

I Have a Question!

Hyaluron Pens

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Plastic Surgical Nursing (PSN), the official journal of the International Society of Plastic and Aesthetic Nurses (IS-PAN) publishes this column to provide evidence-based answers to practice questions from plastic and aesthetic nurses.

HYALURON PENS

As nurses and consumers, we see new trends and fads continually emerging in the beauty industry (Wilkins, 2019). These trends and fads are often promoted via social media (e.g., Twitter, Facebook, Snapchat, Instagram). Unfortunately, some of these new products and procedures lack scientific evidence to support efficacy (i.e., the product's ability to produce the desired or intended result) or safety (Wilkins, 2019). As plastic and aesthetic nurses, we have a responsibility to be knowledgeable about the products we use in our practice and to educate our clients so that they can make informed and safe choices about the care and treatment they choose to undergo (American Nurses Association & International Society of Plastic and Aesthetic Nurses, 2020). The goal of this column is to educate plastic and aesthetic nurses about the hyaluron pen and the potential dangers associated with these devices.

Question: What is a hyaluron pen?

Answer: A hyaluron pen is a small, handheld device that deposits hyaluronic acid filler into the epidermal and dermal layers of the skin using a high-pressure injection process that does not involve needles (Wilkins, 2019). The injection process is intended to be less painful than traditional injection methods (Wilkins, 2019). To use the device, the administrator

- Pumps the chamber to create the necessary internal pressure,
- Presses the device against the client's tissue or skin where the filler is to be injected, and
- Pulls the trigger to force the hyaluronic acid filler into the client's tissue or skin.

Hyaluron pens are sold under a variety of names (e.g., hyapens, fog injection devices, SERA pens, nebulizer injector guns, dermajet; Government of Canada, 2019; Wilkins, 2019).

The pens were initially developed for medical purposes (e.g., injecting insulin, administering vaccines); however, the device is now being marketed for cosmetic procedures and is primarily used to plump lips and smooth facial lines (Wilkins, 2019).

Question: Is the hyaluron pen approved for use?

Answer: Currently, there are no needleless dermal filler injection devices, such as the hyaluron pen, approved for use in the United States (O'Brien, 2019), Canada (Government of Canada, 2019), or Australia (Government of Western Australia, Department of Health, 2019). For this reason, practitioners should not be using or marketing these treatments.

In the United States, only medical devices with U.S. Food and Drug Administration (FDA) approval can be legally marketed for the specific use for which they have been approved (O'Brien, 2019). Health Canada, the department responsible for Canadian health policy, has not authorized the sale of any needleless dermal filler devices and has not evaluated the hyaluron pens for safety, effectiveness, or quality (Government of Canada, 2019). In Australia, the hyaluron pen is considered a therapeutic device that requires registration with the Therapeutic Goods Administration (TGA), the division of the Australian government responsible for approving and regulating the supply, import, export, manufacturing, and advertising of therapeutic goods (i.e., medicines, medical devices, blood, blood products; Government of Western Australia, Department of Health, 2019). The TGA approves and regulates products based on an assessment of risks compared with benefits (Government of Western Australia, Department of Health, 2019).

The dermal fillers used in the hyaluronic pens are also not approved for use and are of unknown origin

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and composition (Thiersch, 2020a). They are often imported from countries outside of the United States (e.g., China, Korea). These countries define drugs and cosmetics differently from the United States. They may not have the same ingredient prohibitions and restrictions as the United States, and they may be subject to much less stringent requirements for safety and quality control (FDA, 2020a). Furthermore, these dermal fillers do not include a list of product ingredients and there is no guarantee of product sterility (Thiersch, 2020a). In some cases, distributing these products may be illegal. Any product ingredient is prohibited if it causes the finished cosmetic product to be unsafe for consumers under labeled or customary conditions for use, even if there is no regulation specifically prohibiting or restricting its use in cosmetics (FDA, 2020b).

Hyaluronic acid-based fillers developed for injection using either a traditional needle and syringe or a syringe and cannula have been approved by the FDA (Thiersch, 2020b) and have also been approved for use in Canada (Government of Canada, 2015) and Australia (Government of Western Australia, Department of Health, 2019).

Question: Should plastic and aesthetic nurses administer dermal fillers using the hyaluron pen?

Answer: In the United States, administering medication, no matter the method used, is part of each state's definition of the "practice of medicine" (Thiersch, 2020a). Only licensed health care providers (e.g., physicians, registered nurses, advanced practice registered nurses, physician assistants) may perform approved aesthetic injections (Thiersch, 2020a). Therefore, any person who administers hyaluronic acid filler using a hyaluron pen must have the same type of professional license required to inject medications using a traditional needle and syringe (Thiersch, 2020a).

Licensed health care professionals can be subject to professional discipline or penalties if they are found using non-FDA-approved medications or devices. Physicians may be able to claim "off-label use"; however, they are not allowed to advertise or promote off-label uses of a product (Thiersch, 2020a). Notably, using medication and devices in an unapproved manner may create standard-of-care and liability issues for the practitioner if the client experiences an adverse outcome (Thiersch, 2020a).

In Australia, when hyaluronic acid is prepared for injection, it is considered a Schedule 4 product that must be prescribed by a medical practitioner and administered by a medical practitioner or registered nurse (Government of Western Australia, Department of Health, 2019). Procedures involving injectable hyaluronic acid and needleless injecting devices may only be offered by registered medical professionals (Government of Western Australia, Department of Health, 2019).

When injecting approved dermal fillers, skilled and knowledgeable aesthetic injectors use safe injection practices and techniques. They are careful to inject the fillers to precise depths and in specific planes to safely achieve a desirable aesthetic outcome. When using a hyaluron pen, it is more difficult for the practitioner to place the filler in the desired location and depth and to administer the exact amount preferred; therefore, the amount of filler that is actually delivered, as well as the specific location and depth of its delivery, can vary from one injection to another (Thiersch, 2020a). The depth and penetration of the injection can also be influenced by tissue density, angle of the injector to the skin, and the amount of pressure applied to the skin before firing (Thiersch, 2020a).

Recently, a variety of unlicensed providers including estheticians, tattooists, lash technicians, and others have been offering lip plumping and wrinkle-erasing services using the hyaluron pen at salons, boutiques, and even in their own homes. The notion that these hyaluron pen injection services are being provided by nonlicensed personnel and offered in nonclinical, possibly unsanitary settings, is alarming. Under no circumstances should anyone perform this treatment unless they hold the appropriate license, have the requisite knowledge and skill to perform the task safely and correctly, and are using the device for the purpose it was intended (Thiersch, 2020a).

Question: Are injections less painful and reactive when using a hyaluron pen compared with using a syringe and needle?

Answer: The evidence indicates that injections are less painful and reactive when a needle and syringe is used. In a study conducted on 304 healthy young adults receiving influenza vaccinations, Jackson et al. (2001) found that the participants who were vaccinated with a jet injector had more pain and redness at the injection site than participants who were vaccinated with a needle and syringe. In another study on 60 young healthy adults receiving influenza vaccinations, Simon et al. (2011) reported that redness and swelling at the injection site occurred more frequently in participants vaccinated with a jet injector than among participants vaccinated with a needle and syringe.

Question: Are there potential risks and side effects associated with the hyaluron pen?

Answer: Using the hyaluron pen to inject dermal fillers may pose health risks (Government of Canada, 2019). Potential side effects may include

- Inflammatory skin reactions,
- Hematomas (i.e., a collection of blood outside of a blood vessel),
- Abscesses (i.e., a collection of pus usually caused by a bacterial infection), and
- Skin staining. (Government of Canada, 2019)

Additional risks associated with hyaluron pens may include bacterial or fungal infections caused by contamination during device filling, transmission of disease caused by cross-contamination between users, and damage to the skin, eyes, or blood vessels caused by excessive injection pressure or operator error (Government of Canada, 2019).

Now, more than ever, it is imperative for plastic and aesthetic nurses to be knowledgeable about the products they use in their practice and to educate their patients regarding the significant risks associated with using unapproved and potentially unsafe products and devices such as the hyaluron pen.

If you have a question about plastic and aesthetic nursing that you would like to see addressed in the I Have a Question! column of PSN, or if you would like to provide an answer to a particular practice question, please contact Sharon Ann Van Wicklin, Editor-in-Chief, PSN, at sharonvwrn@ispan.org.

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