

# Radiofrequency-assisted minimally Invasive Manual Lumbar Discectomy using Disc-Fx System: Outcome of Nine Cases

Shantanu Mallick

## ABSTRACT

**Introduction:** The preferred treatments for discogenic axial or radiating lower back pain are controversial. Available treatments are medication, physical therapy, epidural steroid, percutaneous endoscopic discectomy, open surgical discectomy, etc. A radiofrequency-assisted minimally invasive lumbar manual discectomy with nucleus ablation and annulus modulation by Elliquence's "Disc-Fx system" has been successfully used to treat nine patients for their low back pain.

**Materials and methods:** Nine patients (35–55 years/M:F = 2:7) with lower back pain radiating to leg that failed to improve with conservative managements for more than 6 weeks were assigned. The magnetic resonance imaging shows moderate size of single contained disc herniation at L4-5 or L5-S1 with minimal degenerative changes (preserved disc height). All Disc-Fx procedures were performed in a day care basis under fluoroscopic guidance under local anesthesia with or without minimal sedation. Evaluation with a global assessment scale at 6 weeks, 3- and 6-months interval was done.

**Results:** All the patients underwent Disc-Fx treatment at one level, either L4-5 or L5-S1, after confirming the diagnosis with preoperative provocative discography. Mean operation time was 60 to 90 minutes, mean postoperative recovery time was 60 to 90 minutes, and blood loss was minimal. Mean return to normal day-to-day activities was 7 days. The numerical rating scale score was significantly lower than before operation. No complication occurred except in one patient, who was not satisfied symptomatically (contacted on phone), but did not come for follow-up after procedure till date.

**Conclusion:** Disc-Fx is an effective treatment option in discogenic pain and degenerative moderate contained disc prolapsed without bony and soft tissue stenosis. This minimally invasive approach does have advantages of no bony instability and minimal scarring/adhesion of epidural space, and thus, reduces postoperative complications to a great extent. It reduces hospital stay and leads to faster rehabilitation and early return to work, which reduces the cost of the treatment.

**Keywords:** Annulus modulation, Disc herniation, Disc-Fx, Discogenic pain, Low back pain, Manual discectomy, Nucleus ablation.

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## INTRODUCTION

Low back pain is one of the most widely experienced health problems throughout the world, affecting approximately 85% of the population at some point in their lives.<sup>1</sup> It is the second most frequent health problem, after common cold, for which people see a physician or take leave from work.<sup>2</sup> Most of the time, low back pain improves with conservative treatments; however, refractory cases are treated with surgical procedures.<sup>3-5</sup>

The commonly available treatment for intractable discogenic low back pain and sciatica remains controversial.<sup>6-8</sup> Different studies demonstrate the efficacy of physical therapy,<sup>8</sup> epidural steroid injection and facet joint block,<sup>9</sup> percutaneous discectomy,<sup>10</sup> open discectomy,<sup>11</sup> and fusion and total disc replacement.<sup>12</sup> Last few years, new minimally invasive endoscopic techniques have been introduced by Yeung and Yeung.<sup>13-17</sup>

A radiofrequency-assisted manual lumbar discectomy (Disc-Fx system, Elliquence) will be described in this article, which is an effective technique to treat discogenic radiating pain due to contained disc herniation with minimal degenerative changes (preserved disc height).

## MATERIALS AND METHODS

Nine patients (35–55 years/M:F = 2:7) were chosen, who had radiating lower back pain to leg, who failed to improve with conservative managements almost for 6 weeks. They have been given transforaminal epidural steroid injection. However, patients had short duration of pain relief. Their magnetic resonance imaging reports were showing moderate size of contained disc herniation at L4-5 (seven cases) or L5-S1 (two cases) with minimal degenerative changes (preserved disc height).

All the patients have been counseled for this Disc-Fx technique thoroughly. After taking informed consent, intravenous (IV) line was secured and preoperative

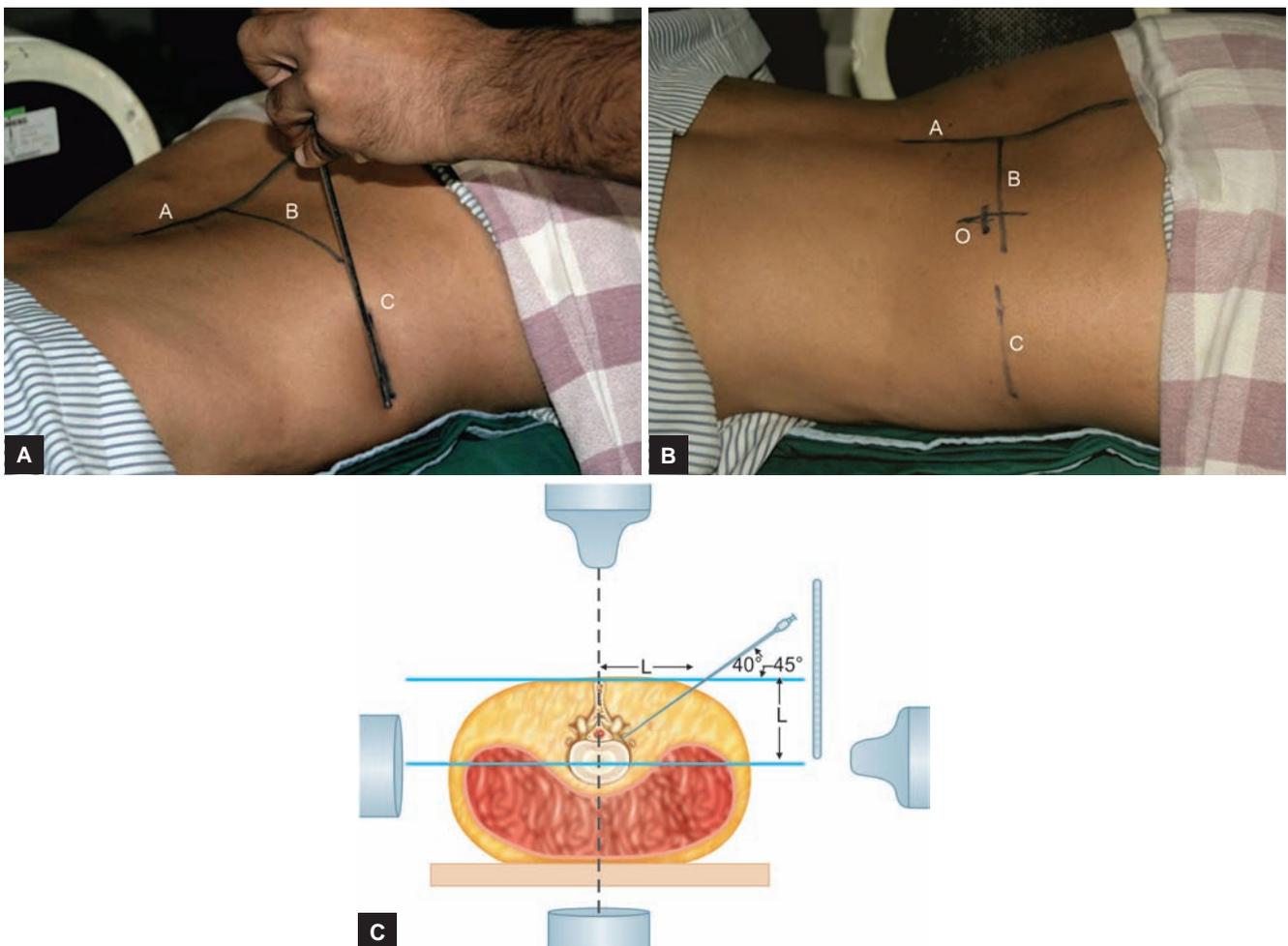
antibiotic (IV cefazolin 1 gm) was given slowly after test dose. Patients were placed in prone position. All the procedures were done under fluoroscopy guidance under local anesthesia with minimal sedation when required (inj. midazolam 0.05 mg/kg and inj. fentanyl 0.8 microgram/Kg), under standard monitoring. Before Disc-Fx procedure, provocative discography was done in every patient to select the appropriate disc to be operated. Annular tear, severe disc degeneration with reduced disc height, ligamentum flavum thickening, and listhesis cases were excluded. All the procedures were done at the level of L4-5 (seven cases) or L5-S1 (two cases) intervertebral disc.

**TECHNIQUE**

Regarding needle entry point, some measurements were done with the help of a straight thin metal rod and marker pen on patients' back under fluoroscopic guidance. First, a line was drawn, joining the lumbar spines (line A). Then another line (line B) was drawn at the middle of the two endplates of the selected disc in anteroposterior (AP) view, which is intersecting the line A perpendicularly. Now, in lateral (LAT) view, another line (line C) was drawn, which was going through the middle of the

endplates of the selected disc (disc inclination line) and the measurement was taken from the anterior margin of the disc to the surface of the back. Now, the same length was marked on the line B from midline on the side determined for doing the procedure. From the lateral end of this measurement on the line B, a perpendicular line is drawn on the line C (Figs 1A and B). This point (point O) on line C was considered as the needle entry point where the needle is inserted at about 45° with the surface of the back toward the disc (Fig. 1C). This is called posterolateral technique or transforaminal technique<sup>18</sup> through the medial end of the Kambin's triangle.

After proper aseptic preparation in prone position, first a 16 or 18 G long spinal needle (15 cm) is introduced through the anesthetized needle entry point. In our regular discography technique through end-on view, keeping the C-arm obliquely, we usually reach in the middle of the disc, which is not accepted here as we have to reach to the dorsal aspect of the disc where the protrusion is there. That is why, only AP and LAT view will help us to enter into the disc at the dorsal part without seeing the oblique view. The progress of the needle is done in AP view and the depth of the needle is checked in LAT view.



**Figs 1A to C:** (A) Measurements for Disc-Fx procedure; (B) Final entry point; and (C) Needle entry angle

In case where a minor directional adjustment is necessary, the use of the plane of the needle bevel is needed (if the needle bevel is facing dorsal, the needle will tend to move ventral when being advanced). First bony resistance encountered is the lateral facet (superior articular process) keeping the needle bevel to the ventral side. The end of the needle is then elevated so that the tip of the needle can go deeper passing under the ventral side of the facet turning the needle bevel dorsally, through the medial aspect of the Kambin's triangle. Local anesthetics (1% lignocaine) should be used in the whole tract, which will be very helpful in carrying out the whole procedure.

Then, taking a small skin incision, a 3 mm dilator and a working cannula attached with "depth-stop" is introduced up to the outer border of annulus under guidance of guide wire. The site of the annular puncture by the needle tip should be the maximum at the medial pedicular line in AP view and the posterior vertebral line in the LAT view of fluoroscopic imaging (Fig. 2A). Otherwise, the chance of dural puncture is more likely to happen before entering into the disc. In the same way, the midpedicular line should be considered for the upper lumbar discs (L3-4 and above) to avoid neural injury because the dural sac is bigger with more nerve tissue, lying more laterally due to the narrow width of the pedicles at the upper levels.<sup>19</sup>

Next step is annular fenestration by which annulotomy will be performed. As the annulus is rich in nerve supply, entering the disc through annulotomy is painful for which small amount of local anesthetics can be injected or minimal sedation can be given at this point. The dilator is removed keeping the guide wire in position and the trephine (annulotome) is inserted over the guide wire and advanced to the nucleus. The trephine is slowly spun and advanced at the same time, thereby, coring a hole into the annulus. The trephine is then removed and the dilator is reinserted. Now the cannula is advanced to the proximal one-third of the nucleus. The guide wire and dilator then removed leaving the cannula as a working portal. The "depth stop" is brought down to the patient's skin and tightened on the cannula, which will prevent distal movement of the cannula.

At this point, a 2.7 mm grasping forceps (Rongeur) is inserted into the cannula and advanced into the nucleus. A manual discectomy is performed and 0.8 to 1.0 gm of nucleus is removed in piecemeal (Figs 2B and C). The excised nuclear material was sent to pathology for verification.

The next step is nucleus ablation with the help of Trigger-Flex radiofrequency flexible-tip bipolar probe. The Trigger-Flex is simultaneously irrigated with continuous saline (mixed with antibiotics) through the port fitted on the handle of the Trigger-Flex. A pressure cuff

was used on the saline bottle to increase the saline pressure going to the probe. A steady drip of saline should be seen coming out of the distal end of the Trigger-Flex at a rate of 1 to 2 drops per second. The probe is advanced into the nucleus through cannula and the placement is verified under fluoroscopy. The Trigger-Flex is squeezed and verified the distal end of the electrode under fluoroscopy to see whether the distal end is reaching out to the desired position. Now, the Trigger-Flex should be squeezed pressing the pedal, labeled for Bipolar Turbo to perform nuclear ablation. It is squeezed for 6 seconds while holding down the pedal. Trigger-Flex handle should not slide in and out in a sawing motion. It should be only squeezed and released. The procedure is repeated six times rotating the handle of the Trigger-flex at 12:00, 2:00, 4:00, 6:00, 8:00, and 10:00 clock position. Studies have shown this will ablate approximately 0.8 to 1.0 gm of nuclear material, which will help to shrink the nucleus<sup>19</sup> (Fig. 2D).

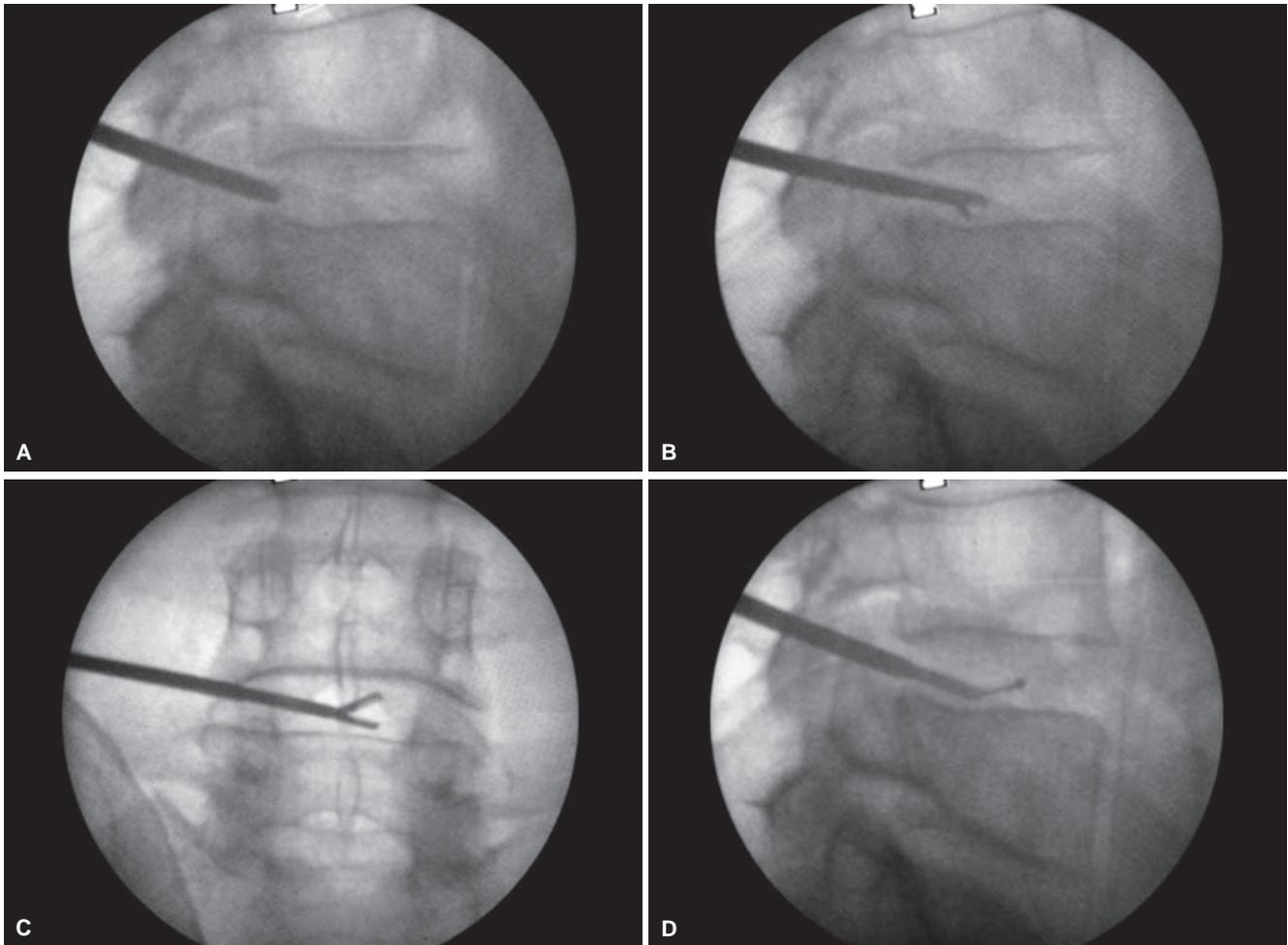
The final part of the procedure is annular modulation or annuloplasty by Trigger-Flex with Bipolar Hemo-mode.<sup>19</sup> In this part of the procedure, the tip of the Trigger-Flex is going to be rubbing along the interior portion of the annulus where the disc is herniated or bulging. Now, withdrawing the tip of the working cannula little into the annulus, the same Trigger-Flex is used with Hemo-mode for annulus modulation. Here, a short burst of energy is applied, which helps tissue contraction (causes a change in collagen), hemostasis, and burning the nociceptors at the posterior part of the annulus. Here, the probe is used for only two-to-three 6 seconds' sweeps in the vertical position or only dorsal area of the disc.

Special measurements for L5-S1 disc treatment have been taken, as this level has unique anatomical limitations as follows: A high iliac crest, presence of ala, larger facet joint and narrow foramen, and narrow intertransverse space (largest at L3-4 and smallest at L5-S1) due to lordotic curvature, which makes the percutaneous transforaminal approach difficult. Because the extraforaminal lumbar nerve root passes across the disc, we have to be very careful to avoid nerve root injury.<sup>20</sup>

Before finishing the procedure, saline wash is given to remove any blood clots or disc materials. Then, the cannula is removed and a small dressing is given on the wound.

## RESULTS

All the procedures were completed successfully without any complications. Average postoperative recovery time is 90 to 120 minutes. Blood loss was minimal. No immediate complication happened in the recovery room. All the patients were advised to give ice-pack massage on the operative site (3-4 days) and to take analgesics with



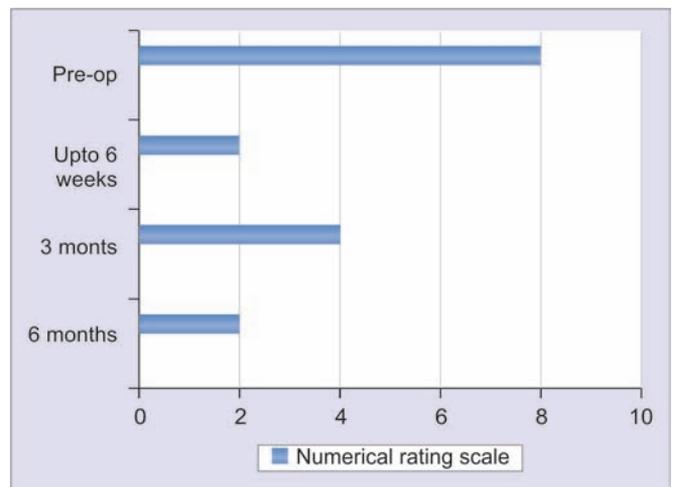
**Figs 2A to D:** (A) Lateral view of fluoroscopic discectomy; (B) Lateral view of manual discectomy; (C) AP view of manual discectomy; and (D) Nucleus ablation with RF probe

muscle relaxants (Myospaz forte) twice daily for 1 to 2 weeks to reduce muscular pain from operative site. They were also prescribed Gabapin 300 mg twice daily with methylcobalamin 1,500 once daily for a month.

One patient had severe radiating pain in right leg (on telephonic conversation), but was lost to follow-up. We tried to contact him, but could not communicate. Evaluation of pain and symptoms was carried out with a numerical rating scale (NRS) in immediate postoperative, 6 weeks, 3 and 6-month interval. The assessment shows following results: A total of 8 of 9 patients (88%) got very good relief (>80%) in “immediate to first 6 weeks” time. Their pain score came down to 2 (postoperative NRS value) from 8 (preoperative NRS value), and patients were very satisfied.

At 3 months, 3 of 8 patients (38%) got slight increase in NRS score (4 out of 10), whereas other 5 patients (62%) were having their NRS score as 3 out of 10. One patient did not turn up for evaluation.

At 6 months, 7 of 8 patients (87%) maintained an NRS of 2 out of 10 with regular physical therapy, whereas 1 patient (13%) was experiencing little more pain (3 out of 10), but was not unhappy (Graph 1).



**Graph 1:** Evaluation of pain with NRS in 6 weeks, 3- and 6-months, interval

## DISCUSSION

The introduction of the intervertebral disc surgery through interlaminar access was done by Mixer and Barr<sup>21</sup>, which was modified by Love. However, the demand was always there for alternative ways to reach

the vertebral column. In 1964, the posterolateral access was used by Smith<sup>22</sup> for chemoneucleolysis, which was the first minimally invasive procedure. Other minimally invasive procedures, i.e., percutaneous discectomy<sup>10</sup> and laser disc decompression and nucleotomy,<sup>23</sup> were well established alongside the endoscopic techniques for intervertebral disc-related pain syndromes. Last few years, using radiofrequency energy, different applications have been added with these previous procedures in vertebral column surgery. Usually, radiofrequency band between 300 to 500 kHz has been used in regular operations, but around 2007, the use of a high frequency (1.7 MHz) band of radiowave, manufactured by the Elliquence Surgi-Max<sup>®</sup> Generator Company, with different modulations (Turbo and Hemo mode) and different biophysical properties have been used through flexible bipolar probes, and the procedure was introduced by Hellinger.<sup>24</sup> This higher frequency helps in reduced heat, which minimizes the tissue alteration.

These two different types of modulations, Hemo and Turbo mode, offer distinct tissue effects, i.e., nucleus ablation and annulus shrinkage respectively.

In Bipolar Turbo mode, elongated energy burst is produced, which causes controlled soft tissue ablation of nucleus pulposus and helps to shrink the nucleus (Fig. 3A), whereas in Bipolar Hemo mode, short burst of energy is produced, which has nonablative effect and causes annular shrinkage and hemostasis (Fig. 3B). Two potential effects are noted in annulus with this thermal modulation. First, because the annulus is rich in collagen, heat may cause local denaturation and shrinkage with thermal modulation, which may impair neurovascularization and growth of new fibers, and this way helps sealing the annular fissure. Secondly, the optimum amount of heat destroys the annular nerve fibers, which are the source of nociception with minimal necrosis.<sup>25</sup> In Turbo as well as Hemo modes, the probe is used only for 6 seconds in cyclic directions for nucleus, and for annulus, only the dorsal area of the disc. Cadaveric study has shown the nucleus tissue ablation of about 1.37 gm and acceptable annular shrinkage with this high radiofrequency.<sup>26</sup> With the help of thermal imaging, the temperature on the end plates does not exceed 40°C, and the temperature in the spinal canal never exceeds

above 42°C even after continuous energy delivery for 30 seconds,<sup>19</sup> which does not have any destructive effect on the spinal cord.<sup>27,28</sup> From a biological point of view, it is postulated that there is the alteration of expression of inflammatory cytokines and prostaglandins in degenerated disc with the help of this heat generated by higher frequency.<sup>29,30</sup> The reliability and effectiveness of this technology has been demonstrated in more than 50,000 endoscopic interventions worldwide.<sup>26</sup>

Indigo carmine dye can be used to color the nucleus after introducing the cannula inside the disc, which helps to visualize the nucleus, if endoscope is introduced, and nucleus material can be confirmed after manual discectomy.<sup>26</sup>

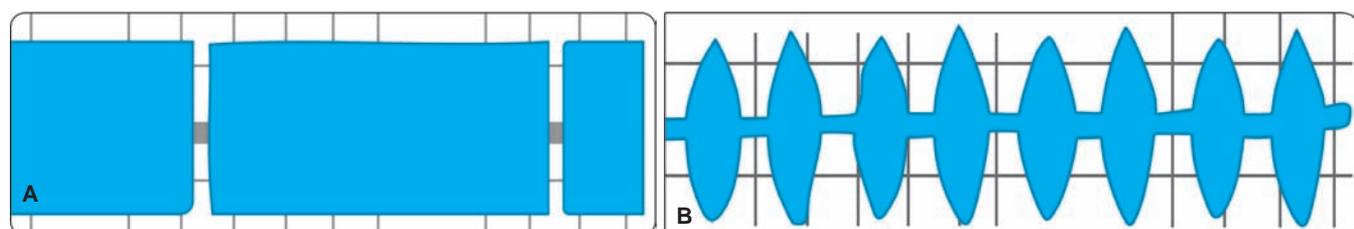
Though incidences of potential complications are very low, approximately 1% or less, the usual risks of infection, nerve injury, dural tears, bleeding, and scar tissue formation are always present as with any surgery. To avoid the complications, visual improvement and patients' cooperation as well as response is very much needed; that is why use of local anesthesia and conscious sedation is superior than general or spinal anesthesia.<sup>26</sup>

Other studies that got positive results:

- Retrospective study of 33 consecutive patients at the Nucci Spine & Orthopedic Institute in the United States<sup>31</sup>
- Comparative study of lumbar discectomy with Disc-Fx and decompression at the Sixth People Hospital of Shenzhen, China<sup>32</sup>
- Retrospective study of Disc-Fx used at the center for minimally invasive surgery in Bogota, Colombia<sup>33</sup>
- Two-year prospective study in Germany<sup>34</sup>
- A role of Disc-Fx in discogenic axial low back pain – a retrospective study in Singapore.<sup>35</sup>

## CONCLUSION

The Disc-Fx procedure is at least equally valuable as other minimally invasive procedures in avoiding an open surgery. It falls in the region between conservative and open surgery within the cascade of therapeutical options for diseases of the discs. The possibility of complications is less in comparison with more invasive procedures. In particular, problems of postoperative epidural scarring and fibrosis can be avoided.<sup>26</sup>



**Figs 3A and B:** (A) Graphical representation of Turbo mode; and (B) Graphical representation of Hemo mode

With a study with a small number of patients though, it cannot be concluded that the Disc-Fx system is a valuable tool for patients with radiating low back pain of discogenic origin to avoid open surgery. However, in carefully selected patients, it may be a good option to avoid open surgery, which supports faster recovery and allows them to return to their work with reduced cost of the treatment. However, more studies are needed to obtain further information.

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