The Feasibility of an Intradiscal Hydrogel Implant for Nucleus Augmentation in Discogenic Pain

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Introduction: Non-operative therapeutic regimens often fail to achieve effective relief in chronic discogenic back pain that rely on natural healing processes to mitigate pain. Current surgical options range from intradiscal electrothermal therapy to lumbar fusion. Discectomy is a procedure validated by the SPORT Study. When discogenic pain progresses to disc herniation caused by failure of the annulus fibrosis to contain the nucleus, radiculopathy may occur. Minimally Invasive surgical treatment options were later developed, notably disc decompression performed transforaminally through Kambin's triangle. Posterolateral Selective Endoscopic Discectomy (SED) and radiofrequency (RF) thermal annuloplasty is a percutaneous endoscopic technique developed by Yeung, Also known as PELD. This promising surgical intervention for discogenic back pain is supported by endoscopic techniques in the literature. SED is a visualized intradiscal procedure that incorporates endoscopic discectomy, evocative chromodiscography, and thermal annuloplasty. (1-5) The current trend in MIS Spine are surgical procedures that focus on intradiscal therapy. Pilot studies on intradiscal augmentation implants of hydrogel sticks following CE mark approval demonstrate high efficacy rate with minimal procedural complications from its use to augment the nucleus. Extrusion, a common concern, for nucleus implants, is much lower than recurrent herniation. Biologics to heal, slow degeneration or even regenerate injured intervertebral discs through Intradiscal augmentation may be a viable step towards that goal.

Study design/setting: A 1997 IRB approved study by Yeung at St Luke’s Medical Center on endoscopic spine surgery for painful degenerative conditions of the lumbar spine determined that endoscopic discectomy with radiofrequency annular thermal modulation can provide back pain relief emanating from the lumbar disc. From this early experience with Selective endoscopic discectomy, a 3mm fluoroscopically guided cannula was developed combining mechanical discectomy with thermal annuloplasty (Disc fx). The results mirrored visualized endoscopic discectomy and thermal annuloplasty. Chronic exposure of the acidic irritants in the annular defects is hypothesized to be the local pain sensitization pathway that leads to...
chronic lumbar discogenic pain (CLDP).
Chronic lumbar discogenic pain is a difficult condition to treat, as its pathogenesis is multifactorial and only partially understood. Non-operative therapeutic methods often fail to achieve sufficient pain relief because chemical irritants emanate from the degenerating disc. Injection therapies with epidural steroids are good at relieving radiculitis, but are less successful at helping low back pain. Surgical options vary greatly, ranging from disc decompression to 360° fusion. The lumbar disc, however is the common source for chronic low back pain.
Chymopapain, an intradiscal procedure validated by Level 1 evidence based medicine is no longer available due to abandonment by industry. Liability issues including transverse myelitis and anaphylactic shock with the earlier less pure chymopapain, caused manufacturers to cease manufacturing this intradiscal drug. Other intradiscal therapies have emerged, but all have focused on the elimination of pain in a degenerating disc by decompression, ablation, and irrigation. The Gelstik option is the first procedure focused on nucleus augmentation rather than decompression and ablation. Favorable results in 1500 implants sold and supported by pilot studies in Spain, England, and Germany demonstrate the efficacy and safety of nucleus augmentation.