

# NEW-FILL INJECTIONS



## cosmetic surgery for facial wasting

Results from a French study of New-Fill (polyactic acid) shows that it may help increase the thickness of the cheek fat pad and other places where fat loss is sometimes apparent. Some people have experienced *lipoatrophy* (fat loss), which is believed to be associated with anti-HIV therapy and in particular the nucleoside analogue (NRTI) drugs. This study involved four injections of New-Fill (3cc in each cheek) at days 0, 15, 30 and 45. A fifth injection was given at day 60 if there was inadequate response.

Fifty people participated and all began the study with a marked and visible reduction in fat tissue in the cheeks (sunken cheeks) as measured by *ultrasonography* (using ultrasound technology to produce an image). At the time of the report, four people had received three injections, 29 had four injections and 17 had five. All volunteers had a dramatic improvement, with the majority regaining fat tissue in the cheeks. Some participants experienced a slight swelling at the injection site.

The manufacturer claims that New-Fill does not directly fill the spaces left empty by *lipoatrophy*. Rather, the product is claimed to build or grow a matrix under the skin which is then filled in by the body's own production of collagen.

New-Fill is not currently approved by the FDA and is not commonly available to physicians. For a time, the product was being imported from France for personal use, but in recent months the FDA blocked bulk importation of the product, arguing that the product

should be classified as a *device* rather than a drug or natural supplement. The agency feels it is thus not subject to the personal importation rules for drugs. Still some people are successfully bringing back personal supplies of New-Fill from Tijuana, Mexico.

Discussions with the FDA are ongoing, looking for a way to make the product available to people in need while further studies are designed. A major problem is that the supplier is a small company that does not have the resources to conduct clinical trials. Some dermatologists offer products they claim are similar, and a few clinics near the Mexican border treat patients with New-Fill or similar products.

Facial *lipoatrophy* may not be physically harmful, but it can add a serious psychological burden for people with HIV infection. Although New-Fill has not been proven to be effective, neither has it shown any serious toxicity to date. Project Inform supports the right of people with HIV to have access to this and similar products.

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