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Purpose

This non-randomized retrospective study was designed to evaluate the effectiveness of treating of superficial artery occlusive disease percutaneously with balloon dilatation with/without stents and surgical femoral to above knee popliteal bypass with synthetic materials.
Methods and Materials

The study was retrospective, non-randomized trial conducted at Kasr Eni hospital, Cairo university and private institution (DR. Erfan and Bagedo general hospital, Jeddah, KSA), between March 2003 to March 2007.

All patients had preoperative measurement of their Ankle Brachial Index (ABI). Baseline ABIs were 0.57 ± 0.19 for the angioplasty group and 0.46 ± 0.22 for the surgical bypass group. All patients were categorized according to revised version of the Joint Council of the Society of Vascular Surgeons and North American Chapter of the International Society of Cardio Vascular Surgeons (SVS/ISCVS) scale for chronic lower limb ischemia. Patients risk factors and co-morbidities, including sex, age, smoking history, diabetes mellitus, hypertension, dyslipidemia, and renal impairment or End Stage Renal Disease (ESRD), all were determined according to the Society of Vascular Surgery reporting standards. Preoperative lesion evaluation was obtained by either MRA or Ultra Fast Multi-axial CT angiography.

To be included in the study, patients had to have atherosclerotic stenotic or occlusive of superficial femoral artery, with no significant aorto-iliac disease. In addition, in the infra-popliteal segment had to be patent and at least one single vessel run off to the ankle.

Enrolled patient were divided into two treatment groups: percutaneous treatment +/- stents or open surgical femoro- AK popliteal bypass with synthetic graft (PTFE and Dacron). The categorization into each group according to TASC 2000 classification for femoropopliteal segment, according to its recommendation in which angioplasty was best solution for TASC A and preferred to B lesions. TASC C and D with associated co-morbidities in whom surgery is contraindicated, angioplasty also used. While bypass group includes TASC C and D lesions or TASC A and B with contraindications to angioplasty, (e.g. high incidence for renal failure with contrast)

Study population. Between March 2003 and March 2007, 118 consecutive limbs in 109 patients met the inclusion criteria. The limbs that were treated with angioplasty with and without self-expandable stents (n=56) in 50 patients. The limbs were treated surgically with PTFE or Dacron grafts (n=62) in 59 patients. In six patients, one limb was treated by angioplasty and the other by bypass surgery. The demographic and associated co-morbidities are summarized in table 1. The two groups, no significant difference was found in the patients co-morbidities.

All patients were categorized according to revised version of the Joint Council of the Society of Vascular Surgeons and North American Chapter of the International Society
of Cardio Vascular Surgeons (SVS/ISCVS) scale for chronic lower limb ischemia. Both groups were identical in the clinical assessment. Most of the patients were suffering of sever claudication to rest pain. None of both groups were asymptomatic and have mild claudication. Clinical grades of both groups are summarized in table 2.

All patients with tissue loss and also with gangrene were diabetics, 25% and 27% in endovascular and bypass groups respectively.

By following the TASC grading system for femoro-popliteal lesions, each limb in both treatment groups was assigned a TASC classification as summarized in table 3. The TASC classifications between the two treatment groups were significantly different. Most of surgical group are TASC C (31/62= 50%) while in the angioplasty group the majority are TASC B (29/56= 51%).

Runoff score was calculated as described by Starr Registry. Each tibial vessel was assigned a score (0= <50% stenosis, 1= 50%-99% stenosis, and 2= occluded) the sum of which is total 0-6. No significant difference in both groups as regard the distal run off. None of both groups had score 5 or 6 as showed in table 4. At least one patent vessel distal run off should be present in all cases.

**Open surgical technique:-**

Femoro-AK popliteal bypass was accomplished in usual surgical fashion. After standard surgical exposure to the vessels, each patients was received a bolus dose of heparin (100 IU/kg) before graft insertion. The choice of the conduit was either PTFE or Dacron grafts. Grafts diameter was either 8 or 6 mm. all the bypass procedures were done under regional anesthesia spinal, combined spinal & epidural anesthesia or local infiltration to femoral & sciatic block. Tunneling of the grafts was done sub-sartorial. Anaestmosis between the graft and artery is done by 5/0 proliene continuous suture. Proper haemostasis and closure with closed suction system drain. 29 (52%) were on a clopidogrel and aspirin regimen post-treatment. all patients were taking aspirin as recommended by the treating surgeon with exception of one due to peptic ulcer. five patients were taking warfarin preoperatively and were continued only on this regimen postoperatively.

**Angioplasty group:-**

All the patients were prone for angioplasty, received loading dose of clopidogrel (300mg) one hour before the procedure with exception for patients with diabetic retinopathy that complicated by retinal hemorrhage.
In the setting of well-equipped Cath-lab (endovascular suite with a fixed imaging unit) with C-arm (Siemens Coroskop) and under local infiltrative anesthesia (10-20 ml of 1% Xylocaine) with controlled sedation (1-2 mg Dormicum) all interventions were performed. All lesions were tackled through ipsilateral approach using standard Seldinger technique. 6f sheath is the slandered for vessel cannulation. Selective angiography was done in multiple angles. A Glow’N’Tell (Lemaitre vascular Inc., USA) tape was used in most of cases for better localization. After angiography, proper localization of the lesion and also assessment of vessel diameter pre and post lesion

A bolus dose of (100 U/Kg) of sodium heparin were given once access is gained and further increments were given hourly with objective of Activated Clotting Time (ACT) to be kept above 250 second during the whole procedure. After crossing the lesion, in both stenotic and obstructive lesions of these segments, balloon angioplasty was done, diameter of balloon is 0.5-1mm less the native vessel; balloon inflation was done at the lower luminal pressure & for 60 seconds. In the long segments, more than one inflation was needed starting distally first. Different balloons were used including

Stenting was done using nitinol self expandable stents with diameters of 4-7mm, depending on the diameter of the native artery; most were 6mm. Stents were applied if the residual stenosis is more than 30% or flow limiting dissection of the lesion. Stents were deployed to cover healthy segment distal and proximal to the lesion.

After stenting, another biplane angiography was done to assess the degree of residual stenosis and technique success was defined in the study that the residual stenosis after stenting is less than 30%. If still significant residual stenosis after stenting, post stenting balloon dilatation were done using a larger balloon diameter for 30 seconds inflation. Post treatment, all patients in the angioplasty group took clopidogrel and aspirin for a minimum of 6 months except of two refused to take aspirin due to gastric troubles.

Postoperative assessment & follow-up examination:-

Clinical outcome was assessed with Society Vascular and International Society of Cardiovascular Surgeons assessment scale. The scale assigned a score of +3 for markedly improved symptoms combined with ABI >0.9 and +2 for improvement at least in a single chronic lower limb ischemia category combined with increase in ABI more than 0.15 above the preoperative measurement and +1 from either a single category improvement or an increase in ABI more than 0.15 or 0 for unchanged symptoms and -1 to -3 for deterioration of the symptoms and ABI (mild, moderate, and severe; respectively).

Duplex scanning of treated arterial segments was performed at 1, 3, 6 and 12 months. Stenosis free patency was defined by absence of stenosis more than 50% of treated
arterial segment. Criteria of detection of restenosis greater than 50% are increase of peak systolic velocity (PSV) above 150 cm/sec.

Analysis of the data were performed using Fischer two sample of variance and Multiple Logistic regression analysis using the Analysis ToolPak of Microsoft Excel office 2007 application.

Table 1

<table>
<thead>
<tr>
<th></th>
<th>Endovascular group</th>
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</thead>
<tbody>
<tr>
<td>Patients (n)</td>
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<td>59</td>
</tr>
<tr>
<td>Male gender</td>
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<td>34</td>
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<tr>
<td>Age, mean +/- SD</td>
<td>71 +/- 9.9</td>
<td>65.9 +/- 10.7</td>
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<tr>
<td>Diabetes</td>
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<td>29</td>
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<td>24</td>
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<td>Hypertension</td>
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<td>11</td>
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<tr>
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<td>COPD</td>
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<td>Renal impairment</td>
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Table 2

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<td>0</td>
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<tr>
<td>1 mild claudication</td>
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<td>0</td>
<td>0</td>
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<td>2 moderate claudication</td>
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</tr>
<tr>
<td>3 severe claudication</td>
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<tr>
<td>4 rest pain</td>
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<td>5 tissue loss</td>
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6 tissue loss with gangrene

### Table 3

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<tr>
<td>B</td>
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<td>C</td>
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<td>D</td>
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### Table 4

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Fig. 0

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Results

Percutaneous angioplasty +/- stenting was technically successful in all treated limbs. Self-expandable stents were used in 38 limbs \((38/56 = 67\%)\). Mean of 1.8 stents per limb. The mean diameter of the stent was 6 mm \((4 \text{ to } 7 \text{ mm})\). The mean total length of artery covered with the stent was 7.6 cm.

Femoral-AK popliteal artery bypass was successfully performed in all treated limbs in the surgical group. Dacron grafts were used in 18 limbs \((29\%)\), and ePTFE was used in 44 limbs \((71\%)\).

Immediate procedure-related and early postoperative, non-thrombotic complications were observed in seven limbs \((12.5\%)\) with the angioplasty group. In one patient, a dissection was created in the SFA at the entry point with extravasations of contrast. Cross over technique with retrograde contra-lateral femoral artery puncture and a stent was used to exclude the dissection. Another patient developed sub-intimal dissection with worsen distal run off in whom urgent bypass surgery is needed (femoro-lower popliteal bypass). One patient experienced transient severe leg edema in the treated limb. Deep venous thrombosis was ruled out, and the edema resolved by elevation of leg and bed rest. One patient reported severe thigh pain in the treated limb that required readmission to the hospital for pain management. The pain resolved #24 hours without any identifiable pathology. Two patients had a small groin hematoma that resolved without intervention. Last patient developed femoral pseudo aneurysm that required surgical repair.

In the surgical bypass group, early postoperative complications were observed in six \((10\%)\). Three patients developed a groin lymphocele, a groin seroma, and a small superficial groin wound dehiscence, respectively. The patient with a groin lymphocele was returned to the operating room for washout and re-closure of the wound. One patient developed gaped groin wound with severe infections and he required long hospital stay \((27 \text{ days})\), in which several times of debridement and drainage were done and vacuum machine dressing was applied. One patient developed severe neurotic pain in the leg and foot that was treated by neurolipitic medications and improved. The last one developed persistent swelling in the leg and foot \((\text{acute lymphodema})\) that takes three months to resolve.

Clinical outcome was assessed with Society Vascular and International Society of Cardiovascular Surgeons assessment scale in the first month postoperative. An improvement in clinical grade occurred in 52 limbs \((92\%)\) in the angioplasty group and in 54 limbs \((94\%)\) in the surgical bypass group. The overall mean clinical improvement was nearly equal in both groups \((86\%)\). Deterioration of vasculature in angioplasty and surgical groups was 7\% and 8\% respectively. No changes in hemodynamic after intervention in surgical and endovascular groups was 6\% and 7\% respectively. At 12 months, the mean improvement in ABI was the same in both groups with no significant statically different values. The clinical grade improvement showed in the table 5.
Correlation between the clinical improvement and demographic features for both groups showed that diabetes is an important factor that plays significant role in the outcome. All patients showed deterioration clinically were diabetic in both groups.

Median follow-up duration was 12 months for both treatment groups.

During this period, 11/56 (20%) of the angioplasty failed secondary to thrombosis and significant restenosis (>50%). An early thrombosis occurred in the recovery room the same day of the procedure in one patient and he required immediate surgical thromboectomy and heparin infusion. One stent thrombosis occurred within the first month after stent implantation, angiography was done and thrombolytic therapy applied with successful recanalization and limb salvage. The other 9 significant stenosis (>50%) and occlusion were detected after a mean period of 7+/− 2.3 months after angioplasty.

Of these 9 patients, two were successfully recanalized with intra-arterial tissue plasminogen activator-mediated lysis followed by balloon angioplasty of underlying stent stenosis. Three were in need for re-intervention by angioplasty and stenting for significant in-stent restenosis. Three were converted to open surgical bypass (three to the AK popliteal artery) as they were suffered from total occlusion of the SFA with failure for recanalization. Finally, one of the patients was found to have heparin-induced thrombocytopenia and amputation eventually was performed owing to progressive tissue loss. This patient had tissue loss preoperatively.

Overall, 11 interventions had to be performed in the angioplasty group during 12 months. Interventions required for 6 patients with TASC D, 4 patients with TASC C and one patient with TASC B.

Major amputations were done for 6 limbs (6/56= 10.7%) during the 12 months period.

In surgical group, one patient developed graft thrombosis in the 1\textsuperscript{st} month postoperative with critical limb ischemia. Immediate surgical re-intervention required in form of femoro-distal popliteal bypass with successful perfusion and limb salvage. This patient was TASC D category.

Nine patients (14.5%) developed graft stenosis and occlusion during mean of 6.9 ± 4 months after graft placement. Three patients showed significant stenosis at the proximal stenosis and balloon angioplasty for these lesions was done successfully with good re-perfusion of the ischemic limbs. Three required femoro-distal bypass. Last three patients required major amputations with failure for limb salvage.

Total major amputations needed for surgical group were 5 (5/62=8.6%) during 12 months period follow up.

Cumulative primary patency rates were calculated with use of the life-table method. At follow-up at 1, 3, 6 and 12 months, the respective primary patency rates were 96.0%,
89.0%, 85%, and 80%, for the angioplasty group and 98.0%, 93.0%, 88.0%, and 83.0% for the surgical bypass group. Table 6 summarizes the cumulative primary patency rate in 12 months follow up.

No significant difference between both groups as regard the primary patency rate in the 1st year follow up was detected. In addition the percentage of major amputations in both groups was 8.9% and 10.7% in surgical and angioplasty groups respectively with no statistical difference. All patients required major amputations were suffering of tissue loss and rest pain. No major amputation was done in the claudicating patients in both groups.

### Table 5

<table>
<thead>
<tr>
<th>Clinical grade improvement</th>
<th>Endovascular group</th>
<th>Surgical bypass group</th>
</tr>
</thead>
<tbody>
<tr>
<td>+3</td>
<td>33 (58.92%)</td>
<td>36 (58.06%)</td>
</tr>
<tr>
<td>+2</td>
<td>12 (21.42%)</td>
<td>14 (22.58%)</td>
</tr>
<tr>
<td>+1</td>
<td>3 (5.35%)</td>
<td>3 (4.83%)</td>
</tr>
<tr>
<td>0</td>
<td>4 (7.14%)</td>
<td>4 (6.45%)</td>
</tr>
<tr>
<td>-1</td>
<td>1 (1.78%)</td>
<td>2 (3.22%)</td>
</tr>
<tr>
<td>-2</td>
<td>2 (3.57%)</td>
<td>2 (3.22%)</td>
</tr>
<tr>
<td>-3</td>
<td>1 (1.78%)</td>
<td>1 (1.61%)</td>
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### Table 6

<table>
<thead>
<tr>
<th>Primary patency follow up</th>
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</tr>
</thead>
<tbody>
<tr>
<td>N %</td>
<td>N %</td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>54/56 96</td>
<td>61/62 98</td>
</tr>
<tr>
<td>3 months</td>
<td>50/56 89</td>
<td>58/62 93</td>
</tr>
<tr>
<td>6 months</td>
<td>48/56 85</td>
<td>55/62 88</td>
</tr>
<tr>
<td>12 months</td>
<td>45/56 80</td>
<td>52/62 83</td>
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</table>
Conclusion

The choice of open surgical bypass vs. percutaneous angioplasty and stenting for femoro-popliteal segment is still of controversial. Nevertheless, in our study shows no significant difference in synthetic bypass vs. endovascular fashion provided you apply the TASC recommendations for the SFA treatment. However still we need longer period follow up, bigger population and to do randomized comparative study between endovascular & bypass surgery.
References


7. TASC Working Group. Management of peripheral arterial disease (PAD) (Transatlantic Inter-Society Consensus (TASC)). *Eur J Vasc Endovasc Surg*. 2000; 19:S1-S244.


Personal Information

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Date of birth: 11-8-1973

Nationality: Egyptian

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EDUCATION AND QUALIFICATIONS

• MD degree of general Surgery. Faculty of Medicine, Cairo University, December 2005.
• M.Sc. degree in General Surgery. Faculty of Medicine, Cairo University, March 2001, Signed up: Excellent.
• M.B. B.Ch. Faculty of Medicine, Cairo University, April 1998, Signed up: Excellent with honor.

WORK EXPERIENCE

• Current job:
  v Vascular consultant at Dr. Erfan and Bagedo hospital, Jeddah, KSA, since May 2005.
  v Lecturer of general and vascular Surgery at Cairo University Hospitals since December 2005.
  v Consultant of vascular surgery in New Kasr El-Eini teaching (French) and Manial specialized university hospitals, Cairo since 2005.

• Member of:
  v Egyptian society of vascular surgery since 2003.
  v Saudi vascular society since 2006.
v CIRSE, Cardiovascular intervention of radiology society of Europe since March 2009.

  * Courses and seminars:

v Participated in 2 AAA procedures with quantum workshop hold in Leuven, Belgium at February 2003.

v Completed wound management seminar hold by Johnson and Johnson Company in Jeddah, KSA at february 2007.

v Attending a course in management of DVT by Saudi council of health at May 2007.

v Attending basic and advanced endovascular training course hold by the universities of Auckland and Waikato, New Zeland at November 2007.

v Complete course for Endovenous laser ablation for varicose vein at Leis page, Germany, 2008.


v Completed the basic life support provider course (CPR) according to guidelines of Saudi and American heart association. Certificate is valid till October 2011.

v Attending the advanced trauma life support course for doctors according to guidelines of American college of surgeons committee on trauma at King Fahd armed forces hospital, Jeddah, KSA. The certificate valid till 4 June 2012.

  * Papers and publications:


Clinical utility of magnetic resonance angiography (MRA) in the diagnosis and treatment of Takayasu’s arteritis. Ragab Yasser; Emad Yasser; El-Marakbi A; Gheita Tamer. Clinical rheumatology 2007; 26(8):1393-5.


Conferences and symposiums:

• Lecturer at 8th international symposium on vascular surgery update in collage of medicine, King Saudi University, Riyadh, KSA at January 2010.

• Attending with poster presentation at ESR (European society of radiology) conference, Vienna, Austria. At March 2009.


• Lecturer and of organizer committee of annual symposium of Jeddah Cardiovascular imaging and interventions at 2007, 2008 and 2009.

• Attended the annual congress of the Egyptian society of vascular surgery since 2000-2009.

• Lecturer at 7th international symposium on vascular surgery update in collage of medicine, King Saudi University, Riyadh, KSA at January 2008.

• Attending and active participation at the 26th annual meeting of Egyptian society of surgeons, February 2008.

• Attending first scientific meeting of the SSVS held in Jeddah, KSA. At March 2007.

• Attending 5th annual scientific conference of Saudi thoracic society at March 2007.

• Lecturer at 7th vascular surgery and 5th interventional radiology conference of Saudi german hospital group, Jeddah, KSA. At November 2007.

• Attending updates in management of diabetic foot infection meeting hold in Dubai, United Arab Emirate at September 2006.

• Lecturer and attending at emergency and critical care scientific meeting at Dr. Erfan and Bagedo hospital, September 2006-2009.
v Attending and lecturer at cardiology scientific update meetings at Dr. Erfan and Bagedo hospital, September 2006-2009.

v Attending and lecturer at internal medicine scientific update meetings at Dr. Erfan and Bagedo hospital, September 2006-2009.

v Attending and lecturer at hospital grand round of Dr. Erfan and Bagedo hospital, September 2006-2009.

v Attending at neuroscience scientific update meetings at Dr. Erfan and Bagedo hospital, September 2006-2009.

v Attending the 3rd congress of North African and Middle East chapter of international union of angiology in Aswan, Egypt at March 2005.

v Attending the international vascular and endovascular congress at Alexandria, Egypt, October 2003.

v Attending and active participation in 21st summer meeting of the Egyptian society of surgery hold in Alexandria, Egypt at September 2003.

v Attending update on carotid artery disease meeting hold in Ghent, Belgium at March 2003.

v Attending and participate in live case presentation in sixth congress of the middle east and north African chapter of international society of cardiovascular surgery at October 2002.

• Work experience:

v Intern at Cairo University Hospitals for one year from 1-3-1996 to 28-2-1997 including 2 monthly rotations at the following sections: General Surgery, General Medicine, Gynecology & Obstetrics, Pediatrics, Emergency & Trauma (one month) & intervention radiology.

v Resident (SHO) in the department of general and vascular Surgery at Cairo University Hospitals from 16-3-1997 to 16-3-2000.

v Assistant Lecturer of general and vascular surgery at Cairo University Hospitals from April 2001 to October 2005.

v Lecturer of general and vascular Surgery at Cairo University Hospitals from October 2005 till now.

v Working as vascular attachment and trainee for three months at Leuven, Belgium under care of Professor Andree Nevelsteen from 1-3-2003 to 1-6-2003.
Vascular consultant at Dr. Erfan and Bagedo hospital from September 2005 till now

Job description and privilege:-

ý Responsible for all vascular and endovascular interventions including arterial, venous, dialysis and chemotherapy access and diabetic foot care

ý Responsible for running outpatient vascular clinic for 6 days/week with morning and afternoon shifts.

Procedures that carried from 2006-2009:-

ý Arterial bypasses including anatomical and extra-anatomical, most of bypasses were femoro-distal (infra-inguinal) with average 45 cases/year.

ý Carotid endarterectomy with average 5 cases/year.

ý AAA (open intervention) with average 4 cases/year.

ý Vascular injuries repair with average 20 cases/tear.

ý Arteriovenous access with average 60 cases/year.

ý Diabetic foot debridement and amputations with average 80 cases/year.

ý Varicose vein surgery and ELVES with average 50 cases/year.

ý Injection sclerotherapy at OPC with average 8 sessions/week.

ý Endovascular interventions including angioplasty and stenting, AV fistula and venous angioplasty, IVC filters Permicaht and Portacath insertions with average 55 cases/year.

Vascular work from 2006-2009:-

<table>
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<th>Data</th>
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<th>Operative procedures</th>
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1257
**ACTIVITIES AND INTERESTS:** playing basketball with good computer skill.

**ADDITIONAL INFORMATION:** married and having two daughters.

**REFERENCES**

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