

# *Cool Excimer Laser Assisted Angioplasty (CELA) Vs Tibial Balloon Angioplasty (TBA) in Management of Infragenicular Tibial Arterial Occlusion in Critical Lower Limb Ischaemia (CLI) TASC D<sup>E</sup>*

## *A Pivotal Observational Analogy Congregate Proportional Analysis Over 36 months Six L Trial*

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# Introduction

- *Endovascular revascularisation for Critical Limb Ischaemia is the Gold Standard & First line of therapy*
- *Despite the advances' of EvR , there is still concern about complex Tibial lesions*
- *However EvR is the alternative to distal arterial bypass reconstructive surgery*

# *Excimer Laser Assisted Angioplasty*

- *Excimer Laser produces photo-acoustic ablation which disrupts*
  - *Molecular bonds at the cellular level*
  - *Liquefying & vaporising Thrombus & Organised Clots*
  - *Softening the fibro calcific plaque with 50% diameter gain*
  - *No thermal damage to surrounding tissues*

# *Aim of "Six L" Trial*

- *To compare the outcome of CELA Vs TBA in Tibial vessel occlusion in patients with CLI, TASC D<sup>E</sup>*
- *Primary endpoint is Sustained Clinical Improvement*
- *Secondary endpoints are*
  - *Binary Restenosis Rate*
  - *Target Lesion Revascularisation*
  - *Target Extremity Revascularisation*
  - *Amputation Free Survival*
  - *Survival Free From Major Adverse Events*
  - *Primary, Assisted Primary, Secondary patency rate*

# *Patients & Methods*

- *2004-2008, 1246 patients were referred with PVD*
- *372 patients had CLI*
- *45 patients had TASC D<sup>E</sup>*
- *Pivotal Observational Analogy Congregate Proportional Analysis Over 36 months*

# Methods

- *All intervention were done with Pre-operative Duplex Ultrasound*
- *Patients on Statin, Aspirin & Clopidogrel*
- *All patients are ASA IV<sup>E</sup>*
- *Follow up at 6weeks, 3months & 6 monthly*

# Demographics

	TBA 25 patients	CELA 20 patients
Total Procedures	n=32	n=24
Total number of limbs	n=28	n=22
Males : Females	10:15	10:10
Age (years)	70 (48-96)	68 (52-86)

# Vascular Related Risk Factors

	TBA	CELA
Hypertension	47% (n=15)	50% (n=12)
Hyperlipidaemia	69% (n=22)	75% (n=18)
Diabetis Mellitus	75% (n=24)	66% (n=16)
Smoking	84% (n=27)	88% (n=21)
Ischaemic Heart Disease	31% (n=10)	38% (n=9)
Renal Insufficiency (Cr>2.0 mg/dl)	16% (n=5)	13% (n=3)



# Clinical Presentation

	TBA	CELA
<i>Rutherford Category 4</i>	25% (n=8)	21% (n=5)
<i>Rutherford Category 5</i>	75% (n=24)	79% (n=19)
<i>Occlusive Lesions</i>	53% (n=17)	58% (n=14)
<i>Stenotic Lesions</i>	47% (n=15)	42% (n=10)
<i>De-Novo Lesions</i>	72% (n=23)	54% (n=13)
<i>Recurrent Lesions</i>	28% (n=9)	46% (n=11)

# Duplex & Per-Operative DSA Findings

	TBA	CELA
	25	20
TASC D <sup>E</sup> Lesions	n=32	n=24
Anterior Tibial Artery	n=19	n=10
Posterior Tibial Artery	n=6	n=6
Peroneal Artery	n=4	n=5
2 Vessels	n=3	n=3
3 Vessels	n=0	n=0



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# *Tibial Balloon Angioplasty*

## *TBA*



MEET Congress  
Cannes 2008

Department of Vascular & Endovascular Surgery  
[www.vascular.ie](http://www.vascular.ie)



**Ollscoil na hÉireann, Gaillimh**

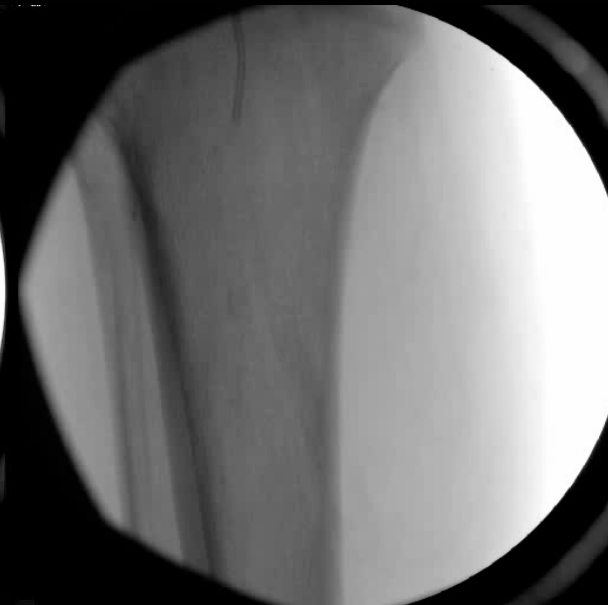


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# *Cool Excimer Laser Assisted Angioplasty* **CELA**



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# Adjuvant Procedure

	TBA 32	CELA 24
<i>Adjuvant Procedure</i>		
<i>SFA, Popliteal angioplasty +/- Stenting</i>	<i>n=24</i>	<i>n=16</i>
<i>Vein graft angioplasty</i>	<i>n=0</i>	<i>n=1</i>
<i>PTFE graft angioplasty</i>	<i>n=0</i>	<i>n=1</i>
<i>Subintimal Approach</i>	<i>6</i>	<i>0</i>
<i>Tibial Stents</i>	<i>12 stents in 10 procedures</i>	<i>13 stents in 10 procedures</i>

# Technical Success

	TBA	CELA
	32 Procedures	24 Procedures
Technical Success (Residual stenosis of <30%)	75% (n=24)	83% (n=20)

- *Technical outcome was independent of procedure, stent placement, multilevel interventions, and adjunctive procedures*

# Procedure Complications

	<i>CELA</i>	<i>TBA</i>
<i>Dissection</i>	3	3
<i>Vessel Injury</i>	1	2
<i>Groin Hematoma</i>	0	1
<i>Compartment Syndrome</i>	1	0

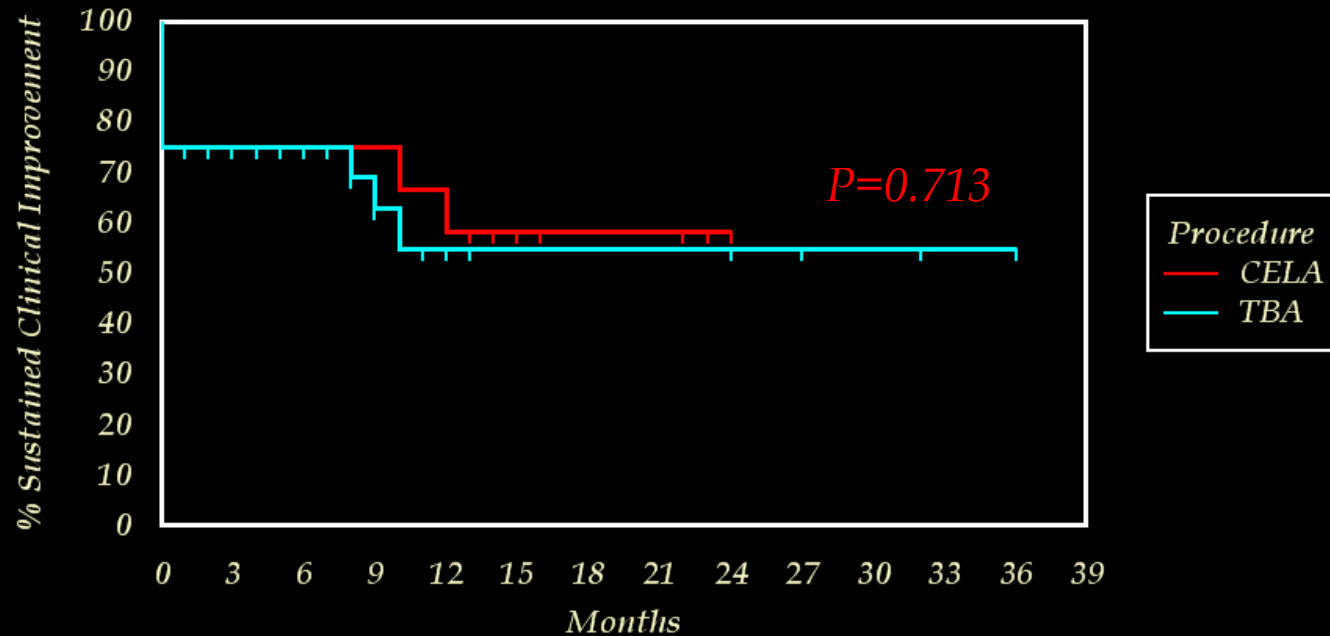
# Immediate Clinical Improvement

	TBA	CELA	X <sup>2</sup>
<i>Improvement to Rutherford Category 3 or less</i>	57%	64%	<i>P=0.076</i>
<i>Hemodynamic Success (ABI improved by 0.15 or greater)</i>	66%	57%	<i>P=0.093</i>



# Sustained Clinical Improvement

*With Freedom from Target Lesion Revascularisation (TLR) or Amputation*



Number at risk

Group: CELA

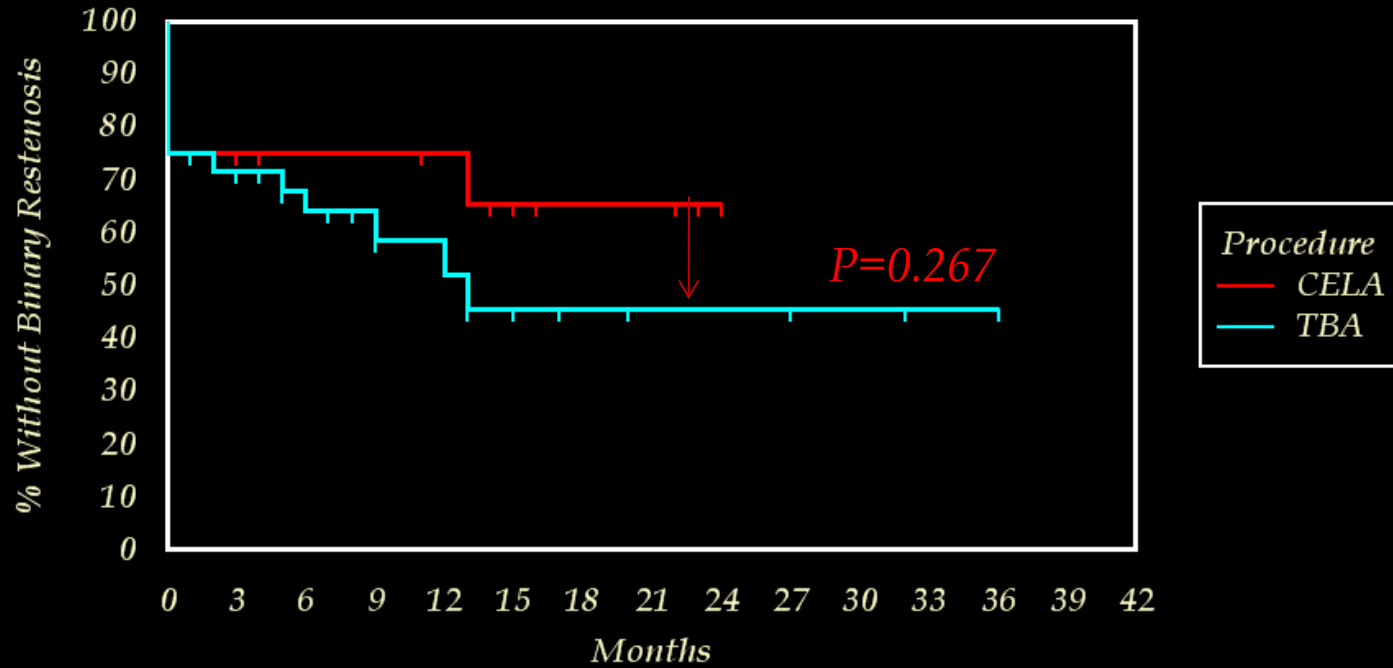
18 12 9 9 7 4 3 3 0 0 0 0 0

Group: TBA

24 21 16 8 5 4 4 4 3 2 2 1 1 1

Mean Sustained Clinical Improvement TBA: 11 months  
CELA: 14 months

# Binary Restenosis



Number at risk

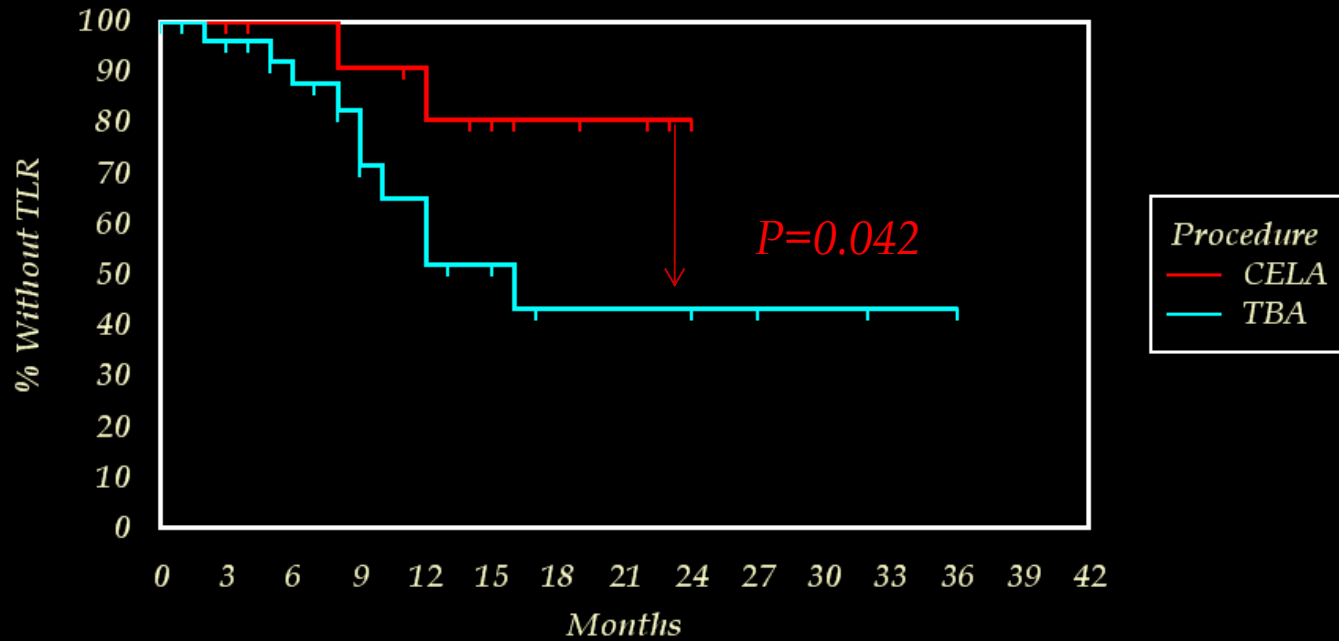
Group	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42
Group: CELA	18	12	9	9	8	5	3	3	0	0	0	0	0	0	0
Group: TBA	24	21	16	9	8	5	4	3	3	2	2	1	1	1	1

Mean 1ry Continued Anatomic Success

TBA: 10 months

CELA: 12 months

# Target Lesion Revascularisation



Number at risk

Group: CELA

20 14 11 10 8 6 4 3 0 0 0 0 0 0 0

Group: TBA

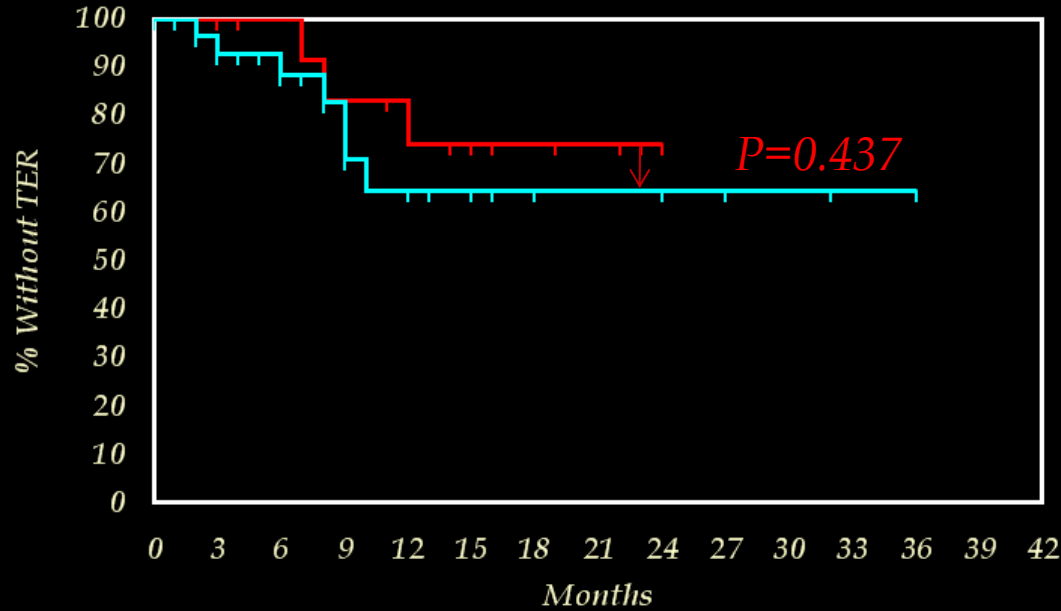
28 25 20 11 8 6 4 4 3 2 2 1 1 1 1

Mean Time to TLR

TBA: 9 months

CELA: 12 months

# Target Extremity Revascularisation



Procedure  
 — CELA  
 — TBA

Number at risk

Group: CELA

21 15 12 10 8 6 4 3 0 0 0 0 0 0

Group: TBA

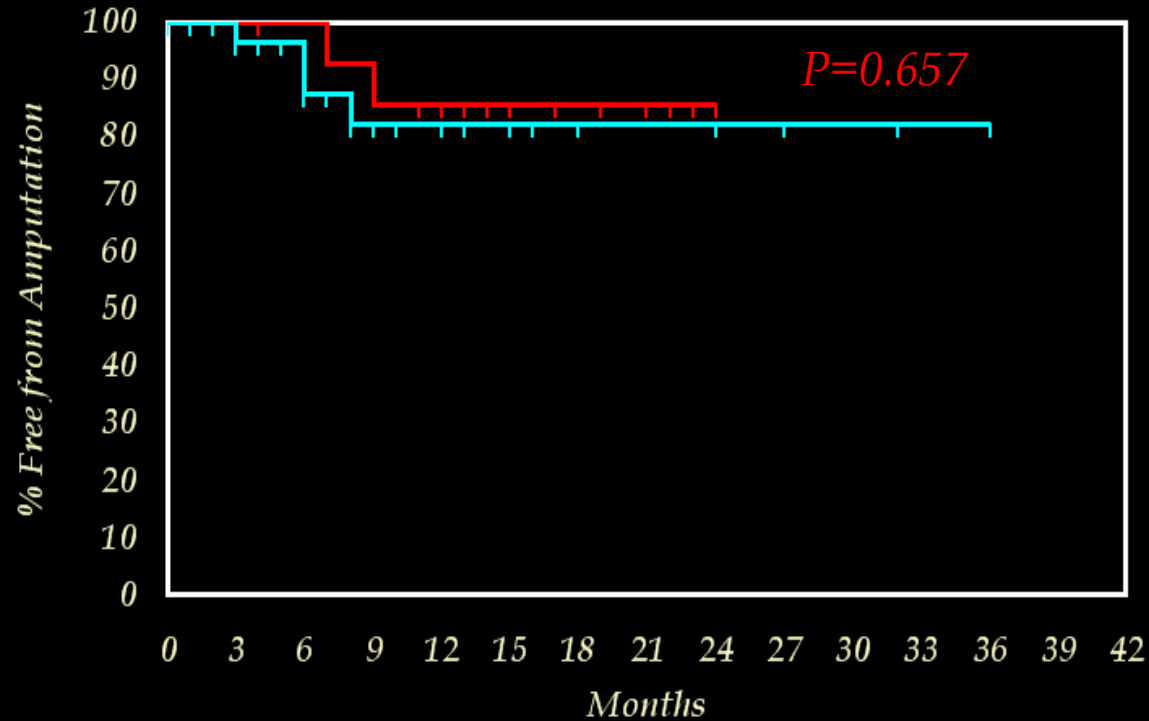
30 25 19 11 8 6 4 4 3 2 2 1 1 1 1

Mean time to TER

TBA: 10 months

CELA: 11 months

# Amputation Free Survival



Procedure  
 — CELA  
 — TBA

Number at risk

Group: CELA

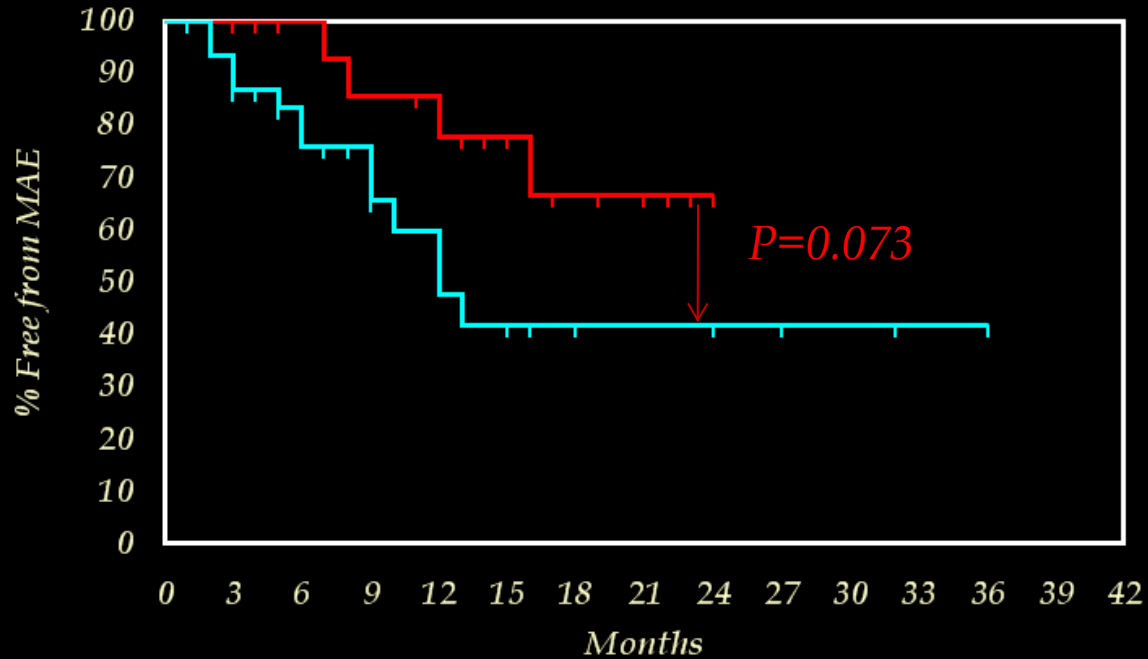
23 17 14 12 10 7 6 4 0 0 0 0 0 0

Group: TBA

30 26 19 11 8 6 4 4 3 2 2 1 1 1 1

3 Year Limb Salvage Rate TBA 88% vs CELA 91%

# Major Adverse Event



Procedure  
 — CELA  
 — TBA

Number at risk

Group: CELA

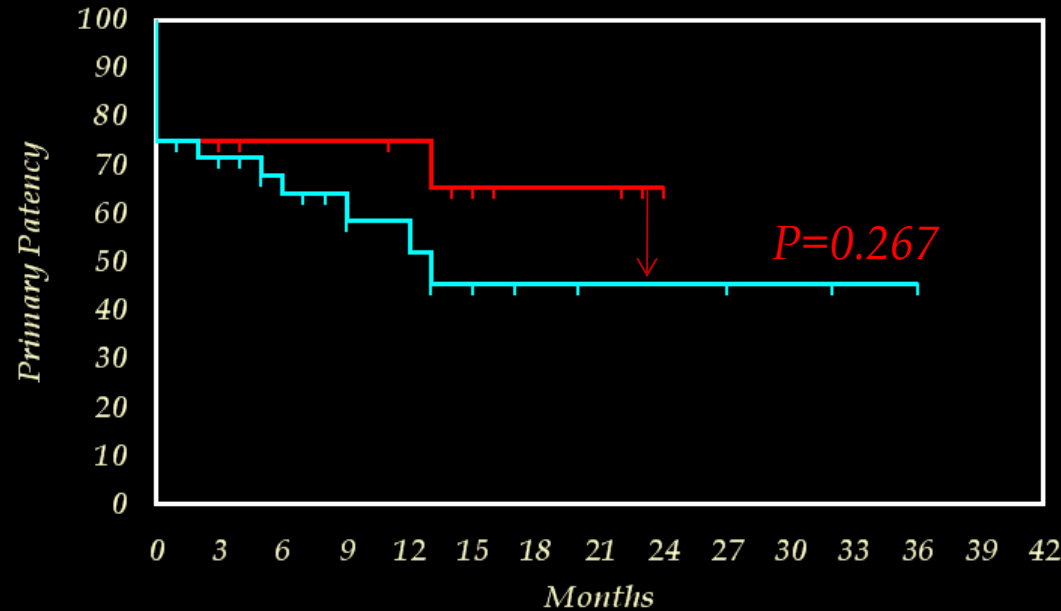
24 18 14 12 10 7 5 3 0 0 0 0 0 0

Group: TBA

32 26 20 11 8 6 4 4 3 2 2 1 1 1 1

Survival Free From Major Adverse Events TBA: 9 months  
 CELA: 11 months

# Primary Patency



Procedure  
 — CELA  
 — TBA

Number at risk

Group: CELA

18 12 9 9 8 5 3 3 0 0 0 0 0 0 0

Group: TBA

24 21 16 9 8 5 4 3 3 2 2 1 1 1 1

**TBA**

**CELA**

1ry patency at 1 year

60% (n=19)

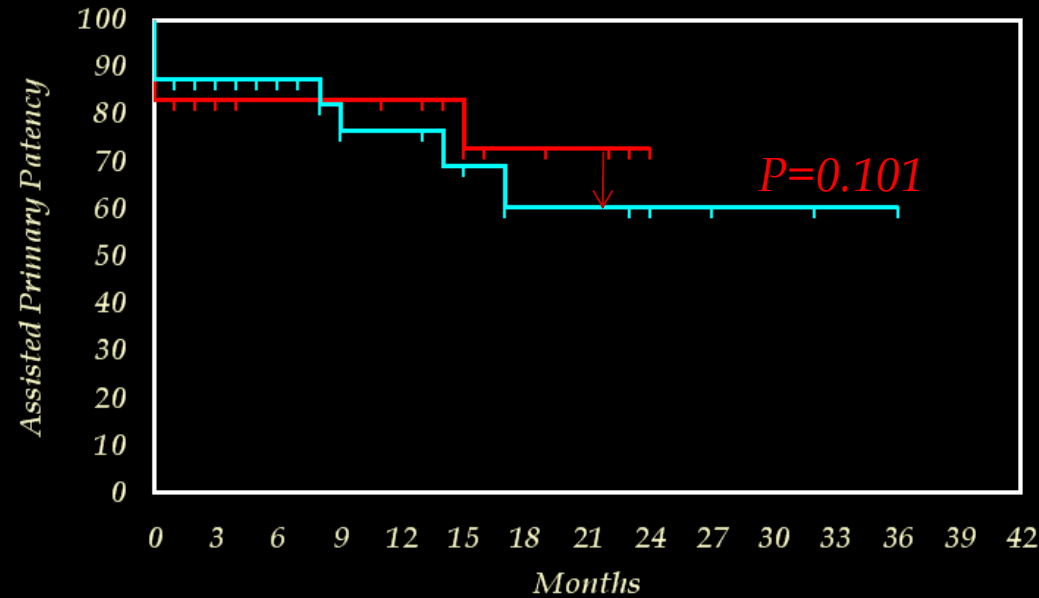
75% (n=18)

1ry patency at 2 year

56% (n=18)

71% (n=17)

# Assisted Primary Patency



Procedure  
 — CELA  
 — TBA

Number at risk

Group: CELA

20 14 11 11 10 6 4 3 0 0 0 0 0 0

Group: TBA

28 25 20 12 12 8 5 5 3 2 2 1 1 1 1

**TBA**

**CELA**

Assisted 1ry patency at 1 year

81% (n=26)

83% (n=20)

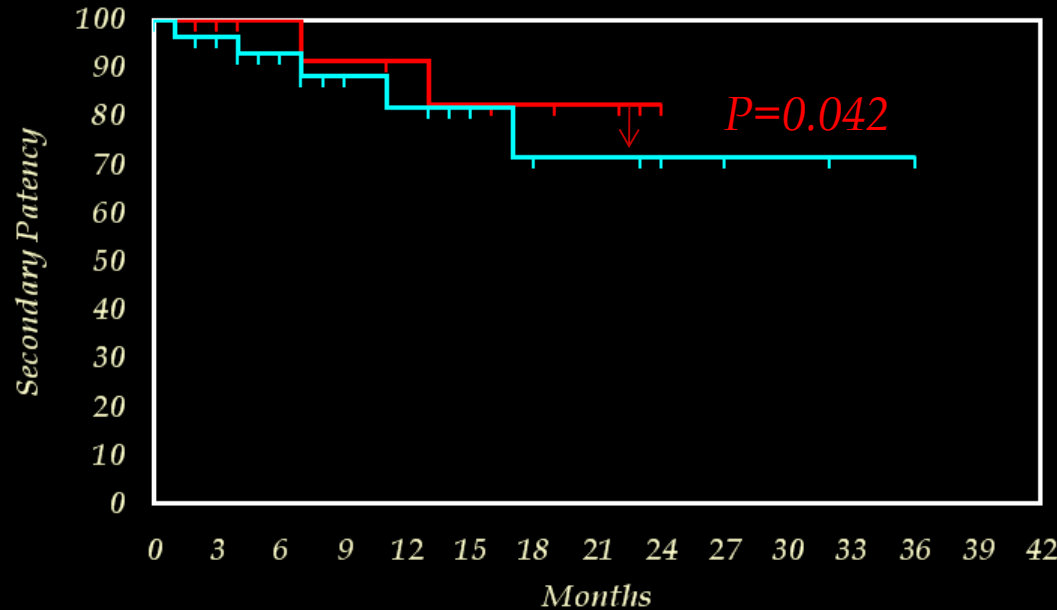
Assisted 1ry patency at 2 year

75% (n=24)

79% (n=19)



# Secondary Patency



Procedure  
 — CELA  
 — TBA

Number at risk

Group: CELA

20 14 12 11 10 6 4 3 0 0 0 0 0 0

Group: TBA

30 27 21 13 12 8 5 5 3 2 2 1 1 1

**TBA**

**CELA**

2ry patency at 1 year

88% (n=28)

96% (n=23)

2ry patency at 2 year

81% (n=26)

92% (n=22)

# *Prospective Clinical Prelude*

- *Ostial lesions with Distal poor run off vessels*
- *Lesser prospect of Distal embolisation*
- *Ameliorate PTA where the wire can cross but not the Balloon*
- *An adjuvant in the armamentarium for complex tibial lesions in high risk patients*

# Discussion

- *Dwindle the rate of immediate failure, is the recipe to perk up patency & limb salvage*
- *Proximal SIA for long occlusive lesions & CELA for Crural vessels " TASC D<sup>E</sup> " have expanded our indication for EvR*
- *Futile endeavour at Crural PTA can be treated successfully with redo Crural PTA & doesn't spoil subsequent attempts at bypass grafting*

# Conclusion

- *Tibial EvR Bestow An Exceptional Outcome in CLI TASC D<sup>E</sup>*
- *Both CELA & TBA Imparts Recuperated Anatomical, Clinical & Technical Success Rates In Complex Tibial Vessel Lesions*
- *CELA had Enhanced TLR & Superior Survival Free From Major Adverse Events & better Secondary Patency Rate*