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Excellent lid contour

New material for ptosis repair offers ease of placement, good results

Product can be placed through traditional small incisions with fascia needle or through open eyelid approach

New Product Focus

By Liz Meszaros



Dr. Black

Detroit—Ptose-Up (FCI Ophthalmics Inc.) is a viable alternative to traditional sling materials for ptosis repair. Ease of use, durability, and low complication rates are just some of the benefits of this new material.

“Our experience with expanded polytetrafluoroethylene (ePTFE) shows it to be an ideal material for frontalis suspension,” said Evan H. Black, MD, assistant professor of ophthalmology and director of ophthalmic plastic surgery and orbital disease, Kresge Eye Institute, Wayne State University School of Medicine, Detroit. “Compared with existing materials, it is easier to place, requires less surgical time, and provides excellent lid contour and function with minimal bulk in the eyelid.”

Ptose-Up is manufactured from ePTFE, a derivative of Gore-Tex, and a non-toxic polymer used in various other implantable medical products, including vascular grafts and hernia repair patches. Unlike other implantable materials, ePTFE is biocompatible. Unlike silicone, ePTFE is a porous, solid material.

J.M. Ruban, MD, designed Ptose-Up specifically for frontalis suspension in patients with significant ptosis and poor levator muscle function.

“I became acquainted with the product in Europe in 1999, while observing frontalis suspension ptosis surgery there,” Dr. Black said. “It was not yet FDA approved. I began using it with IRB/HIC approval

for a congenital ptosis study in 2000, which I reported at the annual meeting of the Association for Research in Vision and Ophthalmology. Since FDA approval, I have used the product almost exclusively for repair of ptosis with poor levator function as a frontalis suspension material.”

Easy to place, correct

Ptose-Up is thin and easy to place or remove if necessary. According to Dr. Black, long-term success of 2 to 3 years seems to be good.

“Ease of surgical placement is one of the best features of the product,” Dr. Black said.

“It can be placed through traditional small incisions with a fascia needle, or through an open eyelid approach,” he added. “The bio-integratability and minimal bulk of the product allow the surgeon to achieve results that were previously not possible with alternative materials such as Supramyd.”

The Supramyd is a 3-0 suture that is less than 1 mm thick. Ptose-Up, in comparison, is 2 or 3 mm wide, and this larger size may make for better positioning between the orbicularis muscle and the tarsus.

“It certainly has better longevity than Supramyd suture or silicone slings, in my opinion,” he said. “There are no controlled studies on Ptose-Up versus bank fascia lata or autologous fascia lata, but in my experience, the longevity appears comparable.”

Ptose-Up is 150 mm long and available in a 2- or 3-mm width, with a thickness of 0.35 mm and a porosity of 50 μ m. The product is biocompatible and biointegratable, non-toxic and non-allergenic, and ready-to-use.

Assessing results

Dr. Black undertook a prospective study of 10 eyes

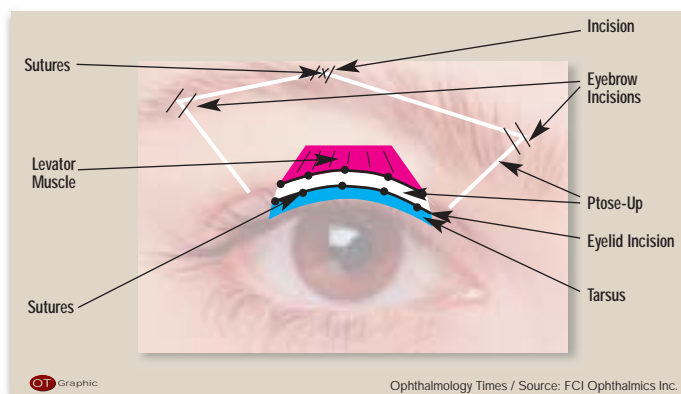


Figure 1 Ptosis repair is easily achieved with the use of Ptose-Up, a product made of expanded polytetrafluoroethylene.

in eight patients with congenital-type ptosis and poor levator function (less than 5 mm). Ptose-Up was placed through eyelid and suprabrow incisions.

At week 1 and 1 month postoperatively, all 10 eyes had a satisfactory marginal reflex distance (MRD) 1, defined for this study as an MRD1 within 1.5 mm of the contralateral eye or 3 to 5 mm in bilateral cases. Nine of 10 eyes maintained this at the 6-month follow-up. Eyelid contour was acceptable in eight of the 10 eyes, with a slight central peaking in one eyelid that may require revision. In the other eye, the sling material slipped off of the tarsus, and reoperation was required at 6 months.

“I now use Ptose-Up almost exclusively for my frontalis suspensions, and I am very pleased with the results,” Dr. Black said. OT

FYI

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Dr. Black did not indicate any proprietary interest in the product.

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