

The Tulyp System: A Novel Extracorporeal Pump that Provides Superior Limb Perfusion Compared to Passive Bypass in a Preclinical Model of Acute Limb Ischemia

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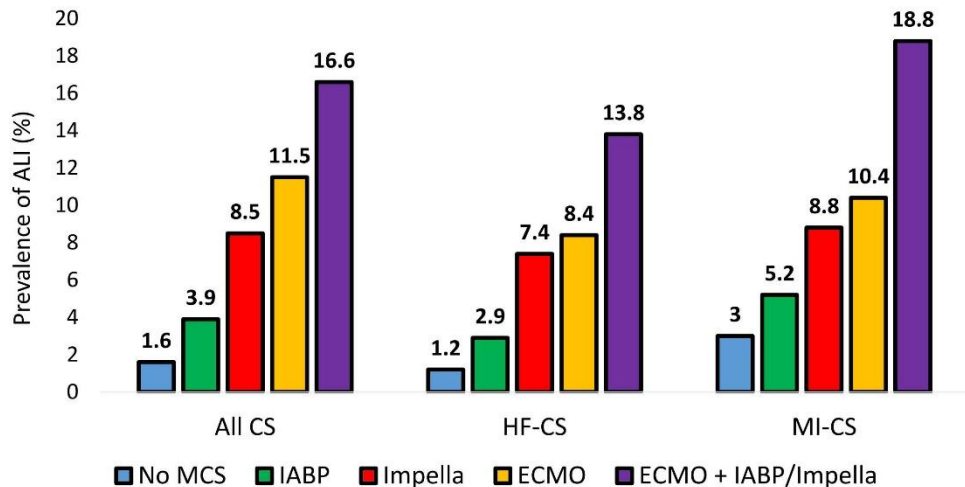
Disclosure of Relevant Financial Relationships

I, Peter Natov, DO NOT have any financial relationships to disclose.

Acute Limb Ischemia: An Enduring Problem

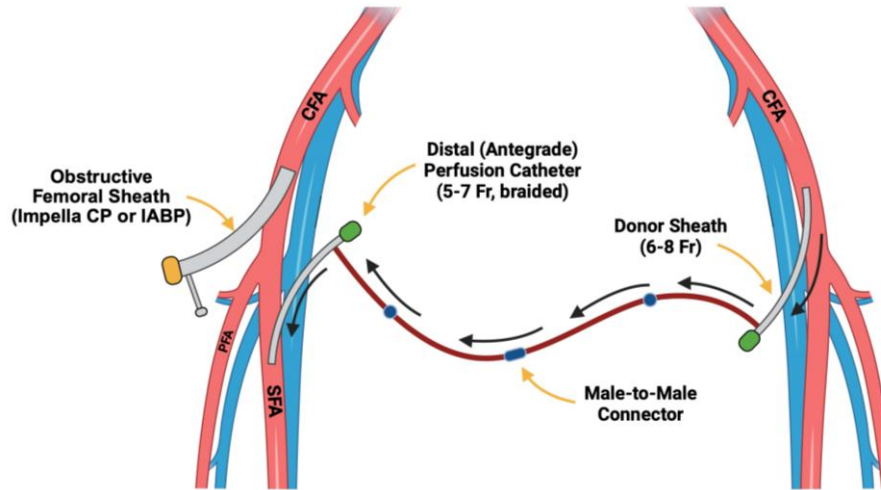
- Continued high morbidity and mortality despite advancements in revascularization strategies
- An important complication of large-bore vascular access for temporary mechanical circulatory support devices

Outcomes	<i>n</i> (%)
Length of stay, days (± SD)	11 (9)
30-day limb-loss, <i>n</i> (%)	43 (19)
30-day mortality, <i>n</i> (%)	21 (9)
30-day readmission, <i>n</i> (%)	45 (19)
1-year limb-loss, <i>n</i> (%)	65 (34)
1-year mortality, <i>n</i> (%)	39 (17)



Passive Bypass

- Passive arterial bypass, e.g., femoral-to-femoral circuit, delivers blood into a distal perfusion catheter beyond an obstruction
 - Dependent on native cardiac output, systemic blood pressure
 - Challenges with inadequate limb flow/pressure and catheter clotting



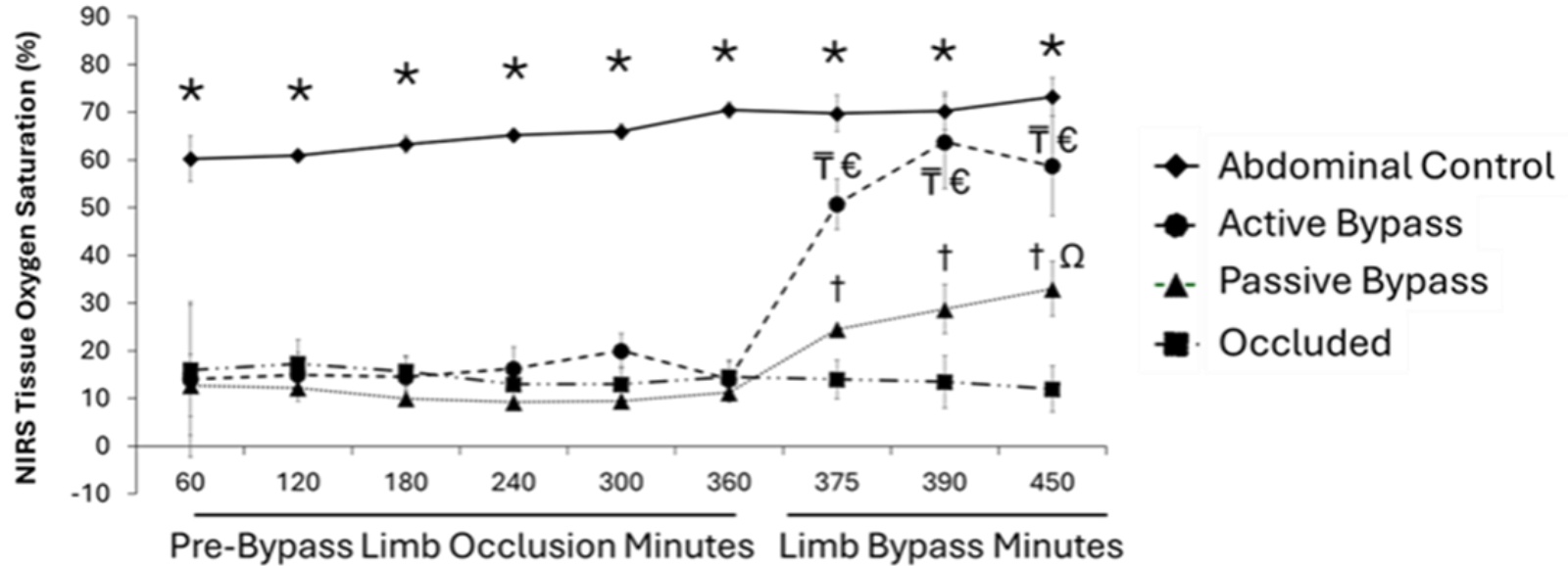
Hypothesis: Active Bypass Is Better

- Actively pumping blood into an ischemic limb (“active bypass”) provides superior limb perfusion compared to passive bypass
- Tulyp: a novel extracorporeal rotary pump system that pressurizes a vascular compartment and optimizes blood flow

Animal Model of Acute Limb Ischemia

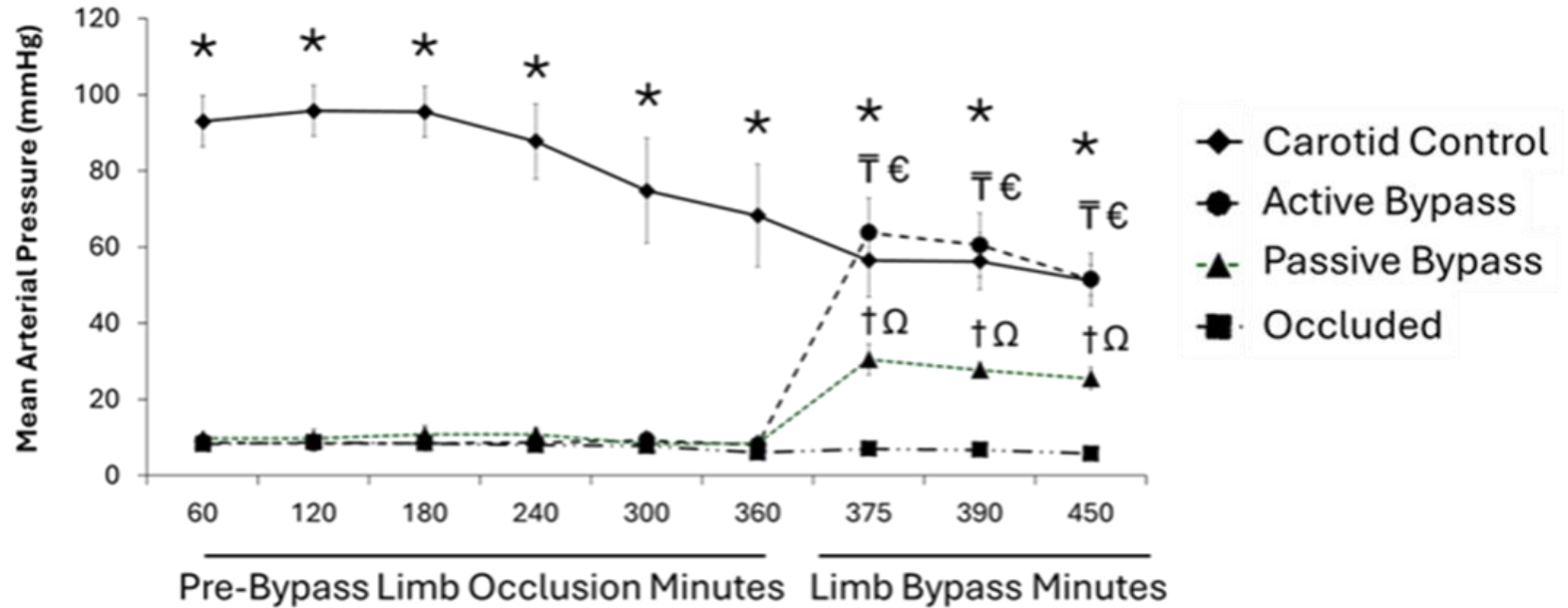
- ALI in adult swine (n=4):
 - 6 hr of aortic balloon occlusion and bilateral femoral artery ligation
 - Right lower limb: no reperfusion
 - Left lower limb: sequential reperfusion strategies
 - 90 min passive bypass: 12-Fr carotid donor sheath connected to a 7-Fr distal perfusion catheter in superficial femoral artery
 - 90 min active bypass: Tulyp rotary pump connected to this circuit
- Endpoints:
 - Mean arterial pressures (MAP) of carotid artery and tibial artery
 - Near infrared spectroscopy (NIRS) of the abdomen and ischemic calf

Optimal Limb Perfusion with Active, Not Passive, Bypass



* Control vs Occluded † Control vs PB Ω PB vs Occluded
 ‡ AB vs PB ‡ Control vs AB € AB vs Occluded

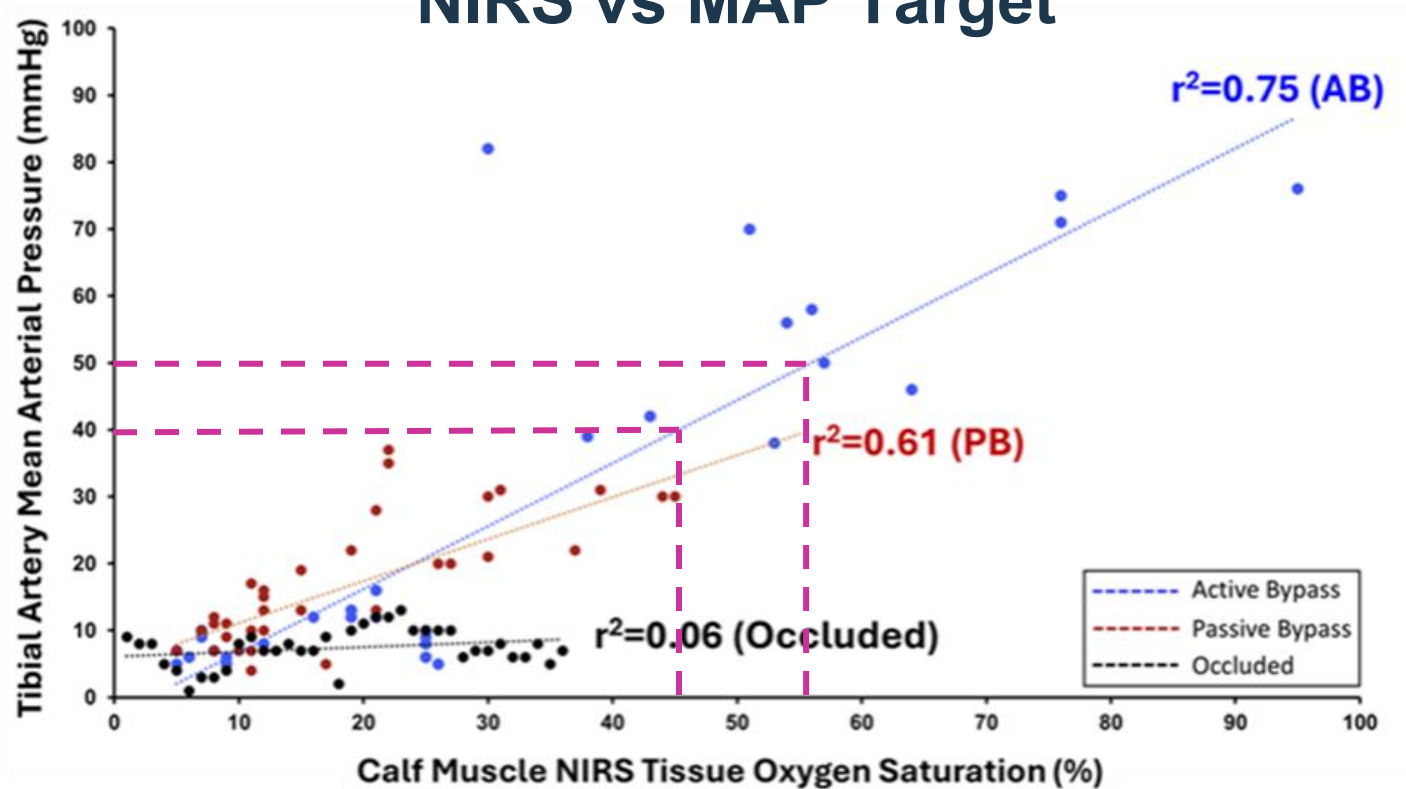
Optimal Arterial Pressure with Active, Not Passive, Bypass



* Control vs Occluded † Control vs PB Ω PB vs Occluded
 ‡ AB vs PB € AB vs Occluded

Direct Correlation Between NIRS and Limb Pressure

NIRS vs MAP Target



Conclusions

- Active bypass with the Tulyp System provides superior limb perfusion compared to passive bypass in a preclinical model of ALI
- The sensitivity threshold for NIRS as a marker of limb perfusion remains to be determined. A direct correlation exists with NIRS above 40.
- Clinical studies testing the safety, feasibility, and utility of pressurized perfusion using the Tulyp system are underway.