

Fibrosoft- A novel non surgical treatment of
Dupuytren's, Ledderhose's and Peyronie's- fibromatosis disease.

Brisbane, Queensland , Australia

Email: fibrosoft@icloud.com

Clinical photographs & incidence

Dupuytren's disease – Hands
Ledderhose's disease- Feet
Peyronie's disease- Penile



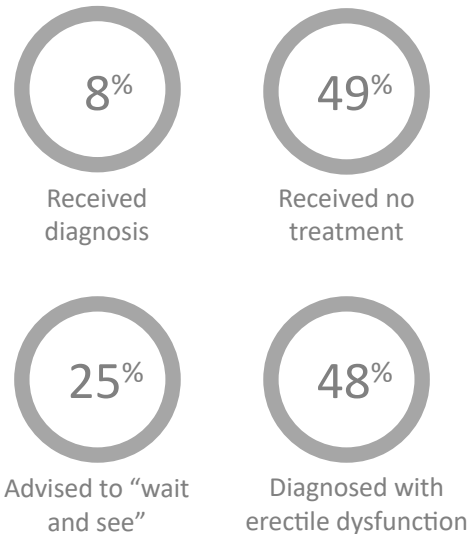
Dupuytren's disease- Hands-Clinical presentation
75% of 75 yrs old Northern European affected



Ledderhose's disease- Feet-Clinical presentation
Affecting 1% of general population

Peyronie's disease

- 92% of men with Peyronie's disease did not receive that diagnosis the first time they saw an HCP for penile symptoms ⁽¹⁾
- Percentage of men who visited an HCP * for penile symptoms



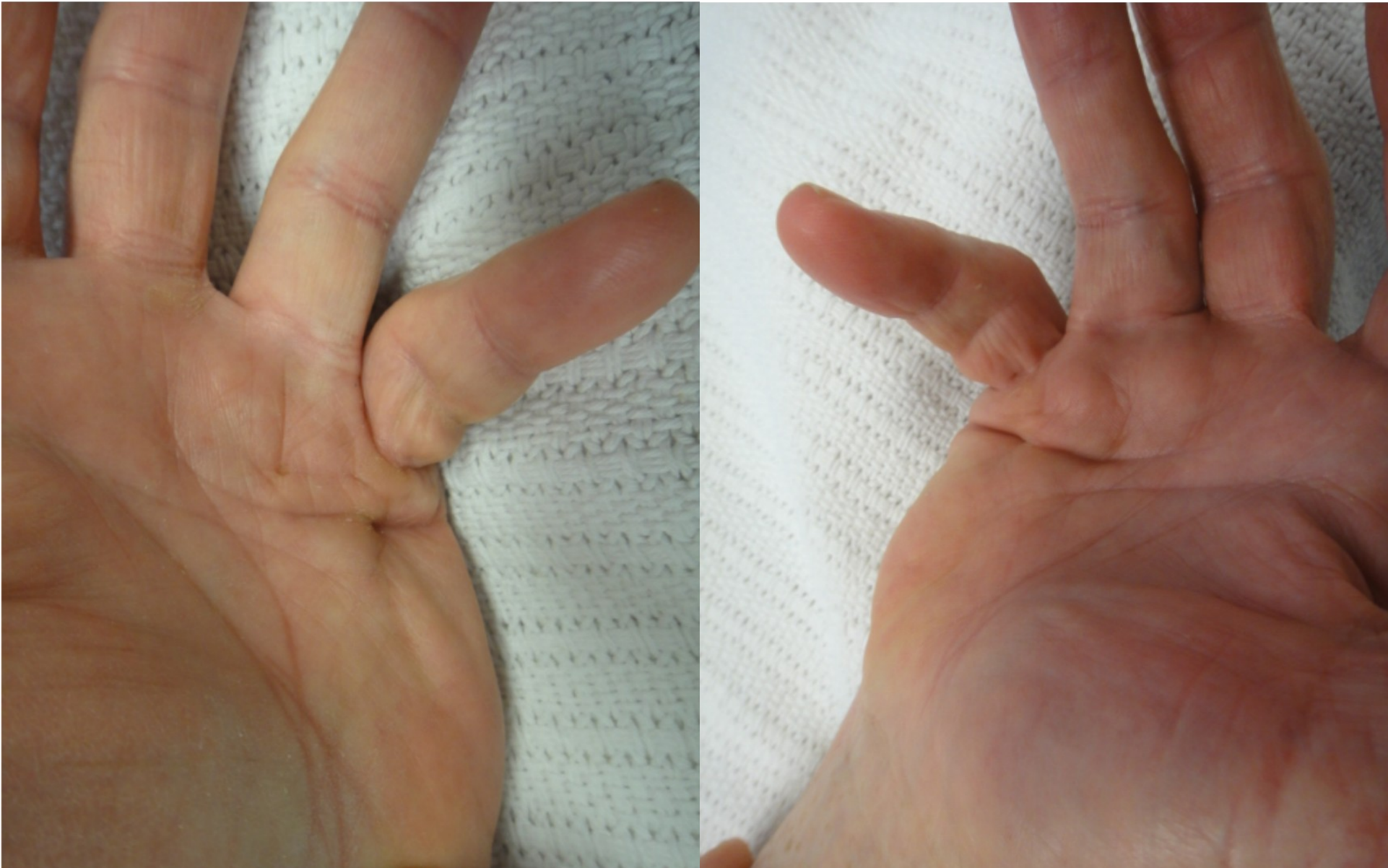
~ 1 in 10

men may have Peyronie's disease in the U.S. ⁽²⁾

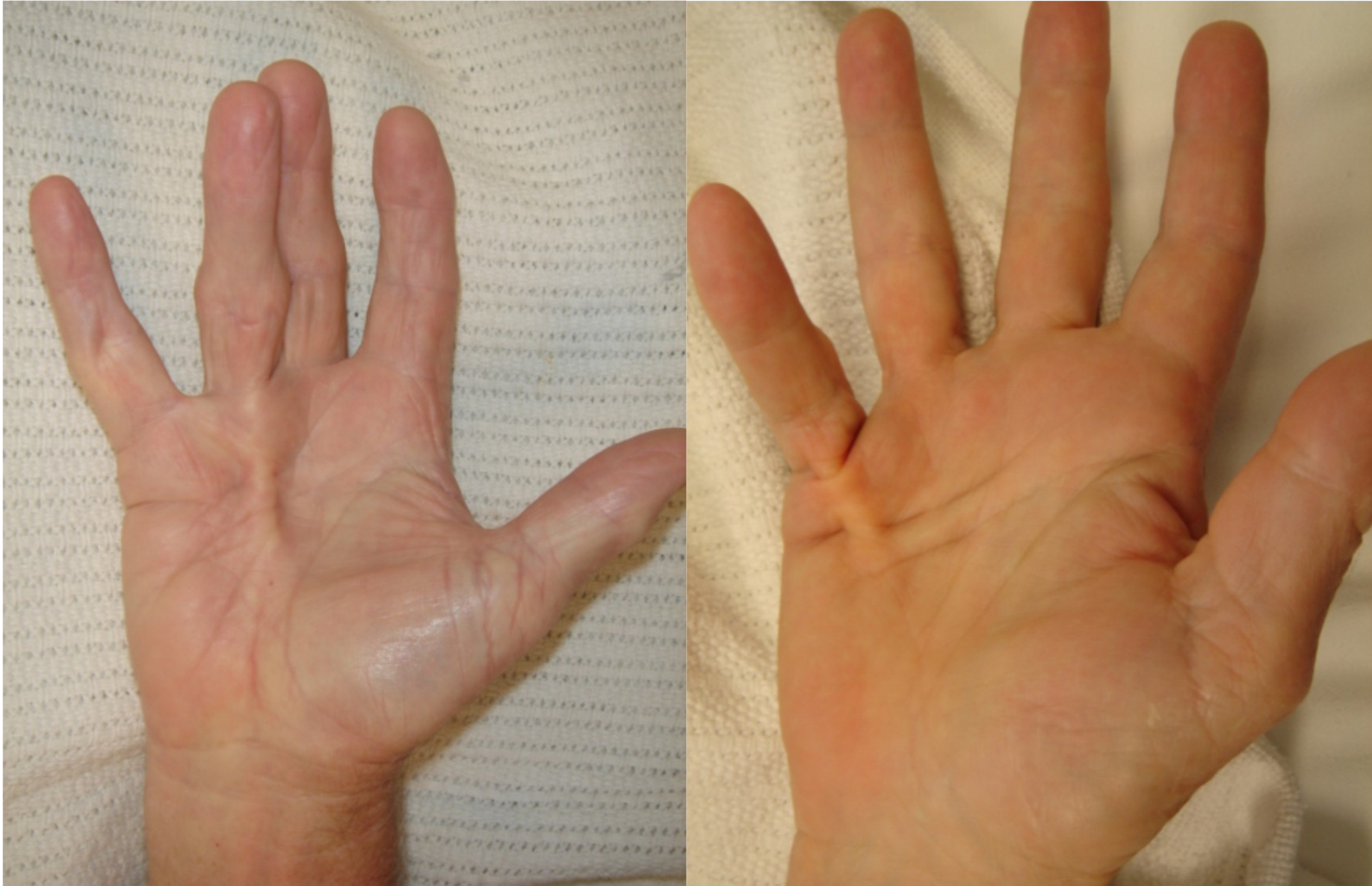


* HCP=healthcare professional.

1. DiBenedetti DB, Nguyen D, Zografos L, Ziemiecki R, Zhou X. A population-based study of Peyronie's disease: prevalence and treatment patterns in the United States. *Adv Urol.* 2011;282503. doi:10.1155/2011/282503.
2. Stuntz M, Perlaky A, des Vignes F, Kyriakides T, Glass D. The prevalence of Peyronie's disease in the United States: a population-based study. *PLoS One.* 2016;11(2):e0150157.



Dupuytren's disease- Hands-Clinical presentation



Dupuytren's disease- Hands-Clinical presentation



Ledderhose's disease
 1% of population;
 1: 20 Dupuytren's patients affected

Fibromatosis diseases

- Characterized by excessive collagen deposition
- Impacts 30% of the population over 65 years in the USA, UK, and Australia
- Accounts for 28.8 million affected individuals, excluding Europe.
- Dupuytren's 75% of 75 yrs old Northern European affected
- Peyronie's 1:10 men
- Ledderhose's 1% of population; 1: 20 Dupuytren's patients affected.
No treatment available- surgery not recommended

Fibromatosis diseases

- Surgery remains the general standard.
- “Surgical intervention is generally advised against”.
- An effective non-surgical alternative would be generally preferred and readily achieve high acceptance.

Fibrosoft

Mission

Develop and market a novel non-surgical treatment for fibromatosis-mediated diseases, leading to greatly improved patient outcomes.

Vision

To become the premier global leader in fibromatosis therapy.

Fibrosoft

- Fibrosoft, our novel, non-surgical, injectable formulation.
- Stimulates normal physiological pathways involved in collagen production and turnover by producing collagenases endogenously at the normal physiological levels within the proteolytic cascade, thereby preventing abnormal collagen accumulation.
- Restores tissue homeostasis through the combined effects of increased collagenase activity and the activation of normal collagen production pathways and thereby mitigates the fibrotic response.

Clinical photographs outcome
before (pre) and after (post) treatment

Dupuytren's disease – Hands
Ledderhose's disease- Feet
Peyronie's disease- Penile

Before



After



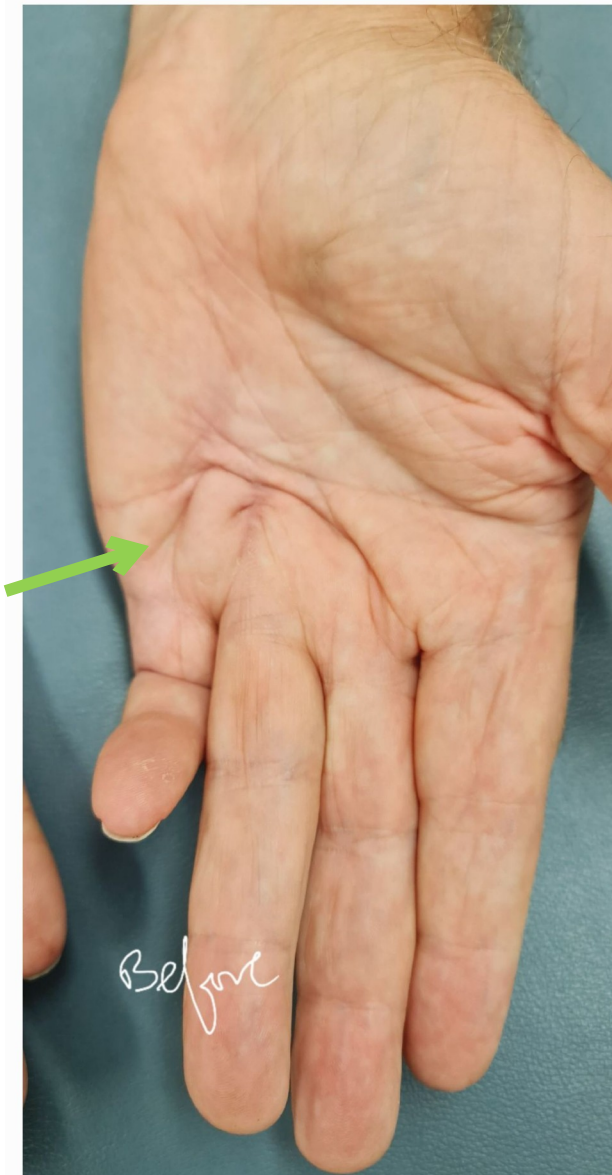
Before



After



Before



After

After



Before



Before



After



After



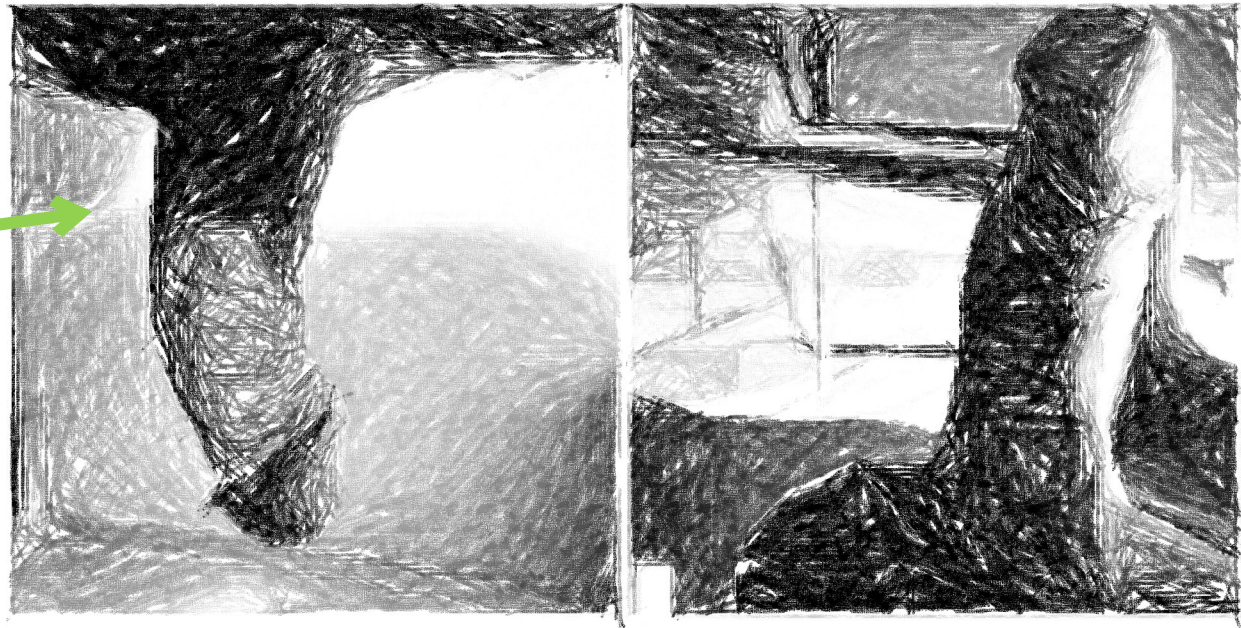
Before



Peyronie's disease



Before



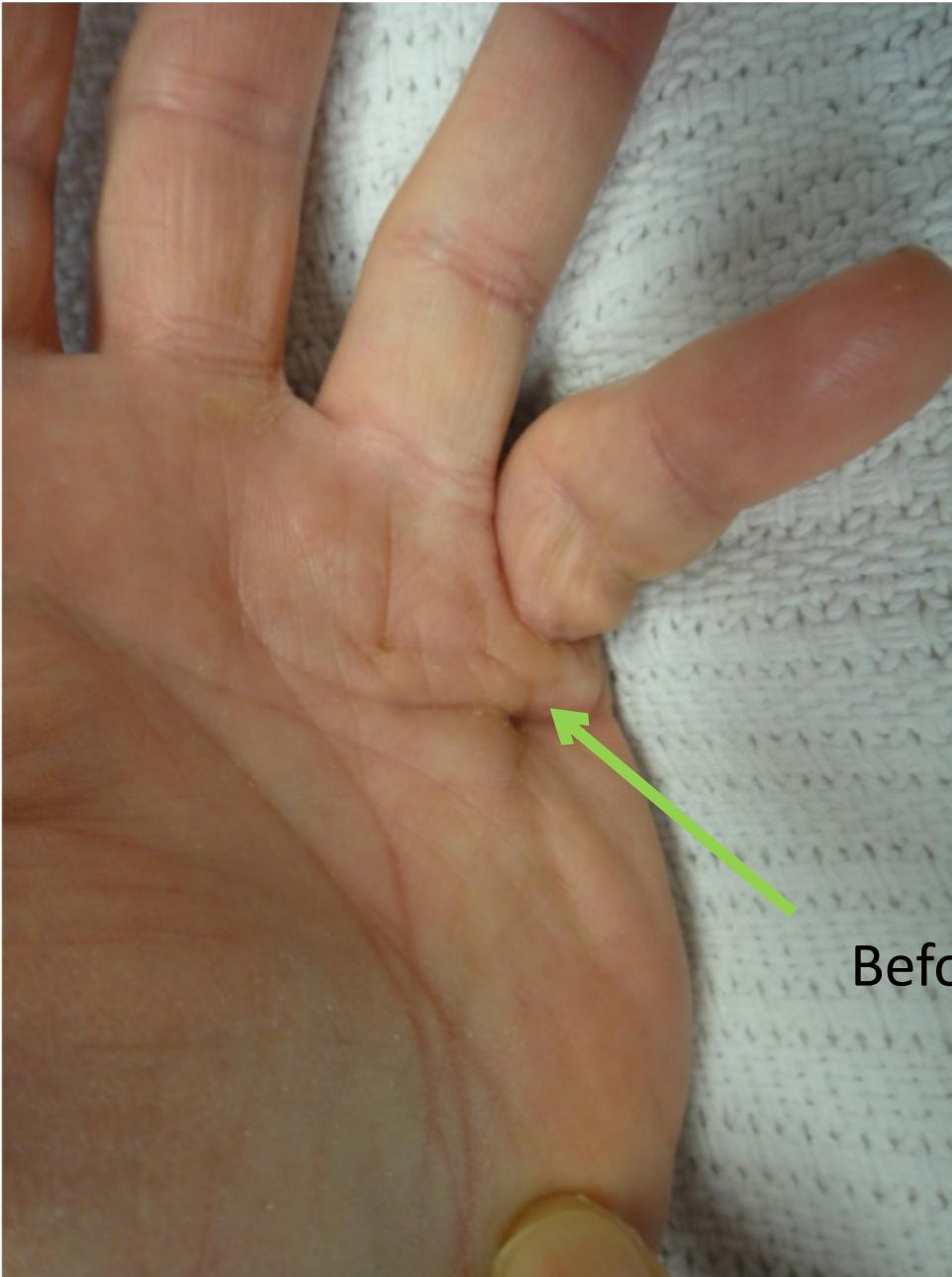
After

After

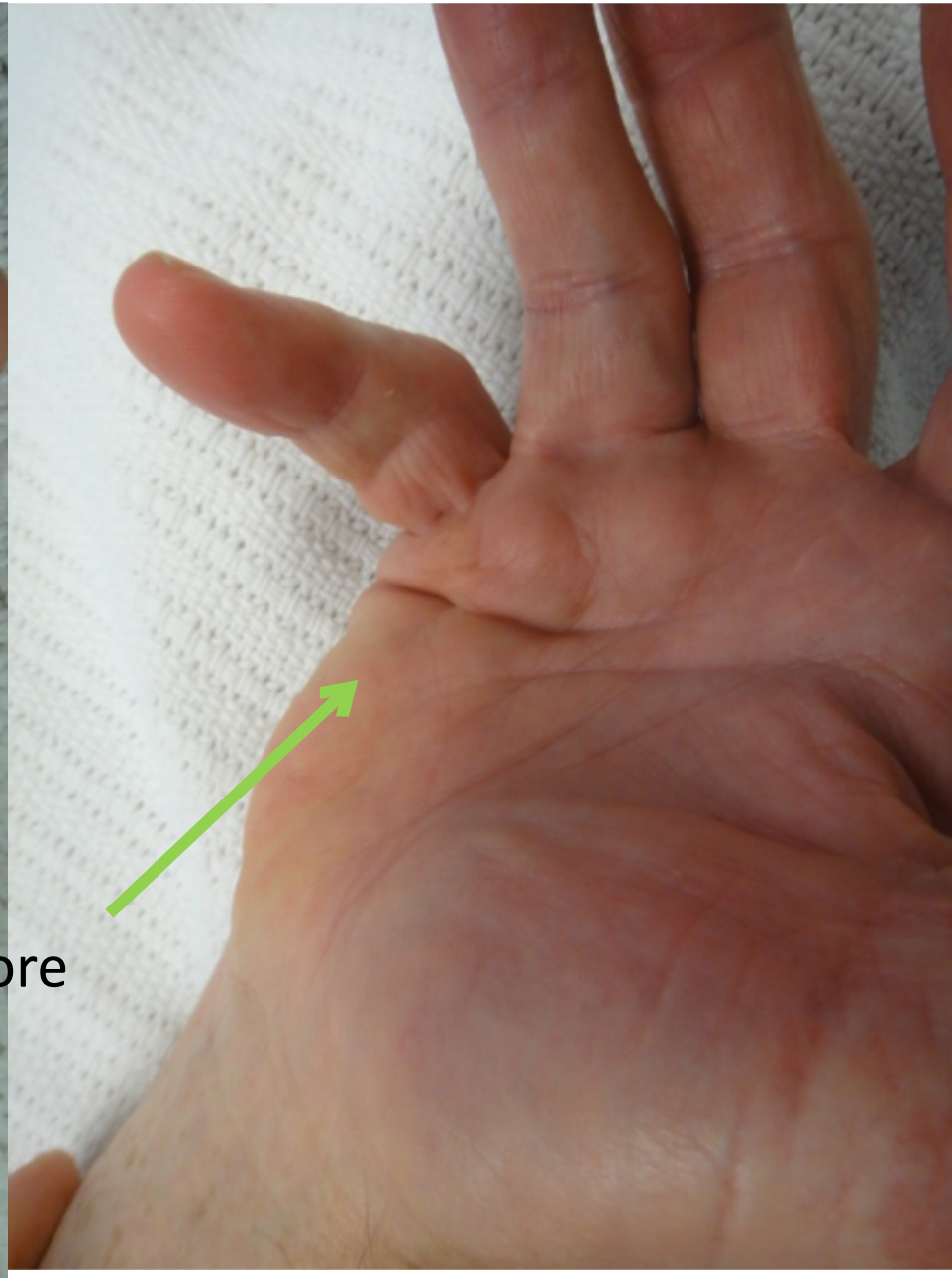


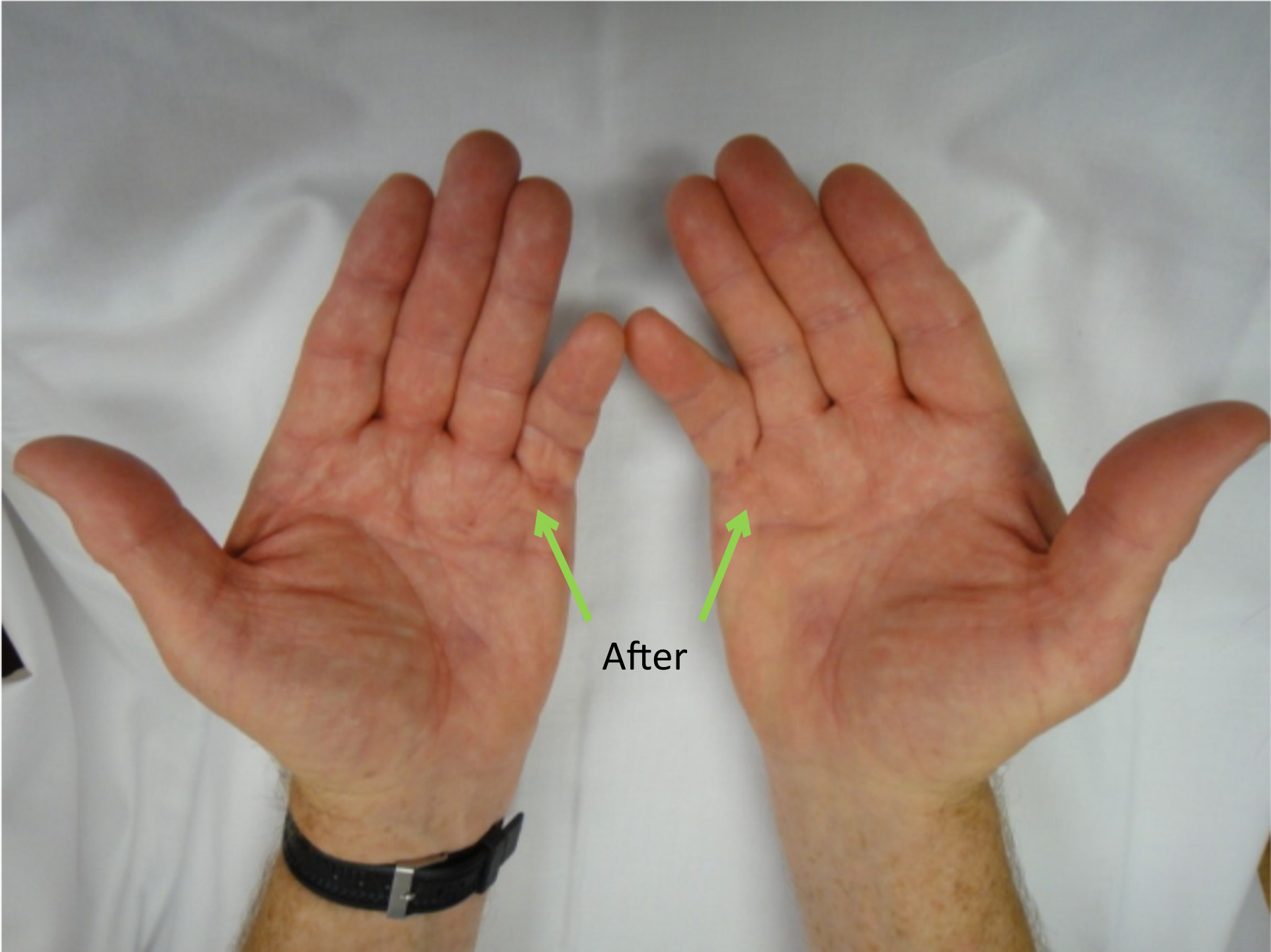
Before





Before





After

Before



Pre treatment

After



Post treatment injection 2 months post

Our Real-World Clinical Experience

- Broad patient population with varying symptoms ¹⁻²
 - 270+ patients treated to date with our novel injectable formulation, Fibrosoft.
 - Treatment achieves 30% improvement following first injection.
 - Safe. No SAEs (Significant Adverse Effects)
 - 90% of patients return for follow-on treatment , approximately 6 weeks later.

1. Dupuytren's Disease: Prevalence, Incidence, and Lifetime Risk of Surgical Intervention. A Population-Based Cohort Analysis. Dieuwke et al_Plastic and Reconstructive Surgery 151(3):p 581-591, March 2023.

Clinical experience

- Fibrosoft formulations have been developed and evaluated on Dupuytren's, Ledderhose's, and Peyronie's nodules. 270+ patients treated highlighting our formulation efficacy and safety.
- The 3 years follow-up study revealed significant therapeutic benefits across all three conditions. Notably, no treatment-related serious adverse events have been reported to date, underscoring our formulation safety profile.

1. D. Chin et al, c-DNA microarray technique-the final frontier in plastic surgery research? The ANZ Journal of Surgery, Vol 70S, 78, 2001
2. D. Chin et al, Analysis of head and neck cancers using cDNA microarrays: comparison of matched normal oral mucosa and primary tumours. The ANZ Journal of Surgery, Vol 73S A55 2003.
3. D. Chin et al, The human genome and gene expression profiling. J Plast Reconstr Aesthet Surg, 59: 902-911, 2006.



indicated for the treatment of adults with Dupuytren's contracture with a palpable cord.

Safety Information

Uncontrolled portions of clinical trials showed that severe tendon ruptures occurred after XIAFLEX[®] injection of XIAFLEX[®] into collagen-containing structures such as tendons or ligaments of the hand, resulting in damage to these structures and possible injury such as tendon rupture or ligament injury. Therefore, XIAFLEX[®] should be injected only into a palpable cord with a MP or PIP joint contracture. Care should be taken to avoid injecting into tendons, ligaments, blood vessels, or other collagen-containing structures of the hand. When injecting a cord affecting the fifth finger, insert the needle no more than 1/2 inch in depth, and avoid injecting more than 1/2 inch from the palmar digital crease.

Local adverse reactions in clinical trials included bruising, erythema, edema, tendon rupture, ligament injury, complex regional pain syndrome (CRPS), and sensory abnormality.

Uncontrolled portions of the clinical trials (Studies 1 and 2) showed that a higher proportion of XIAFLEX[®]-treated patients compared to placebo-treated patients (14%) had local reactions (pruritus) after up to 3 injections. The incidence of XIAFLEX[®]-associated pruritus increased with the number of XIAFLEX[®] injections.

See Brief Summary of the Full Prescribing Information on adjacent page.

Although there were no severe allergic reactions observed in the XIAFLEX[®] studies (e.g., those associated with respiratory compromise, hypotension, or end-organ dysfunction), severe reactions including anaphylaxis could occur following XIAFLEX[®] injections. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX[®] injections.

In the XIAFLEX[®] trials (Studies 1 and 2), 70% and 38% of XIAFLEX[®]-treated patients developed an ecchymosis/contusion or an injection site hemorrhage, respectively. The efficacy and safety of XIAFLEX[®] in patients receiving anticoagulant medications (other than low-dose aspirin) within 7 days prior to XIAFLEX[®] administration is not known. Therefore, use with caution in patients with coagulation disorders including patients receiving concomitant anticoagulants (except for low-dose aspirin).

The most frequently reported adverse drug reactions (≥5%) in the XIAFLEX[®] clinical trials and at an incidence greater than placebo included: edema, peripheral, contusion, injection site hemorrhage, injection site reaction, pain in extremity, tenderness, injection site swelling, pruritus, lymphadenopathy, skin laceration, lymph node pain, erythema, and axillary pain.

XIAFLEX[®] For adults with Dupuytren's contracture with a palpable cord

Experience CORD-DISRUPTING EFFICACY delivered nonsurgically

XIAFLEX[®] is the only FDA-approved, nonsurgical choice with proven efficacy. XIAFLEX[®] is a combination of two types of collagenase which appear to work synergistically to provide enzymatic disruption of the collagen in the Dupuytren's cord.

• 44% to 64% of XIAFLEX[®]-treated patients* achieved a reduction in contracture to 0° to 5° at 30 days post-treatment of the selected joints (MP and PIP) 30 days after up to 3 injections* compared to the 0° to 5° of patients receiving placebo achieved contracture reduction to 0° to 5° of normal†

Go to XIAFLEX.com, call 1-877-XIAFLEX (1-877-942-3639), or contact your XIAFLEX[®] representative for more information or to enroll for procedure training today.

Come visit us at ASPS Annual Meeting
Booth #919



*Based on 2 clinical studies of adult patients with a palpable cord. Initial degree of contracture was 20° to 90° for MP joints and 20° to 80° for PIP joints.
†Mean age 60 years.

XIAFLEX
collagenase clostridium histolyticum

Fibrosoft- Competitive advantage

- Patients return for repetitive treatment over 3 to 6 months period until function is restored
- Transient minimal side effects in comparison with current competitor- *Xiaflex

	*Xiaflex	*Placebo		Fibrosoft
				out of 270+cases treated
Allergic reaction	15%	1%		0
Contusion	78%	3%		2 cases transient
Peripheral oedema	73%	5%		2 cases transient
Haemorrhage	38%	3%		1 case
Pain	35%	4%		0

*Reference source: Xiaflex homepage www.dupuytren-online.info/index.html

Problems with Xiaflex

- Expensive US\$3,250.00 per vial will require 2-3 visits
No rebate from Medicare or Insurance
- High Complications rate
 - Flexor tendon rupture (0.3%)
 - nerve injury
 - allergic reaction (15%)
 - CRPS(complex regional pain syndrome)
- Endo Therapeutics has strong caution using Xiaflex for Dupuytren's disease (hands) due to high complications
Currently Xiaflex is only use for Peyronie's disease
<https://www.xiaflex.com/>

Fibrosoft Patent status

- **USA**
 - US Application Granted No. 18/555,377
 - US Patent No. 12,280,095 on 22 April 2025.
- **Europe**
 - European Application No. 22859663.1
 - Under accelerated prosecution
- **Australia**
 - Granted Australian Patent No. 2022335159
 - Australian Divisional Application No. 2024200488
- **Projected Expiry Date:** 25 August 2042- (* Brisbane Olympic City 2032)

Brisbane – Olympic City 2032

Email: fibrosoft@icloud.com