

ANGIOPLASTIE ET RECANALISATION DES ARTERES JAMBIERES

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CLINIQUE LOUIS PASTEUR



Techniques and Results of Tibio-peroneal Angioplasty

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Below-knee interventions

Infra-popliteal or Infra-geniculate arteries PTA

Tibio-fibular angioplasty

Popliteal artery branches angioplasty

Crural arteries angioplasty

- Lower extremity arterial occlusive disease limited to these arteries is rare and it is unusual for patients with intermittent claudication to have lesions limited to this segment
- Most patients have additional proximal lesions , frequently in the femoro-popliteal segment ,and rest pain or tissue loss
- Among those with involvement of multiple infrapopliteal vessels, the prevalence of diabetes is high
- Surgical and endovascular intervention at this level entail an inherently higher risk of failure and exacerbation of ischemia



Tibio-peroneal diseased arteries & Diabetes

- 1 out of 3 people with diabetes has PAD
- 15 % of diabetic patients will develop a lower extremity ulcer during the course of their disease of which 15- 20% will lead to amputations
- Foot ulcers lead to 85 % of lower extremity amputation in diabetics . 9 to 20 % will undergo a second amputation
- The risk of a leg amputation is up to 40 times greater for a person with diabetes
- 50-60 % of all- non traumatic amputations are performed on diabetics

PAD & Amputation



- Over 250 000 amputations are performed annually as a result of complications associated with PAD (USA+ Europe)
- 40% of amputee die within 2 years of amputation
- The professional nursing care costs in US home after an amputation has been estimated at 100 000\$ per year



Treatment options

■ Medical

- Risk factor modification
- Exercise therapy
- Drug therapy

■ Surgery

- Bypass grafts
- Amputation
- Endarterectomy

■ Endovascular Therapy

- PTA
- Stenting (Bare, Self-expandable, DES, Absorbable)
- Atherectomy
- Thrombolytic therapy (adjunctive)
- Laser
- Cryoplasty

Vascular procedures for outflow improvement

Hirsh A & all , J. Am.Coll.Cardiol, 2006;47, 1- 192

Outflow Procedure	Operative Mortality (%)	Expected Patency Rate (%)
Fem-AK popliteal vein	1.3 to 6.3	66 (5 years)
Fem-AK popliteal prosthetic	1.3 to 6.3	50 (5 years)
Fem-BK popliteal vein	1.3 to 6.3	66 (5 years)
Fem-BK popliteal prosthetic	1.3 to 6.3	33 (5 years)
Fem- Tib vein	1.3 to 6.3	74 to 80 (5 years)
Fem- Tib Prosthetic	1.3 to 6.3	25 (3 years)
Composite sequential bypass	0 to 4	28 to 40 (5 years)
Fem –Tib blind segment bypass	2.7 to 3.2	64 to 67 (2 years)
Profundoplasty	0 to 3	49 to 50 (3 years)



CLI “ Gold standard” Pedal Bypass

A decade of experience with dorsalis pedis artery bypass:
analysis of outcome in more than 1000 cases

Pomposelli FB, Kansal N, Hamdan AD & all

J. Vasc . Surg . 2003 Feb ; 37 (2) 307-15

**1032 pedal bypass for limb salvage in 865 pts
(92 % diabetic) from year 1990 to year 2000**

- ✓ Mortality rate within 30 days = 0.9%
- ✓ 5 year primary patency rate = 56.8%
- ✓ 5 year secondary patency rate = 62.7%
- ✓ 5 year limb salvage rate = 78,2%
- ✓ 5 year patient survival rate = 48.6%



Tibio-peroneal angioplasty

First studies

- Early series using Dotter technique demonstrated the feasibility of PTA in this segment although the complication rate was high (Sprayregen S, 1980) , (Tamura S, 1982) , (Stark EE, 1984)
- For several years tibio-peroneal angioplasty was considered inherently more difficult if not impossible because of the spasmogenicity of these vessels and their small size .
- These factors ,the potentially adverse consequences of complications of failure , and the opposition of several surgeons, have tend to keep the interventionists away from this region



From **Savage** angioplasty to **Salvage** angioplasty

- Implementation of coronary technology along with better medical therapy (aspirin, statins...) have revolutionized the field of peripheral angioplasty and improved the results.

➤ LIMB SALVAGE AT 2 YEARS

STUDY	1 YEAR	2 YEARS
➤ SCHWARTEN (1991) :	83 %	75 %
➤ DURNAM (1994) :	77 %	77 %
➤ SOS (1996) :	76 %	76 %

bypass but equivalent to prosthetic



BELOW THE KNEE ANGIOPLASTY

Hirsh A & all , J. Am.Coll.Cardiol, 2006;47, 1- 192

- **Results of meta-analysis (1282 limbs)**
- **Based on a random meta-regression analysis of the results from various sources ,each weighted with the inverse of the variance**
- **Technical success: 93 % (90 to 96 %)**
- **Primary patency : % (95% CI)**
 - **1 year : 79 (68 to 90)**
 - **2 year : 74 (65 to 85)**

TASC & SCVIR for infrapopliteal lesions

<p>P T A</p>	<ul style="list-style-type: none"> •Type A •Single stenosis <1cm in tibial or peroneal vessels 	<ol style="list-style-type: none"> 1. Two or more stenoses: <i>If patient also has rest pain & femoropliteal PTA or CLI, then PTA</i> 2. Isolated stenoses: <i>Exercise</i>
<p>P T A & O R S U R G E R Y</p>	<ul style="list-style-type: none"> •Type B •Multiple focal stenoses of tibial or peroneal vessel <1cm each •1 or 2 focal stenoses, 1cm each at tibial trifurcation •Short tibial or peroneal stenosis combined with femoro popliteal PTA 	<ol style="list-style-type: none"> 3. Occlusions < 3cm, 2 to 3 stenoses in 2 tibiofibular arteries : <i>Individual indication</i> <i>CLI: Femorocrural bypass</i>
<p>S U R G E R Y</p>	<ul style="list-style-type: none"> •Type C •Stenoses 1-4cm in length •Occlusions 1-2cm each in tibial or peroneal vessels •Extensive stenoses of the tibial trifurcation 	<ol style="list-style-type: none"> 4. Multiple occlusions, diffuse arterioscleroses of 2 to 3 arteries : <i>Atherectomy after consultation. If patient has CLI, treatment options include femoropedal bypass, sympathectomy, laser assisted PTA</i>
<p>S U R G E R Y</p>	<ul style="list-style-type: none"> •Type D •Tibial or peroneal occlusions longer than 2 cm •Diffusely diseased tibial or peroneal vessels 	



TASC II 2007

Norgreen &all, Journal of vascular surgery , 2007

- Patient with critical limb ischemia require multidisciplinary care to avoid limb loss.
- Angioplasty of a short anterior or posterior tibial artery stenosis may be performed in conjunction with popliteal or femoral angioplasty. Use of this technique is usually not indicated in patients with intermittent claudication.
- There is increasing evidence to support a recommendation for angioplasty in patients with CLI and infra-popliteal artery occlusion where in-line flow to the foot can be re-established and where there is medical co-morbidity.
- In the case of infra-popliteal angioplasty ,technical success may approach 90% with resultant clinical success of approximately 70% in patients with CLI. Salvage rates are reported as being slightly higher



TASC II 2007

Norgreen &all, Journal of vascular surgery , 2007

- Predictors of successful outcome include a shorter length of occlusion and a lesser number of vessels treated.
- The complication rate (2.4%-17% depending upon definition) can usually be treated by endovascular or surgical techniques and a failed angioplasty does not preclude subsequent bypass.
- It remains controversial whether infra-popliteal PTA and stenting should be performed in patients with intermittent claudication for improvement of outflow and for an increased patency of proximal PTA, stenting and bypass surgery.



Goal & Principles of the treatment

➤ Clinical goal

- Improves the healing of trophic ulcers
- Reduce the level of leg amputation
- Reduce the duration and the rate of hospitalizations

➤ Vascular goal/Procedural goal

- Create a straight in line artery to the foot
- Improve the total arterial flow to the foot
- Delay or reduce the recurrence of CLI & restenosis
- Prevent CLI in the contra-lateral leg



➤ **Good techniques
determine the
success**

Prepare the patient and yourself

The Patient

- Assess the cardiac, renal ,cerebro-vascular & respiratory of the patient ► Delay if possible to prepare the patient
- Medical treatment before Procedure
 - Plavix the day before (75 mg) , 2 to 6 h before (300 to 600mg)
 - Aspirin (75 to 360mg)
 - Renal Insufficiency : Hydratation ,Bicarbonates
 - Prevention of spasms: Calcium antagonist (Verapamil)
- During Procedure
 - UFH
 - LMWH (Enoxaparin 0.5mg/Kg IV)
 - Bivalirudin
 - IIb-IIIa Inhibitors

The physician

- Be prepared to a long and cautious procedure
- Have all the tools ready in your laboratory
- It is a 2 to 3 hours procedure
- This permanent question in your mind :

Does this indication deserves the cost, the effort &serve the interest of the patient

Bien faire et se tenir en joie
SPINOZA

Determine the access

Parameters to consider case by case

- ✓ Has this leg treated before (PTA, Surgery)
- ✓ Number & locations of lesions to be treated ;
 - ✓ Femoral+Popliteal+1 or 2 leg artery
 - ✓ Popliteal occlusion + 1 or 2 leg artery
 - ✓ 1or several leg arteries
- ✓ Is a staged procedure or during fem-pop grafting preferable
- ✓ Is one side easier or impossible to puncture
- ✓ Is one side easier to close

Inflow & Outflow

Echo
CT
MRI





Inflow lesions (iliac / Femoral /popliteal)

Yes

No

Contra lateral approach

Antegrade approach

Treat the inflow lesions

**Advance Introducer
to Popliteal Artery**

Calf artery

Stenosed

Occluded

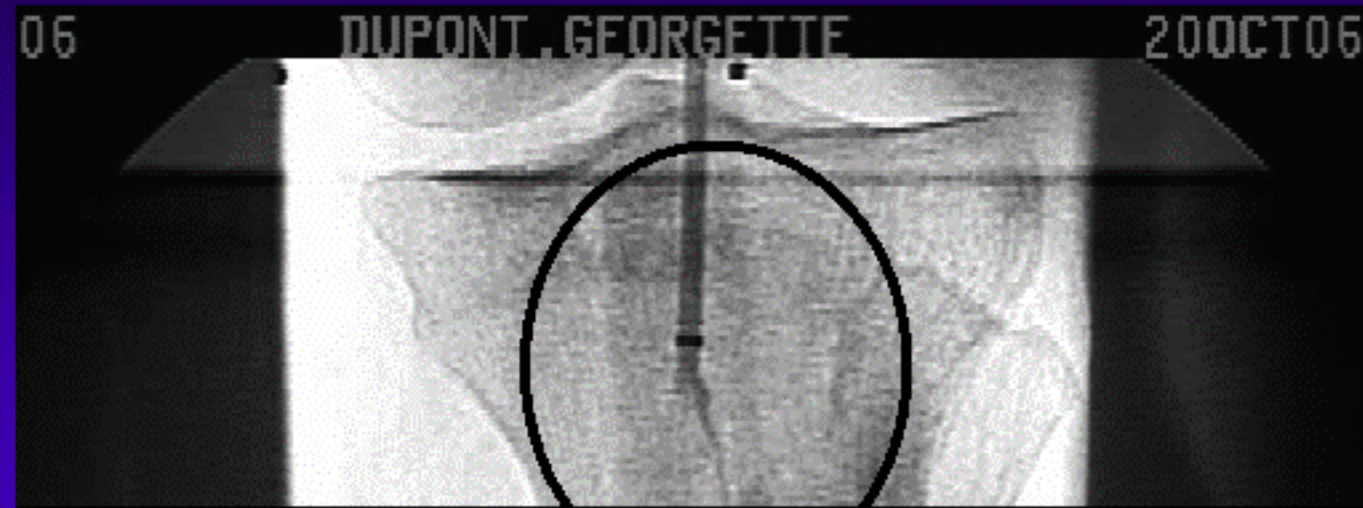
Length
Single
Multiple
Calcification
Rigidity

Short / long Ballons
Cutting Ballons
Bare Metal Stents ?
Drug Eluting Stents ??

Retrograde
Distal Approach
Micro-puncture
techniques

Place the extremity of the introducer

- The 6F Braided introducer (Cook, Arrow, Terumo) or the 6 F guiding catheter should be long enough to be close to the tibio-peroneal site
- The access is permanently flushed with saline to avoid clotting and to facilitate the crossing of hydrophilic guidewires





Select the right tool

- **Tools to dilate**
- **Tools to cross**
- **Tools to debulk**
- **Tools to maintain**
- **Tools to prevent restenosis**

Tools to dilate Balloons

Over 0.014 Inches Guidewire

➤ Coaxial or monorail balloons

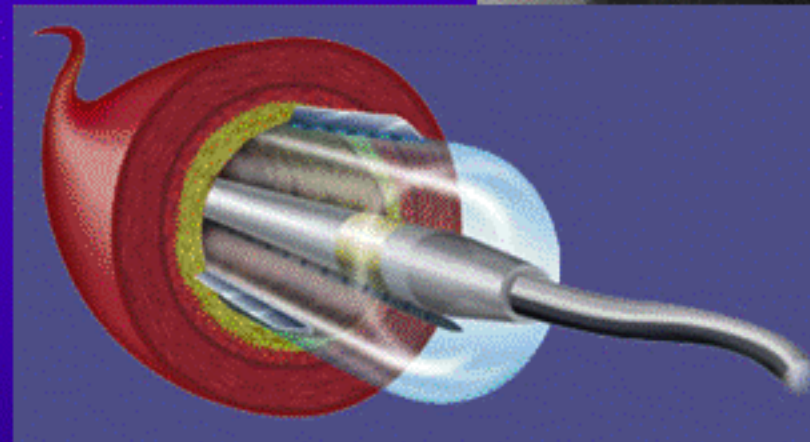
- Length from 1 to 10 cms
- Diameter from 1.5 to 3.5 mm
- With hydrophilic coating
- Semi or non compliant balloons

➤ Cutting balloons

- Length 6,10,20mm
- Diameter 2.0 until 4.0 mm

➤ Scoring balloons

- Angiosculpt: external nitinol scoring edge



Balloon type & Characteristics of lesions

	Short < 2cm	Medium 3 to 4cm	Long >4cm	Calcification	Kissing & bifurcation	Contra- Lateral Approach
Monorail	+++	++	-	+	+++	++
Coaxial	+	++	+++	++	+	±
Long	N.a.	N.a.	+++	++	-	±
Cutting	+++	++	+	+++	++	++
Scoring	+++	++	++	++	++	++

Balloon type & Characteristics of lesions

	Stenosis	Occlusion	Distal Bypass	Proximal	Troncular	Distal & Pedal
Monorail	+++	++	+	-	+	+++
Coaxial	+	+++	++	+++	++	-
Long	multiples	+++	+	+++	++	+
Cutting	++	-	+++	+++	++	-
Scoring	++	-	+	+++	++	-



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Tibio –peroneal angioplasty Five-year follow-up

G. Dorros, M.Jaff 1all, Circulation Oct 2001

- TPVA was successful in 270 of 284 CLI limbs (95%), with 165 limbs requiring dilatation of 333 ipsilateral inflow obstruction to access and successfully dilate 486 of 529 (92%) tibio-peroneal lesions
- Clinical success : 95%
- Clinical 5 year follow-up of 215 of 221 successful CLI patients (97%) with 266 successfully revascularized limbs revealed:
 - Bypass :8%
 - Amputations : 9%
 - Limb salvaged :91%

Partial results

- **Cutting balloon :**
 - Short lesions (diabetic lesions)
 - Restenotic lesions
 - Bifurcation
 - Anastomotic bypass graft lesion
- **Angiosculpt scoring balloon**
 - Calcified lesions



Favorable immediate results
No long term superiority for patency
Limb salvage rate ?

Interest of coronary monorail balloons Kissing of TBT and proximal AT & PT

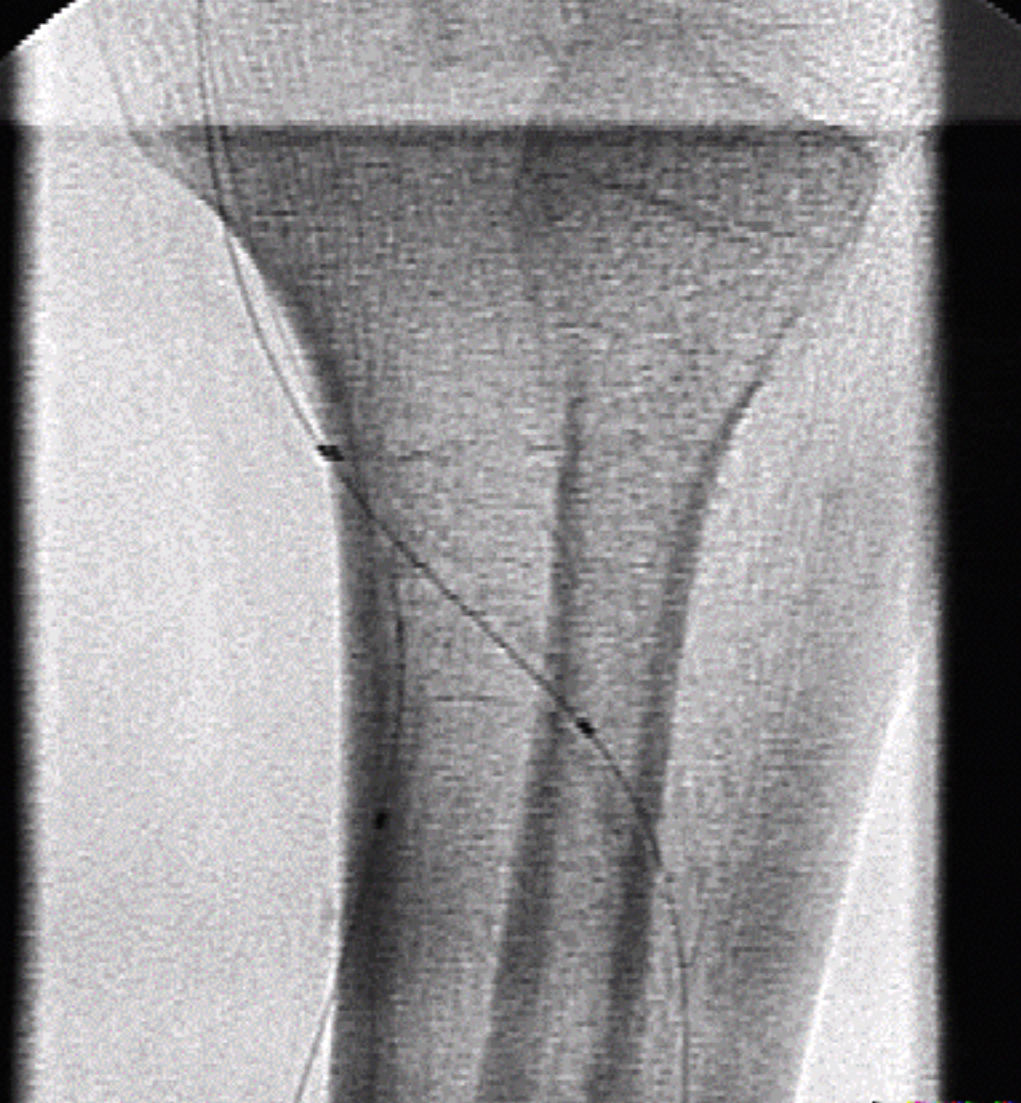
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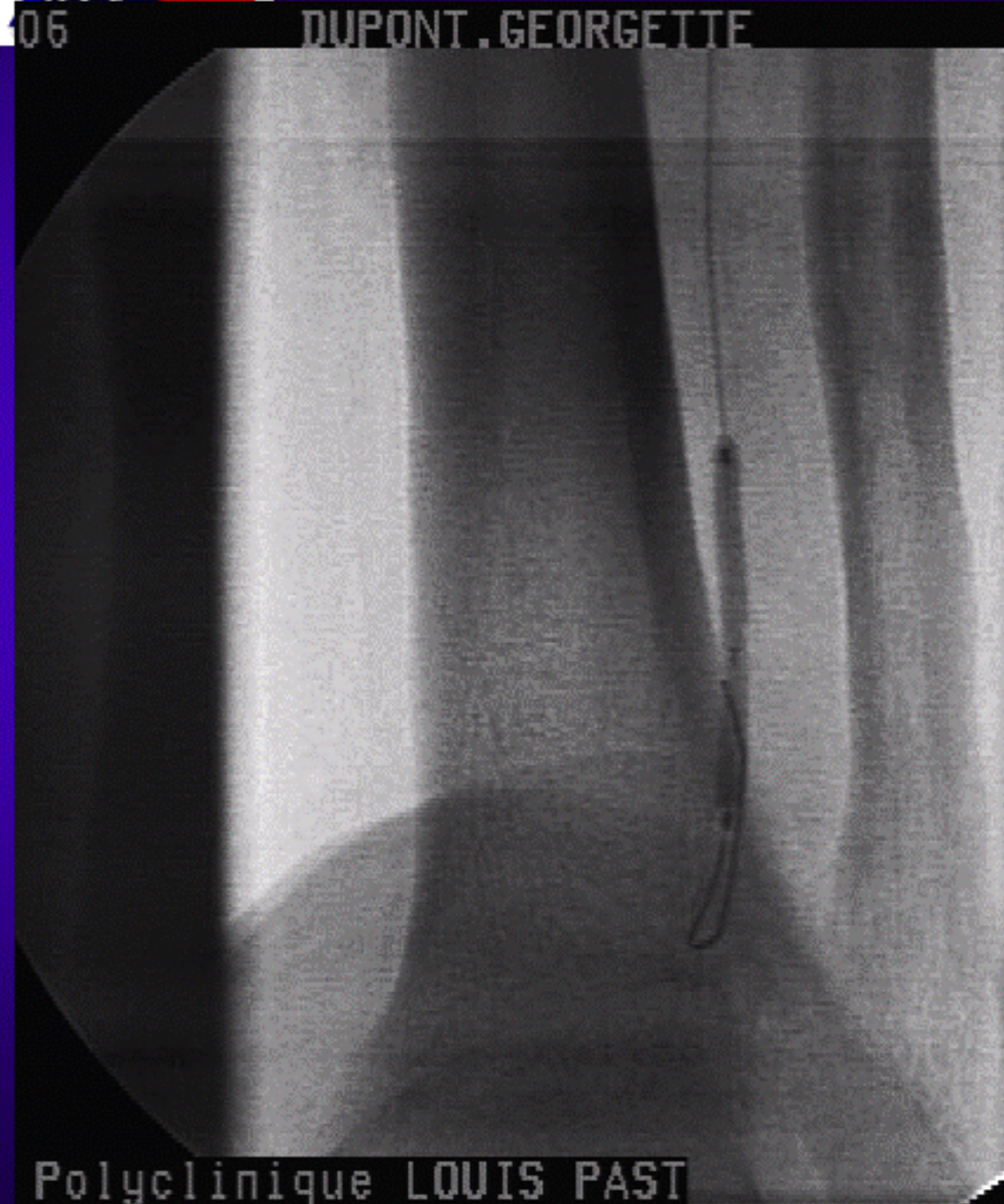
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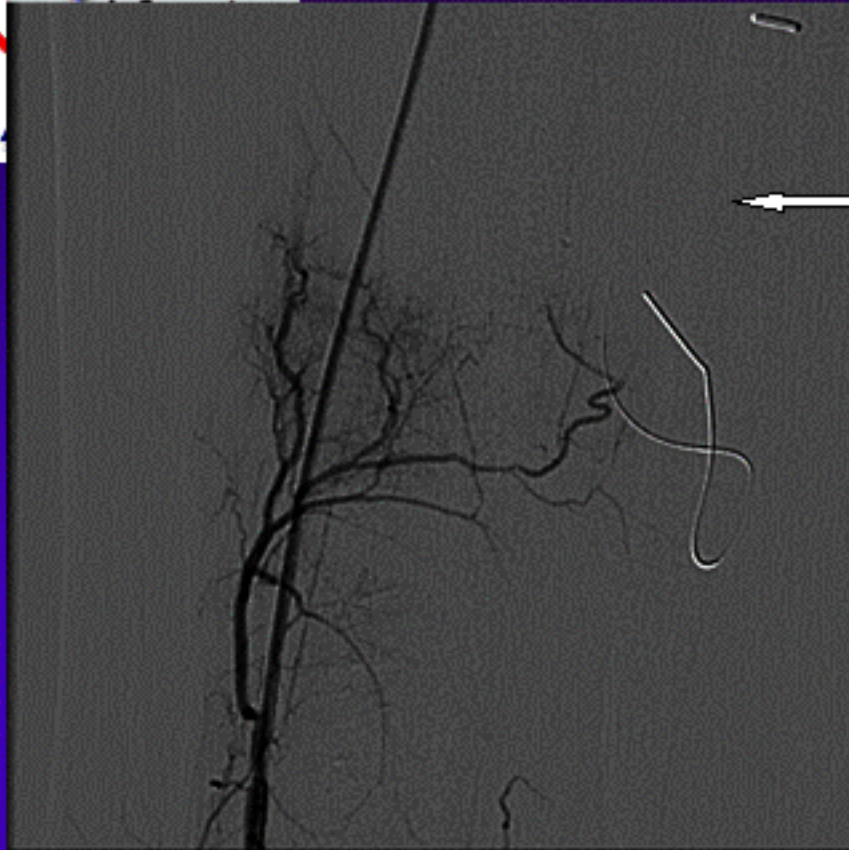
Sub-intimal angioplasty of anterior tibial art.



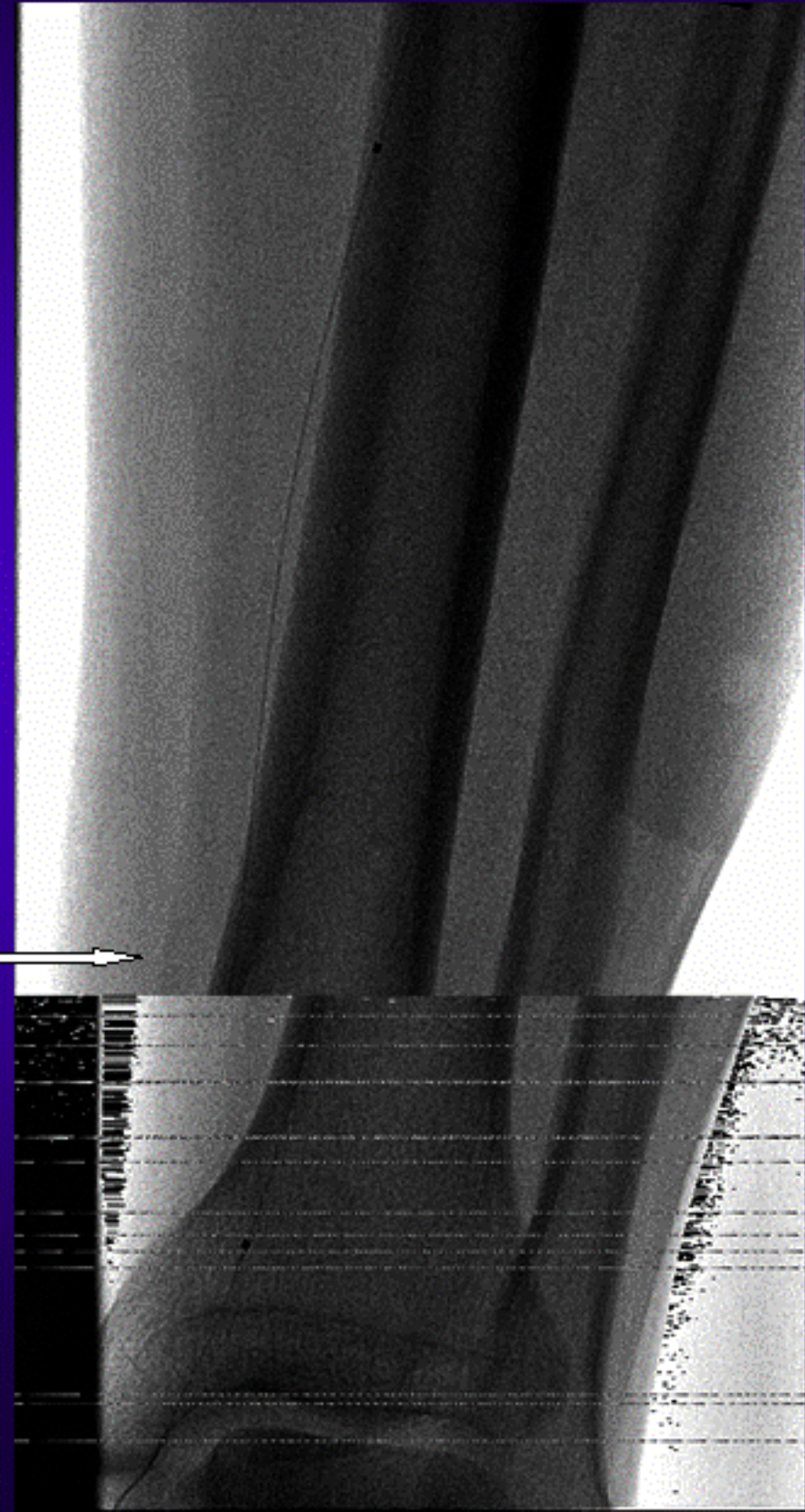
Tibio-peroneal Trunk occlusion



Recanalization of Post-Tibial



0.035 J 1.5 mm
Terumo GW
▶ 4F Terumo
cath.



Exchange for
0.014
Pilot 150
Abbott GW



Subintimal angioplasty of isolated infragenicular vessels in lower limb ischemia : long term results

Ingle H, Nasim A, Bolia A & all J Endovas Ther. 2002; 9(4): 417-8

- **Retrospective study from 1997 to 2000**
- **67 consecutive pts , 70 limbs**
- **Median length of occlusion :**
 - **Below- knee popliteal artery :6cm (1-10)**
 - **Tibio-peroneal trunk : 4cm**
 - **Anterior tibial: 21cm (1-35)**
 - **Posterior tibial : 10 cm (1-30)**
 - **Peroneal : 5cm (1-20)**
- **Technical success: 86% , Clinical success: 80%**
- **The cumulative limb salvage rate : 94% at 3 years**
- **Mortality rate : 19% at 1 year,43 % at 2 years,& 51 % at 3 years**
- **SIA is safe & effective for treating isolated crural vessels in pts with severe LLI**



SIA in lower limb ischaemia

- We feel that these are excellent results in a high risk group of patients and cannot justify withholding SIA as a first-line treatment for critical ischemia .
- Again , there are no randomized trials comparing angioplasty with bypass surgery.
- However it is safe , does not preclude surgical intervention if necessary and certainly avoid surgery in many patients .
- SIA has a definite learning curve
- Widespread acceptance require randomized controlled studies



Results of percutaneous Subintimal angioplasty using routine stenting

Treiman GS , Treiman R, Whiting J J. Vasc.Surg. 2006; 43 (3):513-9

- From 1999 through 2004
- Initial technical success in 26 (90%) of 29 patients
- Mean follow-up 38 months
- During follow-up 16 arteries reoccluded
- Success: 1y: 85%, 2y: 64%, 3y 18%, 4y:9%
- SIA is technically successful in most patients with few complications
- Most procedures provide short-term clinical success and have allowed for successful wound healing and temporary relief of rest pain
- However , late arterial patency is poor with a high rate of symptoms recurrence . Nevertheless limb salvage rates are significantly better than arterial patency.

Tools to cross

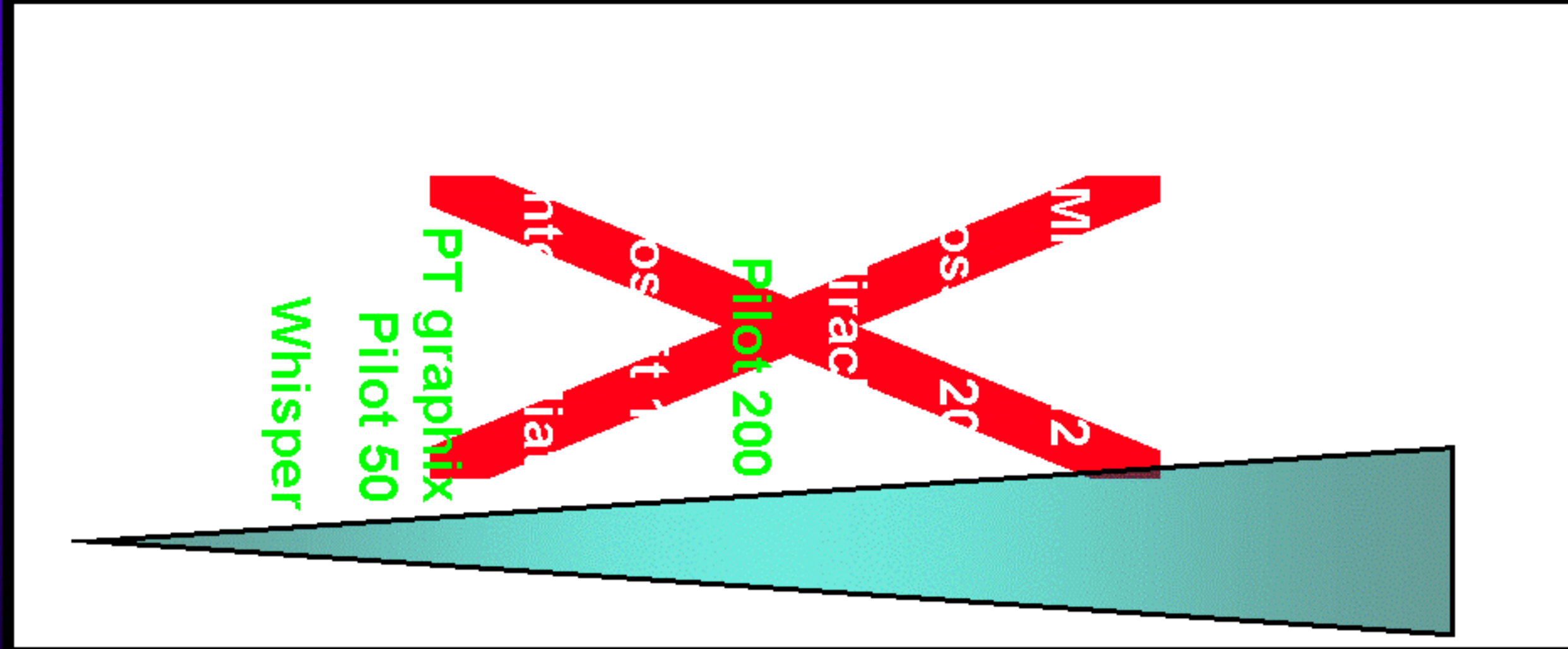
- **Support catheter to enhance the pushability of the guidewire ,or orient the GW ,or allow the exchange of guidewires**
 - **Micro-balloons (Ryujin), Venture ,Tornus ,Quick cross**
- **Dedicated devices:**
 - **Ultrasound, laser, micro-dissection, Radio-frequency, Ultrasound**
- **In case inability to cross with a balloon consider opening a channel with Rotablator**



Crossing tools & Penetration Power

New generation **0.014"** coronary guidewires

- **With** or without hydrophilic coating
- With incremental stiffness and extra-support (penetration power)





Excimer Laser angioplasty in critical limb ischemia

Laird J & LACI investigators, J Endovas Ther 2006

- Not anymore considered as a stand alone technique
- It requires complementary balloon angioplasty
- It is abandoned as a debulking device
- It is used today as a crossing tool device in 5 to 10 % of angioplasty procedure in uncrossable lesions
- All the recent trials have failed to show its superiority in stenosis
- For occlusions the LACI open trial have shown a 6 monts limb salvage rate of 92%

SilverHawk™ Plaque Excision



- ✓ Removes obstructing plaque from arteries by scooping it out
- ✓ 3 steps procedure
- ✓ Biopsy tool to study plaque : Merck Research Lab: LEAP platform
- ✓ Plaque factors ≠ Risk factors

Two-year results after directional atherectomy of infrapopliteal arteries with the SilverHawk device

- 49 BTK lesions in 36 pts
- Popliteal : 6, TPT : 25, Peroneal:10, Ant tibial :5 ,Post tibial: 3
- 9 in stent-lesions , 22 % occlusions
- Mean lesion length: 48 ± 28 mm
- Results :
 - 33% treated after pre-dilatation ,67% primary DA
 - 40% additional balloon angioplasty
 - Primary and secondary patency rates:
 - 1 year: 67% and 91%
 - 2 year: 60% and 80%
 - The One year and 2 year cumulative event-free survival rate were: $58\% \pm 8\%$ and $46\% \pm 9\%$
- Conclusion:
 - BTK lesions can be treated successfully and safely with DA

**Balloon
in 73%**



Talon Study

- One of the largest peripheral population assembled to date
- Over 700 patients and 1500 lesions enrolled to date
- Specimens collected for excised plaque study
- Acute results, 6 & 12 months follow up
- Bilateral femoral lesions exclusively
- Complications rate : 1.6%
- Average procedural time: 27 minutes
- 12 months freedom from TLR : 79%

Distal embolization ? Conflict of interest ? Therapeutic niche ?

May be good science from it ! Genomic , Plaque factors

Until now The Fox makes a Hollow sound



Registries of Patients treated with Excisional Atherectomy

	Patients/ lesions	Primary group	Lesion length (occlusion%)	Location	Clinical patency	Primary patency
Talon	728/1517	Claudicant/ CLI	8.4 cm (28.6)	SFA/BTK	79%	NA
Yancey	16/18	CLI	>3.0 cm	SFA/BTK	NA	22%
Kandzari	69/76	CLI	6.4 cm (34%)	SFA/BTK		Not reported
Keeling	60/66	Claudicant/ CLI	8.8 cm (27%)	SFA/BTK		67% (90-40%)
Zeller	84/131	Claudicant/ CLI	9.0 cm (8.5%)	SFA/BTK	NA	64% (84-54%)
Total	957/1808					

	Rotablator	Silverhawk	Orbital Ather.	Pathway Ather	Laser Turbo
De Novo					
Stenosis	+	+++	++	++	++
Occlusion	-	+++	±	++	+++
Instent					
Restenosis	±	±	+	+	+
Occlusion	-	±	+	+	++
Calcium	+++	-	++	+++	+
Length ≥ 10 cm	±	±	+	+	+
Thrombotic	-	+++	-	-	++
ABK/BTK	ABK/BTK	ABK/BTK	ABK/Pop	ABK/Po	ABK/?



Atherectomy raising questions

- *Distal embolization ?*
- *Cost justification?*
- *Quality of the mid and long term results?*
- *No control arm in the majority of the studies*
- *Several Studies will be necessary to define their Therapeutic niche*

Tools to maintain

- Short BM stents < 15mm . 30mm
- Long DE stents < 33mm . 66mm
- Self-expandable stents in Nitinol for tibio-peroneal lesions > 60mm

➤ **65 years careless
woman with
diabetes**

- **Stable coronary
insufficiency**
- **Four ulcers and
rest pain**



Right Foot

XPERT 4 F SAMPLES



Ø3/20

Ø4/30

Ø5/40

Ø6/40

STENTING BELOW THE KNEE IN PATIENTS WITH CLI CURRENT TECHNIQUE:

- 4F self-expanding nitinol stent (\varnothing 3 - 4 mm)
- Indication is stent implantation in vessels with a diameter of 2.0 - 3.5 mm
- Stenting of longer regions (20 - 60 mm) possible
- (Xpert 3/60 will be launched 2007)
- Improvements of the results in comparison with stainless-steel stents can be expected



Tools to use in chronic situations

- Tools to dilate
- Tools to cross
- Tools to debulk
- Tools to maintain
- **Tools to prevent restenosis**



Below The Knee Chill

365 –day outcomes

Das T, Gray B, McNamara T

- **Goal: Cryoplasty** have a viable mechanisms of action to reduce elastic recoil and restenosis :
 - SMS apoptosis
 - Reduced dissection
 - Decreased recoil
- **BTK Chill** is a prospective ,multi-center trial of 100 pts with chronic critical ischemia (Fontaine Stage III or IV)
- **Study Endpoints**
 - **Primary:**
 - Acute technical success
 - Freedom from amputation
 - **Secondary**
 - Serious events related to the use of Cryoplasty®
 - Absence of major amputation of the target limb at 30,90,365 days



Below The Knee Chill Primary End point Summary

- Acute technical success → 97%
- 180 day freedom from major amputation → 93%
- 1 year freedom from major amputation → 85%

Conclusion:

- ❖ Demonstration of safety & efficacy
- ❖ High technical success & low dissection & stent rates
- ❖ Durable clinical benefit
- ❖ High rate of limb salvage at one year

BELOW THE KNEE PTA - COMPLICATIONS

- **DISSECTION**
- **ARTERIAL SPASM**
- **SLOW FLOW OR NO REFLOW**
- **ACUTE OR SUBACUTE THROMBOSIS**
- **PERFORATION**
- **ARTERIAL RUPTURE**
- **HEMOLYSIS**
- **EMBOLIZATION**

ADJUNCTS

- **Treatment of spasm :**
 - Nitroglycerin , Verapamil
- **Treatment of thrombus:**
 - Thrombo-aspiration
 - Thrombolysis
- **Treatment of Embolization**
 - Prevention :Protecting devices
 - Thrombo-aspiration
- **Closing the groin**



Outstanding problems

- ✓ Possible role for drug eluting stenting?
- ✓ Absorbable stents
- ✓ Optimised drug therapy?
- ✓ More aggressive approach:
 - ✓ To achieve more than one run off vessel?
 - ✓ To treat specific vessels
 - ✓ PTA of collateral vessels?
- ✓ Open tibial artery better than just open peroneal artery?

Conclusion : 1

**A properly employed
endovascular approach
leaves the door open for
surgery**



Why Doesn't Everyone Do this ?

- Previous ineffectiveness of Coronary Interventional Technology Below the Knee
- Time
 - Coronary Intervention : 30 to 60 minutes
 - Tibio-peroneal intervention : 60 to 150 minutes
- No reimbursement in several countries
 - Tibio-peroneal stents
 - Specific devices : Cryoplasty, Atherectomy...
 - Laser



~~Lower limb amputations in 2003 in France~~

- x 14
- 9% i
- Risk
- l
- c
- Ex
- Re

~~In France 70% of
the amputations
are performed without
any attempt of
revascularization~~



Conclusions 2

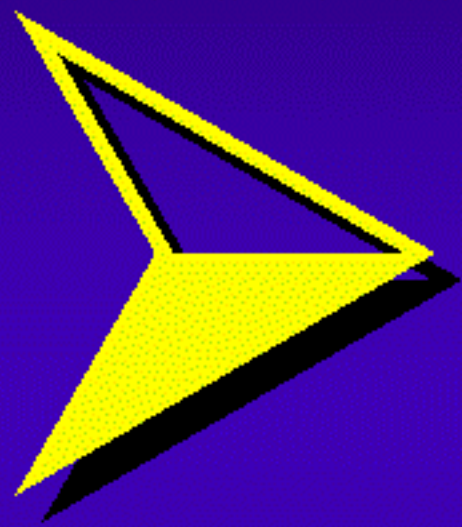
- Refinements in vascular technique and technology have allowed revascularization to the pedal vessels ,with remarkably durable long-term results giving more impetus to an aggressive approach to limb salvage even in patients with diabetes
- Considering the success of tibio-peroneal angioplasty it appears appropriate to expand the indications and to include selected patients with life-style limiting claudication in whom surgery is inadequate or not feasible



Conclusions 3

Within the context of this changing climate , it is an appropriate time to examine and potentially redefine the role of both endovascular and open surgical intervention for a population that has not traditionally been offered revascularization

- Claudicant
- Old
- High risk patient



END