

Research Article

The Use of Filling Treatments in Various Areas of Face, Using Hyaluronic Acid of Different Concentration, their Safety and Impact on the Appearance, Attractiveness and Patients' Quality of Life

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Abstract

Introduction: Fillers are substances that are injected in a specific volume either subcutaneously or deeply to the bone. Lifting the superficial layers of the skin they help to fill tissue deficits and correct the shape of different parts of face. Thanks to it the firmness and volume is restored and when the treatment is properly carried, the patient looks younger and better. Fillers are used not only in order to rejuvenate, but also to improve the appearance, remove asymmetry or to adjust it to current beauty cannons that prevail in a given region of the world. The use of aesthetic medicine treatments is advisable if we care about good appearance and delaying the effects of aging.

Aim of the study: the purpose of the research is to present the influence of facial fillers with varying degrees of concentration on patient's appearance. Assessment of the impact on the change in the respondent's attractiveness after a filling procedure, the attitude of the environment towards them after such a procedure as well as what the level of satisfaction is with the improvement in the area of the filler injection, and the level of satisfaction with the natural appearance after the procedure. Presentation of complications after the treatment, time of returning to patient's normal activities and how and whether pain and discomfort was felt during the application of the filler. The research also tests the non-materialistic impact of the treatments on patients' life quality. Using photos taken before and after the filling procedure (0, 1, 3, 6, 9 months after the treatment); the effects of improving the appearance of various facial areas was presented.

Materials and methods: The study involved 15 patients (12 women and 3 men) aged from 34 up to 56 years of age (the average age of the respondents is 39), using filling procedures (facial) based on cross-linked hyaluronic acid with different concentration - 15 mg/ml, 20 mg/ml and 25 mg/ml.

Results: 100% of respondents rated their appearance at months 1, 3, 6 and 9 after surgery, in a scale 1-4, 1- very natural; 80% of patients noticed an improvement in their appearance after the filling procedure; At months 0 and 1; 80% of respondents rated their satisfaction with improvement in the area of filler injection, in a scale of 1-6, 1, meaning extreme satisfaction. At month 3 after the procedure, as many as 93% of respondents checked 1, six months after the procedure 93% respondents checked 1 and 2. After 9 months still 73% rate their satisfaction from the improvement in the area of injections at the level of 1 and 2. 73% of the respondents answered, that they were able to return to their normal functioning immediately after the procedure.

Conclusion: 100% of respondents will be willing to repeat the filling procedures in the future. 67% of the respondents answered, that the effects are better than after previous filling treatments; 27% of the respondents noticed an improvement in the attitude of the environment towards them after they had undergone the filling treatment. 67% of the patients admitted that after having undergone the filling treatment their quality of life (in a non-material way), has improved.

Keywords: Aesthetic medicine; Fillers; Facial aesthetic; Hyaluronic acid; Quality of life; Safeness

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Introduction

Aesthetic medicine is a relatively new branch of medicine, which originated in France. The founder of aesthetic medicine is a French endocrinologist Jean Jacques Legran. The word aesthetics comes from Greek aesthetics, meaning a sense or love of beauty. Aesthetic medicine touches broadly defined preventive healthcare and the dissemination of a healthy lifestyle. This is a dynamically developing branch of medicine. Regardless the fact that it is a young medical speciality, a significant proportion of medical products and preparations used for aesthetic medicine procedures have been known in medicine for years. Aesthetic and antiaging medicine is a field of medicine that is supported by professional knowledge and experience, which similarly

to other medical disciplines gives great effects in preventive treatment [1,2].

Fillers are substances that are injected in a defined volume subcutaneously or deep into the bone. Through lifting the superficial layers of the skin, they fill the defects (e.g., wrinkles, furrows, folds) as well as correct the shape of individual facial areas (e.g., the shape of the mouth, nose, chin, temporal region, zygomatic area, face oval, etc). Hyaluronic Acid (HA) is also used for lips enlargement and for correction of their contour and disproportion between the upper and lower lip. For people who have a poorly defined lip contour, HA can also be used to highlight it. After a treatment using Hyaluronic Acid, lips become more defined, better moisturized, they change profile which gives them a younger look. In most cases the swallow nest disappears after a few hours, however it is possible that it will not cease to be visible up to a few days. The final effect, that is satisfying for patients after filling treatments, is visible after 2-3 weeks.

Fillers are used not only in order to rejuvenate but also to correct asymmetrii, look or to adjust the appearance to current beauty canons that prevail in a given region of the world. Taking advantage of aesthetic medicine treatments is advisable for individuals who care about their good look and delaying the effects of aging [1]. Fillers are also used in aesthetic gynecology. Thanks to the special IPN-like technology, the injected gel is more resistant to hyaluronidase and free radicals, and also the comfort of application of the substance to the dermis is improved [3-5].

There is a great selection of biodegradable and non-biodegradable fillers available on the market, which provides long lasting or temporal effects. The biodegradable fillers get absorbed and extracted from the body. Their safety profile is high; however, they are not long lasting and the treatments need to be regularly repeated (every 6-18 months). The long-lasting fillers are not biodegradable and often result in the formation of granulomas, the formation of which is the result of the presence of micro-coatings, thanks to which the filler is stable. However, such fillers may play a key role in HIV-infected patients who develop lipoatrophy (fat loss) and it would be desirable to achieve lasting correction and in patients with stabilized scleroderma [6].

The most frequently used filling substance in aesthetic medicine is Hyaluronic Acid (HA), belonging to biodegradable fillers. Hyaluronic acid is a natural component of our body, it is glycosaminoglycan (mucopolysaccharide). It was first discovered in 1934 by scientists from the American Columbia University - Karl Mayer and John Palmer.

In young skin, HA occurs on the periphery of collagen and elastin, while in skin that undergoes significant aging processes, such connections disappear. The consequences of a decrease in collagen, elastin and HA content in the skin are: wrinkle formation, furrow formation, slacky and dry skin [7,8]. Fillers based on hyaluronic acid are currently considered the gold standard in aesthetic medicine due to their safe use, very good aesthetic effects and product durability. In addition, HA has a greater biological capacity compared to other fillers. Therefore, allergic reactions rarely occur after treatments using HA.

HA is safe and is also used in other fields of medicine, e.g. in eye surgery, orthopaedics. HA is able to bind about a thousand times more water than its weight. Numerous HA chains intertwine and cross each other, thus creating solutions with high elasticity and viscosity, giving the skin cohesion and elasticity. Hyaluronic acid together with

collagen and elastin is responsible for the physical appearance of the face. Its amount in the skin decreases with age, which leads to its worse hydration, flaccid skin, a decrease in its firmness and wrinkles. Injections with HA are the most commonly used and safe method of filling wrinkles, folds and furrows in a natural way.

Techniques for applying fillers depend on its type and place of application, as well as the depth of application. A thorough assessment of aesthetic defects of a given patient is made when the patient is in a sitting position. Such a procedure does not require special preparations. However, 4 days before the procedure, drugs from NLPZ group should not be taken, in additional 45 minutes before the procedure (in the case of substances that do not contain lidocaine inside the pre-filled syringe), area that are to be treated ought to be anesthetized with a special cream (e.g., EMLA). The preparation is selected by a doctor depending on the place of correction, skin quality, depth and type of wrinkles and folds. For a few hours after the procedure an extensive face expression, as well as touching an injected area should be avoided. Immediately after the procedure, slight redness, swelling, minor hematomas and slight pain may appear at the application area, but these symptoms usually disappear on their own within a few days. For about 3 days, alcohol, excessive exercise and exposure to sunlight and heat (solarium, sauna, heat from the fireplace) shall be avoided [1].

The effect after the procedure is immediate but not final. For some time, the patient may still feel filler deposits in the skin. The final effect of using the filler ought to be seen after two weeks and when it comes to more cross-linked preparations, the results are to be seen even after 4 to about 6 weeks. Only after such period of time, patients are fully satisfied with the procedure [1].

The following work presents the impact of facial fillers with varying degrees of HA concentration on patient's appearance. It assess the impact on the change in the respondent's attractiveness after a filling procedure, the attitude of the environment towards them after such a procedure as well as what the level of satisfaction is with the improvement in the area of the filler injection, and the level of satisfaction with the natural appearance after the procedure. The research demonstrates the complications after the treatment, time of returning to patient's normal activities and how and whether pain and discomfort was felt during the application of the filler. The work also tests the non-materialistic impact of the treatments on patients' life quality (i.e., meeting new people, making friends, improving relationships with the surrounding or with the current partner, etc.).

Materials and Methods

The study involved 15 patients (12 women and 3 men) ranged from 34 to 56 years of age, who have been using filling procedures (facial) based on cross-linked hyaluronic acid. 6 respondents for the first time in their life used (any) aesthetic treatments. 9 patients had previously used aesthetic procedures (such as needle mesotherapy, medical peels, laser therapy, IPL, HIFU, botulinum toxin and even fillers, etc.), however, at the time of performing the filling procedure in a given area during the following research, no filling procedure had been performed for a minimum of 2 years.

Patients received one of three types of fillers (Dr. ArJo Fine, Dr. ArJo Balance, Dr. ArJo Ultra) with varying levels of hyaluronic acid concentration - 15 mg/ml, 20 mg/ml and 25 mg/ml. Only one filler was intended for each respondent. Main ingredient - reticulated hyaluronic acid; source - bacterial fermentation; pH 6,00-7,50; cross

- linking agent - BDDE <0,5 ppd; total endotoxin <0,5 EU/ml. The preparations were applied to various parts of the face (lower eyelids, tear trough, zygomatic region, 1/3 lower part of the face (cheeks), nasolabial folds, lips, drooping corners of the lips, "puppet lines", chin and jawline - face oval), choosing the preparation depending on the needs. Because the preparations do not contain lidocaine, before the procedure EMLA cream was applied to the face, for anesthetic purposes. Patients answered the questions in the survey before the surgery, and after the 1st, 3rd, 6th and 9th month after the surgery. Pictures were also taken before the procedure, immediately after the procedure, and in the 1st, 3rd, 6th and 9th month of the study.

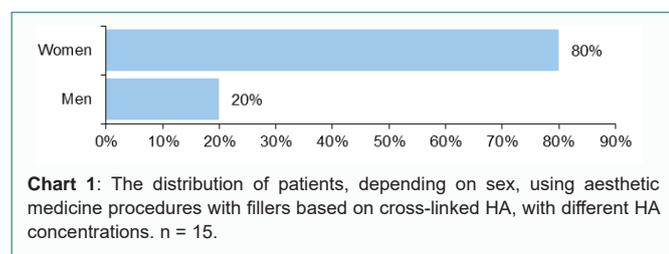
Only participants who expressed consent were included in this study. Participation in the survey was voluntary and anonymous. The subjects completed the surveys anonymously. They were informed of the purpose of conducting the investigations and that the resulting data would be used: for scientific research.

The survey was aimed at obtaining a wide range of information about patients using filler containing cross-linked hyaluronic acid treatment (Dr. ArJo fillers) with varying degrees of HA concentration. Information on:

- Experiencing pain and unpleasantness and discomfort during the procedure, when applying filler;
- Complications after filling procedure;
- The speed of returning to normal functioning in life;
- Satisfaction with improvement in the area of the filler injection;
- Satisfaction with the natural look after the filling procedure;
- Influence on the change of the respondent's attractiveness after the filling procedure;
- Attitudes of other people towards them, after a filling procedure;
- Assessing the quality of life in a non-material sense after a filling procedure.

Results

The study involved 15 patients (12 women and 3 men) aged from 34 up to 56 years of age (the average age of the respondents is 39), using filling procedures (facial) based on cross-linked hyaluronic acid with different concentration – 15 mg/ml, 20 mg/ml and 25 mg/ml (Chart 1).



The patients were asked the following question: What kind of complication appeared after the filling procedure? The answers included the following possible complications: bruising, hematomas, erythema, edema, pruritus, discoloration at the injection site, lumps or papules at the injection site, abscesses, and also "others" - where respondents were to write other complications (none of the

respondents wrote anything), and "there were no complications" (6 respondents gave such an answer). 5 patients experienced bruises; however, they were small and lasted only a few days (maximum up to 4). Lumps and papules at the injection site - checked by 4 people, however for two of them the effects disappeared after two days, for one - after 4 days and only for one patient they were visible up to one week. Erythema- was experienced by one patient; however it seemed to be caused by stress during the procedure and disappeared 30 minutes after. One respondent developed a swelling which disappeared after 3 days without any intervention or pharmaceutical help from a doctor (it was not necessary).

Patients very fast returned to their normal functioning. As many as 11 people (73%) answered that they were able to return to a normal life immediately after the procedure. 3 people indicated that after 1 day and only one after 3 days.

Patients were asked about experienced pain and discomfort during the procedure, and filler application. In both cases respondent could choose one of 6 answers. To the question of how you assess the pain felt during the procedure, they could answer as follows: 0 - I did not feel the pain at all; 1 - I felt slight pain; 2 - the pain was low; 3 - it hurt quite badly; 4 - I wanted the procedure to end as soon as possible because I felt a serious pain; 5 - I couldn't stand the pain, I won't repeat the procedure again. To the question of how you assess the pain felt during the filler application, the respondents could answer as follows: 0 - the sensation was very normal, as any other procedure; 1 - the procedure was slightly uncomfortable, I only felt light discomfort; 2 - the procedure was unpleasant, I felt discomfort; 3 - the procedure was very unpleasant, I felt a strong discomfort; 4 - I wanted the procedure to finish as soon as possible, because the sensation was very unpleasant; 5 - I won't repeat the procedure again.

The pattern of responses in both cases was similar and depended on whether the patient had previously used aesthetic procedures or if it was their first treatment. Patients for whom it was the first procedure chose answer 3 or 4 (they felt significant pain and discomfort during the procedure). The patients who had previously used a filling procedure and had a comparison, typically answered 1 or 2. No patient selected (in both cases) answer 5, that means that each respondent will repeat the filling procedure in the future, even though some patients chose answer 3 or 4.

The patients were asked a question: If you had previously used a filling procedure, how do you assess the present one in comparison to the previous? There were four possible answers - it was my first procedure, so I have no comparison; the effects are similar to the previous filling procedures; the effects are worse; the effects are better than the previous filling procedures. It is important to note, that no one chose the answer that the effects are worse than the previous filling procedures. 6 of the respondents had never before used aesthetic treatments and that was their first one. Thus, out of 9 people (100%) who had already used filling procedures, as many as 6 (67%) indicated the answer that the effects are better than after previous filling procedures.

The patients were asked a question: Could you please assess your level of satisfaction with an improvement in the area of filler injection? A 6-point response scale was used, where 1 means extreme satisfaction and 6 means extreme dissatisfaction. The answers were as follows depending on the month after the procedure:

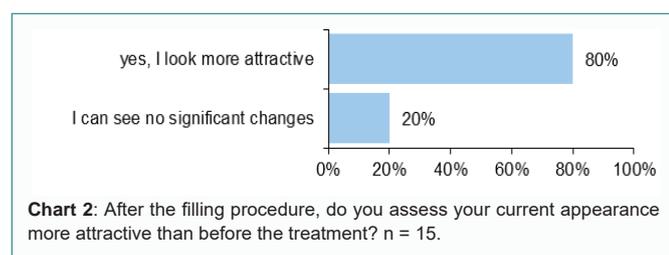
- In month 0 (the day of the treatment) and 1 month after

the procedure: 12 patients checked the answer 1 (extreme satisfaction) and answers 2, 3,1,4 were checked respectively each by one patient.

- 3 months after the procedure: 14 patients checked the answer 1 and one person answer 2.
- 6 months after the procedure: 10 patients checked the answer 1,4 patients answer 2 and one person answer 3.
- 9 months after the procedure: 6 patients checked the answer 1, 5 patients answer 2 and 4 person's answer 3.
- During the whole research the respondents have been accessing their satisfaction, with improvements in the area of injection, very high. In months 0 and 1% to 80% of respondents checked the answer 1 - extreme satisfaction. The dissatisfaction of few individuals (three) resulted from the fact that the patients needed more filler in a given area and, unfortunately, the study intended only one filler per one respondent. Hence, in the third month after treatment as many as 93% of respondents checked the answer, and 6 months after the procedure still 93% of respondents checked the answer 1 and 2. 9 months after the procedure 73% of the respondents checked answers 1 and 2.

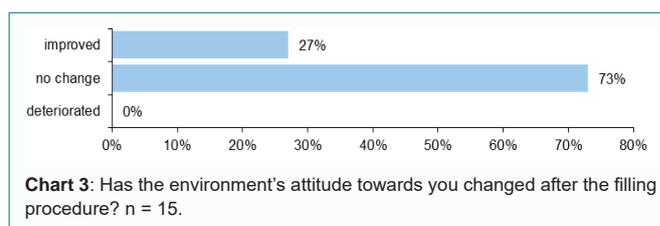
The patients were asked to assess their satisfaction with their natural look after the filling procedure on a 4-point scale from 1 - meaning a very natural look to 4 - extremely unnatural. The answers were as follows depending on the month after the procedure: only one person indicated that her appearance after the procedure is unnatural. She rated it on a 4-point scale as high as 3 (very high), but it was a patient who had never used aesthetic procedure before in her life. In addition, it was this patient who had swelling that lasted for 3 days. 1, 3, 6 and 9 months after the procedure, all people (100%) rated their appearance at 1 - meaning very natural.

The patients were also asked if according to them they look more attractive after the procedure than before. There were three answers to choose from: "yes -I look more attractive", "no - I look less attractive", "I haven't noticed significant changes" (Chart 2).



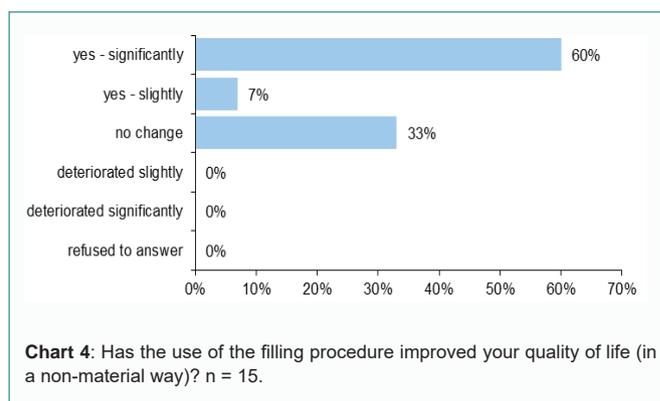
The first thing that should be noted is the fact that none of the respondents checked the answer two. The vast majority (80%) of patients noticed an improvement in their appearance after the filling procedure. The influence of cross-linked hyaluronic acid filling procedures on the environment's attitude towards the patient was also examined. The patients were asked if after the filling procedure, the attitudes towards them have changed (Chart 3).

27% of respondents noticed an improvement in the attitude of the environment towards them after a filling procedure. None of the respondents indicated deterioration in the attitude of the environment after the procedure.



The patients were asked the following question: Has the use of the filling procedure improved your quality of life (in a non-material way)?

There were 5 possible answers to choose from, as well as the option to refuse answering, which was not chosen by any respondent (Chart 4).



As you can see, 67% of patients admitted that after having undergone a filling procedure, their quality of life, in a non-material way, has improved (Figures 1-9).

Discussion

Aesthetic medicine is a medical branch that copes with human's health in the following aspects: appearance, image, aesthetics, well-being, visible skin changes and the patient's discomfort in quality of life [1].

The need to be beautiful and attractive has always existed, but today it is more clearly marked than ever before. As a result of aging, there are numerous changes, including patient's appearance, which is often not well taken. Doctors of all specialties look after the health of patients to the full extent. Plastic surgeons or aesthetic medicine doctors help to preserve youth and vitality. Numerous studies have shown that patients are more likely to choose non-invasive procedures (aesthetic medicine), as opposed to plastic surgery, hoping for a younger and more attractive appearance [1,2,10].

One of the most common reasons for using aesthetic procedures is the desire to look more attractive - it was an above average reason indicated by 86% of respondents in research conducted by Dr. Gałęba A [1]. On 603 patients of both sexes, aged between 21-61, benefiting from aesthetic medicine treatments (needle mesotherapy, fillers, chemical peels, botulinum toxin administered to correct wrinkles). The second reason is the desire to look young (70% of respondents) [1]. Garner in his research presented that the most important reason for using aesthetic medicine is the increase in dissatisfaction with own appearance [9]. The goal of aesthetic medicine is to satisfy patients according to their appearance requirements, eliminate hang-ups and restore self-esteem [1]. Patients want to look younger and more attractive [1,11].



(a)



(b)

Figure 1: Before and immediately after the treatment. 1ml of 25 mg/ml HA concentration was applied to the nasolabial folds and the zygomatic area.



(a)



(b)

Figure 2: Before and 1 month after the treatment (1 ml of 25 mg/ml HA concentration was applied to the nasolabial folds and the zygomatic area).



(a)



(b)

Figure 3: Lips - 1 ml filler with a concentration of 20 mg/ml HA. The photo on the left shows the patient before and immediately after the procedure. The photo on the right was taken before and 1 month after the treatment.



Figure 4: Tear troughs - 1 ml filler with a concentration of 15 mg/ml HA. The pictures show the patient before and immediately after the treatment (visible injection sites).

The patients in the above study were asked whether in their opinion, after the filling procedure they look more attractive than before the procedure. The vast majority, as much as 80% of patients noticed an improvement in their appearance after the filling procedure. In a study conducted by Gałęba A. in 2011 [1], 94% of respondents gave such an answer. In addition, in the same study [1], more than 40% of respondents noticed an improvement in the attitude of the environment towards them after using aesthetic procedures, as a result of which they became more attractive. In the following studies, 27% of respondents noticed this kind of improvement. The 13pp difference results also from the fact that in studies conducted in 2011, patients could benefit from the number of treatments they desired to achieve the effect that satisfied them (and could combine various treatments). In the current study, only one filler (1 ml) was used, for a given respondent, therefore some patients needed more material, the consequence of that was the fact that the before and after effect was not always significantly visible, and therefore the environment may have not noticed changes after the procedure.



(a)



(b)

Figure 5: Chin, drooping corners of the lips - 1 ml filler at a concentration of HA 15 mg / ml. The pictures show the patient before and 1 month after the procedure (the patient doesn't smile in the second picture, after the treatment; it is unfortunately visible in the picture without covering the eyes).



(a)



(b)

Figure 6(a): Figure 6(a): The first photo shows the patient before and immediately after the treatment (visible injection sites).
Figure 6(b): Picture was taken before and 1 month after the treatment.

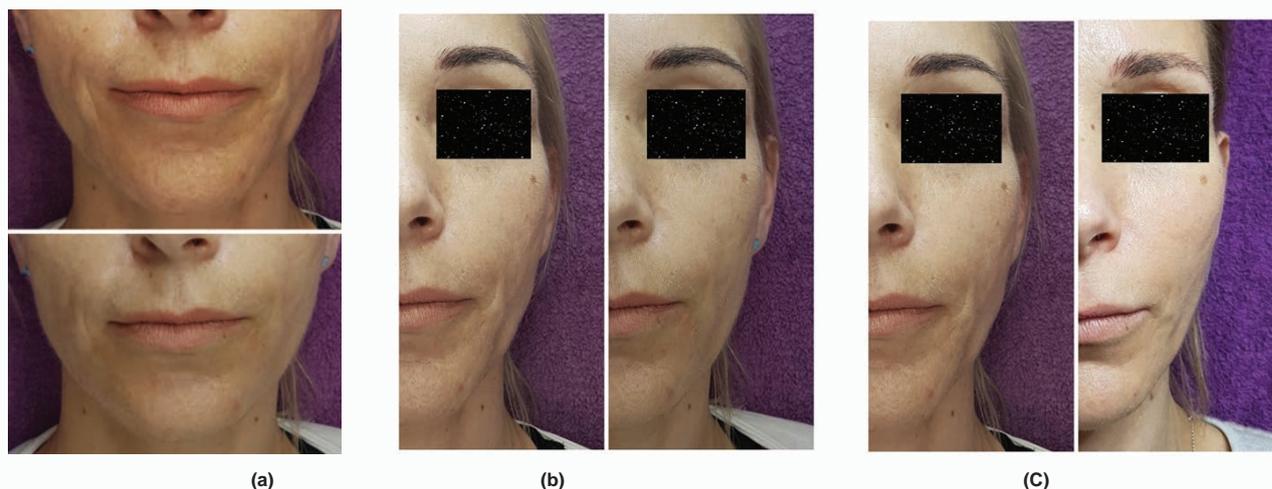


Figure 7: 1/3 lower part of the face - 1ml filler with a concentration of 15 mg/ml HA.
Figures 7(a) and 7(b): Show the patient before and immediately after the treatment;
Figure 7(c): Before and after 9 months.

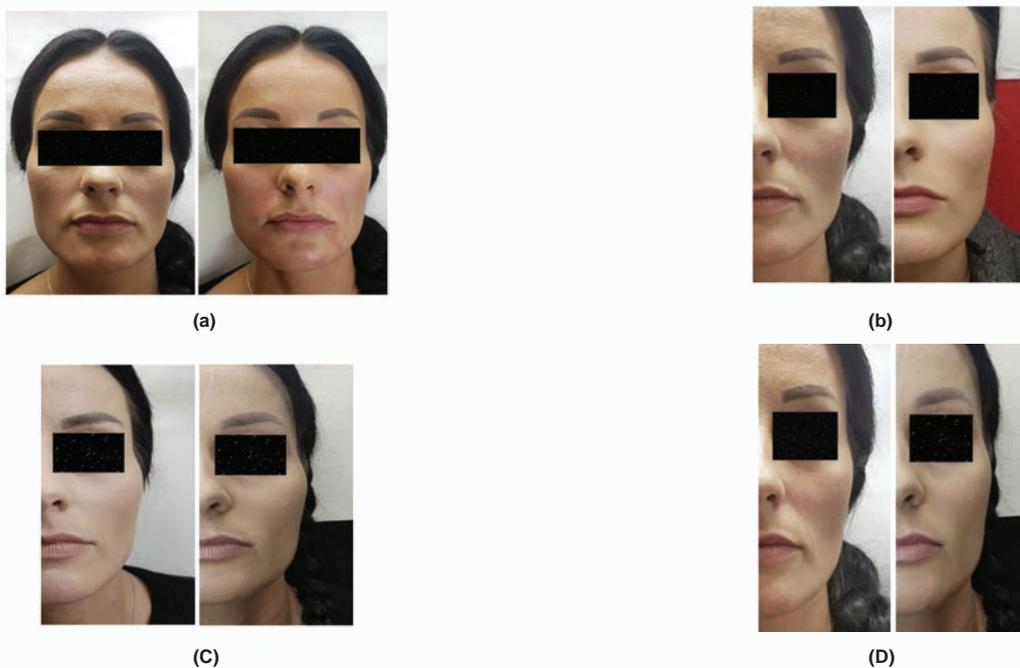


Figure 8: 1 ml filler with a concentration of 20 mg/ml HA (zygomatic region, nasolabial folds, drooping corners of the lips).
Figure 8(a): The first photo shows the patient before and immediately after the treatment (visible erythema).
Figure 8(b): Picture was taken before and 1 month after the treatment.
Figure 8(c): Picture was taken after 6 and 9 months after the treatment.
Figure 8(d): Last photo is showing the patient before treatment and after 9 months after the treatment.

During the entire 9-months study, respondents rated their satisfaction with the improvement in the area of filler injection very highly. In month 0 and 1% to 80% of the respondents rated their satisfaction with improvement in the area of the filler injection on a scale of 1-6, 1, meaning- extremely satisfied. In the 3rd month after the procedure, as much as 93% of respondents choose the answer 1, six months after the procedure 93% of the respondents checked answers 1 and 2. After 9 months still 73% assessed their satisfaction with the improvement in the area of the injection at the level of 1 and 2. The differences in the answers at the beginning were caused by the fact that the patients were allowed only one dose of filler (1 ml), and

sometimes, as it was mentioned before, the patients needed a higher dose, and that is a reason of their initial dissatisfaction. In the studies conducted by the Italian researcher Rauso R. [12], which also assessed the level of patient satisfaction with the obtained effect after filling procedures, the results are as follows: on a 10-point scale, the level of satisfaction after 1 month is 7.84/10, after 3 - 7.2/10 and after 6 months - 6.16/10.

In a study conducted by A. Gałęba [1,11] noted that undergoing aesthetic medicine treatments has a strong association with the improvement of quality of life (in non-material terms) of patients.



Figure 9: 1 ml filler with a concentration of 20 mg/ml HA (zygomatic area, nasolabial folds, marionette lines).

Figure 9(a): The first photo shows the patient before and 1 month after the treatment.

Figure 9(b): Photo is showing the patient before treatment (up) and after 1 month (down) and after 9 months after the treatment (right).

Almost $\frac{3}{4}$ of the respondents (73%) admitted that the use of such treatments, their quality of life in terms improved (in non-material terms). In current studies, a similar percentage of respondents, as much as 67%, admitted that after having undergone the filling procedure their non-material quality of life has improved.

Conclusions

- 100% of the respondents are willing to repeat the filling procedure in the future.
- 100% of the respondents rated their appearance at months 1, 3, 6 and 9 after the treatment, on a scale from 1-4, 1 - meaning very natural.
- 80% of the patients noticed an improvement in their look after the filling procedure.
- In month 0 and 1 - 80% of the respondents rated their satisfaction with the improvement in the area of filler injection on a scale from 1-6, 1 - meaning extremely satisfied. In month 3 after the procedure 93% of the respondents chose the answer 1; 6 months after the procedure 93% of the respondents chose the answers 1 and 2; 9 months after the procedure still 73% of the respondents chose the answers 1 and 2.
- 73% of the respondents answered that right after the procedure they were able to return to their normal functioning.
- 67% of the respondents answered, that the effects are better than the previous filling procedures.
- 67% admitted that after having the procedure done, their quality of life (in non-material meaning), has improved.
- 27% of the respondents noticed the improvement in the attitudes of others towards them after having the filling procedure done.

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