

Using Bioengineered Collagen Matrix During Trabeculectomy

Biodegradable polymer implants show promise for improving the function of filtering blebs.

BY ROBERT RITCH, MD

The burgeoning field of tissue engineering and the related discipline of drug delivery offer tremendous opportunities for improving medical care.¹ Recently, a clinical trial conducted in Taiwan and China investigated the utility of an engineered collagen matrix for preventing the formation of scars after glaucoma drainage surgery. This article presents some of the preliminary results.

BIOENGINEERING BASICS

Surgeons have begun using bioengineered tissue to stimulate the regeneration of cells around poorly healed wounds. These implants are produced by seeding progenitor or precursor cells onto a polymer scaffold

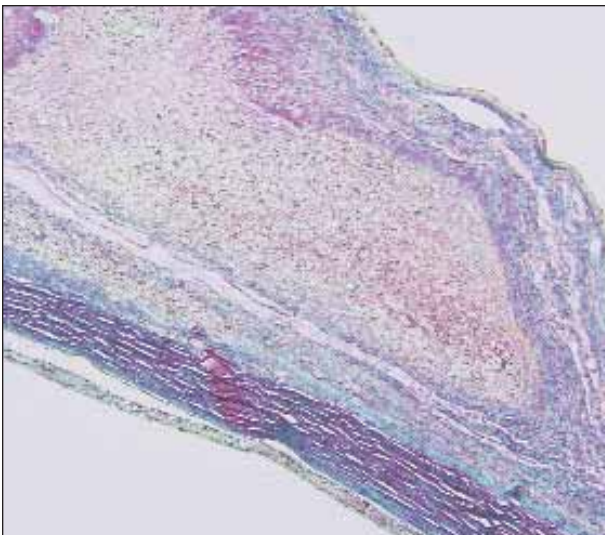


Figure 1. A cross-section from a rabbit eye shows that the Oculugen implant (Life-Spring Biotech, Inc., Taipei, Taiwan) is covered by conjunctival epithelium by 7 days postoperatively.

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and culturing the matrix under conditions that favor the cells' maturation. Species-specific cells, either harvested from tissues surrounding the wound, or cells cultured in the laboratory, including stem cells, can be

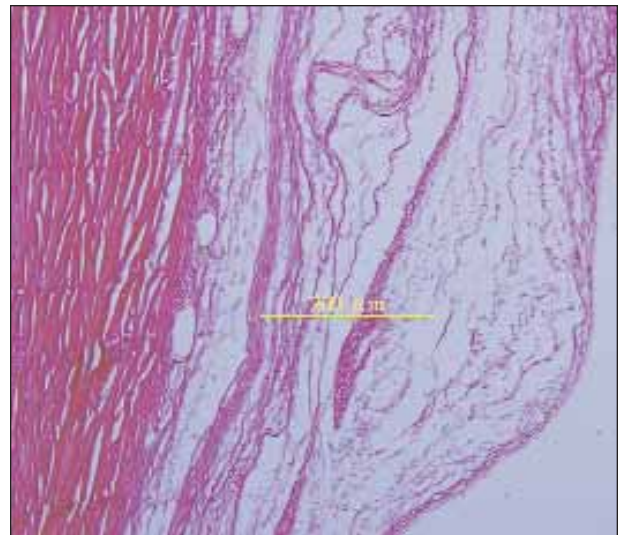


Figure 2. By the 28th postoperative day, the Oculugen implant's polymer matrix has degraded, leaving behind a loose alignment of collagen fibers inside the bleb.

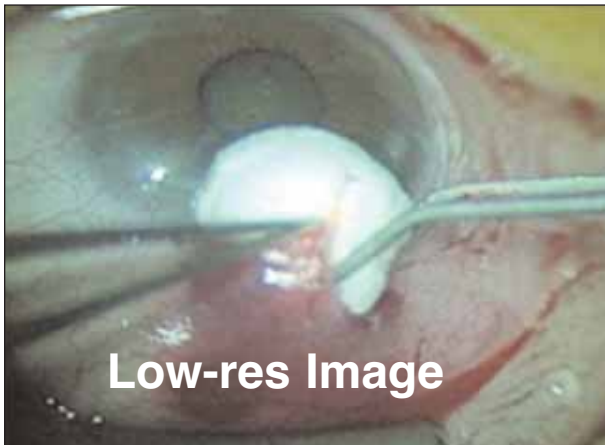


Figure 3. The surgeon places an Oculusgen biodegradable collagen matrix implant in the eye of a patient during a fornix-based trabeculectomy.

used in regenerative processes. Biodegradation of the polymer scaffold results in the formation of structures that are remarkably similar to the normal tissue.

Wei-Chen Hsu, MD, an assistant professor of ophthalmology at Taipei Medical University Hospital in Taiwan, used this concept to develop the Oculusgen biodegradable collagen matrix implant (Life-Spring Biotech, Inc., Taipei, Taiwan). The implant normalizes subconjunctival wound healing and prevents scarring after trabeculectomy by encouraging the random reorganization of regenerating myofibroblasts, fibroblasts, and the secreted extracellular matrix on the scleral surface (Figures 1 and 2). Henry Shen-Lih Chen, MD, a glaucoma specialist and assistant professor of ophthalmology from Chang Gung Memorial Hospital in Taipei, Taiwan, is currently overseeing a multisite, historical, controlled, clinical study of the implant.^{2,3}

RESEARCH RESULTS

Surgeons at Chang Gung Memorial Hospital and Zhong-Shan Hospital of Fudan University, Beijing Hospital and People's Hospital of Beijing University in China, placed the Oculusgen biodegradable collagen matrix into the eyes of 59 patients who underwent trabeculectomy (Figure 3). The implant was placed on top of the scleral flap before suturing.

All but four of the patients were 40 years of age or older. Fourteen of them (23.7%) had primary open-angle glaucoma, 15 (25.4%) had neovascular glaucoma, six (10.2%) had other types of glaucoma, and 21 had undergone previous surgery for the disease. The procedure was defined as a complete success if the patient achieved postoperative IOPs of less than 21 mm Hg without medications.

“The implant prevents scarring ... by encouraging the random reorganization of ... myofibroblasts [and] fibroblasts on the scleral surface.”

Six months postoperatively, the mean IOP among the operated eyes had decreased by 58.3% from 38.7 ± 7.5 mm Hg to 16.1 ± 3.2 mm Hg. Patients who received the Oculusgen biodegradable collagen matrix also used fewer IOP-lowering medications postoperatively (0.3 ± 0.2 vs 2.1 ± 0.9) than they did preoperatively. No significant intraoperative complications were observed, but postoperative complications included transient shallow anterior chambers (6.8%), hyphema (8.5%), and hypotony (13.6%). No endophthalmitis or long-term complications were observed, and the implant had an overall and complete success rate of 98.3% and 89.9%, respectively.

CONCLUSION

Trabeculectomy tends to fail over time as scars form along the filtration pathway, especially in patients who have undergone previous glaucoma surgery. Antifibrotic agents, such as mitomycin C and 5-fluorouracil, are associated with late complications, including cystic blebs, leaking, hypotony, and endophthalmitis.⁴

Preliminary clinical results suggest that the biodegradable Oculusgen implant may be a simple, effective intervention for treating refractory glaucoma that is safer than antifibrotic agents for preventing scarring after trabeculectomy. ■

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