The Use of One Soft Tissue Augmentation Product in Place of Another: Repercussions of Product Substitution in the Aesthetic Market

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With the arrival of new injectable soft tissue augmentation products, there is typically a surge of interest by both physicians and patients. This has been the case with Restylane® and other cosmetic injectable products. However, unethical physicians and other injectors may not use the product that they present to patients. Typically, this type of bait-and-switch behavior is motivated by greed. Since there is no oversight or governing body to regulate the training or product use by injectors, patients are left to their own devices when receiving cosmetic care. This article documents an instance in which a patient was told that she would receive one product, paid for that product, but was actually treated with a different product. She only learned of this switch when she presented to another physician complaining that Restylane, the product she was told she was treated with, did not work. Physicians and patients should be made aware of the potential for abuse with product substitution. In this instance, the only damage was the patient's wasted time and money involved in the treatment. However, the potential for harm also exists, and this constitutes a much more serious risk

Approximately 3 million people had soft tissue augmentation in 2005.[1] These individuals spent more than $1.3 billion on these procedures, and more than 80% of them were treated with a hyaluronic acid. As newer toxins, including other forms of botulinum toxin type A and subtypes, enter the marketplace, it is likely that pricing will serve as a point of differentiation for some of these products.

Currently, there are several hyaluronic acid fillers approved for use in the United States. These include Hylaform®, Hylaform Plus, Captique™, Juvéderm®, and Restylane®. Imminent approval of Perlane® is likely to expand this list in the near future. Given the plethora of hyaluronic acid fillers, there is significant potential for patients to develop unjustified perceptions about the costs and attributes of products that may be misrepresented. This article illustrates one such instance and highlights the need for greater public education regarding variations of filler products as well as for greater scrutiny of product pedigrees.

To add to the confusion about different types of fillers and toxins, there are a host of different people performing cosmetic procedures. Some of these individuals are not physicians, whereas others are physicians lacking specialty training in dermatology, plastic surgery, or another relevant specialty.

Consideration of various types of product substitutions for hyaluronic acid fillers and botulinum toxins

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will be discussed. Tactics employed for product substitution, including compounding, importation, and other techniques, will be considered in an attempt to increase public awareness and enhance patient safety. Potential solutions for this problem are also considered in the hope that a meaningful dialogue will result in enhanced patient safety.

CASE REPORT

A 57-year-old woman presented for consultation regarding her aging skin. During the consultation, she was noted to have Fitzpatrick skin type II with moderate photodamage. In addition, she had substantial tissue loss with deep nasolabial creases and marionette lines. She had no significant past medical history. The patient's primary concern was her photoaging; her secondary concern was her nasolabial creases. Specifically, she wanted to know what alternatives were available for her since, as she stated, "Restylane did not work."

This last statement initiated a discussion of treatment received approximately 10 weeks previously. The patient was questioned specifically about the product used and whether it was Restylane or another hyaluronic acid. She related that the physician told her that she received Restylane and stated that when she returned to the physician's office following the first injection, she received additional injections of the same product.

Since the patient had decided that Restylane simply did not work, she refused to consider another attempt to use it or any related products. Alternative products, including calcium hydroxylapatite and poly-L-lactic acid, were discussed, but given the expense and lack of effect of her previous injections, she deferred any treatment.

After questioning the patient more directly regarding the type of product injected, she was adamant about the name of the product used. Furthermore, she was aware that some fillers are more expensive than others, and she stated that she paid for a more expensive hyaluronic acid filler rather than a less expensive one. A records request was obtained to verify the product used. The progress note from the date in question is remarkable for several features. Most important, the product labels placed in the patient charts are not from Restylane but rather from less expensive alternatives. There is no indication of where these products were injected or any mention of whether or not topical or injectable anesthetic was used. Finally, it is noted in the record that 90 units of botulinum toxin type A were injected, with some marks made on a diagram of the neck.

DISCUSSION

This case highlights an increasingly prevalent problem with injectable aesthetic procedures—substitution of products without the patient's knowledge or consent. Despite the botulinum poisoning that occurred from the use of raw toxin instead of botulinum toxin type A, there remains little oversight of materials injected or of who injects them.

In this instance, a less expensive product was injected, although the patient was informed that and charged as if the more expensive product had been used. The concomitant use of botulinum toxin type A raises a second, related issue of product dilution. Finally, it is worth considering the training of the physician involved in this instance, who does not hold any certifications from specialty boards recognized by the Florida Board of Medicine, which regulates the profession for which the physician is licensed.[2]

The average cost per syringe of the products actually used on this patient is about one half of the cost of Restylane. The only incentive for an injector to misrepresent a less expensive product as one that is more expensive is financial gain; if the physician's goal were to use the less expensive product for its intrinsic properties, the use of the product would have been disclosed to the patient.

Restylane was compared with Zyplast® for approval by the US Food and Drug Administration and was noted to provide a "more durable aesthetic improvement than Zyplast."[3] In this study, Restylane provided a correction that lasted for at least 6 months in approximately 70% of the patients treated. A recent study comparing Perlane with Hylaform demonstrated that Perlane was superior in duration.[4] Although this study did not compare the products in question in this instance, it highlights the substantial variation in the duration of correction obtained with different hyaluronic acids.

Other hyaluronic acid products injected include the compounded hyaluronic acids sold at various "aesthetic training seminars" that usually cater to nonspecialists attempting to become cosmetic doctors. The quality and integrity of these products is variable.

Product dilution offers another opportunity for suboptimal patient outcomes and perceptions that various products and procedures "don't work." One common method employed by some botulinum toxin injectors is to reconstitute a 100-unit vial with up to 10 mL of saline rather than a smaller amount. In these instances, patients overpay if one considers the number of units injected. These patients typically believe that botulinum toxin type A does not work for them or that it only lasts for 2 months and is not worth the investment, never realizing that the treatment they received was not optimal dosing. Many of these patients will not consider having botulinum toxin or filler injections after this type of experience.

Product dilution for hyaluronic acid products is less easily accomplished than that for botulinum toxins and

usually occurs with dilution of one syringe used for several patients. For instance, a 1-mL syringe may be divided into two 0.5-mL syringes, and patients are then injected with a syringe of material that represents only one half of the standard syringe. An alternative method consists of swapping a smaller-sized syringe for a larger one. Both of these methods typically result in the patient receiving minimal correction. As with patients who are treated with overly diluted botulinum toxin type A, individuals who do not receive full dosing of hyaluronic acids may be lost to future aesthetic treatments because of their suboptimal outcome.

Less subtle methods of substitution may or may not be as dangerous or deceptive. Some physicians and other injectors rely on imported products to provide inexpensive patient treatments. In the best of cases, these products are identical to those purchased through authorized channels. For instance, a product that is purchased by a physician through an authorized distributor in the United Kingdom or Canada might be shipped to a physician in the United States who could then provide treatments at a significant cost advantage to his or her competitors. In these cases, patients are receiving the products that they expect to have injected. Other physicians purchase these products from third-party vendors. In these cases, the quality of the product and whether or not it is what it purports to be depend solely on the integrity of the vendor. Counterfeit hyaluronic acid fillers appear to have reached the US market, and these products are injected without patients' knowledge or consent.

CONCLUSION

The potential for product substitution or dilution exists whenever a product is used for aesthetic or medical purposes. Solutions to several of the potential abuses discussed in this article include better patient education about the procedures, products, and physicians performing them. Simple efforts could include teaching patients to inquire about the training of the physician and to view the product labels, including holograms and other product security and safety features. These solutions could be implemented by the professional societies as well as the makers of the products. Regulatory solutions could also be instituted that would mandate a visual confirmation of each product used and an affirmation of its pedigree with each patient. This last measure would increase the time and paperwork associated with each injection, although it may also be skirted by individuals intent on substituting products.

It is hoped that this illustration of an instance of product substitution provides an opportunity to discuss and address this issue. Doing so would benefit the vast majority of physicians who adhere to standards and, more importantly, help patients receive the treatments they expect.

REFERENCES

1. Morretti M. Global Aesthetic Market Executive Summary. July 2006. Available at: http://www.miinews.com/exec_summaries/GAM%20Executive%20Summary.pdf. Accessed January 3, 2007.
2. Florida Department of Health Medical Quality Assurance Web site. Available at: http://www.doh.state.fl.us/mqa. Accessed December 22, 2006.
3. Narins R, Brandt F, Leyden J, et al. A randomized, double-blind, multicenter comparison of the efficacy and tolerability of Restylane versus Zyplast for the correction of nasolabial folds. *Dermatol Surg.* 2003;29:588-595.
4. Carruthers A, Carey W, De Lorenzi C, et al. Randomized, double-blind comparison of the efficacy of two hyaluronic acid derivatives, Restylane Perlane and Hylaform, in the treatment of nasolabial folds. *Dermatol Surg.* 2005;31:1591-1598.