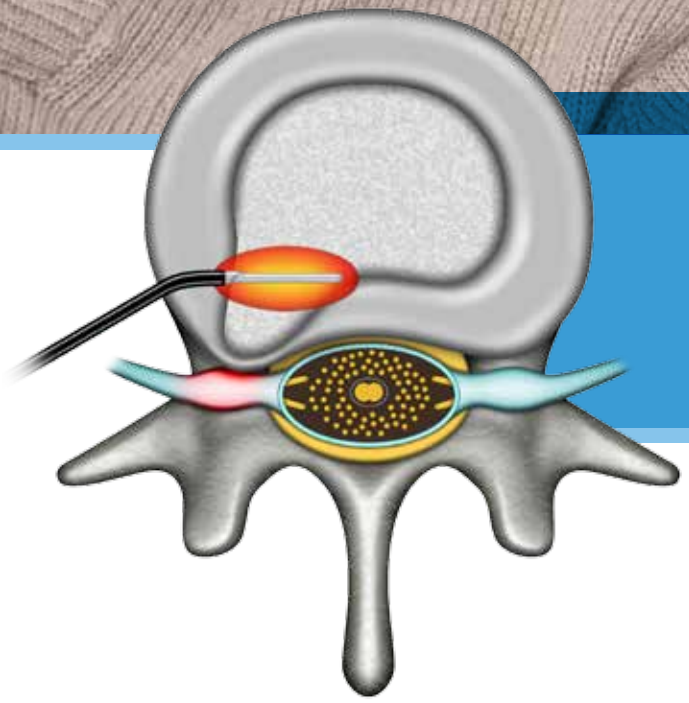


Flextrode

Intradiscal RF Pain Management

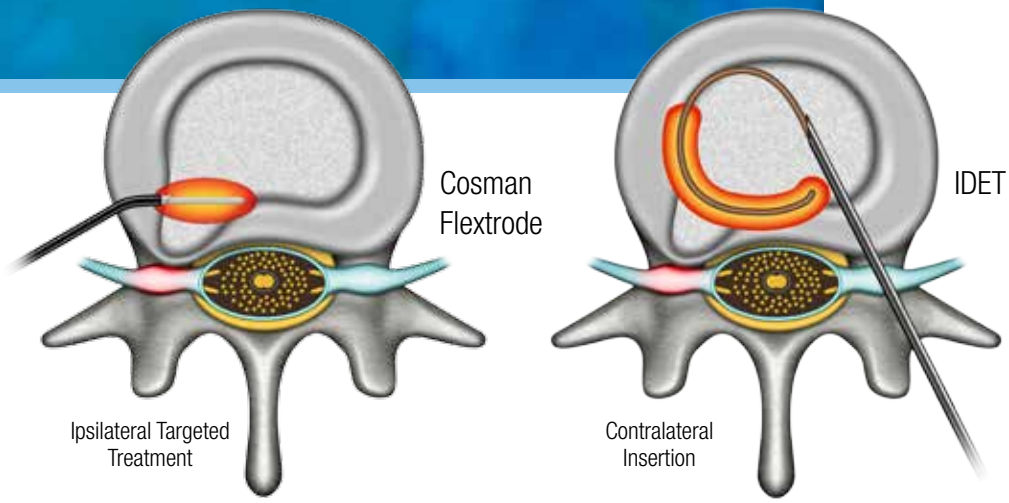
COSMAN

The Leader in RF Medicine Since 1952

Revolutionizing the Treatment of Discogenic Pain

Direct Placement Reduces Disruption

The Flextrode simplifies placement and avoids disruption of anterior and contralateral disc.



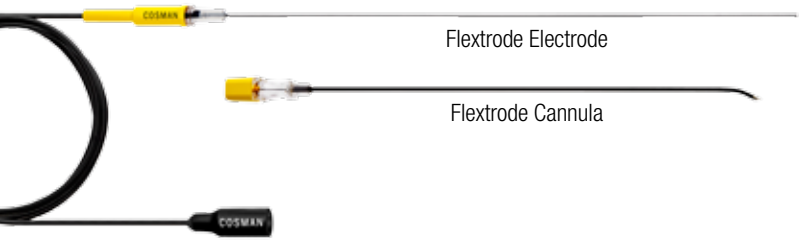
Robust and Steerable

The Flextrode is steerable to the posterior and lateral intervertebral disc, including L5/S1. Solid steel construction avoids breakage through insertions and withdrawals.

G4 Automatic Stepped Temperature Program

Choose automatic control to simplify treatment, or manual control to adapt to clinical conditions.

G4 Four-Output RF Generator



Equipment

- Flextrode Kit (FLEX-K151320-5P)
  - Electrode Tip (13mm, 20ga)
  - Cannula (15cm, 17ga)
- Cable (CB114-TC)
- G4 RF Generator
- Ground Pad (DGP-PM)

Flextrode Case Reports

Treatment of Radicular Pain due to Disc Prolapse
by Dr. Andrea Marek, Klinik Diakonissen in Linz, Austria.

Patients

The Cosman Flextrode was used to treat radiculopathy in 15 patients having medial or mediolateral disc prolapse and nerve root entrapment, without disc sequestration or an extraforaminal portion, confirmed with MRI. Patients were not treated with epidural steroid injection.

- L5/S1: 7 patients
- L4/L5: 7 patients
- L2/L3: 1 patient

Flextrode Placement

1. The patient is placed in prone position on an x-ray fluoroscopy table, sedoanalgesia is administered, the surgical site is prepared for aseptic technique, and the skin is numbed at the cannula insertion site using local anesthetic.
2. Aseptic technique and fluoroscopic guidance are used throughout Flextrode placement and treatment.
3. Using an extrapedicular approach ipsilateral to the prolapse (Fig. 1), the Flextrode cannula is oriented parallel to a single vertebral end plate and advanced through Kambin's triangle (Fig. 2) into the posterior disc. The cannula tip is oriented mediolaterally and its bend is within the disc.
   - Too shallow a cannula angle risks puncture of the epidural space and damage to the nerve roots or spinal cord.
   - Too steep a cannula angle risks treatment too anterior in the disc.
4. The Flextrode electrode is inserted through the cannula so its tip extends out of the cannula mediolaterally into the posterior disc proximate to the prolapse.
5. With the patient awake, Sensory (50Hz) and Motor (2Hz) stimulation are applied using 3 Volts amplitude and 1msec pulse width.
   - If any tingling sensation or motor response is evoked, including in any dermatome at or below the Flextrode level, the Flextrode is repositioned away from the spinal canal and nerve roots, and stimulation is repeated.
   - The Flextrode electrode is always withdrawn into the cannula before repositioning.
6. Before RF is delivered, sensory and motor stimulation, and lateral, AP, and oblique x-ray views are used to confirm that the Flextrode cannula and electrode metallic active tips are fully within the disc and spaced from the spinal canal and nearby nerves.

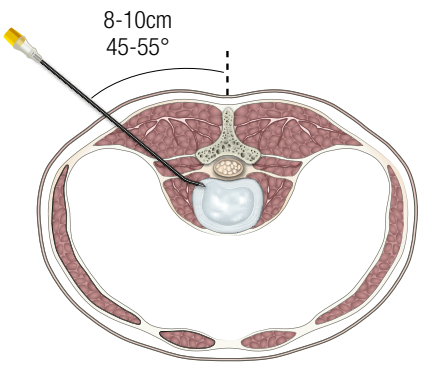


Figure 1. Flextrode introduced into the disc using a posterior-lateral extrapedicular approach.

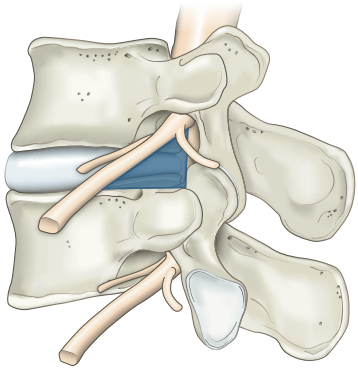


Figure 2. Kambin's "safe" triangle is shown in blue.

These case reports describe Flextrode placement and treatment performed by Dr. Andrea Marek. They are not intended to be used as a medical guide or instruction.

The treatment of any patient is the sole responsibility of the administering physician. Refer to the instructions for use for all devices before treatment.

Cosman Medical does not advise on use of products for a particular patient.

Flextrode Case Reports

Treatment

1. Radiofrequency (RF) is applied to Flextrode for 4 minutes using set temperature 80°C.
2. The patient is continuously monitored for signs of discomfort.
3. Following RF application, the Flextrode electrode is withdrawn, and Ceftriaxon 0.5mL (corresponding to 75mg) is injected into the disc through the Flextrode cannula.
4. The cannula is withdrawn and a bandage is placed over the skin insertion site.
5. After the procedure, the patient is observed for 2 days in the hospital, including 24 hours of bed rest.

Outcomes

Pain relief was assessed informally retrospectively. Of the 15 patients treated:

· 8 patients: pain reduction during hospitalization.

· 3 patients: pain reduction within 14 days.

· 4 patients: no pain reduction, 2 patients treated surgically.

Example L5/S1

· Clinical: Left S1 radiculopathy, 36 years old.

· MRI: Mediolateral L5/S1 disc prolapse (Fig. 7).

· Following the general placement steps, the cannula is tilted in the sagittal plane to avoid the iliac crest (Figs. 3-4). This restriction can lead to a more anterior placement (Fig. 6) than at other disc levels.

· Treatment is performed with the electrode and cannula positioned as shown in Figs. 5-6.

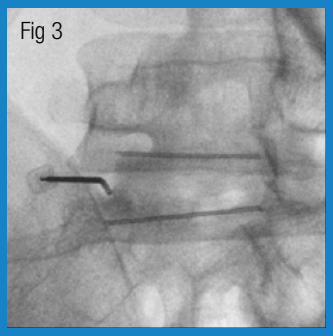
Example L2/L3

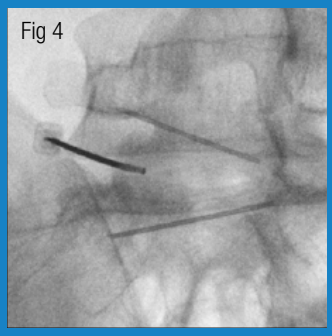
· Clinical: Left L3 radiculopathy, 53 years old.

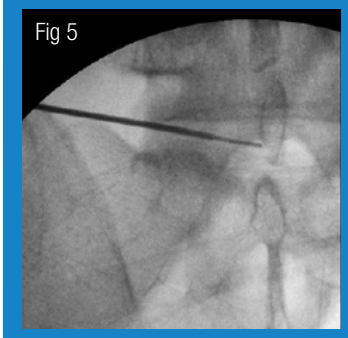
· MRI: Mediolateral L2/L3 disc prolapse (Fig. 8).

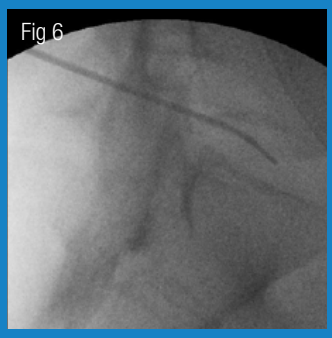
· Following the general placement steps, the cannula is inserted 8cm from midline, and 55° from AP (35° from lateral) in the axial plane.

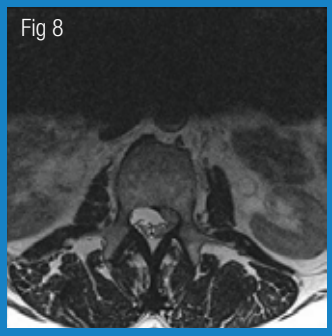
· Treatment is performed with the electrode and cannula positioned as shown in Figs. 9-10.

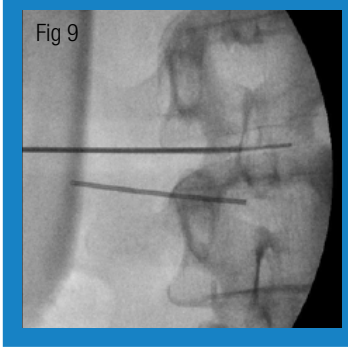












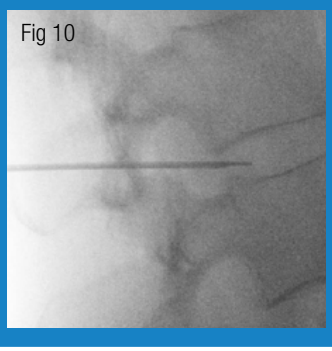


Fig 3: Flextrode cannula insertion past the iliac crest and through Kambin's triangle. Fluoroscopic tilt: 20° lateral, 15° craniocaudal.

Fig 4: Advancing the cannula through the annulus fibrosus.

Fig 5: Electrode and cannula positioned for treatment in the medio-lateral posterior disc near the prolapse (AP view).

Fig 6: Electrode and cannula positioned for treatment. The bend in the cannula shaft indicates the active tip is within the disc (lateral view).

Fig 7: MRI of Example L5/S1.

Fig 8: MRI of Example L2/L3.

Fig 9: Electrode and cannula positioned for treatment in the medial posterior disc (AP view).

Fig 10: A lateral view confirms that the electrode tip is within the posterior disc, not in the spinal canal.

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SPI12834 Rev A 20150511