McGowan Institute for Regenerative Medicine
A program of the University of Pittsburgh and UPMC

TissuGlu: First Tissue Adhesive Approved by FDA for Internal Use

The U.S. Food and Drug Administration (FDA) has approved a surgical glue known as TissuGlu, making it the first tissue adhesive approved for internal use. TissuGlu was developed by Cohera Medical, Inc., a company spun out of the University of Pittsburgh in 2006. McGowan Institute for Regenerative Medicine faculty member Eric Beckman, PhD, and oral and maxillofacial surgeon Michael Buckley (formerly of Pitt's School of Dental Medicine) developed the adhesive technology in collaboration.

TissuGlu is a biodegradable, biocompatible product that provides surgeons with an alternative to stapling, stitching, or less-effective surgical wound sealants currently used to close large tissue flaps resulting from abdominoplasties (tummy tucks) and other surgical procedures.

"The original collaboration between Michael and myself was targeted at an entirely different technology and clinical issue, where we essentially stumbled upon the potential to create a biocompatible adhesive," said Dr. Beckman, the George M. Bevier Professor of Engineering in Pitt's Swanson School of Engineering. "Clinicians have lacked internal adhesives that are both strong and safe, and it's exciting that TissuGlu is the first internal tissue adhesive to be approved by the FDA."

TissuGlu completed European clinical trials in 2010 and received a CE mark certifying its conformity with European Union health standards in July 2011; Cohera Medical launched its first products in September of that year in Germany.

Surgeons use TissuGlu by using a hand-held applicator to apply drops of TissuGlu liquid. After applying the drops, the surgeon positions the abdominoplasty flap in place. Water in the patient's tissue starts chemical reactions that bond the flaps together and cure the adhesive into a flexible solid. The surgeon then proceeds with standard closure of the skin using sutures. Compared to other options, TissuGlu seals large-lap wounds more effectively, reducing fluid buildup and potentially the need for drains and offering a number of other advantages, including a lower risk of postoperative complications arising from drain use.

"The FDA's approval of the first synthetic adhesive for internal use will help some abdominoplasty patients get back to their daily routine after surgery more quickly than if surgical drains had been inserted," said William Maisel, deputy director for science at the FDA's Center for Devices and Radiological Health.

The FDA's review of TissuGlu included data from a clinical study of 130 participants undergoing elective abdominoplasty. Half of the participants received surgical drains while the other half received TissuGlu and no drains. The study results showed that 73 percent of participants who received TissuGlu required no postoperative interventions to drain fluid that had accumulated between the abdominoplasty tissue flaps. Those who did require intervention, however, were more likely to require another operation to insert surgical drains.

Participants who received TissuGlu without surgical drains were generally able to return to most daily activities such as showering, climbing stairs, and resuming their usual routines sooner than those who had surgical drains. There was no difference between the two groups in reported levels of pain or discomfort due to the surgery.

Read more…

U.S. Food and Drug Administration

Reuters

University of Pittsburgh News Services

Pittsburgh Business Times

Cohera Medical, Inc. Press Release

Cohera Medical, Inc.: TissuGlu Surgical Adhesive

PRNewswire

KFVS-12

Pittsburgh Post-Gazette

VOA News

Back to Home Page