

Efficacy study of novel monophasic dermal implant containing cross-linked hyaluronic acid associated with amino acids for treatment of hands photoaging

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BACKGROUND
Following the face, the hands represent the second most prominent indicator of an individual's age. Typically, subcutaneous fat loss accentuates the visibility of veins, tendons, and bony contours on the dorsum of the hand^(1,2). Additionally, prolonged exposure to UV light throughout one's lifetime renders the hands especially susceptible to cutaneous pigmentation alterations, commonly referred to as photo-damage⁽³⁾. The most commonly conducted interventions involve filler injections, laser treatments, and fat grafting⁽⁴⁾.

OBJECTIVE
Investigation of a novel monophasic dermal implant containing cross-linked hyaluronic acid associated with amino acids (CE-marked Medical Device Class III, RRS® HA Long Lasting, Skin Tech Pharma Group, Spain) for its moisturising and volumising effects on the skin of the back of the hand in the treatment of photoaging. This study, which is part of the post-marketing clinical follow-up activities, aimed to evaluate the efficacy of the product in the treatment of the signs of ageing on the hands, with an additional focus on the evaluation aspects of safety profile.

METHOD
A multinational, multicenter, open-label, single-arm, before-after study conducted from July to November 2023 involved 10 study centers across Albania, Bulgaria, Georgia, Macedonia, Serbia, and the United Kingdom. The study included 60 clinical cases, with participants predominantly female (93%) and male (7%), aged between 56 and 65 years. The participants exhibited primarily moderate wrinkles and dull skin radiance.
A deep dermal injection was executed using a 22G x 70mm cannula (semi-rigid, blunt tipped), delivering 1.5 ml per hand through a retrograde technique. Employing 6-7 lines per hand, an approximate amount of 0.2 ml of the product was applied per line. A gentle massage was administered to ensure even distribution of the product. Assessments of effectiveness on Day 7 and Day 30 included the Hand Grading Scale⁽⁵⁾, skin laxity, and skin laxity using 4-graded descriptive-numeric scales. Patient and physician satisfaction were also evaluated through the Global Aesthetic Improvement Scale (GAIS).

INJECTION DEPTH	Deep Dermal - Sub Dermal
VOLUME PER LINE	up to 0.2 mL / Line
NUMBER OF LINES	6 - 7
CANNULA	22 G x 70 mm Semi-rigid blunt-tipped
TOTAL VOLUME	3 mL (1,5 mL / hand)

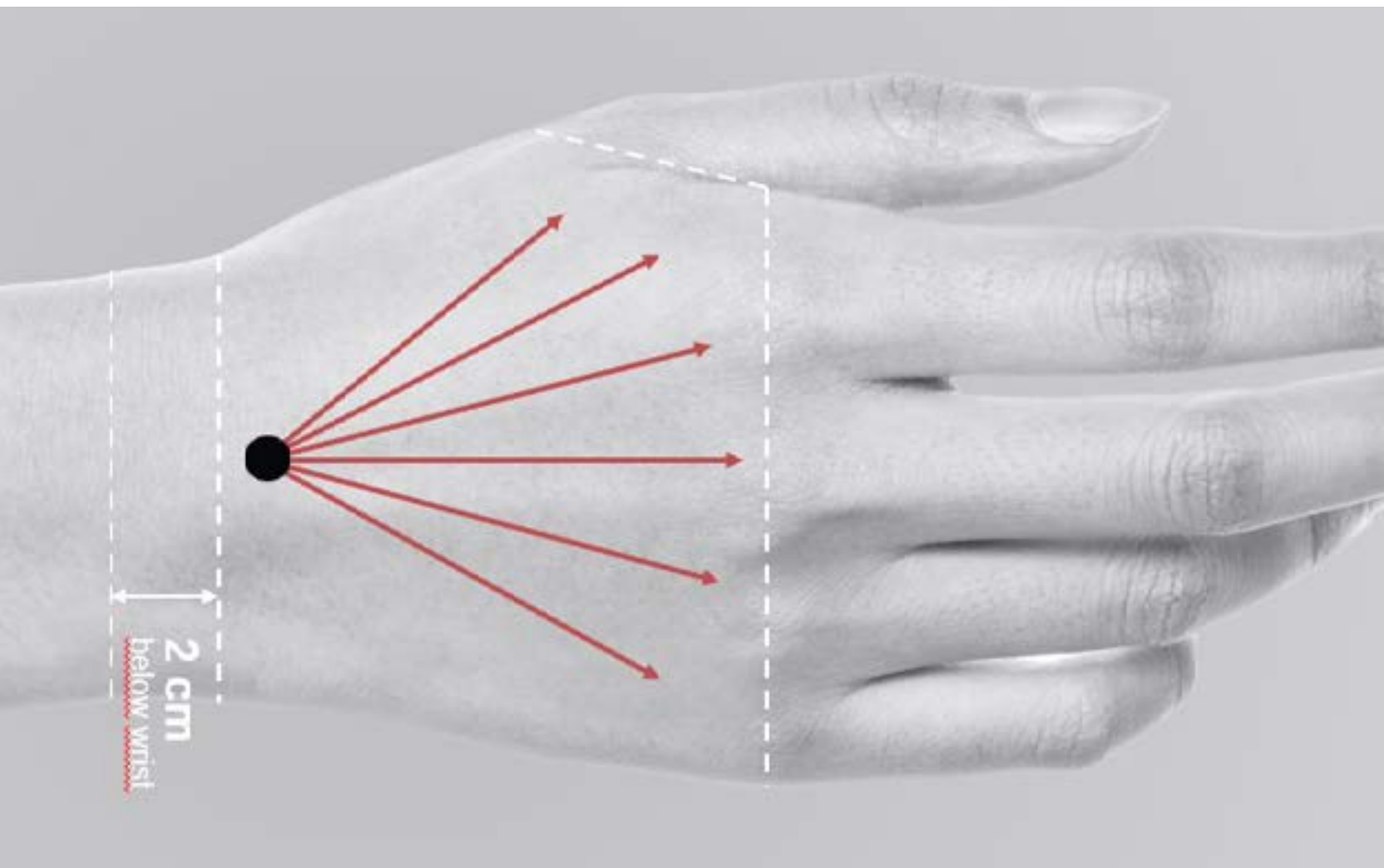


Figure 1. Application scheme on the hand

RESULTS
A statistically significant reduction in the skin laxity grading scale was observed, starting with an initial mean value of 2.17 on Day 0 and decreasing to 1.83 on Day 30, reflecting a 16% decrease compared to baseline measurements. Regarding skin radiance, a notable transformation occurred from an initial mean value of 3.00 on Day 0 to 2.10 on Day 30, resulting in a 30% improvement by the study's conclusion.

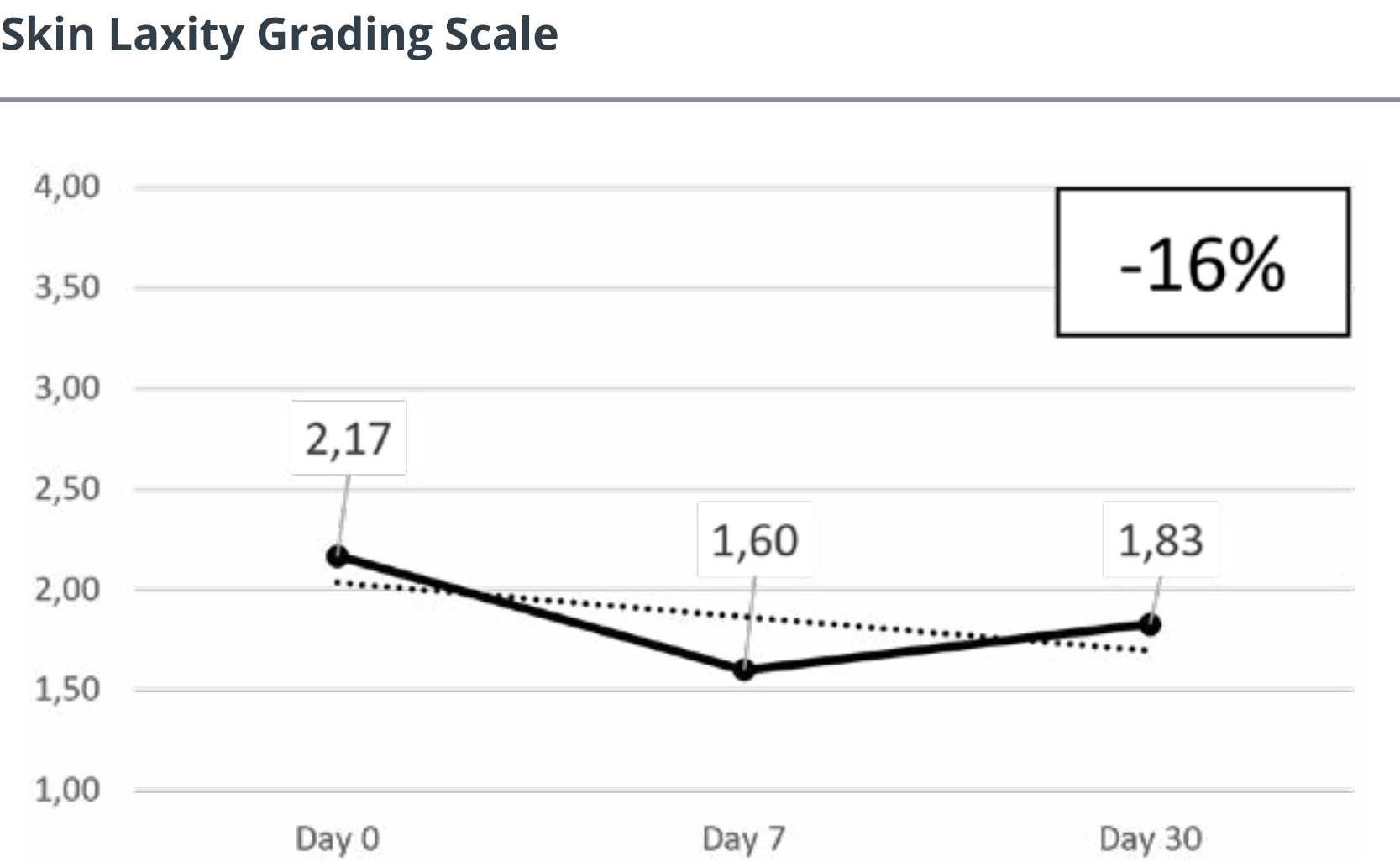


Figure 2. Result of the Skin Laxity Grading Scale assessment.
*4-point Skin laxity numeric descriptive scale include the following grades: 1 - Mild/Minimal laxity, 2- Moderate laxity, 3 - Advanced laxity, 4 - Severe laxity.

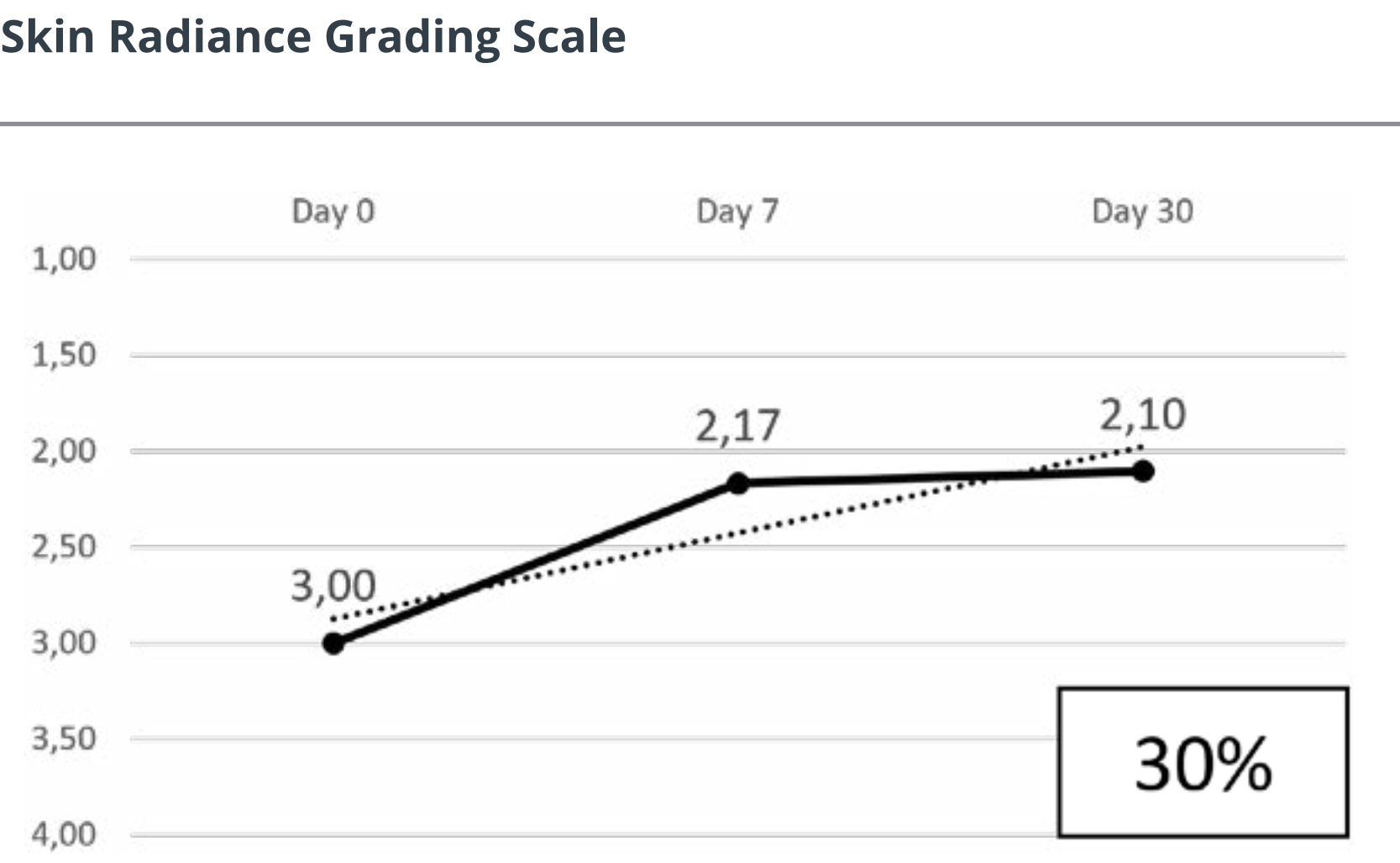


Figure 3. Result of the Skin Radiance Grading Scale assessment.
*4-point Skin radiance numeric descriptive scale include the following grades: 1 - Very Bright: Exceptionally radiant skin, full of vitality and with intense glow; 2 - Radiant: Healthy glow and luminous skin. Smooth skin with even tone; 3 - Dull: Uneven tone and texture with lack of brightness compared with healthy skin; 4 - Very dull: lackluster, fatigued, and devoid of natural glow skin.

The Hand Grading Scale displayed a transformation of the severity of hand photoaging, commencing with an initial mean value of 2.77 on Day 7 and diminishing to 1.72 on Day 30, ultimately representing a 38% reduction by the study's conclusion, with a success rate of 62% among all patients.

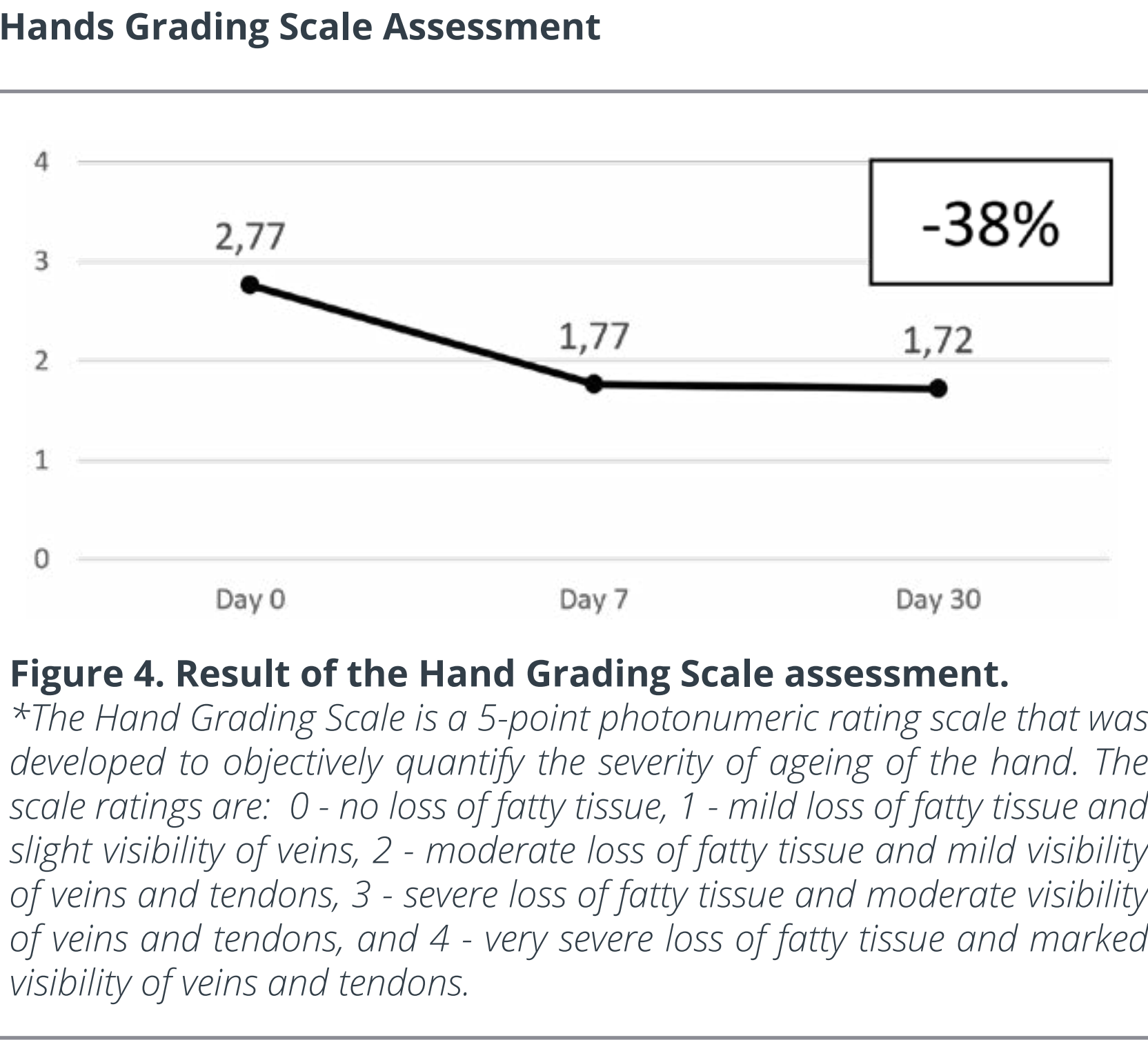


Figure 4. Result of the Hand Grading Scale assessment.
*The Hand Grading Scale is a 5-point photonumeric rating scale that was developed to objectively quantify the severity of ageing of the hand. The scale ratings are: 0 - no loss of fatty tissue, 1 - mild loss of fatty tissue and slight visibility of veins, 2 - moderate loss of fatty tissue and mild visibility of veins and tendons, 3 - severe loss of fatty tissue and moderate visibility of veins and tendons, and 4 - very severe loss of fatty tissue and marked visibility of veins and tendons.

Following product administration, patient self-evaluations on Day 30 revealed that 90% of patients perceived their appearance as "Much Improved" (35%) or "Improved" (55%). Physicians noted positive progress in 100% of cases during the last control visit on Day 30 (67% of improved and 33% of much improved scores).

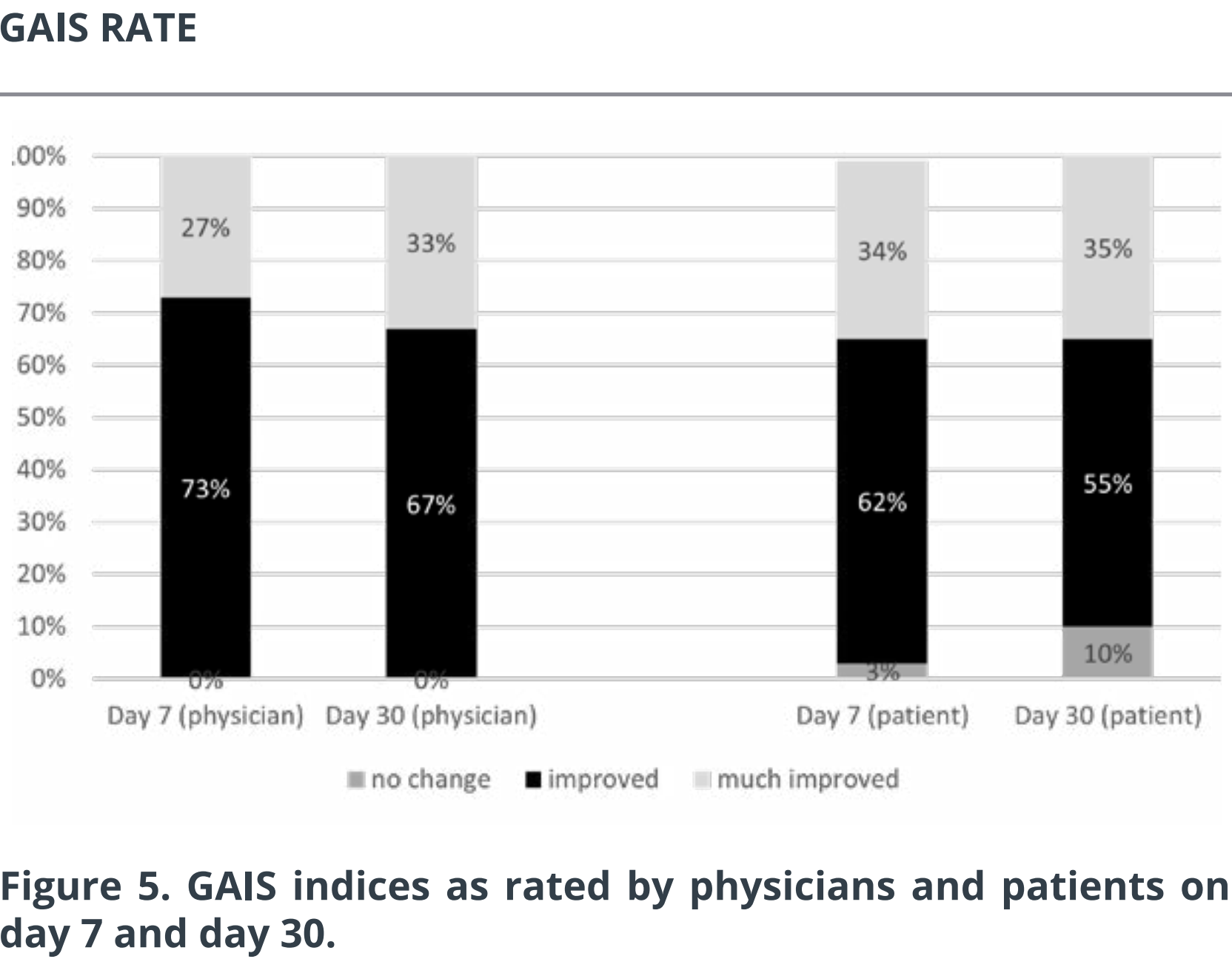


Figure 5. GAIS indices as rated by physicians and patients on day 7 and day 30.

The majority of observed effects resulting from local application where pain was one of the most frequent effects observed during the treatment.

CONCLUSIONS
The outcomes of the case reporting activity reaffirm the product's remarkable efficacy while underscoring its exceptional safety profile. The use of novel monophasic dermal implant, RRS® HA Long Lasting, containing cross-linked hyaluronic acid associated with amino acids for hand rejuvenation proves to be a safe and effective non-surgical intervention, successfully reducing signs of photoaging on the dorsal hand while maintaining high safety standards.

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Clinical case 1.
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Clinical case 2.
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Clinical case 3.
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