

VALUE OF INFORMED CONSENT IN AESTHETIC DENTAL PROCEDURES

S. Zerbo, G. Malta, G. A. Scardina, P. Messina, and A. Argo*

ABSTRACT

In the last decade there have been an exponential increase in both the supply and demand for non invasive aesthetic procedures involving the face and the lips to contrast age changes in the perioral area.

We briefly report the main non invasive aesthetics treatments in which dentists are involved and the professional liability related to the issues of informed consent. To avoid deontological and judiciary consequences the informed consent has to be obtained by the patient before any clinical procedure and documented in medical record. Recently Italian law no. 219/2017 highlighted the principle of autonomy and self-determination of patient and maximizes an optimal relationship between patient and healthcare professionals through a shared decision making.

Particularly, in aesthetic dentistry procedures, the clinical details must be discussed with the patient as well as the indications, potential side effects, complications, expected result and limitation of chosen treatment.

Keywords: shared decision making, informed consent, aesthetic dental procedures, perioral rejuvenation

INTRODUCTION

As established by Law of 24 July 1985 no 409 and subsequently amended “the object of the dentistry profession includes activities relating to the diagnosis and treatment of diseases and congenital and acquired abnormalities of teeth, mouth, jaws and related tissues”. Following on 2014 the Italian High Council of Health expressed a favorable opinion on the execution by the dentist of therapies with an aesthetic purpose only if they are "correlated" to specific dental treatments and limited to the perioral area.

The main aims of aesthetic dentistry is primarily at improving patient’s physical appearance and social attractiveness. The face is the part of the body considered most important with regard to attraction and social integration. After the eyes, the teeth, the mouth and the smile are the most important element in esthetic evaluation.

* Corresponding Author’s Email: stefania.zerbo@unipa.it

With increasing age the smile becomes elongated and less appealing and changes the morphology of lips characterized by a reduction in the vermilion border, lower lip lines, thinner lips, and disappearance of Cupid's bow. Facial aging process is characterized by breaking down of the underlying muscles, thinning of the epidermis, atrophy of the subcutaneous fat layers, progressive loss of organization of elastic fibers and collagen in the dermis, therefore the volume loss and gravity can lead to an exaggerated depth of the nasolabial and mentolabial creases [1-2].

In the last decade there have been an exponential increase in both the supply and demand for non surgical aesthetic procedures invasive involving the middle and lower third of the face because non invasive and less risky and expensive methods. As reported by American Society for Aesthetic Plastic Surgeons the number of surgical and minimally invasive cosmetic procedures performed in the United States in 2018 represents a 2 percent increase from 2017 in total cosmetic procedures. Overall, there were 15.9 million minimally invasive cosmetic procedures performed in 2018 (up 2 percent), with the top five being Botulinum toxin type A.

In addition to injection of dermal fillers, the use of botulinum toxin, laser treatments and carboxytherapy are the most relevant non surgical aesthetic procedures performed to treat skin imperfection, gingival hyperpigmentation and age-associated changes.

BOTULINUM TOXIN

Botulinum toxin is an injectable neuromodulator derived from neurotoxins produced by *Clostridium botulinum*, the bacterium responsible for botulism. Initially used for medical indications, botulinum toxin injection has now become one of the most requested procedures in facial rejuvenation.

Botulinum toxin type A is used for treat aesthetic dental conditions like deep nasolabial folds, radial lip lines, high lip line and black triangles between teeth [3, 5].

Recent studies show that facial rejuvenation therapy involving botulinum toxin type A and hyaluronic acid filler injections combined leads to improvement in skin quality and aesthetic appearance as well as to patient satisfaction [6-7].

In general, adverse reactions are uncommon and localized although there are not enough data on the long term safety of this drug, especially when used for cosmetic reasons. Serious adverse events have been reported in the literature due to dose dependent and attributed to local diffusion of botulinum toxin in adjacent areas [8-9].

DERMAL FILLERS

Fillers are used for reduce the signs of facial aging process, attenuate wrinkles, augmenting the volume of the lips or correct skin defect or imperfection such as hypoplasia or atrophy lips; scars due to acne or trauma, remodeling the shape of the visage.

In recent years, the number of available filling agents has also increased dramatically, improving the range of options available to physicians and patients.

All the fillers may be divided in terms of their duration of effect in two categories: fillers biodegradable or temporary that are absorbed through the human body after a period of time and fillers not biodegradable or permanent because are not absorbed by human organism.

Common biodegradable fillers are hyaluronic acid (HA), collagen, calcium hydroxylapatite, and poly-L-lactic acid with HA-based fillers [10].

Permanent fillers include polymethylmethacrylate microspheres, hydrogel polymers and highly purified forms of liquid silicone; they are rarely used because more burdened by complications [11].

Collagen is a natural protein that is a major component of the extracellular matrix of the skin and other connective tissues in the body. Bovine collagen was the first facial filler approved for cosmetic use in the United States. Afterwards human-derived bioengineered and porcine collagen are used as dermal filler. Collagen can be used to correct traumatic and post-acne scars, wrinkles and to increase the lips volume. The effects of collagen fillers generally last for 3-4 months. The use of autologous fibroblasts for the augmentation of dermal and subcutaneous defects represents a potentially exciting natural alternative to the use of other filler materials for its long-term corrective ability and absence of allergic adverse effects proved by clinical application [12-13].

The most widely biodegradable fillers in both Europe and the USA are HA derivatives. The HAS is a natural polysaccharide, biocompatibility and used in aesthetic dentistry to correct the volume of the lips and nasolabial and mentolabial wrinkles and imperfections of the soft tissues. The main advantage of HA fillers is that they can be quickly and easily reversed by the injection of hyaluronidase into areas in which elimination of the filler is desired, either because there is excess HA in the area or to accelerate the resolution of an adverse reaction to treatment or to the product. It is used for the correction of moderate to severe facial wrinkles and folds. The effect of this filling material lasts for approximately 6-12 months. In general, a lower incidence of complications has been reported with HA fillers compared with the semi-permanent and permanent fillers [14, 16].

Although rejuvenation of the perioral area with dermal fillers is a safe procedure all dermal fillers are associated to risk of both early and late complications [17].

At present available fillers are considered to be very safe, but as any minimally invasive treatment there is a potential risk of complications. Several adverse events are related to the material and to erroneous or inappropriate injection techniques. The main adverse reactions are early and typically last a few days such as: blindness, swelling, redness, pain and bruising at the injection side. Severe and rare delayed adverse events, also, have been reported in the literature, including pigmentary changes, allergic reaction, infections, nodule formation, tissue infarction and migration of filler material [18, 23].

Understanding the different characteristics, risks, and limitations of the available dermal fillers and a careful patient selection can help dentist to improve patient outcomes and reduce the risk of complications [24].

The physician must also have the ability to prevent unnecessary discomfort and bruising during treatment and must be able to recognize and manage complications should they develop during or after treatment [25].

To reliably obtain successful outcomes, the dentist must have a good knowledge of facial anatomy, of the material being used and of the injection technique.

Treatment must be individualized, taking into account factors such as the age, skin thickness, aesthetic preferences, expectations, motivating factors, risk tolerance, the facial area to be treated, ethnicity and budget.

LASER THERAPY

Laser therapy is increasingly used to treat facial wrinkles, acne scars and other skin blemishes. Recent literature highlights that laser therapy has more optimal efficacy in the treatment of gingival hyperpigmentation than other techniques such as: chemical methods; cryosurgery, electrosurgery, and gingival abrasion [26, 28].

The common complications including pain, bleeding, edema, infection, and impaired wound healing.

CARBOXYTHERAPY

Carboxytherapy is indicated for redesigning the oval of the face, to eliminate dark circles, both for the restoration of the dermis microcirculation and for the stimulating effect on fibroblasts for the production of new collagen, elastin and hyaluronic acid, glabellar and cheek nose wrinkles, to restore turgidity to the neck and décolleté. The subcutaneous administration of the gas reduces the depth of fine wrinkles, visibly increases skin elasticity and brightness, significantly improves face contouring [29-30].

For the antiaging therapy, work protocols have been developed by the Gisc (International Carboxy Therapy Study Group) [31-32].

To carry out this gentle lifting, the wrinkle is removed by inserting the tiny needle at a depth of about one millimeter (at the intradermal level). Carbon dioxide is then blown in painlessly, which for a few seconds inflates the treated area. A superficial emphysema is thus created which is reabsorbed in a few moments, with the result of smoothing the wrinkle. In practice it works directly on the wrinkle, creating a sort of "tunneling" to hit the wrinkle in a targeted way. It takes about half an hour to treat the entire face and the gas is injected into the various areas: the periorbital area, the glabella, the nasogenien area, the perioral area, the neck and décolleté. The result is immediate, the face immediately appears younger and smoother. And without the slightest pain. This treatment can be combined with amino acids, fillers and vitamins, which become even more effective and last longer because they act directly on the support structure, built by carboxytherapy.

The session lasts 15 to 20 minutes. During gas delivery, if the patient is particularly sensitive, a slight discomfort is felt that depends on the speed of the flow and the individual sensitivity. It is sufficient to reduce the speed to overcome these problems. The results are observed quickly: Carbon dioxide, in addition to favoring the disposal of waste and toxins, performs the antiaging function, intervening in the cell regeneration process, leaving the skin more toned and compact.

For dark circles the principle of CO₂ therapy ensures better oxygenation of the upper layers of the skin, through vasodilation and neoangiogenesis. The procedure involves injecting CO₂ into the dermis very superficially. 3-4 sessions are enough 3-4 weeks apart.

The use of carboxytherapy in association with bio-revitalization based on polynucleotides, amino acids, vitamins (A, C, E, B), minerals (Ca, Mg, K, N, Cl), antioxidants and hyaluronic acid enhances their effects and makes it more durable. It is not a "filler, but a natural stimulation of the cell renewal process with an increase in the degree of

hydration and elasticity. Carboxytherapy can also be associated with peeling and mesotherapy with vitamins and antioxidant and moisturizing substances. With the peeling a medium or deep superficial exfoliation of the skin is obtained with a subsequent cell regeneration process, in order to improve a skin imperfection or to prevent and strengthen the anti-aging effect of the treatment. The action of carboxytherapy in skin rejuvenation is different from the actions of biorevitalization, peeling or biostimulation, but it appears as complementary to them. The well oxygenated and vascularised skin, hydrated, receives better the actions of the other three procedures.

Usually the treatment includes from 5 to 10 sessions to be carried out on a single or bi-weekly basis. The protocol to be followed by the patient will however be decided by the doctor, who will evaluate the specific case from time to time: the treatment programs are personalized and home treatments are also combined. The maintenance program includes a carboxytherapy session a month.

LEGAL AND ETHICAL BASIS OF INFORMED CONSENT

The need to acquire the prior consent of the patient is not only based upon shared ethical principles but also upon ethical codes and legal regulations.

The Convention on human rights and Biomedicine (Oviedo, 1997) and the European Charter of fundamental Rights (Nizza 2000) states that free and informed consent is a human fundamental right to safeguard individual's autonomy. The respect for autonomy means allows the patients to make free and informed decisions on their medical care in accordance with their values, needs and wishes.

The Article 5 of Oviedo Convention declare that

“an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as o the purpose an nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time”. The Article 3 of European Charter of fundamental Rights states “everyone has the right to respect for his or her physical and mental integrity. in the fields of medicine and biology, the following must be respected in particular the free and informed consent of the person concerned according to the procedures laid down by law”.

Both articles protect the principle of self-determination in medical cure as, also, highlighted by Italian Constitution in article 32

“.. no one may be obliged to undergo any health treatment except under the provisions of the law ...”.

After a long political, social and juridical debate, in December 2017 the Italian Parliament approved a Law no 2801/2017 on informed consent and advanced treatment directives [33].

The law states (art.1) -according to the previous statements in the current version of May, 2014 of Italian Medical Ethics Code – that

“no medical treatment can be initiated and continued without the free and informed consent of the person concerned, except in cases expressed provided by law”.

According to new law every patient has the right to receive complete information on the proposed treatment but has the right to accept or refuse the proposal procedure.

An important aspect of the Law 219/2017 is to emphasize the value of patient's time to decide. In the scenario outlined by the law every patient has the right to have enough time to discuss with the health professional benefit, risks, therapeutic alternative to ensure a shared decision making.

It has to be highlighted that the new Italian law establishes that informed consent must be obtained and documented in written form or, if the patient is not able to do it, through video recording.

If the patient is unable to provide consent, the patient's legal representative or, in the case of a minor, the patient's parent(s), represents the patient in the consent process. The patient or legal representative must have every opportunity to understand the risks, benefits, and alternatives of the proposed treatment or procedure [34].

INFORMATION AND CONSENT

In Italy, in recent years, there is been an exponential increase in dental medicine and in aesthetic dentistry of claims related to issues of informed consent.

Italian dentists need to be trained to become aware of information and consent are two distinct processes closely connected that should be dealt with separately and specifically [35, 38].

The information must include an exhaustive discussion of objectives, risks, and benefits of each aesthetic dentistry option including nature of the treatment; materials, final result quality and duration, procedural complexity, need for patient compliance, number and duration of appointments, time lapse between treatment beginning and ending. The information within the therapeutic relationship must be given in a manner which is compatible with the individual patient's educational level and psychological and emotional status.

The aware refusal to undertake dental treatment/procedure exempt the professional from liability even though the patient is informed about the possible risks of not proceeding with the proposed treatment [39].

Informing the patient on aesthetic dental treatment may become a difficult mission, if considering the wide range of materials and techniques used in aesthetic dentistry.

In the field of aesthetic dentistry the information must include a complete discussion of objectives, risks, and benefits of each option, the potential acute and late complications of treatment including the consequences of not choosing the treatment/procedure so as to make a shared decision making.

The health professional should discuss the relative benefits of fillers and other competing or complementary treatments (for example, botulinum toxin type A and surgery), duration of effect, and benefits and risks of each option.

The set of information that dentists must give to patient for aesthetics dental treatment are reported in Figure 1.

Dear Sir / Madam

the purpose of aesthetic medicine treatments fulfils the medical duty of guaranteeing the patient not only health but also of improving the physical appearance for his psychological well-being and social attraction and acts in particular on the face.

like all the procedures complications can arise that it is our duty to illustrate:

- with the use of **botulinum toxin** adverse reactions are rare and localized; however, in the literature serious cases of dose-dependent type and related to the spread of the drug in the areas adjacent to the treatment are reported
- **dermafillers** can have effects related to the material used and the injection techniques. short-term reactions - which in any case last from a few hours to a few days - include blindness, swelling, redness, pain and bruising on the injection side. long-term reactions instead may be: pigment changes, allergic reaction, infections, nodule formation, tissue infarction and migration of the filling material;
- with the use of **laser therapy** the common complications include pain, bleeding, edema, infection and impairment of wound healing;
- on **carboxytherapy** slight adverse effects such as edema, pain at the injection site, ecchymosis, erythema, all of which disappear in a few days, are described in the literature.

The major contraindications for all aesthetics procedures are:

<ol style="list-style-type: none"> 1. Angina pectoris 2. Apnea during sleep 3. High blood pressure 4. Blood pressure failure 5. Bacterial infections of the skin in the acute phase 6. Viral infection / local inflammation 7. Gangrene 8. Congenital heart disease 9. Chemotherapy and neoplasms 10. Dialysis 11. Epilepsy 12. Phlebitis or pulmonary embolism 13. Severe anemia, hemorrhagic diseases 	<ol style="list-style-type: none"> 14. Haemophilia 15. Severe heart failure 16. Patients with immunosuppression or using immunosuppressive drugs 17. Chronic obstructive pulmonary disease 18. Diabetes mellitus 19. Recent heart attack 20. Kidney failure 21. Pregnant and breastfeeding women 22. The use of acetazolamide and diclofenamide 23. Congestive heart disease 24. Severe cerebrovascular diseases 25. Aortic stenosis 26. Acute thrombosis
--	--

If you have any of these conditions, notify the dentist immediately!!!

Attention before signing this form We invite you to read it carefully and mentally review what we have said and the information provided to you. Do not hesitate to ask us for additional information if something is not clear to you or to express your dissent.

Thank you

INFORMED CONSENT/DISSENT

◊ I consider myself adequately informed and I am obliged to follow the proposed therapeutic/preventative procedure

◊ I refuse to undertake proposed therapeutic / preventive procedure even though informed about the possible risks of not proceeding with the proposed treatment

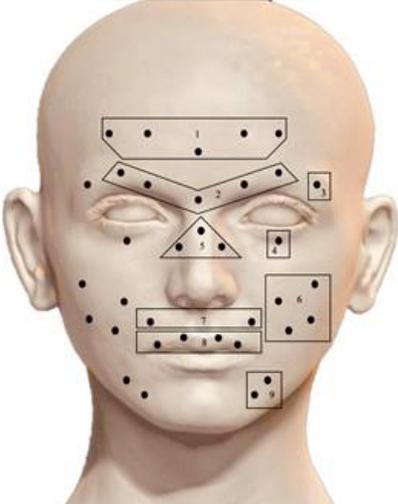
There, Signature

Pag. 1/2

(Figure 1 continued on next page).

Dear Sir / Madam

in this section, for greater clarity, we report the injections point where the therapy and / or injection will be performed:

	<ol style="list-style-type: none"> 1. Forehead wrinkles; 2. Glabella 3. Brow lift 4. Lower eyelid 5. Dorsal and lateral bunny lines 6. Mild check lines 7. Gummy smile 8. Upper lip drooping 9. Marionette lines
---	---

Attention before signing this form We invite you to read it carefully and mentally review what we have said and the information provided to you. Do not hesitate to ask us for additional information if something is not clear to you or to express your dissent.
Thank you

INFORMED CONSENT/DISSENT

I consider myself adequately informed and I am obliged to follow the proposed therapeutic/preventative procedure

I refuse to undertake proposed therapeutic / preventive procedure even though informed about the possible risks of not proceeding with the proposed treatment

There, Signature

Pag. 2/2

Figure 1.

The dentist will discuss with the patient what the best options are among several aesthetic treatments so that the patient understands and can choose the most appropriate rejuvenating treatment based on a variety of factors including: the patient's age, psychological disorders, motivating factors, timing, cosmetic area to be addressed, and the desired outcome [40].

Moreover, it must also be underlined that the informative process must include the economical aspects of the medical intervention, which in private dentistry are frequently quite expensive for the patient and often represents to be a potential source of conflict with the dentist.

Consent must be documented in the medical record, and consent forms may serve to document the physician's discussion with the patient.

A useful method of documentation is a physician note in the medical record or in electronic health record indicating that a comprehensive discussion took place and that the consent of the patient was obtained.

The note should also include the date and the time of the discussion, as well as the content of the discussion, an evaluation of the patient's understanding and a signature of patient.

As emphasize, few years ago, by the Court of Milan

“the signing of any pre-printed form can never be reduced to a formal act, with the aim of relieving in advance the doctor from his medical responsibility. A patient should sign the consent form after a detailed information process and a careful reflection, after an appropriate lapse of time, in order to be fully aware of all aspects regarding the treatment.”

A careful patient selection is imperative for reducing undesired outcomes. Obtaining a complete history is a crucial first step in this process; if a patient has a history of excessive bleeding, bruising, or abnormal scar formation, it is important to document that information and ensure that the patient is aware that this might occur as a result of dermal filler injections. Some requests for aesthetic dental procedures come from patients with psychological disorders, and in these cases is important to give a complete explanation of the real results that are obtainable. If the information given by the dentist to the patient is not sufficient to understand realistic expectations, the perception of a negative (or unsatisfactory) result of treatment might be the cause of a medical claim [41].

At the same time, the physician needs to clearly differentiate between the needs and interests of the patient, and make this difference clear to the patient, choosing the minimally invasive procedures, which are associated with lower risks and better results [42,47].

The dental aesthetical treatments need to strike the right balance between the aesthetic aspect of teeth and their functioning; some aesthetic procedure might have a negative effect upon function of teeth.

So in cases in which the risks of the aesthetic procedures for the health of the patient are significant and unjustified the dentist has the deontological obligation and the legal right to refuse to supply a determined procedure.

CONCLUSION

In the last decade there have been an exponential increase in demand for non invasive aesthetic procedures involving the face and the lips to contrast age changes in the perioral area.

Most malpractice claims are related to issues of informed consent; for these reason the clinical details must be discussed with the patient as well as the indications, potential side effects, complications, expected result, cost and limitation of chosen treatment.

Consent or refuse of the proposed treatment must be documented – as highlighted by the Italian Law 219/2017 on informed consent - in the medical record to document the physician's discussion with the patient.

REFERENCES

- [1] Suryadevara AC. Update on perioral cosmetic enhancement. *Curr Opin Otolaryngol Head Neck Surg* 2008;16:347-351.
- [2] Van der Geld P, Oosterveld P, Kuijpers-Jagtman AM. Age related changes of the dental aesthetic zone at rest and during spontaneous smiling and speech. *Eur J Orthod* 2008;30:366-73.
- [3] Nayyar P, Kumar P, Nayyar PV, Singh A. BOTOX: Broadening the Horizon of Dentistry. *J Clin Diagn Res* 2014;8:12 4.
- [4] Duruel O, Ataman-Duruel ET, Berker E, Tözüm TF. Treatment of Various Types of Gummy Smile With Botulinum Toxin. *AJ Craniofac Surg* 2019;3:876-878.
- [5] Rao LB, Sangur R, Pradeep S. Application of Botulinum toxin Type A: An arsenal in dentistry. *Indian J Dent Res* 2011;22:440-5.
- [6] Molina B, David M, Jain R, Amselem M, Ruiz-Rodriguez R, Ma MY, Kerrouche N, Georgantopoulos SP, Radeau T, Boineau D. Patient Satisfaction and Efficacy of Full-Facial Rejuvenation Using a Combination of Botulinum Toxin Type A and Hyaluronic Acid Filler. *Dermatol Surg* 2015;41:25-32.
- [7] Dayan SH, Ho TT, Bacos JT, Gandhi ND, Kalbag A, Gutierrez-Borst S. A Randomized Study to Assess the Efficacy of Skin Rejuvenation Therapy in Combination With Neurotoxin and Full Facial Filler Treatments. *J Drugs Dermatol* 2018;17:48-54.
- [8] Yiannakopoulou E. Serious and Long-Term Adverse Events Associated with the Therapeutic and Cosmetic Use of Botulinum Toxin. *Pharmacology* 2015;95:65–69.
- [9] Wollina U, Konrad H. Managing Adverse Events Associated with Botulinum Toxin Type A. A Focus on Cosmetic Procedures. *Am J Clin Dermatol* 2005;3:141-50.
- [10] Monheit GD. Advances in collagen fillers. *J Drugs Dermatol* 2009;8:812–17.
- [11] Hexsel DM, Hexsel CL, Iyengar V. Liquid injectable silicone: history, mechanism of action, indications, technique, and complications. *Semin Cutan Med Surg* 2003;22:107-14.
- [12] Zeng W, Zhang S, Liu D, Chai M, Wang J, Zhao Y. Preclinical safety studies on autologous cultured human skin fibroblast transplantation. *Cell Transplant* 2014;23:39-49.

- [13] Meng-Yao T, Rong J, Ying Z, Yao-Ming S, Bao-Shan S, Lu Z, Yu-Guang Z. Advances in the research of autologous fibroblast injections for aging skin. *Plast Aesthet Res* 2016;3:83-5.
- [14] Stojanovič L, Majdič N. Effectiveness and safety of hyaluronic acid fillers used to enhance overall lip fullness: A systematic review of clinical studies. *J Cosmet Dermatol* 2019;18:436-443.
- [15] Bass LS. Injectable Filler Techniques for Facial Rejuvenation, Volumization, and Augmentation. *Facial Plast Surg Clin North Am* 2015;23:479-88.
- [16] Monheit GD, Rohrich RJ. The nature of long-term fillers and the risk of complications. *Dermatol Surg* 2009;35(Suppl 2):1598-1604.
- [17] Luebberding S, Alexiades-Armenakas M. Critical Appraisal of the Safety of Dermal Fillers: A Primer for Clinicians. *Curr Derm Rep* 2013; 2:150–157.
- [18] Chiang YZ, Pierone G, Al-Niaimi F. Dermal fillers: pathophysiology, prevention and treatment of complications. *J Eur Acad Dermatol Venereol* 2017;31:405-413.
- [19] Wagner RD, Fakhro A, Cox JA, Izaddoost SA. Etiology, Prevention, and Management of Infectious Complications of Dermal Fillers. *Semin Plast Surg.* 2016;30:83–86.
- [20] Funt D, Pavicic T. Dermal Fillers in Aesthetics: An Overview of Adverse Events and Treatment Approaches *Plast Surg Nurs* 2015;35:13-32.
- [21] Funt D, Pavicic T. Dermal fillers in aesthetics: an overview of adverse events and treatment approaches. *Clin Cosmet Investig Dermatol* 2013; 6:316-23.
- [22] Zielke H, Wölber L, Wiest L, Rzany B. Risk profiles of different injectable fillers: results from the Injectable Filler Safety Study (IFS Study). *Dermatol Surg.* 2008;34: 326-335.
- [23] Chatrath V, Banerjee PS, Goodman GJ, Rahman E. Soft-tissue Filler–associated Blindness: A Systematic Review of Case Reports and Case Series. *Plast Reconstr Surg Glob Open* 2019; 7:1-13.
- [24] Sherman RN. Avoiding dermal filler complications. *Clin Dermatol.* 2009;27:S23–S32.
- [25] Haneke E. Managing Complications of Fillers: Rare and Not-So-Rare. *J Cutan Aesthet Surg* 2015;8:198–210.
- [26] Khalilian F, Nateghi Z, Janbakhsh N. Gingival depigmentation using lasers: A literature review. *Br J Med Med Res* 2016;12:1-7.
- [27] Gul M, Hameed MH, Nazeer MR, Ghafoor R, Khan FR. Most effective method for the management of physiologic gingival hyperpigmentation: A systematic review and meta-analysis. *J Indian Soc Periodontol* 2019;23:203-15.
- [28] El Shenawy HM, Nasry SA, Zaky AA, Quriba MA. Treatment of Gingival Hyperpigmentation by Diode Laser for Esthetical Purposes. *Open Access Maced J Med Sci* 2015;3:447–454.
- [29] Brandi C, D’Aniello C, Grimaldi L, Bosi B, Dei I, Lattarulo P, Alessandrini C. Carbon dioxide therapy in the treatment of localized adiposities: clinical study and histopathological correlations. *Aesthetic Plastic Surgery* 2001;25:170-4.
- [30] Pinheiro NM, Crema VO, Millan BM, Carvalho FA, Mendonça AC. Comparison of the effects of carboxytherapy and radiofrequency on skin rejuvenation. *J Cosmet Laser Ther* 2015; 17:156-161.
- [31] Klinika GHC. Carboxytherapy: a new non-invasive method in aesthetic medicine. *Cas Lek Cesk* 2006;11:841-3.

- [32] Nach R, Zandifar H, Gupta R, Hamilton JS. Subcutaneous carboxytherapy injection for aesthetic improvement of scars. *Ear Nose Throat J* 2010;89:64-6.
- [33] Law 219/2017 'Provisions for informed consent and advance treatment directives' in Gazzetta Ufficiale della Repubblica Italiana, n. 12, 16 January 2018.
- [34] Prestileo T, Argo A, Triolo V, Zerbo S, Procaccianti P. Informed consent and minors: HIV testing in Italian legislation. *Le infezioni in medicina* 2008; 4:200-3.
- [35] Tortorici S, Argo A, Buzzanca ML, Burruano F, Tetè S. Ambulatory therapeutic alliance [L'alleanza terapeutica in ambulatorio] *Giornale dell'Odontoiatra* 2010;27:22-26.
- [36] Argo A, Buzzanca ML, Burruano F, Tetè S. Information, consent and therapeutic alliance in ambulatorial oral surgery. *Italian Oral Surgery* 2009;3:155-164.
- [37] View at Publisher Houry BS, Houry JN. Consent: a practical guide. *Australian Dental Journal* 2015; 60:138-42.
- [38] Rini MS, Zerbo S, Ventura Spagnolo E, Malta G, Baldino G, Argo A. Oral cancer and treatment information involved in therapeutic decision-making. *Clin Ter* 2019;170:216-222.
- [39] Sfikas PM. A duty to disclose. Issues to consider in securing informed consent. *J Am Dent Assoc* 2003;134:1329-33.
- [40] Theobald A, Wong B, Quick A, Thomson W. The impact of the popular media on cosmetic dentistry. *N Z Dent J* 2006;102:58-63.
- [41] Rayess HM, Svider PF, Hanba C, et al. A Cross-sectional Analysis of Adverse Events and Litigation for Injectable Fillers. *JAMA Facial Plast Surg.* 2018;20:207-214.
- [42] Engelman DE, Bloom B, Goldberg DJ. Dermal fillers: complications and informed consent. *J Cosmet laser ther* 2005;7: 29-32.
- [43] Chate RA. Truth or consequences: the potential implications of short-term cosmetic orthodontics for general dental practitioners. *Br Dent J* 2013;11:551-3.
- [44] Spatafora F, Argo A, Campisi G. The role of the dentist in aesthetic medicine: Rules and indications (Il ruolo dell'odontoiatra nella medicina estetica: Norme e indicazioni). *Dent Cadmos* 2012;6:301-18.
- [45] Tortorici S, Argo A, Buzzanca M, Burruano F, Tetè S. Information, consent and therapeutic alliance in ambulatorial oral surgery (Informazione, consenso e alleanza terapeutica in chirurgia orale ambulatoriale) *Italian Oral Surgery* 2009;8:155-64.
- [46] Grippaudo C, Oliva A, Ricci B, Grassi S, Bartoletti E, Romana Grippaudo F. L'utilizzo dei dermal filler in odontoiatria in Italia: aspetti clinici e medico-legali *Dent Cadmos* 2018;4:306-314.
- [47] Argo A, Seidita F, Zerbo S, Ventura Spagnolo E, Messina P, Scardina G.A. Orthodontic guidelines and assessment of medicolegal liability (Linee guida in ortodonzia e attuale valutazione dei profili di responsabilità). *Dent Cadmos* 2016; 3:161-8.