

Emerging Conservative Treatment Modalities for Lumbar Disc Disease and OA of the Knee for Orthopaedic Review Course

By: Timothy McTighe, Executive Director, JISRF
Terrigal, Australia, 11/99



Notes

The 1990's have seen significant growth in surgical procedures for both Lumbar Disc Disease and OA of the Knees. Often growing momentum of surgical treatment tends to dampen consideration of conservative options. This paper's objective is to review two new treatment modalities that should be considered in the face of mild to moderate symptoms prior to surgical intervention.

Both of these approaches are similar in that they are new to the market and indications and results are still being defined.

Lumbar Disc Disease

Treating low back pain is one of the most challenging problems facing the health care community today. Approximately 20 million Americans are affected, most of whom are in the prime years of their lives. Low back pain is believed to be the most common cause of disability for people under the age of 45 in the U.S. Direct and indirect treatment costs exceed \$60 billion annually.

Current conservative treatment starts with physical therapy and traction, then progresses to more invasive measures such as epidural steroid injections, SpineCath RF procedure and traditional surgery.

Spinal decompression is possible with traditional pelvic traction, however, this is not a viable treatment consideration in today's health care environment. The challenge is to provide decompression while remaining ambulatory.

Various forms of devices are available including abdominal binders, corsets and rigid TLSO braces. However, these devices have proven inconsistent in providing pain relief and some clinicians view them as ineffective. A new conservative device has been recently introduced that is designed to decompress the spine.

The Orthotrac™ Pneumatic Vest is designed to off-load 30-50% of patient's body weight by inflation of pneumatic coil lifters built into the front and back of the vest. The design allows patients to be ambulatory while participating in prescribed exercise programs.

To evaluate the effectiveness of these options a patient being treated for degenerative disc disease underwent MRI evaluation while wearing six different orthopaedic devices. The MRI series was then evaluated by two independent radiologists in a blind review to determine the degree of decompression obtained with each device.

The devices studied

- Orthotrac™ pneumatic vest
- Abdominal binder
- Industrial binder
- Corset
- TLSO body jacket
- Rigid TLSO



Notes

The evaluations demonstrated that an increase in the disc space heights, smaller disc herniations and wider foraminal openings were obtained only with the Orthotrac pneumatic vest.

On a personal note, this device is currently being used by my wife and my mother. My wife's diagnosis is L:4-5 level, mild spinal canal stenosis with mild annular bulging of the disc. L:5-S1, mild degenerative arthritic changes of bilateral facet joints.

My wife has used the device for the past 7 months. She wears the vest 2-3 times a day for approximately 20 minutes per period. She has received significant relief of pain, elimination of pain medication and has been able to go back to her full daily schedule including an occasional game of golf.

My mother's CT scan demonstrates some mild degenerative change at the apophyseal joints L:3-4. L:4-5 there is moderate degenerative change of the apophyseal joints, with some slight disc osteophyte formation and evidence of moderate to marked canal stenosis. There is moderate bilateral intervertebral foraminal narrowing at L:4-5.

L:5-S1 there is degenerative change of the apophyseal joints at L:5-S1 and some mild disc osteophyte complex. There is some mild narrowing at the foramen due to a spur.

She wears the Orthotrac vest 4-5 times a day from 30 to 60 minutes per treatment. She has more relief in the vest, however, the device has allowed her to increase her daily activities by approximately 25%. She can now go shopping for up to 2 hours and do some limited gardening.

In one recent study of over 300 patients who wore the Orthotrac pneumatic vest for at least 8 weeks, 69% experience significant improvement in both outcomes and quality-of-life indicators.

Summary

Additional studies are underway demonstrating early evidence that the Orthotrac vest decreases the level of pain, improves the quality of life and is cost effective as compared to the cost of surgery.

This new conservative treatment can be a valuable tool in treating low back pain caused by intervertebral disc disorder or mechanical low back pain syndrome. It also appears to make sense to consider this treatment approach before more expensive surgical procedures.

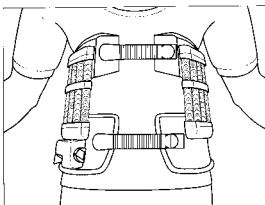


Figure 1. Orthotrac Pneumatic Vest: Separately inflatable compartments anterior, posterior, and lumbar.

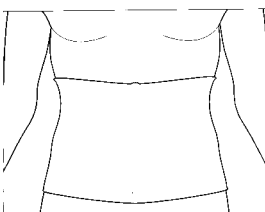


Figure 2. Abdominal Binder: Elasticized band with hook and pile closure.

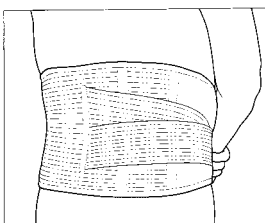


Figure 3. Industrial Binder: Flexible plastic stays with V-shaped compression straps in front and back.

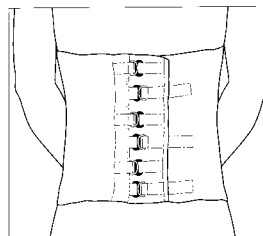


Figure 4. Corset: Center pull strap truss with two pairs of shaped steels above and below the waist.

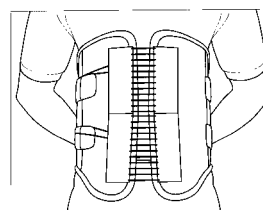


Figure 5. TLSO Body Jacket: Spine and abdominal compression adjusted with bilateral power pulley units; with axillary straps.

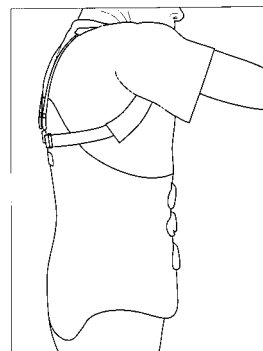


Figure 6. Rigid TLSO: Spine and abdominal compression adjusted with bilateral power pulley units.

Conservative Treatment for OA of the Knee

Viscosupplementation with Hylan G-F20 (Synvisc®) is an innovative treatment for OA knee pain in which pathological synovial fluid is supplemented with a fluid that has similar physical properties to those of the synovial fluid of a healthy young individual.



Notes

**Total Knee Procedures
+200,000 in U.S.**

**OA of the knee
effects approximately
10 million knee joints
in the U.S.**

**Two Primary Patient
Groups**

- **Late-stage indicated
for TKR**
- **Mild to moderate
pain indicated for
NSAID Therapy**

**Pain Drives OA
Treatment**

**Synovial and capsular
tissue are the primary
sources of pain.**



Notes

Synovial Fluid

- Highly influences intercellular matrix of joint soft tissues
- Unique combination of elasticity and viscosity
- Hyaluronan responsible for elastoviscous properties
- Elastoviscosity critical for joint function
- Elastoviscosity reduced in osteoarthritis

Elastoviscosity and Pain

- Pain receptors in synovial tissue are influenced by elastoviscosity of matrix hyaluronan
- Inflammation and effusion decrease elastoviscosity and sensitize pain receptors

Viscosupplementation

- Replaces pathologic synovial fluid
- Supplements elasticity and viscosity
- Reduces pain and improves mobility

Hylans

- Cross-linked hyaluronan
- Increased molecular weight or continuous molecular network
- Higher elastoviscosity than hyaluronan
- Longer tissue residence time

Products Available for Viscosupplementation

Trade Name	Composition	Molecular Weight	Residence Time	% Elasticity @ 5 Hz	% Elasticity @ 1 Hz
Artzal®	1% hyaluronan	0.7 million	1-2 days	40	21
Hyalgan®	1% hyaluronan	0.6 million	1-2 days	30	2
Synvisc®	0.8% hylan	0.6 million	1 week	80	81

Hylan G-F 20

- Elastoviscosity similar to healthy synovial fluid
 - Elasticity = 111 ± 13 Pa (at 2.5 Hz)
 - Viscosity = 25 ± 2 Pa (at 2.5 Hz)
- Designed as a synovial fluid prosthetic device
- A series of three injections provides pain relief for up to 6 months or longer
- Excellent tolerability in clinical trials and clinical practice

Retrospective study in 458 knees with mild/moderate OA

Lussier

Relationship of X-Ray grade on overall response to treatments in patients ages 22-92



Notes

Medical X-Ray Grade I



**Number of
Patients: 68**

**% Better or
Much Better:
91%**

Medical X-Ray Grade II



**Number of
Patients: 138**

**% Better or
Much Better:
80%**

Medical X-Ray Grade III



**Number of
Patients: 180**

**% Better or
Much Better:
76%**

Medical X-Ray Grade IV



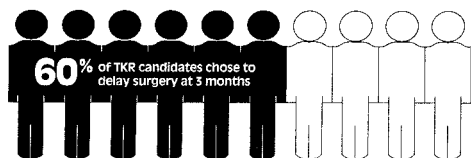
**Number of
Patients: 57**

**% Better or
Much Better:
58%**



Notes

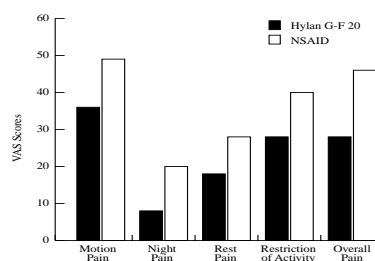
Patients recommended for total knee replacement (TKR) who opted to delay surgery in a prospective, open-label, multicenter clinical study (n=60)



Hylan G-F 20 vs. Continuous NSAID Therapy

M.E. Adams, M. Atkinson, A.J. Lussier, J. Shultz, K. Siminovitch, J.P. Wade, M. Summer
Canada

Hylan G-F 20 vs. NSAID Pain Scores (VAS) Repeat Measures Analysis



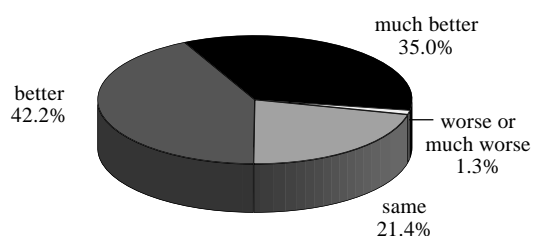
Experience with Hylan G-F 20 in Routine Canadian Practice

A.J. Lussier, C.W. McFarlane, W.P. Olszynski, A. Cividino, W. Potashner
Canada

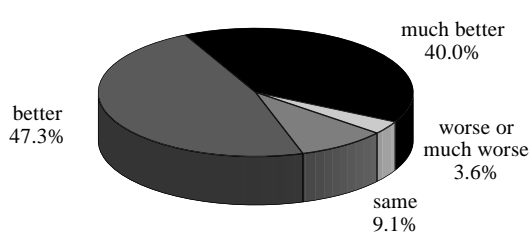
Experience with Hylan G-F 20 in Routine Canadian Practice

- 336 patients, 458 knees, 1537 injections
- 122 bilateral treatments
- 2nd course in 41 patients, 56 knees
- Mean age: 65 years \pm 1
- 63% female, 37% male

Clinical Response to First Course of Hylan G-F 20 Viscosupplementation



Clinical Response to Second Course of Hylan G-F 20 Viscosupplementation





Notes

Duration of Efficacy

- Mean time to retreatment: 8.4 months (± 0.5)
- Range: 3 to 19 months
- Distribution of efficacy duration:

< 3 months	19%
3-6 months	28%
6-12 months	39%
> 12 months	15%

Hylan G-F 20 is Effective Across All Radiologic Grades

Medial X-ray grade	% Better or much better	% Using fewer analgesics
I	91%	74%
II	80%	63%
III	76%	47%
IV	56%	22%

Safety Profile in Clinical Practice

- No systemic adverse events
- 42 transient local reactions noted in 28 patients (no sequelae)
- Rate of local reaction in this study: 2.7% per injection
- Local reaction does not predict treatment failure
 - 69% still clinically improved
 - 66% received subsequent injections

Safety Data on Synvisc®

Postmarketing Medical Surveillance Through June 1999

- 1,792,414 injections
- No systemic reactions attributed to Synvisc
- 2,050 local reactions (0.11% per injection)

Viscosupplementation with Hylan G-F 20 Clinical Conclusions

- Hylan G-F 20 treatment is clinically and statistically superior to control
- Hylan G-F 20 is as good as or better than continuous NSAID therapy
- Duration of efficacy in clinical practice has ranged from 3 to 19 months (mean duration = 8.4 months)

Viscosupplementation with Hylan G-F 20

Indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics, e.g. acetaminophen

Summary

Current studies and growing usage clearly demonstrates the use of Hylan G-F 20 (Synvisc) is a safe, reliable and cost effective procedure for the treatment of OA knees (particularly the mild to moderate grades I, II, & III).

Summary (continued)

The medical community, especially surgical, needs to stay abreast of new and innovative nonsurgical procedures. Over indication of surgery can bring compromised results with increased cost and the potential of further government regulation.