



## The Wrinkle in Facial Injections and Implants: Safety Questions

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In the eternal search for eternal youth, some new technique or material is always being touted as the next best thing. Women and men seek out long-lasting non-surgical procedures that will reduce wrinkles and make them look more like celebrities. Here are examples of four types of injectables used as alternatives to face-lifts: Botox, silicone injections, Artecoll and Gore-Tex implants. How well do they work and how safe are they? The news is not especially good.

Consumer protections exist but don't always work as well as they should. Injectable substances are subject to approval by the U.S. Food and Drug Administration (FDA). Most are labeled as Class III devices, which means that they require pre-market approval (PMA) before being sold to the general public. For instance, Botox is Class III and needed to be proven safe and effective before it could be approved for sale. Those FDA safeguards sound impressive. Loopholes, however, are large enough for millions of unsuspecting consumers to pass through.

The major loophole, called off-label use, is that products proven safe and effective for one use or one type of patient then get used in other ways for other types of patients. For example, once a product is found safe and effective for wrinkles, it can be used for lip augmentation—even though it may never have been tested for that purpose. And if a product is tested only on very healthy white women, it may not be as safe for less healthy women, or men, or certain racial or ethnic groups.

Certain products require skill to minimize the risks, but once it is approved, any kind of physician can offer the service. Sometimes, physicians who are not well trained in a specific procedure may offer the procedure anyway, and harm can result. Finally, since many cosmetic injectables are available in Canada, Mexico and elsewhere, patients sometimes leave the country for these procedures or doctors bring them into the United States illegally, making safety claims that are not true. A lot of money is to be made in the quest for the “fountain of youth,” most of it at the expense of patients unaware of the potential consequences.

### Botox

Botox, or Botulinum Toxic Type A, is a protein produced by the same bacteria that causes botulism, a severe food poisoning.<sup>1</sup> It was first approved for medical use in 1989 to treat eye-muscle disorders and then for a neurological disorder that causes severe neck and shoulder contractions.<sup>2</sup> Approved just last year by the FDA for cosmetic use on frown lines, Botox is the Number One non-surgical procedure in the United States today, according to the American Society for Aesthetic Plastic Surgery 2002 statistical report.<sup>3</sup> It cited more than 1.6 million Botox treatments in 2002, an increase of more than 2,000 percent since 1997, when 65,000 were performed.

The procedure involves injecting a small dose of the toxin into selected muscles, thus blocking a chemical that signals the muscle to contract and, in effect, paralyzing the muscle.<sup>4</sup> Botox injections last about 3 to 6 months. They are an effective treat-

ment for wrinkles, but should not be injected more than once every 3 months. The most common adverse effects are headaches, droopy eyelids, and nausea. These usually are temporary but can last several weeks or even several months—the same as the cosmetic benefits. There is also the risk of severe, debilitating headaches that can last more than a month. Another troublesome issue, which Dr. David Becker of the Weill Cornell Medical College has raised, is that excessive use could lead to the creation of wrinkles when untreated muscles overcompensate for the paralysis in treated ones.<sup>5</sup> In addition, psychologists worry that overuse can damage a person's ability to make facial expressions that are an essential part of communication.<sup>6</sup>

The FDA approved Botox based on its effectiveness for one type of wrinkles: the frown lines between the eyebrows. Physicians can use it legally, however, for other wrinkles. Such off-label use is common in medicine and assumes that a physician can use his or her own knowledge and experience to make the best decisions for patients. In many such cases, however, physicians trust that the use will be safe and effective, even though there may be no data to back up that hope.

Lately, concern has been growing over the sometimes casual attitudes toward a treatment that involves injecting a toxin into the face. Botox parties are as casual as their predecessor Tupperware parties. The American Society of Plastic Surgeons has concerns, however, about the frequency of partygoers' injections; it cites the need for proper consultations and sterile environments in order to ensure safety, the very things that may be compromised in a social gathering.<sup>7</sup> The price of injections offered at parties is tempting to patients, however, since it is usually lower than the average scheduled appointment fee of \$400.<sup>8</sup>

### **Injectable Silicone**

Injectable silicone is perhaps one of the most controversial treatments of this kind. First used to increase breast size in the 1940s and 1950s, liquid silicone injections were found to cause infections, granulomas (bumps), deformities and even death when the silicone migrated to the lungs and other parts of the body. Nevada first banned liquid silicone injections because the problems were so evi-

dent in Las Vegas showgirls, and a federal ban followed.<sup>9</sup> Nevertheless, liquid injectable silicone (LIS) continued to be used illegally in this country as well as in Mexico, Canada, and parts of Europe. The FDA considers silicone injections dangerous, but a legal loophole—arising from approval of two LIS products (Adatosil and Silikon 1000) for treating detached retinas—has resulted in their being legal since 1994.<sup>10</sup> Since the FDA law allows doctors to administer a “legally marketed device” to their patients,<sup>11</sup> doctors may inject liquid silicone as an off-label use.

Recently, reports have surfaced about the rising popularity of silicone parties. As with Botox parties, those who attend are eager for a quick, affordable way to look younger and curvier; unlike Botox parties, however, they are usually very secretive and typically more devastating for the “patients.” These parties have been especially popular in Florida, where many unlicensed doctors from South America are treating mainly women and transsexuals, usually for only a few hundred dollars.<sup>12</sup> When complications such as inflammatory reactions arise, however, the patients must pay thousands to plastic surgeons and dermatologists. Several deaths have been reported.

Silicone injections are less dangerous when performed by a well-trained physician using sterile procedures, but even then problems can occur. Since no studies have been done, it is not known how often immediate or long-lasting problems arise from silicone injections. Certainly, some patients are satisfied and recommend the procedure to their friends. But what happens to that permanent filling years later? As faces age, wrinkles move slightly, and what was a filled-in wrinkle can instead be a permanent raised ridge of silicone, several inches long, near the wrinkle. Because problems with silicone often require surgery, three Swiss medical associations as well as the Swiss government health agency have issued a warning against the use of silicone, the new product Artecoll, and other permanent treatments for cosmetic purposes. Noting that experience indicates a risk for disfiguring late complications, including visible nodules and swelling, they concluded that the benefits do not outweigh the risks.

## Artecoll

A “wrinkle filler” that has failed to win FDA approval is Artecoll, another permanent injected material used to plump up wrinkles and enhance the lips.<sup>13</sup> Artecoll (also called Artefill) is a Class III device composed of 75 percent bovine collagen and 25 percent Plexiglas microbeads.<sup>14</sup> When problems arise, surgical removal may be necessary. Artecoll is injected through a tunneling technique with a hypodermic needle. The plunger is depressed and deposits the Artecoll while pulling out of the skin, leaving a small cylindrical mass of Artecoll. Each microbead is coated in bovine collagen to keep from clumping together; after the body gradually absorbs the collagen, it replaces it with its own collagen and causes a plumping up of the wrinkles or lips.

Artecoll has been used for several years in Canada and Europe. In the United States, Artes Medical, Inc. applied for FDA approval, based on a one-year study of 117 women and 11 men. An FDA Advisory panel recommended approval in 2003, but the FDA has not agreed. Meanwhile, Artecoll has come under increasing scrutiny and criticism from Swiss and Canadian doctors. Three Swiss medical societies issued a warning against its use in the face because of reports that it causes granulomas, which lead to unsightly bumps that usually have to be removed surgically.<sup>15</sup> Many Canadian doctors disavow its use for lip augmentation for the same reasons. A large portion of the medical community believes Artecoll can cause inflammatory reactions that induce scar tissue, making removal of the beads nearly impossible without causing some lip disfigurement.<sup>16</sup> In 2003, the Canadian company that sells Artecoll claimed that only 10 cases out of 8,000 patients worldwide have reported nodules within two years,<sup>17</sup> but interviews with Canadian doctors indicate many more problems. Plastic surgeons explain that they don’t report lumpy lips because it doesn’t seem sufficiently important, but that means that there is no way to determine how many patients have experienced unattractive and sometimes disfiguring lumps and nodules.<sup>18</sup>

What does the research show? The statistician advising the FDA voted against Artecoll’s approval because the manufacturer’s clinical study did not prove that it was any more effective than collagen, a popular temporary treatment for wrinkles. The

manufacturer’s own studies indicate that within the first year, 16 percent of the 128 patients had complications, including persistent swelling, lumpiness, flu-like symptoms, and blurred vision.

Unfortunately, as the Swiss government and published studies have pointed out, large unsightly bumps can appear several years later.<sup>19</sup> It also is important to recognize that the company finds the best physicians possible to evaluate its new products, and they are carefully trained. Once a product is sold, any physician can use it, and many will not be as skilled or carefully trained.

Yet another major concern deserves attention: Artecoll has not been tested on African or Asian Americans, two groups known to be at increased risk of scarring and autoimmune disease. For that reason, the Congressional Black Caucus of the House of Representatives, the National Medical Association and the National Research Center for Women and Families jointly wrote letters to the FDA commissioner, urging him to delay any approval until the product is adequately tested on these large minority groups.

## Gore-Tex

Gore Medical Products has been getting attention due to the mainstream introduction of Gore-Tex implants as alternatives to face-lifts. That’s right – the same material used to waterproof jackets and boots is now being hailed as a breakthrough in cosmetic surgery. Having been used successfully in 1971 as a surgical implant for damaged arteries and other vascular parts, Gore-Tex has become widely accepted in surgery, and is now touted for cosmetic enhancements.

In the past decade, Gore-Tex implants have been used for lip augmentations or enlargements, and now the company claims that its Subcutaneous Augmentation Material (S.A.M.) will get rid of wrinkles while helping the body create the tissue it needs to stay wrinkle-free.<sup>20</sup> Gore S.A.M. is made from a chemical compound known as e-PTFE (the same substance that is used for Teflon) and is described as a permanent yet reversible way to achieve the results of a face-lift without undergoing complicated surgery. Gore S.A.M. has primarily been used to reduce or eliminate the folds that run from the side of the nose to the corners of the mouth. The FDA approved the use of e-PTFE for facial augmentation and lip reconstruction but ini-

tially specified it not be used for wrinkles or lip augmentation.<sup>21</sup> A form of Gore-Tex (Soffform) was approved for research in 1997. Gore-Tex products have not been specifically approved as safe or effective for wrinkles, lip augmentation, or other types of “facial rejuvenation,” and the long term risks have not been studied.

A typical Gore-Tex implantation entails a small incision in the face or lip just under the skin. The surgeon lifts up the tissue to create a small cavity or hole for the implant, then trims the implant material to fit facial contours and inserts the implant, securing it in place. Some incisions require stitches; swelling can be treated with a cold compress; and bruising will sometimes occur.<sup>22</sup>

Although the company points out that more than 4 million implants have been used and there have been no allergic reactions,<sup>23</sup> the absence of objective research on these patients makes these reports questionable. Other problems have been reported, such as irritation, slow healing, discomfort, and the implants’ being visible under the skin and extruding because of the constant movement of the mouth. Infections also have occurred, requiring the implants to be removed and replaced.<sup>24</sup> In light of the similarity to Teflon, it is important to note that Teflon implants were used in the 1980’s for jaw joint problems, and were removed from the market after causing permanent irreversible damage to the jaw bones and skulls of many patients.

Since 2003, the Environmental Protection Agency (EPA) has demonstrated increasing concern about a chemical processing aid known as PFOA, which is used to make several products, including Gore-Tex. EPA is concerned that PFOA exposure may cause health problems.<sup>25</sup> EPA has imposed penalties against the companies that use PFOA for withholding information about the harmful effects of PFOA on human health and the environment, but what are the potential risks of Gore-Tex when it is implanted in the human body for many years? Nobody knows; no research exists.

## Conclusion

Injectables are an increasingly popular cosmetic procedure. They pose these safety issues:

- ♦FDA does not require studies of minority groups; it doesn’t even require studies to specify the race of those individuals studied.

- ♦FDA does not require long-term safety data, but some of these products have long-term consequences.
- ♦The FDA neither studied nor approved some of these products for the cosmetic purposes that are now popular: Botox for wrinkles other than those near the eyebrows, silicone injections in the face, Gore-Tex as used in the face.
- ♦Complication rates may be much higher when these procedures are done by physicians who are not Board-certified or well-trained for the specific procedures.

Patients want a long-lasting solution to their wrinkles, but injections of permanent substances such as silicone and Artecoll raise important long-term safety questions. The FDA should carefully consider the information provided by other countries that have approved these products and are now warning against their use because of concerns that the risks outweigh the benefits. It is also very important to acknowledge that the clinical trials conducted by companies for FDA approval are short-term studies that represent the best-case scenario under the best-trained physicians the company can find. Once a product is sold, any physician (or even dentists) can use it, and since this is a cash business, many physicians prefer this to their own specialties. Patients may not even think to ask what kind of training a physician has; they assume he or she is well trained or wouldn’t be doing the procedure. Unfortunately, that assumption may not be correct.

## Footnotes

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**2** *ibid*

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**5** “Botox ‘may cause new wrinkles.’” <http://news.bbc.co.uk/2/hi/health/2772263.stm>

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