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

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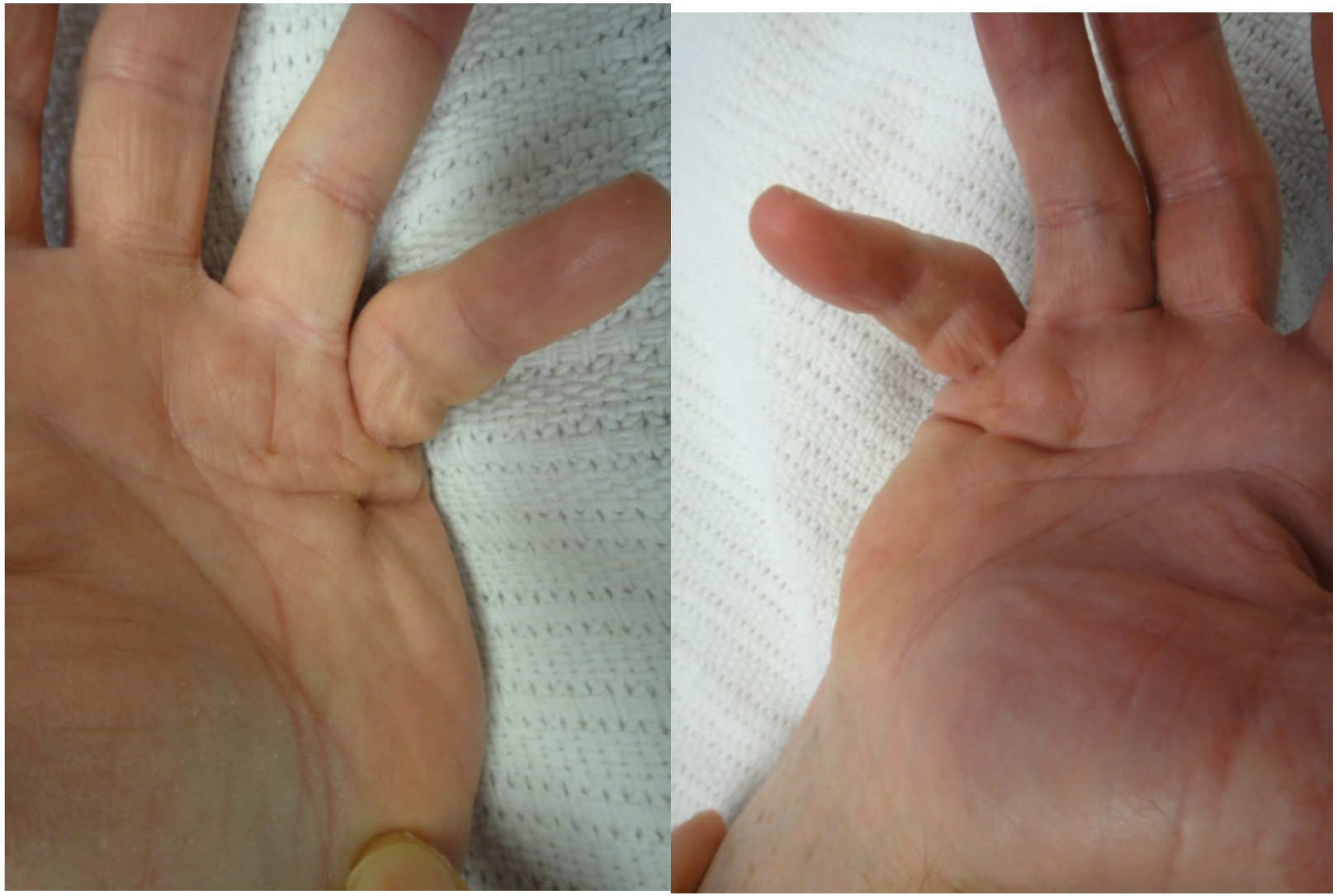
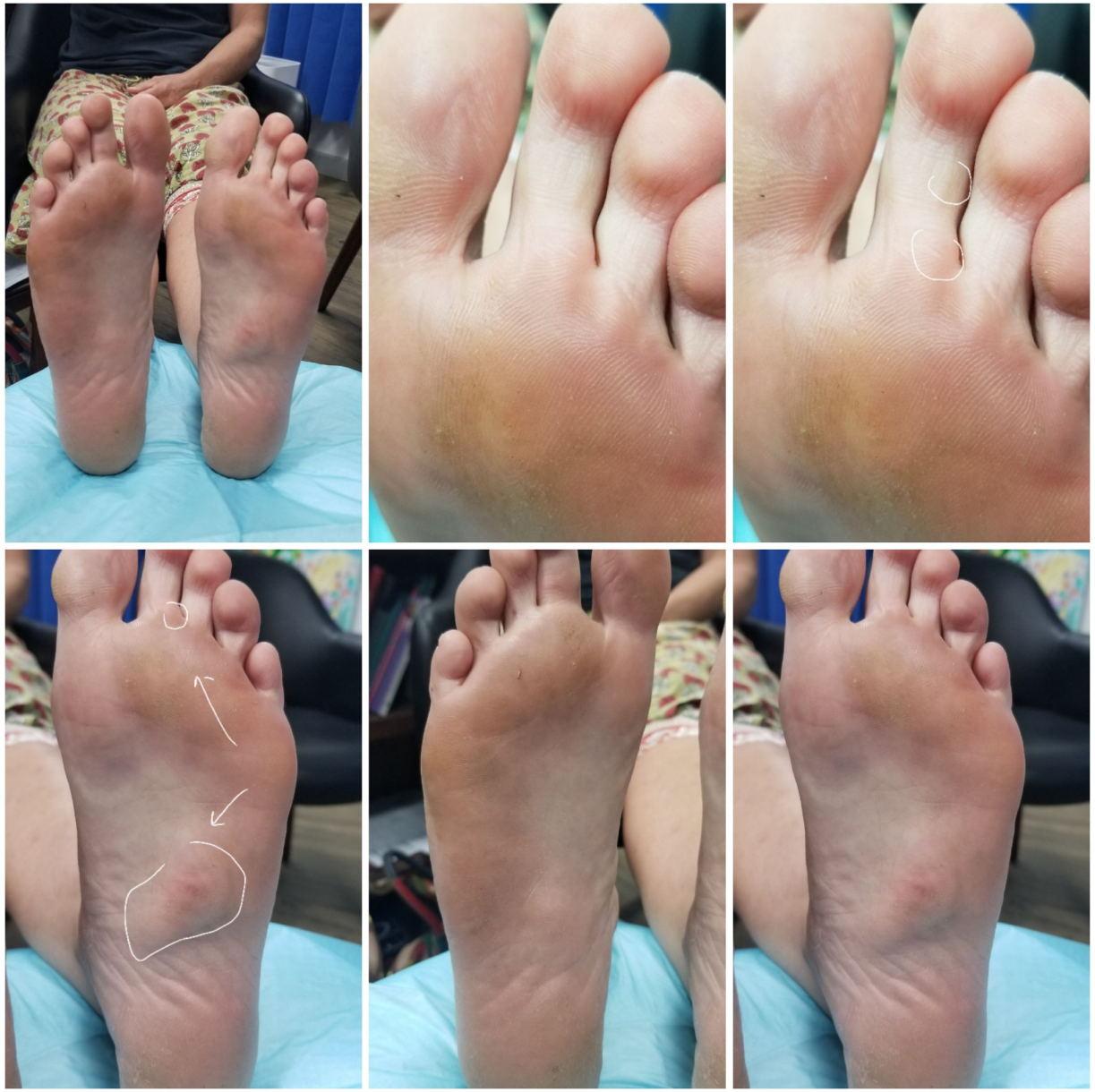
Clinical photographs & incidence

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

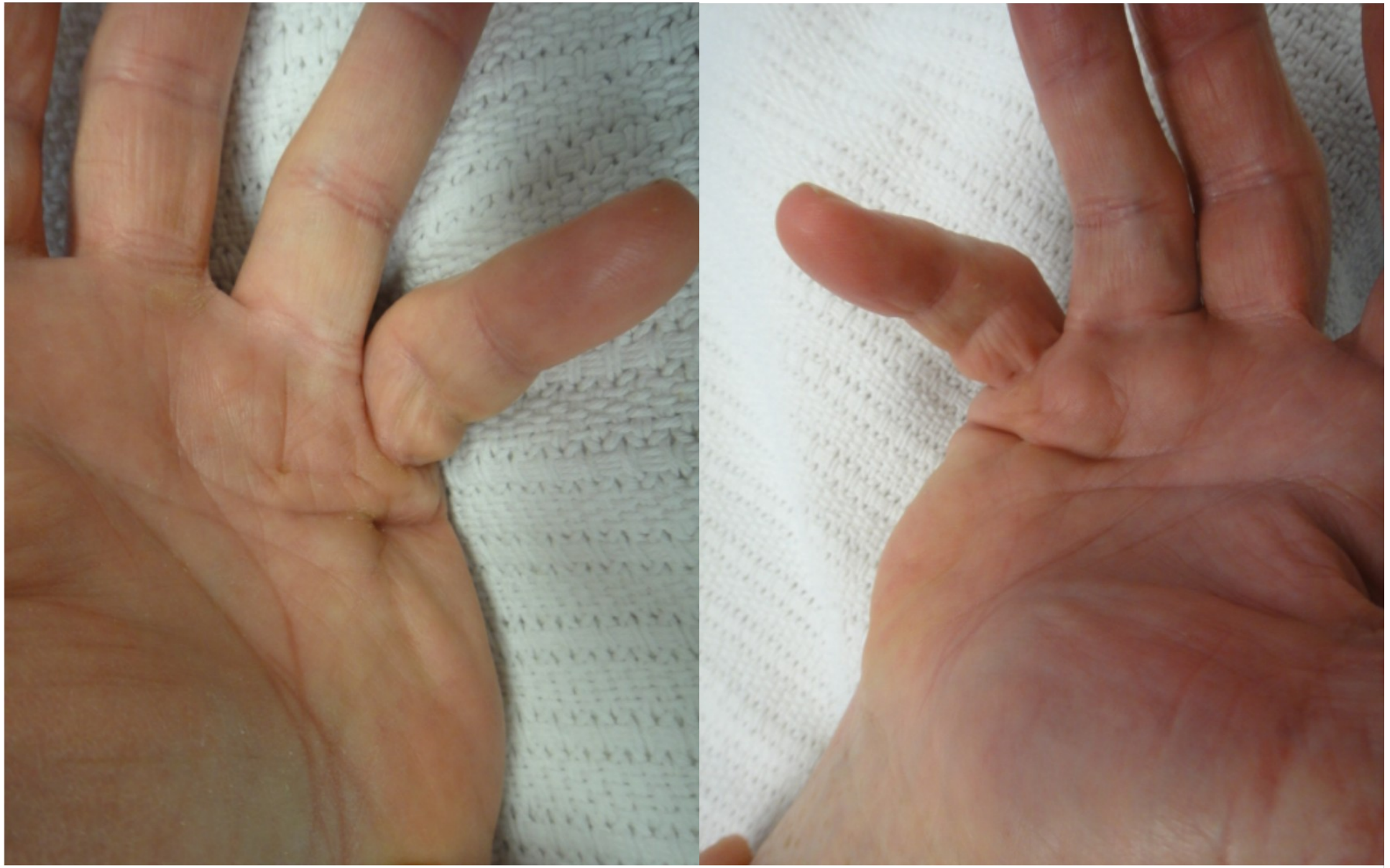
- 92% of men with Peyronie's disease did not receive that diagnosis the first time they saw an HCP for penile symptoms [1]
- Percentage of men who visited an HCP * for penile symptoms

~ 1 in 10

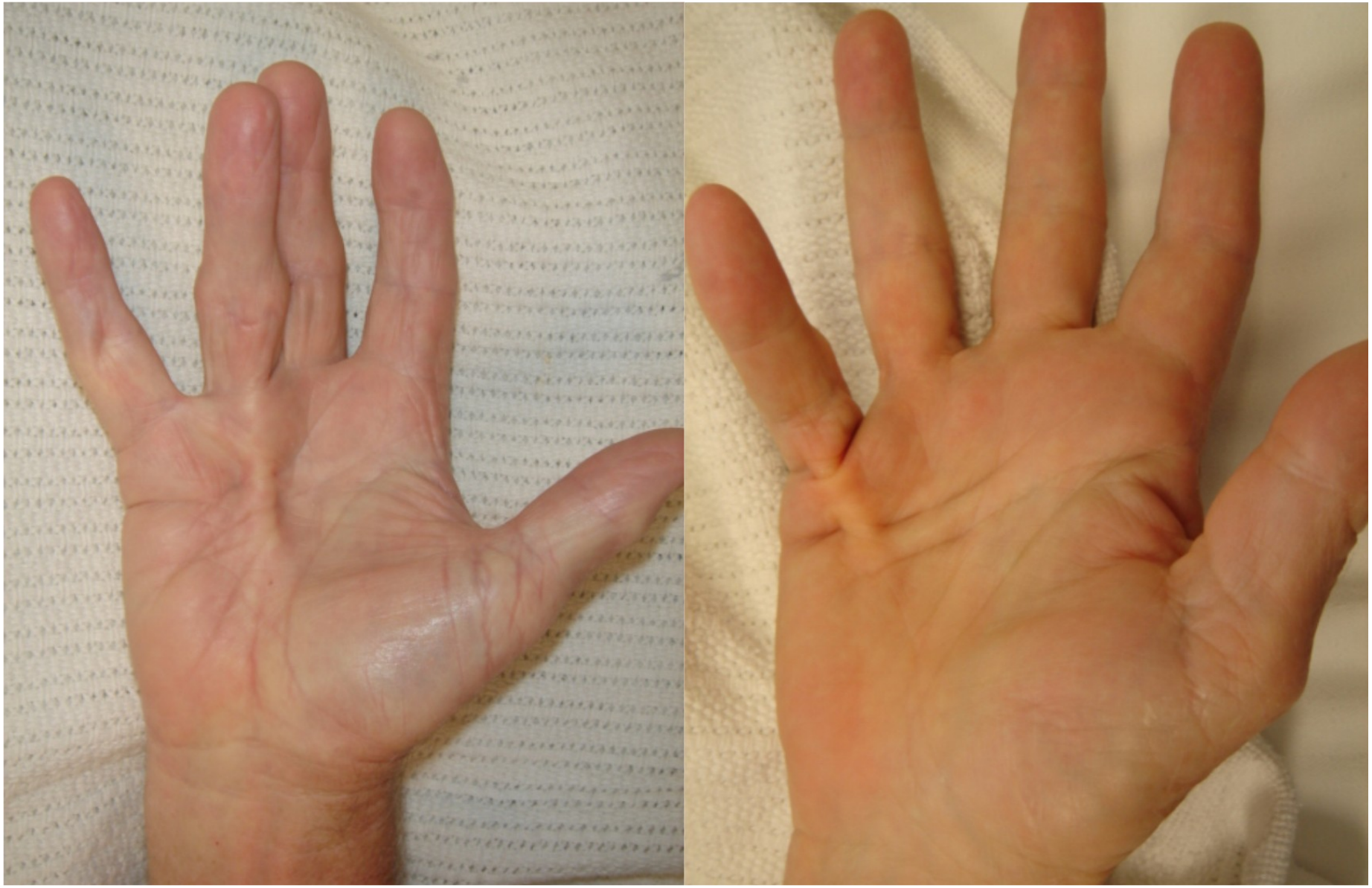
men may have Peyronie's disease in the U.S. [2]

* HCP=healthcare professional.

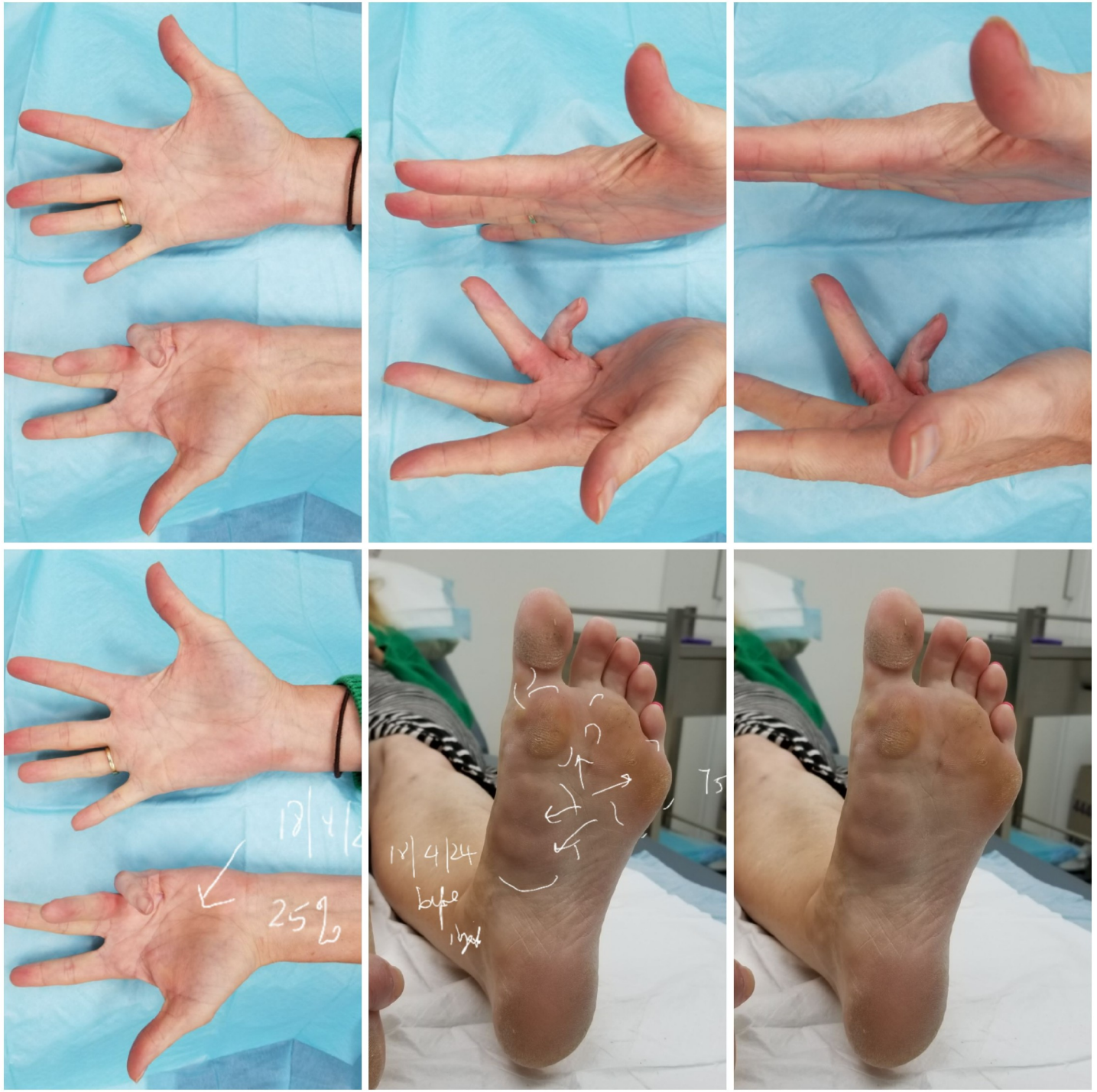
1. DiBenedetti DB, Nguyen D, Zografos L, Ziemiecki R, Zhou X. A population-based study of Peyronie’s disease: prevalence and treatment patterns in the United States. Adv Urol. 2011:282503. doi:10.1155/2011/282503.
2. Stuntz M, Perlaky A, des Vignes F, Kyriakides T, Glass D. The prevalence of Peyronie’s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

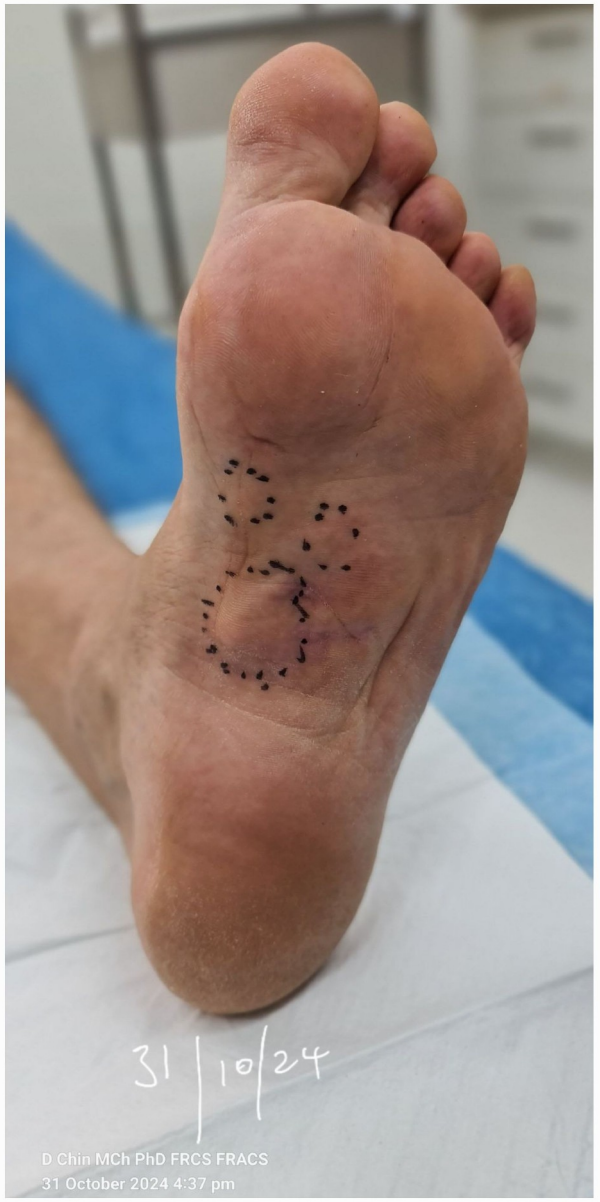
- Stimulates normal physiological pathways involved in collagen production and turnover by producing collagenases endogenously at the normal physiological levels within the proteolytic cascade, thereby preventing abnormal collagen accumulation.

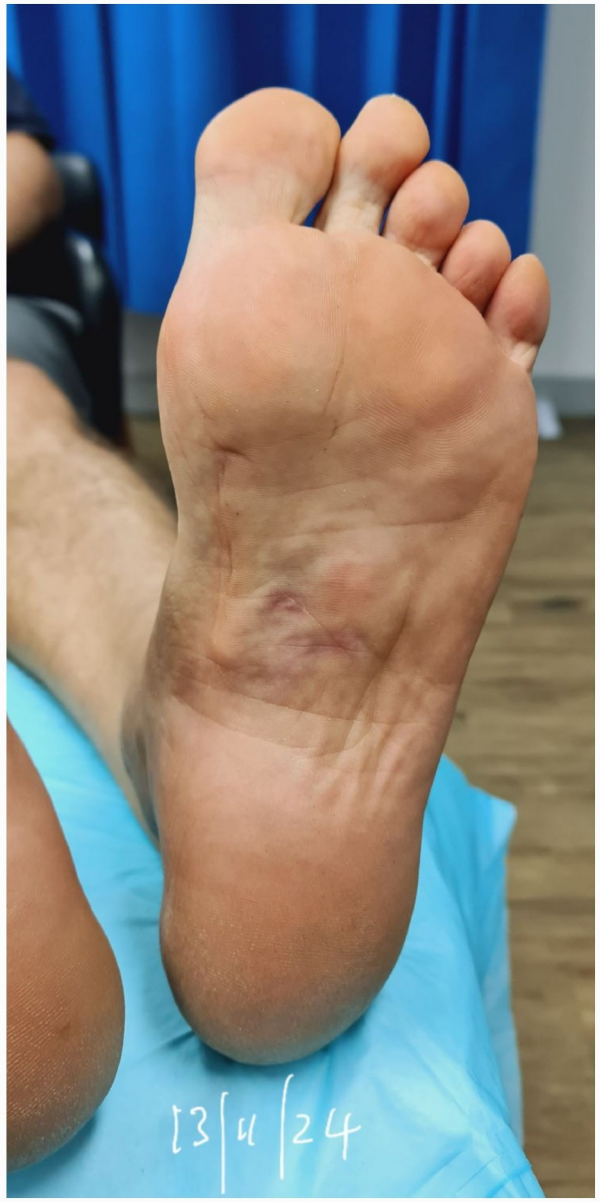
- Restores tissue homeostasis through the combined effects of increased collagenase activity and the activation of normal collagen production pathways and thereby mitigates the fibrotic response.

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

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

Before





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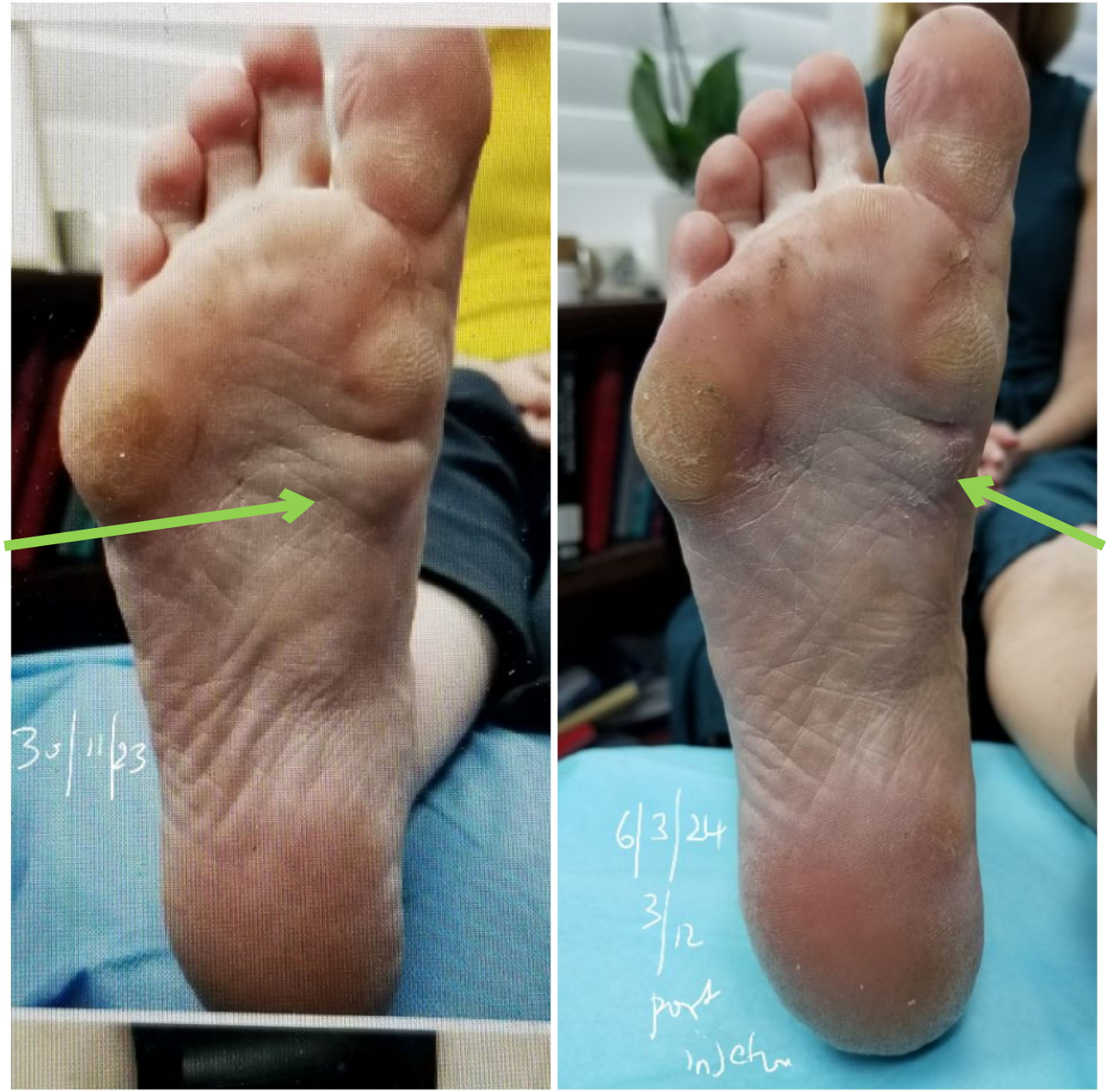

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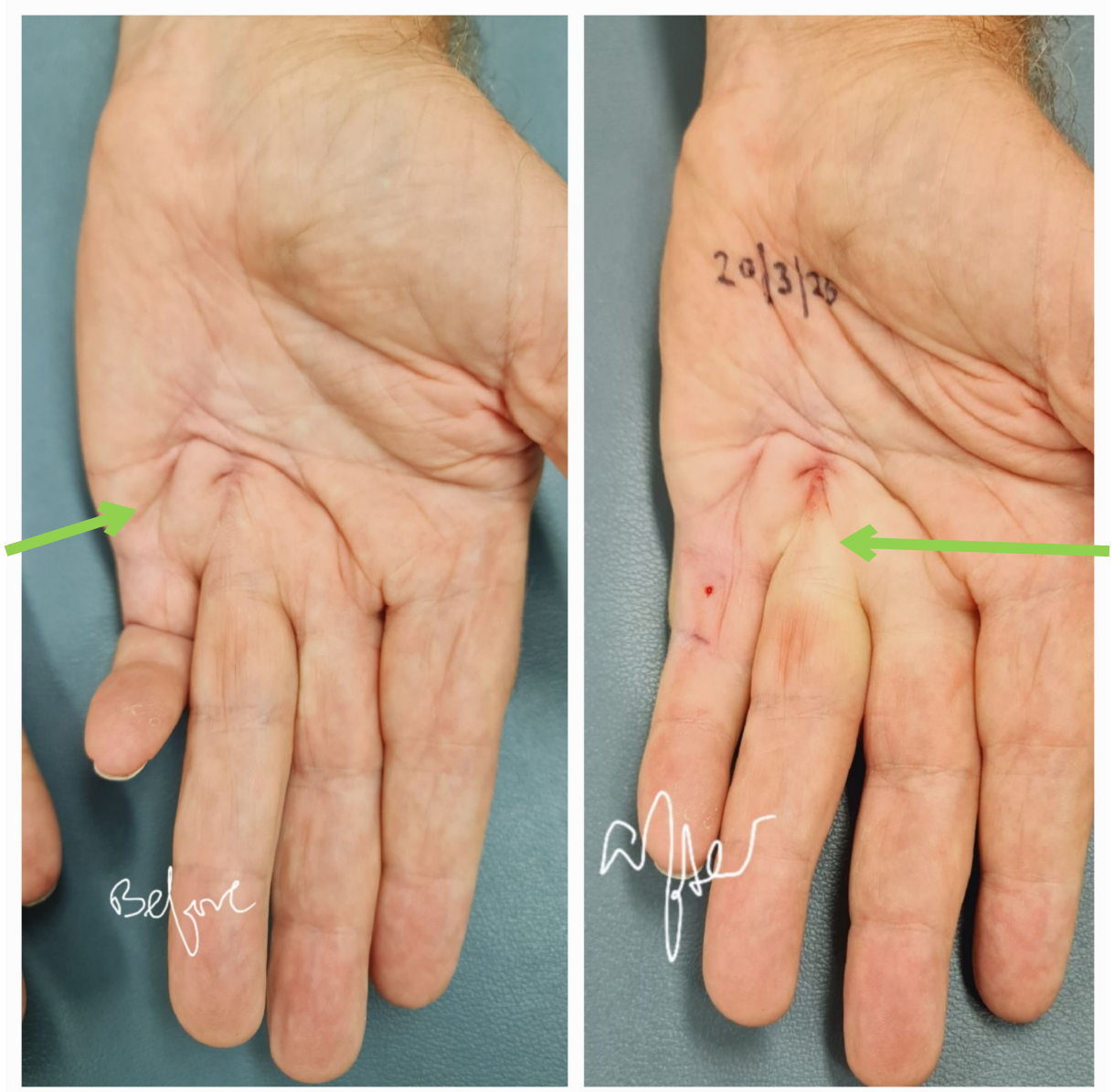

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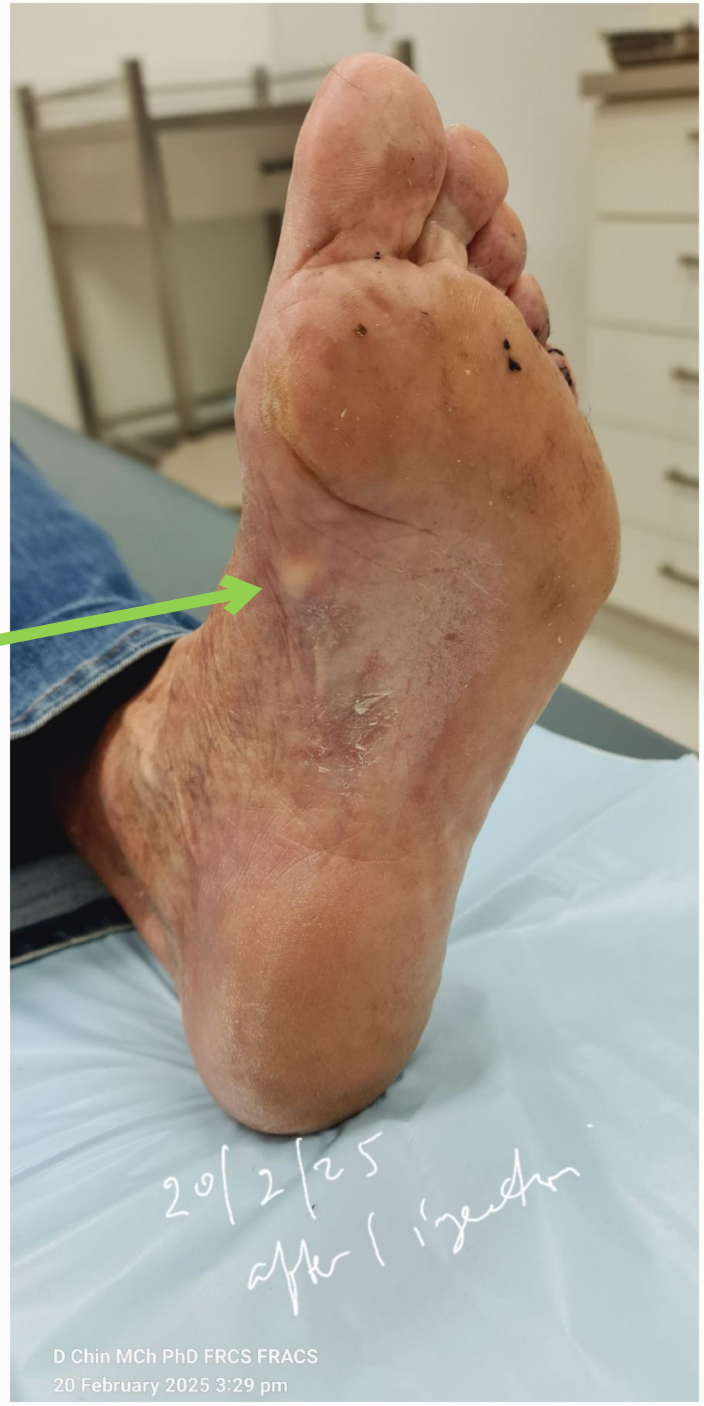

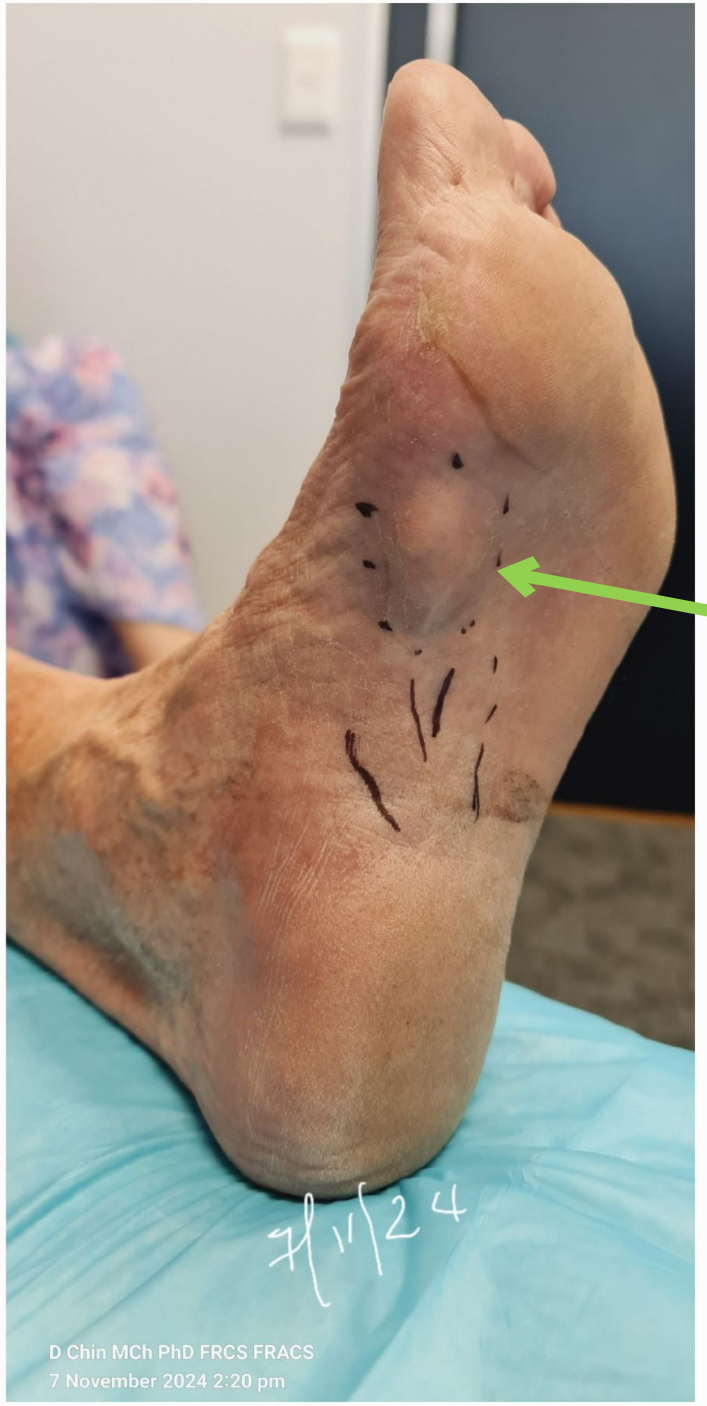

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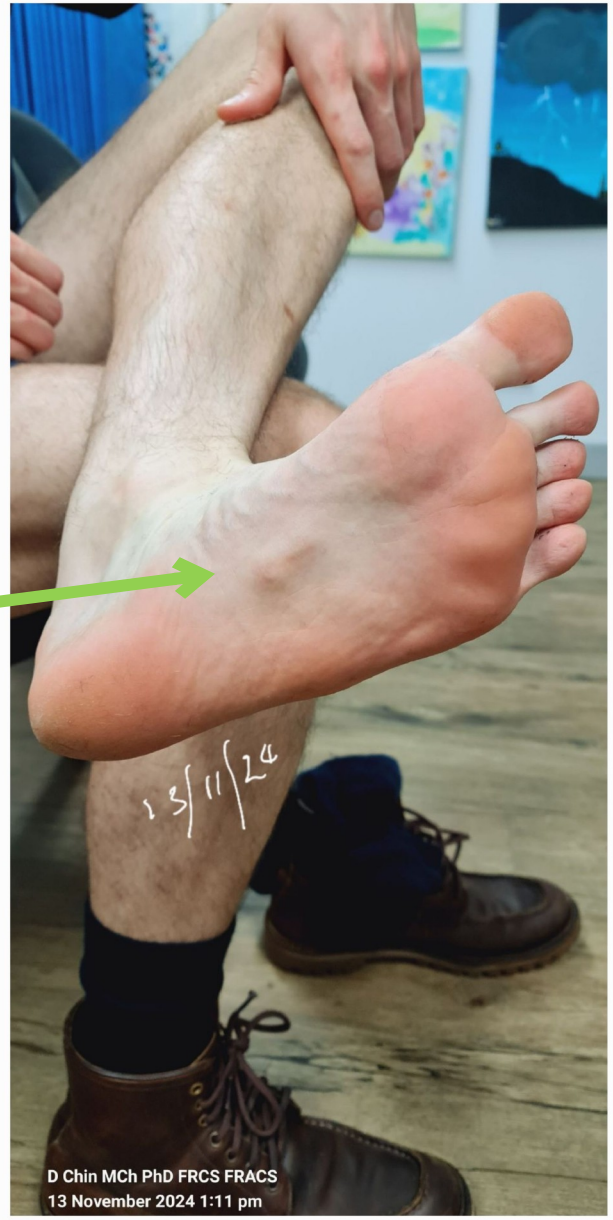

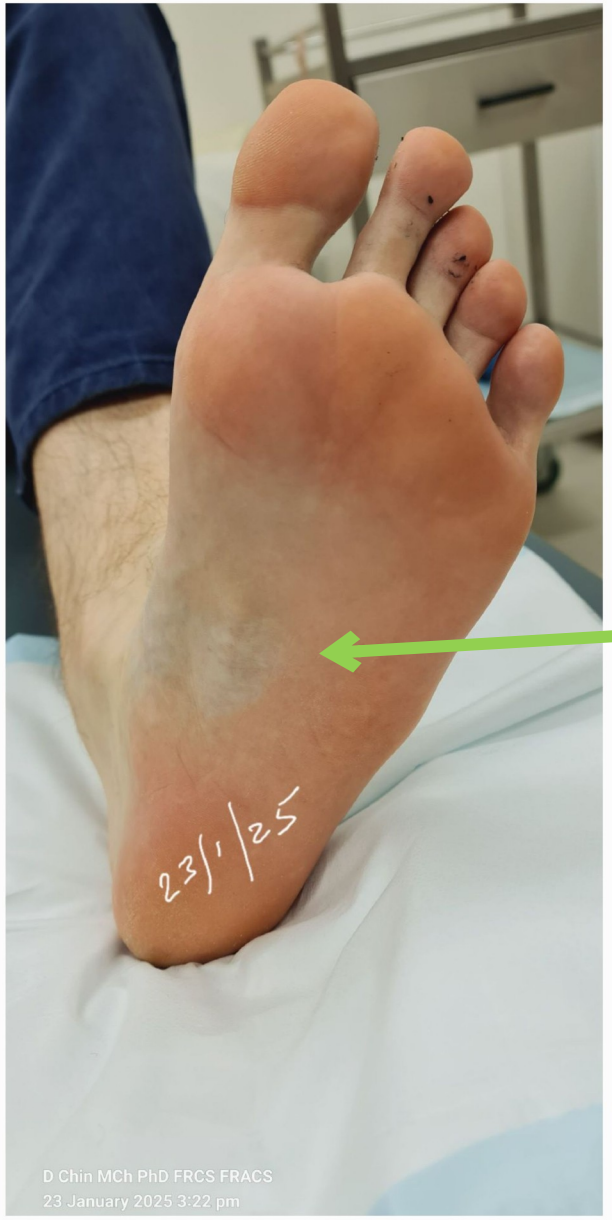

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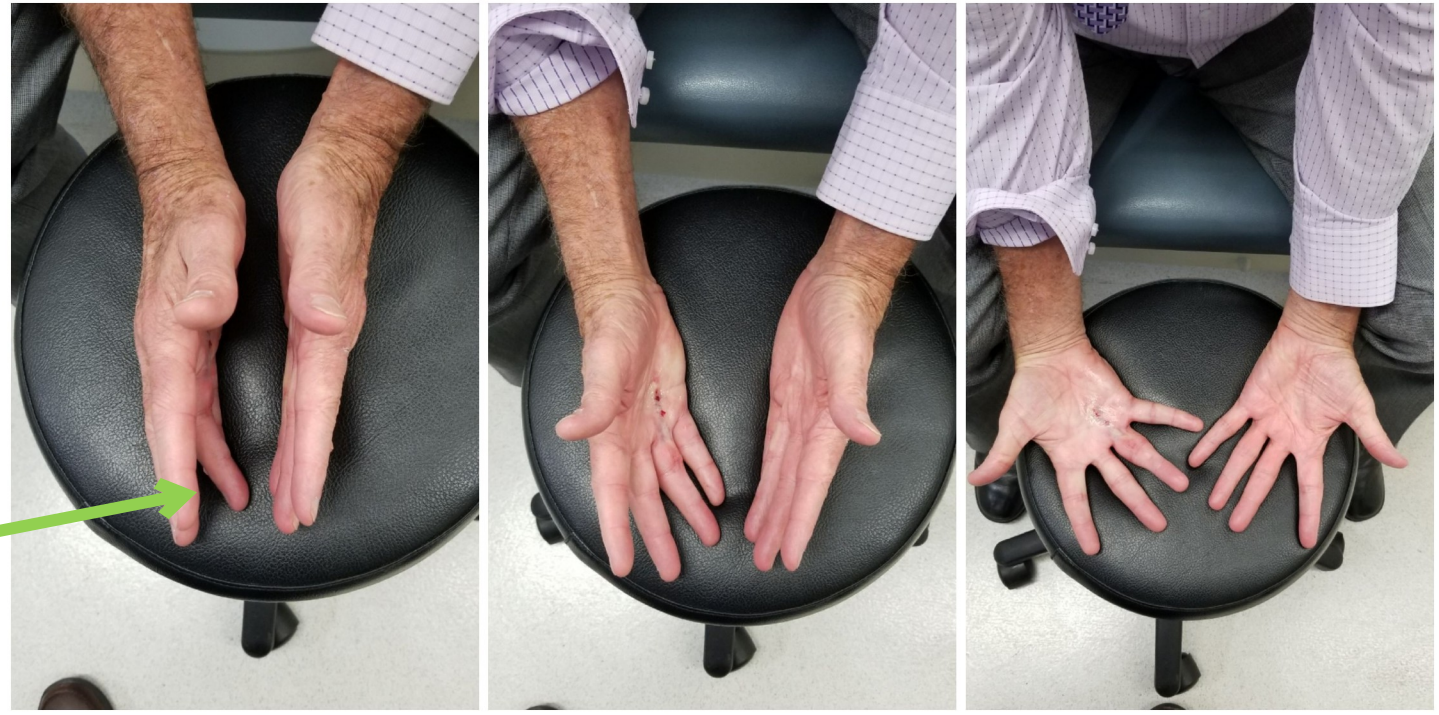

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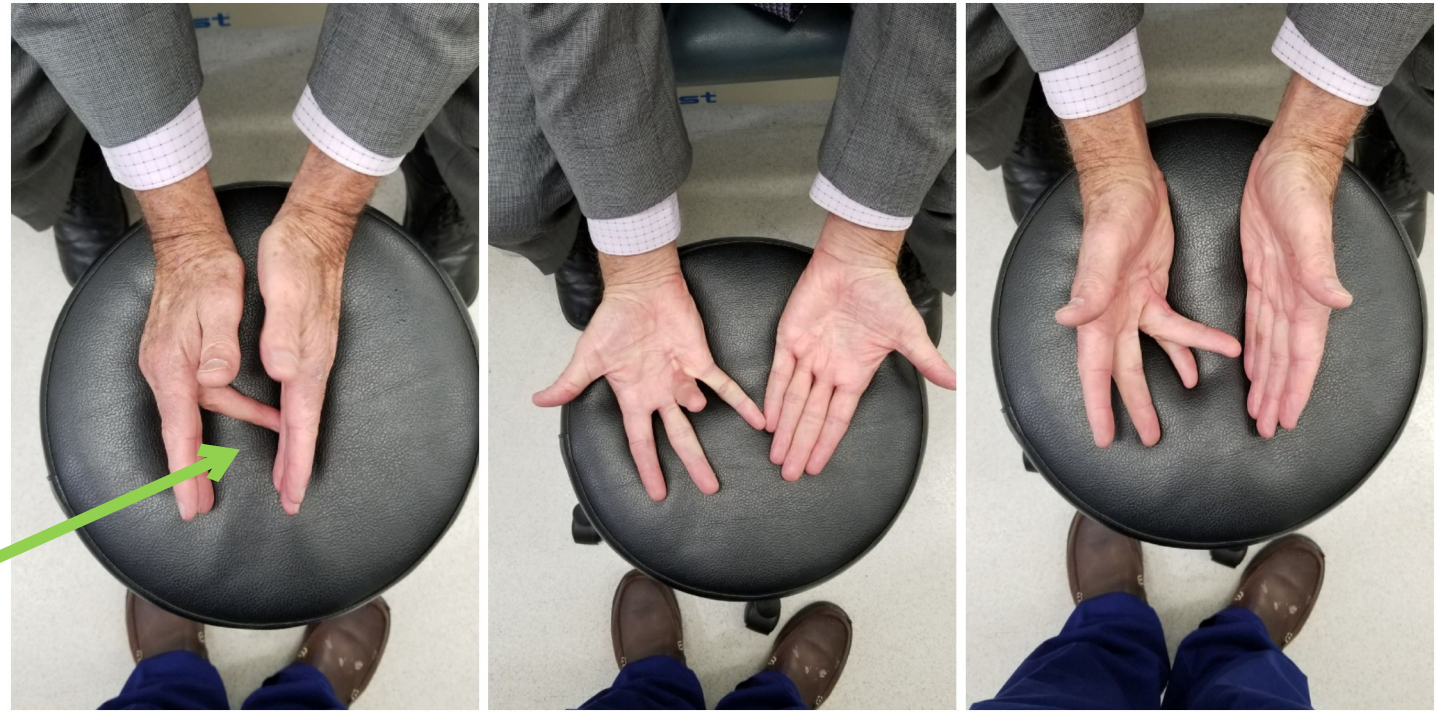
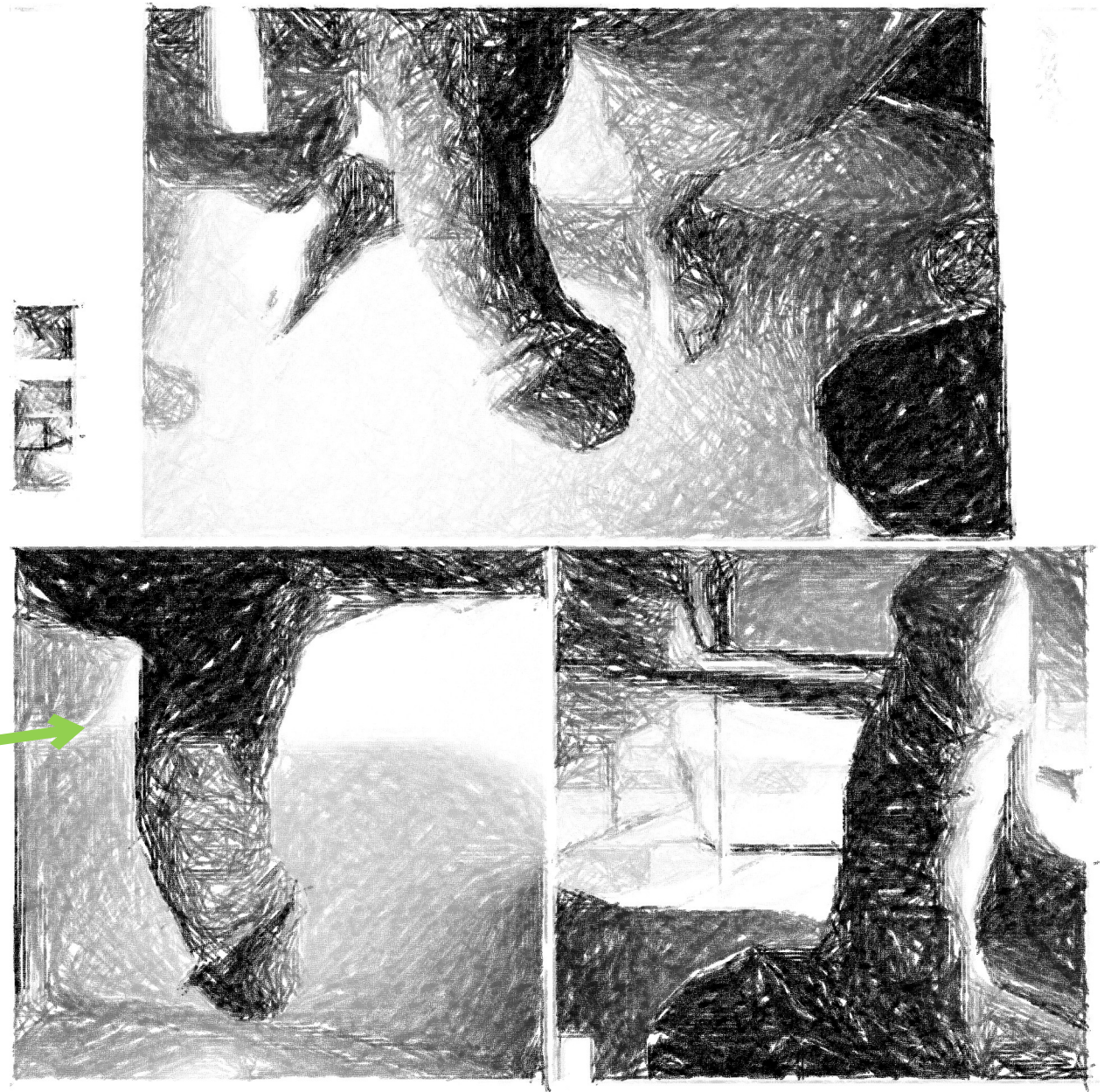


Peyronie’s disease



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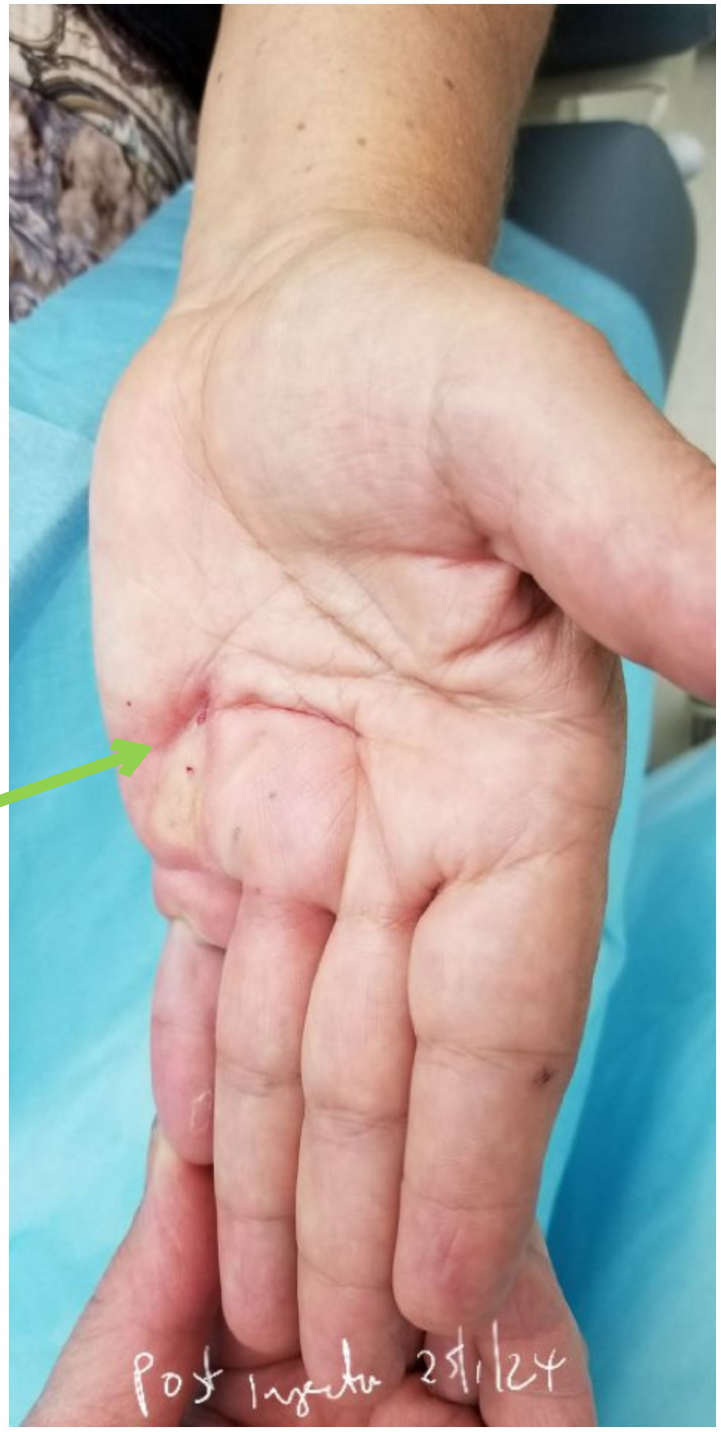

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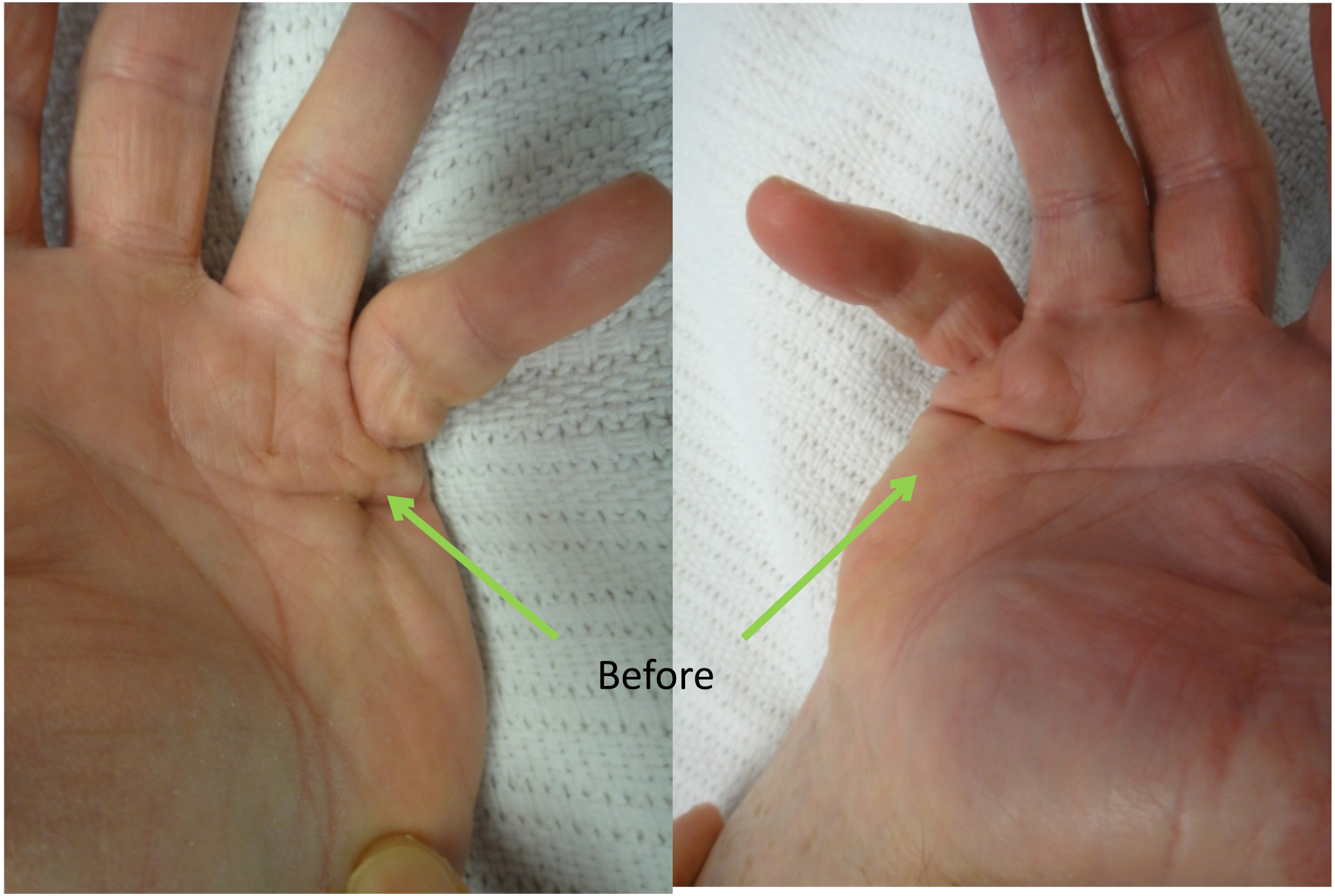
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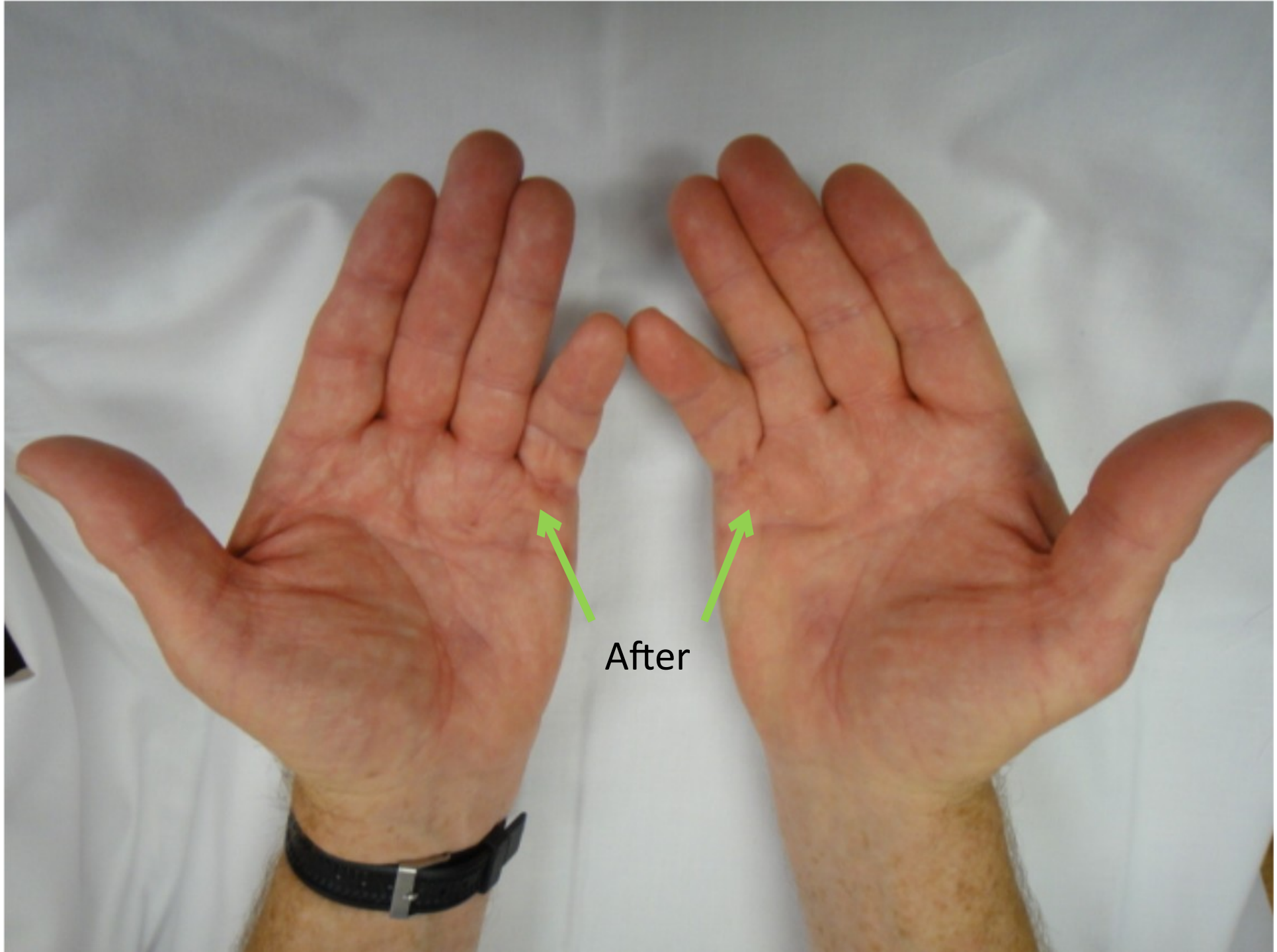
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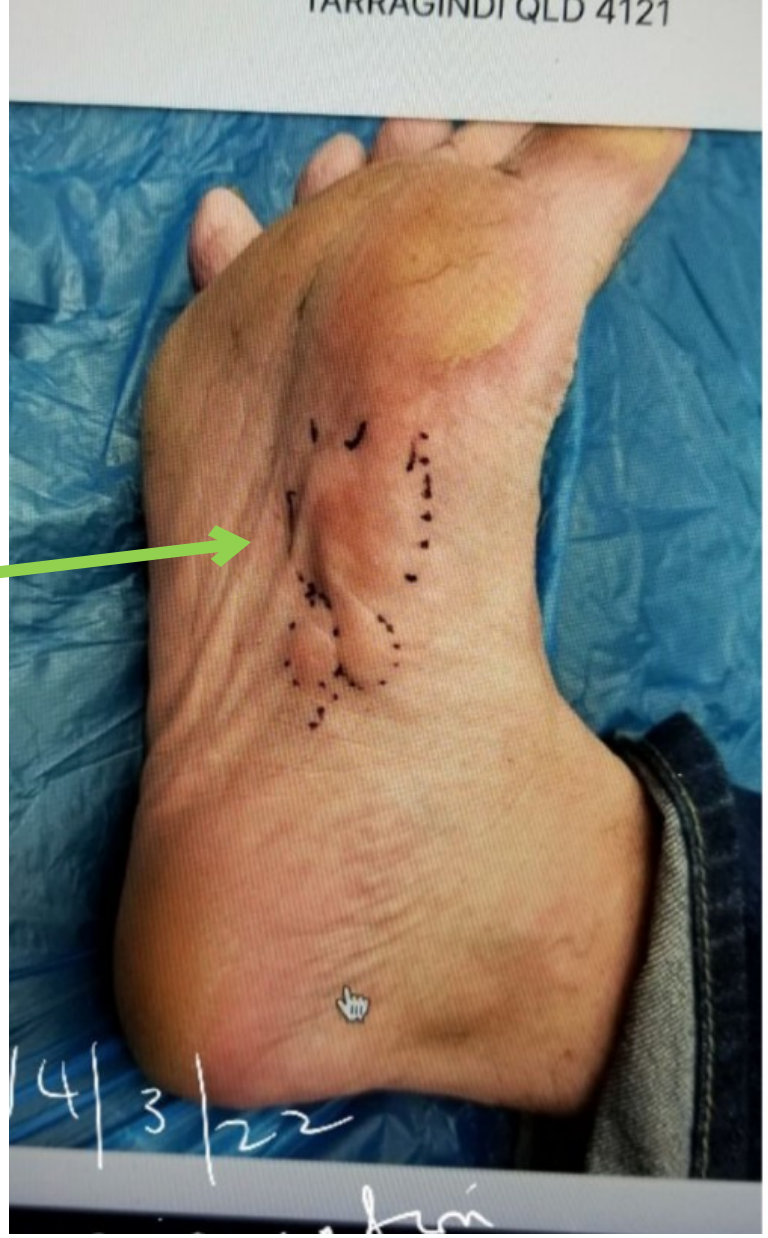

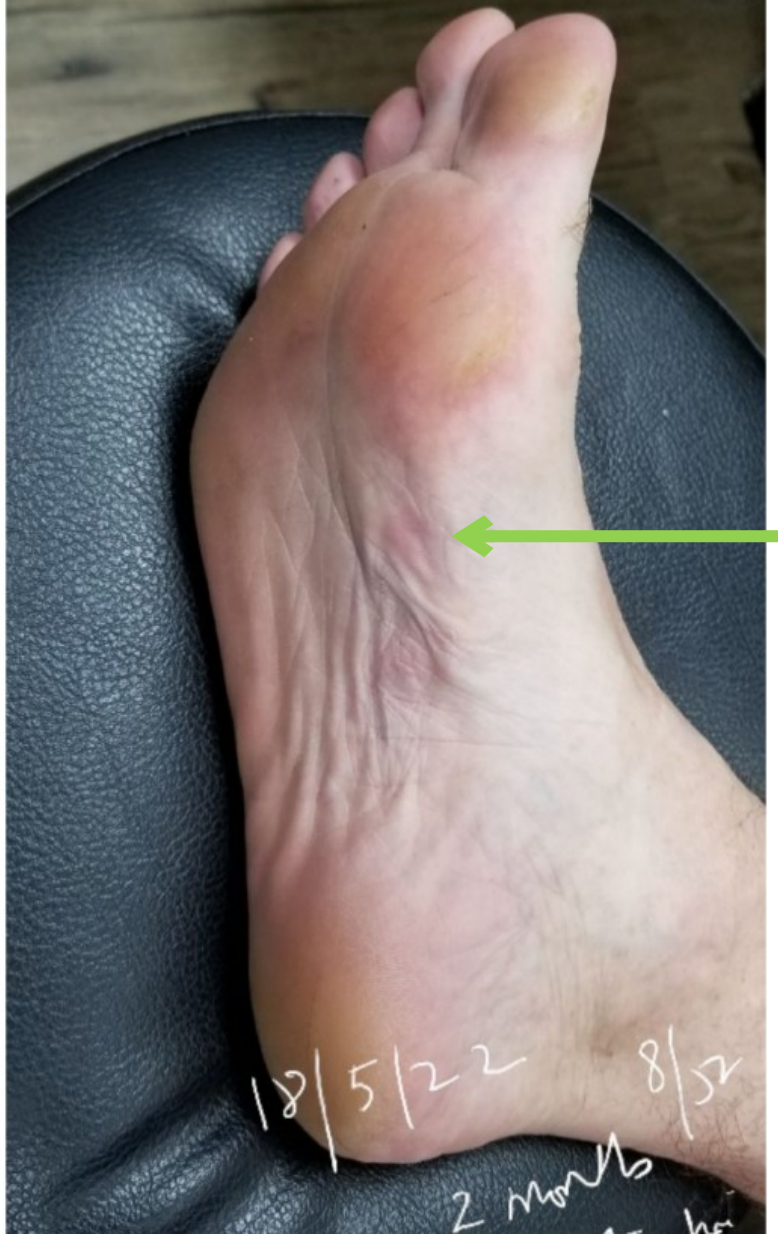

After

Pre treatment

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.

Nearest competitor

Endo Therapeutics

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

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