



A nurse's guide to safer application of Hyaluronic acid fillers and management of complications.

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Abstract

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Hyaluronic acid injections are rapidly increasing as an aesthetic treatment in Finland. The treatment is not regulated by Valvira as it is classified as a CE- marked medical device. This means that no healthcare or medical training is required to inject the products available on the market. Inadequate training, knowledge, and guidelines for the safer application of fillers and management of complications do not exist for this treatment. There is an increased risk of complications, not only for the non-healthcare professionals but also the trained nurses that attempt to self-learn and treat patients despite the lack of official guidelines and adequate anatomical knowledge. The purpose of this thesis is to condense the existing knowledge and considerations into a Finnish functional guide and checklist before treatment and highlight the most important areas that need to be mastered before treating any patients. The aim of this guide is to increase safety of the patient and improve treatment outcomes. This functional guide will shine light on the subject and benefit nurses that are looking to acquire the appropriate skillset for this treatment. The guide will reduce the risk of complications and increase safety and practical knowledge, help avoid complications and how to treat them. The data has been collected from scientific research articles and books limited to 2010. All research points out a few main considerations. Patient assessment, anatomical knowledge, product placement and understanding the possible complications and how to manage them.

A written guideline, checklist and complication management list has been produced with the key concepts. The Theoretical framework and prototypes have been appraised by a Medical Doctor specializing in plastic surgery and a Registered Nurse, adding transparency and validity to this thesis from a medical and nursing perspective. The appraisals were considered in the final processes of this thesis before making changes to the prototype and final product. The guide will be tested and used in practice by nurses participating in filler workshops at the Face Designers clinic in Helsinki that specializes in fillers and training professionals in their application.

The guidelines do not replace an extensive anatomical knowledgebase or medical training and should only help to point out the areas of concern and help checklist when assessing patients for treatment.

Key words: Hyaluronic acid, Dermal Fillers, Facial anatomy, Complications, Injection guidelines

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1. Introduction

For years, there has been serious and concerned discussions about the permits needed to inject (HA) fillers in Finland. The risks of causing vascular occlusions, blindness, infections and other adverse reactions cannot be accurately reported and do not always get appropriately diagnosed because of the lack of legal regulation. No reliable data on complications can be found that would accurately reflect on this problem (suomenplastiikkakirurgiyhdistys. 2019). Most countries in the world require a healthcare degree in nursing or doctors' license to perform these treatments. In July 1.2021 Sweden finally passed a law that restricts the injection of fillers to medically trained nurses and doctors. The Finnish plastic surgery association (Suomen Plastiikkakirurgiyhdistys r.y. - Chirurgi Plastici Fenniae) wrote a letter of recommendation for Valvira in 2019. (The National Supervisory Authority for Welfare and Health is a centralized body operating under the Ministry of Social Affairs and Health in Finland.) Recommending that Finland follow the regulations and restrict these injectable (HA) fillers to medically trained professionals. So far, no new regulations have been put in place by Valvira, despite recommendations and increasing rates of complications. Restricting the treatment only to medically trained professionals is the most efficient way to increase safety. (suomenplastiikkakirurgiyhdistys. 2019) This thesis aims to condense the international recommendations for treating patients safely. The main purpose of the guideline is to help increase safety of the patient and decrease risk of adverse events related to the injection of (HA) fillers until government guidelines are put in place. The current EU regulation states that HA fillers are classified as CE- marked medical devices and can be operated by anyone that has received user instructions from the import company and do not require medical overseeing by Valvira (EU-asetus Valvira 2010.). The manufacturing company is responsible for the safety of the product in all stages of its use (Fimea. 2015.) Tukes (Turvallisuus ja kemikaalivirasto Tukes 2023.) and Valvira monitor the market but do not regulate who can inject. (Fimea 2023) *Legality on the subject has been limited to its definition in this Thesis due to its larger scope. Clinics are responsible for making sure all required permits are in place.*

2. Background

Hyaluronic acid fillers are the second most popular aesthetic procedure in the world after botulotoxin injections. Fillers are considered safe and relatively cheap. The results are instant and reversible. As the procedures become more common, the number of complications and adverse effects related to HA injections increase in relation. Most common complications are due to over correction, miss placement of product or lack of knowledge in

anatomy, technique, and product biology. Rare but possible complications are infections, Anaphylaxis, vascular occlusion necrosis, blindness, and strokes (Vedamurthy M. 2018.). (Find complications explained in section 3.1.1.)

HA fillers are classified as medical devices and do not require any specialist training in Finland. (Duodecimlehti 2021.) The import companies are responsible for providing application instructions and no general healthcare guidelines exist for these treatments in Finland. Although no specialist can guarantee complete safety and risks are still involved. Complications can be significantly reduced by increasing knowledge of aseptic work, anatomy, technique, product placement and their characteristics. Research also highlights the need for understanding the possible complications and management of them. Especially when it comes to vascular occlusions and blindness. Nurses do not train in this specialized area, and it is not considered as a medical treatment. (EU-asetus Valvira 2010). There is a no-man's land, lacking knowledge and official guidelines for treatment and complications management in the fillers market in Finland.

2.1 Theoretical framework

The main considerations have been collected through various research articles by surgical and medical journals, studies, guidelines, and recommendations to treat patients safely and prevent and manage complications. Similar articles or guidelines cannot be found in Finnish. The evidence based theoretical framework highlights the main findings to the following 1-8 categories. (Find considerations in image 7. Pre-Assessment 2.7)

1. Assessment of the patient
2. Anatomy and theory of ageing
3. Application technique
4. Product knowledge and placement
5. Danger zones and vascular considerations
6. Treatment planning
7. Complications and their management
8. Post treatment and guidance

2.2 Hyaluronic acid fillers

Hyaluronic acid fillers (HA) have been used to correct facial features since the late 1970's, but it wasn't until the early 2000 that the first FDA approved HA fillers spread to the market and formed the product families that we know today. The name Hyaluronic acid comes from the Greek word Hyalos. Meaning vitreous. This is a gel structured sugar molecule in its simplicity. It's become one of the most used ingredients in cosmetics and fillers due to its remarkable ability to bind water molecules, adding a moisture or volumizing effect. (Papakonstantinou E, Roth M, Karakiulakis G. 2012.) HA fillers can be very useful in aesthetic

augmentation and reconstruction of the tissue planes if they are applied correctly for their best indicated use by injecting the gel into the targeted tissue plane. Understanding the basic science behind HA gel and what products to choose for a specific indication is essential to successfully achieve a positive patient outcome and minimize risks of complications (Fattahi, Salman 2019). *Having a basic knowledge of the physical and chemical relationship that HA fillers have on the tissues is key to performing safer treatments and reaching optimal results.* (Solish, Beer 2010.)

2.3 Hyaluronic acid

Hyaluronic acid (HA) is naturally found in tissues and skin, providing moisture, support, lubrication and fluidity of nutrients and ions. This incredible sugar molecule glycosaminoglycan (GAG) can bind 1000 times its own molecular weight to retain water molecules. (Papakonstantinou E, Roth M, Karakiulakis G. 2012.)

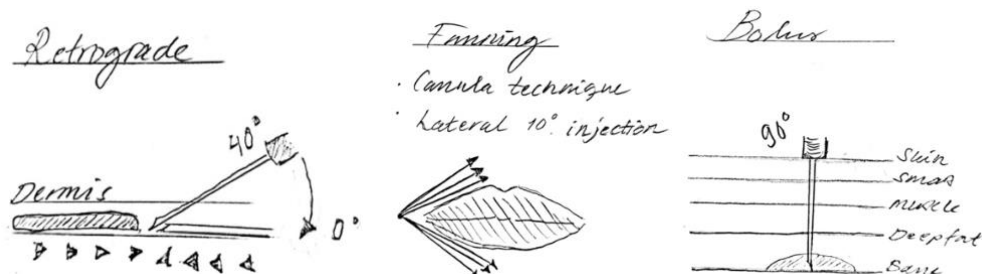
Table 1. Filler classification 1-4/ a-c (Vedamurthy M. 2018.)

1. Non-permanent biodegradable
 2. Semipermanent biodegradable
 3. Permanent reversible
 4. Permanent nonreversible
-
1. Temporary: Reversible with hyaluronidase, duration <18 months
 2. Semipermanent: Reversible with hyaluronidase >18 months
 3. Permanent: Non reversible more than 24 months

It is important to understand the biology of the fillers and technique to understand the complications they may cause. The longer lasting product with a higher percentage crosslinked HA, also has a higher particle size and attracts more water. This is called a high G prime. A high G prime puts more pressure on the tissue its placed, causing more swelling and potentially increasing the risk of vascular complications and infections. The most common complication being the unattractive outcome with a duration of more than 18 months and increased risk in all commonly accruing adverse events. (Vedamurthy M. 2018.) The Thesis topic has been limited to Classification: 1. Non-permanent biodegradable/ Temporary: Reversible with hyaluronidase, duration <18 months. (See Table 1. Filler classification 1-4/ a-c)

2.4 Application of HA fillers

The application of HA fillers is done by injecting a targeted tissue plane with HA gel. The fillers come in onetime prefilled syringes and sterile packages, usually containing a 1ml syringe of Hyaluronic acid and two needles. The needles are typically 26G/13mm. The package contains two product tags. One for the patient and one for the practitioner. The syringe has a Luer lock mechanism. This locks the needle to the syringe and prevents the pressure from removing the needle when injecting (Teosyal 2023). The targeted area is disinfected before injection and a topical anesthetic cream is applied. The injections are done in a 10-90° angle depending on the tissue layer being targeted. From a visual aspect. A 3D approach to anatomy is needed. The best results are achieved through multilayering techniques of fanning, boluses and retrograde injections. (Aesthetic Surgery journal 2022.) The HA gel is thick and creates pressure inside the needle much more than a liquid would. It is important to always inject slowly and not add too much pressure. Aspiration is recommended to check for vascular puncture before injecting a small amount of product. (J Clin Aesthet Dermatol. 2020.) It is equally important to inject the right product into the correct tissue plain. (Vedamurthy M. 2018.) *The logistical properties are not discussed in this thesis due to the instructions provided by privately owned corporations. Fillers do not require storage considerations other than a cool room temperature and out of sunlight and syringe exposure more than procedure time to ensure gel quality (Face Designers. Teosyal instructions)*



Images 1-3 Drawings by Annika Haikala. Demonstration the most common injection techniques. Retrograde, Fanning, Bolus. (Explained below 1-3) (Aesthetic Surgery journal 2022.)

1. Retrograde techniques are injections targeted superficially into the dermis and subcutaneous plane. Administered in a 40° angle then advancing laterally before aspiration and an anterograde (forward) retrograde or (backward) injection of gel until exit of the entry point.
2. Fanning techniques are generally used for larger surface planes and canula techniques in superficial fat compartments and deep fat compartments. One entry point is used

to insert an introducer needle, then needle or cannula. Then advancing retrograde and anterograde in many directions advancing and retracting the cannula simultaneously injecting small amounts of gel. *A blunt cannula will increase safety with this technique* (Aesthetic Surgery journal 2022.).

3. Bolus techniques are used when targeting deep planes. For example, DMCF (Deep medial Cheek fat) With the help of an introducer needle an entry point is made and a cannula or needle is inserted and advanced in a 60° angle to the surface of the bone. A bolus is injected to target the specific plane. No HA gel is injected with a bolus technique. *Vascular complications can accrue in any tissue plane. Caution should be taken equally in superficial injections* (J Clin Aesthet Dermatol. 2020.).



Pictures 1-4 By Annika Haikala (Face Designers clinic owned products, Art Filler, Teosyal Ultra Deep, Soft Fill cannula, Teurumo needle) Demonstrating the typical packaging and injection needle/cannula.

Table 1: Typical Indications for HA fillers: (Neurotoxins and fillers in facial aesthetic surgery. 2019)

Lips/ Lip line (vermillion) /Perioral (around the mouth)	Volume, moisture, support, symmetry, Autotrophy, skin quality
Lines and wrinkles. Perioral rhytids, nasolabial folds, Glabella (<i>High-risk area for vascular occlusion</i>) (Plast Reconstr Surg Glob Open. 2016.)	Wrinkles around the mouth, between nose and mouth (nasolabial) and glabella (between the brows).
Cheek, jaw, chin, temples	Deep injections for volume and symmetry. Correction of atrophy.
Tear trough (under eye)	Augmentation of hollows and dark sagging under eyes

2.4 Facial anatomy

A comprehensive understanding of facial anatomy is a critical component of any esthetic procedure (Towne, B. M., & Mehra, P.(eds.) ProQuest 2019). We easily associate skin and its main functions to be superficial or just beneath the epidermis. We are familiar with the top layers of the skin. Epidermis, dermis and subcutaneous and often consider age processes to be visible and superficial instead of in the deeper structures of the tissue, superficial and deep fat layers, muscle, fascia, and bone. All publications used for this anatomical review mention the paramount importance of anatomical knowledge and theory of ageing. (Heydenrych, Kapoor, Boule. Clinical, cosmetic, and investigational dermatology. 2018). *The main anatomical structures and landmarks will be discussed in this paper as the scope of this subject is too large to cover a comprehensive knowledgebase of facial anatomy. This summary of the facial anatomy is enough to cover the basic knowledge base of a nurse planning to train for this skill.*

2.5 Facial anatomy in 3D

By looking at the facial anatomy from a 3D perspective, it demonstrates a more accurate image of the facial tissues and structures. The face should be viewed as a 5 layered structure from the bone up. The tissues age and function differently, support and maintain the anatomical shapes of the face forming the natural valleys and hills that we see in women and

men among different ethnicities. Each tissue layer provides the face with its own functions and react differently to motion, ageing, water retentions and atrophy/hypertrophy of the fat pads (Aesthetic Surgery journal 2022.). (Review theory of ageing 2.5)

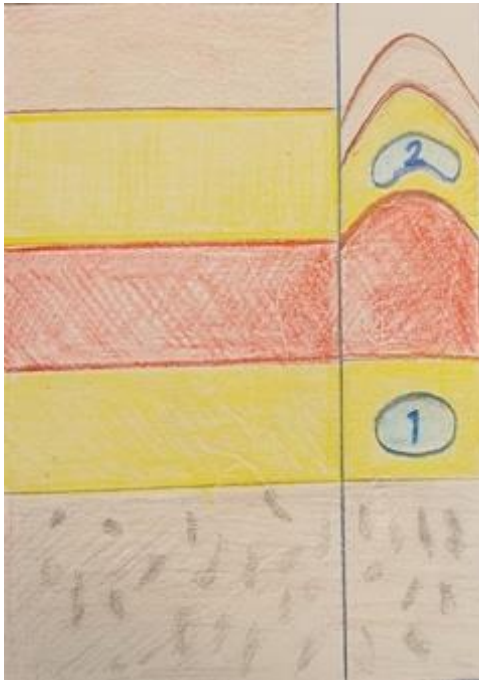


Image 2: Drawing by Annika Haikala: Demonstrating the 5 tissue layers without and with muscles contracting. Skin, SMAS, Muscle, Deep fat pad, Periosteum. 1. Placement of fillers in the deep fat compartments stay static as muscles contract. use higher G prime for volume. 2. Placement of filler in the superficial fat compartments for dynamic tissues and product with a low G prime. Muscle contraction will add anterior projection of the tissue plane. (Aesthetic Surgery journal 2022.)

The bone (periosteum) and deep fascia are static and do not move along with the rest of the tissue, they hold up and protect important structures such as the eyes, nose and mouth. Deep fat pads on top of the bone are static and do not migrate but deteriorate with age. These fat pads give shape and volume, for example to the malar banks (cheeks) and lie beneath the muscle. The deep fat pads also remain static as they connect to the muscle. The facial muscles create our expressions and the superior tissue layers move along with it. The SMAS layer. A superficial layer of fat (The superficial musculoaponeurotic system) is dynamic and elastic. It moves with facial expressions, giving the cheeks a full round shape as we smile, dimples and grooves. The SMAS layer is often discussed in aesthetic publications due to its significant function of the skin and ageing (Aesthetic Surgery journal 2022.). Finally, we have the top subcutaneous fat, dermis, and epidermis. These facial structures have been described in a simplified way and may be rewired in much greater detail in numerous studies, articles,

and cadavers. There is much known about the tissue structures of the face, but there is still a lot to be learned when it comes to the characteristics of the fat pads and their relation to ageing (Towne, B. M., & Mehra, P.(eds.) ProQuest 2019). *There are some important arteries to be aware of. However, no guide or knowledge can guarantee with 100% certainty that there won't be a vascular injury. Every individual is different, but we can make some general assumptions about vascular anatomy.* (Heydenrych, Kapoor, Boulle. Clinical, cosmetic, and investigational dermatology. 2018)

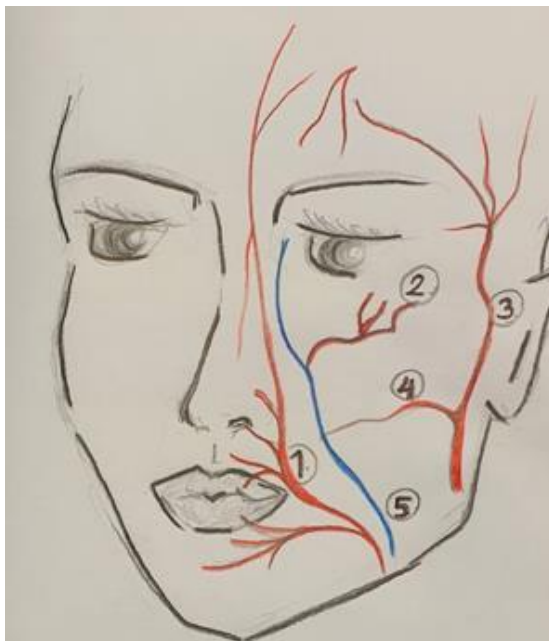


Image 3. Drawing by Annika Haikala: Demonstrating the common vascular structure to be aware of 1-5. 1. (FA) Facial artery, 2. Infra Orbital Artery, 3. Superficial temporal artery, 4. Transverse facial artery, 5. Facial vein. (Red Artery, Blue vein) (Aesthetic Surgery journal 2022.).

1. The Facial Artery (FA) is probably the most common artery to be aware of as it's the main provider of blood to the face and sits in a very commonly injected area around the chin, lips, nasolabial folds, and glabella. The positioning of the artery varies between individuals laterally, but the general rule is it runs vertically up towards the nasojugal groove beside the facial vein.
2. The Infraorbital Artery runs close to the (FA) and (FV) Facial vein. It comes up the infraorbital foramen and branches out laterally supplying the lower eyelid and mid cheek groove, medially to the nose and upper lip.

3. The Superficial Temporal Artery runs up from the parotid gland supplying blood around and past the ear, then temporal and parietal parts of the face.
4. The Transverse Facial Artery runs laterally from the superficial temporal artery towards the mid cheek and branching out in two. This artery is located mostly in the subcutaneous tissue.
5. The facial vein (FV) runs vertically close to the facial artery. It's the main venous drainage in the face.

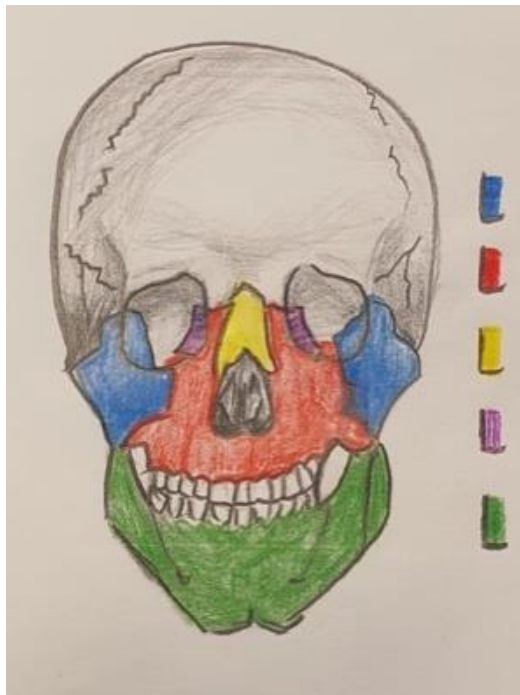


Image 4: Drawing by Annika Haikala: Demonstrates the skulls bone structures and injection planes targeted for volume and shaping. Deep injections on to the bone. Typically done as a bolus with a 90° angle and a high G prime static product (Aesthetic Surgery journal 2022.). Zygomatic, Maxilla, Nasal, Lacrimal, Mandible. Injection points of the sphenoid bone and frontal bone have been left out of this scope due to its high risk of vascular complications. (Plast Reconstr Surg Glob Open. 2016.)

2.6 Theory of ageing

Before treating any patient with fillers and having the anatomical knowledge of the face, it is equally important to understand the ageing process and morphological changes in the tissues. This area is fascinating and complex but still largely unknown. Intrinsic and extrinsic factors in combination of three-dimensional and volumetric changes and thinning of the skin describe ageing in its simplest of ways. There are many different changes and individual factors that in

combination form a degenerative process (Towne, B. M., & Mehra, P. (eds.) ProQuest 2019). *It is argued that it's in the fat layers, facial shapes, and shadows that youthful look lies in understanding* (International journal of women's dermatology 5 (2019) 52-67). The bone structure and its ageing are important to know to be able to take advantage of the different landmarks. Understanding the processes of atrophy in the different bone structures and tissues is needed. As we begin to age in our 30's (The Facial Aging Process From the "Inside Out" Aestet surg J 2021). The static structures of the bone and deep fat compartments of the skin start to atrophy and lose volume, the superficial dynamic tissues lose elasticity and sag over time. The combination of the two causes the skin to sink and migrate as well as wrinkle and create shadows. Knowledge deficit in these areas often lead to overtreating only the visible changes of the superficial tissue planes, creating un-natural looking results. This can even create an increased ageing look and heavy affect as volume and weight is added to the dynamic top layers of the skin. (International journal of women's dermatology 5 (2019) 52-67)

2.7 Pre assessment

Assessing the patient thoroughly before treatment ensures, you are not treating any inappropriate patients. Fillers can be helpful in many cases but can easily be very detrimental for patients with dysmorphic tendencies (Clinical, cosmetic, and investigational dermatology 2015:8 2005-214).

- Inappropriate patients refer to indications of beliefs and ideologies that distort the patient personal view on safety and anatomical objectives, often leading to reoccurring over filling and disregard to what is in their own best interest.
- (BDD) Body Dysmorphic Disorder refers to a mental health condition where a patient has dysmorphic tendencies and self- obsess about their appearance and flaws. (NHS 2023)

Patient history, health assessment and written and signed consent are always a part of the pre assessment, including assessment of any cutaneous and intrinsic factors. *Informed consent*: "Ensure informed consent for nursing and/or medical care. This includes the right to choose or refuse treatments." ICN code of ethics for nurses 2021. (ICN. 2021.)

History of any previous treatment with fillers, Botox or other aesthetic procedures including complications or negative outcomes, skin conditions, medication. Especially any anticoagulative properties, infections, skin conditions and other contraindications. Many types of measuring tools can be used to assess the symmetry and optimal shapes of a face, anterior projection, skin quality, ageing, trauma. The client's age, gender and ethnicity

should be considered to achieve a natural looking result. (Clinical, cosmetic, and investigational dermatology 2018.11 603-611.) There are different types of assessment tools that can be used to plan the treatments in accordance with the natural anatomical landmarks. Glogau, Fitzpatrick, Ricketts plane. (Clinical, cosmetic, and investigational dermatology. 2018). The assessment tools help to evaluate the appropriate placement of a filler in relation to the natural anatomical findings and landmarks. Filler placement should not only be safe but aesthetically pleasing. Measuring tools can be useful when evaluating the symmetry and assessing the correct placement of fillers for an optimal anatomical shape. This can be misleading with some measures. The ricketts plane measures the anterior projection from the tip of the nose to the pogonion in order to find out the optimal projection of the lips and chin. This measure can be misleading. Ideally, the lips should be in line with the tip of the nose and chin. The ricketts plane can be misleading. Common sense is recommended when using these measures. The image below demonstrates the difference between two patients and how the ricketts plane isn't ideal with patients that have a big nose and/or weak chin. (Teoxane academy Dr. Kam Lally)



Image 5. Drawing by Annika Haikala. The side profile of a patient. Ricketts plane assessment. Tip of the nose to pogonion. Demonstrating how the projection changes depending on the size of the nose and chin.

2.7.1 Injection safety

There are no guaranties for a safe injection. But through knowledge of anatomy, tissue functions and multilayer techniques do increase safety. Results can be optimized by having maximum control and understanding over the decisions you make for the patient. This includes choosing the right injection technique and applying the right type of product. (Vedamurthy M. 2018.) *The considerations found in this thesis support the renewal of injection regulations in Finland and restricting them to healthcare professionals with a medical degree. The regulations will bring about government (Valvira) issued standards and ad safety to the prevention and management of patient related complication and reporting them.*

2.7.2 Procedure

Aseptic technique should be a priority. This includes working in a clean space with disinfected surfaces and protective sheets, drapes, or trays to set up the treatment table. (Clinical, cosmetic, and investigational dermatology. 2018). Hand hygiene and gloves are a part of aseptic work. (5 moments of hand hygiene (WHO 2023.)

- The treatment area is cleaned with a disinfectant over 70% alcohol.
- The syringe is no longer sterile once taken from the package.
- Avoid touching anything the tip of the needle or contaminating it on the surface of the skin.
- General awareness of hygiene and cleanliness is at almost importance.
- Patient guidance will ensure hand hygiene after the patient leaves (Clinical, cosmetic, and investigational dermatology. 2018.).

2.8 Post treatment assessment

Assessment of the patient starts with the pre-assessment. The post assessment is an important part of the treatment and increases the patient feeling of safety and satisfaction. The post treatment assessment is an opportunity to observe the skin in case of adverse events and react to them immediately if necessary. The post assessment includes guidance, documenting, verbal and written instructions and recommendations. After pictures should always be taken for the record with confidentiality. A successful HA treatment should not create severe reactions, hematomas, erythema, edema, or pain. The skin may have some small entry point marks and mild swelling and redness. Most of the irritation is generally caused by the alcohol and mechanical handling of the skin. The irritation should calm down in the first few hours' post treatment. Mild bruising and pain may be observed, and some swelling is normal up to 2-5 days post treatment. (Vedamurthy M. 2018.).

2.8.1 Complications

Treatments are increasing in the world and there are more than 100 products on the market by 2018. The treatment is cheap and provides instant results and is relatively safe. As the treatment gets more common, so do the complications. (Vedamurthy M. 2018.) Vascular occlusions are reported 1 | 100 000 and 50% of those accrue in the glabellar area. Other typical areas are nasolabial folds, nasal tip, and alar triangle. (Journal of clinical and aesthetic dermatology. 2020) As mentioned, anatomical, technical and product knowledge is very important but as the complications increase. It is important to recognize them and be

able to treat them urgently and correctly to avoid adverse events and obtain optimal client satisfaction. (Vedamurthy M. 2018.) The considerations will be focused on the classification 1.a non-permanent biodegradable Temporary: Reversible with hyaluronidase, duration <18 months. (Review section Hyaluronic acid 3.2 for HA classification) (Vedamurthy M. 2018.)

2.8.2 Most common complications

There are no reliable statistics on complications due to under reporting of complications. This is partially due to HA filler classification as CE- marked devices. The need for a legal reform is evident. It can be noted once more that the government issued legislation would produce accurate data in this area.

- *Over correction* is a common treatment complication where product is placed in excessive amounts in the treatment area. This results in an unpleasing outcome aesthetically and can cause complications such as malar edema, nodules, tyndl effect (injection too superficial). This type of complications is recommended to be removed with Hyaluronidase. (Vedamurthy M. 2018.)
- *Vascular occlusions* are caused by a partial or full blockage of the vessel, causing skin necrosis. Immediate intervention is needed when first signs of vascular injury or occlusion is noted. Urgent interventions may prevent the adverse reaction if managed correctly. Hyalace injections should be close at hand with a medically trained doctor able to administer the injections following the treatment protocol. (Plast Reconstr Surg Glob Open. 2016.)

2.8.3 Management of complications

Vascular occlusion related necrosis incidence is 1 in 100 000 cases. 50% are related to the glabellar area. This complication is highly under reported due to unexperienced injectors and poor knowledge base. An internet survey, 62% of 52 experienced injectors worldwide reported one or more intravascular events. These include all types of injectable fillers. Caution should be taken when choosing the right type of filler to use. (Plast Reconstr Surg Glob Open. 2016.)

Symptoms:

- Severe pain in the injection area (Severe pain should not be present during this treatment).
- Bleaching of the skin even after the removal of the needle. Pale bleaching usually follows the direction of the vascular structure getting blocked.
- The skin feels cool and numb. The treatment area will feel cooler compared to the non-affected areas of the skin due to the compromised blood supply in the tissue.

Special consideration should be made in the glabellar region, nasal triangle, and nasolabial folds. (*Supra orbital artery, supratrochlear artery, and branches of the ophthalmic artery*)

Note that no injectable area of the face is 100% safe, and the risk remains in the less vascular tissues. Avoiding vascular occlusions should be the highest priority and some preventive actions can be taken. Be aware that these recommendations cannot be relied on entirely.

(Plast Reconstr Surg Glob Open. 2016.)

1. 3D Anatomical knowledge of the area and vascular structures and their depth.
2. Aspiration of 30 seconds or more is encouraged.
3. Slow injection.
4. Inject small volumes.
5. Avoid scared areas.
6. Avoid bolus technique in high-risk areas.
7. Prefer blunt needle
8. Caution with patients that have done rhinoplasty or other surgery in the area.
9. Look for early warning signs.
10. Use reversible degradable HA fillers and correct product placement.

Treatment of vascular occlusions should be assessed by a medically trained doctor and contacted immediately if a vascular occlusion is suspected. (Plast Reconstr Surg Glob Open. 2016.) *Interventions include:*

- Stop treatment immediately if symptoms appear.
- Capillary refill time (CRT) assessment
- Firm massage in the area
- Heat application
- Pain management
- Contact Doctor or plastic surgeon.

Medical interventions

- Hyaluronidase protocol (ACE group High Dose Hyaluronidase protocol)

- Aspirin
- Antibiotics

3. Purpose and aim

The purpose of this Thesis is to provide nurses working in aesthetic clinics an overall understanding of the type of knowledge and skill required to treat clients and patients with HA fillers independently. The aim is to provide a compact and summarized theory base and step by step guide for assessment, treatment and complication management based on the literature findings. The functional guide will be printed and tested in practice at the Face Designers clinic. Because the clinic is owned by the author, the guide will be tested by nurses participating in the professional filler workshops. The results will be documented and can be used to evaluate the usability and usefulness of the guide in the future by the author. The guide can also be distributed to other clinics for testing.

4. Method

The original planning started in the spring of 2020. The planning phase contained a clear idea of writing a functional thesis and producing a written guide for practical use in facial dermal fillers. The topic was chosen because of a personal career and interest in filler treatments. I wanted to do the thesis on my own so I chose a topic I would feel passionate about. A functional thesis was chosen so it could reach as many nurses as possible working with aesthetic fillers. A written guide was drafted to be in English, Finnish, and Swedish, but finally it was decided that only a translated version would be produced in Finnish on the bases of the English prototypes.

The topic itself relies heavily on evidence-based knowledge and scientific facts. The theoretical frame needed to be well thought out and limited so that it wouldn't become too extensive. The section on anatomy has been narrowed to just the few main considerations and that is why injection techniques had to be limited to the very basics as well. The focus changed quite naturally towards safety, complication prevention and patient assessment after most of the medical articles and publications indicated the same considerations.

Original thesis idea was built from a few key concepts.

1. Define HA fillers.
2. Define HA filler injection technique.

3. Define HA injection aseptic.
4. Define HA injection safety.

The work was further defined in a later stage and limited to the final key concepts.

1. Hyaluronic acid fillers
2. Hyaluronic acid
3. Application of fillers
4. Facial anatomy in 3D
5. Theory of ageing
6. Pre assessment
7. Injection safety
8. Post treatment assessment
9. Complications

5. Planning and prototyping

The topic and planning began in the spring of 2020. I wanted to write this thesis on my own and use my experience and knowledge of 16 years I have in the field of aesthetic fillers. I chose a functional thesis because I felt it to be the best form of thesis to provide a practical guide for nurses to use. There has been a clear understanding of the lack of knowledge in the field from the very beginning. The challenges have at times been to identify and limit the topic to the core purpose and aim of the thesis. Planning, researching, and writing on my own has felt difficult at many stages of this project due to not having a sparring partner in the topic and covid creating a situation of distance working alone.

Originally the guide was supposed to only work through some of the main considerations of the treatment and techniques. The research clearly indicated a need for knowledge in complication management as a key point in increasing safety of the patients. As patient safety was one of the main focuses of this thesis. A section on complications was added and a complications chart was designed to help a nurse quickly act if complications accrue. The topic was adjusted accordingly. All images and drawings in this thesis have been produced by Annika Haikala. The product images have been taken at the Face Designers clinic. No external imaging or comments have been used. The drawings are inspired by the articles and books used in this Thesis.

<i>Inclusion of 22 publications</i>	<i>Exclusion of 34 publications</i>
-------------------------------------	-------------------------------------

Publication after 2010	Publication before 2010
Keywords: Hyaluronic acid, Dermal Fillers, Facial anatomy, Complications, Injection guidelines	No relevant subjects of specific treatments
Medical evidence-based publications including the key words	Bias publications by privately owned corporations

The Planning of the prototype

The drafting of the prototypes has been a part of the thesis process from the beginning. The main considerations formed quite naturally as the medical publications all raise similar key points. This strengthens the reliability of these conclusions translated into this list of considerations.

Patient suitability prototype. The patient evaluation and assessment considerations. This form should be helpful in check listing the main considerations when evaluating the suitability of a patient for HA filler treatment. *Image 9: Drawing by: Annika Haikala: Assessment for patient suitability 1-9. Anatomical assessment, anamnesis, medication, treatment history, indications, product requirements, treatment plan, treatment, post treatment assessment.* Graphics made using Canva. (Guide prototype)

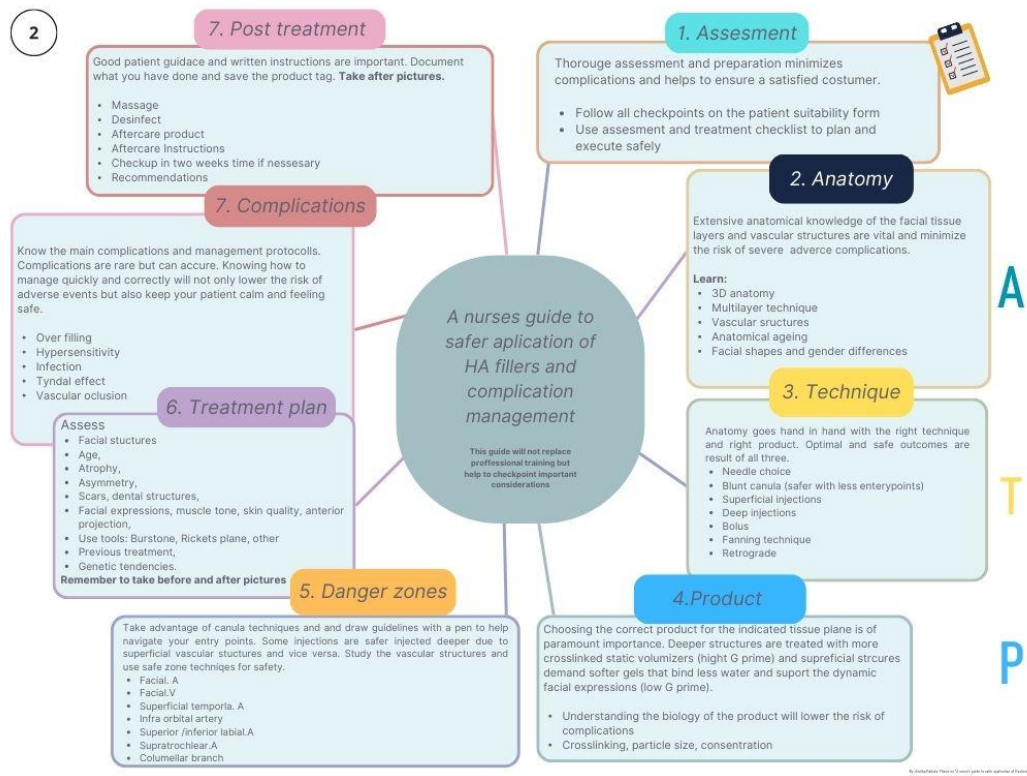
1. Anatomical assessment
2. Anamnesis
3. Medication
4. Treatment history
5. Indications
6. Product Requirements
7. Treatment plan
8. Treatment
9. Post treatment assessment



A nurse's guide to safer application of HA fillers and complication management Prototype.

These steps are based on the key concepts and considerations highlighted in the theoretical framework and research. This checklist can be used to guide a nurse toward acquiring an adequate knowledge base to perform safer filler treatment and minimize the risk of complications. *Image 7. by Annika Haikala: Assessment stages and considerations 1-7.* 1. assesment, 2. anatomy, 3. technique, 4. product, 5. danger zones, 6. treatment plan, 7. complications, 8. post treatment. Graphics made using Canva. (Guide prototype 2)

1. Assessment
2. Anatomy
3. Technique
4. Product
5. Danger zones
6. Treatment plan
7. Complications
8. Post treatment



Checklist safer filler application prototype. For easy and quick check listing in practical use during assessment, planning, treatment and post management. These checkpoints have been collected from the literature used in the theoretical framework. *Images Checklist 1-2 By: Annika Haikala.* Main considerations discussed in the theoretical framework 1-8. Graphics made using Canva.

- Assessment
- Anatomy.
- Technique
- Product.
- Danger zones.
- Complications.
- Post treatment.

Checklist



SAFER FILLER APPLICATION

ASSESSMENT

- | | |
|---|---|
| <input type="checkbox"/> Treatment wishes | <input type="checkbox"/> Allergies |
| <input type="checkbox"/> Previous treatment | <input type="checkbox"/> Dysmorphia |
| <input type="checkbox"/> Medication | <input type="checkbox"/> Previous complications |
| <input type="checkbox"/> Illnesses | <input type="checkbox"/> Age/gender (anatomy) |

ANATOMY



- | | |
|---|---|
| <input type="checkbox"/> Asymmetry | <input type="checkbox"/> 3D anatomy/ Fat pads |
| <input type="checkbox"/> Ageing/ Atrophy | <input type="checkbox"/> Genetic tendencies |
| <input type="checkbox"/> Facial expressions | <input type="checkbox"/> Facial shape/gender |
| <input type="checkbox"/> Anatomy of ageing | <input type="checkbox"/> Skin quality |

TECHNIQUE



- | | |
|--|--|
| <input type="checkbox"/> Aseptic work | <input type="checkbox"/> Deep/ Superficial injection |
| <input type="checkbox"/> Safe zone assesment | <input type="checkbox"/> Fanning /Retrograde/Bolus |
| <input type="checkbox"/> Needle/Canula | <input type="checkbox"/> Injection plane |
| <input type="checkbox"/> Numbing cream | <input type="checkbox"/> 10°, 40°, 90° injection angel |

PRODUCT



- | | |
|--|--|
| <input type="checkbox"/> HA quality | <input type="checkbox"/> Storage |
| <input type="checkbox"/> Indication | <input type="checkbox"/> One time use |
| <input type="checkbox"/> Duration | <input type="checkbox"/> Personal use |
| <input type="checkbox"/> Cross linking | <input type="checkbox"/> Product tag for documentation |

Checklist



SAFER FILLER APPLICATION

DANGER ZONE

- | | |
|---|--|
| <input type="checkbox"/> Facial.A | <input type="checkbox"/> Infraorbital.A |
| <input type="checkbox"/> Facial.V | <input type="checkbox"/> Superior/inferior labial.A |
| <input type="checkbox"/> Superficial temporal.A | <input type="checkbox"/> Supratrochlear.A |
| <input type="checkbox"/> Transverse facial . A | <input type="checkbox"/> Columellar branch |

TREATMENT PLAN

- | | |
|--|---|
| <input type="checkbox"/> Before pictures | <input type="checkbox"/> Financial discussion |
| <input type="checkbox"/> Discuss options | <input type="checkbox"/> Explain treatment |
| <input type="checkbox"/> Product application | <input type="checkbox"/> Go over risks |
| <input type="checkbox"/> ml/side | <input type="checkbox"/> Consent |

AVOID COMPLICATIONS

***ATP = Anatomy, Technique, Product**

- | | |
|---|---|
| <input type="checkbox"/> *ATP knowlage | <input type="checkbox"/> Slow injection |
| <input type="checkbox"/> Desinfect skin | <input type="checkbox"/> Aspiration |
| <input type="checkbox"/> Blunt canula | <input type="checkbox"/> Low pressure |
| <input type="checkbox"/> Small-caliber needle | <input type="checkbox"/> Complications management |

POST TREATMENT

- | | |
|--|--|
| <input type="checkbox"/> After picture | <input type="checkbox"/> Good hygien |
| <input type="checkbox"/> Patient guidance | <input type="checkbox"/> No alcohol, drugs 24h |
| <input type="checkbox"/> Checkup 2 weeks | <input type="checkbox"/> No sun, sauna, swimming 24h |
| <input type="checkbox"/> No "touching" 6h | <input type="checkbox"/> Call if any problems |

Filler complications management prototype. Recognizing complications and managements help identify adverse events that require immediate intervention and management. These complications have been collected from the theoretical framework and the key considerations that need to be considered for the safety of the patient. Legal and responsibility falls under the manufacturing company. The purpose of this list is to help guide a nurse prevent, identify and manage in situations of adverse events. *Image 1-2 by: Annika Haikala. Complications, symptoms, and management of:*

- Pain
- Erythema
- Edema
- Over correction
- Papulopustular lesions
- Hematoma/Ecchymosis
- Infection
- Hypersensitivity
- Sterile abscess
- Necrosis of the tissue (vascular occlusion)
- Visual impairment
- Stroke

As recommended by the critical appraisal. Anaphylaxis should be brought to complication management. The Medical publications did not bring this complication up a high-risk complication. Considerations need to be made if this should be a part of this scope.


Filler Complication management

Complication	Symptoms	Management
Pain	Some mild pain is normal due to injections. Sharp pain in the vascular rout during or after injection. Move to vascular complication management.	Topical anesthetic cream can be used to ease the feeling of pain. Most HA fillers contain 3% Lidocain and help manage pain. Use small-caliber needles and long blunt canulas for less entry points. Inject slowly
Erythema	The procedure always causes mild redness. Check for allergies and use products, gloves that are suitable for skin. In case of more sever redness or rash. Hypersensitive skin should be considered.	Mild redness will pass in a few days. Cold compression and soothing lotion may help to calm down the redness. In case of hypersensitive patients. Management: Topical steroids, propranolol, Tacrolimus
Edema	Mild swelling is normal after the treatment up to 2 weeks. Severe swelling is not usual and can be related to hypersensitivity or infection. Delayed onset hypersensitivity can accure weeks after the treatment.	Mild swelling can be managed with an ice pack and light massage. Avoid sauna, sunbathing and heavy workouts for a few days. Management: Hypersensitivity edema - Steroids/anti-histamin. Late onset hypersensitivity - Steroids + hyaluronidase removal
Overcorrection	This is a common complication although many wish to over correct purposfully. In many cases treatment may be difficult and not recommended. Asymmetry, lumps and unpleasing results can be reverced medically.	The Hyaluronic acid may be dissolved with hyaluronidase. Single to multiple injections. Tyndal effects can sometimes be treated with a needle punkture to drain the nodule.
Papulapustular lesions	Small acne like lesions may accure in the seatglands of the skin and often due to the injections being too superficial.	These lesions may be avoided by firm massaging post treatment. A stinging can be used for cleansing of the lesions at home.
Bruising, ecchymosis, hematoma	Bruising is fairly normal reaction with injections. However larger hematomas and ecchymosis can uncomfortable and unattractive for over a week. Severe reactions require invesigation and monitoring Considerations vacular injury	Firm pressure on the injection site may help stop the hematoma from forming. No omega 3, fatty acids, alcohol or anticuagulants are recommended for at least 2 day prior to treatment. Caprilon can be used to prevent bleeding topically or iv, enteral.

Filler Complication management

Requires specialist medical attentions

Complication	Symptoms	Management (Consult MD)
Infection	<ul style="list-style-type: none"> • Edema • Erythema • Warm skin • Abscess at injection site • Fever 	Acute infections usually occur 2 or more weeks post treatment Mild infection symptoms may pass with time but can require medication. <ul style="list-style-type: none"> • Antibiotics • hyaluronidase • Drainage of abscess
Hypersensitivity	<ul style="list-style-type: none"> • Severe edema • Angioedema 	Hypersensitivity can be visible immediately after the treatment or as delayed reaction <ul style="list-style-type: none"> • Cold pack • systemic steroids • Antihistamins
Sterile abscess	<ul style="list-style-type: none"> • Edema • Erythema • Abscess 	Similar to infection with visible abscess at the injection site An abscess can be drained if sterile. Antibiotic treatment (Tetracycline)
Necrosis of the tissue	Vacular occlusion symptoms first stage includes painless bleaching followed by: <ul style="list-style-type: none"> • White colourless skin • Numbness • Severe pain along the face 	Late onset symptoms include darkening of the skin and turning black PROMPT ACTION REQUIRED! <ul style="list-style-type: none"> • Stop treatment immediately • light massage • Warm compress • Hyaluronidase protocol • Topical nitroglycerin, aspirin,
Visual impairment	Embolism of the ophthalmic vasculature <ul style="list-style-type: none"> • immediate visual loss • severe pain 	PROMPT ACTION REQUIRED! <ul style="list-style-type: none"> • Stop treatment immediately • Ophthalmologic consultation • Ocular massage • Hyaluronidase protocol
Stroke	<ul style="list-style-type: none"> • Blindness • Hemiplegia 	A stroke is very rare and caused by high pressure injections. Filler emboli enters the carotid artery following a cerebral ischemic event PROMPT ACTION REQUIRED! <ul style="list-style-type: none"> • Specialist consultation • Call 112



6. Ethics

As healthcare professionals and nurses. The goal should always be to work in the best interest of the patient and improving their health. Making every effort to maintain professional standards by being educated and using medical research and studies for personal development and development of better practice and safety of patients (Haddad LM, Geiger RA. Nursing Ethical Considerations. 2022) Ethical considerations need to be considered further in the proses of creating the final Finnish guide. Due to scheduling challenges with the Medical Doctors validation. Final comments and finishing touches will be made to the final product. It should be highlighted for the reader that the guide and checklists do not replace any medical training, nor does it stand to take responsibility for any treatment complications. This thesis should be used to guide professional training and help target any knowledge base that needs improving.

7. Strength/ Limitations

The strength of this functional thesis has been my knowledge in the field of HA fillers for 16 years. A strong basic knowledge base in the field and treatment of clients as a cosmetologist. Close collaboration with the filler specialist in Switzerland and training platforms with specialists around the world. Personal visits to HA gel laboratories and training facilities in Geneva. Workshops in complication and safety management and access to regular medical cadavers and workshops. Critical appraisal from a RN has added reliability and clarity. She has brought out very important otherwise unnoticed points and given this thesis great nursing perspective and value. The Doctors validation will support the final guide, so it can be used reliably. Limitations of this thesis is the close familiarity to the subject. It has been challenging and sometimes mind clouding to review and write with a bias and subjective tone. However, the medical publications and research found on the subject has been clear and resources easily found to support evidence-based facts. Last minute scheduling issues have delayed the final comments and results from the medical doctor which will be missing from this report but considered in the final product.

Recommendations

This thesis has clearly highlighted the focus points that should be studied before being able to safely treat patients with fillers. The medical publications and the letter of recommendations made by Suomen Plastiikkakirurgiyhdistys, including the appraisals and conclusions of this thesis all highlight the urgent need for a legal reform and clarification of guidelines. Main focus being: Anatomy, complications and management, adverse vascular events management and removal (hyaluronidase) protocol. The theoretical base of this thesis is convincing enough to conclude that more knowledge and professional regulations should be increased. The final validations of the surgeon will create a strong base for developing this project further. This thesis aims to condense the main international safety recommendations for treating patients safely. The main purpose of the guideline is to help increase safety and decrease risk of adverse events related to the injection of (HA) fillers until government guidelines are put in place. *Registered nurse* appraisal was brought in for the final stage of the prototyping and changes to the report. The purpose of this appraisal was to add value and reliability from a nursing perspective. The authors background in filler treatment ads a potential risk for the thesis to be biased. *Summarizing the review of the thesis*, I would conclude that Haikala's functional design of the thesis has a great value, relevancy, and potential for the further revolutionizing regulative measures in the aesthetic field.

Comments

- Overall design of the guide and its structure promote a preventative approach to the procedures emphasizing the client's health and safety as a main value for the author.
- Client suitability guide created by the thesis author demonstrates author's healthy approach to the aesthetic procedures. These values are strongly reflected in the aim of the thesis and author's recommendation for the legislation and regulation to be done in the aesthetic field in Finland.

Recommendations

- considering a logistic condition as a potential risk factor affecting quality of the product.
- The process of the designing the guide and description of the main parts of the guide e.g., complication management should be provided comprehensively to increase transparency of the work.
- Several suggestions for the ethics' section of the thesis may include data privacy and security in terms of storage and processing of the taken pre- and post-treatment pictures;
- Description of the trial of the guide and related ethical concerns such as who will be testing the guide (transparency); service provision accountability as an ethical issue.
- Additionally, does author aim to report the results of clinical tests of the guide within this thesis?

These recommendations have been considered in the thesis and changes were made accordingly.

- EB nursing and aseptic technique was highlighted.
- Logistics was considered and noted in the thesis.
- Comprehensive description of complications was noted and agreed with. The scope of complications and management is too large to be included in such magnitude. This point will be added to the results and highlighted in the conclusions to note its importance.
- The ethics section has also been altered to address some of the legal aspects in this thesis to ad accountability. Data privacy and security in terms of storage and processing of the taken pre- and post-treatment pictures is a good suggestion but also too large to be discussed in this thesis in full. Suggestions have been noted and changes made to support the recommendation and ad clarity.

- Description of the trial of the guide and related ethical concerns such as who will be testing the guide (transparency); service provision accountability as an ethical issue. Recommendation is noted and agreed as a high priority. Changes will be made according to the scope of this thesis.

8. Appendix

Critical Appraisal on the thesis

“A nurse’s guide to safer application of Hyaluronic acid fillers and management of complications.”

Thesis author: Annika Haikala

This critical appraisal is provided to thesis author on the interim phase of thesis manuscript. The critical appraisal is aimed to bring a view of a registered nurse into the evaluation of a nurse’s guide prototype as well as theoretical background and general structure of the thesis. This critical appraisal is aimed to help thesis author to improve the practical guide and thesis manuscript and, possibly, mitigate subjectivity of these manuscript parts. *In addition to this text, there were short comments on the thesis manuscript provided to the thesis author.*

The aim and purpose of the thesis are stated clearly. The chosen method of the thesis is relevant and appropriate to the aim of the thesis. A target group of the practical guide is determined clearly and specifically. Additionally, the author may consider if the guide’s target group is proposed mainly as a future user considering specifics of current legislation and regulations for the aesthetic service provision in Finland [see the Abstract and Introduction sections of the thesis]. All the mentioned parts of the thesis (aim, method, user target group) are professionally argued by the author.

Overall design of the guide and its structure promote a preventative approach to the procedures emphasizing the client’s health and safety as a main value for the author. Client suitability guide created by the thesis author demonstrates author’s healthy approach to the aesthetic procedures. These values are strongly reflected in the aim of the thesis and author’s recommendation for the legislation and regulation to be done in the aesthetic field in Finland.

Among small questions or improvement suggestions for this thesis can be e.g., considering a logistic condition as a potential risk factor affecting quality of the product. In other words, how the author considered possible effects of disturbed or insufficient environmental conditions during the transportation or storage chains on the HA products (in particular, - temperature, prolonged exposure to the light). Or brief reporting on exclusion of these risk factors can be considered.

The process of the designing the guide and description of the main parts of the guide e.g., complication management should be provided comprehensively to increase transparency of the work. This would provide a reader with more information and justification for several crucial aspects such as medication-based management of complications. In addition, reporting on the management of the possible anaphylactic reaction can be included in the guide and the thesis manuscript text as a part of the safe health-related service.

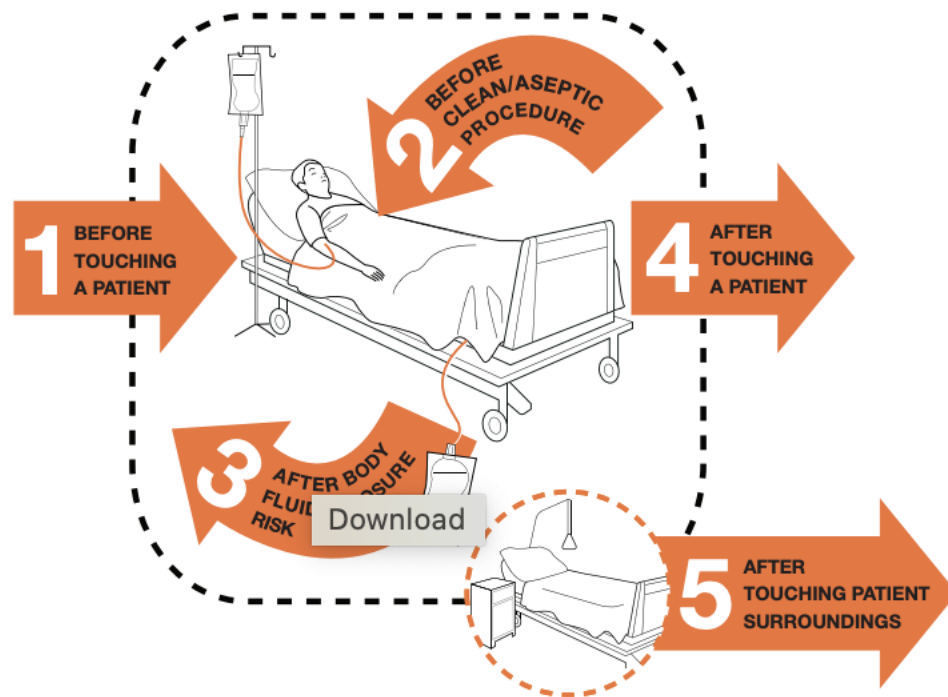
Several suggestions for the ethics’ section of the thesis may include: data privacy and security in terms of storage and processing of the taken pre- and post-treatment pictures; description of the trial of the guide and related ethical concerns such as who will be testing the guide (transparency); service provision accountability as an ethical issue. Additionally, does author aim to report the results of clinical tests of the guide within this thesis?

Summarizing the review of the thesis, I would conclude that Haikala’s functional design of the thesis has a great value, relevancy, and potential for the further revolutionizing regulative measures in the aesthetic field.

02.06.2023

Aleksandra Akmaikina, Registered Nurse

Your 5 Moments for Hand Hygiene



1	BEFORE TOUCHING A PATIENT	WHEN?	Clean your hands before touching a patient when approaching him/her.
		WHY?	To protect the patient against harmful germs carried on your hands.
2	BEFORE CLEAN/ASEPTIC PROCEDURE	WHEN?	Clean your hands immediately before performing a clean/aseptic procedure.
		WHY?	To protect the patient against harmful germs, including the patient's own, from entering his/her body.
3	AFTER BODY FLUID EXPOSURE RISK	WHEN?	Clean your hands immediately after an exposure risk to body fluids (and after glove removal).
		WHY?	To protect yourself and the health-care environment from harmful patient germs.
4	AFTER TOUCHING A PATIENT	WHEN?	Clean your hands after touching a patient and her/his immediate surroundings, when leaving the patient's side.
		WHY?	To protect yourself and the health-care environment from harmful patient germs.
5	AFTER TOUCHING PATIENT SURROUNDINGS	WHEN?	Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving – even if the patient has not been touched.
		WHY?	To protect yourself and the health-care environment from harmful patient germs.



World Health
Organization

Patient Safety

A World Alliance for Safer Health Care

SAVE LIVES
Clean Your Hands

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May 2009

8.1 Images and graphics

Images 12-13. By: Annika Haikala. Graphics made using Canva.

All drawings and images and graphics were made or taken by Annika Haikala using Canva for guide prototyping. Product Images were taken at the Face Designers clinic owned by Annika Haikala. Anatomical images were drawn and inspired by the resources used in this Thesis and anatomical publications to best demonstrate the key concepts discussed in this thesis.

9. A nurse's guide to appropriate application of Hyaluronic acid fillers
In process and awaiting surgeons validations

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