Coflex®

Mesfin A. Lemma, MD
Minimally Invasive Spine Surgery, Scoliosis Surgery, Baltimore, MD

Overview

- The Coflex procedure is a relatively new option used as an adjunt in the treatment of moderate to severe lumbar spinal stenosis.

- The device (shown on right) is a small, titanium implant that provides spinal stability without the mobility loss associated with spinal fusion.
- It is an implant option in specific cases where the bone resection required to adequately decompress the spinal stenosis may lead to instability, but where fusion may not be necessary.
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Who performs the procedure?

- Coflex is best performed by a **fellowship-trained spine surgeon**. Ask your surgeon about their training, especially if your case is complex or you have had previous spinal surgery.

What to expect before the procedure:

- In the weeks prior to your surgery, **pre-operative testing** will be conducted either by your primary care physician or the pre-admission testing department of the hospital.
- One week prior to surgery, you will need to **stop taking aspirin, NSAIDs** or other medications that thin your blood and may increase bleeding.
- You will be given instructions and supplies to **cleanse** the back of your spinal area the day prior to your procedure.
- You are to have **nothing to eat or drink after midnight** on the night before.

What to expect during the procedure:

- Just before the procedure starts you will have an intravenous (IV) line started so you can receive fluids and medications to make you relaxed and sleepy. The procedure is performed under **general anesthesia** (you are asleep). Medications will be given through the IV to put you to sleep and a tube is inserted in your throat to supplement your breathing. **IV antibiotics** are administered and monitors are placed to check your heart, blood pressure, and oxygen level. A Foley catheter in the bladder is typically not required.
- The procedure typically lasts **about 2 hours,** depending on the specifics of the case. This is what to expect once the procedure begins:

1. Surgical approach

- You are positioned face down (prone) on a specialized, cushioned operating table.

- The area of your back where the incision will be made is cleansed with a special solution to the kill germs on the skin.

- A small skin incision is made in the midline directly area overlying the affected area of the lower back.

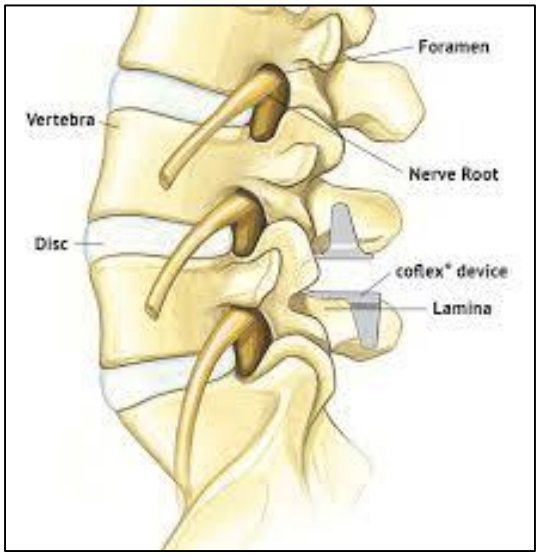
- The spinal muscles are gently separated to expose the affected area of the spine.

2. Decompression

- Surgical decompression of the spinal nerves is performed, which includes the removal of overgrown bone and soft tissue as well as protruding or herniated disc material.

3. Stabilization

- The Coflex® device is then inserted until it is secured to the bones spanning the treatment area (figure on right).



4. Closure

- The skin is closed with absorbable sutures (stitches).

- A small dressing is applied over the incision and you are then taken to the recovery area.

What to expect after the procedure:

- Patients are typically in the hospital for **1 - 2 nights.**
- In the recovery area, you will be observed until you recover from the anesthesia, then transferred to the floor.
- You will be encouraged to get out of bed and move around as soon as you are able to. A back brace is typically not required.
- Pain pills on an empty stomach may result in nausea, so initially IV pain medications are self-administered through a PCA, or **patient-controlled analgesia**.
- IV fluids will be continued until you can drink fluids well by mouth.
- Once you are able to drink normally, your diet will be advanced to your **normal diet** and you will be switched to pain pills.
- **Physical therapy and occupational therapy** will see you prior to your discharge from the hospital to make sure you are comfortable walking, escalating stairs and performing other activities of daily living.

Recovery and rehabilitation at home:

- Keep in mind, everybody is different, and therefore the amount of time it takes to return to normal activities is different for each individual.

- Patients are encouraged to **walk as much as possible** but to **avoid lifting or bending** early on. Discomfort should decrease a little each day, like a dimmer switch as opposed to an on-off switch.

- You will be seen in the office at **2 weeks**, then at regular intervals thereafter. Xrays will be obtained periodically to monitor healing.

- Most patients are able to return to most activities by 6 weeks, although complete recovery may take between 6 and 12 weeks. You will **not be able to drive a car for about 6 weeks**, depending on the specifics of your case.

- Signs of infection such as **swelling, redness, draining, or fever > 101.5ºF** should be brought to your surgeon's attention immediately.

- It is important to keep your incision **dry** for a period of 2 weeks to give your incision time to seal. You may sponge bath during this period.

- You will be seen in the office at **2 weeks**, then at regular intervals thereafter. Radiographs will be obtained periodically to assess the healing.

What are the expected outcomes?

Outcomes following the procedure are generally very good. In a prospective study of 215 patients who received the Coflex® implant, **86% had a successful outcome** after two years. A successful outcome meant they had relief from their pain and did not require additional surgery.

What are the possible risks?

In skilled hands, the Coflex procedure is very safe and effective. However, no surgery is without possible risks. These risks can be minimized by choosing an experienced surgeon to perform your procedure, and by adhering to your surgeon's instructions before and after your procedure. General complications of any surgery include bleeding, infection (1%), blood clots, and reactions to anesthesia. Specific complications related to Coflex may include:

- **Persistent nerve pain.** The primary cause for persistent nerve pain following spinal surgery is an inadequate decompression. This complication can be avoided by seeking out an experienced, fellowship-trained spine surgeon.

  It is important to note that another common cause of persistent symptoms is nerve damage from the compression itself, not the surgery. Compression may permanently damage the spinal nerves rendering it unresponsive to surgery.

- **Nerve root injury (1 in 1,000) or bowel/bladder incontinence (1 in 10,000)**. Paralysis would be extremely unusual since the spinal cord stops at about the T12 or L1 level, and surgery is usually done well below this level.

- **Cerebrospinal fluid leak (1% to 3%)**. If the dural sac is breached, a cerebrospinal fluid link may be encountered but does not change the outcome of the surgery. Generally a patient needs to lie down for about 24 - 48 hours to allow the leak to seal.

- **Implant failure.** In rare cases, the Coflex implant may shift, required revision surgery. This risk is increased in patients with osteoporosis (weak bone).