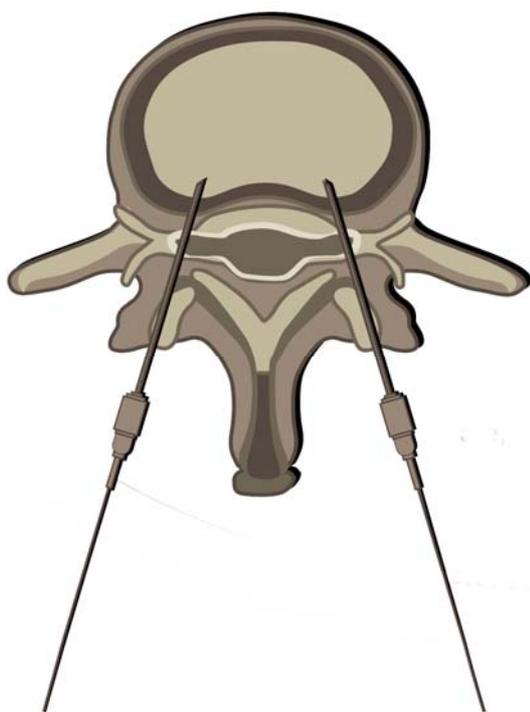


NeuroTherm[®] Diskit II

The Diskit II is developed for treating discogenic pain in the lumbar (and thoracic) region. The diagnosis should be made first by anamnesis and physical examination (low back pain with(out) unilateral or bilateral ischialgia, provocation by cumulative loading, sitting intolerance, pain on (de)flexion, no severe neurological deficit, tenderness over the spinous processes at the painful level(s)). Next the diagnosis must be confirmed by MRI scan and preferentially by discography. Before performing discography other nociceptors like the facet joints, the SI joint and the hip joint should have been diagnosed and treated.



Principle

The Diskit II is composed of two straight sharp insulated needles of 15 or 20 cm length with active tips of 20 mm; the proximal end of the active tip has a radiopaque marker.

Also, two thermocouple electrodes of suitable length (15 or 20 cm) are in the kit. These are needed for electrostimulation and making the (P)RF lesion bilaterally in the annulus.

After placing the needles in the annulus bilaterally in the disc under fluoroscopic control, electrostimulation with 2 and 50 Hz until 2 Volts is performed, injection of a mixture of half/half local anesthetic and dye is administered, and a RF dual lesion with conventional heat or a pulsed RF treatment is performed. Note: the ground plate is used only during electrostimulation and not during the dual electrode procedure whether thermal lesion

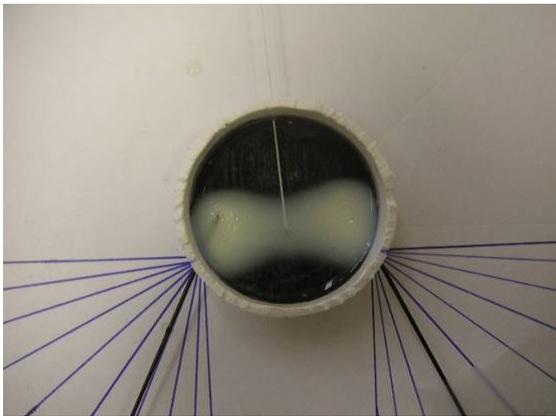
or pulsed RF mode is selected.

In conventional RF Lesion Mode, the lesion is created only around the electrode tip. The NeuroTherm NT1000 /1100 generator has the unique algorithm called Dual Electrode; one electrode is active and the other functions as the ground plate. The ground plate on the skin is only used for electrostimulation prior to applying the treatment radiofrequency. Since the electric field takes shape in between both electrodes, the RF heat lesion and the electric field is not only developing around the electrode tips but, also, in the tissue found between the two active tips. The resulting treatment potential may influence the interior portion of the disc by denervating nerve endings in the annulus believed to exacerbate the pain experience, initiate an autoimmune response within the disc and possibly inducing healing processes.

The NeuroTherm NT1000 /1100 generator has the unique algorithm called **Dual Electrode**; one electrode is active and the other functions as the ground plate. The ground plate on the skin is only used for electro stimulation prior to applying the treatment radiofrequency. Since the electric field takes shape in between both electrodes, the RF heat lesion and the electric field is not only developing around the electrode tips but, also, in the tissue found between the two active tips.

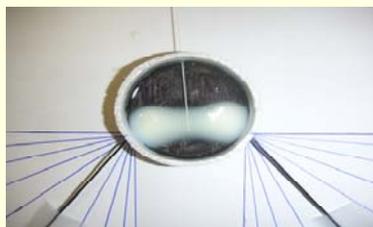
If the heat and/or the electric field is applied on the 2 electrodes the lesion should also develop in between them, thereby also reaching the posterior part of the disc. In fact other sophisticated and more expensive devices like discrode and the IDET were developed to be able to reach the posterior part of the disc, the diskit II is developed to reach this goal in a simple safe and easy way.

To test the concept in the Neurotherm laboratory the actual disc was simulated by using a round polystyrene cup with a diameter of 45 mm. This cup was filled with egg white to a height of 5 mm. The egg white was at a temperature of approx. 37°C to start with.



After a 3 min 90grC dual lesion with the diskit electrodes in the lateral position of the egg white cup the central temperature reached 65grC, making it plausible that with placement of lateral electrodes in the disc also a clinical effect could be achieved in the middle of the disc.

Dual electrode lesion laboratory NEUROTHERM 2005



Disc simulation

To simulate the actual disc we use a round polystyrene cup with a diameter of 45 mm. This cup is filled with egg white to a height of 5 mm. The egg white will be at a temperature of approx. 37°C to start with.

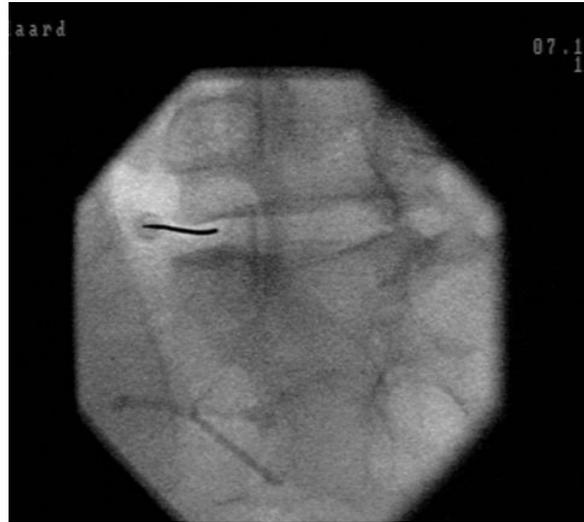
Technique

X-Ray View

The patient is in the prone position with a pillow under the abdomen and with AP fluoroscopic control the disc level to be treated is identified. In a slightly oblique view (15-20°) the lateral part of the disc is made visible and with rotation in the sagittal plane the disc space is projected in its optimal height.

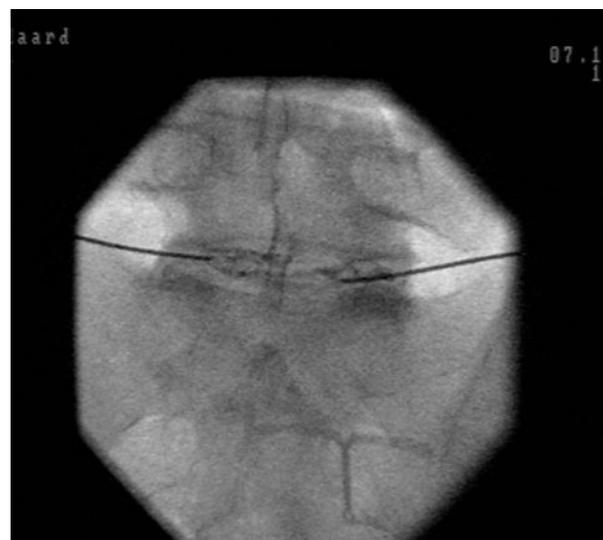
Needle Placement

The entry point of the skin lies a little more medial compared to the entry point in discography (mostly 6-7 cm out of the midline), whereas, in discography the needle tip must be placed in the nucleus, the Diskit II electrode must be placed in the annulus.



If necessary the patient may have a little conscious sedation (propofol or alfentanil or midazolam) and local anesthetic is injected into the skin in the presumed needle trajectory. With the fluoroscopic tunnel vision technique (the direction of the needle is the same as the direction of the X-ray beam) the needle tip is aimed just lateral of the superior articular process of the facet joint, inferiorly passing the segmental nerve and trying to avoid contact with it.

The needle must be brought into the disc straightforward without bending it. Generally, one feels a loss of resistance phenomenon once the annulus is entered. In the lateral fluoroscopic view the needle tip must be positioned into the ventral part of the disc, but not penetrating its boundaries. The proximal end of the active tip of the needle (20 mm) is fluoroscopically marked, in order to confirm that the total length of the active tip is in the annulus. The second needle is placed contra laterally in the disc in the same way.



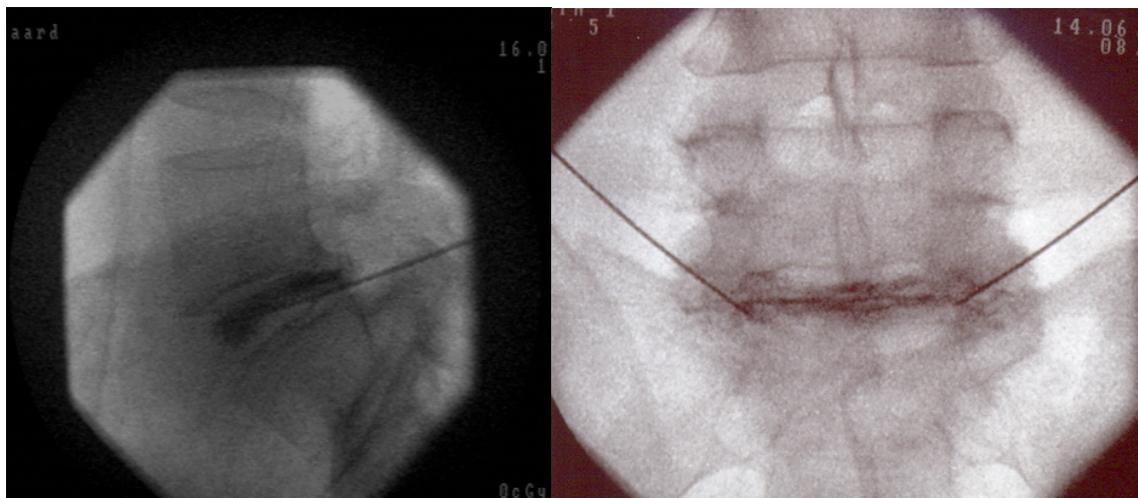
RF Generator Set Up

The stylets of the needles are removed and the electrodes are placed for electrostimulation. In the NT 1000/ 1100 RF Generator, simply select the Thermal Lesion by pressing the green Thermal Lesion box on the right hand side of the display in the **"Procedure Setting"** Screen. Under the drop down for **'Step'** select **'Custom 1, 2, or 3'** press **"Accept"** or 'Dual Electrode' Pulsed RF Modes. (For setting up the step profile please refer to Custom profile set up)

With 50Hz (sensory) and 2Hz (motor) stimulation until 2V, the thresholds are determined, confirming the presence or absence of neural tissue in the annulus, in several cases causing a concordant stimulation.

The impedance at each side is displayed on the RF generator screen. The NT 1000/1100 will automatically choose the electrode with the highest impedance as the active one, because at that side the chosen lesion temperature will be reached first while the other side will function as the ground plate and the temperature at that side will be lower.

After communicating with the patient through each needle disco/annulography stimulation threshold, inject about 2 ml of a mixture of lidocaine 2% and dye to confirm the anatomical conditions and provocation of the discogenic pain.



Custom Step Profiles

The custom step profile facility gives the user the ability to create three lesion profiles. Custom step profiles are only supported by single electrode or dual Electrode. The NT1100 defines a step profile using the following variables:

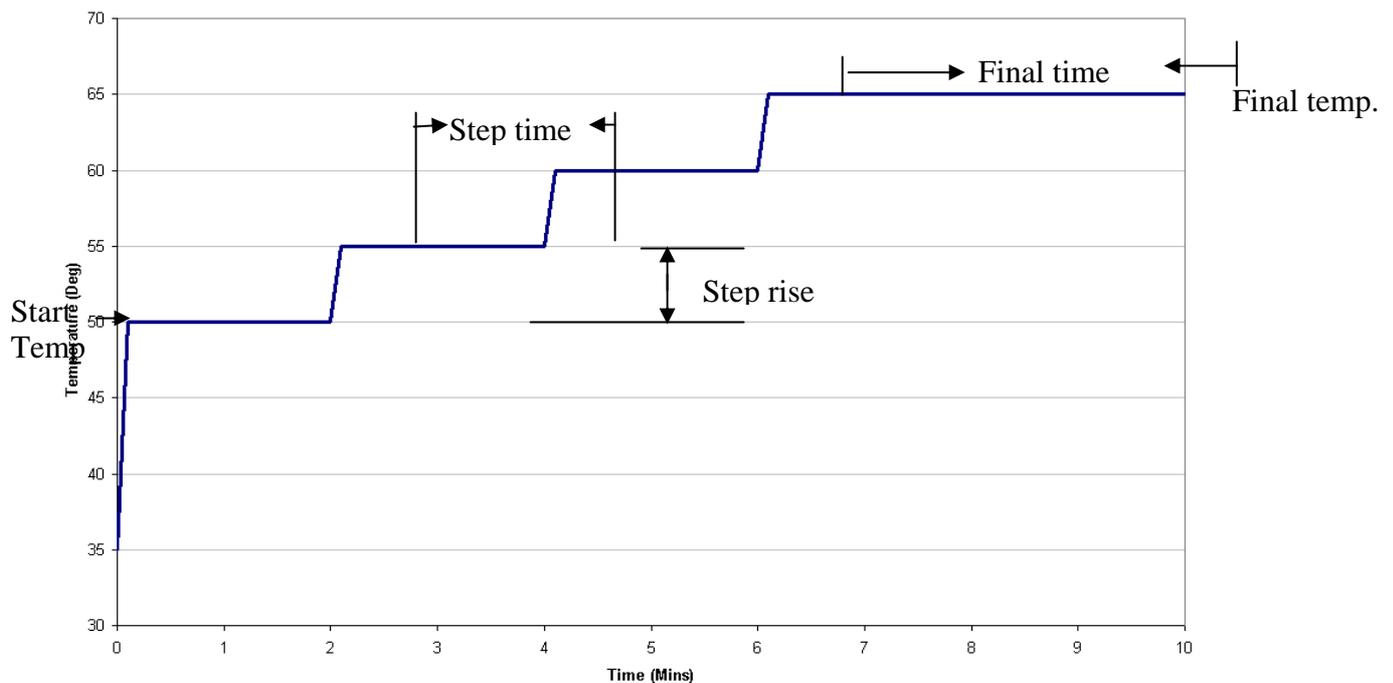
Start Temperature: The initial temperature in degrees centigrade that the profile should hold before the making the first step rise.

Step Time: The time in minutes the profile should hold at each step temperature.

Step Rise: The increase in Temperature in degrees centigrade of each step.

Final Temperature: The temperature in degrees centigrade that the profile should hold at after the last step rise.

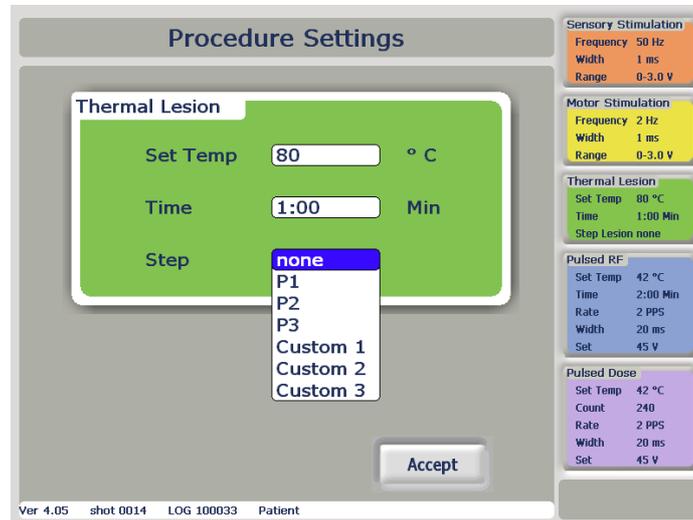
Final Time: The time in minutes that final temperature is held at before the end of the lesion for this example we will create a custom step profile of the following:



From the graph, the key profile variables are identified as:

Start Temperature: 50°C
 Step Time: 2 Mins
 Step Rise: 5°C
 Final Temperature: 65°C
 Final Time: 4 Mins

- To access the custom step lesion firstly access the Thermal Lesion by pressing the green Thermal Lesion box on the right hand side of the display in the "Procedure Setting" Screen. Under the drop down for 'Step' select 'Custom 1, 2, or 3' press "Accept"



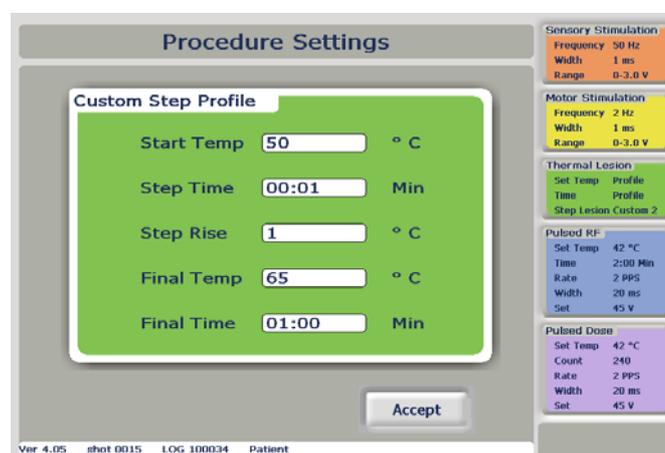
Settings available

(The Bold Numbers are the Default settings)

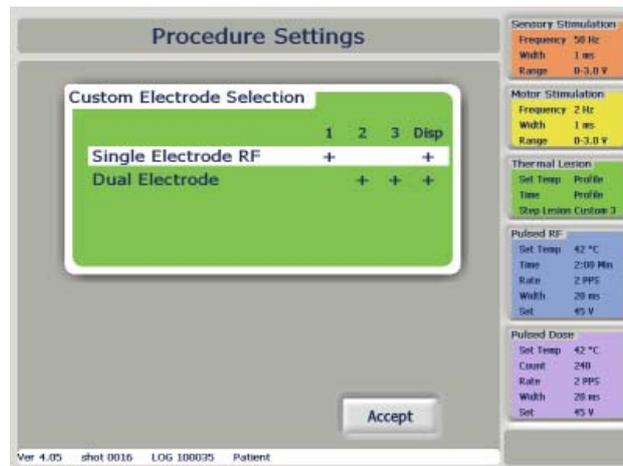
- Start Temp [50,55,60°C]
- Step Time [0.01 0:10,0:30,1:00,**2:00**, 3:00 Min]
- Step Rise [1,**5**,10°C]
- Final Temp [**65**,70,75,80,85,90°C]
- Final Time [1:00,2:00,**4:00**,6:00,8:00,10:00 Min]

For use with the Diskit programme start temp at 60 degrees, step time is 2 minutes, step rise is 10 degrees, final temperature is 80 degrees and final time is 6 minutes

- This will give the user a menu for custom step profile for the Thermal lesion. Use the dropdown boxes to enter the profile variables **Start Temperature: 50°C, Step Time: 00.01 Min, Step Rise: 1°C, Final Temperature: 65°C, Final Time: 1 Min**. When completed press 'Accept'



3. The user will then be given a menu which requires a selection of the electrodes For this example we will select ‘**Single Electrode**’ RF, and press ‘**Accept**’ (for the diskit select dual electrode)



4. The user will then be returned to the “**Procedure Setting**” screen. To then progress sensory and motor tests press ‘**Accept**’. When ready to perform the lesion, press the

 button. Then press the ‘**Auto Start**’  When complete, a tone will sound and power will be removed from the NT1100.

Pulsed RF Treatment

The ‘Dual electrode’ option is selected in the NT 1000/1100. Using this RF modality, the ground plate is required. Pulsed RF parameters should be set at:

Frequency: 2Hz
 Pulse Width: 10 ms
 Amplitude: 60V
 Max. Temperature: 50°C
 Set Total Time: 10 minutes.

Post-Procedure

When the procedure is terminated, an intradiscal injection of 1 ml of Cefuroxim 100mg/ml through the needles must always be done as antibiotic prophylaxis.

The results of treatment with the RF dual lesion and PRF treatment are comparable. After RF lesioning, the patient can have long lasting (2months) flare-up pain, but no neurological deficits have been reported. Whereas, after PRF treatment, flare-up pain rarely occurs and when it does usually lasts only for a few days.

Study results (O.Rohof, Sittard the Netherlands)

After informed consent we treated a patient group of 61 patients May 2006- Sept 2007: 61 pat: 33 f, 28m. Mean age 45.8Y,

Clinical suspicion disc pathology, on clinical exam, 26 MRI.

Discography at least 3 levels: 59, concordant level(s) 51.

Mean VAS 7.9

Treated levels: L2/3: 3, L3/4:4, L4/5:15, L5/S1:40

Follow up at 11 weeks: n=58: mean VAS 5.3

45 patients satisfied, 19 very satisfied, 14 no effect

VAS reduction >2 in n=34,

Flare-up pain n=23 up to 2 months, some very severe

After publication of Teixeira and Sluijter about the results of PRF disc treatment (2006), we also performed a study on treatment of 46 patients with a dual disc treatment with PRF.

N=46, 27f, 19m, mean age 46.4y

VAS baseline 7.24

Positive discography (performed at at least 3 levels) n=35

Levels: L2/3: 1, L3/4: 4, L4/L5: 10 , L5/S1: 27

PRF 2 electrodes 2/20, 60V, 12 min

Follow up after 11.4 weeks n=30

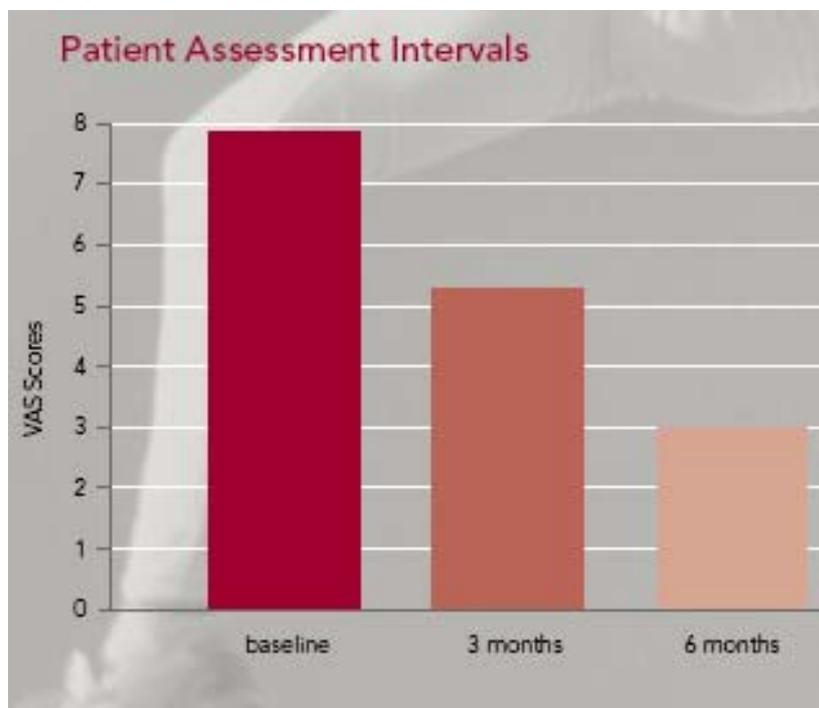
Mean VAS 4.6

11 patients had >50% improvement

8 patients flare up of < 3 wks (less severe)

The Pulsed RF treatment seems a preferred alternative, but the results need to be confirmed in further studies.

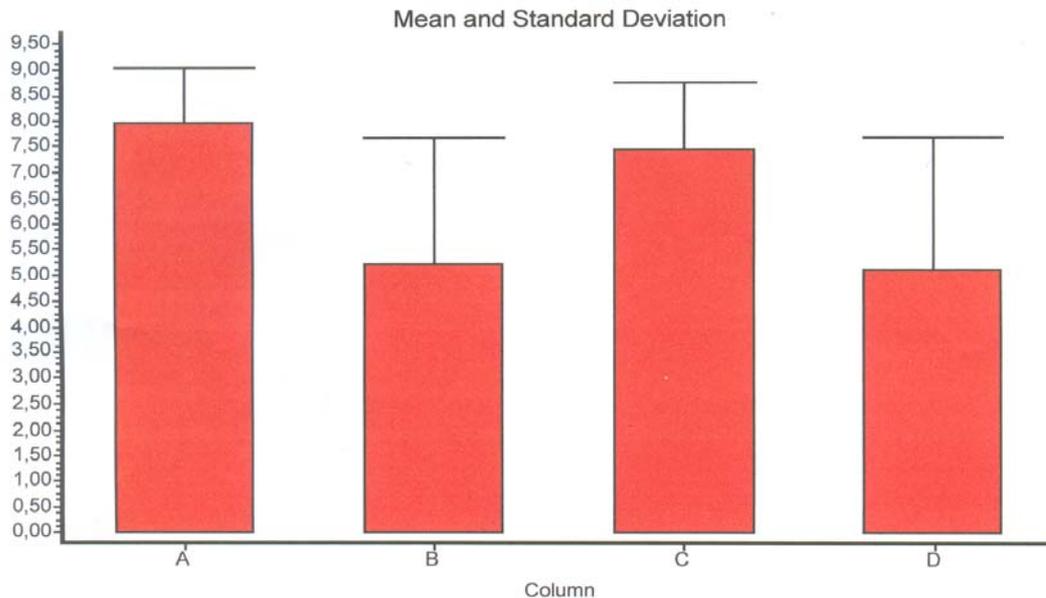
Preliminary results using the Diskit II suggests a significant decrease in VAS scores (minimum 2 points) following a three month follow up of 61 patients treated with continuous radiofrequency. Treatment levels ranged from L2/L3, L3/L4, L4/L5, and L5, S1, with the bulk of patients receiving treatment at L5/S1 (66%). Of the patients who returned for the three month post-treatment assessment, 95% reported a significant decrease in VAS. While 74% reported overall satisfaction with the Diskit II treatment. At the six month follow up, the returning patients reported a mean VAS score of 3.



Results RF dual lesion disc n=61

Done by Dr. Olav Rohof Sittard the Netherlands

Comparison of results RF dual disc lesion (2 left bars) and PRF dual disc treatment (2 right bars)



Result RF dual lesion n=61

Results PRF dual lesion n=46

PATIENTS

The first patient is a 49 y old police officer who was successfully conservatively treated for a herniated disc L5/S1 several years ago. He developed an exacerbation of LBP and ischialgia on the left side, but now conservative treatment failed.

On physical examination he had a kyphoscoliosis, and a biphasic deflexion, no signs of a radicular syndrome and no neurological deficit. He had a paravertebral tenderness over the lower lumbar spine (facet joints) and over the spinous processes L4 and L5 (mostly a sing of discogenic pain).

The MRI showed spondylodisarthrosis of the lower lumbar spine especially L5/S1, the disc L3/4 shows a left paramedian , subligamentary preforaminal protrusion without canal stenosis or nerve root compression. Facet arthrosis L4/5 and L5/S1.

On the L5/S1 level no disc herniation and a remaining disc height of about 20%.

We made a diagnosis: mechanical low back pain of the posterior (facets) and anterior (disc) compartment with some neurogenic irritation of the L5 and S1 segment.

Treatment: a facet denervation L2-L5 bilaterally was performed with RF heat, followed by a physiotherapeutic trainings program, with which the patient had a 70% improvement.

Eight months later however there was a recurrency of the pain and for the ischialgia he was successfully treated with a pulsed RF treatment of the left dorsal root ganglion L5 and S1.

His residual backpain was so severe VAS 8/10, that he could work anymore, and a multilevel discography was scheduled.

At the L2/3 level: a normal discogram , 1.3 ml, no pain

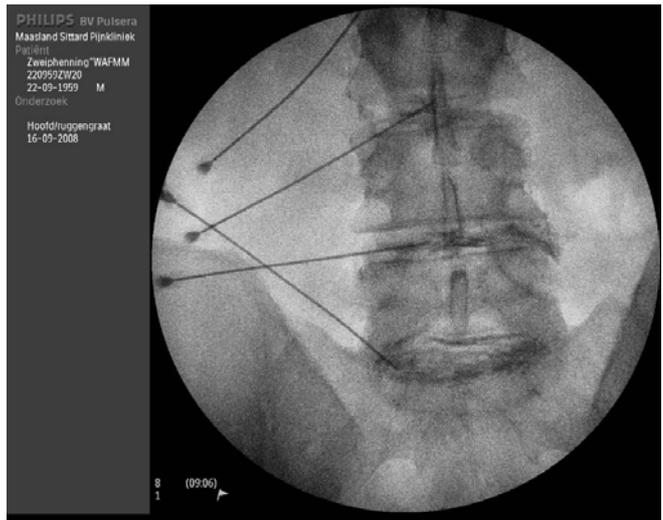
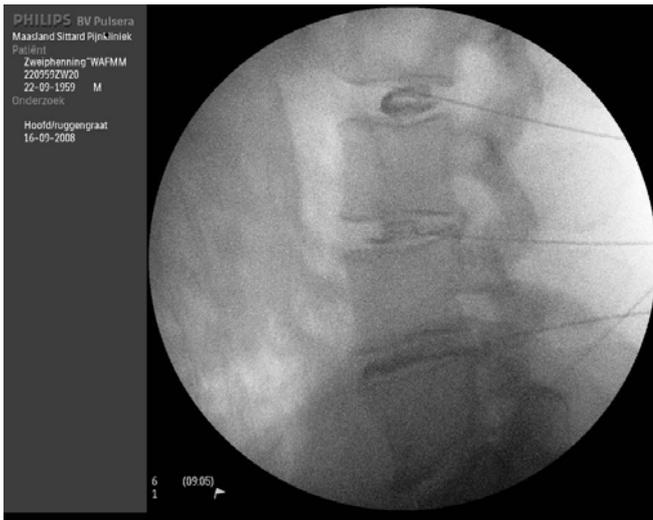
At L3/4: 1.4 ml, pressure +, VAS 8/10, concordant pain, internal disc disruption, no leakage.

At L4/5: 2.5 ml, pressure +/-, VAS 6/10, concordant pain, leakage.

At L5/S: 2.0ml, pressure +, very degenerative disc, disc height 20%, VAS2/10,

Conclusion: the levels L3/4 and L4/5 are the painful levels.

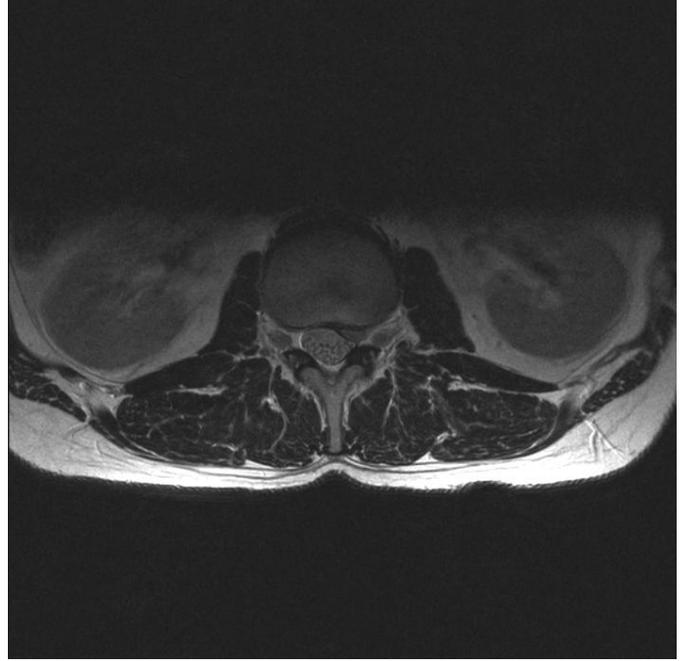
Discography fig 1 and 2



After informed consent the patient was scheduled for the bisegmental RF dual disc treatment.

The second patient is a 50 y old man with also a back pain history of several years. With conservative treatment NSAIDs and manual therapy and a physiotherapeutic trainings program his back pain without ischialgia remained, and an MRI was performed. On the T2 weighed study there was a disc hernia L2/3 on the left side without root compression, and the neurosurgeon found no operative indication. On discography L2/3 the patient had a concordant pain with a VAS of 8/10,

After informed consent he was scheduled for the RF dual disc procedure at the L2/3 level.



*Special Thanks to Dr. Olav Rohof (Orbisconcern, Sittard, The Netherlands)
for creating this technique manual and providing efficacy data*

Contact Information:

NeuroTherm

2 DeBush Ave., Suite A-2

Middleton, MA 01960

United States

Toll Free: +1 (888) 655-3500

Phone: +1 (978) 777-3916

Email:

usasales@neurotherm.com

429 Brighton Road

Croydon, Surrey, CR2 6EU

United Kingdom

Phone: +44 (0) 20 8660 4374

Fax: +44 (0) 20 8660 9417

Email: sales@neurotherm.com

Modemstraat 20

1033RW Amsterdam

The Netherlands

Phone: +31 204 702 702

Fax: +31 204 702 701

Email: nlsales@neurotherm.com