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HYALURONIC ACID FILLER AND IMPROVED SELF-ESTEEM

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Henry Delmar, Eva Guisantes, Pier Antonio Bacci, Pyra Haglund, Wojciech Marusza, Lyudmil Peev, and **Valérie Philippon** discuss findings from the European ART (Art Reflexion Therapy) survey on self-esteem after aesthetic corrective treatments with HA filler

ABSTRACT
There is relatively limited information on patient and physician satisfaction with hyaluronic acid (HA)-based dermal fillers.
Objective: To better understand the psychological impact of dermal fillers, the large European ART® (Art Reflexion Therapy) survey was performed, which had the objective of assessing patient-perceived impact on the use of the ART FILLER® range of HA fillers on self-image and self-esteem.
Methods: The study involved 176 investigators in 8 European countries who administered 1036 questionnaires to patients undergoing cosmetic procedures. A physician questionnaire was also administered.
Results: The median age of first aesthetic treatment was between 40 and 45 years. Physician-assessed ease of modelling was rated high or very high in more than 80% of cases. At the one-month follow-up visit, overall 98.5% of patients reported improvement in the Global Aesthetic Improvement Scale; 73.2% of patients reported improved self-image, 63.9% referred greater confidence, and 55.5% felt more dynamic. The sum of Rosenberg's self-esteem scale for all countries increased from a mean of 33.63 to 34.46 after one-month, which corresponds to high self-esteem, while the difference between perceived age and actual age increased from -1.27 years initially to -3.54 years after treatment. The majority of adverse events were of mild intensity and transient.
Conclusions: The results of the present pan-European survey reinforce the positive impact that the ART FILLER® line of HA-based dermal fillers can have on patient-evaluated outcomes, including self-esteem and well-being.

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AT PRESENT, THERE IS AN INCREASING variety of dermal fillers available for aesthetic rejuvenation purposes that correct facial wrinkles and folds, facial volume deficits, fine lines, and improve skin quality; such products are also used for facial contouring and the augmentation of lips and cheeks[1]. The use of dermal fillers is now challenging, and in many circumstances replacing, more invasive and traditional aesthetic surgical treatments[2]. Indeed, according to the International Society of Aesthetic Plastic Surgery, more than 11 million non-surgical aesthetic procedures were performed in the US in 2016, of which over 3 million involved the application of resorbable fillers[3].

Many of the newer fillers are based on hyaluronic acid (HA) and its derivatives, and the Cosmetic Surgery National Data Bank Statistics of the American Society for Aesthetic Plastic Surgery reported that in 2016 there was a 16% increase in the use of HA fillers compared to the previous year with almost 2.5 million procedures performed[4]. Over 90% of such procedures were performed on women.

Correction of nasolabial folds has been suggested to have a positive impact on the subject's overall well-being, quality of life and self-esteem with potential improvements even in social interactions[5-9]. Despite their increasingly widespread use, with millions of subjects treated, there have been surprisingly few studies carried out on patient and physician regarding the overall benefits of HA-based dermal fillers. This is an important aspect, especially considering that the overall objective in the use of dermal fillers is to increase the patient's attractiveness and self-confidence.

Self-esteem is a complex psychological concept that refers to the overall positive or negative judgment of oneself and encompasses confidence in one's judgments, opinions, convictions and strengths[10,11]. Self-esteem takes into account how one is perceived by others, and thus has a strong impact on how one perceives the outside world. Poor self-esteem can be associated with unhappiness and difficulties in interpersonal relationships, both professional and private. For example, in an Australian survey of adults who had used aesthetic plastic surgery, a correlation was found between higher self-esteem, job satisfaction and a reduction in the number of burnout cases[12]. Thus, the perception of one's own physical appearance has an impact on wellbeing and is an important parameter to evaluate when considering the outcomes of aesthetic procedures.

Accordingly, the potential psychological impact of a rejuvenated and/or improved appearance can be expected to have considerable influence on patient's self-perceptions and psychological well-being although this

has been poorly documented to date. In particular, since randomised trials are not suited to assess patient-related outcomes such as self-esteem in aesthetic procedures, survey data appears to be a rational means of obtaining patient impressions before and after dermal filler procedures. There is, however, only very limited data on the impact on self-esteem from the use of aesthetic dermal fillers, and there is thus the need for additional information on the patient-perceived success of treatment with HA-based fillers.

To address this lack of data, the European ART® (Art Reflexion Therapy) survey was performed, whose primary objective was to assess the impact of HA-based filler range, the ART FILLER® range, on self-image and self-esteem. The present study is the largest such survey carried out to date, and one of the few large surveys to assess treatment impact on self-esteem. Such data is important not only to give clinicians some insight about post-procedural success but also to give the patient a new way of considering aesthetic procedures beyond simple aesthetic outcomes.

Materials and Method

Study design

The present multicentre survey was a prospective, real-life, descriptive study that involved a total of 176 investigators (29 in France, 20 in Sweden, 19 in Italy, 6 in Greece, 12 in Bulgaria, 37 in Poland, 46 in Spain, and 16 in Portugal). Investigators were contacted among those routinely using ART FILLER® products[13] who freely agreed to participate in the study. The investigators were given a series of questionnaires to administer to consecutive patients undergoing dermal filler treatments for rejuvenation treatments with one or more ART FILLER® products. There were no strict patient selection criteria regarding age, sex and contraindications to take part in the study, which was thoroughly explained to all patients, along with a signed informed consent form. A total of 1036 questionnaires were received, of which 964 were completed in their entirety to allow data collection and insertion into a common database.

Study questionnaires and assessments

This survey involved two questionnaires: one for patients, and one for physicians. The patient questionnaire was also divided into three parts to assess:

- The patients' self-image in their private and professional lives, previous aesthetic treatments, their opinion of facial features and skin quality, wishes for modification/correction and a self-esteem 'real age versus apparent age scale'
- Results after the injections, on the same day
- Changes noticed 1 month after the injections, with responses to the same questions as before the injections. Patient self-esteem was assessed using Rosenberg's Self-esteem Scale, which is one of the most frequently-used questionnaires for measuring overall self-esteem[14]. The test has ten questions with four possible responses, scored from one to four, and all responses are summed to obtain the total score. Higher scores indicate higher self-esteem.

The physician questionnaire was divided into three parts:

- Pre-injection to determine the patient's treatment plan
- At the time of the dermal injections to indicate the product(s) used per zone and the volume injected in mL, to note the practitioners' impression of ease of injection, the product's ease of modelling (moldability) and injection comfort, and to assess tolerance
- At a 1 month follow-up visit to assess the overall aesthetic result (physician GAIS—Global Aesthetic Improvement Scale), note the patient's impressions, assess tolerance and determine the treatment follow-up plan.

Descriptive statistics were used to compare patient and physician assessments.

> **"In an Australian survey of adults who had used aesthetic plastic surgery, a correlation was found between higher self-esteem, job satisfaction, and a reduction in the number of burnout cases."**

Study products

The ART FILLER® range of products was used, which includes four complementary products that enable zone-by-zone correction of wrinkles and volume through specific filling, smoothing and sculpting. ART FILLER® Universal, an injectable implant intended to fill in medium to deep depressions via injection in the mid dermis or deep dermis, as well as plumping up lips and enhancing their outline; ART FILLER® Volume, an injectable implant indicated for restoring facial volumes via subcutaneous, supraperiosteal injection; ART FILLER® Lips, an injectable implant intended to enhance lip outline or plump up lips; ART FILLER® Fine Lines, an injectable implant intended to fill in superficial wrinkles and fine lines (such as crow's-feet and peri-oral lines) via injection in the superficial dermis. Each investigator was allocated 10 boxes of products, containing two syringes each (four ART FILLER® Universal, three ART FILLER® Volume, two ART FILLER® Fine Lines and one ART FILLER® Lips). Injection modalities and product selection were left to the physician's discretion.

Results

Patient characteristics

A total of 964 completed questionnaires were collected and entered in the database. Patients were distributed into four age groups: ≤40 years, 41–50 years, 51–60 years and ≥60 years (*Table 1*). The vast majority of women were employed (80.1%) regardless of the country. France had the highest proportion of non-working participants. Among those currently working, sales-related occupations were the most frequent, representing 22.9% of patients presently working; 20.2% held administrative positions, 13% worked in communications/marketing and 43.8% in other fields. Most women were also currently in a relationship. Of ▷

▷ interest, most women had also previously undergone aesthetic treatments, while only 25.8% had undergone aesthetic surgery. In Spain, France, and Italy nearly one in three patients already had aesthetic surgery. The median age of first aesthetic treatment was between 40 and 45 years, depending on the treatment (botulinum toxin—45.2 years, HA injection—44.3 years, laser—40.3 years, peeling—40.4 years, mesotherapy—44.1 years). There were no substantial differences between countries regarding patient demographics.

Quantities and types of products injected

On average, each patient received an injection of 1.56 mL of ART FILLER® Volume, 1.46 mL of ART FILLER® Universal, 1.12 mL of ART FILLER® Fine Lines and 1.04 mL of ART FILLER® Lips. ART FILLER® Universal was used for 30–35% of all injections. Injections with ART FILLER® Fine Lines and ART FILLER® Lips were more specific to certain countries. Injections with ART FILLER® Lips represented 25% of the injections in Italy and 9.6% in Portugal. ART FILLER® Lips was predominantly used in Italy and Sweden. This product represented less than 15% of the total use of products in Bulgaria and Greece, wherein ART FILLER® Fine Lines represented nearly one-quarter of total product use.

The number of products used in individual patients per country is shown in *Table 2*. As can be seen, the number of product combinations varied widely. In Bulgaria, the majority of women received treatment with 3 or more products, and only 4.9% were treated with a single product. On the other hand, 76.8% of those in Sweden were treated with a single product, and only 5.8% were treated with three products. With the exceptions of Portugal and Greece, in other countries, the majority of women underwent treatment with a single product (*Table 2*). Concerning the individual products used, while the individual percentages varied by country, it was clear that ART FILLER® Volume and ART Filler Universal were the most frequently employed, followed by ART FILLER® Lips. The most common combination when two products were used was ART FILLER® Volume and ART FILLER® Universal, while when three or more were employed ART FILLER® Volume, ART FILLER® Universal, and ART FILLER® Fine Lines (26.2% of women in Bulgaria and 17.1% of women in Greece, with the remaining countries <5%).

Table 1 Patient characteristics

AGE (YEARS)	%
≤40	23.1
41-50	30.9
51-60	27.6
≥60	18.4
Currently employed	80.1
Currently in relationship	70.6
Previous aesthetic treatment	70.6
Previous aesthetic surgery	25.8

Table 2 Number of products used per patient by country

COUNTRY	1 PRODUCT (%)	2 PRODUCTS (%)	≥3 PRODUCTS (%)
Bulgaria	4.9	39.4	55.6
France	56.4	30.1	12.5
Greece	42.8	25.8	31.4
Spain	64.8	24	5
Italy	55.4	36	8.4
Poland	73.6	20.8	5.7
Portugal	23.4	57.4	5.8
Sweden	76.8	17.4	5.8

Physician-related endpoints

In general, the most common site of injection was the nasolabial folds, followed by the cheeks and lips. Other sites, such as the chin, forehead, jugal fold, temples, nose and other were injected much less (generally <5%). The average for the physician GAIS was 1.88, with the highest score in Bulgaria at 2.38 and the lowest in Sweden at 1.71. Ease of injection was considered high or very high in more than 80% of subjects for all products combined. Considering individual products, ART FILLER® Fine Lines had the highest rate of approval, with more than 90% of practitioners reporting high or very high ease of injection (*Figure 1A*). There was no substantial variation in physician-assessed ease of injection by country.

Ease of modelling was rated high or very high in more than 80% of cases, with the highest scores (>90%) for ART FILLER® Fine Lines and ART FILLER® Universal (*Figure 1B*). There was no substantial variation in physician-assessed ease of remodelling by country. All products were assessed by physicians to be associated with good injection comfort. Very high or high rates of injection comfort were reported for ART FILLER® Volume, ART FILLER® Universal, ART FILLER® Fine Lines, and ART FILLER® Lips in 86.8%, 90.8%, 94.6% and 76.3% of physicians. The comfort of injection was high or very high in 52.6% of the cases for ART FILLER® Lips and 69.3% of cases for ART FILLER® Fine Lines in Sweden, while it was high or very high in 77.8% of the cases for ART FILLER® Lips in Portugal. In all the other cases, for all products and countries, injection comfort was rated as high or very high in more than 80% of cases. There were no other substantial differences in ratings of injection comfort between countries.

Patient-related endpoints

The Global Aesthetic Improvement Scale (GAIS) is a five-grade subjective score used to assess both patient and investigator satisfaction with aesthetic outcomes. At the one-month follow-up visit, overall 98.5% of patients surveyed reported an improvement in GAIS (*Figure 2*). While some differences were apparent between

countries, these mainly involved judgments of the degree of improvement (i.e. very strongly improved vs strongly improved or improved).

A self-esteem score was established in the group population of 889 patients who had filled in questionnaires at the time of injection and at one-month follow-up. Of these, 73.2% of patients reported an improved self-image, with 63.9% reporting greater confidence and 55.5% feeling more dynamic (*Figure 3*). A large proportion of subjects also felt that their professional image and working relationships had been improved.

The Rosenberg self-esteem scale is a 10-item scale that measures global self-worth by measuring both positive and negative feelings about the self. All items are answered using a 4-point Likert scale format ranging from strongly agree to strongly disagree. The sum of Rosenberg's scale for all countries improved from an initial mean value of 33.63 to 34.46 after 1 month, which corresponds to high self-esteem. Most country-specific data showed modest improvement with the exception of Portugal (3.78 vs 3.82), while the highest improvements were seen for Italy (2.97 vs 3.28), France, (3.04 vs 3.31) and Greece (2.98 vs 3.37).

Likewise, subjective evaluation of facial appearance and skin quality was seen to be improved at one month; there were no substantial variations in responses between countries (*Figure 4*). In terms of facial appearance, subjects reported a perception of being rested, fresh and photogenic; while for skin quality, women referred to seeing themselves as brighter, and with a prettier complexion and texture. Virtually all women indicated that they would do the treatment again (country range 92.4-100%) and that they would recommend it to their friends and peers (country range 94.6-100%). The perceived value for money was calculated on a scale of 1 to 5, where a score of 1 indicates 'very poor' value for money and 5 'excellent' value for money. Overall, the value for money was considered good, with average scores ranging from 3.84 for Italy to 4.54 for Bulgaria. The overall average was 3.98.

With regards to perceived age of subjects, the difference between the perceived age and actual age increased, from -1.27 years initially to -3.54 years after treatment, for the group of women who responded to questionnaires at the time of the injection and one month later (*Figure 5A*). Thus, after treatment, women felt that they looked a mean of 2.27 years younger than before the procedure. In addition, the majority of women referred that they were 'satisfied' or 'very satisfied' with their body image following the procedure, although only the face was treated, ranging from >80% to almost 95% (*Figure 5B*). While there was some intercountry variability, the overall degree of satisfaction was very positive.

Figure 1a Ease of injection by product

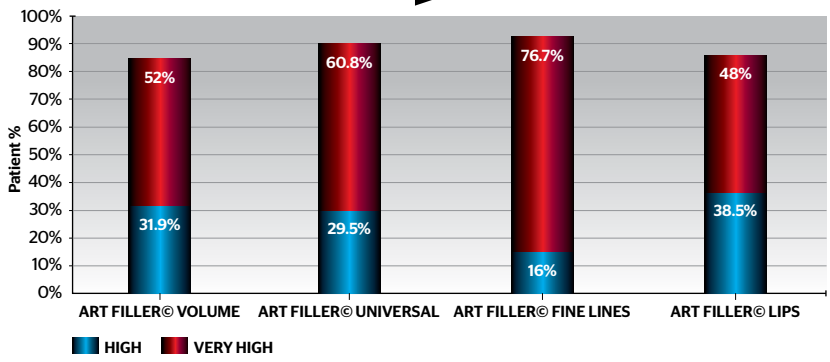


Figure 1b Ease of modelling

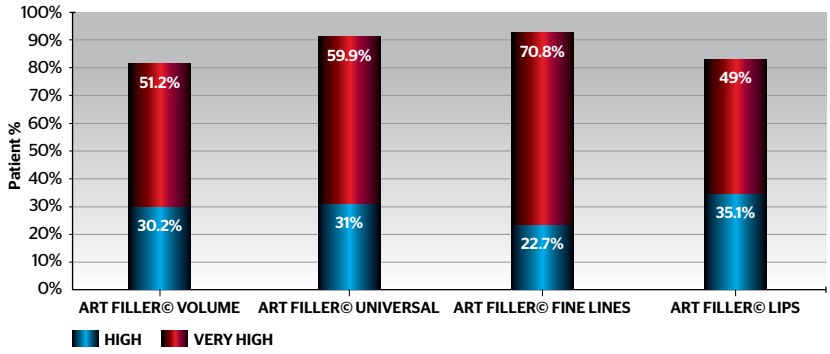
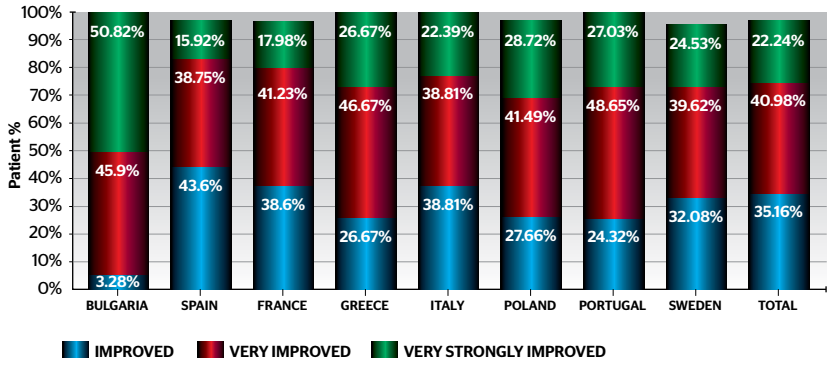


Figure 2 Patient ratings using GAIS post-procedure



Tolerability

Immediately following the injection session, adverse events were observed in 95 of the 964 patients (9.9%; *Table 3*). A total of 125 events were reported in 95 patients, the most frequent of which was oedema (4.0%; 39 events), followed by haematoma (2.8%; 27 events) and erythema (2.2%; 21 events). At one month after the injection, 81 adverse events were reported (8.4%); consistent with the adverse events at the initial session, the most frequent were oedema (2.8%) and haematoma (1.4%). The majority of adverse events that were rated were considered to be of mild intensity (38 of 66; 57.8%), and the majority were also transient (41 of 61; 67.2%). The vast majority of adverse events were considered by the investigators to be possibly, probably or definitely injection-related (55 of 57; 96.5%). ▷

> "The Global Aesthetic Improvement Scale (GAIS) is a five-grade subjective score used to assess both patient and investigator satisfaction with aesthetic outcomes."

Figure 3 Perceptions at one-month follow-up of self-esteem

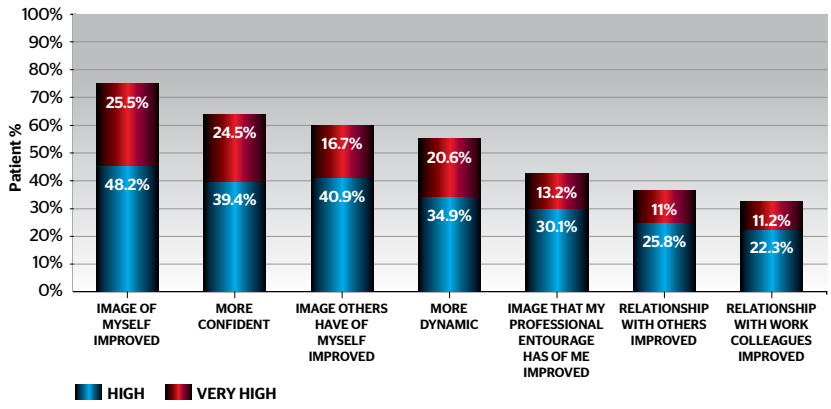
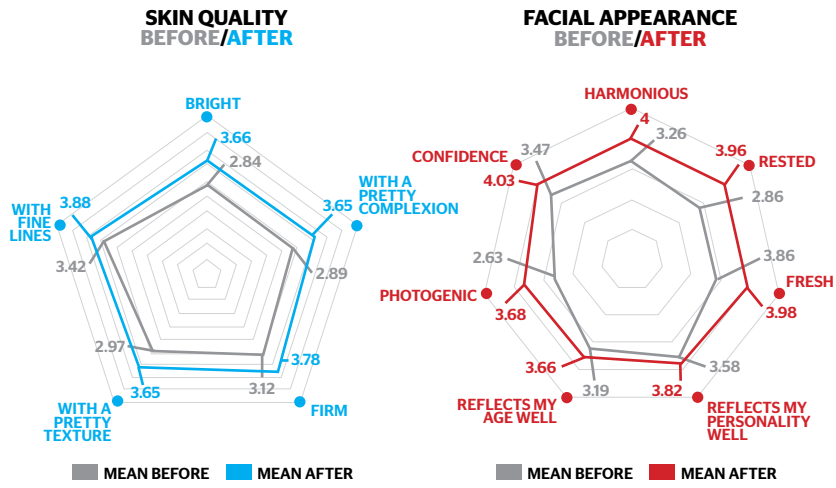


Figure 4 Subjective assessment of facial appearance and skin quality before the procedure and after one month



▷ 86.4% of AE occurred in three countries: Spain (n=41), Italy (n=20) and Sweden (n=9). Greece and Portugal reported only one case of oedema each.

Discussion

To our knowledge, the present survey is the largest to date evaluating patient-rated perceptions of aesthetic changes following treatment with dermal fillers. Such changes are important since they can have a profound influence on the patient's overall self-perceived attractiveness and well-being as well as self-esteem and social interactions. This pan-European survey involved eight countries, and demonstrated positive correlations, albeit to different degrees, in all endpoints assessed and in all settings. Firstly, improvements in the GAIS in virtually all women were referred. While some differences in the degree of improvement could be noted between countries, such differences might in part be attributed to differences in subjective ratings. For example, a similar degree of improvement might be rated as very strongly improved by a woman in one country, and as only strongly improved by a woman in another. Nonetheless, such results are not unexpected, and previous studies have also documented improvements in the GAIS using other types of HA-based dermal fillers[15-18].

> "Adverse events were seen in less than 10% of women, the majority of which were transient and self-resolving."

Adverse events were seen in less than 10% of women, the majority of which were transient and self-resolving. Moreover, the majority of adverse events were related to the injection itself, i.e. oedema, hematoma, and erythema. In this regard, some differences were noted between countries in the frequency of adverse events, which might suggest that investigator experience plays a role in the appearance of such adverse events. However, the present study was carried out under 'real-life' conditions, and assessment of adverse events with individual investigators was beyond the scope of the present survey.

Considering potential subjective differences in perceived ratings, confirmation of the benefits of the dermal filler treatments was also seen in the overall improvement in self-esteem, as women reported feeling that they had an improved self-image while feeling more confident and more dynamic. Such self-perceived differences also have the potential to improve interpersonal and professional relationships, which the majority of women also reported as having improved as a consequence of the cosmetic treatments. These results are confirmed by a previous study in 40 women who underwent minimally invasive cosmetic procedures evaluated using the self-esteem scale of Rosenberg reported that these procedures resulted in improvement in both quality of life and self-esteem, even after 6 months[6]. Thus, such procedures are likely to be effective in the long-term.

In addition, subjective improvements in facial appearance and skin quality were reported by the majority of women, which was reflected in a higher perception of a fresh appearance and being more photogenic. In fact, on average, women reported that they looked >2 years younger than their actual age after the treatment. A multicenter study in 235 patients with a volumizing HA filler also reported that the majority of women were satisfied with facial appearance in the long-term (89.8% at 6 months; 75.8% at 2 years), and reported looking an average of 3 years younger at 2 years, further confirming the patient-reported benefits of HA fillers in the long-term[17].

Lastly, it is important to point out that virtually all women, across all countries, referred that they would undergo the treatment again. This is a significant finding since over 70% of women had already undergone aesthetic treatments, and about 25% had had some form of surgical intervention. The relevance of this lies in the fact that dermal filler treatments with HA are non-invasive compared to surgical treatments, and are well-tolerated. Past studies in smaller patient groups have also reported that women undergoing such treatments had a high likelihood of returning for additional treatment as well as their willingness to recommend treatment to others[15,18-20].

Concerning physician-related endpoints, it is worth

Figure 5a Median difference in years of perceived vs. actual age before the procedure and after one month by country

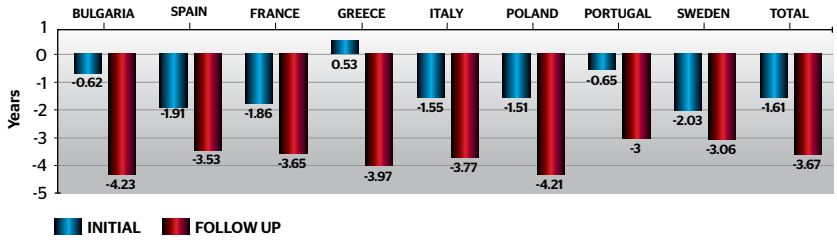


Figure 5b Percentage patients who were satisfied or very satisfied with body image post-procedure

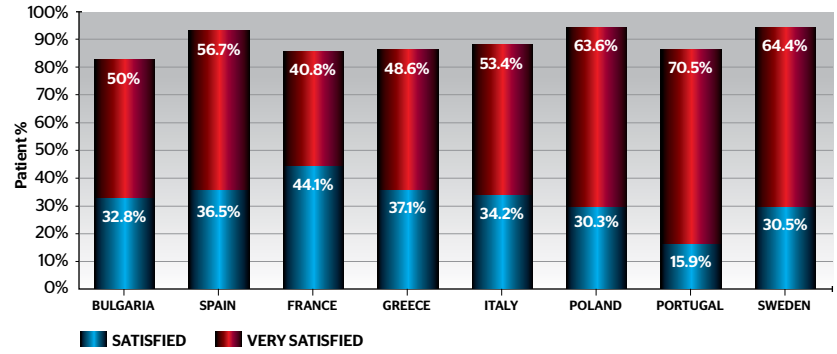


Figure 6 (A) Before and (B) After ART FILLER® dermal filler treatment

highlighting that the ART range of products was rated highly in terms of ease of injections and modelling, with no significant variation in responses by country. The products were also considered to be associated with a high degree of injection comfort. While encouraging, it should, however, be kept in mind that there were no technical limitations in injection technique for the study, and investigators were free to choose whatever technique they preferred. In addition, different injection techniques are used for various areas of the face and with different products, but the entire product range was still evaluated favourably.

There are several limitations to the present study. While prospective, the patient-reported outcomes were not fully validated and only subjective impressions were considered. In addition, being pan-European, there were no study protocols for use of a standardised injection technique or strategy. All correction plans and treatment protocols were individualised by the investigator and the subject undergoing cosmetic treatment, even if it is clear that different treatment plans were used when comparing different countries. For example, multiple products were used in more women in Bulgaria than in Sweden, but such differences may also reflect geographic differences in the desired cosmetic effects to be achieved. At any rate, however, such situations are reflective of real-life settings. In addition, only the ART FILLER® range of products was used, although the study was not conceived to be comparative but rather had the primary goal of assessing patient-reported outcomes after treatment to investigate how these affect the patient's self-esteem and opinions about the overall outcome of the procedure. Lastly, the time of follow-up evaluation was limited to one month.

The present study is one of the few and largest to date to assess the impact of dermal filler treatment on self-esteem, and there still remains an objective need for additional information on how women perceive the cosmetic changes after treatment with HA-based fillers. It is clear from the present data and previous studies that positive correlations are seen between HA injections and objective aesthetic improvement. Moreover, dermal fillers appear to have a genuine impact on self-perceived attractiveness, self-esteem and quality of life, even if ▷

Table 3 Adverse events after the initial injection and after one month

ADVERSE EVENT	INITIAL N (%)	ONE MONTH N (%)
Oedema	39 (4.0)	27 (2.8)
Haematoma	27 (2.8)	14 (1.4)
Erythema	21 (2.2)	4 (0.4)
Palpation irregularity	8 (0.8)	2 (0.2)
Pain	4 (0.4)	6 (0.6)
Exudation	4 (0.4)	3 (0.3)

Figure 7
(A) Before and (B) After ART FILLER® dermal filler treatment

▷ the latter was not assessed with a specific questionnaire. These treatments also appear to have a positive influence on social and professional interactions. The ART FILLER® line of products was associated with high favorability by physicians in terms of ease of use and modelling. The entire product range was well tolerated, and the majority of adverse events were mild in nature, transient and self-resolving. Our results reinforce the benefits that the ART FILLER® line of HA-based dermal fillers has on patient-evaluated outcomes and physician-assessed endpoints. These benefits are, indeed, reflected in the fact that virtually all patients would undergo the procedure again and would recommend it to others. The results also confirm for the first time in a pan-European real-world setting the positive impact that dermal fillers can have on self-esteem and well-being measured dedicated survey-based questionnaires.

> "Dermal fillers appear to have a genuine impact on self-perceived attractiveness, self-esteem and quality of life, even if the latter was not assessed with a specific questionnaire."

▶ ***Declaration of interest*** *The authors acknowledge FILLMED by FILORGA for providing the fillers used in the present study.*

▶ ***Figures 1–5*** *© Dr Delmar*

▶ ***Tables 1-4*** *© Dr Delmar*

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Key points

- Poor self-esteem can be associated with unhappiness and difficulties in interpersonal relationships. Thus, the perception of one's own physical appearance has an impact on wellbeing and is an important parameter to evaluate when considering the outcomes of aesthetic procedures
- The European ART® (Art Reflexion Therapy) survey was performed to assess the impact of the ART FILLER® range on self-image and self-esteem
- The present multicentre survey was a prospective, real-life, descriptive study that involved a total of 176 investigators with a total of 964 completed questionnaires collected and entered in the database
- The Global Aesthetic Improvement Scale (GAIS) is a five-grade subjective score used to assess patient satisfaction with aesthetic outcomes. At the one-month follow-up visit, overall 98.5% of patients surveyed reported an improvement in GAIS
- A total of 73.2% of patients reported an improved self-image, with 63.9% reporting greater confidence and 55.5% feeling more dynamic
- The sum of Rosenberg's scale for all countries improved from an initial mean value of 33.63 to 34.46 after 1 month, which corresponds to high self-esteem
- The difference between the perceived age and actual age increased, from -1.27 years initially to -3.54 years after treatment