EFFECTIVENESS OF INTERMITTENT, PNEUMATIC COMPRESSION FOR THE TREATMENT OF VENOUS ULCERS IN SUBJECTS WITH CHRONIC (SECONDARY) LYMPHEDEMA

Results of A Prospective Randomized Clinical Trial

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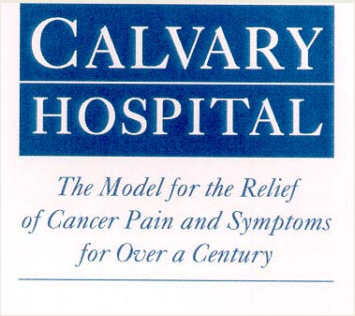


Secondary Lymphedema

- Caused by:
  - an inadequate lymphatic drainage system due to constriction
  - obliteration from:
    - Surgery
    - Radiation
    - Trauma
    - Untreated CVI
    - Infections
- Can develop immediately post-operatively, or weeks, months or even 10 to 20 years later

Lymphedema

- Accumulation of lymph in the interstitial spaces
- Caused by a defect to lymphatic system

- Abnormal collection of excess tissue proteins
- Edema
- Chronic inflammation
- Fibrosis
- Bacterial & Viral infections
- Cutaneous Manifestations

Diagnostic Features

- Swollen feet
- Deep creases at joints
- “Square toe”
- “Shovel toe”
- Stemmer’s sign

Untreated Lymphedema

- Tissue channels to increase in size and number
- Reduction of oxygen through the transport system
- Interference with wound healing
- A culture medium for bacteria and virus that can result in various infections
- Fibrosis (hardening) of the extremity tissue in chronic inflammatory conditions

Treatment Options

- Medications
  - Antibiotics, diuretics, anticoagulants, pantothenic acid, pyridoxine, hyaluronidase no proven therapeutic value
- Surgery
  - Debulking, microsurgical resection, liposuction
  - do not improve lymph flow
  - many complications
- Complete Decongestive Therapy (CDT)
  - Treatment of choice

Study Design

- Prospective
- Randomized
- One Center Open Label
- Controlled v. Std Care
- Run-in phase
- 32 Week duration

- Primary endpoint
  - Rate of Wound Healing
  - Pain Relief
  - Incidence of Infections
- Secondary endpoints
  - Edema control
  - QOL

Goals of Treatment

- Pain, exudate, odor control
- Wound Healing
- Soften subcutaneous tissue
- Prevent infection
- Decrease limb size
- Increase patient function
- Weight loss

Inclusion Criteria
Hard-to- Heal Venous Ulcers

- Lower leg ulcer due to CVI
- Ulcer size >20 cm2
- Ulcer history >1yr
- Non-Responders
  - (Failed healing with compression alone)
  - Pain index >6

Big Old Wound

cm
1
2
3
4
5
6
SPECIMEN FM
DATE 4-28-05

cm
2
SPEC. 23711
DATE 4/13

SPECIMEN
DATE

Exclusion Criteria

- Ulcer of non-venous etiology
- ABI <0.75
- Wound Infection
- Current use of systemic corticosteroids
- Chemo or radio-therapy
- Subject is presently confined to bed or chair
- Participation in another clinical study

Statistical Design

- Intent-to-treat
- Wound Pain, Leg edema (Fisher's exact test)
- Time to healing & relative rate of healing (Kaplan-Meier & log rank chi-square test)

Treatments

- **IPC plus Compression**
  - **4LB* applied twice weekly**
  - **IPC therapy for 1h bid**
- **Compression alone**
  - **4LB* applied twice weekly**

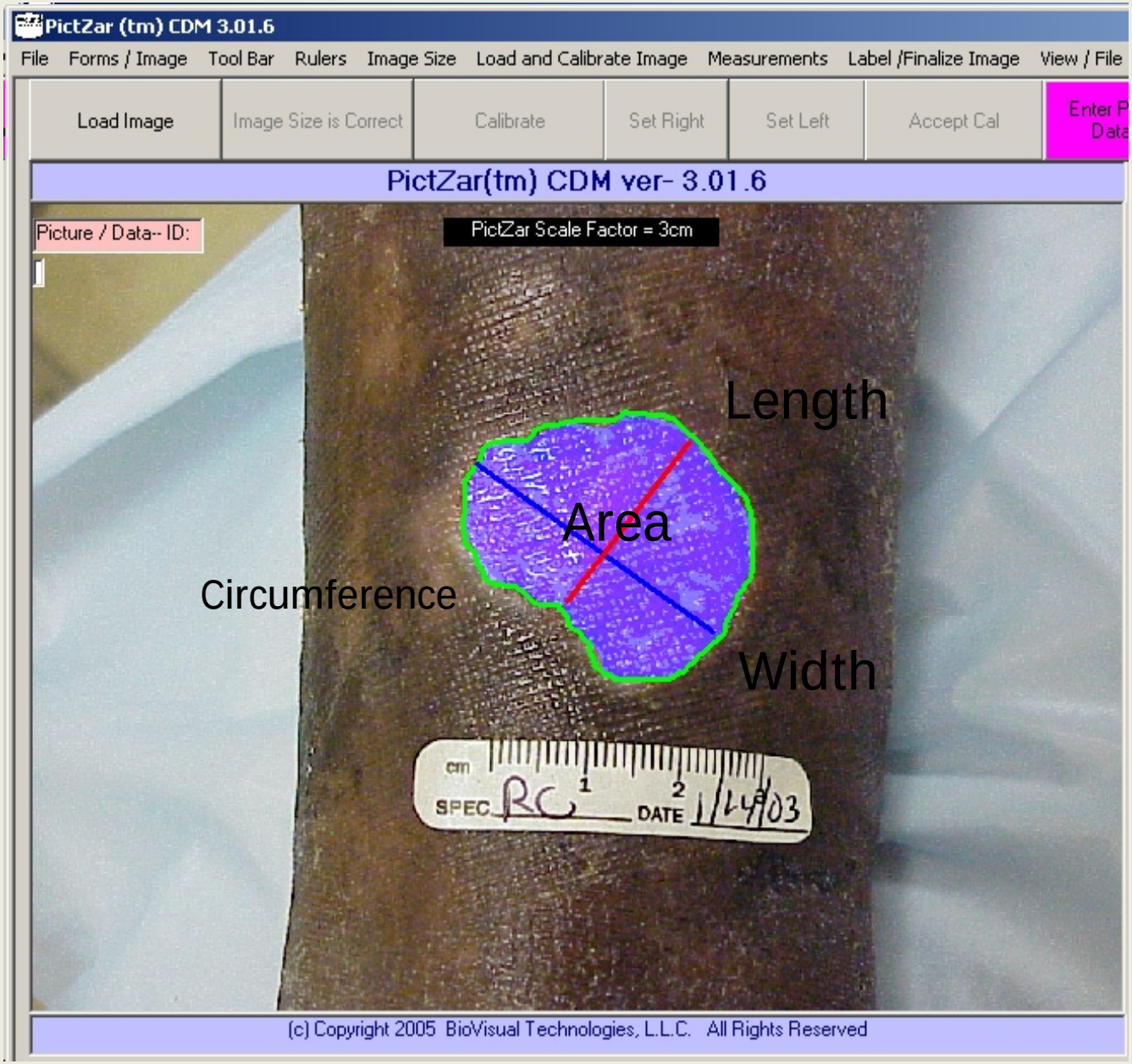
*Profore, Smith & Nephew, Largo, FL

Compression Bandages were applied once weekly at the clinic and once weekly by a visiting nurse. Bandaging was only performed by trained professionals

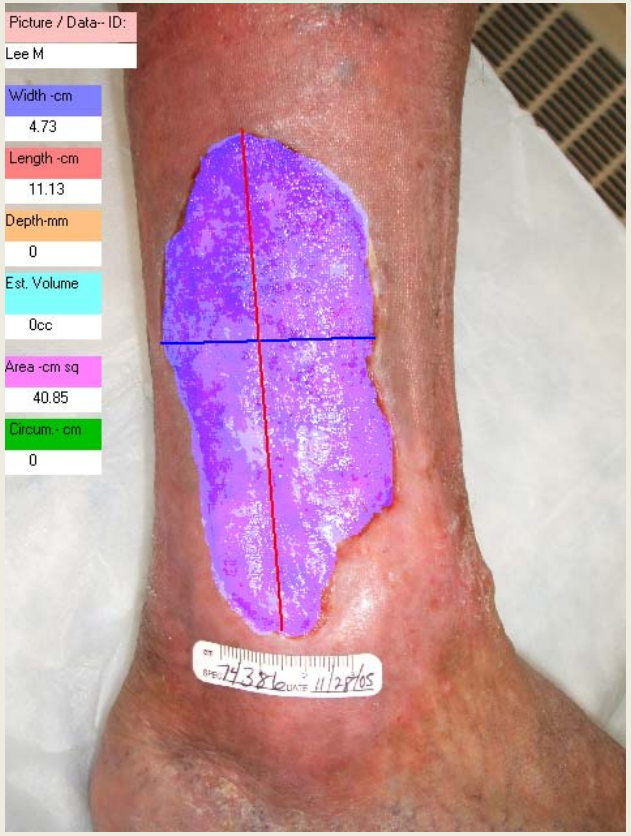
Test Agent*

- 4-Chamber, gradient, sequential, pneumatic
- Short Sleeve (19”) 3/4 Sleeve (31”)
- 1 hour bid (morning & evening)
- Pre-set and locked at 50 mmHg
- Therapy sessions in the decubitus position
- Daily diaries
- IPC devices checked every 4 weeks
- Subject / family in-service provided

PDP Software (PictZar™)

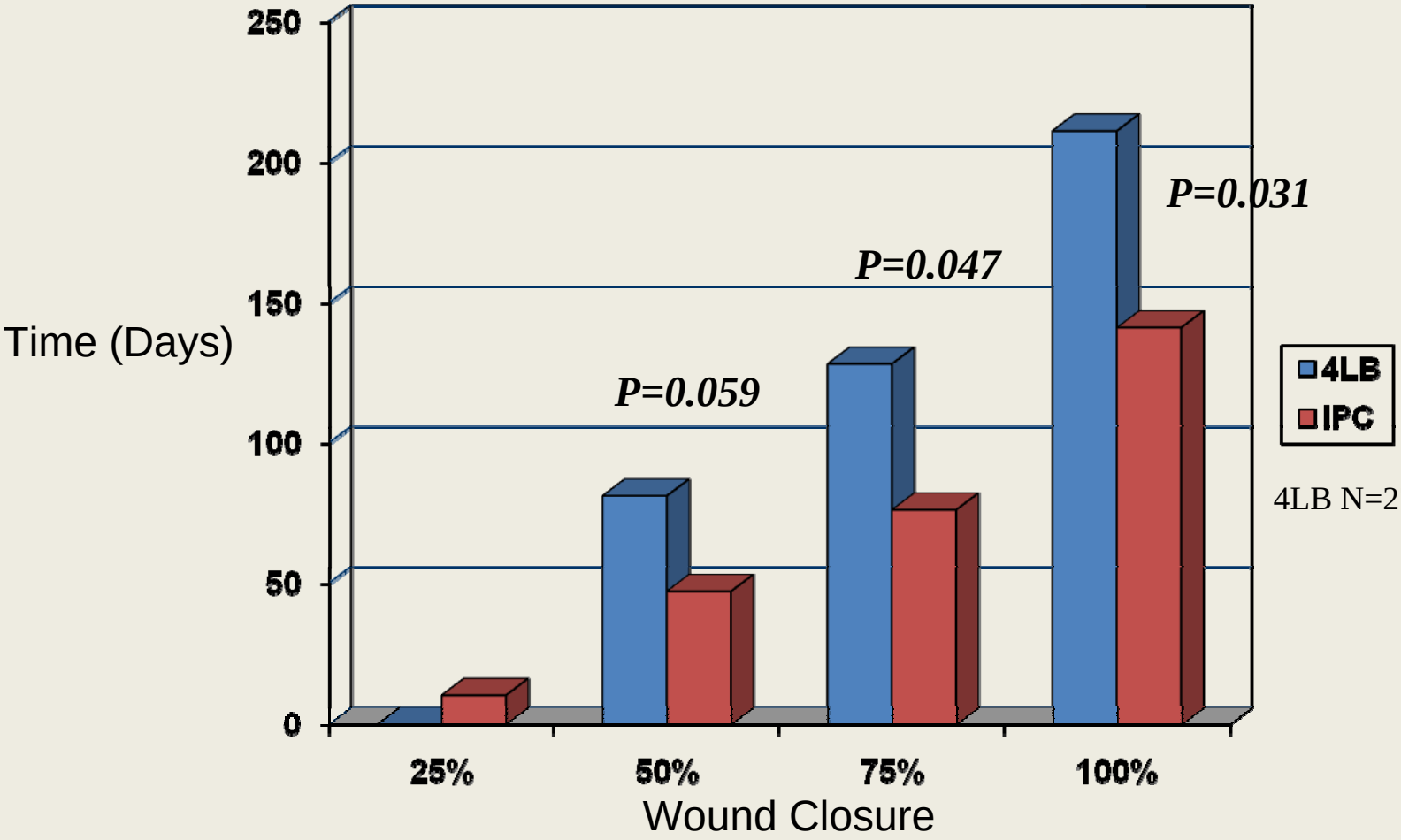


Wounds were measured using digital photograph planimetry*



* PicZar™ BioVisual Technologies, LLC

Median Time to Wound Closure by 8 Months (N=52)

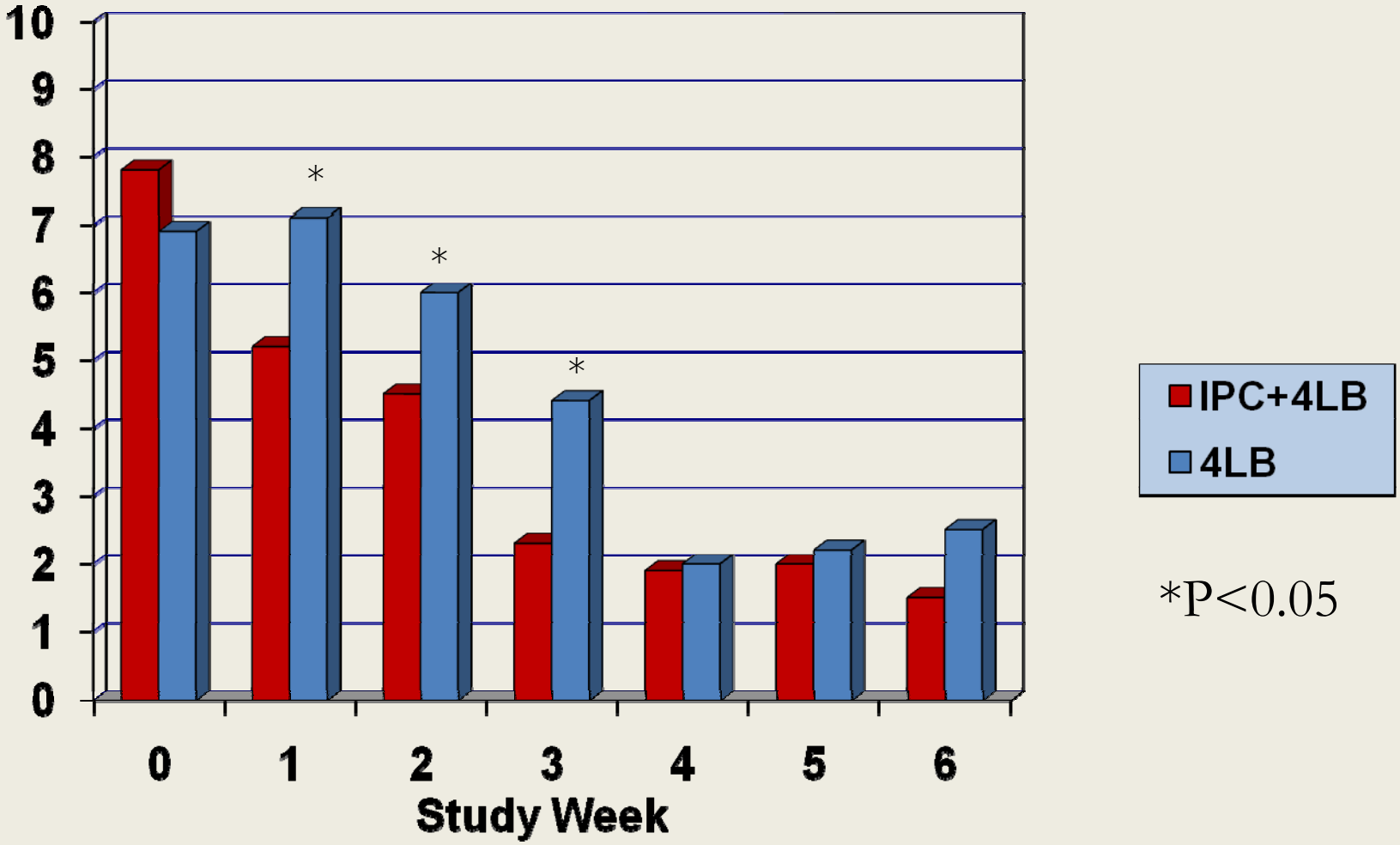


4LB N=27 IPC+4LB N=25

04/26/05

05/11/05

VAS Wound Pain Scores



*P<0.05

Rate of Healing

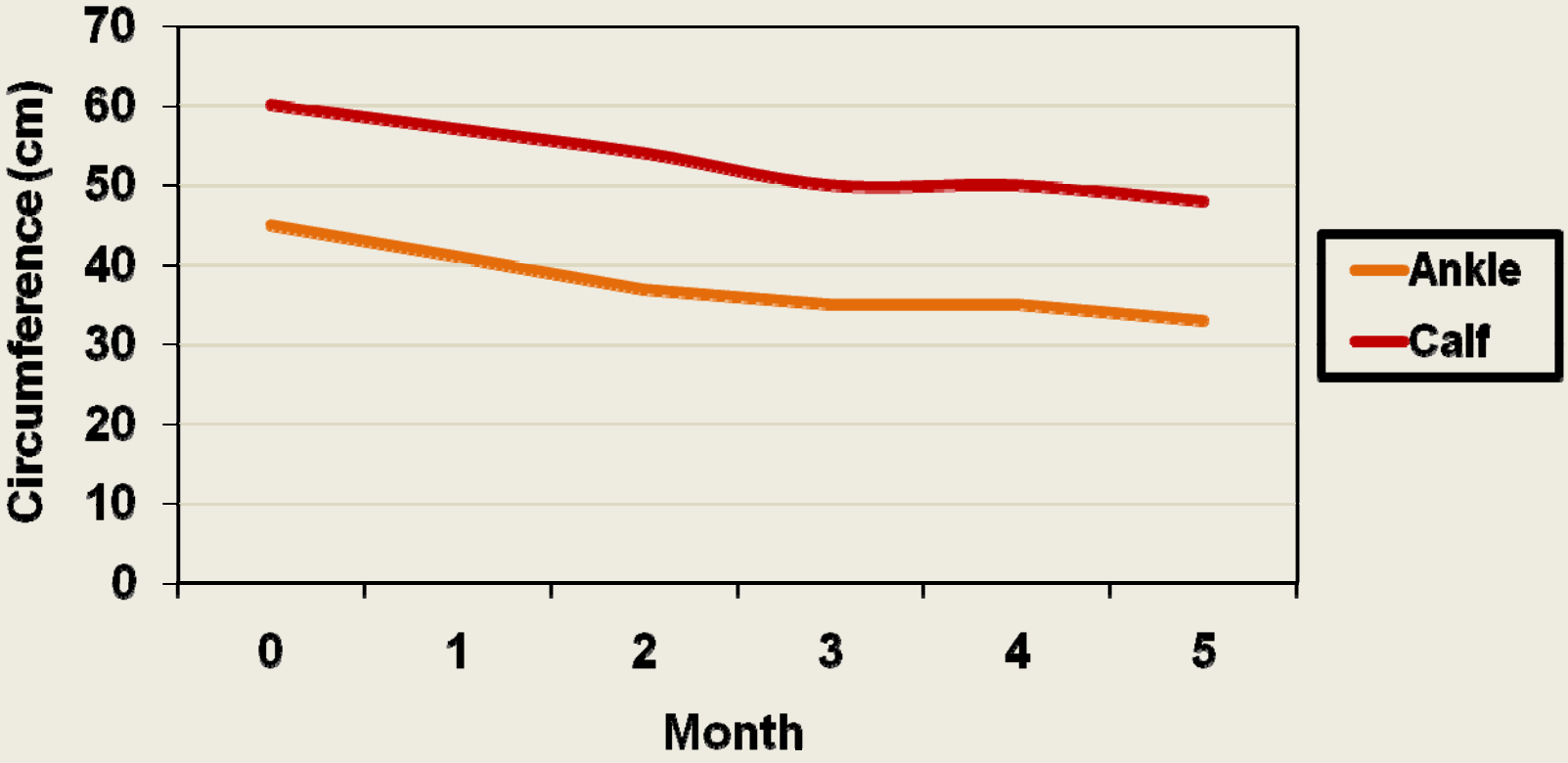
Treatment	**4LB**	**4LB plus IPC**	**P value**
Rate of Closure mm/day ± SEM	1.1 ± 0.4	2.3 ± 0.7	0.026
N	25	27	

Leg Edema

Ankle & Calf Circumference

Group	Baseline Ankle/Calf (cm)	Week-20 Ankle/Calf (cm)	% Δ Ankle/Calf (cm)
IPC plus 4LB	46.5/59.3	37.6/48.2	19.1/18.7
4LB (Control)	44.7/56.4	39.6/49.2	11.0/12.7

EDEMA


70
60
50
40
30
20
10
0
Circumference (cm)
0
1
2
3
4
5
Month
Ankle
Calf

Conclusions

- The median time to healing by 8 months was 135 days for the IPC-treated group and 198 days for the control group ($p=0.039$)
- The rate of healing was 1.1 mm/day for the control group and 2.3 mm/day for the group treated with IPC ($p=0.026$)
- Compared to subjects treated with compression alone, the group treated with IPC reported less pain at each evaluation point for the first 6 weeks.
- The IPC treated group had greater reduction in leg edema (18% vs 12%)

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