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Body Skin Laxity Treatment Using Hybrid Cooperative Complexes of Hyaluronans: A Real-World Data Evaluation of Patient-Reported Satisfaction

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Abstract

Background: The Profhilo® Body Kit is indicated for the treatment of skin laxity of the body and consists of the Profhilo® Body hyaluronic acid (HA) injectable, the HA-containing Profhilo® Figura Body Patch and the Profhilo® Figura Body Cream.

Aim: To assess real-world data of patient-reported satisfaction associated with the Profhilo® Body Kit treatment for skin laxity of the inner arms, abdomen, décolleté, and knees.

Methods: The Profhilo® Body injection and Profhilo® Figura Body Patch were administered on Day 0 and Day 30; the Profhilo® Figura Body Cream was applied daily between the two injections. Surveys were conducted using a web app tool (Day 0, Day 30 and 30-days after second injection) and assessed patient discomfort (Visual Analogue Scale), treatment effectiveness, and psychological and social function (effects assessed using four categories: 'not at all', 'a little', 'a lot' and 'very much').

Results: Patients (N=50; 83% female) were treated at centres in Italy (n=35) and in the Netherlands (n=15). Most patients had no/mild procedure-related pain (86%) and the majority of post-injection symptoms disappeared within 48 hours (94%). Over 80% of patients reported that treatment benefited them 'a lot' and 'very much', with improvements in skin laxity, skin hydration and skin firmness/tone; beneficial treatment effects were also reported for enhancement of body image, appearance and improvement in relationships.

Discussion and Conclusions: These results indicate a high-level of patient-reported satisfaction due to the Profhilo® Body Kit and this contributes to the growing body of evidence supporting the use of Profhilo® Body for the treatment of skin laxity.

Keywords: Patient satisfaction; Profhilo Body; Hyaluronic Acid; Skin Laxity; Quality of Life.

Introduction

Skin aging is a multifaceted and ongoing process that impacts both the function and look of the skin, and the timing and rate of aging differs from person to person [1-3]. Aging can cause the skin to become rough and loss of skin elasticity, affecting not only the face but also other areas of the body including the arms, knees, abdomen, neck, décolleté, and hands [4,5]. Skin aging is driven by intrinsic drivers such as genetics and extrinsic factors such as sun exposure, environmental pollutants, nicotine, and significant fluctuations in body weight (for instance, due to diet or pregnancy) [4-6]. Aging leads to a reduction in the skin's hyaluronic acid (HA) and collagen levels, which in turn diminishes skin elasticity and contributes to the aging process [7]. Hyaluronic acid-based injectable treatments have gained popularity in the field of aesthetic medicine for addressing wrinkles, skin sagging, and roughness across various body regions, such as the face, inner arms, abdomen, and knees [5,8-11]. These HA treatments aim to reverse aging effects by restoring lost volume, enhancing skin elasticity and moisture, and are also known to boost collagen synthesis [11].

Several HA formulations are available, differing in degree of cross-linking, gel consistency properties, and concentration [12], and they have shown efficacy in several body areas, including the face, inner arms, abdomen and knees [5,8-11]. Profhilo® Body is a novel HA preparation by IBSA that is based on stable hybrid cooperative complexes (HyCoCos), and it is the first product which is developed by NAHYCO® Hybrid Technology, an innovative thermal production process patented by IBSA. Profhilo® Body is indicated for body treatment, for contour redefinition and for laxity remodelling of the brachial area, abdomen and other areas affected by skin laxity. Profhilo® Body also comes as part of a Profhilo® Body Kit, which includes the Profhilo® Body injectable, the HA-containing Profhilo® Figura Body Patch and the Profhilo® Figura Body Cream. According to the treatment protocol, patients usually receive the Profhilo® Body injection and Profhilo® Figura Body Patch on Day 0 and Day 30 and they apply the Profhilo® Figura Body Cream daily between the two injections [13]. Intradermal administration of Profhilo® Body is recommended according to the Bio Aesthetic Point (BAP) technique, which specifies 10 injection points on 3 horizontal levels in a 3-4-3 pattern. In addition to following the treatment protocol, selecting the appropriate patient for treatment is also critical for achieving optimal outcomes. Patients with body areas which exhibit skin laxity, limited adipose tissue and limited muscular ptosis are ideal candidates for treatment. Conversely, patients with ptosis of the muscle, excess adipose tissue and minimal skin laxity may not achieve optimal outcomes due to the presence of these features.

Clinical studies have shown the benefits of the separate components of the Profhilo® Body Kit. Profhilo® Body improved skin elasticity and skin roughness for the inner arms, abdomen and knees of participants with mild to moderate skin roughness and laxity [5]. The Profhilo® Body Figura Patch exhibited effectiveness for reducing skin redness and improving moisturisation after skin irritation, and the Profhilo® Figura Body Cream significantly improved moisturisation and elasticity in the leg area of female patients with dry skin and mild-to-moderate skin atony. Importantly, the treatments exhibited positive safety and tolerability profiles [5,13,14]. While clinical studies are necessary for assessing technical and clinical improvements, it is also important to determine the patient's perception of treatment quality and optimal outcomes. Specifically for aesthetic interventions, patient satisfaction is a key outcome [15]. To date, outcomes have only been assessed for the individual components of the Profhilo® Body Kit. This real-world data evaluation aimed to assess real-world patient-reported satisfaction and effectiveness associated with Profhilo® Body Kit treatment for skin laxity of inner arms, abdomen, décolleté, and knees.

Materials and Methods

Patients were treated for skin laxity of the inner arms, abdomen, décolleté or knees using the Profhilo® Body kit, which included Profhilo® Body injectable, Profhilo® Figura Body Patch and Profhilo® Figura Body Cream. Profhilo® Body is a 3 ml prefilled syringe containing 48 mg of high-molecular weight HA and 48 mg of low-molecular weight HA. Intradermal administration of Profhilo® Body treatment was administered according to the BAP technique, which specified 10 injection points on 3 horizontal levels in a 3-4-3 pattern. The Profhilo® Figura Body Patch is a 20 cm^2 patch containing HA as sodium hyaluronate (molecular weight: 300 - 800 KDa), and is applied to the body area after treatment [14]. The Profhilo® Figura Body Cream comprises of a high concentration low- and high-molecular weight HA, as well as Matrixyl® 3000 (a complex of a combination of two peptides) that has been shown to improve skin moisturisation and elasticity [13].

Administration procedure

Patients were administered Profhilo® Body HA-injectable on Day 0 and Day 30, according to specific instructions and injection sites for their indicated body areas, with the Profhilo® Figura Body Patch placed on the site of administration after each injection and removed after 2-5 hours. After the body patch was removed (i.e. patch used after the first Profhilo® Body injection), patients applied the Profhilo® Figura Body Cream once a day to the treatment area until Day 30 (Figure 1).

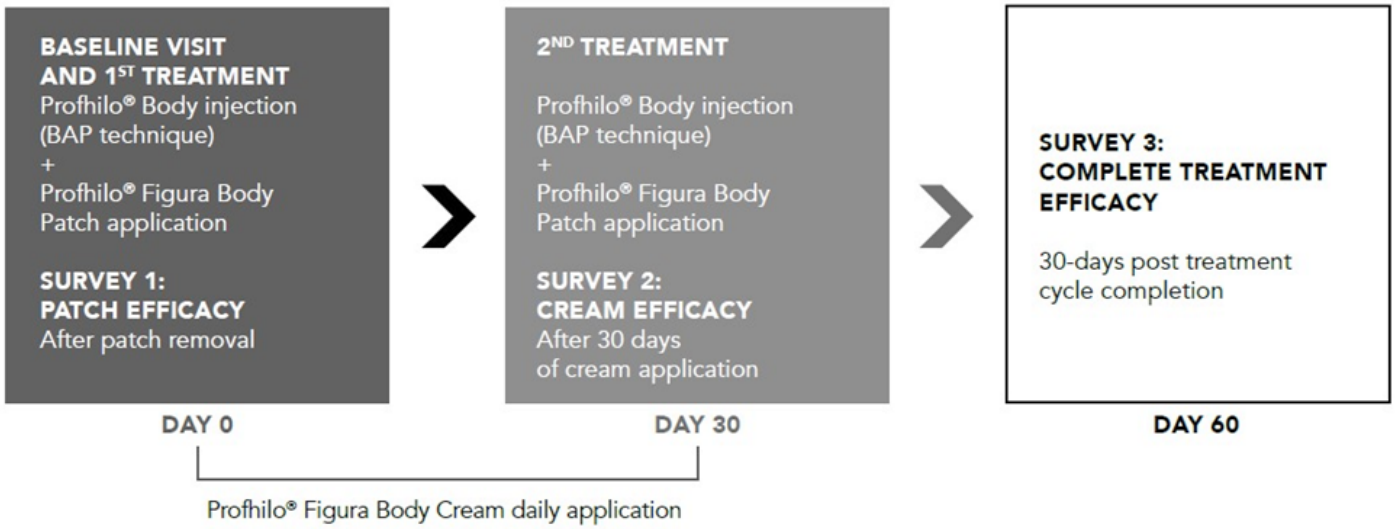

Figure 1: Participants, treatments and evaluation timeline.

Patient Survey

Patient surveys were conducted at different time points and they were focused on patient satisfaction and treatment effectiveness. The surveys were a part of the Profhilo® Body Kit satisfaction web app tool, which was shared with the patient by the treating physician after each of the 2 treatment sessions. After Profhilo® Body administration on Day 1, a card with a QR code was provided and scanned by the patient which enabled access to 2 surveys: 1. a Profhilo® Figura Body Patch survey, for completion after patch removal, and 2. Profhilo® Figura Body Cream survey, which became accessible 30 days after QR scanning (i.e. after 30 days of cream application). After the Profhilo® Body administration on Day 30, an additional QR code was provided for access to a third survey for completion 30-days post-administration.

Outcomes

Efficacy outcomes (soothing, moisturising and hydration effects, skin firmness/tone, skin laxity) and psychological and social function outcomes (body image and appearance, social relationships) were assessed by patients through specific questionnaire based on their impact (not at all, a little, a lot, very much). Patient discomfort was assessed using the visual analogue scale (VAS; 0 = no pain, 10 = worst pain imaginable).

Results

A total of 50 patients were treated at centres in Italy (n=35) and in the Netherlands (n=15). Patients were mostly female (83%), and the median age was 53 years (range: 40-64). Patients were treated for skin laxity of the inner arms (35%), abdomen (35%), décolleté (20%), and knees (10%). More than 97% of patients applied the patch between 2 to 5 hours, and more than 95% of patients applied the cream for 30 days. All patients completed the required surveys.

After treatment injection, the majority of patients (86%) reported experiencing no pain or mild pain, with 14% reporting moderate or severe pain; no patients reported very severe or worst pain possible (Figure 2a). The majority of patients experiencing pain reported that these symptoms disappeared in the 24-hour period (72%) and 48-hour period after treatment (94%), with only a small proportion of patients still experiencing pain ≥72 hours post-injection (6%) (Figure 2b).

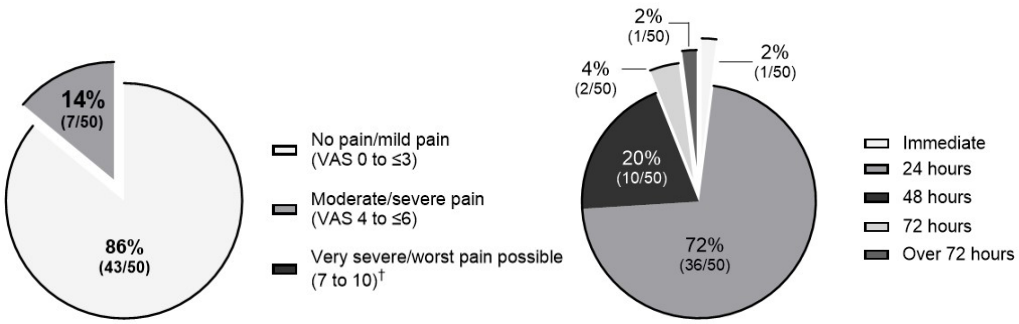

Figure 2: Discomfort survey across patients following treatment injection A) Percentage and number of patients reporting pain or not; B) Time required for post-injection pain to disappear and related percentage and number of patients. Abbreviations: VAS, visual analogue scale. † No patients experienced very severe/worst pain possible.

Patient-reported efficacy following Profhilo® Figura Body Patch and Profhilo® Figura Body Cream treatment was positive, with most patients reporting that treatment benefited them 'a lot' and 'very much' (Table 1). The majority of patients rated the Profhilo® Figura Body Patch as having a treatment effect of 'a lot' or 'very much' with regard to soothing action (62% and 20% of patients, respectively) and moisturising action (54% and 40%, respectively) on the treated area. Similarly, for Profhilo® Figura Body Cream, the majority of patients reported a treatment effect of 'a lot' or 'very much' with regard to improvement in skin hydration (34% and 60%, respectively) and skin firmness/tone (38% and 56%, respectively) on the treatment area (Table 1).

Patient-reported efficacy for the complete Profhilo® Body Kit (i.e. Profhilo® Body injection, Profhilo® Figura Body Patch, Profhilo® Body Cream) was also positive; more than 80% of patients reported that treatment with the kit benefited them 'a lot' and 'very much' (Table 2). The majority of patients rated the Profhilo® Body Kit as having a treatment effect of 'a lot' or 'very much' with regard to improvement in skin laxity (62% and 18%, respectively), skin hydration (28% and 48%, respectively) and skin firmness/tone (36% and 22%, respectively; (Table 2)).

Assessment	Treatment effect, % (n/N)			
	Not at all	A little	A lot	Very much
How do you assess the soothing action of the patch in the treated area?†	0% (0/50)	18% (9/50)	62% (31/50)	20% (10/50)
How do you assess the moisturising action of the patch in the treated area?†	2% (1/50)	4% (2/50)	54% (27/50)	40% (20/50)
To what extent has the cream treatment improved your skin hydration?‡	0% (0/50)	6% (3/50)	34% (17/50)	60% (30/50)
To what extent has the cream treatment improved your skin firmness/tone?‡	0% (0/50)	6% (3/50)	38% (19/50)	56% (28/50)
† > 97% of volunteers applied the patch between 2 to 5 hours; ‡ > 95% of volunteers applied the cream for 30 days				

Table 1: Efficacy survey across patients following Profhilo® Figura Body Patch and Profhilo® Figura Body Cream.

Assessment	Treatment effect, % (n/N)			
	Not at all	A little	A lot	Very much
To what extent has the Profhilo® Body Kit treatment improved your skin laxity?	4% (2/50)	16% (8/50)	62% (31/50)	18% (9/50)
To what extent has the Profhilo® Body Kit treatment improved your skin hydration?	2% (1/50)	22% (11/50)	28% (14/50)	48% (24/50)
To what extent has the Profhilo® Body Kit treatment improve your skin firmness/ tone?	4% (2/50)	38% (19/50)	36% (18/50)	22% (11/50)

Table 2: Efficacy survey across patients following Profhilo® Body Kit treatment.

Psychological and social function was also surveyed after treatment with the Profhilo® Body Kit. Most patients rated the Profhilo® Body Kit as having a treatment effect of 'a lot' or 'very much' regarding enhancement of body image and appearance (56% and 12%, respectively). For improvement in relationships, the majority of patients experienced a treatment effect of 'a little' (36%) or 'a lot' (42%; Table 3).

Assessment	Treatment effect, % (n/N)			
	Not at all	A little	A lot	Very much
To what extent has the entire Profhilo® Body Kit treatment enhanced your body image and appearance?	10% (5/50)	22% (11/50)	56% (28/50)	12% (6/50)
To what extent has the entire Profhilo® Body Kit treatment improved your social relationships?	16% (8/50)	36% (18/50)	42% (21/50)	6% (3/50)

Table 3: Psychological and social function survey across patients following Profhilo® Body Kit treatment.

Discussion

In this real-world evaluation, treatment with the Profhilo® Body kit (Profhilo® Body injection, Profhilo® Figura Body Patch, Profhilo® Body Cream) was associated with positive patient-reported outcomes. Over 80% of patients reported that treatment with the complete kit benefited them 'a lot' and 'very much' regarding improvement in skin laxity, skin hydration, and skin firmness/tone; beneficial treatment effects were also reported for enhancement of body image and appearance and improvement in relationships. Additionally, over 80% reported that treatment with Profhilo® Figura Body Patch and Profhilo® Figura Body Cream benefited them 'a lot' and 'very much' about soothing action and moisturising action, and improved skin hydration and skin firmness/tone. Importantly, most patients reported only mild pain associated with treatment injection and that post-injection symptoms disappeared in the 48-hour period after treatment. Taken together, these patient-reported results suggest a high level of satisfaction with the Profhilo® Body kit, including the specific effects of the Profhilo® Figura Body Patch and Profhilo® Figura Body Cream. The positive results of this real-world survey confirm previously reported results. Clinical studies of Profhilo® Body for treatment of skin laxity by Sparavigna et al, 2023 [5] and Sparavigna et al, 2022 [16] also assessed patient-reported treatment satisfaction, with the majority of patients reporting improvements in skin laxity and skin hydration. Additionally, when taken into consideration with the other studies, this real-world evidence survey enlarges the cohort of patients treated with Profhilo® Body.

Patient satisfaction is a key outcome for aesthetic interventions, underlining the importance of the high patient-reported satisfaction levels in this evaluation [15]. Key elements for patient satisfaction include selecting the right candidate and setting treatment expectations before treatment [17]. Patients with body areas for treatment which exhibit skin laxity, limited adipose tissue and limited muscular ptosis are optimal candidates for treatment with the Profhilo® Body kit. Furthermore, patients will have different treatment goals, expectations and motivations for undergoing treatment, and clinicians are increasingly encountering greater patient diversity with respect to race, ethnicity, age, and gender [18]. Indeed, patients with clear signs of skin laxity and roughness and without or few ptosis of the muscle and adipose tissue should be selected. Selecting the appropriate patients and setting expectations for treatment outcomes on a patient-by-patient basis are important for patient-perceived treatment success.

When choosing aesthetic treatments, patients seek to improve their physical appearance but also their QoL (quality of life) and social well-being [19,20]. In a study, which interviewed patients about drivers for considering cosmetic dermatological treatments, mental and emotional health issues were the most frequently mentioned motivators. Patients cited depression and anxiety due to their current looks, the burden of trying to hide unwanted physical traits and desire for increased confidence as key drivers [19,20]. This highlights the importance of the psychological and social function survey results of this survey, which indicates that the Profhilo® Body Kit provided positive improvements in social relationships and body image and appearance for most patients. However, there was a proportion of patients who experienced no improvement/limited improvement in social relationships and body image and appearance. There are several potential contributors to these results, including unrealistic treatment expectations, underlying low self-esteem and body dysmorphic disorder [17]. Although investigating these factors was beyond scope of this article, and represents an area for future research, these results further highlighted the importance of selecting the appropriate patients for the treatment and setting the correct expectations through a good patient-doctor relationship on a daily basis.

Common adverse events associated with Profhilo® Body include swelling, redness (erythema) and pain and typically have an early onset (<72 hours after administration), are mild to moderate and transient [2,9,10,21]. Although this current evaluation did not assess specific adverse events or severity, post-injection symptoms

resolved for almost all patients (94%) within 48 hours, consistent with the transient adverse profile for Profhilo® Body. Additionally, the majority of patients reported experiencing no pain or mild pain (86%), with a minority reporting moderate or severe pain (14%) after treatment injection. Importantly, no patients reported experiencing severe pain. These results indicated that treatment-related pain was limited for most patients, supporting the tolerability of treatment administration. Furthermore, these results may also help patients with their treatment choice, as fear of procedure-related pain one of the main treatment barriers [22].

Despite the usefulness of patient-reported outcomes, they are associated with several limitations, including variability in patient interpretation of outcomes such as pain or satisfaction and response bias based on survey format. Other limitations include using a relatively small number of predetermined treatment effect categories and patient-specific factors, which may have influenced outcomes, such as underlying low self-esteem or body dysmorphic disorder.

Conclusion

This is the first real world data evaluation to assess patient-reported satisfaction and effectiveness associated with Profhilo® Body Kit, which includes the Profhilo® Body injectable, the HA-containing Profhilo® Figura Body Patch and Profhilo® Figura Body Cream. This was also the first real world data to assess patient-reported effectiveness for sequential use of Profhilo® Figura Body Patch and Profhilo® Figura Body Cream. Patients reported positive treatment outcomes, including improvement in skin laxity, skin hydration, skin firmness/tone, enhancement of body image and appearance and improvement in relationships. Procedure-related pain was mild for most patients and most post-injection symptoms disappeared in the 48-hour period after treatment. Taken together, these results indicate a high-level of patient-reported satisfaction with the Profhilo® Body Kit and contributes to the growing body of evidence supporting the use of Profhilo® Body for the treatment of skin laxity.

Conflict of Interest: A.M., G.S-D. and R.D. declare no conflict of interest. C.C., F.G., G.B. are employees of IBSA Farmaceutici Italia Srl. The other authors declare that this research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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