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

Spine

1. Clinical assessment of a novel anti-adhesion barrier gel: prospective randomised, multicenter clinical trial of Adcon-L to inhibit post-operative peridural fibrosis and related symptoms after lumbar discectomy.

de Tribolet N, Porchet F, Lutz TW, Gratzl O, Brotchi J, van Alphen HA, van Acker RE, Benini A, Strommer KN, Bernays RL, Goffin J, Beuls EA, Ross JS. Dept Neurosurg,CHU Vaudois, Lausanne, Switzerland,; Dept Neurosurg Kantonsspital Basel, Switzerland; Dept Neurosurg Hop Univ Erasme, ULB, Bruxelles, Belgium; Dept Neurosurg AZ VU Amsterdam, The Netherlands; Dept Neurosurg St Lucas, Amsterdam, The Netherlands; Dept Neurosurg Kantonsspital St.Gallen, Switzerland; Dept Neurosurg Universitätsspital Zürich, Switzerland; Dept Neurosurg, UZ Gasthuisberg, Leuven, Belgium; Dept Neurosurg AZ Maastricht, The Netherlands; Dept Radiology, Cleveland Clinic Foundation, OH, USA.
Am J Orthop **1998** Feb;27(2):111-20

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).

2. **Adcon-L for inhibition of post-operative peridural fibrosis following spinal root decompression : a retrospective clinical data review.**
Greenspan J, Sypert G, Maroon J, Bartie B, Moldawer T, Ma F,Tedford C, Palatinsky E, Fournier M, Lavin P, Beghin J, Rouben D, Kolavo j, Shugart R, Mathern B.North County Neurosurgical Associates, NY,USA, The Sypert Institute, FL, St.Croix Orthopaedics, MN, Southern California Orthopaedic Institute, CA, Tristate Neurosurgical Associates UPMC, PA, Gliatech Medical Inc., Boston Biostatics, Inc., Indiana Back Center,IN, River City Orthopaedic Surgeons, P.S.C.,KY, orthopaedic Associates of DuPage, IL, fort Wayne Orthopaedics, IN, Mid-Atlantic Spine Specialists, VA, USA.
US retrospective clinical study, data with Gliatech, Inc. Review and poster presentation. Data from surgeries **between June 1, 1998 and Oct 30, 2000**.

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 (o.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.
Dept Neurosurg, University Ulm, Germany
J Neurosurg **2001** Oct; 95(2 suppl): 179-89

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
   Chir Main **2001** Oct; 20(5): 384-7

   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.
   Neurosurg Clin N Am **2001** Apr; 12(2): 329-39

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.