



Sculptra:
Myth-busting booklet

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Sculptra: Myths vs. Reality

Introduction

It has been almost 20 years since Sculptra was first approved for aesthetic use in Europe, and over this time, more than 4 million vials have been used.^{1,2} While patient satisfaction levels with the product are extremely high,³ a number of myths have arisen and persisted relating to how it works, its side effects and the optimal reconstitution method.

The purpose of this document is to explore these myths, examine the science behind them, and correct common misconceptions surrounding the product. In addition to busting myths, the booklet provides clear, evidence-based recommendations on how Sculptra can be used to achieve optimal results for your patients.

The Myth:

Everyone gets nodules with Sculptra.

The Reality:

The incidence of nodules is low when using the correct reconstitution method and injection technique.¹

The formation of nodules is a myth surrounding the use of Sculptra. After 20 years of experience, studies show that by increasing the reconstitution volume to 5 mL, the risk of nodule formation is **less than 1%** while still achieving excellent results.^{1,4} Furthermore, those nodules that are formed are typically a non-inflammatory reaction and are caused by product accumulation. In the majority of cases, they are non-visible and asymptomatic, and resolve spontaneously.⁴

Sculptra is suitable for increasing the volume of depressed areas, particularly to correct skin depressions, such as in skin creases, wrinkles, folds and scars, and for skin aging.⁵

In addition to using the Sculptra IFU-recommended **5 mL sterile water reconstitution volume**,⁵ the incidence of nodules can also be reduced by:

- **Ensuring that the environment is sterile.** It is hypothesized that many nodules result from biofilm formation. Prepping the skin with an antiseptic antibacterial agent such as chlorhexidine, using sterile water and maintaining excellent hygiene practices are recommended to mitigate this risk.⁴
- **Injecting at the correct depth.** Injection should be into the deep dermis or subcutaneous layer. To control the injection depth, the skin should be stretched/pulled opposite to the direction of the injection to create a firm injection surface. The 26G sterile needle, bevel up, should be introduced into the skin at an angle of approximately 30-40°, until the desired skin depth is reached.⁵
- **Injecting an appropriate volume.** The maximum volume per each individual injection should be limited to 0.1 mL to 0.2 mL, spaced at a distance of 0.5 to 1 cm. The volume of product injected per treatment area will vary depending on the surface area being treated.⁵
- **Massaging the area immediately after the treatment.** By massaging the area, the product will properly distribute within the tissue to help minimize the appearance of papules or nodules.⁵

The Myth:

It takes a long time to see any results with Sculptra.

The Reality:

Improvements in Wrinkle Assessment Scale scores can be seen from 3 weeks after the final treatment session.⁶

In contrast to hyaluronic acid (HA) fillers, which show immediate results, Sculptra works by stimulating an increase in the patient's own natural collagen production, providing subtle volume and lift. This is a gradual but long-lasting process.^{5,6} Changes in the metabolic pathways are seen within a few weeks of the first injection, with significantly elevated expression of collagen mRNA.⁷ Changes at a tissue level are observed soon after this, with a study showing that patients demonstrated a 66%* increase in collagen type I just 3 months after the first treatment.⁸ Significant changes are also seen in Wrinkle Assessment Scale scores from 3 weeks after the final treatment session, and these improvements continue through to month 25.⁶ The average number of treatment sessions in this study was 3.2 sessions per patient.⁶

* Increase in mean level of collagen type I intensity in stained biopsies.

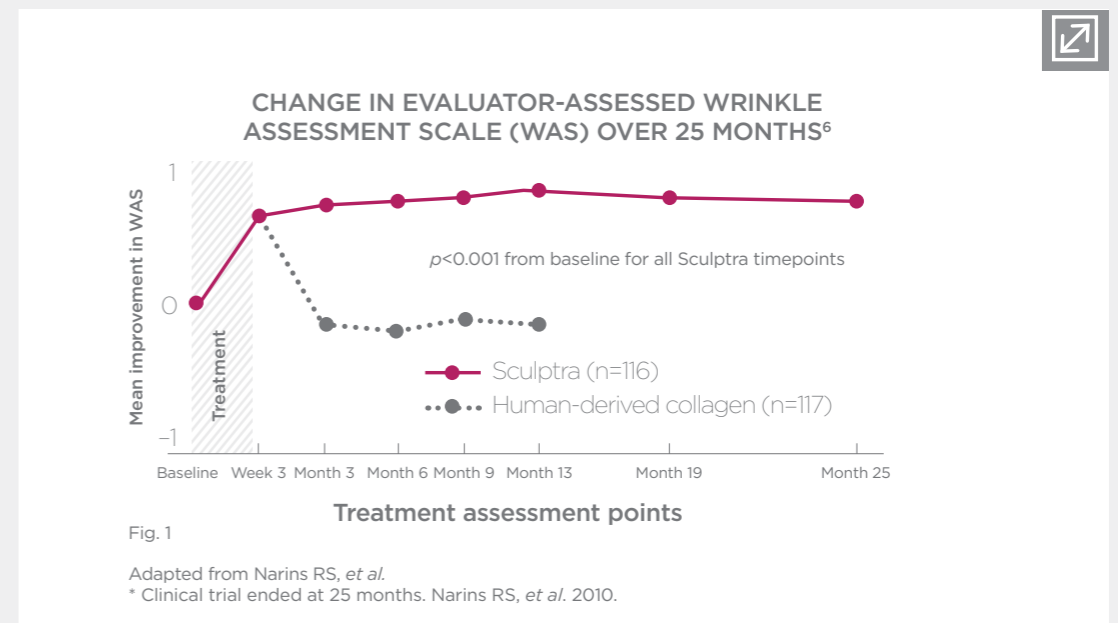
So, in summary:

Although the results are not immediate, Sculptra starts working **2 weeks after the injection is administered** to stimulate collagen production.⁷

- Results can be seen in collagen production and Wrinkle Assessment Scale improvements **within a few weeks** of the final treatment session (Fig. 1).⁶
- The results the patient sees will build gradually over time and can last for **more than 2 years**.^{5,6*}

Additionally, patient satisfaction scores for Sculptra are very positive:

- **80%** of patients who received Sculptra still rated their results as excellent or good 25 months after treatment.³
- **75%** of women surveyed about treatment desires preferred gradual results that last 2 years over immediate results that last 12 months.⁹

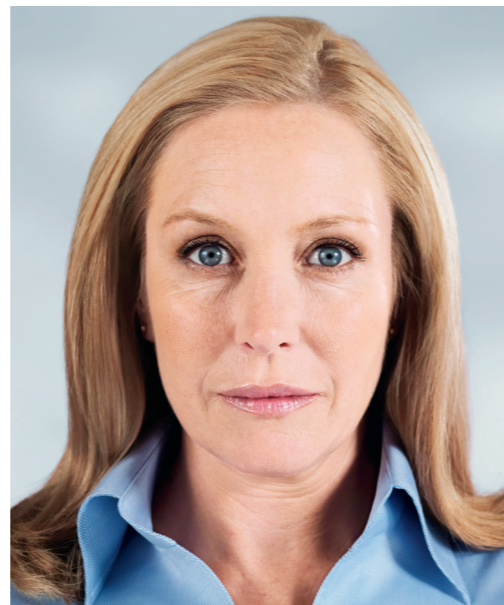


Real Results

Elissa, 49 years old 5 vials of Sculptra over 3 sessions



Before



After 1 month*



After 7 months*



After 25 months*

* Individual results may vary. Photos have not been retouched.

The Myth:

Sculptra needs up to several days/weeks to fully hydrate after reconstitution.

The Reality:

Sculptra can be used 2 hours after reconstitution when following the recommended protocol.

According to its Instructions for Use, Sculptra can be used 2 hours after reconstitution. After slowly adding sterile water for injection, the vial only needs to stand for a minimum of 2 hours to ensure complete hydration. The vial should not be shaken during this period. Prior to use, the vial should be gently agitated until a translucent suspension is obtained. The reconstituted product must be injected within 72 hours of reconstitution.⁵



The Myth:

The effects of Sculptra are the result of scar formation.

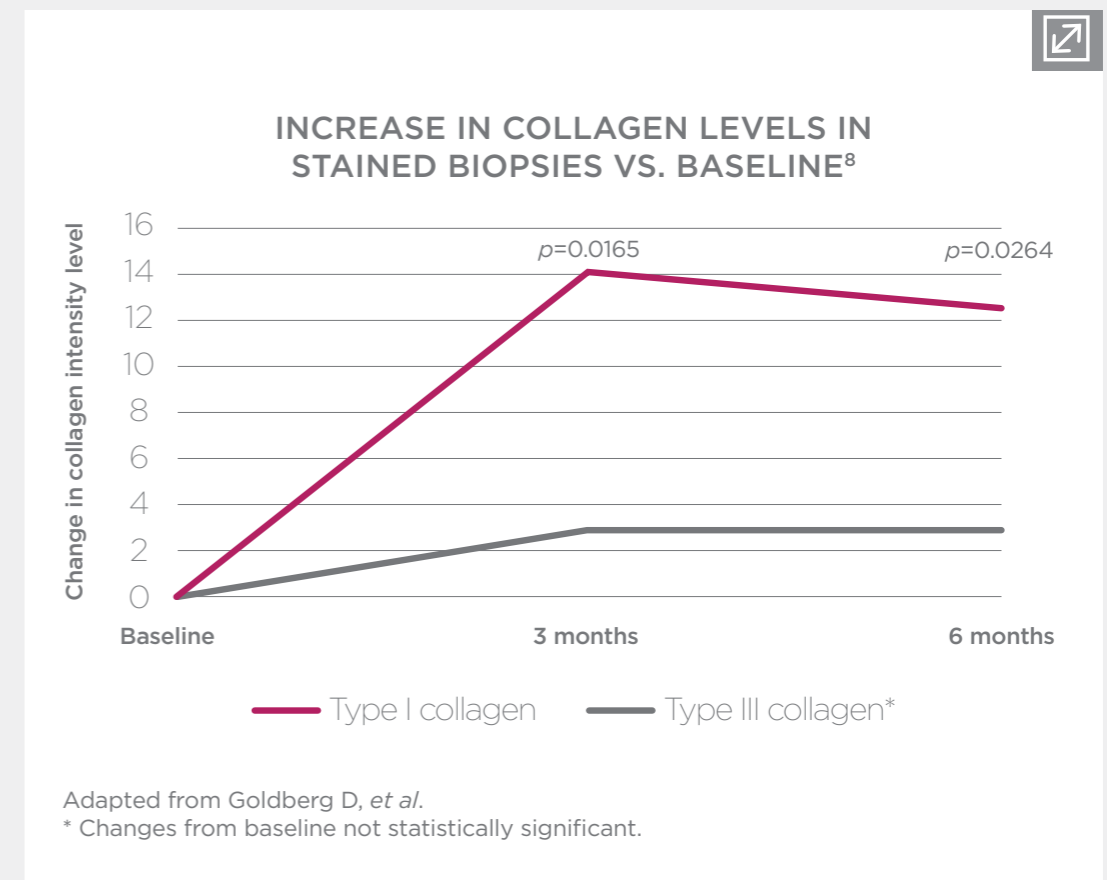
The Reality:

Sculptra stimulates the development of new collagen and this is the primary source of the additional volume.⁸

A common misconception is that the volume created by Sculptra is the result of scar tissue forming under the skin. However, skin biopsies have demonstrated that collagen neo-synthesis occurs in the absence of an acute, significant inflammatory response, and it is this collagen stimulation that restores volume.^{5,8} A study from 2013 investigated the human tissue response to Sculptra by examining the new collagen formation and tissue response at 3, 6 and 12 months. The investigators found that a 66% increase in the mean level of type I collagen was accompanied only by a mild, controlled inflammatory response.⁸ This increase in collagen translates to dermal thickening, with a 2006 study demonstrating a 65.1% increase in skin thickness from baseline, an effect that persisted for at least 12 months.¹⁰

Animal studies have shown similar results, with a mild inflammatory response (suggestive of a typical foreign body reaction) in the first week, marked fibroblastic activity and proliferation by 2 weeks, and gradual ingrowth of tissue fibres by 4 weeks, with no acute inflammatory reaction.^{11,12}

Due to limited data availability on the use of Sculptra in patients with known keloid history, Sculptra should not be used in patients with known history of or susceptibility to keloid formation or hypertrophic scarring.⁵



The Myth:

Sculptra is no different from hyaluronic acid (HA) fillers.

The Reality:

Sculptra works by stimulating the skin's own natural collagen production, in contrast to HA fillers which physically fill the skin.

While Sculptra and HA fillers are both highly effective at adding volume to create a more youthful appearance, they achieve these results through very different mechanisms. HA gels physically occupy the space under the tissue and attract water molecules to restore volume.¹³ This helps to smooth out lines, creases and wrinkles, delivering immediate results. Sculptra works by stimulating the fibroblasts to create new collagen fibres, which occurs more gradually.⁸ It is hypothesized that HA fillers have some effect on collagen type I through stretching of fibroblasts during injection.^{14,15} Although not directly comparable, collagen stimulation with Sculptra is significantly higher and has a longer duration than that seen with HA fillers.⁸

Biopsies taken following treatment with Sculptra demonstrate that as the product itself is degraded within the skin and reabsorbed, there is an accompanying gradual ingrowth of collagen type I.^{7,8} By replacing collagen, Sculptra restores volume in the skin. To achieve these results, Sculptra should be injected into the deep dermis or subcutaneous layer.⁵

	Sculptra	HA Fillers
How quickly are results observed?	Within 3 weeks of the final treatment, gradually building over time ⁶	Immediately following injection
How long do the results last?	More than 2 years^{6*}	May last up to 12 months (on the Restylane [®] treatment plan, which includes 2 re-treatments) ^{16,17}
How many treatments are required?	Number of sessions is determined by the physician, and spaced at least 4 weeks apart ⁵	Number of sessions is determined by the physician
Collagen stimulation	Sculptra has a proven 66% increase in mean level collagen type I intensity in stained biopsies vs. baseline after 3 months ⁸	Mechanism of action is via attraction of water molecules to stabilized HA, thereby adding volume to the skin ^{13,18}

* Clinical trial ended at 25 months. Narins RS, *et al.* 2010.

The Myth:

It is not possible to use HA and Sculptra at the same time.

The Reality:

HA fillers (e.g., Restylane) and Sculptra can be used simultaneously. The optimal treatment plan should be determined by the physician.

In order to address individual patient needs, healthcare professionals may use both HA fillers and Sculptra in their treatment plans. There are no known product interactions between HA fillers and Sculptra. However, the co-administration of both products – and the treatment areas chosen – should be determined by the treating physician.

Best practice would be to wait 2-3 months following the last Sculptra treatment before using an HA filler in the same area. By this time, Sculptra will have stimulated the development of new collagen in the area, enabling the injector to accurately assess if a filler will provide additional benefit (and if so, how much is required), thereby minimizing the risk of over-correction.

HA fillers and Sculptra can be used simultaneously in different areas (e.g., Sculptra in the cheeks and temples and HA filler in the lips) with no concern of product interaction.



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Real Results

Christin 1.5 vials of Sculptra over 1 session



Before



After 21 days*

* Individual results may vary. Photos have not been retouched.

Real Results

Franca, 42 years old 5 vials of Sculptra over 3 sessions



Before



After 12 months*

* Individual results may vary. Photos have not been retouched.

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* Increase in mean level of collagen type I intensity in stained biopsies.

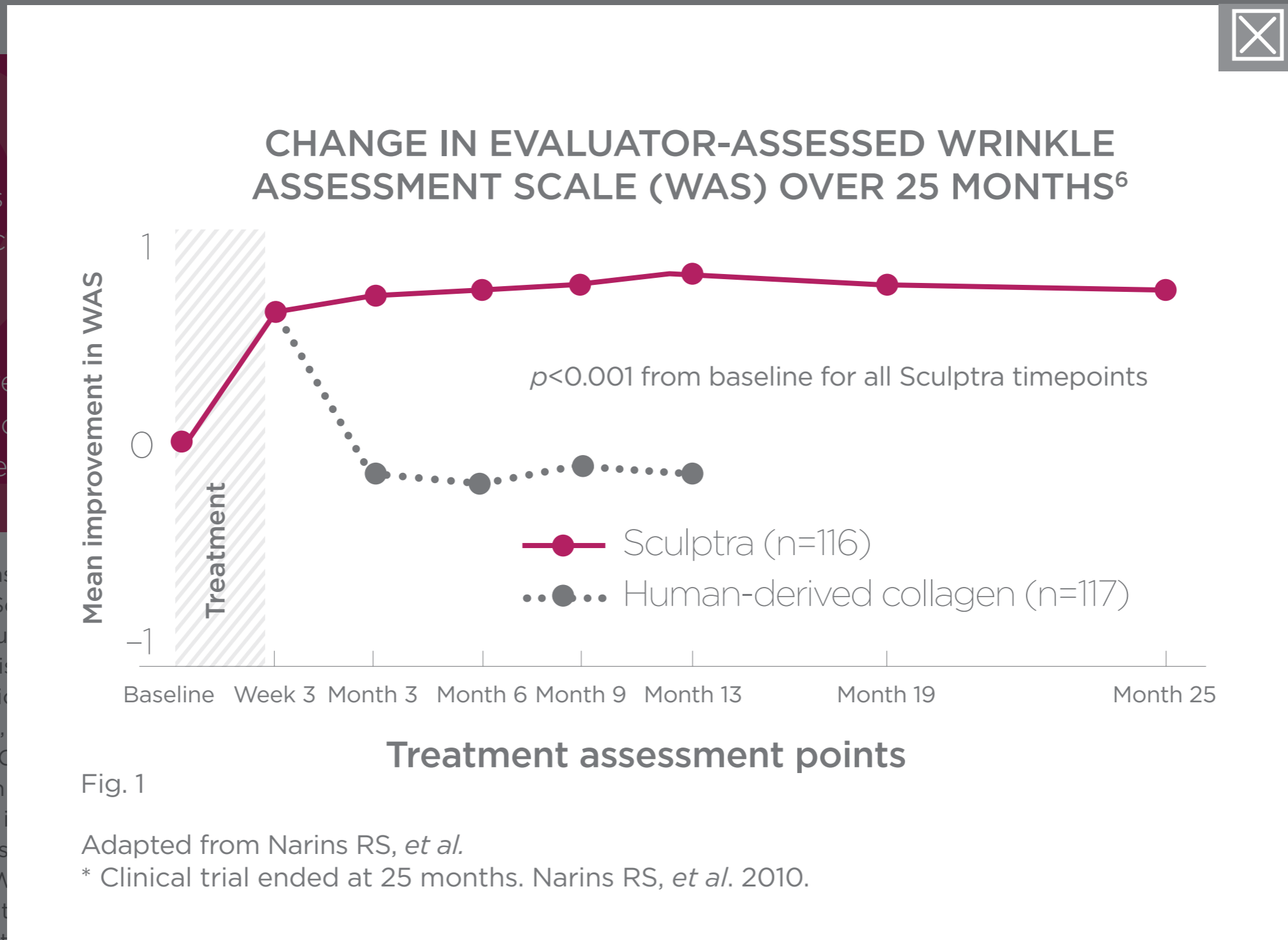


Fig. 1

Adapted from Narins RS, *et al.*

* Clinical trial ended at 25 months. Narins RS, *et al.* 2010.

Adapted from Narins RS, *et al.*
 * Clinical trial ended at 25 months. Narins RS, *et al.* 2010.

The M

The effects of scar formation

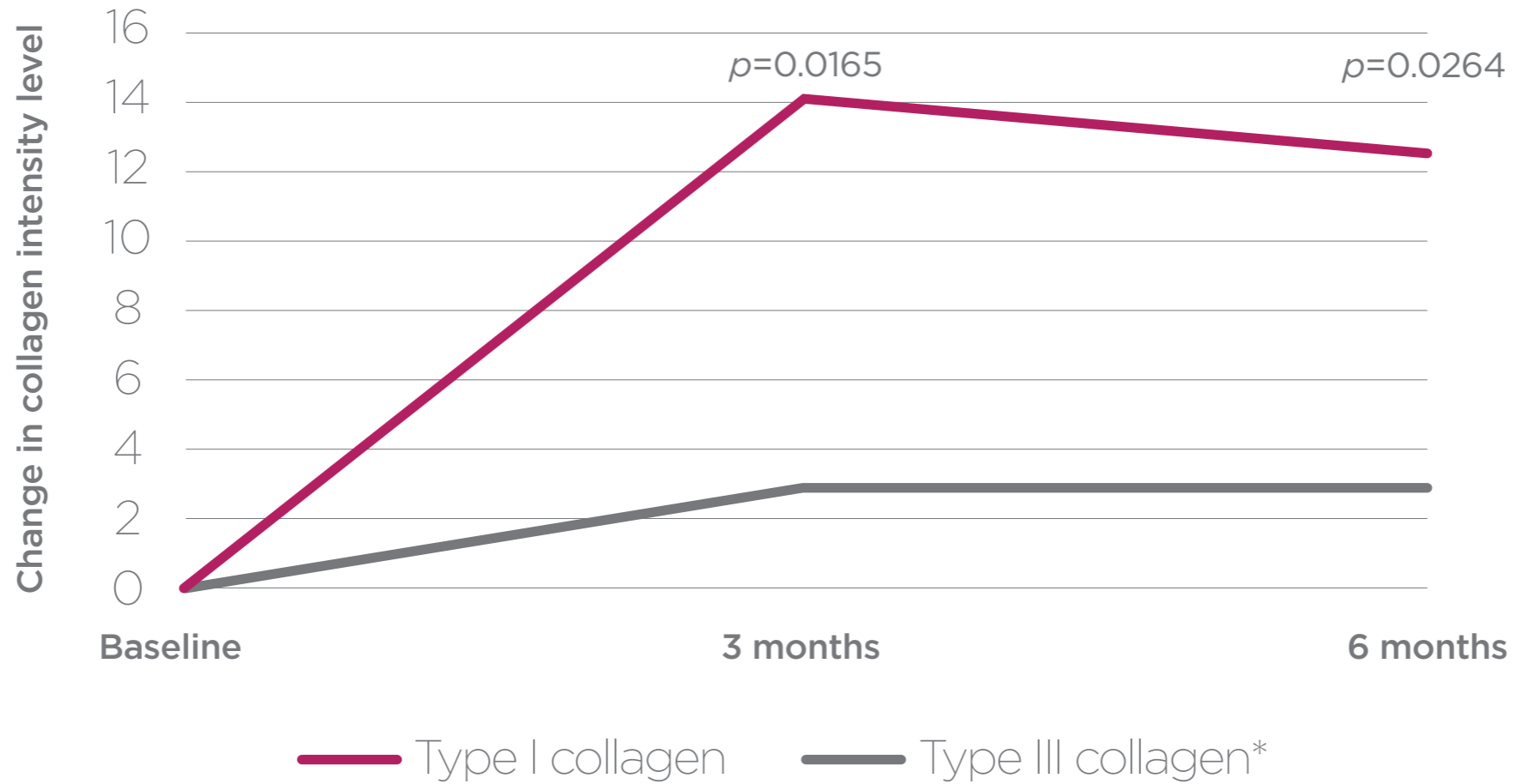
The R

Sculptra stimulates new collagen production of the added

A common mechanism of Sculptra is the stimulation of neo-synthesis of collagen. However, skin aging is characterized by a mild, chronic inflammatory process that restores the human tissue. Sculptra stimulates new collagen production for 12 months. The mean level of collagen is increased by a mild, chronic inflammatory process in collagen treatment. The study demonstrated that at baseline, an effect that persisted for at least 12 months.¹⁰



INCREASE IN COLLAGEN LEVELS IN STAINED BIOPSIES VS. BASELINE⁸



Adapted from Goldberg D, *et al.*

* Changes from baseline not statistically significant.

a mild foreign body activity and of tissue reaction.^{11,12} Sculptra should not be susceptible to

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