



## Disc-FX® – A New Procedure for Minimally Invasive Intervertebral Disc Surgery – A combination of High-Frequency Radiowave Disc Ablation, Annulus Modulation and Manual Nucleotomy/Decompression in a Single Surgery with Endoscopic Assistance

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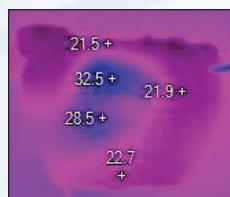


### Introduction

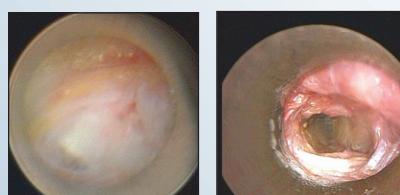
Since the introduction of interlaminar access for intervertebral disc surgery by Mixter and Barr, and its modification by Love, there has always been a demand for additional access paths to the vertebral column. Besides the posterolateral open access according to Wiltse, as early as 1964 the posterolateral access was used by Smith for chemonucleolysis as one of the first minimally invasive procedures. Additional minimally invasive procedures, like percutaneous discectomy, as well as laser disc decompression and nucleotomy, have become established alongside endoscopic techniques as minimally invasive procedures for intervertebral disc-related pain syndromes. In the past few years, different applications based on radio-frequency energy have been added to these procedures in vertebral column surgery. Every technique, from thermocoagulation of the fibrous annulus for "annuloplasty" to "coblation" for nucleoplasty, must be considered a separate procedure with specific effects. This results in special limitations and corresponding indications for the different minimally invasive energy-based techniques of intervertebral disc treatment.

Based on long experience with endoscopic transforaminal intervertebral disc surgery and an overview of 10,000 non-endoscopic percutaneous intervertebral disc surgeries, an analysis of the advantages and disadvantages of all these methods was carried out. The result was a combination of different techniques in a surgery for optimization of the quality of results. An increase in result quality due to the combination of surgeries was already demonstrated by Sang Ho Lee and M. Mayer, with the use of laser and mechanical decompression. The significant component of this newly developed surgery is the use of high-frequency Radiowave application with a controllable probe. While radio frequency techniques currently in use work at frequencies between 300 and 500 kHz, we use a frequency of 1.7 MHz in the band of radiowave provided by the ellulence Surgi-Max® Generator, with

correspondingly different modulations and consequently different biophysical properties. This radiowave technology has proved useful in endoscopic intervertebral disc surgery and is today a significant component of these interventions. The reliability and effectiveness of this technology has been demonstrated in more than 50,000 endoscopic interventions worldwide. The high ablation rate in Bipolar Turbo mode and the modulation of the annulus in Bipolar Hemo mode, with a decompression due to significant shrinkage, have been demonstrated by examination of human cadaver intervertebral discs.



Similarly, safety has been demonstrated with proven negligible thermal convection. There was no higher temperature on the ground plates than 40° celsius controlled by a thermo camera. Also the temperature in the spinal channel was not in a critical range even by continuous application of 30 seconds. The controllable probe allows targeted work in the pathological area. Additional mechanical removal of disc material with a rongeur increases the effectiveness of this method. Free fragments can be removed within the annulus and subligamentarily. Orientation during the surgery is primarily carried out using fluoroscopic control. Optionally, a semiendoscopic inspection can be carried out between the individual work steps. This ensures documentation of the decompression effect and nucleotomy.



2. endoscopic inspection through the working cannula before and after decompression



## Indications

Degenerative changes of the intervertebral disc can lead under certain conditions to pain in the vicinity of the lumbar portion of the spine, with mono- or polysegmental radiation. Similarly, neurological deficits, such as distinct dysesthesia or weakness in the segment-indicating muscles. The intervertebral disc itself can also lead to pain in the lumbar region, due to penetration of nerves and vegetative blood vessels. It must be taken into consideration that the greater part of the pain is derived through the sinuvertebral nerve and from the intervertebral disc, as well as the tissues surrounding the nerves. This often makes an unambiguous mapping between radicular and pseudoradicular symptoms. Moreover, the unambiguous pathoetiology of intervertebrally related pain syndrome has yet to be clarified. Besides mechanical compression, which can often be demonstrated by imaging techniques, vascular and biochemical changes in the segment can be discussed. In particular, venous stasis seems to play a large role in the early phase of the pain syndrome. The smallest changes in the epidural space can result in significant changes in venous flow conditions, thus influencing the course of the disease. Unfortunately, demonstration with today's technical means is difficult.

The decision for an intervention should primarily be made based on a thorough case history and clinical symptomatology. The recording of intervertebrally related symptoms is thoroughly understood, and is the basis for evaluation of an imaged morphological condition. Nowadays, an MRI of the vertebral column is considered the standard. In exceptional cases, a CT scan can also provide the information desired. When evaluating the radiology, agreement with the clinical assignment is important.

The chief application areas of the technique exhibited are contained extrusions and symptomatic protrusions of the intervertebral discs. Advanced degeneration with clear intervertebral pain, just as with annuloplasty, can also be involved. In exceptional cases, good results can also be obtained with lateral and intraforaminal uncontained extrusions.

Before deciding on intervention, all options for conservative therapy, including epidural injection as the gold standard of

intervertebral disc treatment, should have been exhausted. These therapeutic options should also be allotted sufficient time, at least six weeks. The minimization of posterolateral access using a 2.5mm working cannula allows surgery with local anesthesia. Possible complications in the area of the foramen and epidural space can still be avoided with this method. In particular, the frequent irritation of the ganglion within the foramen with postoperative pain syndromes due to larger endoscopy cannulae to be discussed have yet to occur. Due to the low level of operative trauma, fast rehabilitation of the patient can be anticipated.

## Instruments Required

Besides the usual surgical equipment, including suction and irrigation, an image converter is necessary. As an option, a video unit can be used. The core of the intervention is a complete single-use instrument set by Ellquence, with access cannulae, guide wires, trephine, and controllable radio frequency probe. A 16- or 18-gauge spinal needles are also used. Furthermore the radiowave generator "Surgi-Max®" is necessary. The rongeur required for mechanical decompression can also be resterilized and was developed especially for this instrument set. For the optional endoscopic inspection, there is a special lens with an irrigation sheath available. The placement of the instruments requires a fluoroscope with C-arm.

## Performing the Intervention/Surgical Technique



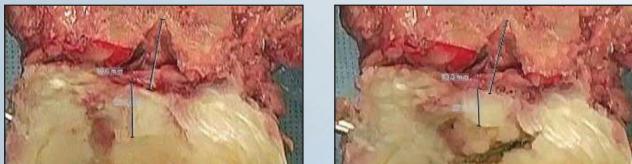
The technical performance of the surgery is simple. Using a posterolateral access, a 16- or 18-gauge spinal needle is introduced transforaminally into the

intervertebral disc. This is possible in side or prone position. The placement is more or less medial with respect to the morphology of the pathology. After an optional discography, a guide wire is placed using the needle. A small skin incision of 3mm is sufficient for introduction of the dilatator and working cannula. These can either be placed on the annulus or an intervertebral disc fragment. An initial endoscopic inspection is carried out along with fluoroscopy, to ensure correct positioning. The three main steps of the procedure will be done through the placed cannula.



3. Decompression by Forceps, Trigger-Flex® for nucleus ablation and modulation of the annulus by bending of the probe

In the next step, either free subligamentary material is removed with the rongeur, or the annulus is opened with the trepan provided, for additional intradiscal work. Additional intervertebral disc material is then removed manually. Then the Trigger-Flex® probe is inserted into the nucleus, and nuclear ablation is performed with a defined energy and frequency modulation. Our cadaver studies have shown that in this step an average of 0.8 grams of disc material is removed, with a corresponding reduction in intradiscal pressure. It is also possible to continue the nucleotomy using the rongeur. The relieved nucleotomy region can be checked with another endoscopic inspection. Next is the modulation of the dorsal annulus by placing the controllable probe on the pathological region. By bending the Trigger-Flex® dorsally and sweeping it an application of radiowave to the dorsal annulus is given. Here, too, a special modulation of the frequency causes a change in the collagen, with shrinkage. Inflamed regions and defects are concomitantly thermally coagulated. Cadaver examinations of these effects with the Trigger-Flex® probe have demonstrated a shrinkage of the annulus of up to 30%. This is confirmed by similar examinations to this effect. Correspondingly, we can show an expansion of the epidural space of up to 9%. This expansion leads to an improvement in the vascular situation, with a possible relief of venous congestion in the ventral spinal canal.



1. Before and after shrinkage of the dorsal annulus with widening of the epidural diameter

Subsequent retraction of the working cannula with a simultaneous endoscopic view can show the epidural space and the nerve roots after the decompression. If necessary, the instruments can be used again for continued decompression.

## Summary and Clinical Relevance/Results

The clinical value of this procedure was evaluated in a prospective controlled study by Hellinger and Feldman 2006/07. The goal was to determine the potential of this combined procedure with radio high frequency. For this initial prospective outcome study, 66 patients with radicular and local lumbar pain symptoms and mild neurological deficits with contained disc extrusions and protrusions were included. The surgeries were performed in two different centered in different cultural areas (Germany and the USA) with different social systems. A standardized protocol was used by independent examiners to record post-operative results, after 6 weeks and after 6 months. Back and leg pain recorded with the visual analog scale showed a significant improvement, from 8.5 to 2 directly post-operatively, and 3.5 after six weeks and 3.3 after 6 months. The Lasegue signs and neurological deficits improved significantly. The original McNab index yielded 90% excellent and good results post-operatively. After 6 weeks and 6 months, 70% were still in this zone. All patients would undergo such a surgery again, if necessary, and recommend it.

Besides the results, the complication rate must also be considered an important factor for the value of an operative procedure. To date with this procedure, there have been no complications. In comparison with other minimally invasive procedures of spinal surgery, we can assume the same low risk of less than 1/1000.

## Summary

The initial clinical results encourage us to include this method in the treatment tool set for diseases of the intervertebral discs. 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 semi-invasive therapy and open surgery within the cascade of therapeutical options for diseases of the discs. The combination of different techniques has proved advantageous, and seems superior to a single percutaneous technique, as other combinations have also shown in studies. The possibility of complications are reduced in comparison with more invasive procedures. In particular, problems of post-operative epidural scarring and fibrosis are avoided. As a minimally invasive procedure, it allows faster rehabilitation, return to work, and thus reduced costs of illness.