ADCON-L and T/N
Short review of most important studies

Spine


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Abstract: A prospective, multicenter, randomised, double-blind, controlled study of Acon-L Anti-Adhesion Barrier Gel was conducted in 298 patients undergoing first-time lumbar discectomy to evaluate the safety and effectiveness of Adcon-L in preventing post-operative peridural fibrosis and in improving patient clinical outcome. After lumbar discectomy, patients were randomised to receive either Adcon-L gel or nothing (control group) at the conclusion of the surgical procedure. Six months after surgery, peridural scar was evaluated by MRI, and post-operative pain and straight-leg-raise angle were assessed. No statistically significant differences between the Adcon-L and control groups were observed in terms of adverse events or wound healing characteristics. Adcon-L gel was shown to be safe and to significantly inhibit
peridural scar compared with the control group (p = 0.002). That peridural scarring was reduced with Adcon-L gel was further supported by direct visualization of scar tissue at re-operation in both groups. Adcon-L treated patients had better clinical outcomes than did control patients. The incidence of activity-related pain was significantly reduced (p = 0.013), straight-leg-raise examination scores were significantly improved (p = 0.024 on the operative side), and Adcon-L reduced low back pain when it was most severe (p = 0.047) and at the end of the day (p = 0.044).


Abstract: This paper is to report the results from a retrospective clinical study of Adcon-L for inhibition of post-operative peridural fibrosis following spinal root decompression. The purpose of the study was to collect surgeon experience data related to the use of Adcon-L following primary lumbar nerve root decompression in adult patients. Ten US investigators (spinal surgeons) have independently collected and reviewed information retrospectively from the post-operative medical records from consecutive series of patients who had undergone a single level, lumbar nerve root decompression with Adcon-L application. Patient records were retrieved for evaluations on demographics, surgical use, and complications, re-operations, medical events and adverse events. There was a total of 847 Adcon-L treated patients of which 819
eligible patients were included in the evaluable analysis. In the evaluable patient population, 64.3% of the patients were male and the mean age was 43 years. An overall medical event incidence rate of 12.7% was seen. Common medical events included pain in limb (1.3%), back pain (0.9%), intervertebral disc herniation (0.9%), headache (0.6%) and insomnia (0.4%). Common adverse events included pain in limb (8.5%), back pain (8.3%), intervertebral disc herniation (3.9%), radiculitis (3.2%), muscle spasms (2.1%), radiculopathy (0.9%) and hypoaesthesia (0.9%). The surgeons review of the medical and adverse events indicated 83.8% were unrelated to Adcon-L and only 16.2% were considered possibly related. No event was considered probably or definitely related to Adcon-L. Re-operations were performed in 4.3% of eligible patients. Of the 35 patients who underwent re-operation, there was no significant peridural fibrosis in 26 (74.3%) patients. A total of 5 eligible patients were seen with cerebrospinal fluid leakage or pseudomeningocele, comprising 0.6% of the total eligible population. There were no anaphylactic/anaphylactoid reactions or patient deaths reported among the 847 patients followed in the study.

3. Results of applying Adcon-L after lumbar discectomy: the German Adcon-L study.
Richter HP, Kast E, Tomczak R, Besenfelder W, Gaus W.
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Abstract: Use of Adcon-L gel has been proven to reduce post-operative scarring in animal experiments. The authors of two controlled clinical studies have also shown positive results when applying the gel. They did not, however, establish patient-oriented endpoints. The authors report a study of Adcon-L in which they focus on patient-oriented endpoints. Patients with lumbar disc herniation were randomised to an Adcon-L treated or control group. Therapeutic success was evaluated using the validated Hannover Questionnaire on Activities of Daily Living (FFbH) 6 months after surgery. The study took place between November 1996 and April 1998 in eight
neurosurgical centers in Germany. A total of 398 patients was recruited; 41 patients dropped out during follow-up. The mean functional FFbH score (100 points = all activities without problem; 0 points = no activity possible) was 78.5 points in the Adcon-L group and 80 points in the control group (not statistically significant). In terms of secondary outcome variables, the Adcon-L group did not have an advantage over the control group. Only the mean magnetic resonance imaging score showed a slight advantage over the control group. The authors concluded that they found no positive effect of Adcon-L in their study.

Hand

1. **The use of Adcon-T/N after repair of zone II flexor tendons.**
Liew SH, Potokar T, Bantick GL, Morgan I, Ford C, Murison MS.
Welsh Center for Burns and Plastic Surgery, Morriston Hospital, Swansea, UK

   **Abstract:** This double-blind clinical trial investigated whether application of Adcon-T/N to zone II tendon repairs improved their outcomes. 59 patients were randomised into control or Adcon-T/N treated groups and all followed an early mobilisation regime following tendon repair. Tendon rupture rates were comparable between the control and Adcon-T/N treated patients. At six months follow-up the Adcon-T/N treated group had significantly better proximal interphalangeal motion.

2. **Treatment of recurrent peripheral nerve entrapment problems: role of scar formation and its possible treatment.**
McCall TD, Grant GA, Britz GW, Goodkin R, Kliot M.
Dept Neurological Surg, University of Washington School of Medicine, Seattle, USA.
Abstract: Extraneural fibrosis is one possible cause of recurrent peripheral nerve problems as a result of nerve compression or tethering. Several different approaches to prevent extraneural scarring after surgery have been studied including wrapping the involved nerve with a graft, the application of various chemical compounds and radiation. Adcon-T/N, an antiscar bioresorbable gel device was evaluated in a retrospective clinical review. 67% of patients treated with Adcon-T/N after re-operation of a peripheral nerve experienced prolonged clinical improvement versus 50% of patients who did not receive Adcon-T/N.