Development of Collagenase Clostridium Histolyticum (Xiaflex) Injection for Fibroporiferative Diseases

Collagenase Clostridium histolyticum (CCH) injection therapy for Dupuytren contracture was developed at Stony Brook University Medical Center "from bench to bedside". This disorder prevents patients from full extension of fingers, severely limits hand function and, prior to the injection therapy, surgery was the only option. Laboratory bench work led to an FDA investigational new drug number (IND) which allowed for FDA regulated Phase 1, 2 and 3 clinical trials (1,2,3). CCH was licensed to industry after Phase 1 and 2 and one Phase 3 clinical trial at Stony Brook University Medical Center. In 2010, CCH injection was FDA approved as "Xiaflex" in adult patients with Dupuytren contracture. Since then, many regulatory agencies around the world have approved this therapy, including the EU countries and Australia. It is estimated there are approximately 13-25 million Dupuytren patients worldwide.

Frozen shoulder (adhesive capsulitis) is a painful condition of the shoulder capsule which severely limits function of one or both arms and can last 2-3 years. Prolonged and painful physical therapy and/or shoulder arthroscopy are some of the present treatment options. CCH injection is currently in FDA regulated Phase 2 clinical trial study in the USA and Australia. Developed at Stony Brook Orthopaedics and licensed to industry early indications suggest that this injection therapy has merit in treating frozen shoulder and reducing recovery time from years to 2-3 months (4). Edematous fibrosclerotic panniculopathy (cellulite), at first thought, may not seem to be a collagen based disorder but it is. Fine collagen "bands", known as septae form, mostly on the thighs and buttocks of women. Adipose or "fat" tissue protrudes through the bands giving the unsightly "mattress-like" appearance. Phase 2 FDA regulated clinical trials are now underway to investigate the safety and efficacy of CCH injection for cellulite elimination. This technology, developed at Stony Brook, has been licensed to industry.