TransDiscal* (Biacuplasty)
Cooled-RF Training Presentation
AGENDA

• Disc Degeneration Overview
• Patient Selection
• Technique
• Precautions
• Appendix
Determinants of Lumbar Disc Degeneration

- Disc degeneration may be explained primarily by genetic influences and complex unpredictable interactions of unidentified factors.

Pathology
Small, posttraumatic peripheral tears of the annulus fibrosus lead to an acceleration in dehydration of the intervertebral disc (Osti et al 1992).

Studies using annular trauma in a sheep model support this theory (Osti et al 1990).

Possible Scenario

- Loss of Nuclear Hydrostatic Pressure
  - Delamination
  - Fissuring
  - Microfracutures of collagen fibrils
  - Sensitization of Nonciceptors
    - PLA2, NO, IL1
    - Repetitive stimulation of DRG

Saal and Saal, 2002; Ozaktay et al., 1998; Schwartz et al., 1995
Mechanisms

- Disc degeneration and injury-centripetal growth of nerve fibers in the disc
- More extensive disc innervation in the severely degenerated human lumbar disc compared with normal discs
- Small unmyelinated nerve components, extensive innervation of the inner parts of the annulus
- The nociceptive properties-substance P immunoreactivity

Coppes MH. Spine 1997;22:2342-2349
Disc Changes

- Vascular ingrowth observed in peripheral tears of the annulus (Hirsch 1953)

- Nociceptors accompany vascular growth—presence of sensory nerve supply in the inner annulus.

- In DDD an association between ingrowth of nerves expressing substance P and disc degeneration. The extent of neoneuralization greatest at the painful levels. (Freemont et al 1997)

Endplate Changes

• Degenerative changes-increased vascularization of the endplates.
• Nerve elements around endplate vessels, role in pressure related pain sensation.
• Correlated the extent of memory pain as determined by discography with the amount of vascularization in the endplates on histological examination.
• The extent of vascularization in the degenerated endplates - moderate correlation with VAS scores after discography.

Weisskopf M. Zeitschrift fur Orthopadie und Ihre Grenzgebiete. 142:174-8, 2004
MRI disc degeneration is the strongest predictor of low back pain (MacGregor et al 2004)

HIZ (high intensity zone) on MRI correlated 65-95% of the time with pain-producing fissured disc (Aprill et al 1998, Ito et al 1998)

### MRI Results: “Normal” Subjects (N = 67)

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<th>Over 60</th>
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<td>Herniated disc</td>
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“A diagnosis based on MRI, in the absence of objective clinical findings, may not be the cause of a patient’s pain, and an attempt at operative correction could be the first step toward disaster.”

Boden et al., JBJS, 1990
Algorithms
Kapural and Goldner, 2005

Back pain

IDD

Discography

Disc lesioning
RF gray ramus communicans
Intradiscal injections
Surgical options: Artificial disc Lumbar fusion

RF
IDET
Bipolar, Nucleoplasty
DMSO
Chymopapain
Patient Selection
Patient Selection

• Inclusion Criteria:
  – Chronic pain (>6 months)
  – At least 50% preserved disc height

• Exclusion Criteria:
  – Patients with Grade 4 or greater annular tear
  – BMI greater than 29.9 (obese)
  – Pregnancy
• “Classic” presentation-axial low-back pain without radicular symptoms
• Occasionally groin and leg pain
• Worse with axial loading and improved with recumbency
• Exacerbated with prolonged sitting.
• Pain typically increases with maneuvers that increase intradiscal pressure (e.g. Valsalva’s).
Medical History

• Persistent low back pain that lasts for more than six months
• No improvement from comprehensive conservative program (must include: intensive exercises, PT and one fluoro LESI)
• Absence of any inflammatory arthritides or non-spinal conditions that may mimic lumbar pain
• Absence of prior surgery at the symptomatic intervertebral disc level

Pauza et al, 2004
Saal and Saal, 2002
Bogduk and Karasek, 2002
Kapural et al., 2004
Physical Examination

• No neurologic findings in the lower limbs
• Negative SLR
• Positive spring-test - reproduction of axial back pain with direct pressure over the suspect spinous process
MRI

- Disc degeneration, desiccation, high-intensity zones

- Possibly loss of disc height, but preserved 50% or more at affected disc level

- MRI should not demonstrate neural compressive lesion

Pauza et al, 2004; Saal and Saal, 2002; Bogduk and Karasek, 2002
Diagnostic Discography

- To identify symptomatic disc level
- Recurrent disc vs scar tissue pain
- Preliminary test to spinal fusion
- Preliminary test for IDET, chemonucleolysis, nucleoplasty
- Negative MRI, symptomatic patient
Technique
• Radiofrequency current is concentrated between electrodes on two straight probes.
• The electrodes are internally cooled allowing deep, even heating and eliminating tissue adherence.
• Temperature sensors allow monitoring at the electrode tips and disc periphery.
• The ideal temperature profile is 55-60°C in the inner posterior disc decreasing to 45°C in the peripheral edge of the posterior disc.
Intradiscal Biacuplasty (IDB)

**Ease of Use**
- Direct percutaneous application of the electrodes into the targeted spinal disc
  - enables better targeting
  - reduces complications

**Large Lesion**
- Cooled probes
- Bipolar heating configuration
- Isotherm lines form a dumbbell shape to cover the posterior segment of the annulus fibrosus.
- High probability to ablate culprit nociceptive nerves
- Structures nearby (collagen in the posterior annulus, vertebral end plates, nerve roots) are not damaged
A Few Preliminaries

• Empiric consensus is to use IV antibiotics preoperatively. Evidence for efficacy within the disc is Grade III/IV, but practice is usually standard of care.

• Do not inject contrast, saline or antibiotic solution into the disc. The effects of drug heating and/or adverse effects of intradiscal liquids on Transdiscal system operation have not been studied.

• Patient prone with pillow under abdomen to minimize L/S lordosis. Pad ankles for comfort.

• Local/IV sedation or MAC per physician preference. No GA.
General Safety Guidelines

- Radiopaque band on TD probes is at least 5mm from the posterior edge of the disc.
- For introducer placement, rotate C-arm until SAP bisects disc (about 35° – 45° from sagittal plane for average patient)
- Introducer should pass lateral to superior articular process (SAP) but should not make contact to prevent injury to the z-joint
- TD probe should be placed at centre of disc height to ensure probe is far away from either endplate

![Diagram showing introducer placement and TD probe positioning](image-url)
OR Procedure

- After establishing and marking cephalo-caudal angulation angle, rotate C-arm obliquely (left or right) to place superior articular process approximately 1/3 across the endplate, NOT ½ way, as for discography. Preferred introducer path is closer to the median sagittal plane.

- Mark skin site overlying insertion point and infiltrate local anesthetic.

- Ease trocar insertion by skin puncture with 18 ga needle or scalpel blade insertion (stab).
Procedure Adjustment

- Temperature adjustment to set temp. of 50°C slightly increases lesion size.
- Approach Angle is 35 - 45° from the median to ensure the probes are <2.5cm apart and in the posterior annulus.
- Increased approach angle brings probes close enough to create a confluent lesion across the posterior annulus.
- Without repositioning, monopolar lesions are created around each electrode to heat the posterolateral corners.
  - 35° - 45° approach angle
  - Bipolar lesion at 50°C for 15min
  - Monopolar lesions at 60°C for 2.5min each
1. **Locate Disc Level to be Treated**

- Obtain a true anterior-posterior (AP) view of the disc to be treated. This is confirmed by flat endplates and equal distance between the pedicles and the spinous process.

- Rotate C-arm obliquely until medial border of SAP bisects the disc.
2. **Locate Skin Insertion Site**

- Locate entry target to the disc using a radiopaque tool. Mark the skin insertion site using a marker.
- Inject anesthetic along the introducer tract. Avoid anesthetizing area around the spinal nerve so the patient can respond to any sensation indicating potential injury to the nerve.
3. **Advance Introducer into Disc**

- Maintain the oblique view and advance the introducer to the disc aiming for the middle of the disc height.
- Advance the introducer about 1 cm into the disc. The depth markings on the introducer are spaced apart by 1 cm. In an AP view advance introducer from A to B.
4. **Confirm Introducer Position**

- Confirm introducer position in lateral view. Introducer should be approx. 1cm deep and in the posterior 1/3 of the disc.
- Repeat Steps 2 – 4 on the contra-lateral side of the disc.
5. **Insert Probe into Disc**

- Remove the stylet from the introducer and insert the probe.
- **Note:** Never reposition an introducer without the stylet inserted. Hollow introducer is not sharp or strong enough and may break.
6. **Confirm Probe Placement**

- Confirm depth of probe placement in lateral view. For safety, the radiopaque (RO) band should be at least 50% of the inserted probe length.

- This insertion depth will likely correspond to 1/3 to 1/2 of total disc depth.

### Diagram

- **Radiopaque band of probe**
- **RO band of probe**
- **Disc Depth**
  - 50%
  - 1/3
  - 1/2
7. **Confirm Probe Placement**

- Check probe placement in AP view. The distal tips of the probes should align with the medial border of pedicles. If lateral, advance the probes to the medial border of pedicles.

- Confirm in lateral view again that the probe tips are no deeper than midline of the disc, if adjustments are made.
Final View with Probes
Safety Slide

• During the biacuplasty procedure, subjects should be awake and communicating with the physician conducting the procedure.

• If the subject develops pain radiating to the lower extremities or symptoms which are concordant with heating at the segmental nerve root or cauda equina, the heating protocol should be stopped immediately.

• The physician should re-confirm the location of the electrodes within the intervertebral disc. The procedure can be restarted per the Investigator’s discretion upon confirmation of probe placement; confirmation that the device or its components are not malfunctioning, etc.
8. Perform Bipolar Lesion

- Connect the probes to the Y-cable
- Fasten the luer locks of the probes to the tubings of each tube kit
- Check the lesion setting on the generator is:
  - Set Temperature = 50°C
  - Duration = 15min
- Press the Start button on the Generator to begin bipolar lesion
9. **Perform Monopolar Lesion**

- Check the lesion setting on the generator is:
  - Set Temperature = 60°C
  - Duration = 2.5 min

- Press the Start button on the Generator to begin first monopolar lesion
TransDiscal System During Procedure
Finishing up...

- After procedure completion, remove probe/trocars and discard. Obtain hemostasis, remove residual irritating prep and apply dressing (Bacitracin and bandaids)

- Avoid lumbosacral torsion by placing LSO on patient before log-rolling patient onto stretcher for transfer to PACU.

- Discharge patient with instruction sheet with written activity guidelines, emergency contact information and short course of post-op analgesics.

- Detailed Post-Op Care instructions in appendix
Precautions
Potential Complications

Recorded or known to date: NONE

Introducer Placement Problems:

• Hyperlordosis or tall iliac crests – minimize lordosis while positioning by using pillows – Trocar requires linear path to disc
• Do NOT perform with < 50% normal disc height.
• Do NOT bend trocar nor probes!
Potential Complications

Post-Operative Discitis

• Rare complication. Always use IV antibiotic prophylaxis preop. Effects of heating intradiscal antibiotics NOT known.

• Most common complaint is persistent severe or worsening lumbar pain. May not present with fever, chills, or neurologic changes.

• Symptoms most likely 1-2 weeks post-op, but delayed presentation possible.

• CBC, ESR, CRP only 50% sensitivity.

• MRI-Gd most sensitive.
Potential Complications

Thermal Injuries

- In vivo animal and in vitro human cadaveric studies have demonstrated no injury to the disc, osseous structures, paraspinal musculature, great vessels, cauda equina, DRG, or nerve roots with correct intradiscal probe placement.

- IF one or both probes are not placed correctly, injury due to unwanted heating of these structures is possible.

- The “dumbbell” shaped area of heating has its axis defined by the relative position of the two probe tips. If one or both probes are not placed correctly heating may be ineffective or injurious to normal structures.

- Prevention: Carefully Check probe positions from all views. Do NOT perform with < 50% normal disc height.
Potential Complications

Re-injury to Annulus Post-OP
- Likely associated with increased wall stress events
- Lifting
- Bending/Twisting
- Turning over in bed
- Aggressive, poorly sequenced PT program.
- Trips, slips, falls.

Solutions
- Prescribe graduated activities and specific PT program NOT “Eval. & Treat”
- Use L/S orthosis
THE PAIN STARTS IN MY HUSBAND’S LOWER BACK, THEN IT TRAVELS UP HIS SPINE TO HIS NECK, THEN IT COMES OUT HIS MOUTH AND INTO MY EARS. AND THAT’S WHY I GET THESE HEADACHES.
Thank You
Appendix
Outcomes
A Randomized, Placebo-Controlled Trial of Transdiscal Radiofrequency, Biacuplasty for Treatment of Discogenic Lower Back Pain

- **N = 64 enrolled, 59 treated in 1:1 randomization scheme**
  - Biacuplasty (n = 29)
  - Sham Procedure (n = 30)
  - One and two level disease included
- All patients had positive pain reproduction on discography
- 1, 3, & 6 month follow up
- Outcomes include SF-36, NRS, ODI
- 6 month follow up for all patients
- Study unblinded at 6 months & sham patients allowed to cross over to treatment
A Randomized, Placebo-Controlled Trial of Transdiscal Radiofrequency, Biacuplasty for Treatment of Discogenic Lower Back Pain

Comparative Improvements @ 6 Months*

- **SF36 Function**: 15
- **NRS**: -0.6
- **ODI**: 0.5
- **TransDiscal**: -2.2
- **Sham**: -7.4

* All p < 0.05

Results:
- No procedure-related complications
- Statistically significant improvement @ 6 mths
- 16 mg reduction in daily opioid use

Authors conclude that TransDiscal biacuplasty should be recommended to select patients with discogenic low back pain.
Long term follow up
- 22 active tx (12 mth)
- 20 “cross-over” (6 mth)

Sustained improvements in pain and function

Slight reduction in opioid use

No adverse events

Conclusions: Clinically significant improvements after IDB initially reported at 6 months were maintained at 9 and 12 months. The cross-over subjects had similar improvement in all outcome measures at all observed time points.
N = 67 enrolled, 63 treated in 1:1 randomization scheme

- Biacuplasty (IDB) (n = 29)
- Conservative Medical Management (CMM) (n = 34)

Single level disease confirmed by positive pain reproduction on discography

1, 3, & 6 month follow up

Outcomes include measures of:

- Pain (VAS)
- Function (SF-36)
- Disability (ODI)
- Quality of Life (EQ-5D, PGIC)

CMM subjects could elect to cross-over to IDB + CMM at 6-months, or to continue CMM-alone to 12-months
• **IDB + CMM:**
  - One ablation procedure/patient
  - CMM continued as prescribed by physician

• **CMM for both groups defined as:**
  - Physical Therapy
  - Pharmacological Management
  - Minimally invasion interventions permitted as needed
    - Lumbar-epidural injections
    - Sacro-iliac joint injections
    - Facet-joint or nerve interventions
  - Behavioral Therapy
  - Weight Loss
  - Acupuncture
6 Month Results

- No procedure-related complications
- Statistically significant improvement in pain @ 1, 3, & 6 mths
- Trends indicating functional improvement
- 50% Responder rate (2 point/30% decrease in VAS) vs 18% in CMM group
- 42% of IDB group had >50% reduction in pain at 6 month time point

Conclusion: Superior performance of IDB with respect to all study outcomes suggests that it is a more effective treatment for discogenic pain than CMM-alone.
Main Inclusion Criteria

- Completion of the 6-month follow up of the original effectiveness study
- Consent to continue follow up for additional 6-month following either IDB after crossing over or remaining in CMM group

Main Exclusion Criteria

- Major deviations from protocol criteria
  - 22 active tx reported 12 mth data
  - 25/28 available chose to crossover
  - 22/25 Crossovers reported 6 mth data
IDB: 55% Responder Rate (>2 points VAS or 30% decrease) vs. CMM: 18% at 12 months
41% of IDB group maintained >50% decrease in pain at 12 months
Crossover group responded the same to treatment as originally treated group
Long-Term Results (12-Months) of a Prospective, Multi-Center, Open-Label Clinical Trial Comparing Intradiscal Biacuplasty (IDB) to Conventional Medical Management (CMM) for Discogenic Lumbar Back Pain (LBP)

Originally Treated Subjects – Quality of Life

Graphs showing the quality of life data for originally treated subjects over 12 months. The graphs compare DISC BIACUPLASTY and MEDICAL MANAGEMENT for PGIC and EQ-5D. The data shows a decrease in PGIC from baseline to 1 month and then an increase to 12 months for both treatments, with DISC BIACUPLASTY showing slightly better results overall.

Baseline 1 Month 3 Months 6 Months 12 Months
DISC BIACUPLASTY MEDICAL MANAGEMENT

PGIC
Baseline: 4.3
1 Month: 2.8
3 Months: 2.4
6 Months: 2.8
12 Months: 2.9

EQ-5D
Baseline: 0.57
1 Month: 0.56
3 Months: 0.58
6 Months: 0.57
12 Months: 0.56

MCID = +0.074

Presented at ASRA 2015 (http://epostersonline.com/asrapain2015/node/392, Poster 1106)
Clinically relevant improvements in Pain, Function and Quality of Life maintained through 12 month time point

All metrics reflect similar, consistency message. The outcomes of this study suggest that:

• IDB + CMM more effectively reduces discogenic LBP than CMM, and can rescue individuals who continue suffering from discogenic pain despite of CMM
• IDB + CMM enables better physical functioning, less disability, and a greater positive impact on patients’ health when compared to CMM-alone
• The positive effects of IDB + CMM are durable, lasting up to 12-months after a single IDB treatment

The superior performance of the IDB + CMM treatment with respect to all study outcomes suggests that IDB + CMM is a more effective treatment for discogenic LBP than CMM-alone for carefully selected patients
Case series (n=15)

- Pain > 6 months & positive discogram

6 Month Visit
- 57.1% had > 50% pain relief
- 78.6% had > 10 point ODI improvement

No complications
N=15

• Previously denied IDET
• MRI and discography within 12 months
• Pain > 6 months
• One or two level concordant pain reproduction on discography

• Patients followed >6 months
• Follow-ups 1, 3, and 6 months after procedure
• Computerized questionnaire before visit
• Outcomes include:
  – Oswestry
  – SF-36
  – VAS
  – opioid use
Intervertebral Disc Biacuplasty for the Treatment of Lumbar Discogenic Pain: Results of a Six-Month Follow-Up

Careful selection of the patients may significantly improve the success rate for biacuplasty.

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TransDiscoal Biacuplasty Basic Science
Intervertebral Disc Temperature Mapping During Disc Biacuplasty in the Human Cadaver

Mehul J. Desai, MD, MPH¹, Jeremy Ollerenshaw, PhD², Robert Harrison, MA³, Laura Yu, PhD², Puneet Sayal, MD⁴, Tyler Crone, MS², and Alan Dine, BSN²

Purpose

• To map the intradiscal and peridiscal temperatures when intradiscal biacuplasty (IDB) was performed at increased temperature using a modified lesion approach.

Methods

• Three (3) explanted spines from human cadavers
• Eleven (11) lumbar discs in a non-perfused human cadaver were treated by IDB.
• Temperature profiles in the disc during bipolar lesion at 50°C followed by 2 monopolar lesions at 60°C were mapped using custom thermocouples. Temperatures inside the disc, at the nerve roots, and in the midline ventral epidural space were monitored in real-time using a data-collection system with custom radiofrequency filters.

Results

• Higher maximum temperature was reached intradiscally, and a larger volume of tissue was exposed to neuroablative temperature (> 45°C).
• Temperature at the nerve roots and in the epidural space increased by 2.4°C ± 2.6°C and 4.9°C ± 1.9°C (mean ± SD), respectively, during bipolar lesion.
• Similarly, temperature increased by 2.2°C ± 1.9°C and 0.8°C ± 1.3°C at the nerve roots and in the epidural space, respectively, during monopolar lesion.

Conclusion

The modified treatment paradigm showed intradiscal heating is achieved and is concentrated in the posterior annulus, suggesting minimal risk of thermal damage to the neighboring neural structures.
Cleveland Clinic – Disc biacuplasty study using explanted human lumbar spines.

- Determined parameters (Ramp rate = 2° C/min, Set temp = 40° C, Duration = 12 to 18 min)
- Verified safety to endplates and neural structures posterior to disc
Histological Changes and Temperature Distribution Studies of a Novel Bipolar Radiofrequency Heating System in Degenerated and Nondegenerated Human Cadaver Lumbar Discs

Kapural et al. 2008 Pain Medicine (9): 68-75
• *In vivo* porcine model
  – n = 7 discs (2 animals)
• Temperature monitoring in central annulus & designated “safety zones”
• Histopathology
• Suitable temperature for thermoneurolysis with no damage in safety zones

Peng’s Study

- 21 discs 15 patients with discogenic pain
- 16 aging discs without low back pain
- 10 normal discs-control
- Histopathologic features, basic fibroblast growth factor (bFGF)
- Transforming growth factor-1 (TGF-1)
- macrophages and mast cells distribution

- Painful discs-in growth of vascularized granulation tissue along fissures, extending from the external layer of the annulus
- Pain-strong expressions bFGF and TGF-1 and their receptors
- Pain-Abundant macrophages and mast cells in the granulation zones which was absent in the nongranulation tissue zones of painful discs or aging/control.

• Unclear

• Two hypotheses:
  1. Denervation of the tissue or destruction of the overgrowth of nociceptors
  2. Change the structure of the collagen fibers in the annulus, causing an increase in annular stability

• Histological studies involving IDET did not support these two hypotheses

Denervation

- Number of nerve endings in the experimentally induced annular tear in sheep were counted.

- 18 months after IDET, the number of nerve fibers identified in the posterior annular tear was the same for those specimens that had undergone IDET and those that did not (Freeman et al 2003)

- Irreversible nerve blocks occur at 45 degrees Centigrade in all types of nerve fibers (Smith et al 1981)


The optimal temperature for collagen contraction is 65ºC.

60ºC - lowest temperature at which hydrogen bonds start to break.

No significant increase in shrinkage rate over 75ºC.

Thermal shrinkage also dependent on the duration of the application of heat.

Lower temperatures (60-75ºC), longer time comparable to higher temperature over shorter time.

Post-Operative Care and Rehabilitation
Patient Discharge Instructions

You have recently undergone a procedure called disc biconuloplasty to treat your lower back pain. It was performed on your spinal disc level. Because the procedure involves accessing and heating your spinal disc, it is normal to feel some pain and discomfort at the site of the procedure for about a week or two. Your pain will decrease over time. Using ice packs at the procedure site and taking analgesic medication (medication that temporarily alleviates pain) may decrease your discomfort. However, to ensure optimal recovery and to reduce the chances of further injury, it is important to adhere to the guidelines listed on the following pages.

Once the Procedure is Over, You WILL:

- Go to a post procedure observation room for approximately one hour
- Wear a back brace
- Get a ride home in a reclined position – do not drive after the procedure
- Avoid bending or twisting your back
- Avoid lifting or any other exertion
- Leave your bandages on for 24 hours

During the First 24 Hours, You WILL:

- Feel discomfort and pain at the procedure site. This is normal and will decrease after the first or second week
- Refrain from driving
- Avoid soaking in the bathtub, but showering is okay
- Rest in a reclined position or lying down
- Limit sitting up straight or walking to 10 minutes at a time
- Continue pain medication according to your doctor’s instructions
- Always wear your back brace, except when sleeping or showering

Side Effects

Disc biconuloplasty is a minimally invasive procedure, and side effects are extremely rare. However, if you experience any of the symptoms below, please consult a physician immediately.
Routine Post-Biacuplasty Care

- Written post-op instructions
- 1-2 weeks oral opiate analgesics, then NSAID’s. Muscle relaxant optional.
- LSO - 24x7 x 6 weeks
- L/S functional restoration program
- Education to prevent re-injury
- Return to work or usual activities
Written Post-Op Instructions

• Activity restrictions/guidelines
• Use of orthosis
• Emergency telephone numbers
• Appointment date for follow-up
• Post-op Rx for expectable ache/pain
• Adjunctive ice/heat
• Warning signs of post-op complications:
  • Stiff neck
  • Increasing pain
  • Lower extremity paresthesia
  • Motor deficits
  • Bladder or bowel dysfunction
  • Wound site drainage
Post-Op Orthosis Use

• California LSO tolerated well

• Ask Orthotist to carefully fit with about 15 deg of lordosis

• Patient to bring orthosis to OR for post-op use.

• Orthosis is removed briefly for personal hygiene activities – patient is NOT unstable.
Goals of Functional Rehabilitation after Biacuplasty

- Protection of lumbar spine and prevent injury
- Control pain and reduce inflammation
- Early supervised stretching and mobilization of tissue
- Achieve functional restoration by addressing extensor deconditioning by timely implementation of therapeutic exercise
- Address abdominals, trunk rotator and trunk/hip flexors which may be deconditioned.
- Avoid manual manipulative therapy
Week 1:
- Short periods of walking after procedure
- No driving
- 10 lb lifting limit only

Week 2:
- Gentle stretches
- Lifting restrictions of 20-40 lb x 12 weeks
- Avoid strenuous activity, twisting or sustained flexion
- Option to begin gentle lumbar stabilization exercises with neutral bias and abdominal strengthening
- Instruct therapist to avoid truncal rotation
- NO manual therapy
Weeks 3 - 4:

- Therapist guided stretching, strengthening, ROM. Begin neutral-biased dynamic stabilization program. May remove orthosis during PT sessions.
- Limit L/S flexion to 40° and torsion to 30° during these weeks.
- If not well tolerated in 1st sessions, may convert to aquatherapy based program.
- Minimize driving – < 30 min. only.
Functional Rehabilitation Program

Weeks 5 – 6:

• Progressive strengthening, endurance exercises.
• NSAID PRN
• Education to avoid re-injury.
Weeks 6 – 8:

- Advance physical therapy to dynamic lumbar stabilization as tolerated with limited truncal rotation.
- Exercise may include swimming, bicycling and supervised aerobic exercises.
- Discontinue use of orthosis.
Summary

- Cooled RF is a versatile tool

- Literature basis for cooled RF is strong and growing

- Halyard Health remains committed to the support and encouragement of scientific activity