Complications reported in some recipients of Bio Alcamid

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As mentioned in our previous CATIE News story, some older anti-HIV agents have been associated with lipoatrophy, specifically changes in the appearance of the face. Most anti-HIV drugs used today are not associated with this problem. However, for people in whom these problems have occurred, facial fillers may be an option. One such filler, Bio Alcamid (polyalkylimide), is considered a permanent implant. Reports over the past several years suggest a greater-than-expected risk of complications in people who have received this product.

About Bio Alcamid

Bio Alcamid is 96% water and 4% gel (polyalkylimide) and resembles fatty tissue. It is implanted just under the skin. After surgery, the body surrounds the product with a network or capsule of collagen. This encapsulation is supposed to restrict the body’s exposure to Bio Alcamid and prevent it from moving (migrating) to other parts of the body. According to doctors from the Netherlands, early literature on Bio Alcamid described it as “safe” and possible complications such as infections were supposed to be “rare (about 0.06%).”

Netherlands—A large study

In the past several years, reports have emerged of higher-than-expected rates of complications with Bio Alcamid. Members of the Dutch Society of Cosmetic Medicine conducted a survey of plastic surgeons to find out some of the issues associated with Bio Alcamid. They found that 3,196 patients received 4,738 treatments with this product. Of the 3,196 patients, nearly 5% developed complications, which could be broadly grouped as follows:

- Inflammation – This was the most common problem occurring years after implantation and “mainly after surgical procedures in the face, such as dental procedures,” noted the Dutch doctors. Inflammation associated with the implant also occurred after patients experienced infections in their head and neck. However, in about 50% of patients no obvious cause of infection could be found.
- Accumulation – In some cases, Bio Alcamid seemed to build up in one area, “typically years after [implantation],” according to the doctors.
- Hardening of the capsule – Another complication was hardening of the capsule of collagen surrounding the implant. The doctors stated that this was “generally a visible and disturbing disfigurement for patients.” No obvious reason for this problem could be found.
- Migration – In some cases, the implant would move to another area. This was a problem particularly in the cheeks.
- In HIV-positive people – As part of their larger study, the Dutch doctors also collected data on a sub-group of 270 HIV-positive people who received implants of Bio Alcamid. Overall, the types of complications seen among HIV-positive people were similar to those seen in HIV-negative people. HIV-positive people had slightly more complications (6%) than HIV-negative people (5%).

Ideally, fillers used for reconstructive surgery should be “as safe as possible,” stated the Dutch doctors. However, the complication rates seen with Bio Alcamid are, in their opinion, “too high.” Furthermore, these doctors note that their analysis of the risk-benefit ratio of Bio Alcamid takes into account “the health risk of inflammation and the difficulty treating disfiguring complications.” The Dutch Society of Cosmetic Medicine now advises its members to not use Bio Alcamid.

Scotland—Some changing views
Some plastic surgeons in Edinburgh initially had a favourable impression of Bio Alcamid based on short-term results that they saw. However, now these plastic surgeons have found a high rate of complications appearing after implantation of Bio Alcamid. Some patients even needed intravenous antibiotics along with surgical drainage and further corrective surgery to recover from their complications. The Edinburgh plastic surgeons said that Bio Alcamid "may have significant long-term problems and its use should be restricted or discontinued entirely."

**Israel—Unexpected complications**

Doctors in the Department of Plastic and Reconstructive Surgery at the Sackler School of Medicine at Tel Aviv University in Israel have also unexpectedly found complications among 14 HIV-negative people who received Bio Alcamid. These doctors found that serious complications occurred in patients "without [a history] of trauma or oral [surgery]." The Israeli doctors theorize that perhaps Bio Alcamid may somehow interfere with surrounding tissue, making such tissue prone to infection.

Like several other teams of plastic surgeons, the Israeli doctors found that removing Bio Alcamid that had been implanted for a long period of time was not easy. Traditionally, cuts to the face for drainage and removal of infected tissue and material might be one approach for dealing with complications related to Bio Alcamid. However, this carries the risk of leaving permanent scars. The Israeli plastic surgeons appear to have developed a novel mini-irrigation system that helps make the removal of Bio Alcamid easier.

**Canada—Unexpected long-term complications**

Infectious disease specialists at Toronto’s General Hospital have been struggling to help HIV-positive patients who have infectious complications arising from Bio Alcamid implants. Also, other Canadian doctors plan to publish their experience with complications from Bio Alcamid.

**Caution about permanent fillers**

The complications seen in some users of Bio Alcamid may also occur with some other facial fillers that are considered permanent implants. Part of the problem with evaluating the safety of facial fillers is that the regulation of these products differs from one country to another.

The International Committee for Quality Assurance, Medical Technologies and Devices in Plastic Surgery (IQUAM) has made this important point in one of its reports:

All permanent soft tissue fillers are associated with risks of infections and granuloma formation, which may lead to major disfigurement. This risk of infection depends on many factors, including the following:

- the nature of the soft tissue filler
- the amount of filler used
- the depth of injection
- the part of the body being injected

Plastic surgeons who have reviewed the IQUAM report note that even when products are implanted by very skilled plastic surgeons, the risk of complications can never be ruled out.

IQUAM has found the following:

"Substantial biochemical and biophysical differences exist between commercially available soft tissue fillers as well as variations in their purity.... Clinical studies on new permanent soft tissue fillers offered by manufacturers are mostly not sufficient to predict the incidence of late on-set reactions."

Perhaps the most important point made by IQUAM is this:

"Most [permanent] soft tissue fillers have not stood the test of time and thus should still be considered experimental."

Bearing all of this information in mind, we encourage HIV-positive people who have had permanent soft tissue fillers implanted and who are concerned about complications to discuss any issues with their physician and, if necessary,
obtain a referral from their physician for an experienced plastic surgeon.

**Statements**

As mentioned earlier, the Dutch Society of Cosmetic Medicine now advises its members to not use Bio Alcamid. The Swiss Society for Plastic Surgery has banned the use of permanent soft tissue fillers. Furthermore, the Secretary of the International Confederation for Plastic Reconstructive and Aesthetic Surgery (IPRAS) has issued a warning about the complications that may arise from the use of permanent facial fillers.

—Sean R. Hosein

**REFERENCES:**

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