deaths not related to the surgical procedure, one for acute renal failure and another due to myocardial infarct, after 1 and 5 months, respectively.

The statistical analysis was performed relating patient comorbidity, preoperative clinical status, arterial involvement according to the TASC, the distal runoff, the use of stent and distal filter to arterial permeability and to salvage of the extremity. In the patients that presented arterial permeability after 12 months there were fewer with chronic bronchitis ( $p=0.029$ ), and the patients with best prognosis in terms of extremity salvage were those with less preoperative clinical involvement ( $p=0.003$ ) and those with less involvement of the distal arteries ( $p=0.012$ ).

#### 4. Discussion

Since the 90s there has been a major development in different endovascular treatment devices for peripheral arteriopathy.

Endovascular treatment has taken on an important role as first-choice treatment in infrainguinal arterial lesions. Revascularisation treatment by means of peripheral bypass presents a series of complications such as infection, thrombosis and oedema of the extremity. On the other hand, endovascular treatment delivers a series of advantages, such as shorter recovery time, less hospital stay, lower cost and lower percentage of complications [3].

In 2003, the FDA approved a peripheral directional atherectomy device, SilverHawk (Fox Hollow Technologies, Redwood City, CA), and since then works describing how it works and its outcomes have been published. The main theoretical advantage of this device is plaque excision by means of a rotating blade, hence it would not be necessary to dilate the lesion, reducing trauma on the arterial wall.

Of the 19 patients studied, more than half presented a cardiovascular risk factor such as hypertension, diabetes or smoking, and a lesser percentage, dyslipidemia or a background of ischemic heart disease, chronic bronchitis or chronic renal failure.

In terms of results, of the 10 patients with gangrene, 5 localised and 5 advanced, major amputation was required in only 4 cases, and moreover, in 2 of them, the amputation was more distal than expected, preserving the knee, due to a good procedure outcome, which translates into a better functional recovery of the patient. Similar results to those described by Kandzari et al. [24]. In patients with localised trophic lesion, healing was obtained or a minor amputation was performed, which did not limit the functionality of the extremity. Clinical degree significantly determined salvage of the extremity.

The most frequently lesions treated were type A or B arterial involvement according to the TASC, it was only performed in 10% of TASC C lesions, the most frequent lesion was stenosis of the superficial femoral artery. No statistically significant differences were observed between TASC degree and permeability or salvage of the extremity. In 14 patients, involvement of the distal artery was important, with a single permeable distal vessel or divergent collateral network, distal arterial involvement did present a significant difference in terms of extremity salvage, a greater involvement of the distal arteries presents a greater probability of major amputation of the extremity. Davies et al. [25] refer to the importance of runoff in terms permeability of the endovascular procedure.

The significant complications of the procedure were, in 2 cases, contrast extravasation, observed in the intraoperative arteriographic control, and which were resolved with an covered stent in one and a femoropopliteal bypass in the other, no other type of local or general complications were observed.

In the evolution of the mean ankle–arm index, a substantial increase of 0.4 was observed in the first-month control with regard to the preoperative value, a figure which was maintained 0.22 above the preoperative value after one year.

This work involved infrainguinal arterial monitoring by ecodoppler for the 12 first months, where the mean diameter of the intraarterial lumen was seen to decrease, 0.37 mm in the common femoral, 0.63 mm in the proximal superficial femoral, 1.67 mm in the distal superficial femoral and 1.45 mm in the infrageniclar popliteal, with a more marked progression in the stenosis of the arterial lumen at distal and popliteal superficial femoral level, which would therefore be the arteries most affected by the progression of the arteriosclerotic disease.

In the monitoring with ecodoppler we also observed a reduction in mean intraarterial systolic velocity of 4.18 cm/s in the common femoral artery, 4.79 cm/s in the proximal superficial femoral, 16.4 cm/s in the distal superficial femoral and an increase of 11.9 cm/s in the popliteal infrageniclar, in the superficial femoral artery there was a widening of the systolic curve, disappearance of the negative diastolic wave and a progressive reduction in peak systolic velocity, there being increased velocity in only three cases.

Therefore, monitoring with ecodoppler showed arteriosclerotic progression at femoropopliteal level, which did not necessarily mean clinical worsening, the atherectomy treatment managed to heal the distal lesions which had indicated the intervention, and a correct healing of the amputations performed.

In the statistical analysis that compared the influence of different factors with permeability and salvage of the extremity, statistical significance was observed between the involvement of the distal arterial aperture and preoperative clinical status with salvage of the extremity and a background of chronic bronchitis with the permeability of the procedure. No significant difference was obtained with regard to risk factors, comorbidities, TASC degree, use of stent or distal protection filter with permeability and salvage of the extremity. The use or not of an embolic protection filter is a controversial issue, some works are in favour of using a filter systematically, whereas others only recommend its use if there is a runoff to a single distal vessel or plaque which is regarded as a potential cause of embolisation [26–30]. Our work has not found differences that justify systematic use.

There are several works presenting femoropopliteal atherectomy with good outcomes in permeability and salvage of the extremity [12,13,16–18,21,22], and our study obtained comparable permeability and limb salvage rate after one year. These percentages would be comparable to those obtained with other endovascular treatment devices [31]. Some works obtain atherectomy permeabilities well below these results, thus placing in doubt atherectomy outcomes at infrainguinal level [14,15,20].

This study presents a series of limitations, the number of patients followed up is small and they are the first cases treated in our department, which could impact the learning curve in the results obtained. A long-term follow-up of the patients subsequently treated will be necessary, which may lead to an improvement in outcomes.

Further works that demonstrate the efficacy of this procedure in the medium- and long-term will be needed, which justify performance of the atherectomy with SilverHawk in the endovascular treatment of the peripheral obstructive arteriopathy.

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