

**High Pressure Intermittent Pneumatic Compression (HPIPC)
is an Effective Palliative Option for Peripheral Arterial Disease
(PAD) and Critical Limb Ischemia (CLI) in Patients without a
Surgical Option (Clinicaltrials.gov ID# NCT-01420281)**

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Disclosure

- Yankee's Fan
- None relevant to this presentation

HPIPC Devices



ArtAssist by ACI Medical



BioArterial Plus by
Biocompression Systems



Aircast Arterial Flow by DJO

Compression has also been used successfully to treat PAD and CLI

- **1917** Negative Pressure & Intermittent Compression to treat thromboangiitis obliterans (Burger's disease)
- **1934** Pneumatic compression improved tissue perfusion in subjects with PAOD
- **1991** Enhanced arterial flow with pulse compression
- **2000** Improved walking ability and ABIs in symptomatic PVD
- **2005** RCT shows HPIPC significantly increased ACD compared to supervised exercise
- **2011** Retrospective study of 171 patients without revascularization options treated for 12 weeks with HPIPC limb salvage at 3.5 years was 94%

Sinkowich, Gottlieb *JAMA* 1917;68:961
Reid, Herman *J. Med* 1933;14:200
Herman, Reid *Ann. Surg* 1934;100:750
Landis, Gibbon *J Clin Invest* 1933;12:925

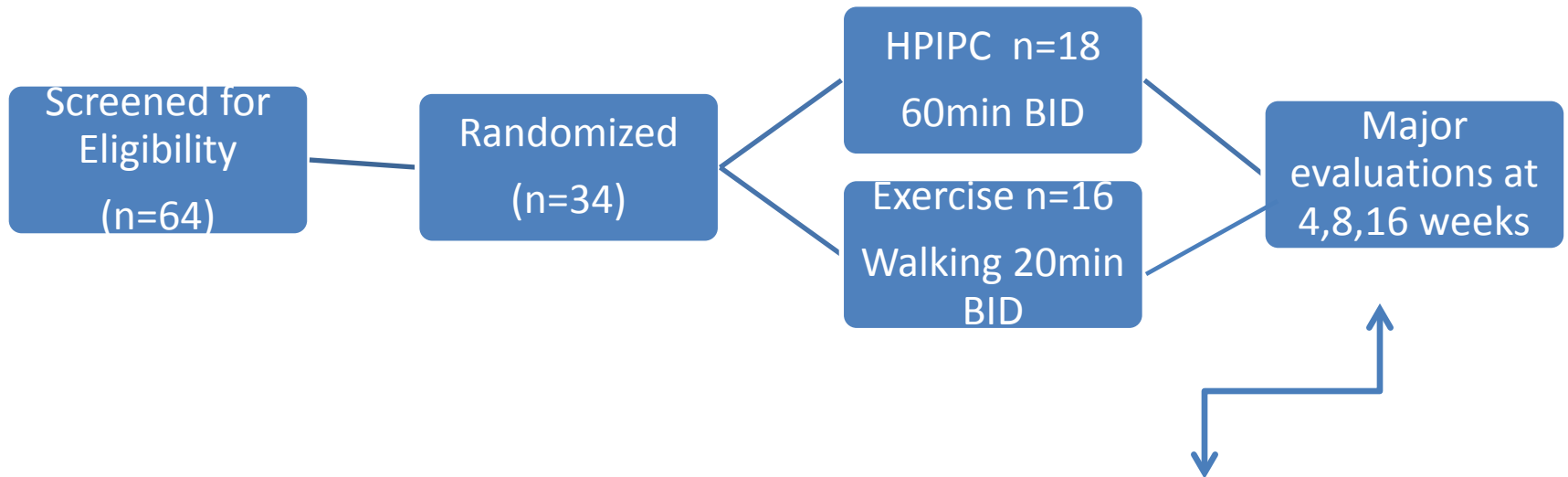
Morgan, et al., *Vasc Surg* 1991 25;8:15
Delis, Nicolaides et al., 2000 *J Vasc Surg* 2000;31:650
Ramaswami, Ayala et al., *J Vasc Surg* 2006;41:794
Sultan et al *J Vasc Surg* 2011: 54 (2); 440-447

Systematic Review

- Embase, MEDLINE, Clinical trial registries (March 2013)
- Quality assessed using Cochrane RIB tool & NICE case-series assessment tool
- 2 CBA studies
- 6 case series
- 1 retrospective CBA study of 171 patients
- 1 prospective CBA study reported significant improvement in claudication distances and SF-36 QOL scores
- Limited results suggest IPC may be associated with improved limb salvage

Study Design

July 2009-December 2013



Evaluations: PWT, Wound Surface Area, rABI, Pain, QOL, Adverse Events

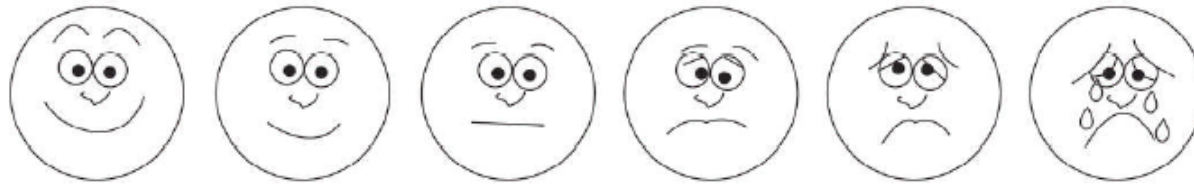
Primary endpoint: PWT, Secondary endpoints included: change in resting ABIs, Change in skin temperature, ulcer healing, relief of resting/wound pain, and quality of life index (QOL).

HPIPC



- The HPIPC device delivers pressures of 120mmHg.
- Cycle times provide sequential compression for 3 sec. (+/- 0.5 sec.)
- A Resting period of 17 second (+/-3.0 sec.)
- Resulting in a 20 second cycle or 3 cycles/minute.
- 60 min BID x 16 wks.

Faces Pain Scale

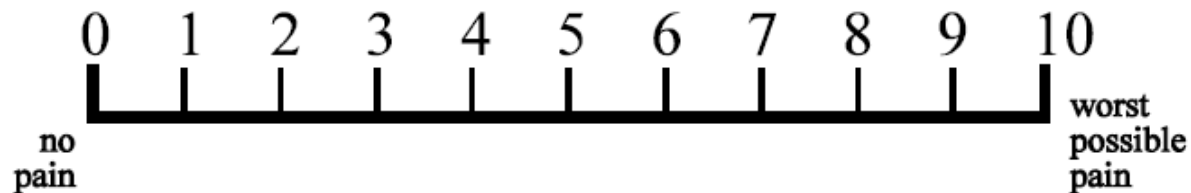


Used to
measure
pain relief

0	2	4	6	8	10
Very happy, no hurt	Hurts just a little bit	Hurts a little more	Hurts even more	Hurts a whole lot	Hurts as much as you can imagine (don't have to be crying to feel this much pain)

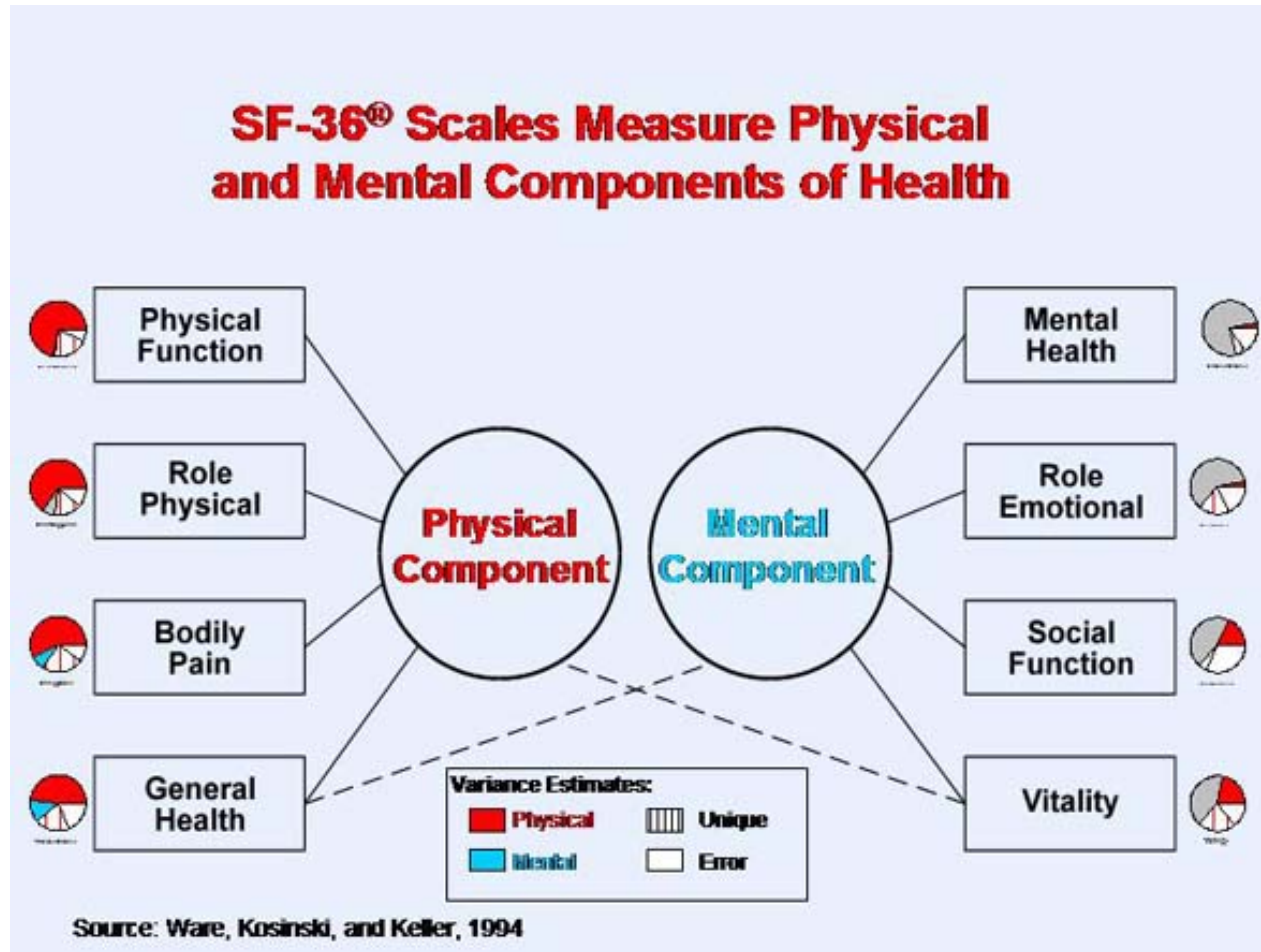
Adapted from:
Hurley& Volicer J.
Am. Dir. Assoc.
2003;4;9-15

Visual Analog Scale (VAS)



Used to
measure
pain index

Short Form-36 Health Survey Questionnaire

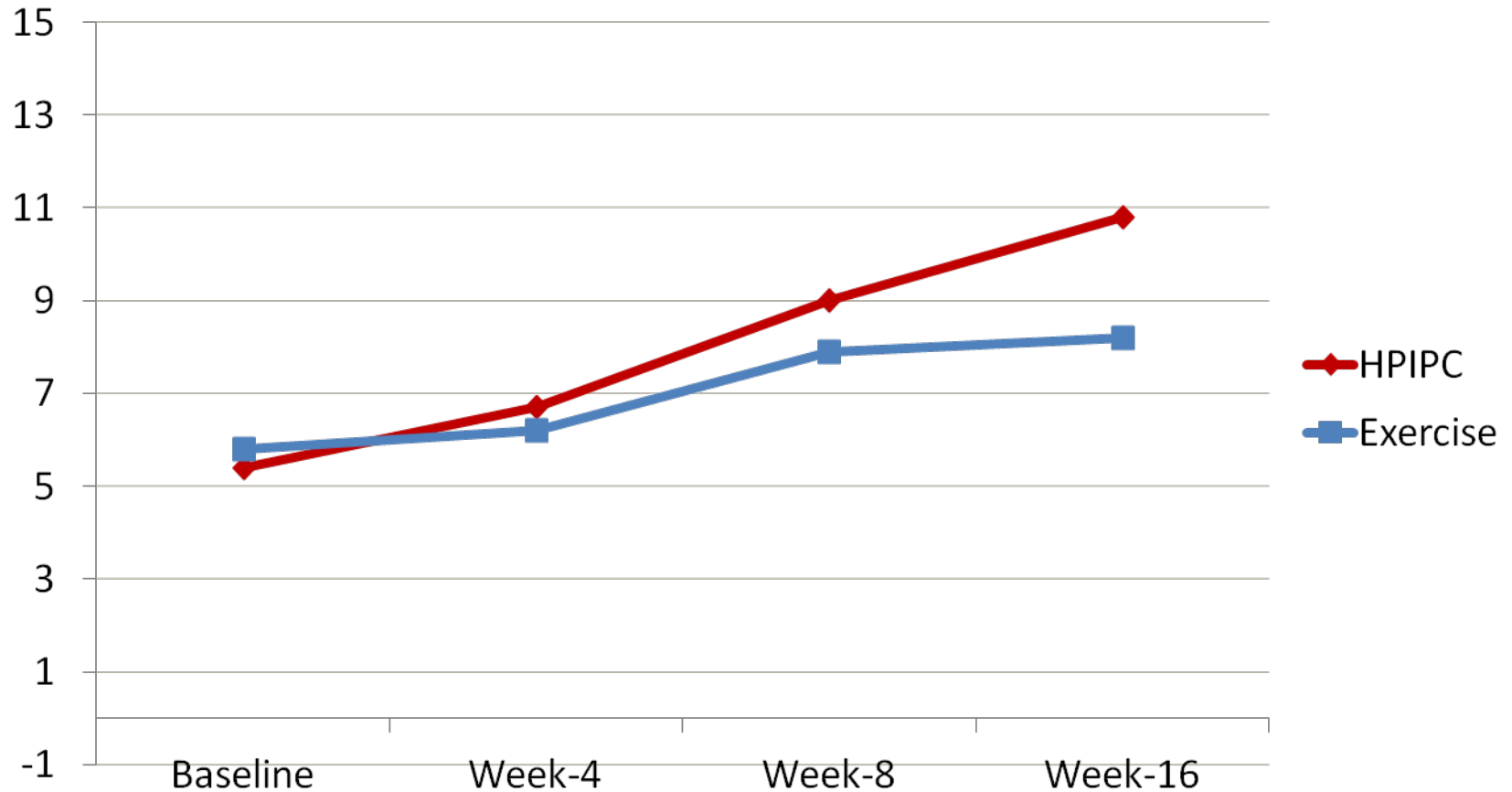


SF-36v2 completed by subjects at baseline, week-8 and week-16.

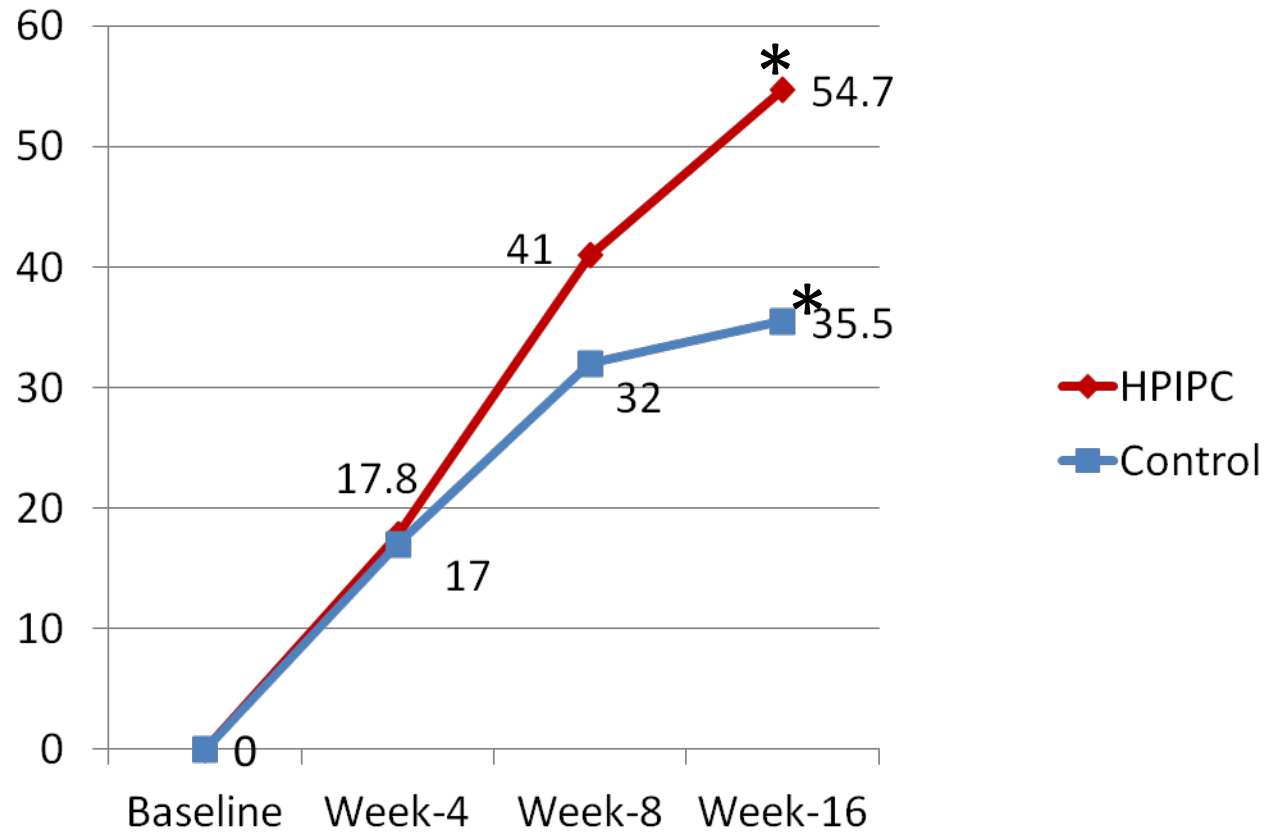
Statistics

- Percent Δ from baseline PWTs were compared using Wilcoxon rank sum test
- Chi-Square used for categorical values
- Student's t-Test used for continuous variables
- Analysis was by intention to treat
- SPSS for Windows version 11.5

Mean Peak Walking Times for HPIPC and Exercise Control



Mean Change from Baseline in PWT at 4, 8 and 16 Weeks for HPIPC and Exercise (Control) Groups



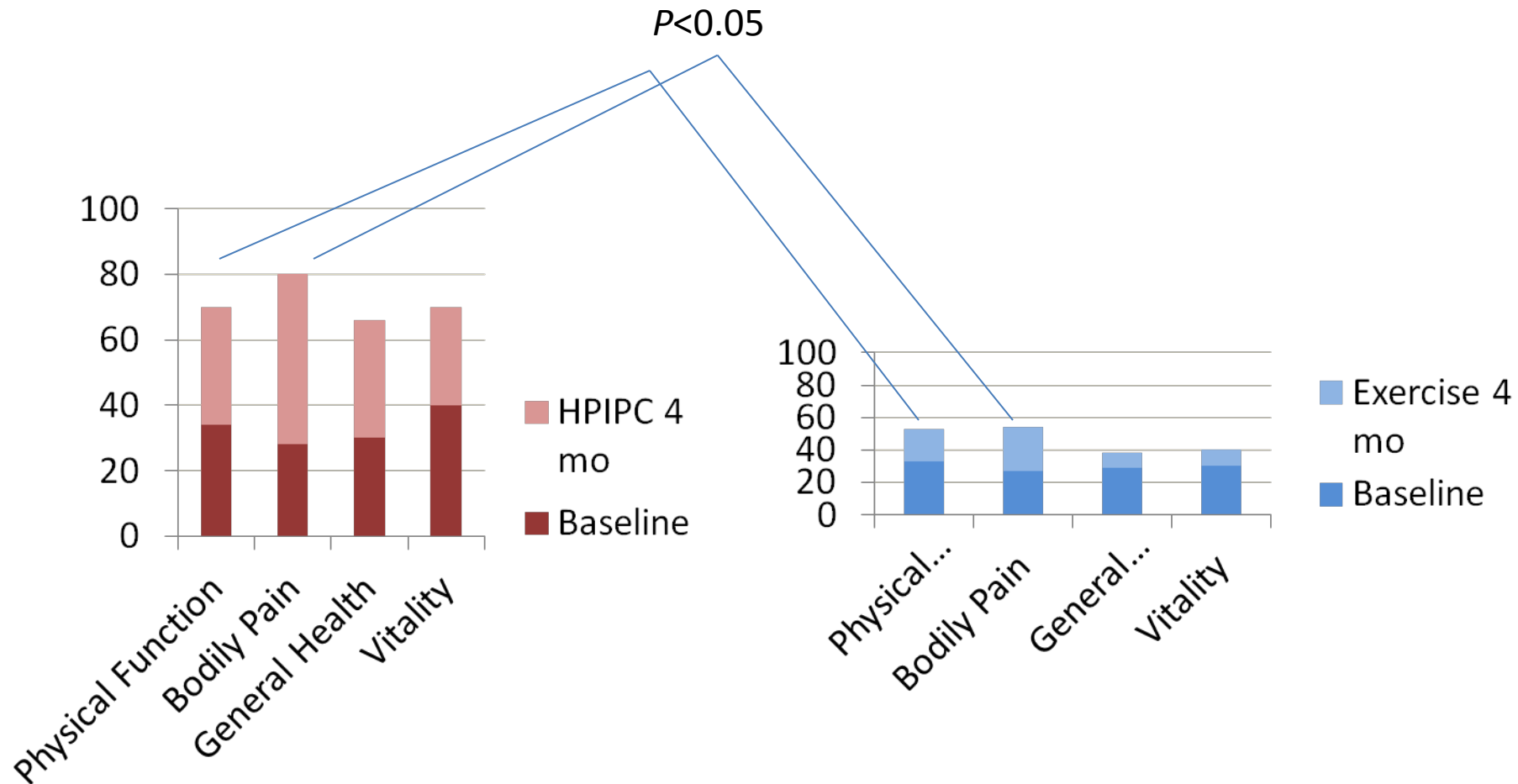
* $P=0.043$

Mean r-ABIs & FCSTI at Baseline and at 8 and 16 Weeks

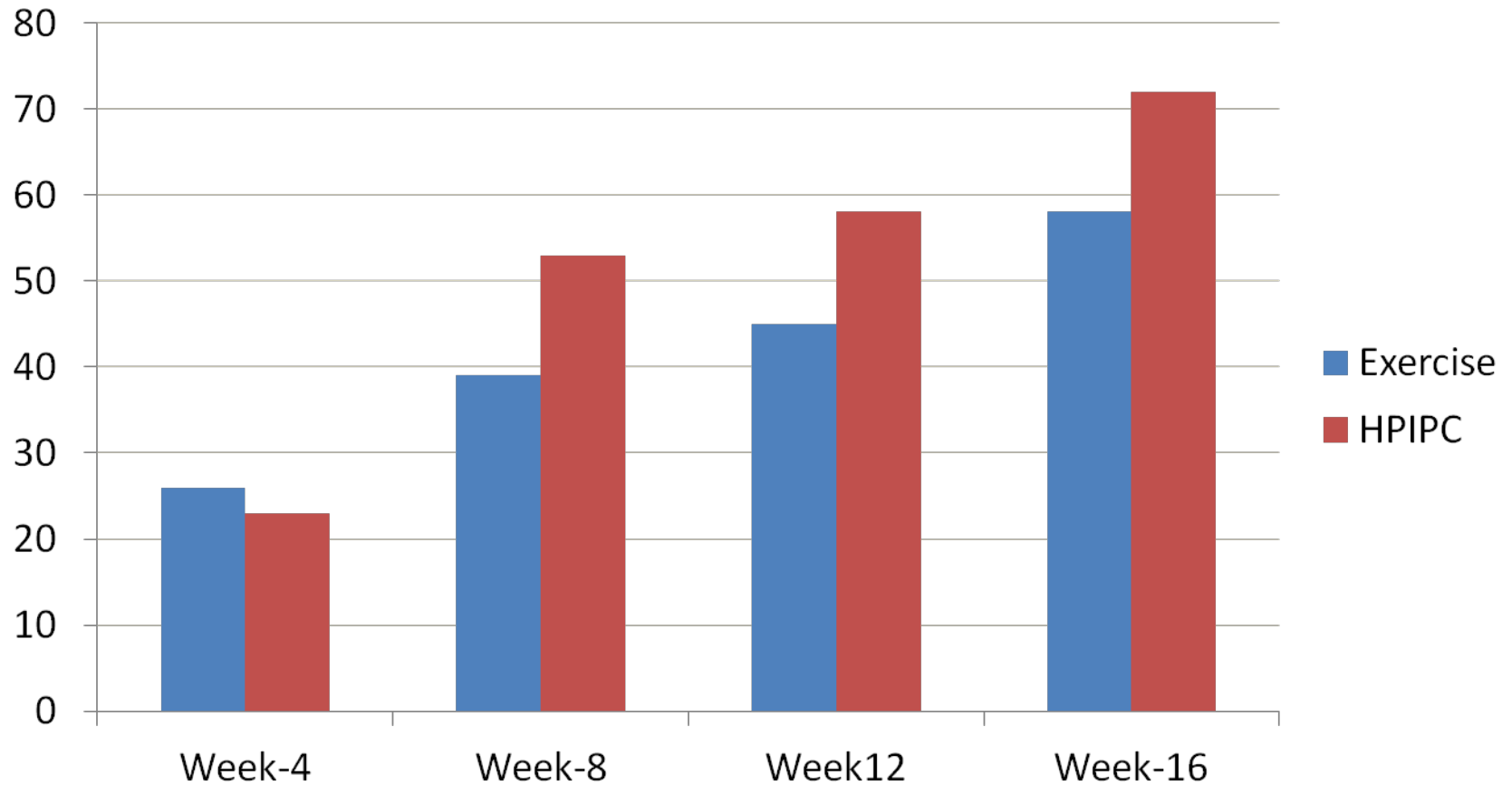
Time	HPIPC	Exercise Control
Baseline	0.58	0.61
Week-8	0.64	0.69
Week-16	0.73	0.71

Time	HPIPC	Exercise Control
Baseline	0.73	0.71
Week-8	0.81	0.74
Week-16	0.88	0.75

Perceived Improvement (QoL) from HPIPC and Exercise SF-36 Health Survey Questionnaire



Mean Percent Reduction in Wound Surface Area



Baseline



Week-4

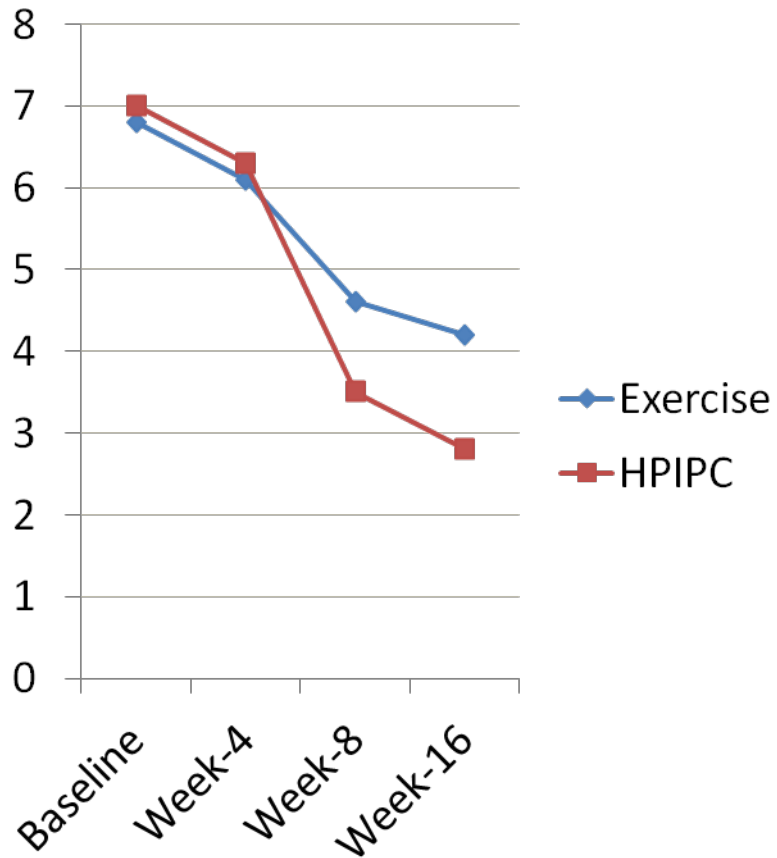


Week-32

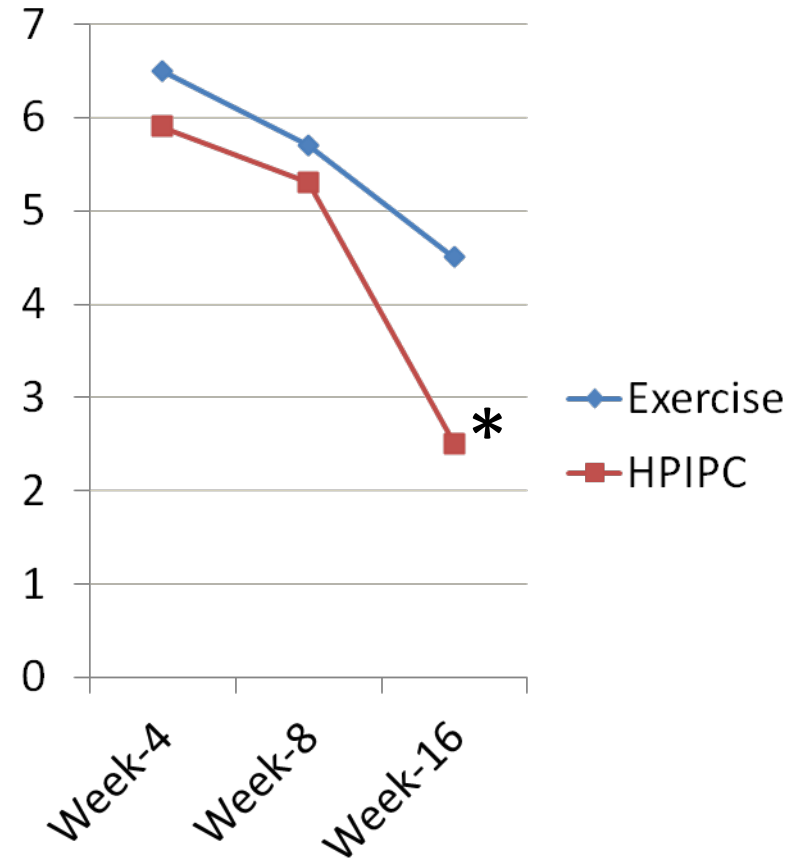


Leg Pain at Baseline and After Treatment

Pain Index (VAS)



Pain Relief (Face Scale)

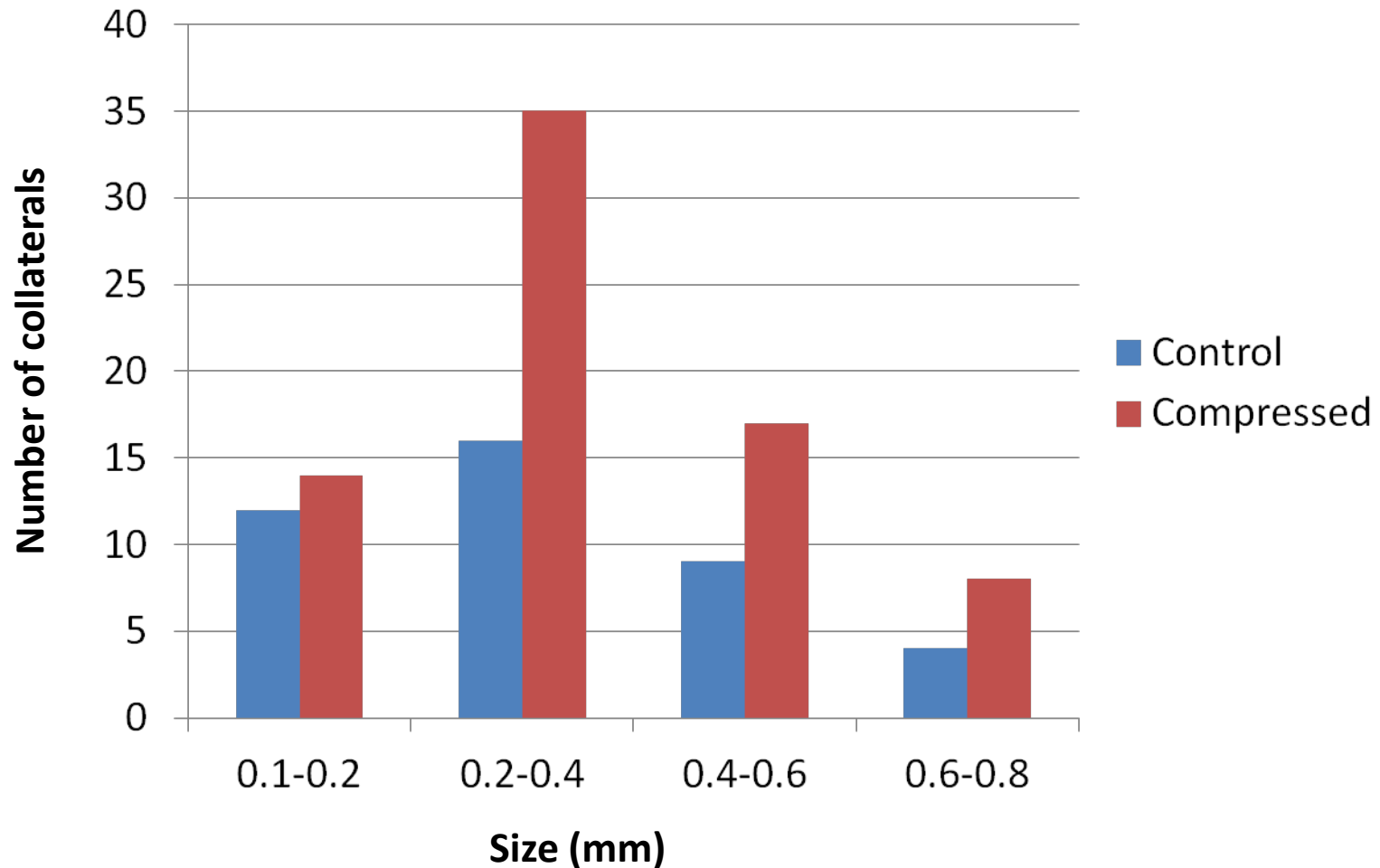


*P<0.05

HPIPC (Postulated) Mechanism of Action

- HPIPC causes forward pulsatile flow, resulting in emptying of blood at that site increasing arteriovenous pressure gradient ($\text{Flow} = \Delta P / \text{Res}$)
- Increase in blood volume and velocity exerts a compressive strain and enhances shear stress on venous endothelium
- Increased production of nitric oxide , prostacyclin, VEGF, as a result of increased shear stress caused by mechanical stimulation (device inflation and frequency cycles)
- Development of collaterals w/ improved perfusion

Histogram of the number of collaterals in different size categories



Acknowledgements

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- Bronx YMCA provided free temporary memberships.