SInergy™ System Refresher Course

Sept, 2008

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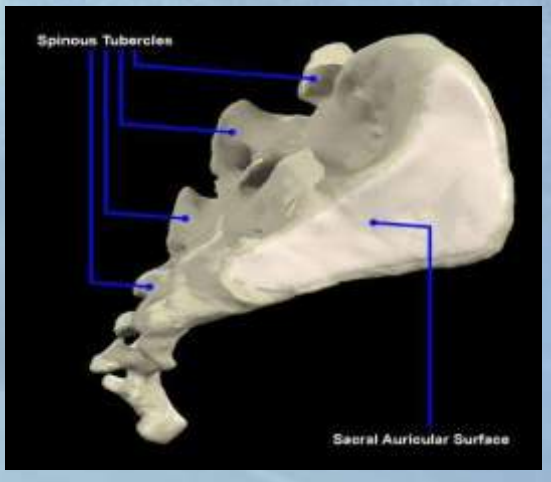
ANATOMY

A/P View - Sacrum

Lateral View - Sacrum

Posterior



Anterior

A/P View of Superficial SI Ligaments

Sacroiliac Joint

- Often referred to as the SIJ
- Largest axial joint in the body with an average area of 17.5 cm^3. Rotates around three axes [2]
- Synovial joint meaning the surface between the ilium and sacrum is lubricated for smooth movements [2]
- However these movements are very small with the total range of motion of the joint rarely exceeding two degrees

Sacroiliac Joint

- Its functions include:
  - Providing support and stability to the vertebral column[1,2]
  - Strength and stability to the pelvis [1,2]
  - Transferring weight from the upper body to the lower body [1,2]

1Cohen S. Anesth Analg. 2005: 101: 1440-1453
2Yin W. et al. *Spine*. 2003; 28(20):2419-2425

Sacroiliac Joint

- Extensive ligamentous structures function to connect the ilium to the sacrum and to limit motion in all movement planes [1,2]
  - Interosseous Ligament: thick ligament connects the ilium to the sacrum in an area directly above the joint posteriorly
- Network of muscles in the area help to deliver muscular force to the pelvic region [2]
- Some attach directly to the SIJ ligaments and affect mobility.
  - e.g. Gluteal muscles

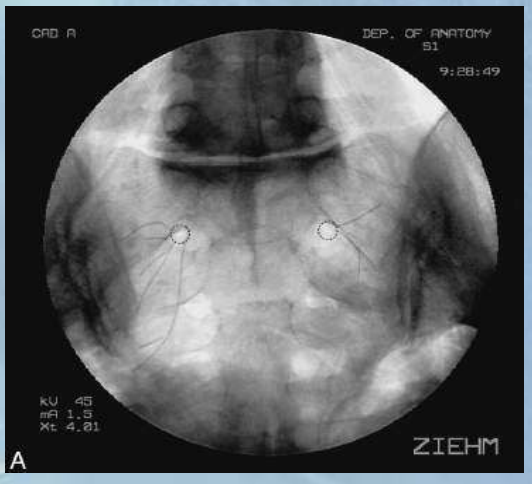
1Cohen S. Anesth Analg. 2005: 101: 1440-1453
2Yin W. et al. *Spine*. 2003; 28(20):2419-2425

SI Joint Innervation

- There is no established consensus on the innervation of the SIJ. Due to a limited number of studies
- Most recent anatomic studies suggest the following:
  - Joint is predominantly, if not entirely, innervated by *posterior primary rami*[1,3,4]
  - Innervation is from the L5 dorsal primary ramus along the sacral ala and from the S1 – S3 lateral branches exiting the posterior sacral foraminal apertures (PSFA)[1]

[1]Cohen S. Anesth Analg. 2005: 101: 1440-1453
[2]Yin W. et al. *Spine*. 2003; 28(20):2419-2425
[3]Grob K. et al. *Z Rheumatol.* 1995;27:117-122
[4]Fortin J. et al. *Spine*. 1994;19(13):1475-1482

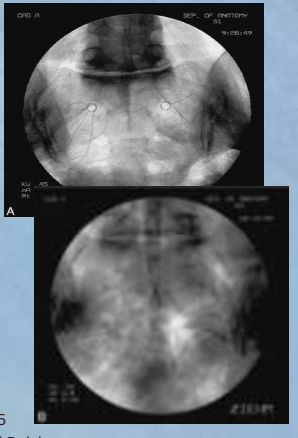
SI Joint Innervation



[2]Yin W. et al. *Spine*. 2003; 28(20):2419-2425

SI Joint Innervation

- The running course of lateral branch nerves is *variable* (like the bony anatomy of the sacrum) from individual to individual, and from an individuals left to right side [2,5]

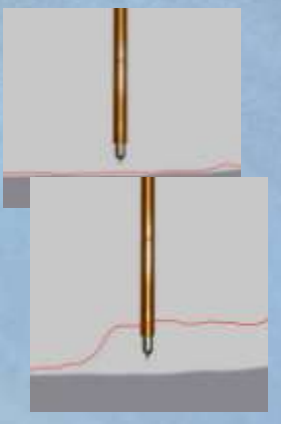


[2]1998[2] Yin W. et al. *Spine*. 2003; 28(20):2419-2425

[5] Willard F. et al. *World Congress on Low Back and Pelvic Pain*. Vienna, Austria

SI Joint Innervation

- Up to 10 mm from the lateral edge of the PSFA, lateral branch nerves lie in the depth between the bony sacral surface and 8 mm superficial to that surface [2]



[2] Yin W. et al. *Spine*. 2003; 28(20):2419-2425

SI Joint Innervation

• Lateral branch nerves exit the S1 – S3 PSFA in windows between 2 o'clock and 6 o'clock on the right and 6 o'clock and 10 o'clock on the left [5]

• No other correlation linking the location of lateral branch nerves to bony landmarks on the sacrum has been reported [2]

[2] Yin W. et al. *Spine*. 2003; 28(20):2419-2425

[5] Willard F. et al. *World Congress on Low Back and Pelvic Pain*. Vienna, Austria, 1998

Summary- Anatomy

- Realistically, RF procedures can only lesion nerves on the posterior side of the sacrum
- Since the SI joint is predominantly innervated by posterior primary rami there is potential for a RF application

PATHOLOGY

Pathology

Characteristics: SI Joint Syndrome

- Pain in the region of the SI joint with possible radiation to groin, medial buttocks and posterior thigh
- Tenderness overlying the posterior joint
- An otherwise normal joint without demonstrable abnormalities
- Made worse by sitting upright for extended periods of time

1Cohen S. Anesth Analg. 2005: 101: 1440-1453
2Yin W. et al. *Spine*. 2003; 28(20):2419-2425

Pathology

Prevalence:

- Intra-articular SIJ Pain in patients with chronic low back pain is 15% to 30%[6,7]
  - Probably more when you include extra-articular (ligamentous) pain
- Compared to prevalence of lumber facet joint syndrome:
  - 15-40% of mechanical low back pain[8]
- There is no surgical treatment option for SIJ syndrome (no fusions)
- Large patient population that is not well studied

[6]Maigne JY, et al. *Spine*. 1996; 21(16):1889-1892
[7]Schwarzer A, et al. *Spine*. 1995; 20:31-37
[8]Schwarzer A, et al. *Ann Rheum Dis*. 1995;54:100-106

Pathology- Summary

- 15-30 % of chronic low back pain is attributed to SIJ Syndrome
- Pain originates in the SI joint and/or surrounding connective tissues

Diagnosis and Patient Selection

Patient Selection

Inclusion Criteria

- Positive clinical pain presentation
  - Pain in the SIJ region and radiating into the buttock, groin, or thigh areas
- Primary pain symptoms limiting functional capacity, preventing return to work, or interfering with activities of daily living
- All conservative therapies have been exhausted. i.e. pharmacological, exercise/physio, etc.
- Demonstrated pain relief after two controlled intra-articular anesthetic injections

Patient Selection

Exclusion Criteria

- Evidence of lumbar or sacral radiculopathy
- Evidence of other neurologic, vascular, or diffuse rheumatologic disease
- Spondylolisthesis at the L5/S1 level

Diagnosis

- Biggest challenge of SIJ Pain is the complexity of diagnosis
- "Pure" SIJ Pain is very difficult to diagnose because it is frequently associated with referred pain from other structures
- Some patients treated for SIJ Syndrome will have multiple sources of pain. i.e. Discogenic pain, Facet Joint Pain, etc,
  - Some combination pain is generally expected by the physician
  - Comparative blocks may need to be conducted in order to rule out other sources of pain

[1]Cohen S. Anesth Analg. 2005: 101: 1440-1453
[2]Yin W. et al. *Spine*. 2003; 28(20):2419-2425

Diagnosis

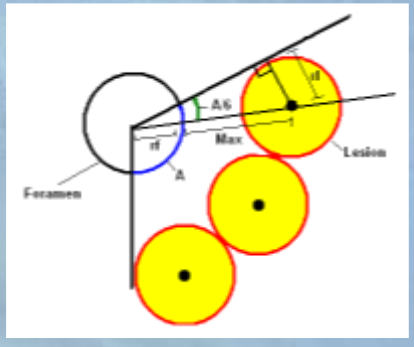
Controlled Diagnostic Blocks

- Anesthetic intra-articular SI joint block is the best diagnostic method currently available
- This method yields the 20% prevalence, but may underestimate total prevalence, as it only diagnoses intra-articular SI syndrome and does not account for ligament and muscle involvement
- However, there is no "gold standard" for diagnosing SIJ Pain

Summary

- No novel diagnostic procedure required
- SIJ Syndrome is diagnosed by clinical presentation and positive response to controlled intra-articular block(s)

Required Lesion Geometry



Sacroiliac RF Lesion Requirements

- Level L5
  - Lesion the primary dorsal ramus at sacral ala
- Level S1, S2, S3
  - Lesion all lateral branches as they exit foramen

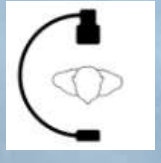
Sacroiliac RF Lesion Requirements

- Spherical lesions are positioned such that all lateral branches are targeted
- At S1 and S2, lesions are made at 2 o'clock, 4 o'clock and 6 o'clock
- At S3, lesions are made at 12 o'clock and 3 o'clock
- At L5 one lesion is made along the sacral ala jest lateral to the S1 SAP

SInergy™ Procedure
Step by Step at Level S2

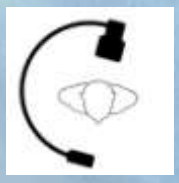
RF Procedure- Step 1

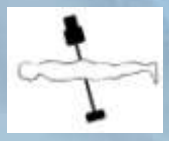
- Image through the L5/S1 Disc



RF Procedure- Step 2

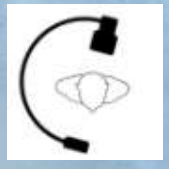
- Rotate the image 15° ipsilateral to identity the foramen

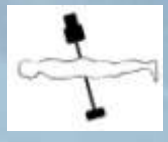




RF Procedure- Step 3

- Place a spinal needle (25Ga) along the lateral wall of each sacral foramen (S1-S3)



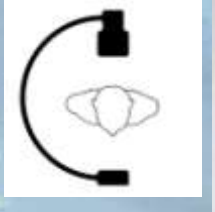


RF Procedure- Step 4

- Confirm transforaminal needle placement with a lateral fluoroscopy image

RF Procedure- Step 5

- Return C-arm to an A-P view. Direct the introducer “down the beam” towards the target

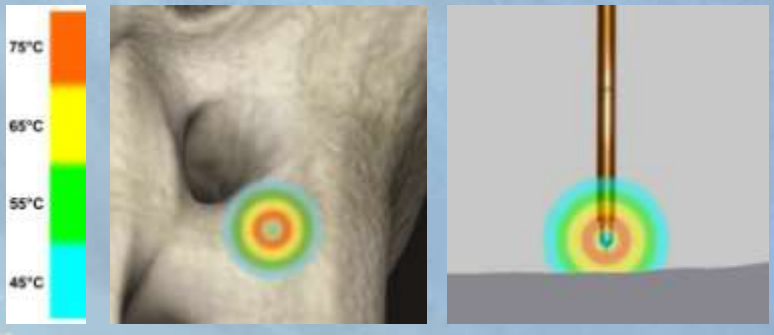


RF Procedure- Step 6

- Remove stylet, insert probe, verify impedance reading < 500 Ω

RF Procedure- Step 7

- Create lesion using Baylis PMG



RF Procedure- Continued

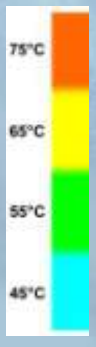
- Remove probe, replace stylet. Repeat steps 5-7 for the second target site.

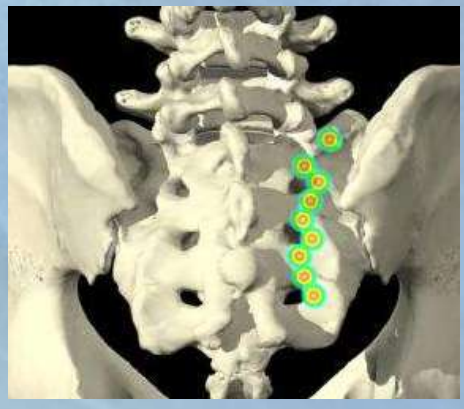
RF Procedure- Continued

- Remove probe, replace stylet. Repeat steps 5-7 for the final target site. Repeat for S1, S3, L5.

RF Procedure- Summary

- Nine lesions required to capture all lateral branches and the L5 dorsal ramus





Pain Management SInergy™ System Components

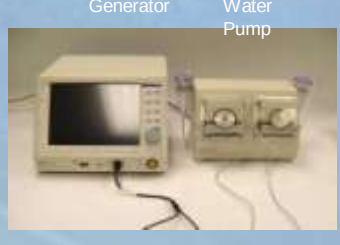
Baylis MEDICAL — SInergy™ System Components

SI Kit Catalogue Numbers

- SIK-17-75-4
  - 1 Pain Management SI Probe (SIP-17-75-4)
  - 2 Pain Management SI Introducers (SII-17-75)
  - 1 Pain Management Tube Kit (TDA-TBK-1)
  - 1 Dispersive Electrode (PMA-GP-BAY)
- SIK-17-150-4
  - 1 Pain Management SI Probe (SIP-17-150-4)
  - 2 Pain Management SI Introducers (SII-17-150)
  - 1 Pain Management Tube Kit (TDA-TBK-1)
  - 1 Dispersive Electrode (PMA-GP-BAY)

Baylis MEDICAL — SInergy™ System Components

- Pain Management Generator (V2.2 Advanced)
  - PMG-115-TD
- Pain Management Pump Unit
  - TDA-PPU-1
- Cooled RF Connector Cable
  - CRX-BAY-CRP
  - PMX-19-14 (V3.0)



System Set-Up

Pain Management Generator

Pump Unit

Connector Cable

Tube Kit

Grounding Pad

SInergy™ Probe

PMG V2.2

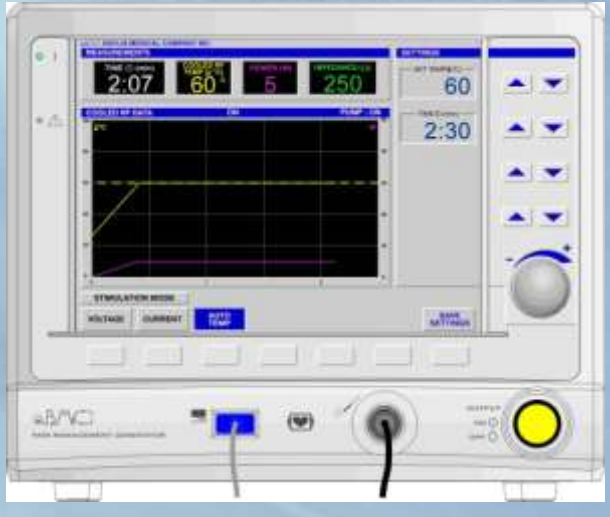
Treatment Mode

The following settings should be saved in Cooled RF mode on the PMG

Auto Temp

- Set Temp (°C) = 60
- Time (min) = 2:30

Treatment Mode



Advanced Settings

The following settings should be saved in the Advanced Settings on the PMG

Cooled RF Settings

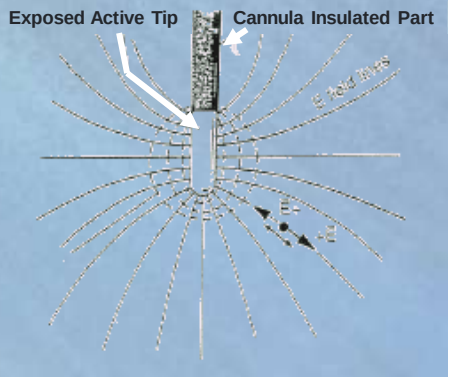
- Ramp Rate = 80°C/min
- Post Treatment Cooling = Disable
- Number of Probes = 1
- Power Limit (W) = 12

Advanced Settings

Physics of Cooled RF

Ionic Heating of Tissue Using RF Cannula

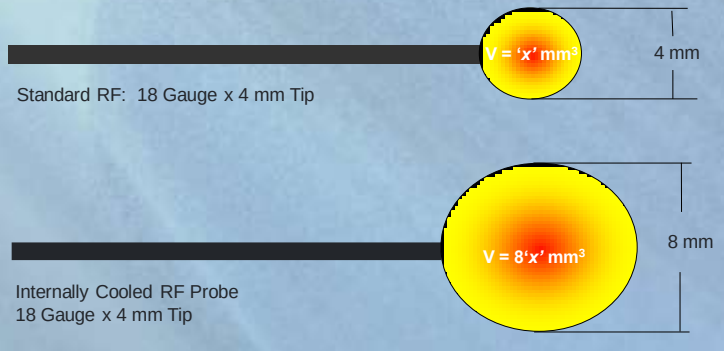
- RF energy is applied
- Ions in surrounding tissue move creating friction
- Friction heats surrounding tissue
- Hot tissue heats probe or electrode by conduction
- Probe thermocouple located at the tip, reads tissue temperature



Ionic Heating of Tissue Using Cooled RF

- Without cooling, the size of lesion is limited by the heat generated in the tissue adjacent to the electrode
- It is not desirable to raise tissue temperature above 95° C
- Cooling the tissue adjacent to the electrode allows effective heating at a greater distance

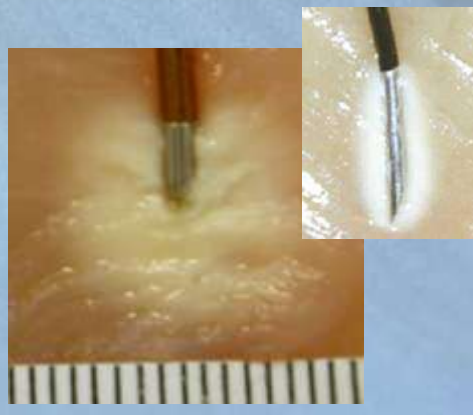
Ionic Heating of Tissue Using Cooled RF



- Internal cooling doubles the lesion radius and increases the lesion volume by a factor of 8

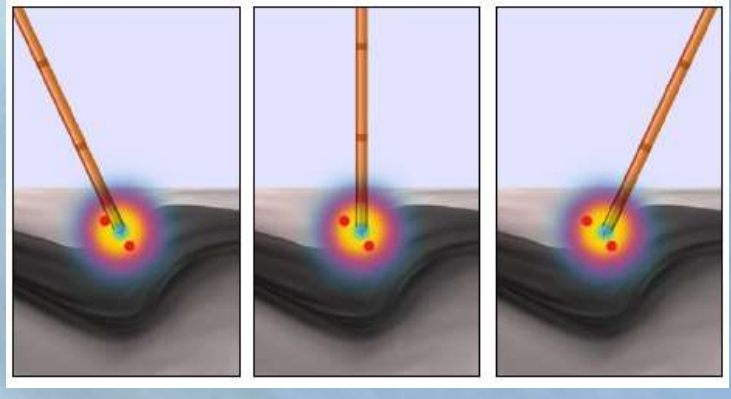
Spherical Lesions

- Internal cooling and small (4mm) active tip size combine to project the lesions distally in a controlled and repeatable manner (8-10mm).
- Lesion will form around bony geometries and can penetrate grooves and crevices



Temperature controlled monopolar electrode produces uniform, *spherical* lesions in non-homogeneous tissue. (ie. ligaments, crevices, fascia)

Perpendicular & Oblique Placement



- Allows for perpendicular or oblique probe placement near the treatment site, due to spherical lesion shape.