Cosmetic Fillers
Perspectives on the Industry

Steven L. Basta, BA

KEYWORDS

• Dermal filler • Cosmetic filler • Industry • Filler market • Injectables market

KEY POINTS

- The cosmetic filler market is characterized by multiple filler materials of varying performance characteristics designed for application in different areas of the face, and by competitive dynamics among major aesthetics companies.
- Marketing in the United States and Europe has been quite different owing to regulatory constraints in the US market, leading to more rapid growth in the European market.
- The US market has evolved significantly in recent years driven by scale and consumer marketing strength among major companies with multiple product portfolios.
- The evolution of the filler market will include new materials, injection techniques, and facilitation devices, and new areas of injection.

EVOLUTION OF THE FILLER MARKET

In the 1980s, the introduction of collagen heralded a new era of minimally invasive aesthetic procedures. In the early days of collagen, some industry analysts estimated the entire dermal filler market could potentially be $40 million in product revenue eventually. Women could hardly imagine getting injections regularly for aesthetic enhancement, and no one could foresee injecting a toxin in the face regularly throughout one's adult life. Needless to say, the aesthetics business has come a long way since then.

In the 1990s, collagen continued to dominate the US filler market, whereas internationally the hyaluronic acid (HA) fillers emerged as the new leaders in the market owing to longevity, performance, and handling advantages versus collagen. Permanent fillers were also introduced in the 1990s in Europe with mixed results. The introduction of HA resulted in rapid growth and differentiation in the filler business in Europe, well before similar improvements were available in the United States.

The launch of Cosmoplast and Cosmederm in the United States expanded the market by eliminating skin testing, but lacked the durability improvement of the HAs. In the filler market, 2003 proved to be a transformative year. The market for dermal fillers expanded profoundly with the approval and launch of Restylane, which offered superior augmentation in a single syringe as compared with a single syringe of collagen. As patient satisfaction improved, and the wave of beauty magazines highlighted Restylane as the best new thing from Europe, adoption of Restylane far exceeded the anticipated level, and approximately doubled the peak adoption of collagen in the first year.

Along with the launch of Restylane, the introduction of other forms of HA, plus new materials such as Radiesse and Sculptra, drove rapid growth in the aesthetics market. The range of products on offer provided a range of lifting and volumizing

Disclosure: Mr S.L. Basta served as CEO of BioForm Medical 2002–2010 and served as CEO of Merz Aesthetics 2010–2011. Mr. S.L. Basta currently serves as CEO of Tigercat Pharma, a pharmaceutical development company developing a therapy for chronic pruritus. Mr S.L. Basta has no current affiliations with any of the aesthetics companies or products described in this article.
590 Berkeley Avenue, Menlo Park, CA 94025, USA
E-mail address: sbasta100@gmail.com

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characteristics; some offered perceived greater longevity than Restylane. The market rapidly segmented based on duration and handling characteristics. Duration is often cited as the differentiation factor, because it is easy to reference a number to describe a product as a "3-month," "6-month," or "12-month" filler. Such labels derived from several factors, including (i) the ease of describing a product based on duration versus the complexity of describing distinctions in handling properties, viscosity, injection effect, and so on, (ii) the desire for companies to be able to differentiate their fillers, and (iii) US Food and Drug Administration (FDA) restrictions on marketing claims, which constrained the ability to describe handling differences to clinicians in terms that implied different clinical outcomes.

Why the United States' and European Union Filler Markets are Different: Regulatory Drivers and History

The regulatory constraints of seeking FDA approval and the limitations on FDA-compliant marketing cause the differences between the United States and the European Union (EU) filler markets. Four key constraints in the US regulatory environment drove the historical US market approval lag and lack of competitive differentiation relative to filler marketing in Europe. These constraints are:

1. Premarket approval requirements in the United States for many years constrained fillers to an approval indication of "moderate to severe lines and wrinkles" and directed all the companies to run comparative trials against collagen. The most confident path to approval for any filler company was to run a direct comparison study against collagen (because it is relatively straightforward statistically to run a noninferiority study against a known weaker competitor). This resulted in the new product approvals for Restylane, Juvederm, Radiesse, Artefill, and other products all demonstrating noninferiority to collagen to get exactly the same approval indication.
2. Making superiority or differential effect claims in the United States is a high hurdle. For example, BioForm performed comparative trials of Radiesse in Europe against Restylane and Juvederm and could use those data in Europe, but the US approval trials were conducted against collagen, so that the comparative data against HA are not in the United States product approval labeling, limiting how it can be used in marketing materials. FDA marketing standards intended to protect patients and physicians from false claims have the unintended consequence in the US filler market of hampering communications that would serve to provide differentiation information. Thus, the marketing of fillers in the US market for many years was restricted to very similar nasolabial fold claims showing similar before and after pictures.
3. The FDA has been focused on correction of defects or disease, and has been much less receptive to enhancement claims. That is what drives a lines/wrinkles focus of filler approvals. It also leads to acne scar or facial lipoatrophy indications. Lip augmentation or facial enhancement, by contrast, is slower to work through the FDA approval process because it is not correcting a deficit. That requirement limits the ability to get more superficial fillers or specifically designed lip fillers through the FDA approval process and limits the range of different fillers available to US physicians.
4. The time and cost of US-approval trials limit the range of fillers available. In the EU, by some estimates more than 50 forms of HA are available, ranging from very light materials designed for middermal injection for superficial wrinkles, to very viscous materials for facial contouring through larger gauge needles. The range of materials in the US market is limited by the need to demonstrate effectiveness of each form of material in the target indication. The trials take several years, and the full approval cycle including manufacturing validations, clinical studies, preclinical studies, and so on can be $10 to $30 million and 3 to 7 years per clinical product form developed. There is diminishing marketing return to the third, fourth, or fifth form of a filler approved within a family of fillers. The time required and cost of developing subsequent forms of fillers in Europe can be 10% to 20% of the US development cost.

Certainly, there is now evolution beyond the lines and wrinkles indication after 30 years of filler development in the United States. The approvals of Sculptra and Radiesse for facial lipoatrophy and the more recent FDA reviews of hand augmentation, acne scars, and facial volume indications for various products open the clinical path to new indications.

The EU filler market provides a completely different competitive profile. By 2010, more than 50 distinct fillers were on the market in several European countries. Counting all the derivative forms and modified viscosities, the number may be much greater now. The US market at the time