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Hyaluron Pen Practices: Establishing Standardized Guidelines for Safety and Efficacy in Aesthetics

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ABSTRACT

The Hyaluron Pen, a needle-free device designed to deliver hyaluronic acid into the dermis, has gained significant popularity in non-invasive aesthetic procedures. However, its misuse by individuals with limited knowledge of injection techniques raises serious safety concerns, with some sources even contraindicating its use due to the risks associated with improper handling. Despite its appeal, the lack of standardized practices poses significant challenges in ensuring safety, efficacy, and optimal patient outcomes. This review examines the current landscape of Hyaluron Pen usage, focusing on variations in practitioner training, device protocols, and procedural techniques. It highlights potential risks, including adverse events such as overfilling, migration, and infection, often resulting from inadequate training, improper usage, and insufficient sterilization practices. Clinical data is reviewed to identify best practices for patient selection, dosage regulation, and post-procedure care. Additionally, we propose a framework for establishing evidence-based guidelines, emphasizing the need for regulatory oversight and uniform training standards in aesthetic medicine. By advocating for standardized protocols, this work aims to enhance the safety, credibility, and effectiveness of Hyaluron Pen applications, fostering trust among both practitioners and patients.

1. INTRODUCTION

Hyaluronic acid (HA), a naturally occurring substance in the human body, is widely used in cosmetic

treatments due to its crucial role in skin hydration and rejuvenation. Discovered in the early 20th century, HA has grown in popularity with the increasing demand for anti-aging and skin care procedures [1]. Non-invasive aesthetic procedures, particularly dermal fillers, have become significantly more popular since the 1980s. Advances in dermal filler technology—from animal collagen extraction to modern HA-based formulations—have expanded the options available to consumers [2]. HA's presence in cosmetic dermatology became prominent after its introduction to the European market in 1996, evolving with advancements in biotechnology. These innovations led to the development of non-animal HA formulations derived from bacterial fermentation using specific streptococci strains, eliminating species-specific concerns and allergic reactions. This shift made pre-injection skin testing unnecessary. Over time, techniques for stabilizing HA were refined, enhancing its longevity, viscosity, and versatility. These improvements have expanded HA's applications, including volume restoration, scar enhancement, and skin hydration, making it a go-to solution for skin rejuvenation. With rare, typically mild side effects, HA's evolution underscores its transformative impact on aesthetic medicine [3]. As such, hyaluronic acid has become a cornerstone of non-invasive skin rejuvenation, driving the growth of anti-aging treatments in the field.

A recent survey conducted by Ratajczak *et al.* (2023) surveyed 513 individuals to gauge awareness of HA in cosmetology, showing increasing recognition among beauty salon clients [1]. HA is not only used in injections for facial areas, particularly the lips, but is also incorporated into various skincare products such as creams, as well as oral and vaginal preparations. The survey findings highlight HA's multifaceted role in skincare, emphasizing its anti-aging properties and its contribution to improving skin vitality and quality of life [1]. Its applications in aesthetics have gained widespread attention, especially in counteracting age-related HA depletion and promoting skin rejuvenation. Exogenous HA is used in gels, creams, fillers, and intradermal injections to improve skin hydration, reduce wrinkles, augment soft tissue, and stimulate collagen and elastin production. Additionally, HA has therapeutic applications in treating conditions like gingivitis, ulcers, and osteoarthritis. Despite these broad uses, its role in non-surgical facial rejuvenation emphasizes the necessity for skilled practitioners to ensure optimal results while minimizing adverse effects [4]. The emergence of bioengineered hyaluronic acid fillers has provided a safe and effective option for non-surgical facial treatments, offering longer-lasting and reproducible results without requiring skin testing. A review from the University of Texas Southwestern Medical Center outlined best practices for HA filler administration, which include evaluating individual anatomy, selecting fillers based on particle size, and choosing precise injection techniques. The combination of HA fillers with botulinum toxin type A can enhance the aesthetic effects and prolong results by up to 50%. When used alongside surgical rejuvenation techniques, these fillers offer a comprehensive approach to facial treatments, improving outcomes and patient satisfaction [5]. As such, adhering to safety protocols and best practices is essential to achieve optimal results, ensuring patient safety and enhancing treatment efficacy.

The increasing demand for longer-lasting and safer dermal fillers has driven the development of advanced HA-based products. The North American dermal filler market is projected to grow at a rate of 12 to 14 percent annually over the next five years, indicating a strong and sustained interest in HA treatments like the hyaluron pen [2]. HA's widespread use in skin hydration, wound healing, and inflammation reduction is a key factor contributing to its popularity. Its aesthetic benefits make it a sought-after ingredient in both skincare and cosmetic treatments [4]. The rise of at-home hyaluronic acid lip fillers, particularly using the "needle-free" hyaluron pen, has gained traction on social media platforms. This device, which uses compressed air to inject HA into the lips, is typically marketed by non-medical professionals. However, concerns have arisen among plastic surgeons and medical organizations due to risks associated with uncontrolled injection depth and non-sterile refilling practices. Moreover, there is a lack of long-term research on the potential complications of its use [6]. While the popularity of non-invasive procedures like the hyaluron pen reflects a growing trend in aesthetic treatments, safety concerns underscore the need for proper regulation and further research into these emerging technologies.

Bonińska (2022) emphasized the importance of mastering injection techniques, especially in high-risk areas like the periocular region, where improper methods can result in severe, irreversible complications,

including blindness [7]. Anatomical variations and retrograde blood flow are crucial factors that need careful consideration when performing these procedures. This underscores the importance of skilled practitioners understanding the vascular structures and adhering to proper injection techniques to ensure patient safety in needle-based aesthetic treatments [7]. As the use of HA fillers becomes more widespread, the risk of ocular complications has increased, with vascular compromise and blindness being among the most serious outcomes. Mortada *et al.* (2022) identified nasal injections as the most common site of complications, with ocular pain often being the first symptom and vision loss the most frequent complication [8]. In some cases, treatment with hyaluronidase, aspirin, and steroids resulted in limited improvement [8]. The rise of skincare influencers on social media platforms such as TikTok has contributed to the spread of dermatology content, but with limited input from board-certified dermatologists. This has raised concerns, particularly regarding the hyaluron pen, a device that lacks the precision of traditional filler techniques and raises questions about safety and efficacy. A study examining six related hashtags revealed that only 8.9% of 518 posts were made by physicians, with over 50% coming from estheticians and general users. This highlights the need for greater physician involvement to provide accurate information and address the potential risks of devices like the hyaluron pen [9]. Similarly, the growing trend of using fibroblast or plasma pens, which are not FDA-regulated, has raised alarm due to their potential to cause depigmentation, scarring, and burns. A study of 200 TikTok posts revealed that only 25% of the content was created by medical professionals, with a mere 6.5% discussing the associated risks, further emphasizing the need for more involvement from healthcare providers to inform the public and counteract misinformation [10]. In conclusion, while HA fillers and non-invasive devices like the hyaluron pen have gained popularity in aesthetic procedures, they also present significant risks, particularly in delicate regions like the periocular area. As social media continues to amplify these trends, healthcare professionals must play a more active role in educating the public about the potential dangers and ensuring patient safety.

2. DISCUSSION

Prospective long-term comparison studies of the efficacy of hyaluron pens versus needle fillers do not exist. Most of the research is on needle-based hyaluronic acid (HA) fillers, which have proven to be effective and safe in numerous clinical applications [11-13]. Hyaluron pens, being needle-free injectors of HA, do not have strong clinical evidence and are not supported by professional organizations to a great degree. Furthermore, information on the prevalence of uncommon complications unique to hyaluron pens is lacking at present. Most of the safety data available for HA fillers are derived from needle injection studies where injection site reactions, hypersensitivity, and granulomas have been observed as complications [12]. Nevertheless, due to the potential for uncontrolled depth and volume of injection, most aesthetic and dermatological societies have recommended against the use of hyaluron pens. The requirement for strict rules in safety can be witnessed across many industries. For instance, implementation of the European Union Medical Device Regulation (MDR) has kept hazardous fillers out of the market, lowering incidence rates of adverse dermal filler-related complications [14]. These illustrations underscore the applicability of regulation in advancing safety practices in a variety of industries.

Mechanism of Action and Technical Features

Hyaluronic acid (HA), discovered by Karl Meyer, often referred to as the father of glycosaminoglycan chemistry, is the most abundant glycosaminoglycan in the human dermis. It is composed of repeating non-sulfated disaccharide units, namely glucuronate-β-1,3-N-acetylglucosamine-β-1,4- [15]. According to Collins (2004), the carboxylic groups of glucuronic acid in HA are ionized in vivo, granting the molecule polarization, hydrophilicity, and increased solubility in water [16]. These properties enable HA to attract and retain water, which helps hydrate the skin and create a supportive matrix by binding collagen and elastin fibers. HA is an essential component of the extracellular matrix in all adult animal tissues, contributing to the maintenance of tissue integrity. However, naturally occurring, unmodified HA is rapidly degraded by

hyaluronidase and eliminated through hepatic metabolism, with a half-life of about 12 hours [17]. To improve its longevity when applied to the skin, HA is chemically crosslinked. In modern cosmetic and aesthetic medicine, crosslinked HA serves as the foundation for many dermal fillers, designed to restore skin volume, elasticity, and overall appearance. Various crosslinking technologies are used to achieve different characteristics, providing diverse options for aesthetic treatments.

In aesthetic medicine, the cross-linking process significantly alters the properties of HA, with the most common cross-linkers being divinyl sulfone in Hylaform and diglycidyl ethers in Restylane and Juvederm [18]. The degree of modification determines the gel's stiffness and durability. A higher cross-link density reduces the distance between polymer segments, creating a firmer gel that can withstand more force without deforming. This characteristic makes it ideal for areas with significant muscle movement, such as the nasolabial folds and marionette lines, which benefit from structural support. Conversely, a lower cross-link density results in a softer gel, better suited for areas with less movement, such as superficial wrinkles or the lips, where a softer, more flexible filler is preferred [19]. In addition to cross-linking, other factors influencing the properties of HA fillers include the source of HA (avian or bacterial), its concentration, the size of the particles, and whether the product is monophasic or biphasic [18]. The FDA regulates these variables, ensuring safety and quality control in the production of HA-based dermal fillers. This stands in contrast to commercial devices, such as hyaluron pens, which do not fall under the same stringent regulations.

A hyaluron pen is a small, needle-free device that utilizes air-pressure technology to inject HA into the skin's epidermal and dermal layers [20]. The device works by generating internal pressure through air pumped into a chamber, which forces the HA filler into the skin [21]. Various brands, such as hyapens, fog injection devices, SERA pens, nebulizer injector guns, and dermajets, sell these devices [20]. While the general mechanism of action of hyaluron pens is well-understood—originally developed for insulin and vaccine administration—there is limited information available regarding the specific composition and efficacy of the HA fillers used in these devices. This raises concerns, as the FDA does not have the authority to mandate that cosmetic manufacturers submit safety data, leaving the quality, safety, and effectiveness of these fillers largely unknown. Additionally, Juch *et al.* (2024) highlight that hyaluron pens lack controlled penetration depth, leading to inconsistent product diffusion and unpredictable absorption [22]. Unlike traditional needle injections, which allow precise depth control, hyaluron pens rely on variable air pressure, which may result in superficial placement or uneven distribution of HA. This irregularity raises concerns regarding treatment efficacy, longevity, and potential side effects such as uneven and unpredictable filler distribution and increased risk of complications. As a result, hyaluron pens may not be subject to the same regulatory standards as FDA-approved HA dermal fillers, raising questions about their safety and reliability in clinical practice.

Additional study into the level of pressure and its impact on strategic delivery of hyaluronic acid is essential to establish safe and standardized practices and procedures for optimal use of hyaluron pens, ensuring more consistent outcomes across providers.

3. CLINICAL APPLICATIONS AND OUTCOMES

The skin is a durable organ, but like all systems, it inevitably succumbs to the aging process [23]. With age, the skin undergoes atrophy, resulting in thinning and reduced elasticity, leading to a loss of its youthful appearance. This decline in skin integrity also affects sensitive areas such as the lips, which lose volume and shape over time.

3.1. The Role of Hyaluronic Acid in Aesthetic Medicine

Dermal fillers, particularly those based on Hyaluronic Acid (HA), have become the most popular non-surgical option for restoring volume and contour to the lips and other areas of the face [24]. One of the main reasons for the widespread use of HA in aesthetic medicine is its cost-effectiveness and minimal discomfort when compared to surgical alternatives. HA has a unique ability to provide non-invasive hydration, which reduces the appearance of wrinkles and improves skin moisture levels. The hydrophilic properties of HA

enhance its effectiveness by drawing water from surrounding tissues, which adds volume to soft tissues [24]. By boosting skin hydration, HA not only delays the aging process but also reduces visible signs of aging, such as wrinkles, while improving overall skin quality [25]. This makes HA an essential tool in aesthetic procedures like lip augmentation, wrinkle reduction, and skin rejuvenation.

3.2. Patient Satisfaction and Risks of Hyaluron Pens

Recent studies on Hyaluron pens, devices that use air pressure to inject HA, suggest that most patients report high satisfaction with their outcomes. A study by Ockerman *et al.* (2024) included 161 participants who underwent approximately 47 treatments using the Hyaluron Pen, with some administered by licensed healthcare professionals and others via self-administration [6]. The results showed that 98.8% of participants had a positive experience with the device, and 97.5% would recommend it to others. Despite these positive reports, the study also revealed significant complications, with 79% of participants requiring additional interventions. These included hyaluronidase injections (59.1%), corrective surgeries (48.8%), emergency room visits (37.8%), and hyperbaric oxygen treatment (24.4%) [6]. These findings suggest that while the Hyaluron Pen can offer a positive patient experience, the procedure does not come without risk. It is also important to note that patient satisfaction can be influenced by individual aesthetic goals, highlighting the need for personalized treatment plans that minimize discomfort and promote a quicker recovery [26]. This underscores the importance of further research to understand the adverse outcomes associated with Hyaluron pens and refine the treatment process to achieve safer and more effective results.

3.3. Duration of Effects: Hyaluron Pens vs. Needle-Based Fillers

When comparing the duration of effects, traditional needle-based dermal fillers tend to provide longer-lasting results than those administered with Hyaluron pens. HA fillers typically last between 6 to 12 months, depending on the type of filler used and the targeted treatment area (e.g., lips, cheeks, nasolabial folds), as noted by Votto *et al.* (2021) [24]. A notable study by Glaser *et al.* (2011) on Juvéderm Voluma XC (VYC-20L), an FDA-approved HA gel, demonstrated that similar injection volumes (approximately 2.0 mL) led to correction durations of 15 to 24 months [27]. Specifically, the anteromedial cheek showed a correction duration of 24 months, the zygomaticomalar region lasted 19 months, and the submalar subregions lasted around 15 months. This evidence supports the notion that needle-based HA fillers tend to have a more prolonged duration of effect compared to those administered with Hyaluron pens. In contrast, there is limited research on the duration of HA treatments using Hyaluron pens, with most product sellers claiming effects last between 3 to 6 months. Additionally, the HA fillers used in Hyaluron pens are not FDA-approved, and their origin remains uncertain [21]. This lack of standardization and scientific backing makes the duration of effects with Hyaluron pens unpredictable, raising concerns about the reliability of the marketed products and their efficacy.

4. SAFETY PROFILE AND COMPLICATIONS

4.1. Risk of Adverse Events

Hyaluronic acid (HA) dermal fillers are widely recognized as safe and effective for aesthetic procedures, but they carry potential risks. The safety of these treatments is influenced by factors such as the injector's expertise, the type of filler, and patient-specific characteristics like skin condition and anatomy [28]. One of the most common complications is overfilling, which can lead to an unnatural appearance, visible lumps, or nodules. This issue often arises from improper injection techniques or excessive filler use in a single area, sometimes requiring corrective measures like massage, hyaluronidase injections, or surgical revision [29]. Overfilling can also exacerbate complications such as contour irregularities and tissue distortion, significantly impacting the natural appearance of the face or body. Product migration, another concern, can result from incorrect injection depth or excessive filler volume, leading to asymmetry or undesirable outcomes

[30]. Severe cases of migration may necessitate medical interventions, including the use of hyaluronidase or surgery, to restore balance and achieve acceptable results. These risks highlight the importance of skilled injectors and thorough patient assessments before treatment to minimize complications.

Incorrect injection techniques can result in severe complications, such as vascular occlusion, which occurs when blood flow is blocked and can cause ischemia and tissue damage. If filler is inadvertently injected into or compresses blood vessels, necrosis or ulceration may occur, necessitating immediate intervention to prevent permanent damage [12]. Infections, though less common, remain a significant risk if sterilization protocols are not meticulously followed during procedures. Contamination of the filler, equipment, or injection site can lead to pain, swelling, abscesses, or cellulitis that may require antibiotics or surgical drainage to resolve [30]. Adherence to strict hygiene standards is therefore essential to reduce these risks and ensure patient safety. In addition to these serious events, mild adverse reactions such as erythema, swelling, bruising, and itching are frequently reported but generally resolve within two weeks [31, 32]. These transient side effects are influenced by the type of HA filler and injection technique, underscoring the importance of proper practices and patient selection [3]. While most complications are manageable, they serve as a reminder of the critical role clinicians play in ensuring optimal patient outcomes through technique refinement and risk reduction.

A rare but serious complication of HA filler injections is blindness caused by vascular embolization into the ophthalmic artery, which can lead to retrograde flow and retinal vascular occlusion [29]. A systematic review of 32 cases revealed that blindness occurred following injections of various materials, including hyaluronic acid. Risk factors identified for this complication include high injection pressure, improper needle or cannula use, and filler placement in high-risk zones [30]. Preventative measures such as aspiration before injection, using small or blunt flexible cannulas, and avoiding high-pressure injections are critical to reducing the likelihood of embolization. Treatment options remain limited, focusing primarily on lowering intraocular pressure and improving retinal perfusion to mitigate retinal hypoxia, though outcomes are often poor. This complication underscores the importance of skilled injection techniques and a deep understanding of facial anatomy to prevent catastrophic outcomes like vision loss.

Severe complications, including granulomas, vascular occlusion, and infections, though less common, often require invasive interventions such as hyaluronidase injections or surgery [12]. Persistent edema, angioedema, and cerebrovascular accidents have also been documented, further emphasizing the need for skilled injectors and rigorous risk assessment. One study reported persistent edema in Asian patients undergoing facial remodeling, successfully treated with hyaluronidase [31]. Angioedema, though uncommon, may require antihistamines or corticosteroids and could necessitate discontinuation of treatment [32]. Cerebrovascular accidents, while rare, highlight the importance of careful patient screening to mitigate risks [33, 34]. Patient education about the signs of complications and the necessity of seeking prompt medical attention is essential to managing these risks effectively. While rare, these severe outcomes underscore the importance of informed consent and preparedness for potential adverse events.

4.2. Management of Vascular Events

Allergic history must be evaluated as prior sensitization to insect or wasp venom has association with higher risk of allergy to filler [35, 36]. Utilization of preprocedural allergy tests may be useful in confirmation of safety of filler usage and confirm if sensitization to the filler has occurred [36]. Additionally, prior to HA filler implementation anatomical considerations involving education and thorough understanding arterial supply of the six major facial danger zones including the glabella, temple, infraorbital tear trough area, lips, nose, and nasolabial fold regions can allow for practitioners to avoid devastating complications or improperly placed filler [37] Necrosis of tissue surrounding treated areas and compromised vessels due to embolization or migration of acidic particles from the vessels to other areas of the face can lead to vascular complications. During utilization of HA fillers, careful attention to pressure settings as well as early clinical observations and monitoring for signs such as intense pain, erythema, swelling, blanching, mottling, or discoloration of the skin after filler administration [37]. The procedure should be immediately stopped if these

signs are noticed and further filler administration in other regions of the face should not be done without determination of the underlying cause. Immediate treatment of ultrasonography guided injections of hyaluronidase into the area where the filler was placed may aid in prevention of epidermal necrosis [38]. In the days after, if treatment site pustules, crusting, erythema, or inflammation are reported then vascular occlusion should be suspected [39]. Specific post-care instructions and advice to the patient on necessary precautions, for example, avoiding use of heavy sunglasses is imperative in order to create a direct line of communication and optimize post-treatment outcomes.

Additionally, adjunctive therapies that combat inflammation, for example, systemic steroids, and antiplatelet medications may help in promotion of blood flow pre and post-procedurally may help in prevention of vascular events or early intervention if vascular events occur [38]. A warm compress may also promote vasodilation. Usage of platelet-rich plasma injections and laser therapy may allow for improvement of aesthetic outcomes through management of vascular events in response to suspected tissue damage that is more dramatic [38]. Follow-up appointments or doppler ultrasound may be utilized if intra-arterial obstruction is suspected [38]. Discharge may involve recommendations of oral antibiotics to prevent superinfection, corticosteroids, and topical protection against ultraviolet light [38, 40]. Specific steps in management may allow for rapid response and excellent treatment outcomes in response to vascular events.

4.3. Identification of High-Risk Patients: Contraindications and Patient Selection

Proper identification of high-risk patients is essential for minimizing complications associated with HA fillers. Contraindications include active infections, poor circulation, or a history of vascular disorders, as these increase the likelihood of severe complications like tissue necrosis [32]. Patients with autoimmune conditions or a predisposition to allergies are also at heightened risk of adverse reactions [41]. Treatment in areas with compromised blood flow—such as the glabella, nasal ala, or forehead—carries a higher risk of ischemic events and necrosis, warranting additional caution [33, 42]. A thorough assessment of the patient's medical history, including past filler treatments and any allergic reactions, is critical to reducing these risks.

Patients with known hypersensitivities to HA or its components should be excluded from treatment due to the risk of immediate or delayed hypersensitivity reactions [41]. Similarly, individuals with active dermatological conditions, such as eczema or rosacea, may have compromised skin integrity, increasing their susceptibility to inflammation or infection. Medications like anticoagulants or immunosuppressants also heighten the risk of prolonged bruising or infection, necessitating careful evaluation before proceeding with treatment [41, 42]. Modifying treatment plans or using test injections can help minimize risks for high-risk individuals.

During consultations, clinicians should obtain a comprehensive medical history, evaluate current medications, and discuss the patient's aesthetic goals. High-risk areas, such as the periorbital and perinasal regions, require special attention due to their proximity to critical blood vessels [43]. Ensuring that the patient's expectations align with achievable outcomes is crucial to reducing dissatisfaction and associated complications. Educating patients about the signs of complications, such as skin blanching or severe pain, and the importance of seeking prompt medical attention can further enhance safety [44]. Proper patient selection and tailored approaches are fundamental to achieving optimal outcomes while minimizing risks in HA filler procedures.

5. CURRENT REGULATORY LANDSCAPE

The CE Mark symbol in Europe signifies that products sold within the European Economic Area meet safety and health standards. Compliance with these standards demonstrates adherence to regulatory scrutiny required for ensuring safety and efficacy [45]. However, enforcement of these requirements can vary across EU member countries, leading to inconsistent regulations for products such as hyaluron pens. In the United States, medical devices can be marketed to the public once approved by the Food and Drug Administration (FDA). In 2021, the FDA issued a warning regarding needle-free devices, including hyaluron pens, due to insufficient data on potential adverse events [46]. The availability of unapproved products through

online retailers further exacerbates the issue, as these devices may contain unregulated materials, posing serious risks to consumers. Similarly, Health Canada issued a safety alert in 2019 and currently prohibits the sale of hyaluron pens in Canada [47]. Overall, the marketing of needle-free hyaluronic acid dermal fillers is limited in many regions due to unresearched potential risks.

The oversight of hyaluron pen usage faces significant challenges due to its accessibility online and its use by non-medical practitioners in aesthetic settings. Aesthetic practitioners, often without sufficient medical training, may lack knowledge of human facial anatomy, proper sterilization techniques, and correct dosing practices. These deficiencies can lead to complications such as tissue damage, filler lumps, and overfilling [48, 49]. The growing trend of self-administration, especially through platforms like TikTok, has raised safety concerns, leading to a 2021 Patient Safety Alert from the American Society for Dermatologic Surgery regarding the risks of children attempting self-injections [50]. Additionally, the presence of counterfeit devices increases patient and provider risks, with granulomatous foreign body reactions noted in cases of hyaluronic acid dermal fillers [51]. These concerns highlight the urgent need for uniform, stringent safety standards.

Policy Recommendations for Safe Usage

Clear policy recommendations are needed to provide guidance for providers and establish uniform requirements for hyaluron pen manufacturers. For instance, mandatory education on facial anatomy, injection best practices, and management of adverse events could streamline procedures and improve patient outcomes. The midface, a particularly complex area for treatment, requires specific training to avoid severe complications like blindness or necrosis [37, 52]. Ultrasound guidance can also enhance safety by allowing practitioners to visualize facial anatomy during procedures, reducing the risk of vascular compromise [53]. Policies should include mandatory training on human anatomy, injection techniques, and adverse event reporting systems. For example, a 10-point plan emphasizing product knowledge, procedural techniques, and complication management strategies could reduce the risks associated with hyaluronic acid dermal fillers [54]. Additionally, standardizing the chemical properties of fillers could lead to more predictable results and safer applications [55]. A comprehensive set of guidelines for aesthetic devices would ensure safer and more consistent outcomes for patients undergoing minimally invasive cosmetic procedures.

6. PROPOSED FRAMEWORK FOR STANDARDIZED GUIDELINES

To ensure the safe and effective use of the hyaluron pen in aesthetic medicine, three fundamental principles must be prioritized: sterilization, dosage accuracy, and patient communication.

6.1. Sterilization

Sterilization is paramount given the heightened risk of infection associated with a needle-free device that utilizes high-pressure technology to penetrate the dermis [55, 56]. Practitioners should adhere to stringent sterilization protocols for both the device and the surrounding procedural environment to mitigate the potential for contamination.

6.2. Dosage Accuracy

Dosage accuracy presents an additional challenge, as variations in pressure and operator technique can lead to inconsistent hyaluronic acid distribution, increasing the likelihood of complications such as overfilling or product migration [44]. Standardizing device calibration and ensuring practitioners have a thorough understanding of appropriate dosages for various treatment areas are crucial steps in minimizing these risks. Training should also emphasize the importance of selecting the correct filler for specific patient needs, as the composition of different hyaluronic acid products can vary in terms of viscosity and longevity, impacting treatment outcomes.

6.3. Patient Communication

Equally vital is effective patient communication. Practitioners must clearly outline the benefits, limitations, and potential adverse effects of hyaluron pen procedures, fostering realistic expectations and informed consent. Transparent communication also builds trust, which is essential for maintaining patient confidence in a field that heavily relies on reputation and outcomes. Ongoing patient education should be part of the post-treatment care, ensuring that patients understand potential side effects and the importance of follow-up appointments. These core principles form the foundation for the development of a comprehensive framework that prioritizes both patient safety and clinical efficacy.

6.4. Training and Certification Standards

The lack of uniform training and certification standards is a critical gap in the current use of hyaluron pens, necessitating the establishment of educational and credentialing requirements [6]. Practitioners should undergo formalized training programs that emphasize the anatomical and technical nuances of needle-free dermal filler administration.

A comprehensive curriculum for hyaluron pen certification should include:

- **Foundational Training in Skin Anatomy and Physiology**: Understanding dermal layers, skin types, and vascular structures to minimize procedural risks.
- **Device Mechanism and Calibration**: Instruction on the function, pressure settings, and safe operation of hyaluron pens.
- **Sterilization and Infection Control**: Protocols for maintaining a sterile environment and mitigating contamination risks.
- **Dosage Calculation and Product Selection**: Training on appropriate hyaluronic acid viscosities, injection depths, and dosage precision for different treatment areas.
- **Hands-on Clinical Training and Simulation-Based Learning**: Practical exercises with models and simulated patient cases to refine technique before live applications.
- **Adverse Event Recognition and Management**: Step-by-step protocols for handling overfilling, migration, vascular occlusion, and infections.
- **Legal and Ethical Considerations**: Understanding regulatory frameworks, scope of practice, and patient consent requirements.

In addition to individual training, certification standards should extend to training institutions themselves, ensuring these entities meet rigorous benchmarks for quality and consistency. Accrediting organizations like the FDA must play a pivotal role in overseeing these standards, providing a framework that legitimizes hyaluron pen procedures as a professional practice rather than a trend driven by unregulated providers.

Several training and certification programs have been introduced or proposed to enhance the safety of hyaluron pen use. In Australia, the hyaluron pen is classified as a therapeutic device and must be registered with the Therapeutic Goods Administration (TGA)—the regulatory body responsible for overseeing the approval, distribution, and advertising of medical devices, medicines, and other therapeutic goods [57]. The TGA's approval process involves a comprehensive risk-benefit assessment, ensuring that only devices meeting stringent safety and efficacy standards are allowed on the market [58].

This regulatory model underscores the importance of structured oversight in aesthetic medicine and could serve as a reference for other regions seeking to formalize guidelines for hyaluron pen use. Programs that integrate mentorship and periodic recertification can further ensure practitioners remain informed about advancements in device technology and updated clinical guidelines. Clear delineation of competencies would not only elevate the skill level of practitioners but also mitigate risks associated with inadequate technique or device misuse.

6.5. Adverse Event Management Protocols

Adverse events, while relatively rare, represent a significant concern in using the hyaluron pen and

demand the implementation of standardized protocols for their management. Complications such as overfilling, product migration, or localized infection require timely and effective intervention to prevent long-term patient harm [56].

Protocols should include step-by-step contingency plans that practitioners can readily implement when complications arise. These plans should outline the initial assessment, appropriate interventions, and criteria for referral to higher levels of care if necessary. For example, infections should be managed with evidence-based antibiotic regimens, while cases of overfilling or product migration may require techniques such as massage, hyaluronidase administration, or more advanced corrective measures. Emergent complications such as vascular occlusion, though rare, must also be addressed in these protocols, with strategies for immediate intervention, including the use of hyaluronidase to dissolve the filler and prevent irreversible tissue damage.

Establishing a system for documenting and reporting adverse events is equally important, as this data can inform future practice and identify trends requiring attention at a systemic level. Finally, practitioners must be trained in delivering empathetic patient communication during complication management, ensuring patients feel supported throughout the resolution process. Clear documentation and follow-up care plans should be established for patients experiencing complications, ensuring continuity of care and proper healing. By prioritizing preparedness, these protocols would contribute to a safer and more reliable approach to hyaluron pen applications.

7. FUTURE DIRECTIONS AND RESEARCH NEEDS

7.1. Advancing Device Innovation

In the rapidly evolving field of aesthetic medicine, the focus on advancing device innovation is crucial for improving treatment precision and minimizing associated risks. New technologies and methodologies are continually being researched and developed to enhance the efficacy of aesthetic procedures. For instance, innovations in hyaluronic pens have introduced more controlled application techniques, allowing practitioners to deliver hyaluronic acid with greater accuracy than when they were first introduced to the market [21]. This not only improves the patient experience but also decreases the likelihood of complications. Continuous advancements in device technology will play a significant role in setting higher standards of care within the industry, ensuring that patients receive safe and effective treatments tailored to their individual needs. Research should also focus on creating and validating new technologies that enhance both the safety and precision of hyaluronic pen applications, reducing operator dependence and minimizing risks.

7.2. Expanding Clinical Evidence

Complementing the push towards innovation is the necessity for expanding clinical evidence surrounding aesthetic procedures. Long-term studies that focus on the safety and efficacy of treatments are essential for building a strong foundation of trust within the medical community and among patients. Conducting these studies provides valuable data that can lead to improved treatment protocols and enhanced patient outcomes. Hyaluronic filler studies have been reported in fields outside of dermatology, such as urology. A long term study assessing the safety and complications of men who received hyaluronic filler as part of a urologic treatment found that there was no additional safety risk to using hyaluronic filler as opposed to other fillers [57]. Following this same logic, hyaluronic fillers used for cosmetic purposes do not pose any additional safety risks. Furthermore, extensive research helps to identify and address potential complications, ultimately reinforcing the credibility of aesthetic practices. By prioritizing well-designed clinical trials, the industry can ensure that practitioners are equipped with the knowledge required to make informed decisions, fostering an environment of safety and reliability.

7.3. Integration of Treatment Modalities

Another compelling trend in the field of aesthetic medicine is the integration of various treatment

modalities. Combining the hyaluron pen with complementary therapies can amplify results and enhance patient satisfaction. For instance, concurrent use of skin rejuvenation techniques in tandem with hyaluronic acid treatments can provide patients with a more comprehensive aesthetic solution [59]. This approach not only offers a synergistic effect but also allows for more holistic care, addressing various patient concerns during a single treatment session. Practitioners should be trained in multi-modality treatment planning to ensure that combinations of therapies are safe, effective, and tailored to each patient's unique needs. As practitioners become more adept at incorporating multiple techniques, they can customize treatments according to individual patient needs, leading to improved overall outcomes.

7.4. Global Collaboration and Standardization

Finally, the importance of advocacy for global collaboration in aesthetic medicine cannot be overstated. A multi-stakeholder approach is essential to creating universal standards that ensure the safety and effectiveness of aesthetic treatments across different regions and practices. By fostering partnerships among practitioners, regulatory bodies, and industry leaders, the field can work towards establishing guidelines and best practices that promote patient safety and quality care. A study done by Ockerman *et al.* showed that out of the 161 participants who have received lip filler from a hyaluron pen, 53% reported learning about the treatment through social media, and an alarming 17% of administers reported learning techniques through social media videos [6]. Self-administration of hyaluron pens contributes heavily to adverse reactions to treatment, highlighting the need to ensure that growth and collaboration should be encouraged among professionals and by professionals. Governments and professional organizations should take proactive measures to combat misinformation and ensure that only certified practitioners are performing these treatments. Such collaboration can also enhance training and education opportunities for practitioners, encouraging continuous professional development. As the industry strives for excellence through collective efforts, the establishment of universal standards will not only elevate the profession but also build trust with patients globally.

8. CONCLUSIONS

The Hyaluron Pen has gained popularity as a needle-free option for delivering hyaluronic acid in aesthetic medicine. Its appeal lies in offering a minimally invasive alternative to traditional needle-based procedures. However, the lack of standardized practices and the prevalence of its use by individuals with limited training present serious safety concerns. Complications such as overfilling, product migration, and infection highlight the risks associated with improper handling and insufficient regulatory oversight. To address these issues, a framework emphasizing practitioner education, standardized guidelines, and regulatory enforcement is essential. Training programs must include a thorough understanding of facial anatomy, proper dosing, and stringent sterilization protocols to reduce the risk of adverse events. The establishment of clear guidelines for managing complications, such as contingency plans for overfilling or infection, and mandatory reporting mechanisms can further enhance patient safety and improve outcomes.

While the Hyaluron Pen offers promise as an innovative tool in aesthetic medicine, its misuse undermines its credibility and potential. The development of evidence-based protocols and robust regulations is necessary to ensure its safe and effective use. By implementing these measures, the Hyaluron Pen can become a trusted option for patients seeking minimally invasive cosmetic enhancements, promoting greater safety and satisfaction in aesthetic medicine.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest regarding the publication of this paper.

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