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The feasibility of a novel hydrogel (HPAN) intra-discal implant for nucleus augmentation

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Introduction & Background: Surgical options to treat painful degenerative conditions of the lumbar spine range from intra-discal electro-thermal therapy to lumbar fusion. Discectomy is a surgical treatment when discogenic pain progresses to disc herniation caused by failure of the annulus fibrosis to contain the nucleus. Transforaminal surgical decompression with thermal annuloplasty is the current most effective minimally invasive endoscopic treatment.

Materials & Method: A pilot study of 20 patients with discogenic pain suspected by radiographic imaging and confirmed by evocative discography and in 188 patients with foraminal stenosis decompressed endoscopically, hydrogel implants were also inserted into the desiccated discs. While patients with discogenic pain patients with stenosis both improved with direct intradiscal and foraminal decompression, adding intradiscal augmentation was hypothesized to provide more lasting relief.

Results: As measured by VAS, Oswestry and patient satisfaction, the pilot studies demonstrate very high clinical efficacy rate with no known extrusions or surgically related complications. The soft, spaghetti like hydrated implants resist extrusion in a relatively intact annulus to provide immediate hydraulic support. Overall results are therefore at least equivalent or superior to discectomy alone.

Discussion: Chronic lumbar discogenic pain is a difficult condition to treat, because its pathogenesis is multifactorial and only partially understood. Non-operative therapeutic methods often fail to achieve lasting pain relief. In a degenerating disc, chemical irritants from the degenerating disc irritate the spinal nerves through "toxic" annular tears. The degenerative disc, decompressed by endoscopic discectomy and thermal annuoplasty, is supported and augmented by a hydrogel implant inserted through an 18 gauge needle. The desiccated, spaghetti like hydrogel "sticks" expand 4-5 times in volume following hydration, and provide intradiscal hydraulic support. The modulus of elasticity of the polymer is closely similar to that of the native nucleus, and through intrinsic buffering activity has the capability to neutralize the acidic pH of the degenerating disc. As a result, Gelstix's™ HPAN-90 nucleus augmentation provides additional benefit by providing intradiscal support following decompression and ablation in the treatment of treating degenerated discs. Surgical options vary greatly, ranging from surgical disc decompression (Sport study) to 360° fusion. Surgical morbidity associated with all fusion techniques, however, while more thoroughly studied is significant when considering only 65 – 80 % of patients obtain satisfactory clinical results. The morbidity of fusion for back pain often creates more problems with adjacent level degeneration or when the procedure fails. The current trend in Endoscopic MIS Spine is surgical procedures focusing on intradiscal therapy. Other intradiscal therapies have emerged, but all have focused on the elimination of pain in a degenerating disc by decompression, ablation, irrigation, or oxidation, but not nucleus augmentation. The addition of a biologic material to enhance healing and nucleus regeneration could be a viable adjunct to nucleus augmentation.

Conclusion: Pilot studies on intradiscal augmentation demonstrate very high clinical efficacy rate with almost no complications. The Gelstix™ nucleus augmentation option is a procedure focused on replacing and augmenting the nucleus rather than decompression and ablation. Preliminary cases warrant further study, especially with biologics currently under study.

Biography

Anthony T Yeung is an internationally renowned world leader, author and lecturer in endoscopic spine surgery and the recipient of numerous awards including Becker's Orthopedic and Spine Review's "Top 100 Spine Surgeons in the Nation," "Health Care Hero" by the Phoenix Business *Journal* and "Top Doc" by *PHOENIX magazine*.

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