Infrainguinal Arterial Occlusive Disease: What Outcomes Should we Expect

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No Financial Disclosures

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Outline

- History
- Indication – “Who Gets a Bypass?”
- Techniques
- Outcomes

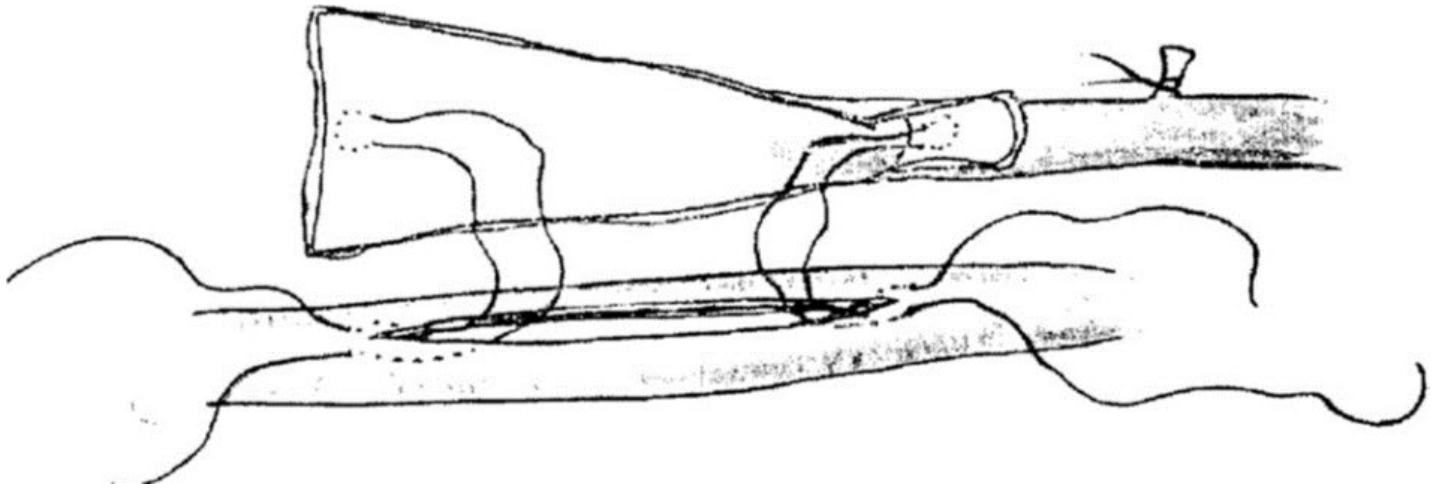
History

Alexis Carrel

- **Believed blood vessels could be sutured**
- **Triangulation technique (end-end)**
- **Won Nobel Prize 1902**
- **Gentle handling of tissue**
- **Sutured by holding needle with his fingers**

Jean Kunlin
1904-1991

Performed first femoral to popliteal artery bypass



Kunlin JL. **Arch Mal Coeur Vaiss**. 1949;**42**:371–374

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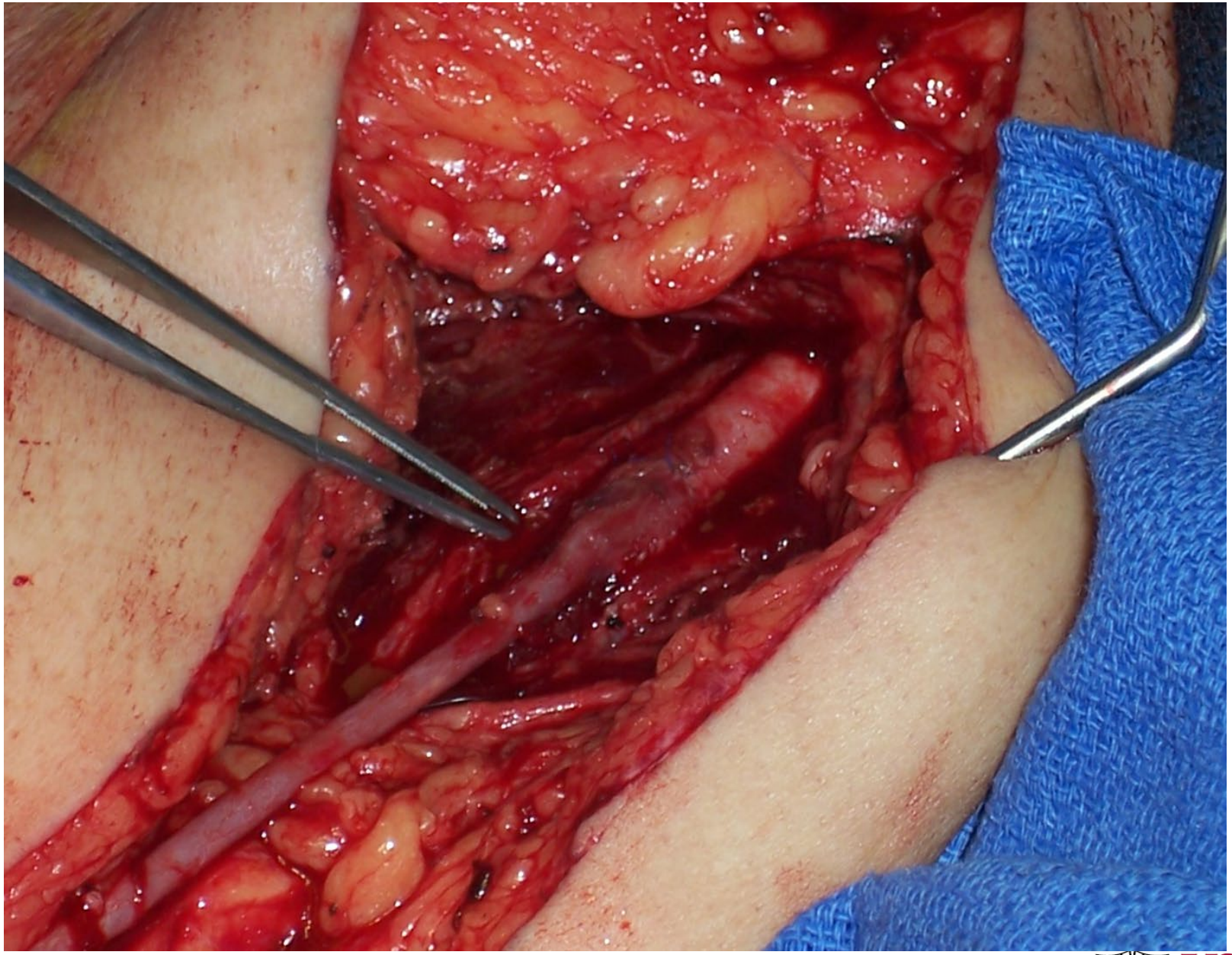
Limb Salvage History

- 1952: Linton – reversed saphenous vein
- 1958: McCaughan - arterial reconstructions to tibioperoneal trunk.
- 1960: Palma – bypass to tibial arteries
- 1966: McCaughan – bypass to tibial arteries at ankle

Linton RR, Darling RC.**Surgery**. 1962;**51**:62–65



Resident Experience

	2010		2019	
	Mean	Std Dev	Mean	Std Dev
Femoral, Profunda Endarterectomy	**10.8**	6	**16.4**	10
Femoral-Popliteal Bypass, Vein	**10.3**	6	**9.5**	5
Femoral-Popliteal Bypass, Prosth	**8.6**	6	**7.2**	5
Translum balloon angio femoral-popl	**18.8**	13	**43.0**	23
Translum atherectomy femoral-popliteal	**4.7**	7	**7.7**	9
Endarterectomy, superf femoral, popl	**2.1**	2	**3.1**	5
Infrapopliteal Bypass, Vein	**15.5**	9	**14.7**	10
Infrapopliteal Bypass, Prosthetic	**4.2**	4	**4.0**	3
Translum ballon angio, tibioperoneal	**11.2**	9	**19.9**	13
Translum atherectomy, tibioperoneal	**2.2**	4	**4.0**	7

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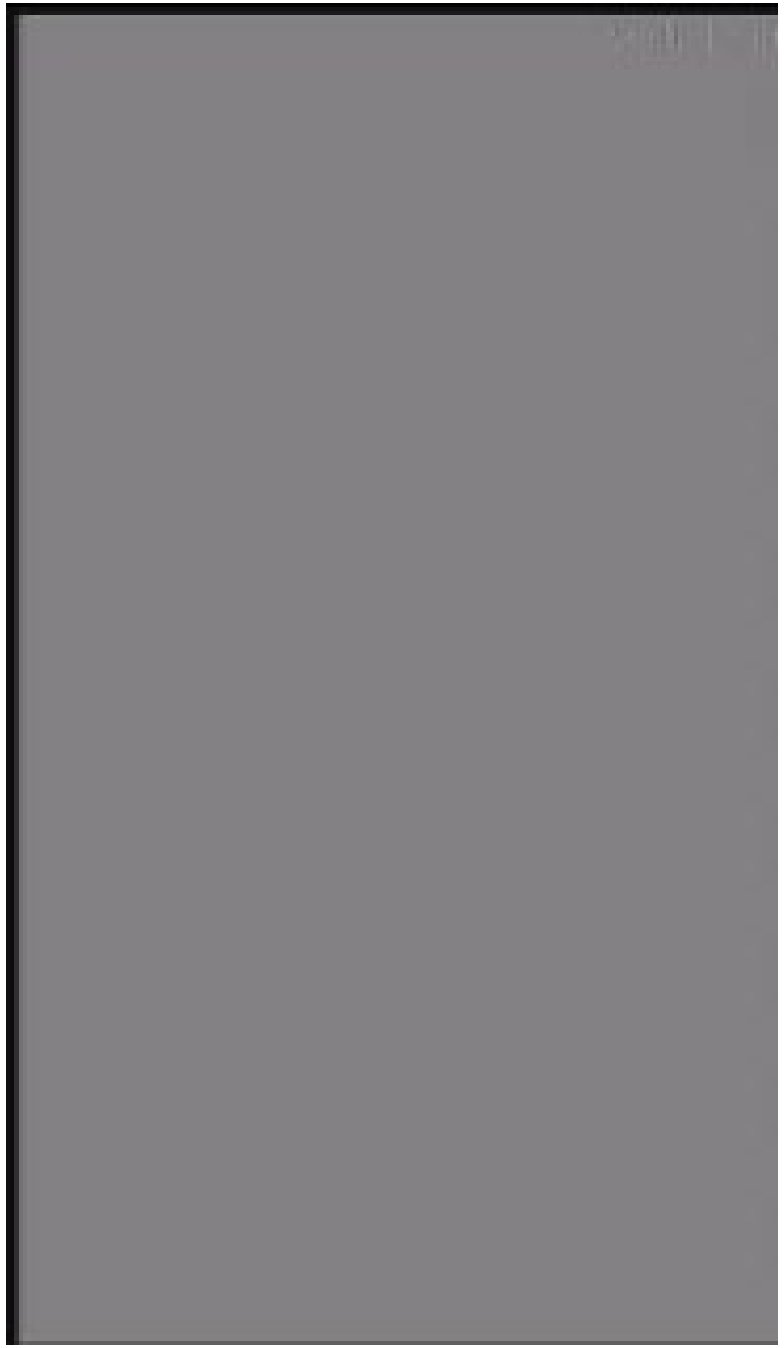
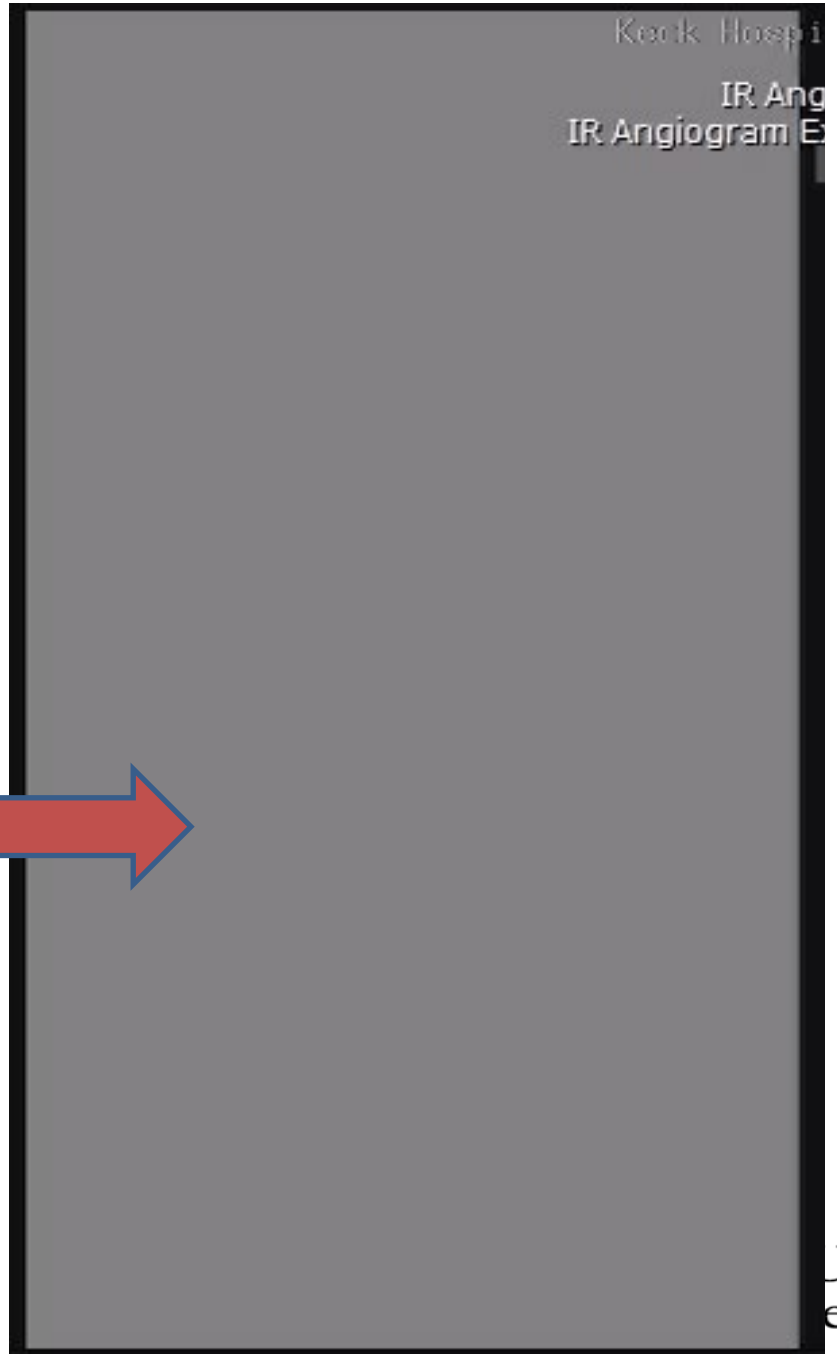
Distal Bypass Technique

- 78 year old male
- Laceration to Right great toe
- HTN
- CVA with residual left sided weakness
- Hypercholesterolemia
- No pedal pulses





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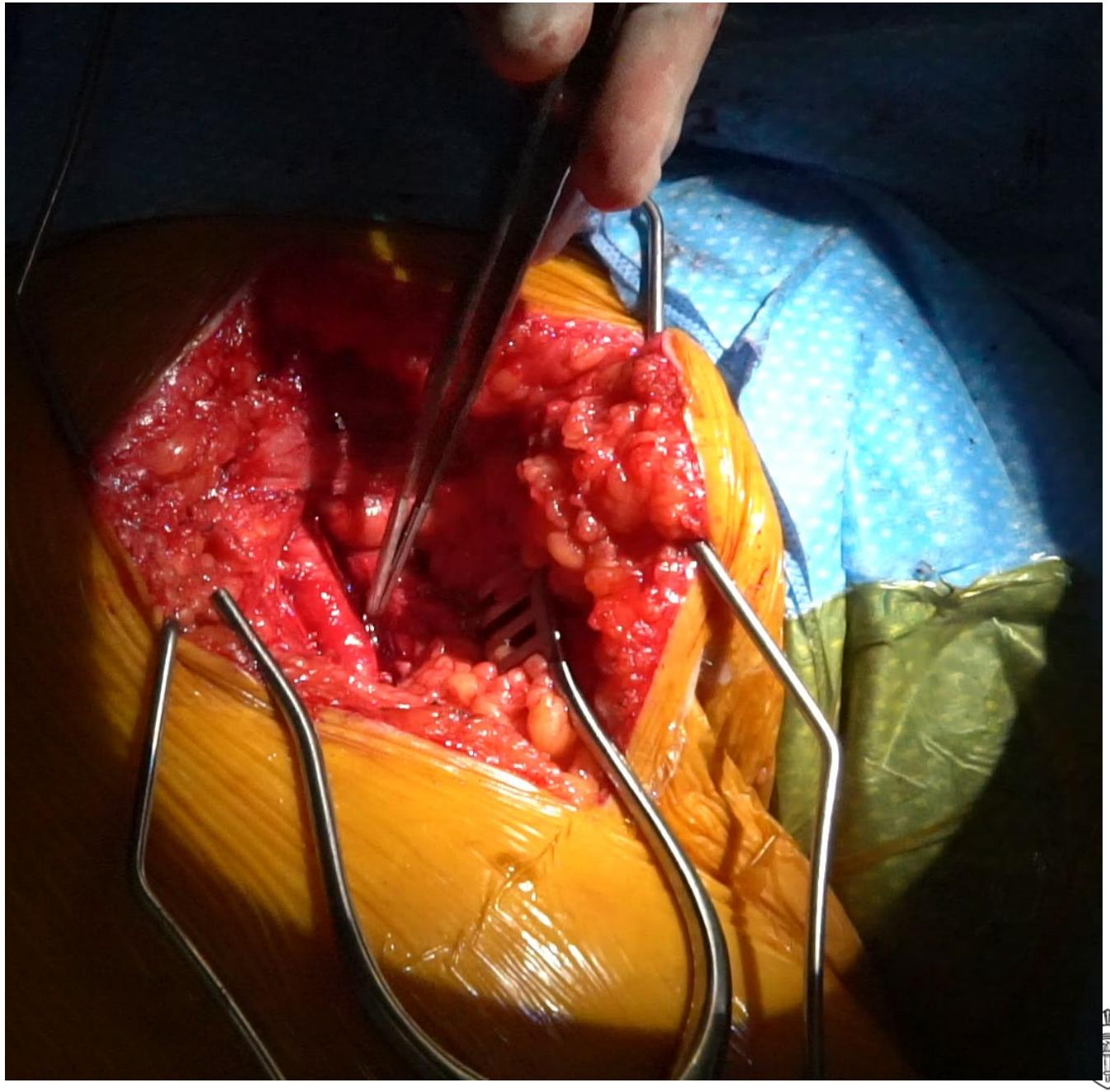

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Inflow for Bypass

- No difference with inflow from CFA or SFA with midterm follow up
- Shorter bypasses are better
- Need to follow long-term
- Surveillance duplex

Vascular 2020 Dec;28(6):722-730

Comparison of mid-term graft patency in common femoral versus superficial femoral artery inflow for infra-geniculate bypass in the vascular quality initiative

Kenneth Tran, Vy T Ho, Nathan K Itoga, more...
Show all authors

First Published May 14, 2020 | Review Article | Find in PubMed | Check for updates
https://doi.org/10.1177/1708538120924908
Article information

Abstract

Objectives

The superficial femoral artery can be used as inflow for infra-geniculate bypass, but progressive proximal occlusive disease may affect graft durability. We sought to evaluate the effect of superficial femoral artery versus common femoral artery inflow on infra-geniculate bypass patency within a large contemporary multicenter registry.

Methods

The vascular quality initiative was queried from 2013 to 2019 to identify patients with >30-day patency follow-up, Rutherford chronic limb ischemia stage 1–6, and an infra-geniculate bypass, excluding those with prior ipsilateral bypass. The cohort was stratified by inflow vessel, with primary, primary-assisted, and secondary patency serving as the primary outcome variables. Multivariate Cox-proportional hazard models and radius-based propensity-score matching were performed to reduce treatment-selection bias due to clinical covariates.

Results

A total of 11,190 bypass procedures were performed (8378 common femoral artery inflow, 2812 superficial femoral artery) on 10,110 patients, with a mean follow-up of 12.8 months (range 1–98). Patients receiving superficial femoral artery inflow bypasses were more commonly male ($p = 0.002$), obese ($p < 0.0001$) and had chronic, limb threatening ischemia ($p < 0.0001$), whereas those with common femoral artery inflow were older ($p < 0.0004$), and had higher baseline comorbidities including smoking ($p < 0.0001$), coronary disease ($p < 0.0001$), and pulmonary disease ($p < 0.0001$). On life-table analysis, there was no significant difference in three year estimated primary (32.1 vs 30.1%, $p = 0.928$), primary assisted (60.5 vs 65.8%, $p = 0.191$), or secondary patency (62.5 vs 66.7%, $p = 0.139$) between superficial femoral artery and common femoral artery inflow groups, respectively. A multivariate Cox model found no significant association between inflow vessel and primary patency (0.96 [0.88–1.04], HR [95%CI]), primary-assisted (1.07 [0.95–1.20], HR [95%CI]), or secondary patency (1.08 [0.96–1.22]). In a propensity-matched cohort ($n = 11,151$), there were small but statistically significant differences in primary, primary-assisted, and secondary patency at latest follow-up (non-time-to-event data) between groups. The largest difference was observed when evaluating secondary patency, with common femoral artery inflow having a marginally higher secondary patency of 88.1% compared to 85.6% for those with superficial femoral artery inflow at latest follow-up ($p = 0.009$).

Conclusions

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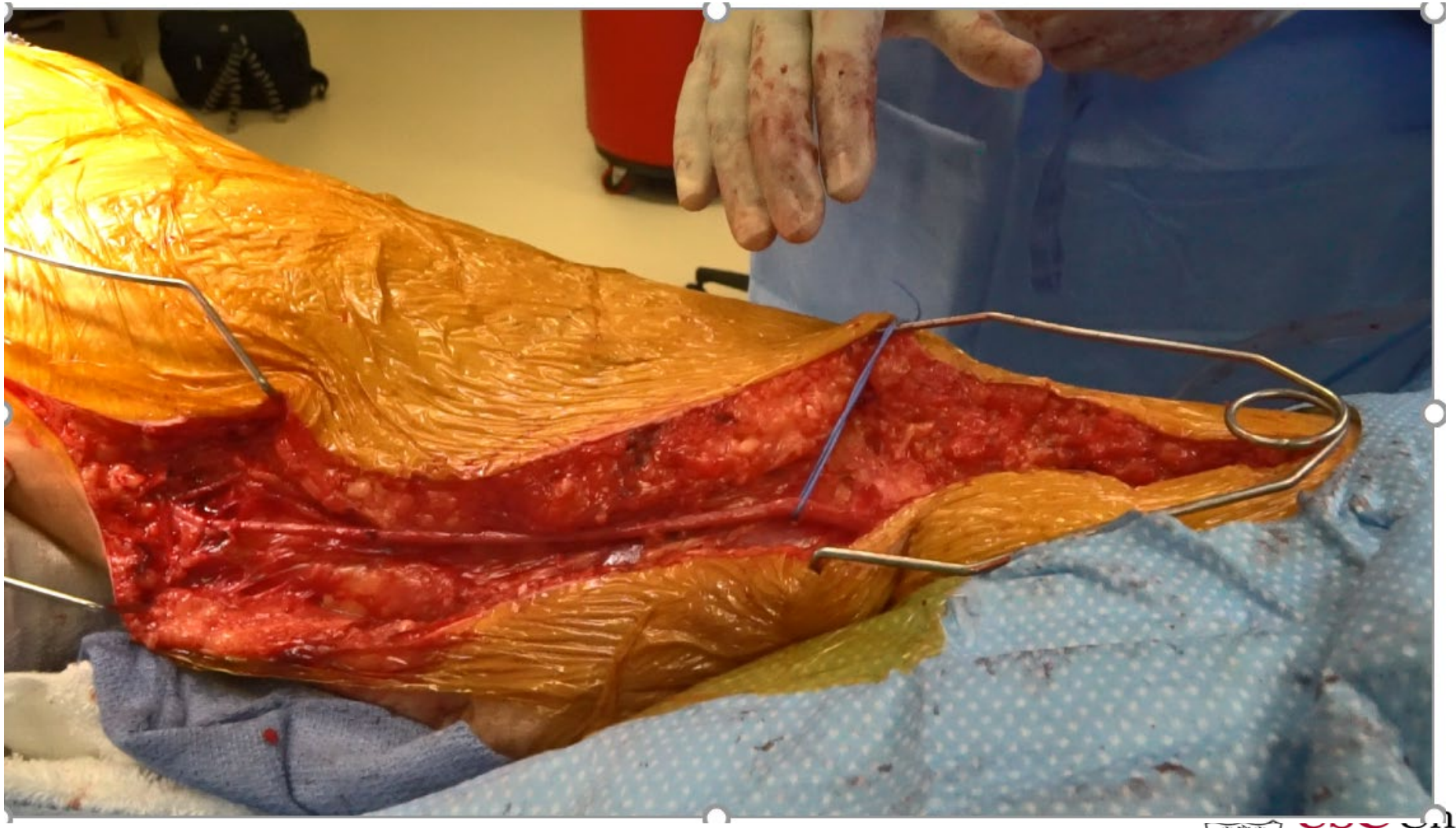
Vein Harvest



Conduit

- GSV greatly preferred
- Alternative
  - Spliced vein
  - PTFE +/- vein cuff
  - Cryopreserved vein or SFA
  - Arm vein
  - Umbilical vein

Methods - Technique

Open Harvest

Endoscopic Harvest

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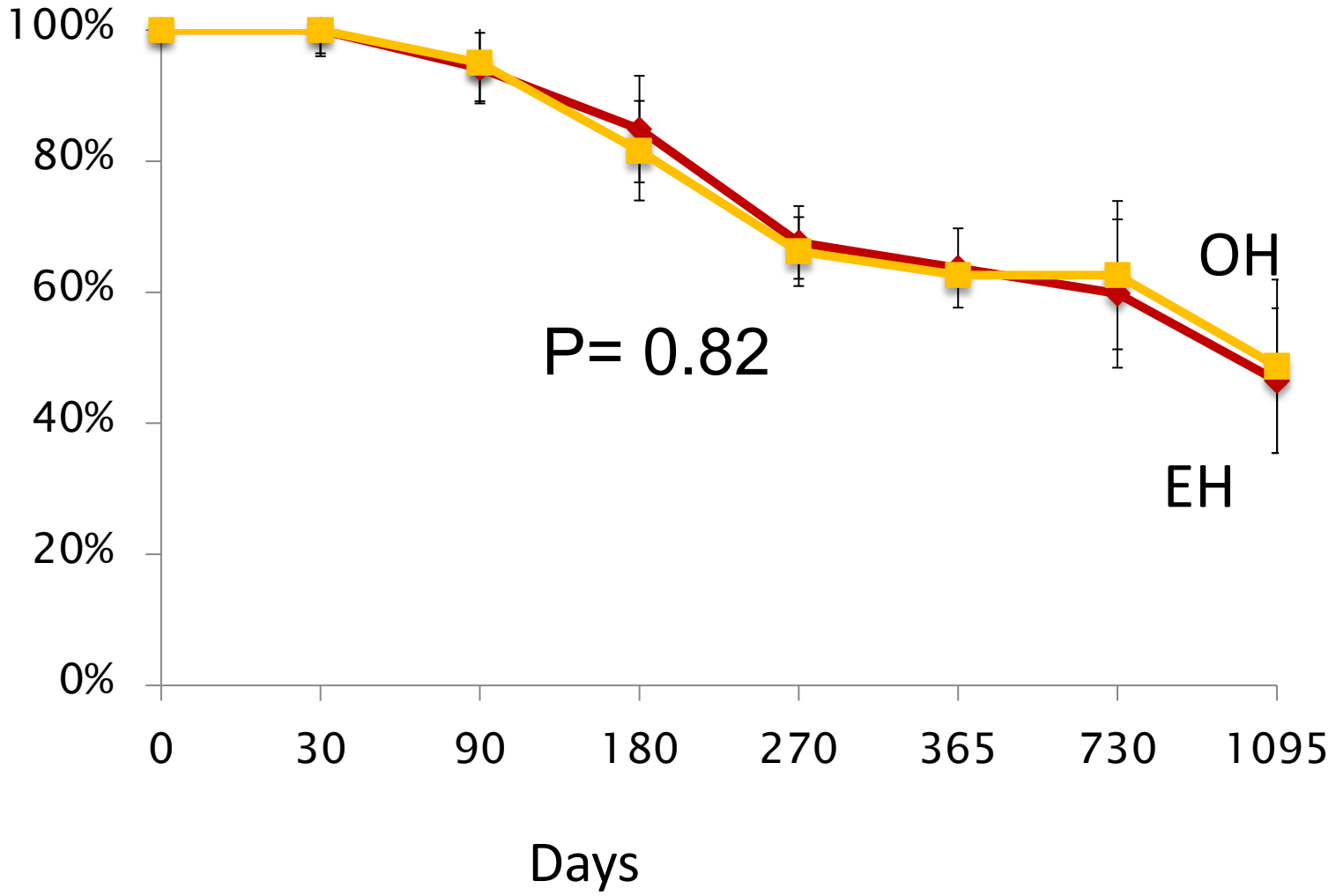
Primary Patency



J Vasc Surg 2013; 57:1489-94

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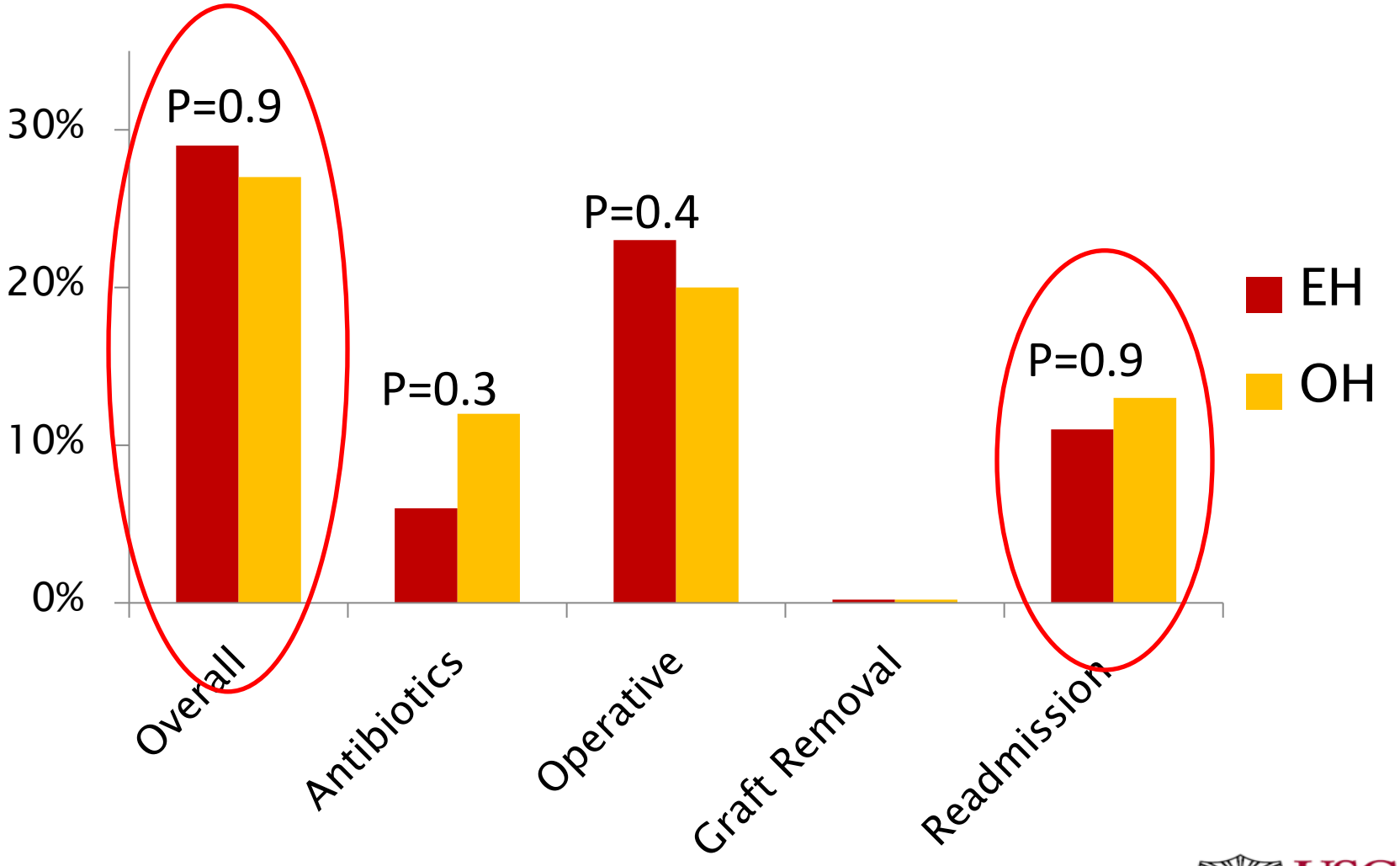
Wound Complications



J Vasc Surg 2013; 57:1489-94

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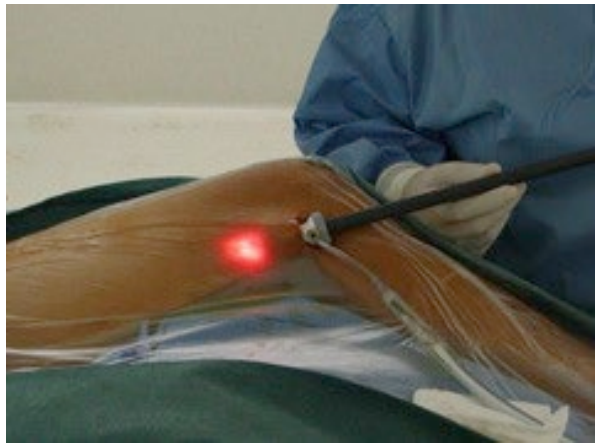
Study Groups

Continuous Incision

Skip Incision

Endoscopic



J Vasc Surg 2015;61:1264-71

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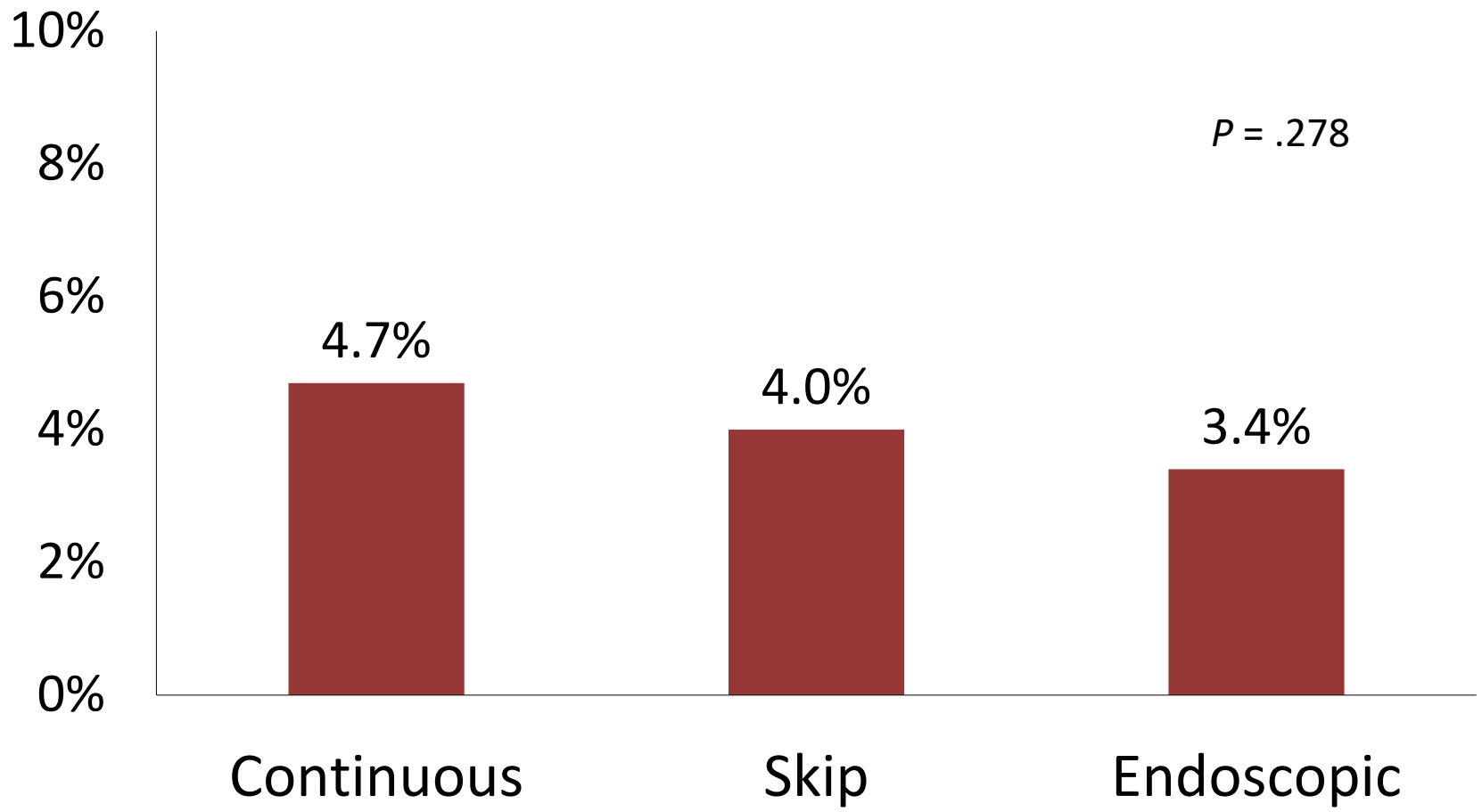
Surgical Site Infection



J Vasc Surg 2015;61:1264-71

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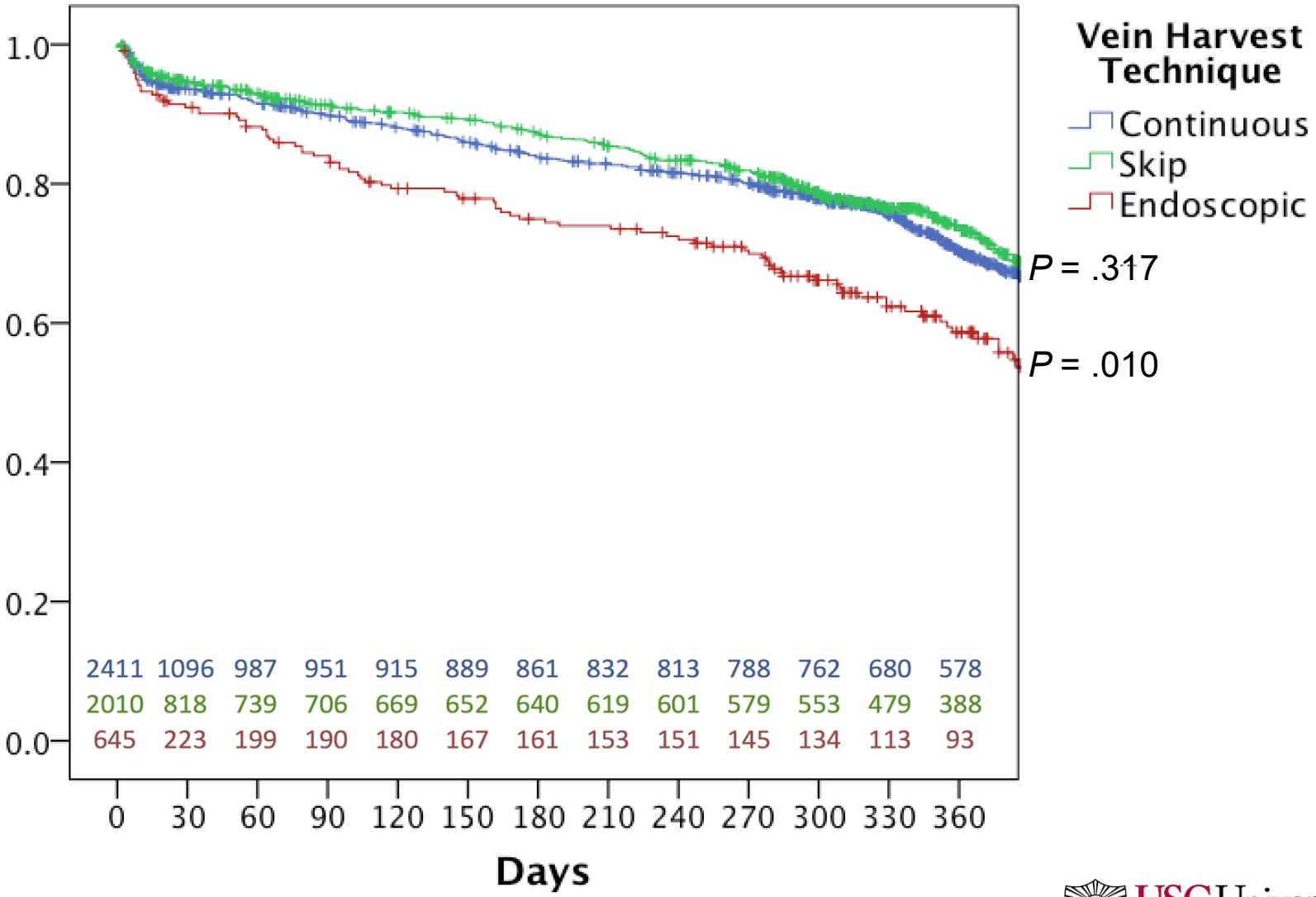
Primary Patency



J Vasc Surg 2015;61:1264-71

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Author/Year	Patients	Wound Comp.	Patency
Gazoni 2006	144	↑	↑
Wartman 2013	76	NS	NS
Santo 2014	251	↑	↓
Eid 2014	88	↑	↓
Jauhari 2014	2343 Meta-analysis	NS	↓
Teixeira 2015	5066 VQI	NS	↓
Khan 2016	153	↑	NS 60 mo
Mirza 2018	505	↑	↓
Kronick 2019	113	↑	↑

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So Is It Worthwhile?

VQI data suggests probably not:

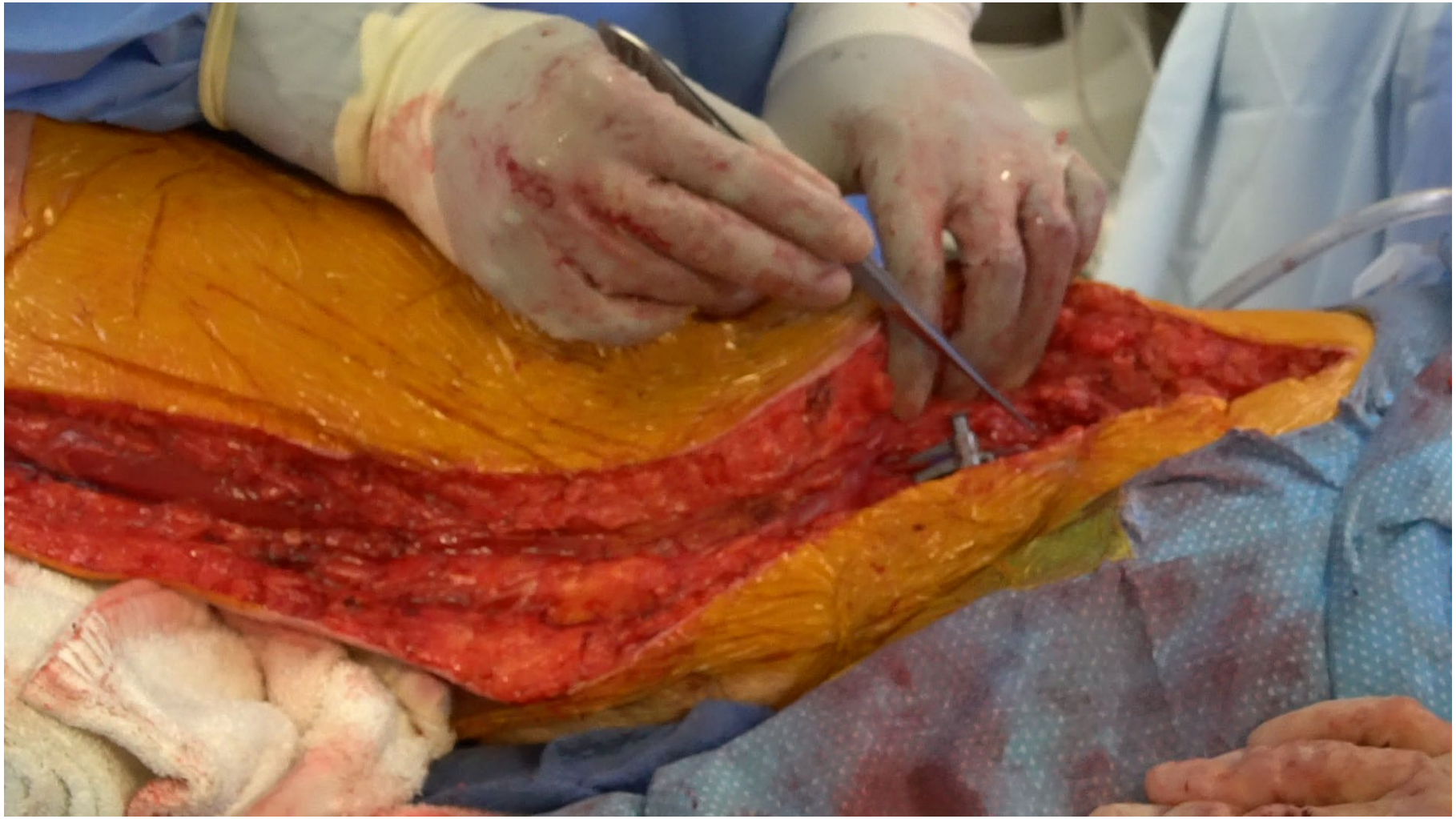
- Incidence of surgical site infections were no different between any of the harvest techniques.
- Endoscopic harvest associated with decreased primary graft patency.

However:

- Operator experience
- Improved instrumentation

So my opinion: **Worthwhile in Select Patients**

- High BMI (Thigh harvest)
- Vein ≥3mm



From the Society for Clinical Vascular Surgery

Effect of infrainguinal bypass tunneling technique on patency and amputation in patients with limb ischemia

Nallely Saldana-Ruiz, MD, MPH, Josefina Dominguez, MD, Sung Wan Ham, MD, Vincent L. Rowe, MD, Gregory A. Magee, MD, MSc, Fred A. Weaver, MD, MMM, Sukgu M. Han, MD, MS, *and* Kenneth R. Ziegler, MD, *Los Angeles, Calif*

ABSTRACT

Objective: We investigated the association of tunneling technique on patency and amputation in patients undergoing lower extremity bypass for limb ischemia.

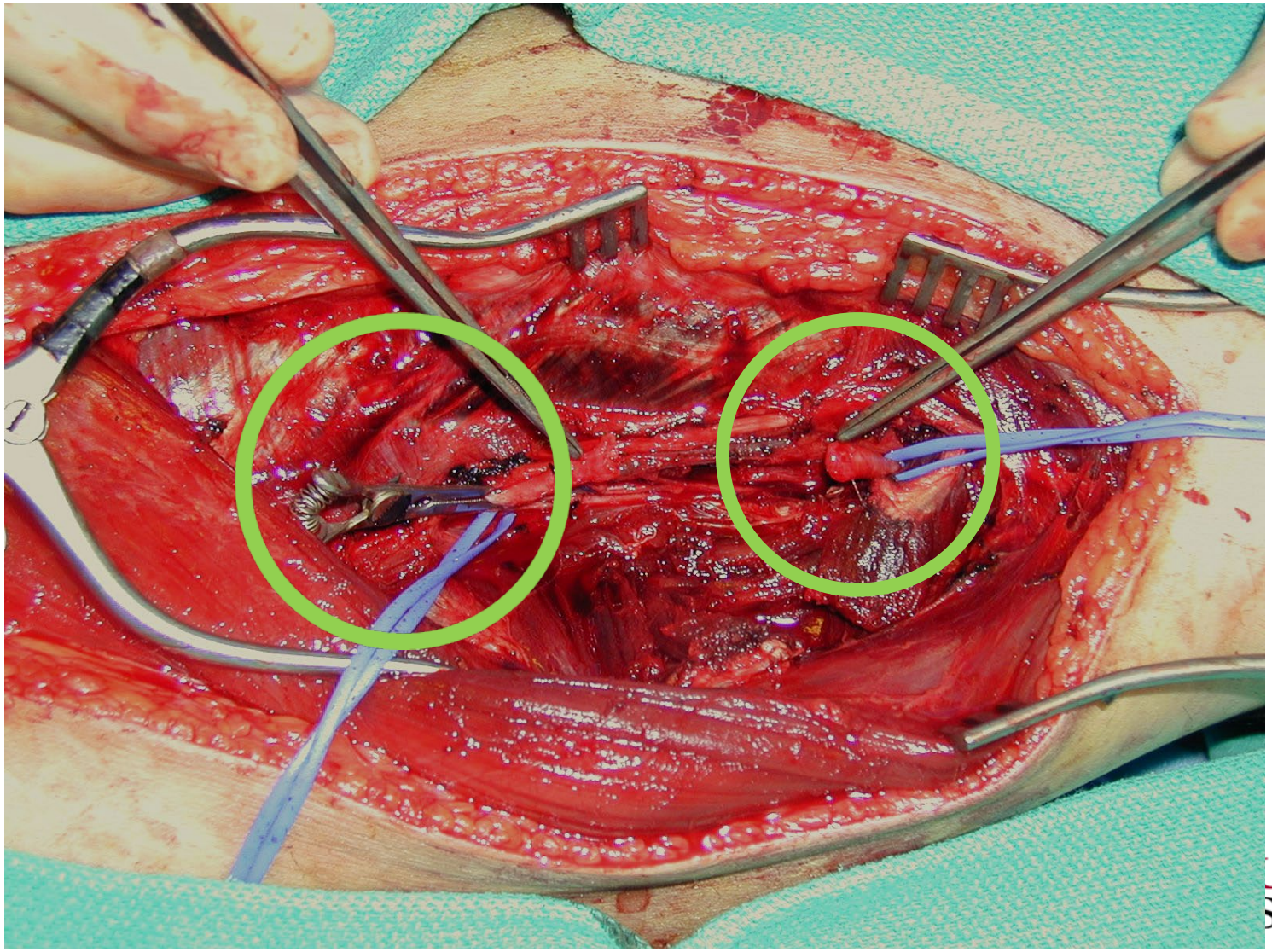
Methods: The National Vascular Quality Initiative database infrainguinal bypass module from 2008 to 2017 was queried for analysis. We excluded cases with non–great saphenous vein grafts, grafts using multiple segments, aneurysmal disease indications, bypass locations outside the femoral to below the knee popliteal artery or tibial arteries, and missing data on tunneling type and limb ischemia. The main exposure variable was the tunneling type, subcutaneously vs subfascially. Our primary outcomes were primary patency and amputation. The secondary outcomes included primary-assisted patency and secondary patency. Univariate and multivariate logistic regression models were used.

Results: A total of 5497 bypass patients (2835 subcutaneous and 2662 subfascial) were included. Age, race, graft orientation (reversed vs not reversed), bypass donor and recipient vessels, harvest type, end-stage renal disease, smoking, coronary artery bypass graft, congestive heart failure, P2Y12 inhibitor at discharge, surgical site infection at discharge, and indication (rest pain vs tissue loss vs acute ischemia) were analyzed for an association with the tunneling technique

Conclusions: Compared with subfascial tunneling, the superficial tunneling technique was not associated with primary patency or major amputation in limb ischemia patients undergoing infrainguinal bypass with a single-segment great saphenous vein. (J Vasc Surg 2021;■:1-9.)

Keywords: Amputation-free survival; Infrainguinal bypass; Limb ischemia; Major amputation; Tunnel technique; Vascular Quality Initiative

Vascular Control



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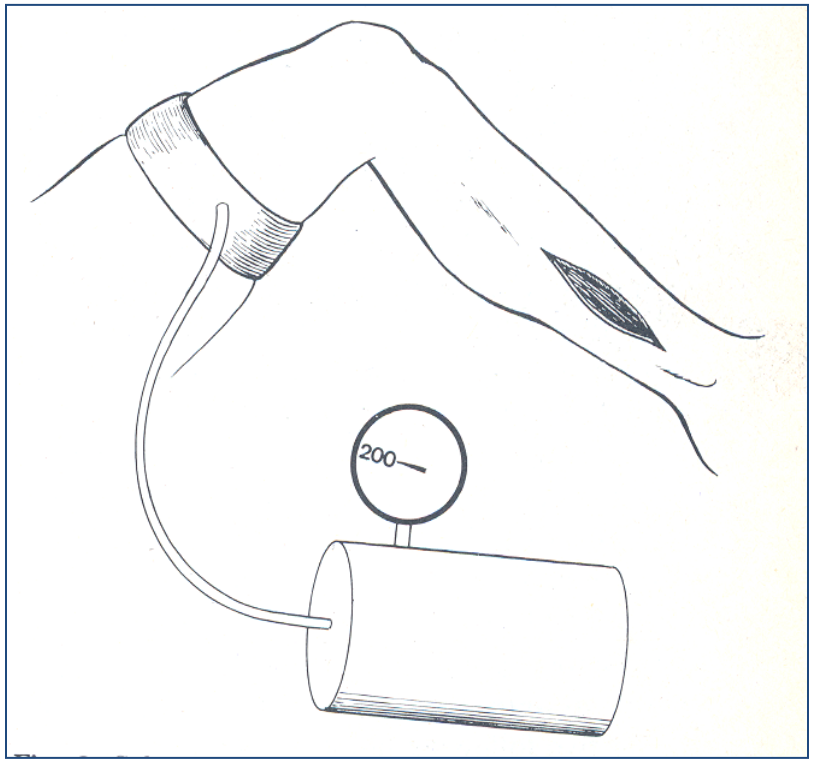
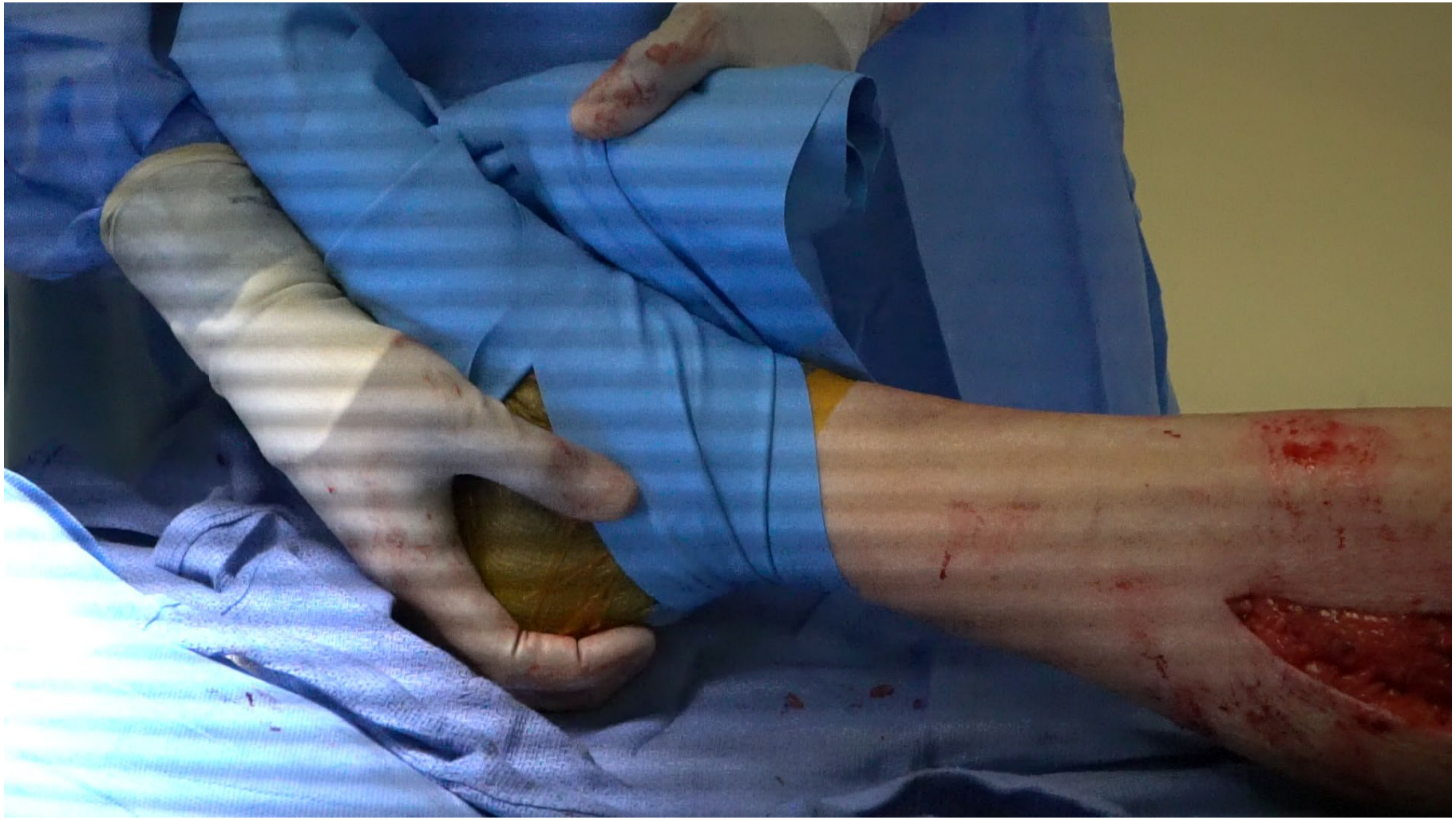
Tourniquet Technique

- Systemic heparin
- Limb elevation
- Esmarck wrap
- Pneumatic tourniquet 250-300 mmHg



Surgery 1980;87:709-13



Pneumatic Tourniquet Occlusion

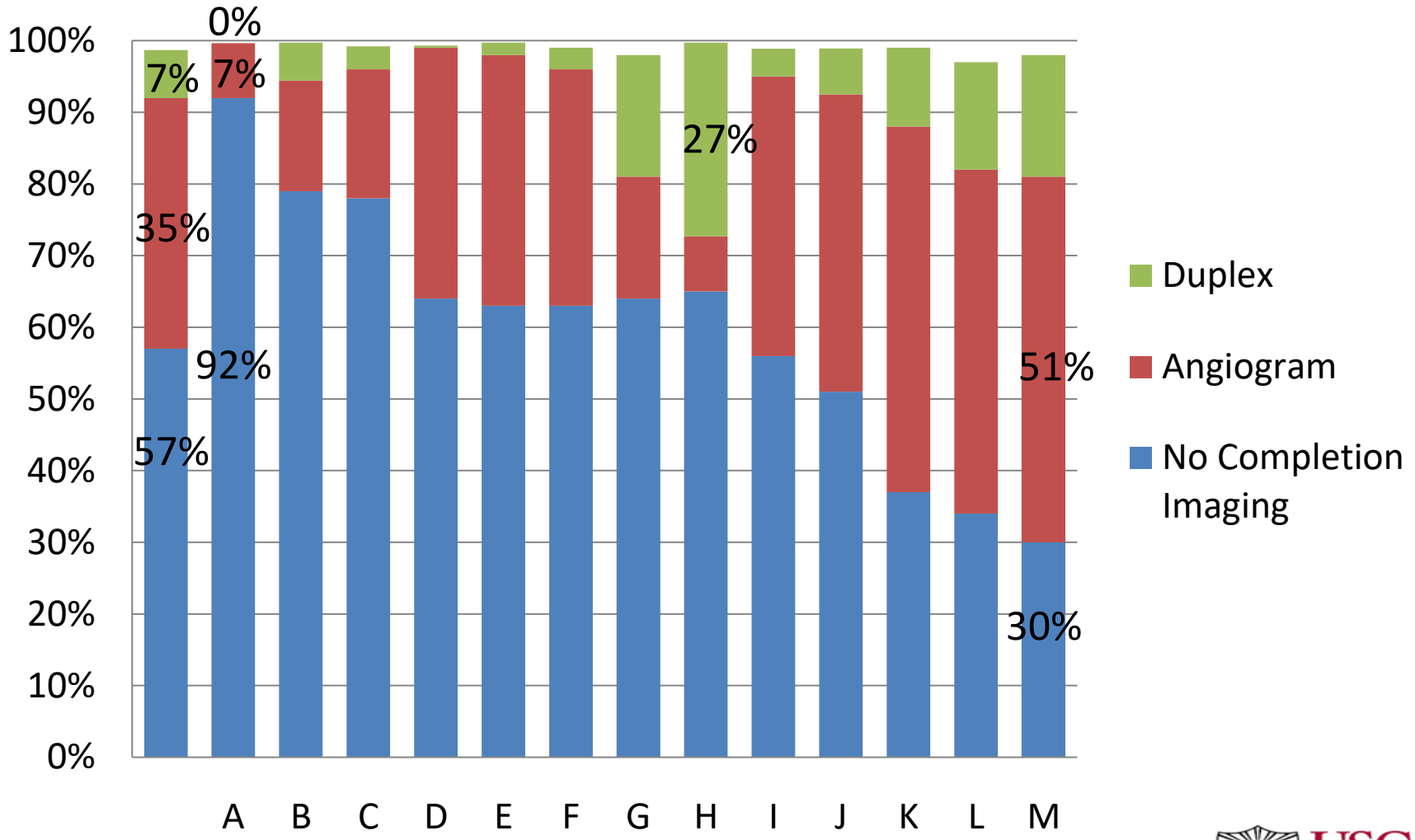
- Bloodless field
- Avoid vessel trauma
- Limit vessel dissection
- Resident training

Completion Imaging

Benefits…

- Immediate assessment of reconstruction
- Prevention of early occlusion/stenosis
- Does **not** decrease need for follow-up imaging
- Fine-tune surgical technique for trainee and junior level attendings

Regional Analysis



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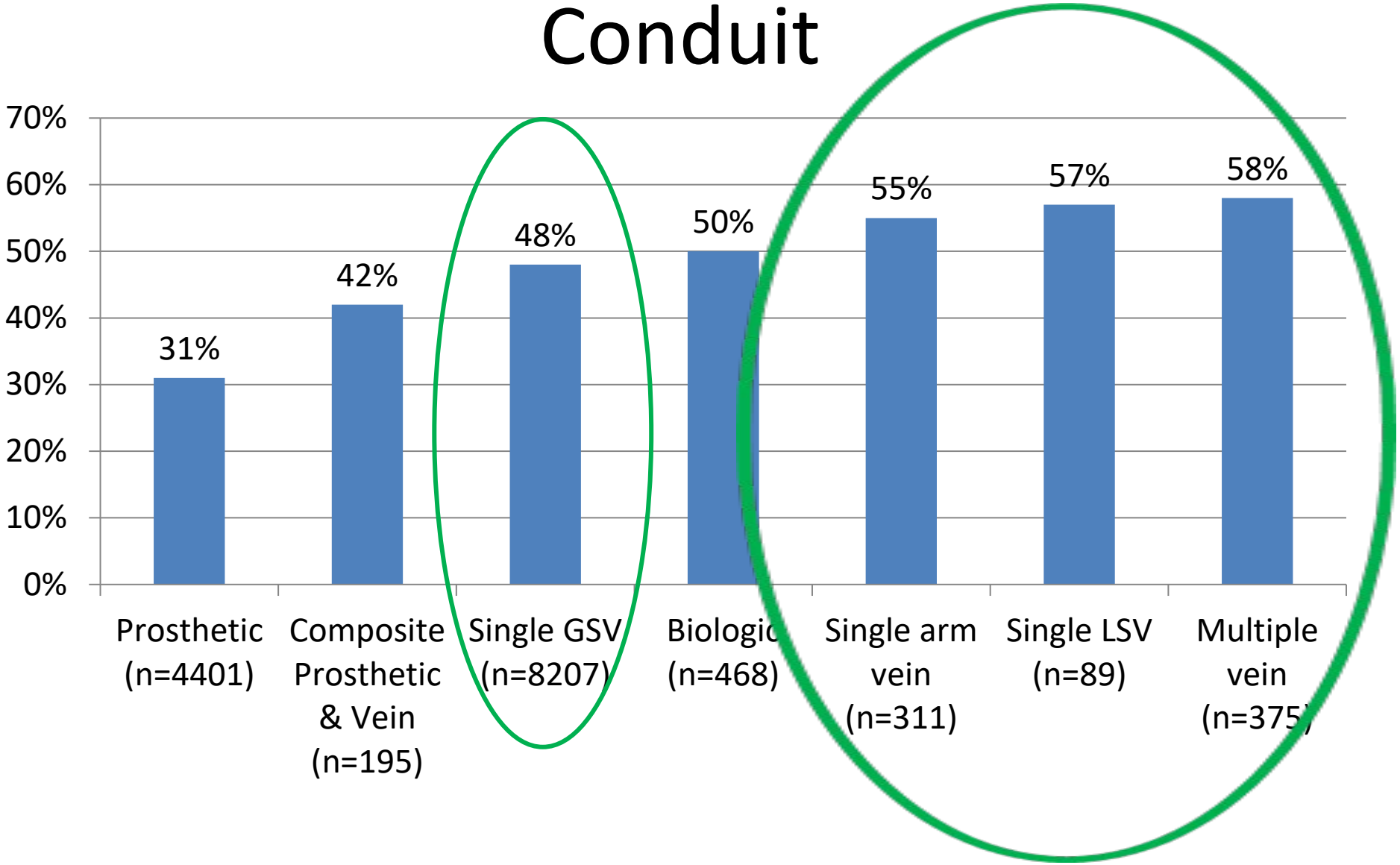
Conduit



J Vasc Surg 2015;61:1258-63

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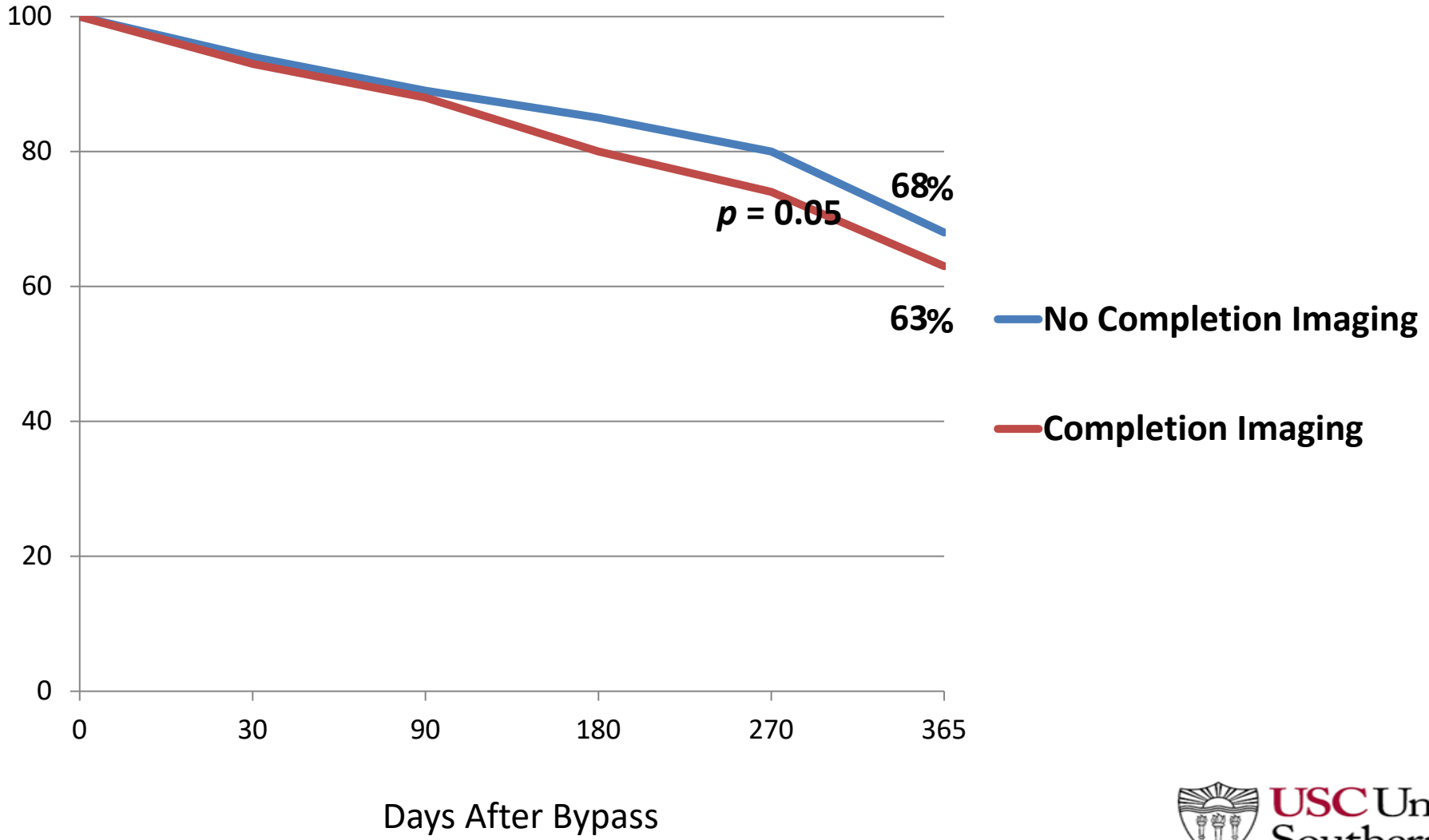
Primary Patency at One Year



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Summary

Tenets

- **Suitable Inflow /Outflow**
- **GSV is best option**
- **Alternative Conduits work, but not as well**
- **Shorter bypass better**
- **Surveillance is important**

Personal Recommendations

- Open vein harvest
- Tourniquet occlusion
- Completion imaging
- Tunneling in safe location
- Immediate amputation of dead tissue in most cases

Outcomes

BASIL Trial

Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial

*BASIL trial participants**

Summary

Background The treatment of rest pain, ulceration, and gangrene of the leg (severe limb ischaemia) remains controversial. We instigated the BASIL trial to compare the outcome of bypass surgery and balloon angioplasty in such patients.

Methods We randomly assigned 452 patients, who presented to 27 UK hospitals with severe limb ischaemia due to infra-inguinal disease, to receive a surgery-first (n=228) or an angioplasty-first (n=224) strategy. The primary endpoint was amputation (of trial leg) free survival. Analysis was by intention to treat. The BASIL trial is registered with the National Research Register (NRR) and as an International Standard Randomised Controlled Trial, number ISRCTN45398889.

Findings The trial ran for 5·5 years, and follow-up finished when patients reached an endpoint (amputation of trial leg above the ankle or death). Seven individuals were lost to follow-up after randomisation (three assigned angioplasty, two surgery); of these, three were lost (one angioplasty, two surgery) during the first year of follow-up. 195 (86%) of 228 patients assigned to bypass surgery and 216 (96%) of 224 to balloon angioplasty underwent an attempt at their allocated intervention at a median (IQR) of 6 (3–16) and 6 (2–20) days after randomisation, respectively. At the end of follow-up, 248 (55%) patients were alive without amputation (of trial leg), 38 (8%) alive with amputation, 36 (8%) dead after amputation, and 130 (29%) dead without amputation. After 6 months, the two strategies did not differ significantly in amputation-free survival (48 *vs* 60 patients; unadjusted hazard ratio 1·07, 95% CI 0·72–1·6; adjusted

Interpretation In patients presenting with severe limb ischaemia due to infra-inguinal disease and who are suitable for surgery and angioplasty, a bypass-surgery-first and a balloon-angioplasty-first strategy are associated with broadly similar outcomes in terms of amputation-free survival, and in the short-term, surgery is more expensive than angioplasty.

angioplasty.

Lancet 2005; 366: 1925–34

Published online November 24, 2005 DOI:10.1016/S0140-6736(05)67704-5

See Comment page 1905

*Trial participants listed at end of report

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Adam DJ. Lancet. Dec 3 2005;366(9501):1925-1934

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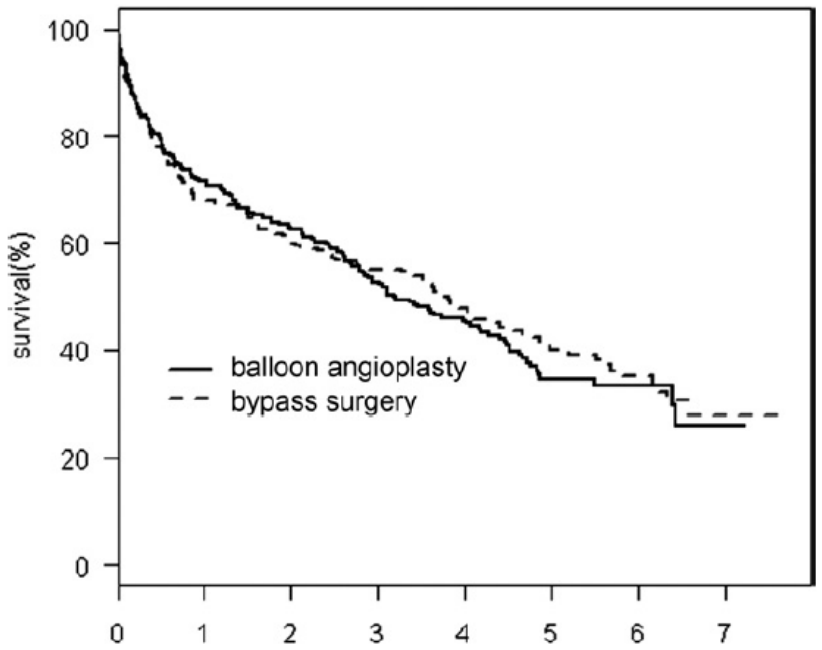
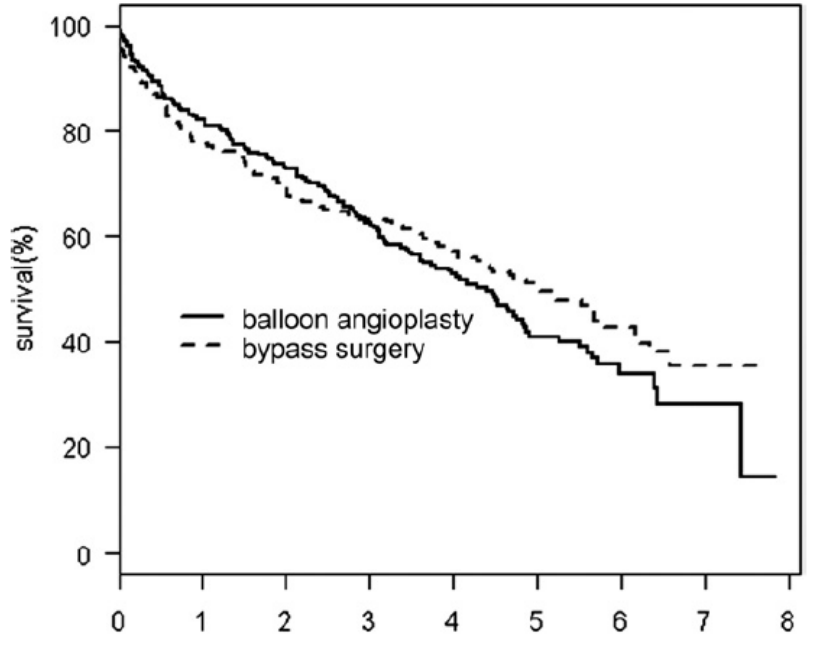
BASIL Trial

Amputation Free Survival



At risk								
Balloon angioplasty	224	160	139	117	87	41	16	5
Bypass surgery	228	154	138	124	93	53	24	6

Overall Survival



At risk								
Balloon angioplasty	224	184	162	139	101	49	19	7
Bypass surgery	228	175	155	142	110	63	31	7

Bradbury A. J Vasc Surg 2010; 51(5 Suppl)5S-17S

BASIL Trial

Thus, patients who survived for 2 years and who were initially randomized to BSX gained a significant 7 months of additional life expectancy and an additional nonsignificant 6 months of amputation-free life expectancy over the subsequent follow-up period compared with those randomized to BAP. Although these may not seem large differences, in the context of a condition with a very poor overall prognosis that is worse than many common malignancies, affected patients and physicians appear likely to view them as meaningful gains in life and limb.

Bradbury A. J Vasc Surg 2010; 51(5 Suppl)5S-17S

Results of PREVENT III: A multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery

Michael S. Conte, MD,[a] Dennis F. Bandyk, MD,[b] Alexander W. Clowes, MD,[c] Gregory L. Moneta, MD,[d] Lynn Seely, MD,[c] Todd J. Lorenz, MD,[c] Hamid Namini, PhD,[c] Allen D. Hamdan, MD,[f] Sean P. Roddy, MD,[g] Michael Belkin, MD,[a] Scott A. Berceli, MD,[h] Richard J. DeMasi, MD,[i] Russell H. Samson, MD,[j] and Scott S. Berman, MD,[k] for the PREVENT III Investigators, *Boston, Mass;*

- Randomized, Double Blinded
- Multicenter – 83 centers (US and Canada)
- Efficacy of edifoligide (EF2 decoy)
  - Competitive inhibitor of EF2
  - Inhibit SMC proliferation and reduce intimal hyperplasia

J Vasc Surg 2006;43:742-51.

Ethnic origin		
White	526 (74.4%)	491 (70.4%)
Black	116 (16.4%)	133 (19.1%)
Asian	3 (0.4%)	7 (1.0%)
Hispanic	53 (7.5%)	54 (7.7%)
Other	9 (1.3%)	12 (1.7%)
CLI criterion (worst)		
Rest pain	184 (26.0%)	169 (24.2%)
Nonhealing ulcer	273 (38.6%)	280 (40.2%)
Gangrene	247 (34.9%)	246 (35.3%)
Comorbidities		
Hypertension	577 (81.6%)	569 (81.6%)
Diabetes	461 (65.2%)	439 (63.0%)
CAD	353 (49.9%)	324 (46.5%)
CVD	144 (20.4%)	140 (20.1%)
Smoking*	520 (73.5%)	513 (73.6%)
Dyslipidemia	393 (55.6%)	373 (53.5%)
Dialysis	84 (11.9%)	86 (12.3%)
Inflow	146 (20.7%)	147 (21.1%)
Infrainguinal (either limb)	190 (26.9%)	193 (27.7%)

Variable	*Edifoligide*	*Placebo*	P *value*
Protocol-specified end points			
Primary trial end point (nontechnical failure)	25.2	25.5	.69
All clinical failures	34.8	36	.51
Freedom from clinically significant stenosis	44.3	46.1	.62
Amputation/ reintervention-free survival	50.1	48.6	.47
Conventional end points			
Primary patency	61.5	59.5	.38
Primary assisted patency	78.6	74.7	.10
Secondary patency	82.6	77.5	.02
Limb salvage	87.7	89.2	.37
Survival	83.2	84.4	.55

J Vasc Surg 2006;43:742-51.

Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia

Michael S. Conte, MD,[a] Patrick J. Geraghty, MD,[b] Andrew W. Bradbury, MD,[c] Nathanael D. Hevelone, MPH,[d] Stuart R. Lipsitz, ScD,[e] Gregory L. Moneta, MD,[f] Mark R. Nehler, MD,[g] Richard J. Powell, MD,[h] and Anton N. Sidawy, MD,[i] *San Francisco; Calif; St. Louis, Mo; Birmingham, United Kingdom; Boston, Mass; Portland, Ore; Aurora, Colo; Hanover, NH; and Washington, DC*

- SVS LEB objective performance goals (OPG)
- Prevent III, BASIL, Circulase II Trials
- Benchmark for future CLI therapies (including endovascular)
- Excluded prosthetic grafts and ESRD patients

J Vasc Surg 2009;50:1462-73.

Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia

Outcome	*Point (95% CI)*	*Efficacy OPG*
MALE + POD	76.9% (74.0-79.9)	71%
AFS	76.5% (73.7-79.5)	71%
RAS	46.5% (42.3-51.2)	39%
RAO	61.3% (58.0-64.9)	55%
Limb salvage	88.9% (86.7-91.1)	84%
Survival	85.7% (83.3-88.1)	80%

AFS, Amputation-free survival; *CI*, confidence interval; *CLI*, critical limb ischemia; *MALE*, major adverse limb event; *OPG*, objective performance goals; *POD*, perioperative death; *RAO*, any reintervention or above ankle amputation of the index limb; *RAS*, any reintervention, above ankle amputation of the index limb, or stenosis.

Rates reported as proportion free from adverse event.

J Vasc Surg 2009;50:1462-73.

Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia

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- Negative factors:
  - Age > 80 years old with tissue loss
  - Poor quality saphenous vein
  - Infrapopliteal level
- Excluded ESRD and prosthetic conduit patients

J Vasc Surg 2009;50:1462-73.

From the Society for Vascular Surgery

Validation of the Society for Vascular Surgery's Objective Performance Goals for critical limb ischemia in everyday vascular surgery practice

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Conclusion: Community and academic centers in everyday vascular surgery practice can meet OPGs derived from centers of excellence in LEB. Quality improvement initiatives, as well as clinical trials, should incorporate OPGs in their outcome measures to facilitate communication and comparison of risk-adjusted outcomes in the treatment of CLI. (J Vasc Surg 2011;54:100-8.)

Results: Across most risk strata, patients in the VSGNE and SVS OPG cohorts were similar (clinical high-risk [age >80 years and tissue loss]: 15.3% VSGNE; 16.2% SVS OPG; $P = .58$; anatomic high risk [infrapopliteal target artery]: 57.8% VSGNE; 60.2% SVS OPG; $P = .32$). However, the proportion of VSGNE patients designated as conduit high-risk (lack of single-segment great saphenous vein) was lower (10.2% VSGNE; 26.9% SVS OPG;$P < .001$). The primary safety endpoint, major adverse limb events (MALE) at 30 days, was lower in the VSGNE cohort (3.2%; 95% CI, 2.3-4.6) than the SVS OPG cohort (6.2%; 95% CI, 4.2-8.1; $P = .05$). The primary efficacy OPG endpoint, freedom from any MALE or postoperative death within the first year (MALE + postoperative death [POD]), was similar between VSGNE and SVS OPG cohorts (77%; 95% CI, 74%-80%) SVS OPG, 74% (95% CI, 71%-77%) VSGNE, $P = .58$). In the remaining safety and efficacy OPGs, the VSGNE cohort met or exceeded the benchmarks established by the SVS OPG cohort.
Conclusion: Community and academic centers in everyday vascular surgery practice can meet OPGs derived from centers of excellence in LEB. Quality improvement initiatives, as well as clinical trials, should incorporate OPGs in their outcome measures to facilitate communication and comparison of risk-adjusted outcomes in the treatment of CLI. (J Vasc Surg 2011;54:100-8.)

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Questions?

Are these results feasible in the “real world”?

- 25% of patients in my practice have ESRD
- Do have to use prosthetic conduits
- 13% over 80 years old

The Society for Vascular Surgery's objective performance goals for lower extremity revascularization are not generalizable to many open surgical bypass patients encountered in contemporary surgical practice

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- All LEB in VSGNE for CLI
- SVS Objective Performance Goals (OPG)
- Included ESRD and prosthetic conduits
- OPG – 65% Non-OPG – 35%

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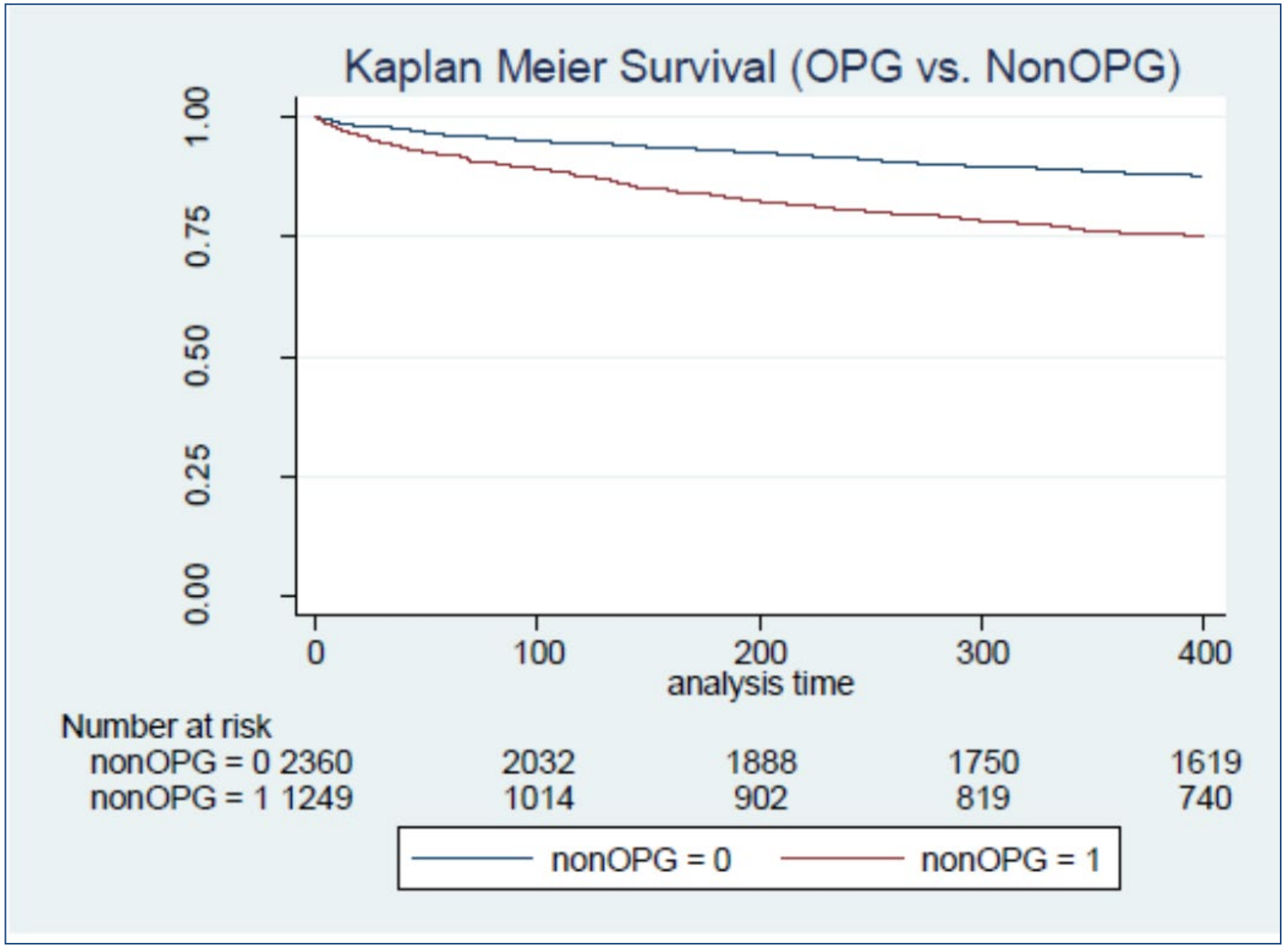
Demographic	*Non-OPG (n = 1249), No. (%)*	*OPG (n = 2360), No. (%)*	P *value*
Age, years	69.2	68.8	.34
Female sex	502 (40.2)	788 (33.4)	<.001
Nonwhite	99 (7.9)	159 (6.4)	.19
Any smoking	1030 (82.5)	1915 (81.0)	.33
Current smoking	423 (33.9)	887 (37.6)	.03
Hypertension	1142 (91.4)	2054 (87.0)	<.001
Diabetes	771 (61.7)	1328 (56.3)	.002
Diabetes requiring insulin	483 (38.7)	691 (29.3)	<.001
CAD	560 (44.8)	783 (33.2)	<.001
History of coronary artery bypass grafting	73 (5.8)	68 (2.9)	<.001
Congestive heart failure	323 (25.9)	414 (17.5)	<.001
Chronic obstructive pulmonary disease	372 (29.8)	593 (25.1)	.003
History of previous			
Ipsilateral bypass	220 (17.6)	240 (10.2)	<.001
Ipsilateral PVI	171 (13.7)	358 (15.2)	.23
Carotid endarterectomy/carotid artery stenting	147 (11.8)	209 (8.9)	.005
Major amputation	86 (6.9)	104 (4.4)	.002
Preoperative aspirin	930 (74.5)	1779 (75.4)	.54
Preoperative statin	865 (69.3)	1601 (67.8)	.38
Popliteal distal target			
Above the knee	441 (35.3)	233 (9.9)	<.001
Below the knee	323 (25.9)	768 (32.5)	<.001
Tibial distal target	328 (26.3)	991 (42.0)	<.001
Pedal distal target	117 (9.4)	349 (14.8)	<.001
Prosthetic conduit	1001 (80.1)	–	–
ESRD	343 (27.5)	–	–

CAD, Coronary artery disease; *ESRD*, end-stage renal disease; *PVI*, peripheral vascular intervention.

J Vasc Surg 2015;62:392-400.



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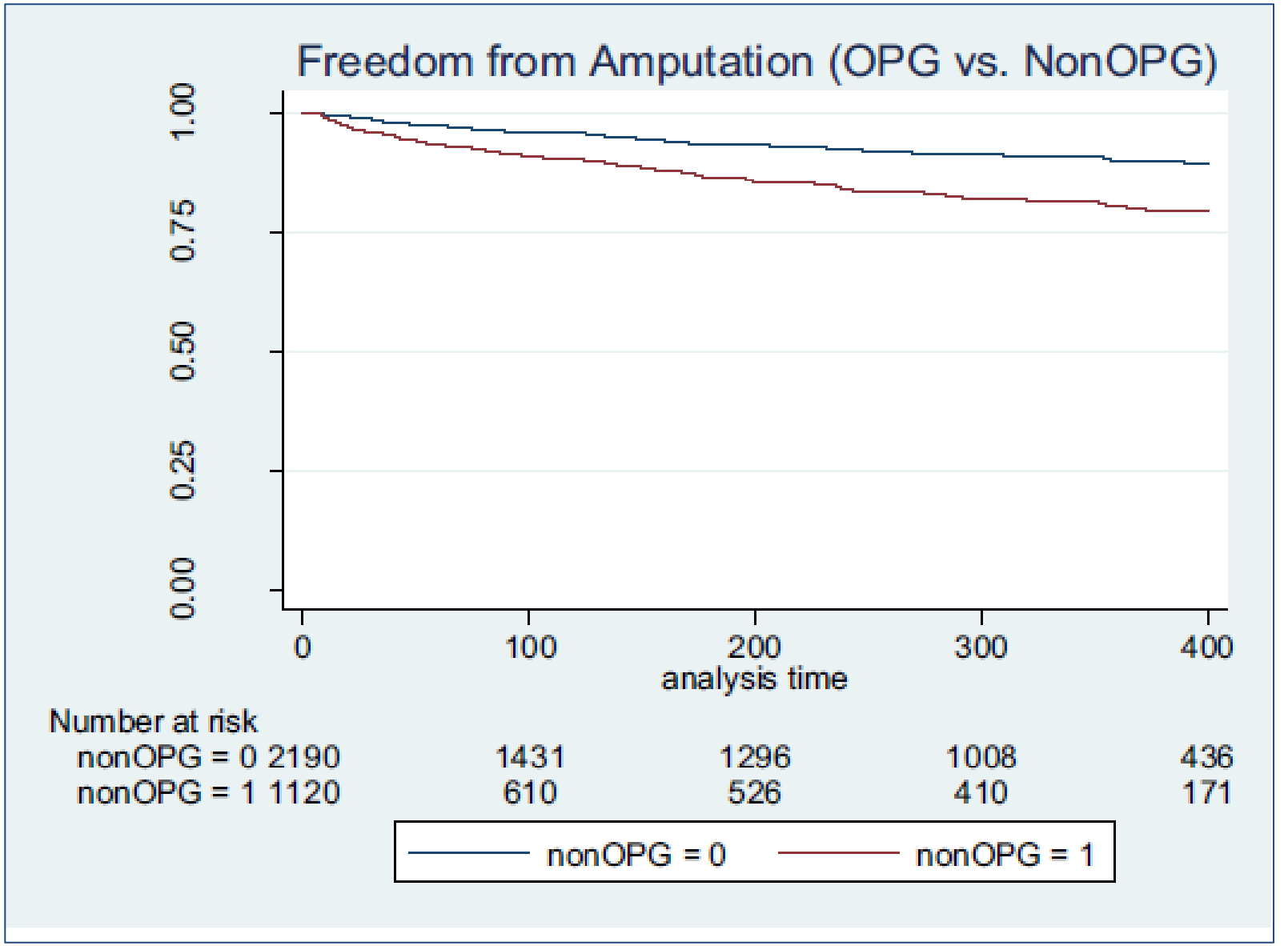

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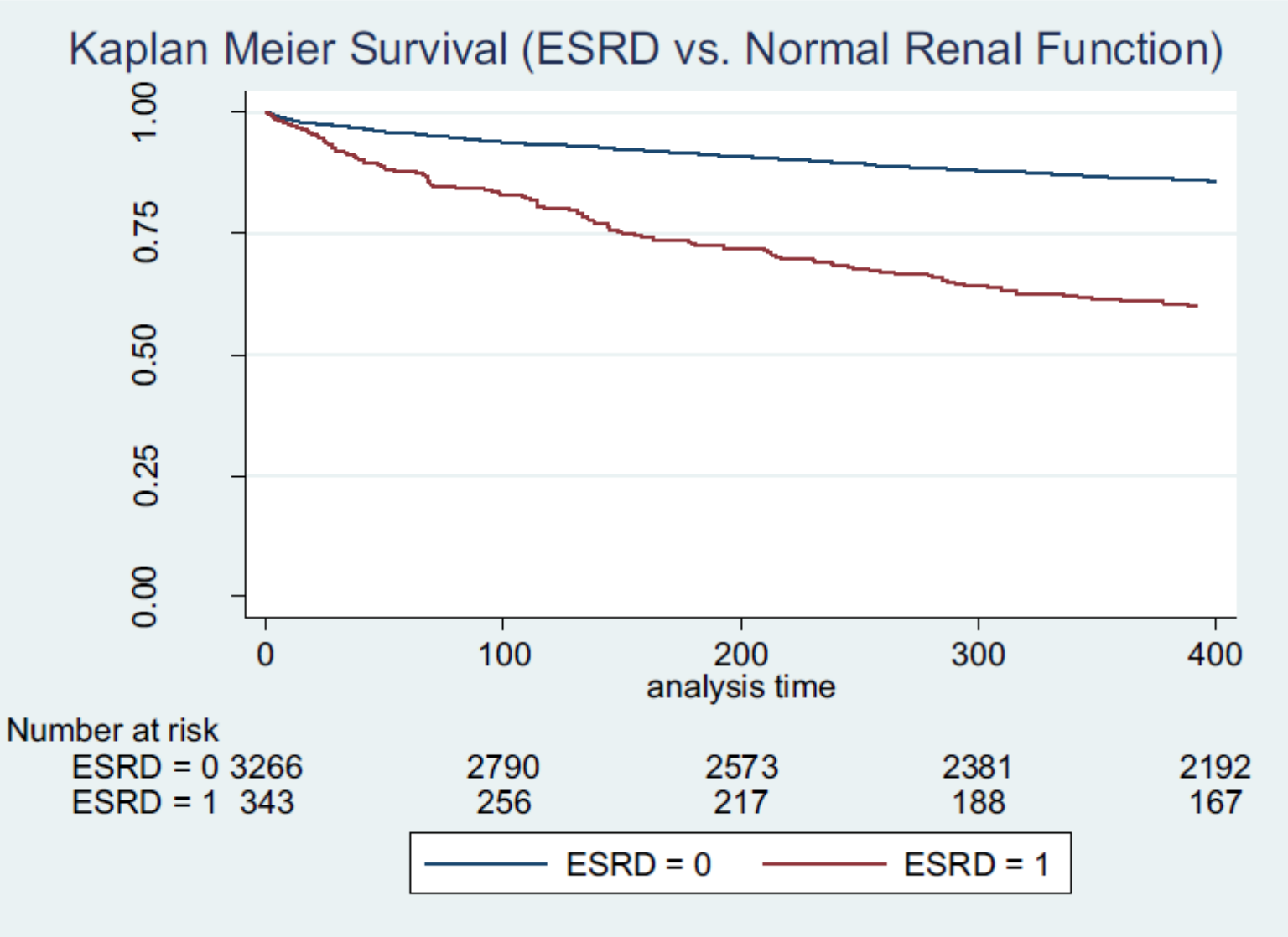
Results

Outcome measures	*Non-OPG group (n = 1249)*	*OPG group (n = 2360)*	P *value*	*SVS OPG, %*
Safety outcomes at 30 days, No. (%)				
MALE	69 (5.5)	113 (4.8)	.34	<8
MACE	115 (9.2)	147 (6.2)	.001	<8
Myocardial infarction	67 (5.4)	110 (4.7)	.35	
Death	65 (5.2)	46 (2.0)	<.001	
Amputation	32 (2.6)	21 (0.9)	<.001	<3
Efficacy outcomes at 1 year, % (SE)				
Survival	75.9 (1.3)	88.3 (.7)	<.001	>80
Freedom from amputation	80.9 (1.6)	90.1 (.8)	<.001	>84

MACE, Major adverse cardiovascular event; *MALE*, major adverse limb event; *SE*, standard error; *SVS*, Society for Vascular Surgery.

J Vasc Surg 2015;62:392-400.



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MALE 30: Risk factor	*OR*	P *value*
Age	0.98	.01
Female	1.46	.02
Nonwhite	0.96	.87
ESRD	0.98	.94

MACE 30: Risk factor	*OR*	P *value*
Age	1.03	<.001
Female	1.21	.17
Nonwhite	1.57	.13
ESRD	1.70	.004
noking	0.64	.01
iabetes	1.42	.02
osthetic	1.28	.10
frapopliteal target	1.35	.03
AD	2.17	<.001

end-stage renal disease; *MACE*, *E*, major adverse limb event; *OR*,

Survival: risk factor	*HR*	P *value*
Age	1.05	<.001
Female	0.87	.02
Non-white	1.72	.002
ESRD	3.41	<.001
Diabetes	1.26	<.001
Prosthetic	1.26	<.001
Smoking	1.20	.01
CAD	1.40	<.001

Amputation: Risk factor	*HR*	P *value*
Age	0.99	.10
Female	1.08	.54
Nonwhite	1.13	.57
ESRD	2.94	<.001
Diabetes	1.16	0.28
Prosthetic	2.15	<.001
Infrapopliteal target	2.17	<.001
Previous ipsilateral bypass	1.54	.004
Previous PVI	1.69	<.001

CAD, Coronary artery disease; *ESRD*, end-stage renal disease; *HR*, hazard ratio; *PVI*, peripheral vascular intervention.

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Recommended Changes

End point	*SVS OPG, %*	*Non-OPG, %*	*ESRD, %*	*Prosthetic, %*
Safety outcomes at 30 days				
MALE	<8	<8	<8	<8
MACE	<8	<11	<16	<11
Amputation	<3	<4	<6	<4
Efficacy outcomes at 1 year				
Survival	>80	>70	>52	>73
Limb salvage	>84	>73	>56	>75

ESRD, End-stage renal disease; *MACE*, major adverse cardiovascular event; *MALE*, major adverse limb event; *SVS*, Society for Vascular Surgery.

J Vasc Surg 2015;62:392-400.

- VQI
- CLTI (Endo and Open)
- Antiplatelet therapy at discharge

Impact of dual antiplatelet therapy after lower extremity revascularization for chronic limb-threatening ischemia

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ABSTRACT

Objective: The optimal antiplatelet regimen after lower extremity revascularization in patients with chronic limb-threatening ischemia (CLTI) is unknown because current recommendations are based on extrapolation of data from trials in coronary artery disease and stroke.

Methods: We identified all patients undergoing an elective lower extremity revascularization for CLTI in the Vascular Quality Initiative registry discharged on a mono antiplatelet agent (MAPT) or dual antiplatelet therapy (DAPT).

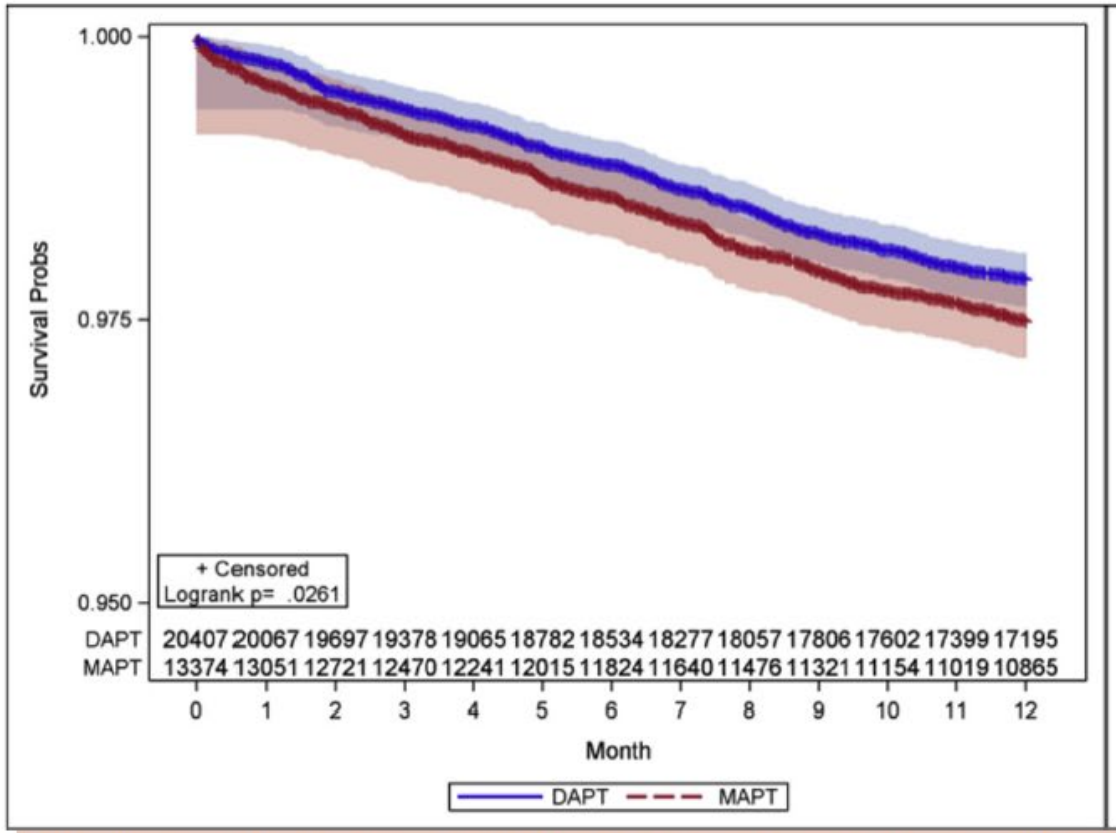
Results: From 2003 to 2018, 50,890 patients underwent revascularization procedures for CLTI, and were discharged on MAPT or DAPT. Of these, 33,781 patients underwent endovascular therapy (EVT), and 17,109 patients underwent open surgery (OS) procedures. The rate of major amputation at 30 days in the target limb in the EVT group was 0.3% and 0.4% in the OS group ($P = .22$). On Kaplan-Meier analyses, patients on MAPT at discharge had a higher risk of 1-year major amputation compared with DAPT after EVT but not after OS procedures. Patients on MAPT had lower overall survival and amputation-free survival at 30 days and 1 year compared with DAPT after both EVT and OS. At 1 year, the MAPT group was at higher risk for target lesion reintervention after EVT compared with the DAPT group (15.9% vs 13%; $P = .0012$). There was no significant difference in thrombosis at 1 year between the MAPT and DAPT groups either after EVT (3.9% vs 3.7%; $P = .3048$) or OS (3.1% vs 3.2%; $P = .2893$). On Cox regression analysis, DAPT was associated with improved survival but not major amputation after both EVT and OS.

Conclusions: In patients with CLTI, DAPT at the time of discharge has a positive impact on amputation-free survival and overall survival after both EVT and OS as well as target lesion reintervention after EVT. DAPT was not associated with a positive impact on major amputation after either EVT or OS. (J Vasc Surg 2021;74:1327-34.)

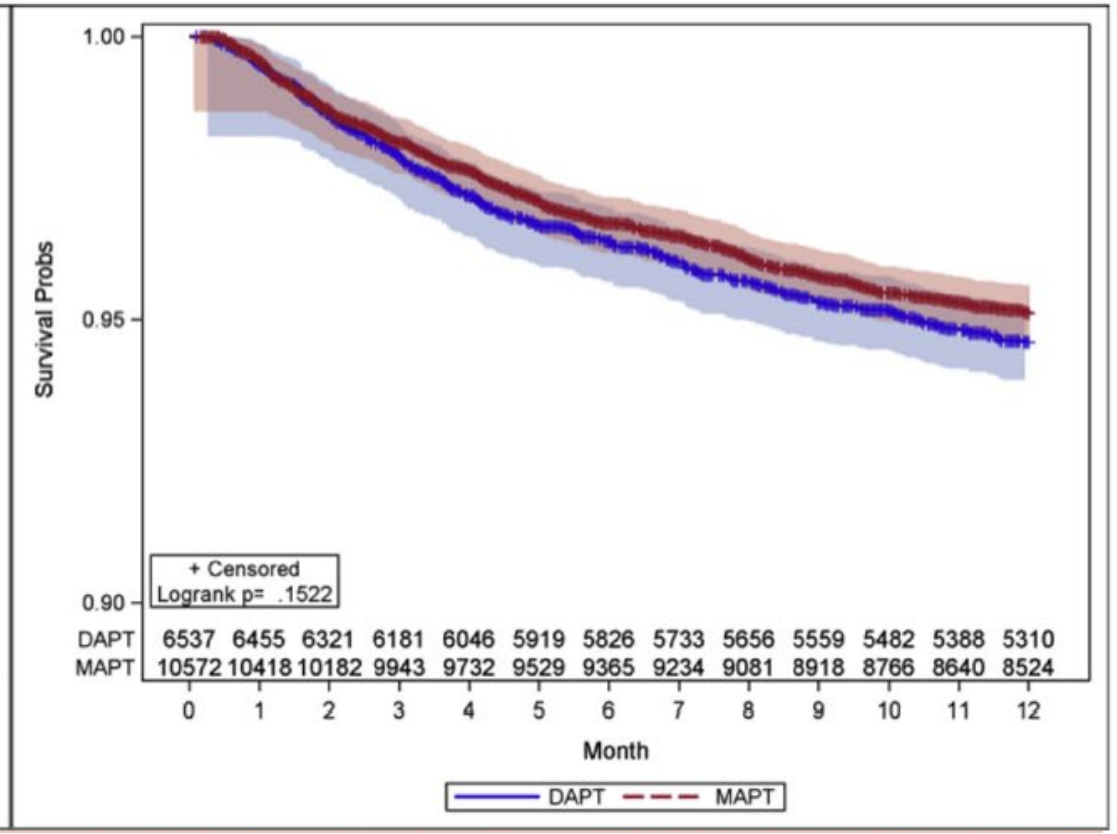
Keywords: Chronic limb threatening ischemia; Dual antiplatelet therapy; Vascular Quality Initiative

Limb Salvage

Endovascular Therapy



Open Surgery



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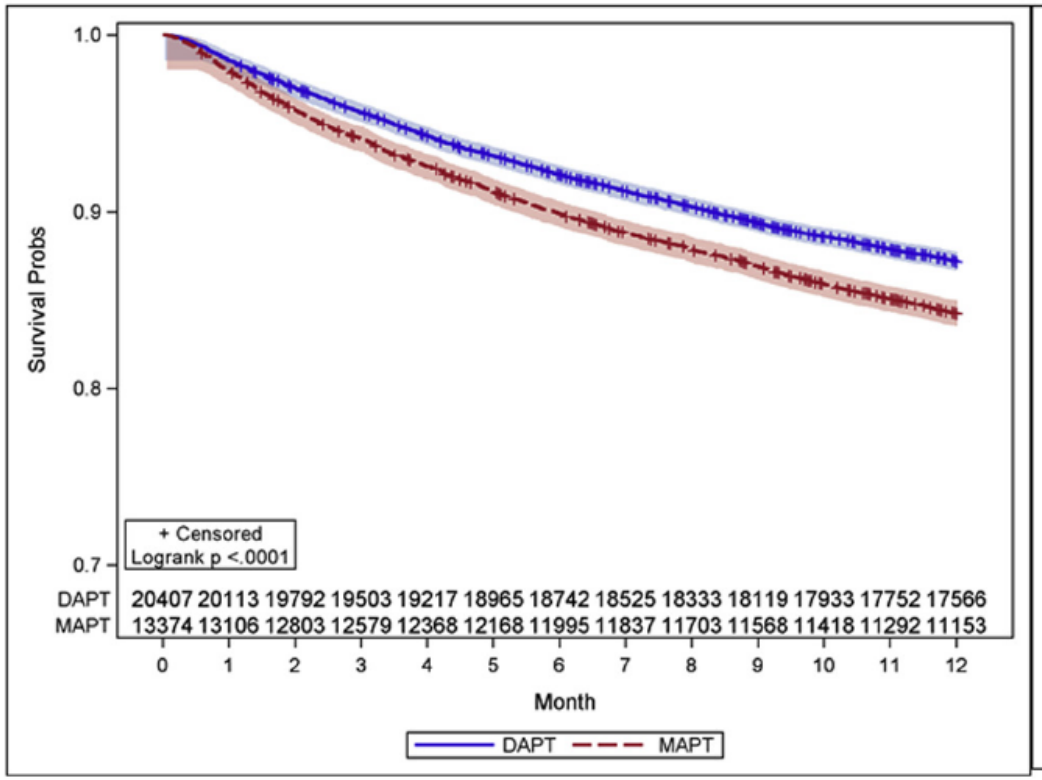
Survival

Endovascular Therapy



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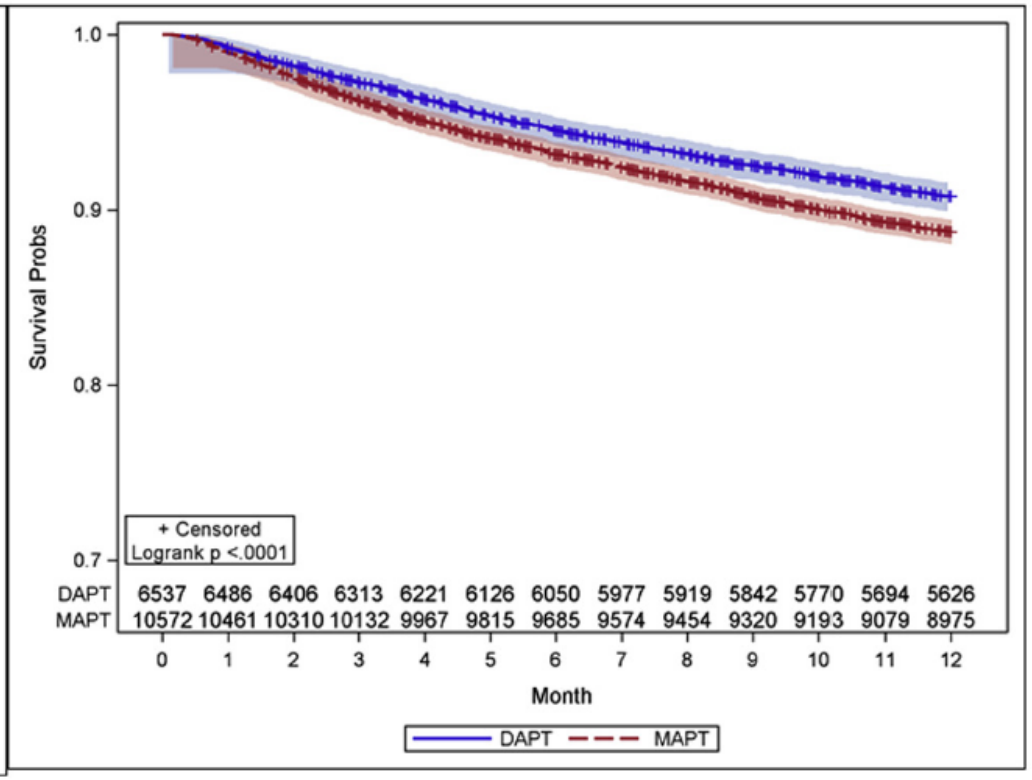

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Conclusion

- Lower Extremity Bypass is still relevant in practice of vascular surgeons
- Patient selection is important
  - ESRD, conduit, anatomy
- Search continues for “modern day real world” outcomes
- Utilize technical nuances to achieve optimal results

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