

September 2, 2003

Doctors Without Scalpels: Seeking to Melt Fat Away

By ANDREW POLLACK



Promotional material from UltraShape, which uses ultrasound techniques

It sounds too good to be true, and maybe it is. But companies are working on ways to eliminate unwanted fat from the body painlessly, without the invasiveness and side effects of liposuction.

None of the techniques have been approved as safe or effective, but believers speak of making fat cells essentially melt away by using sound waves, electricity or injections of a fat-attacking substance.

Doctors warn that many claims in cosmetic surgery are made for techniques that do not pan out, because the industry is driven heavily by fads and advertising.

"Everyone has in their office equipment they purchased they believed to be an end-all that turned out to be a zero," said Dr. Lawrence S. Reed, a plastic surgeon in Manhattan who is on a committee set up by the American Society for Aesthetic Plastic Surgery to investigate new technology.

One technique starting clinical trials uses ultrasound. The high-frequency sound waves are already used by many plastic surgeons to break down fat cells to make them easier to suck out by liposuction. If ultrasound is correctly applied, the companies say, it can break down fat that the body will then gradually absorb and eliminate on its own.

"We just break the fat cells, and the human body does the other part of the job," said Dr. Yoram Eshel, chief executive of UltraShape, an Israeli company that is working on the technique.

Dr. Eshel said UltraShape had tested its technique on 30 people in Israel, though it has not published the results.

"The women we treated talked on the phone or read the newspaper," he said. "There was no pain at all."

Dr. Eshel, a physicist, said that UltraShape hoped to begin clinical trials in Europe soon and in the United States next year and that it hoped to have the technique approved for marketing in the United States in 2005.



Doug Wilson for The New York Times

Dr. Jens Quistgaard is president of LipoSonix, which is working on ultrasonic fat removal with hopes of getting to market in 2006. LipoSonix, a tiny company in Bothell, Wash., is also working on ultrasonic fat removal. It hopes to start its first clinical trial this year but does not anticipate getting to market until 2006, at the earliest, said Dr. Jens U. Quistgaard, the president.

Liposuction is the most common cosmetic surgery procedure, with 373,000 performed in the United States last year, according to the American Society for Aesthetic Plastic Surgery.

The procedure, which involves inserting hollow rods through the skin into fat layers to suck out the fat, often causes bruising and swelling that can last several weeks, and there can be other complications as well, like blood loss, blood clots and even death. A survey of experienced surgeons by the aesthetic plastic surgery society reported death in 1 in 47,415 cases and major complications in 1 of 384 procedures from 1998 to 2000. Previous surveys had shown higher death rates and complications.

The ultrasound technique would use a hand-held transducer much like that used to look at a fetus in the womb. But numerous experts are skeptical about using ultrasound alone, without sucking out the fat.

"If you do a tiny little area on the face or neck, you might get away without sucking," Dr. Gary Rosenberg, a former president of the Florida Society of Plastic Surgery, said. "If you are talking about significant areas, you have to remove the fat."

Dr. Ronald L. Moy, an associate clinical professor of dermatology at the University of California at Los Angeles, said doctors continued to debate the effectiveness of ultrasound when it assists liposuction.

"I think it does a very modest to minimal amount of dissolving fat at this point," said Dr. Moy, who is president-elect of the American Society for Dermatologic Surgery.

The ultrasound companies concede that without liposuction, just a small amount of fat can be removed at once, so as not to overwhelm the body's ability to absorb it. They

envison removing about one to two pounds at a time. Liposuction allows 9 to 10 pounds to be removed at once.

Ultrasound patients would have to make multiple visits, spaced a month or more apart. But each visit would last an hour or less, Dr. Eshel said. "It's a walk-in, walk-out procedure."

There are safety concerns. Dr. Rosenberg said if fat was not removed it could cause infection or enter the bloodstream and cause a clot.

"We have struggled for two decades in liposuction to eliminate that possibility," he said.

Other doctors, however, said they saw little risk of that. Even with liposuction, they said, not all the fat is removed, yet what is left behind does not seem to cause problems.

Another concern is that ultrasound can potentially burn the skin, blood vessels or nerves near the fat being removed. Fat removal would require high ultrasound energy levels. Mr. Quistgaard said LipoSonix would use ultrasound energy about 1,000 times the intensity used in obstetrics.

He added that the energy would be focused in the fat layer below the skin, so that it does not burn the skin on the way through.

"It's sort of like using a magnifying glass out in the sun," he said, where a leaf can be burned only if it is at the focal point of the sunlight.

Dr. Eshel of UltraShape said its technology relied more on vibration than heat to break up the fat cells.

"They are cooking the tissues," he said of LipoSonix.

Neither company is likely to suffer a shortage of patients for clinical trials. People are sending e-mail messages to volunteer, said Mr. Quistgaard, an ultrasound engineer who seems to be still in transition from the staid diagnostic medical industry to cosmetic surgery.

"I've been quoted in Allure magazine," he said.

A 55-year-old Tel Aviv woman who had the UltraShape procedure on her abdomen recalled the sensation of the ultrasound: "I can feel it, but very very on the surface. It doesn't hurt."

She said the technique had made a "big difference" cosmetically though not big enough. "I can't say it's flat enough; I have to be honest," she said of her tummy after having the procedure once. The woman had already planned to have a tummy-tuck operation a

month later, which was performed. She asked that her name not be used because she did not want friends and relatives to know that she had had the procedures.

One believer in the potential of ultrasound is Dr. Rod J. Rohrich, president-elect of the American Society of Plastic Surgeons and chairman of plastic surgery at the University of Texas Southwestern Medical Center in Dallas.

"This actually might be something that has very good science behind it," said Dr. Rohrich, an adviser to UltraShape who may conduct its American clinical trial. "The Israeli data is good from what I've seen."

But he said that doubt would remain until data were published in a peer-reviewed journal.

Ultrasound is not the sole technique being tried to eliminate fat noninvasively. A drug, Lipostabil, supposedly dissolves fat. Chemically phosphatidylcholine, Lipostabil is a substance made by the body that is involved in fat metabolism. The drug is approved for use in some countries as a means of lowering lipids in the blood, not for injecting into the skin to remove body fat. It is not approved for any pharmaceutical use in the United States, though some doctors are obtaining it, apparently from abroad.

The aesthetic plastic surgery society has raised cautions about the technique, saying just one small study has been published on its use to remove fat, work that involved 30 patients who had minor amounts of fat removed from lower eyelids. One concern, the society said, is whether the drug may destroy other lipid-containing tissues besides fat cells.

Lysix Medical, a new company in Eden Prairie, Minn., hopes to use another technique, electroporation, to destroy fat cells. Electroporation uses electric voltage to open pores in cell membranes. It has been worked on for years for delivering drugs through the skin or into tumors.

H. Ali Jaafar, president of Lysix, said that fat cells would be most susceptible to electroporation because they tended to be bigger than other cells. . So if voltage were applied through electrodes on the skin, fat cells would be hit preferentially. If the voltage were high enough, the pores could not close again, and the cells would die.

Mr. Jaafar said he did not think that it would hurt, though local anesthetic would be needed. The company has tested just on rats and is progressing slowly, it says, because of a lack of money.

If those techniques don't work, there are bound to be others tried. "Everybody," Dr. Rohrich said, "would like to have fat removal without surgery."