

A New Treatment for Breast Soft Tissue Fibrosis

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Introduction:

Many lymphedema patients have altered tissue composition and density from soft tissue fibrosis, a result of chronic congestion of high protein fluid. Surgery, radiation therapy and cellulitis can create additional and progressive tissue changes¹⁻⁴. Although soft tissue fibrosis is a common consequence of chronic lymphedema and can compromise function and quality of life, little research has focused on effective treatment modalities.

This case study examined four breast cancer patients with Stage 2 Lymphedema, each post lumpectomy surgery and radiation therapy. Subjects received decongestive treatment for lymphedema in addition to the JoViPitPak®, a new treatment modality for breast fibrosis at the Lymphedema Management Program of Dominican Santa Cruz Hospital. We assessed whether the addition of the new modality would result in greater improvements compared to using decongestive treatment alone for addressing soft tissue fibrosis.

Methods:

All patients:

- Received an initial assessment;
- Were taught manual lymphatic drainage (MLD);
- Used elastic compression for breast edema for two weeks; and
- Then received treatment for soft tissue fibrosis using a JoViPitPak®, a compression garment developed specifically for treatment of soft tissue fibrosis which was worn upon the breast under elastic compression for two hours per day for three weeks.

Assessments are indicated as:

I: Initial: prior to any treatment;

II: Interim: after 2 weeks of conservative therapy for proximal and extremity lymphedema consisting of elastic compression and MLD, prior to introduction of JoViPitPak®;

III: Final: after 3 weeks of treatment with JoViPowerPak® in addition to conservative therapy.

Description of subjects:

- Age range: 39 to 55.
- Post surgical status: 9 months to 12-1/2 years.
- Radiation therapy was completed from 3-1/2 weeks to 12 years prior to start of the study.
- Some subjects had metastatic as well as primary disease.
- Some subjects were concurrently undergoing chemotherapy.
- All subjects had extremity as well as breast lymphedema.
- None had prior treatment to address lymphedema symptoms.
- All subjects had axillary lymph node dissection, making them more vulnerable to breast edema and therefore increased incidence of breast tissue fibrosis⁵.

Assessments performed:

Tonometry

- Instrument used: the Flinders Tissue Tonometer (Flinders Medical Centre, Bedford Park, South Australia, 5042).
- Fibrotic tissue is more resistant to compression than normal tissue and soft pitting edema less resistant to compression than normal tissue; lower readings indicate harder tissue^{6,7}.
- Sites measured were the most palpably dense portion of the affected breast.
- Landmarks (nipple and surgical scars) were used as measurement reference points.

Breast Cosmesis Questionnaire

- Patients used an analog 0-10 scale to self-rate perception of their affected breast compared to non-affected breast in these areas:
- Breast density
- Skin density
- Skin appearance
- Swelling
- Overall cosmetic appearance

Visual Analog Pain Scale

- The horizontal version was used for this study⁸.

Results:

Subjects demonstrated clinically significant improvements in all three domains following additional use of JoViPitPak[®]:

- Subjects demonstrated an average decrease of 4.58% in **tissue density** after conservative treatment, and a **further** average decrease of **14.71%** in tissue density after addition of JoViPitPak[®] (Table A).
- Average perception of **cosmesis** improved by 13.3% after conservative treatment, and a **further** average increase after addition of a JoViPitPak[®] by **47.86%** (Table B).
- Average perceived **breast pain** improved by 50% after conservative treatment and a **further** average improvement after addition of JoViPitPak[®] by **66.67%** (Table C).

Notes:

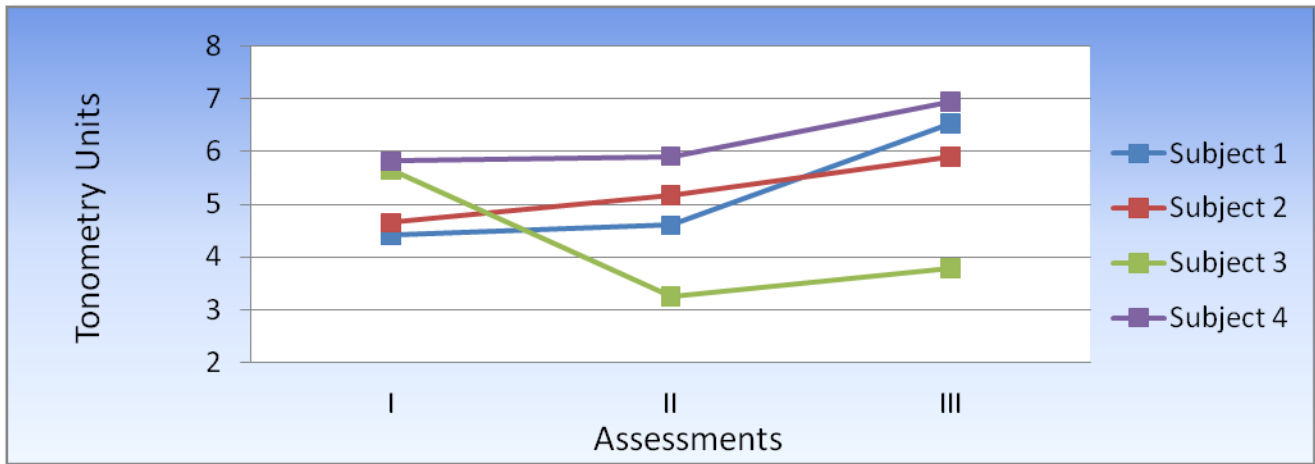
Tonometry: Tonometry measures surface tissue density, not tissue composition. Subject 3 was excluded from the average change between Assessments I and II because her acutely high degree of swelling at the time of the initial assessment yielded a high initial tonometry reading. Her subsequent readings were substantially lower because the layer of soft edema was reduced, allowing more accurate measurement of the change in the denser fibrotic scar and radiated tissue.

Pain: Subjects 1 and 4 had no complaints of breast pain and were excluded from averaging.

Conclusions:

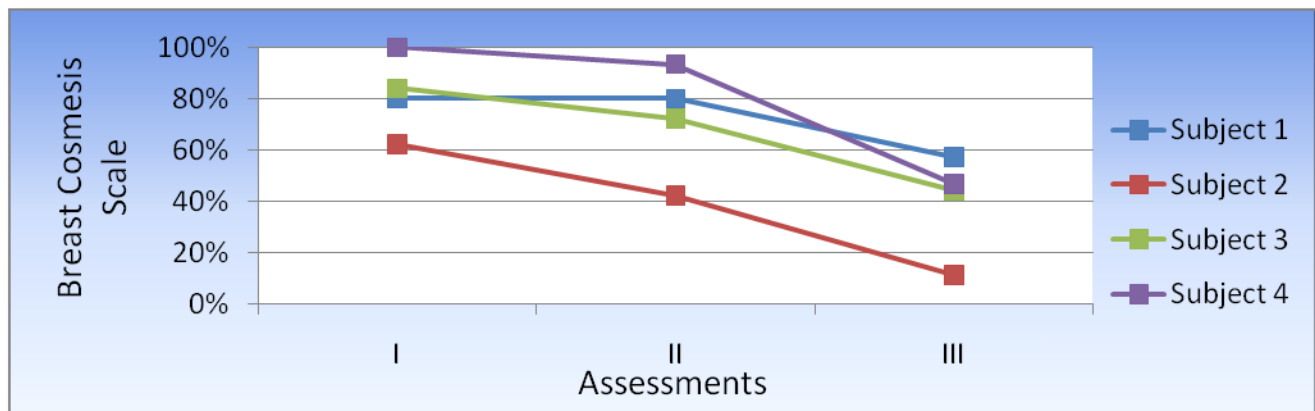
Patients demonstrated favorable results after short-term use of JoviPowerPak[®] for amelioration of soft tissue fibrosis effects. Because early treatment of fibrosis has become standard of care at this facility it was deemed unethical to withhold this new modality; thus comparisons with subjects who received treatment without the JoViPowerPak[®] were not possible. Additional randomized studies involving larger patient populations and longitudinal studies to determine frequency and duration of use are warranted to further assess the efficacy of this treatment approach.

Table A: Tissue Density



	ASSESSMENTS				
	I	II	III	D I-II	D II-III
Subject 1	4.42	4.6	6.53	1.02%	10.49%
Subject 2	4.65	5.17	5.9	11.18%	14.12%
Subject 3	5.65	3.25	3.79	-42.48%	16.62%
Subject 4	5.82	5.91	6.95	1.55%	17.60%
Average				4.58%	14.71%

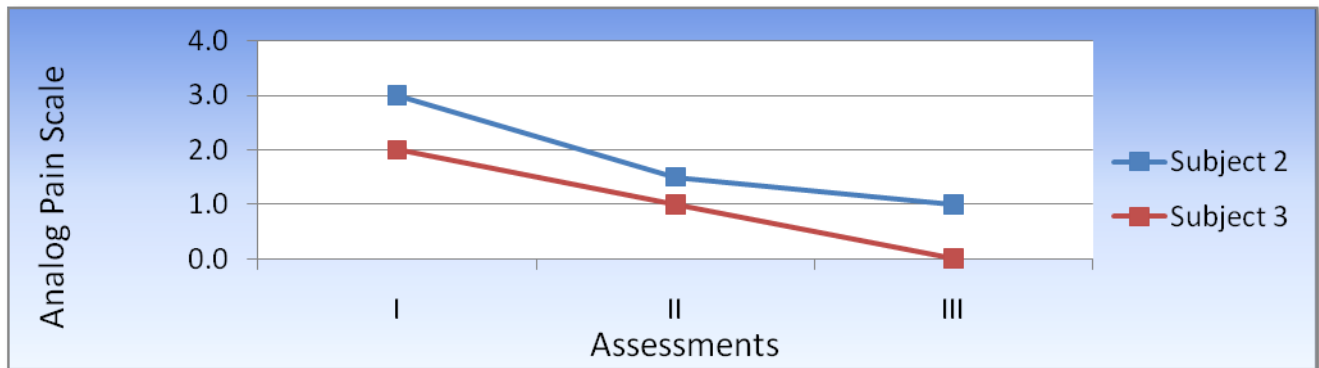
Table B: Cosmesis



	ASSESSMENTS				
	I	II	III	D I-II	D II-III
Subject 1	80.00%	80.00%	57.00%	0.00%	-28.75%
Subject 2	62.00%	42.00%	11.00%	-32.26%	-73.81%
Subject 3	84.00%	72.00%	44.00%	-14.29%	-38.89%
Subject 4	100.00%	93.33%	46.67%	-6.67%	-50.00%

Average				-13.30%	-47.86%
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Table C: Breast Pain



	ASSESSMENTS				
	I	II	III	D I-II	D II-III
Subject 2	3.0	1.5	1.0	-50.00%	-33.33%
Subject 3	2.0	1.0	0.0	-50.00%	-100.00%
Average				-50.00%	-66.67%

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