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BIOSTAT BIOLOGX® Intradiscal Fibrin Sealant Used for the Treatment of Chronic Low Back Pain Caused by Lumbar Internal Disc Disruption: Results of a 12 Month, Prospective Multicenter Pilot Study

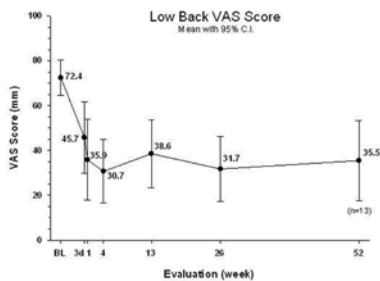
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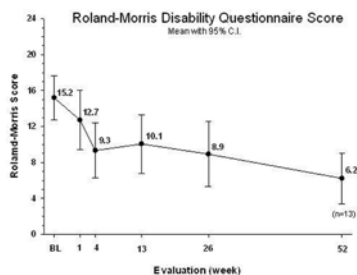
Purpose: To assess the safety and efficacy of intradiscal injection of BIOSTAT BIOLOGX® Fibrin Sealant, delivered using the Biostat® System, to treat chronic low back pain (CLBP) caused by lumbar internal disc disruption (IDD).

Methods: An FDA approved, prospective, nonrandomized, pilot study of the Biostat fibrin injection system was initiated in May 2008 at three institutions. 15 adults with axial CLBP refractive to epidural injection, conservative, and pharmacologic therapies, were enrolled after provocation discography confirmed lumbar discogenic pain with asymptomatic control levels. Patients presented with either single (n=12), or contiguous, two-level (n=3) symptomatic discs. BIOSTAT BIOLOGX Fibrin Sealant was percutaneously injected into symptomatic lumbar discs using this proprietary delivery system. Patients were followed at 72 hours, and at 1, 4, 13, 26, and 52 weeks. Primary outcome measures assessed the short and long term safety of intradiscal injections of fibrin sealant. Secondary outcome measures included assessment of low back pain (Visual Analog Scale, VAS) and function (Roland-Morris Disability Questionnaire, RMDQ).

Results: All 15 patients completed assessment at the 6 month primary endpoint. Two subjects voluntarily withdrew from the study at 52 weeks, prior to completing their final outcome assessments. One procedure-related complication occurred (discitis), where disc aspirate cultures grew mixed oral flora. At 6 months, VAS improved more than 30% from baseline in 13 of 15 subjects (87%), and more than 50% from baseline in 10 of 15 subjects (67%). After 12 months, 8 of 13 subjects (62%) maintained greater than a 30% improvement in their VAS, while 7 of 13 (54%) maintained greater than a 50% improvement in their VAS. When compared with their baseline, at 6 months post treatment, mean VAS decreased from 72.4 mm (95% CI: 64.6 - 80.3) to 31.7mm (17.3 - 46.1), and at 12 months decreased to 35.5mm (17.7 - 53.3). Likewise, the mean RMDQ dropped from a baseline of 15.2 (12.7-17.5), to 8.9 (5.3-12.5) and 6.2 (3.4-9.1) at 6 and 12 months respectively.



[VAS Improvement]



[Roland-Morris Disability Questionnaire]

Conclusion: Intradiscal injection of BIOSTAT BIOLOGX Fibrin Sealant using the Biostat System in adults who suffer with discogenic CLBP is intrinsically safe, although one case of mixed oral flora discitis occurred. Mean reductions in VAS of

51% and RMDQ of 59% at 12 months post treatment demonstrates intradiscal fibrin sealant improves pain and function in patients with symptomatic internal disc disruption.