Disc-Fx – a new combination procedure for minimal invasive disc surgery

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Since the introduction of the interlaminar approach for disc surgery by Mixter and Barr in 1934, search for alternative procedures continues to be on the rise. Chemonucleolysis and percutaneous discectomy as well as laser decompression and discectomy are clinically performed methods besides the rapidly developing endoscopic, minimally invasive techniques for discal caused pain syndromes. In recent years, the use of radiofrequency energy was added to this spectrum with different applications. Techniques ranging from thermocoagulation of the annulus for annuloplasty to the 'coblation' of the nucleus must be considered as individual procedures. There are specific limits and indications for different minimal invasive techniques and technologies currently marketed.

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Based on long time experiences by endoscopic transforaminal surgeries and a review of nearly 10,000 non-endoscopic percutaneous disc surgeries, an analysis of advantages and disadvantages of all of these methods was performed. The result was the development of a combination of the different techniques in one procedure using Disc-FX (Ellman Innovations, New York, US). The essential part of this procedure is the use of a patented high-frequency radiowave device with a patented steerable delivery system (Surgi-Max HRF and Trigger-Flex Bipolar System – Ellman Innovations, New York, US). Meanwhile, common radiofrequency techniques intradiscally work with frequencies of 300–400 Kilo Hertz (kHz), we are using a frequency of 1.7 Mega Hertz (MHz) in the radiowave band of the Electromagnetic Radiation Spectrum. Use of these technologies and techniques has been well proven by endoscopic disc surgery since 1999 and is today an integral part of these procedures. It is in endoscopic procedures that these technologies have demonstrated the safety and efficacy in more than 50,000 cases worldwide. High, specific ablation rate and targeted modulation of the annulus with a significant shrinkage by a negligible temperature distribution are demonstrated by research. The steerable delivery system permits targeted application in the region of the pathology. The manual removal of disc material by a disc rongeur widens the effectiveness of this surgery as free fragments intra-annular and subligamenteous may also be removed. The performance of the procedure is mainly under fluoroscopic guidance. An endoscope may be incorporated into the procedure between the steps of this surgery for direct visualisation of the effects of decompression and nucleotomy.

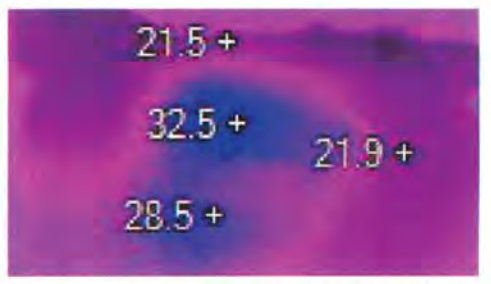
The minimalisation of the posterolateral approach by a working cannula of 2.5mm allows this surgery to be performed under local anaesthesia, which also aids to avoid complications in the foramen and epidural space or related to neural structures. The small diameter of the device helps to prevent the irritation of the ganglion in the foramen with neuropathic pain syndromes widely reported with use of thicker endoscopes. To-date, we have not seen any case of this after this procedure and recovery of the patients is faster due to the reduced surgical trauma.

The technique of the procedure is simple. By a posterolateral approach, a 16 gauge spinal needle is placed in the foramen and inserted into the disc. Over the needle a guidewire is positioned. After a small skin incision of 3mm, the dilation sheath with the working cannula is introduced to the annulus or the disc fragment. At this point, the endoscope may be inserted to check the correct placement. Next, the annulus is opened using a trephine and the trephine is removed after annulotomy is performed. With a rongeur, free disc material is removed from the annulus and nucleus manually. The Trigger-Flex Bipolar probe is brought into the center of the disc and the nucleus ablation is performed by a proprietary energy in the Bipolar Turbo mode. Several studies have shown that this step will remove approximately 0.8g of material out of the disc with a reduction of the intradiscal pressure. Further work with the rongeur is also possible at this step. The cavity in the dorsal disc can now be directly viewed endoscopically as well.

Next, the modulation of the dorsal annulus may be accomplished by directing the steerable Trigger-Flex dorsally. The proprietary waveform of Bipolar Hemo will shrink the collagen, cauterise inflammational structures and stabilise defects. Investigations to this effect of the Trigger-Flex demonstrated shrinkage of the annulus by 30% with a consecutive widening of the epidural space up to 10%. This result leads to an improvement of the blood circulation and reduction of the venous congestion in the ventral epidural space. By further retraction of the working cannula with endoscopic control, the epidural space can be inspected and the nerve root after decompression can be displayed. If necessary, the instruments can be introduced again for further decompression.

With a prospective study, we assessed the feasibility and the potential of this high-frequency radiowave energy based combination procedure. For the first prospective outcome study 64 patients with radicular pain syndromes and simple neurological deficits as well as contained disc extrusions or protrusions has been included. The procedures were performed in two different centres by different doctors in different cultures (US and Germany) with different workers compensation. Outcomes post-operatively were investigated after six weeks and after six month by a standardised protocol partly by independent investigators. The Visual Analogue Scale demonstrates an improvement from 8.45 to 1.98 two days postoperative, 3.53 after six weeks and 3.3 after six months (see Table 1). The Straight Leg Raising Test and the neurological deficits improved significantly. The McNab index is showing on average an 'excellent' outcome postoperatively and 'good' after six weeks and six months as well as the Andrews and Lavyene Score. To-date, there has been no complications. Compared to other minimal invasive procedures, Disc-FX seems to have the same low risk with an expected rate of less than 1 to 10,000 complications as an important factor.

These first results encouraged the investigators to expand upon the applications which seem to be comparable to the other minimal invasive procedures avoiding an open surgery and to fill the gap in the cascade of treatment of discal disorders. The combination of different techniques in one procedure marks an advantage and seems to be superior to any single technique. Cost of the device is less expensive than a full endoscopic procedure and has fewer complications than reported with open surgery. Significant benefits include avoidance of post-operative scaring and fibrosis as well as a faster recovery and the return to work.



Temperature distribution and safety after radiowave application

Use of Disc-FX

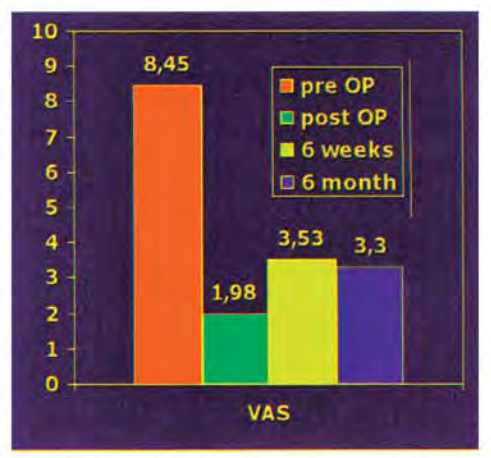
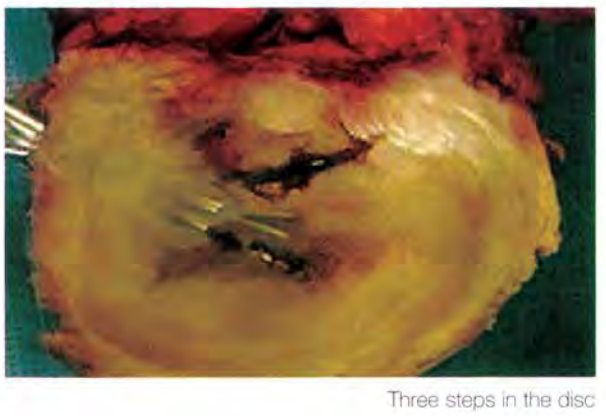


Table 1: Chart of pain (VAS) used in the study

View of the decompressed nerve root in the spinal channel after Disc-FX



Three steps in the disc

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