NEW GLAUCOMA IMPLANT
Collagen implant effective at modulating wound healing in filtering surgery
by Dermot McGrath in Abu Dhabi

A new collagen matrix implant could provide a viable alternative to traditional antimetabolites such as mitomycin C (MMC) and 5-fluorouracil in glaucoma filtration procedures, according to Steven R Sarkisian Jr MD.

“Initial results with the Ologen Collagen Matrix Implant (Optous) are very promising indeed and offers the potential for safer and effective glaucoma surgery which avoids most of the dreaded late complications associated with MMC use,” he told delegates attending the World Ophthalmology Congress.

Dr Sarkisian, glaucoma fellowship director at the Dean A McGee Eye Institute and clinical associate professor at the University of Oklahoma in Oklahoma City, US, explained that Ologen is a porcine extracellular matrix made of atelocollagen cross-linked with glycosaminoglycan. The biodegradable scaffolding matrix induces a regenerative wound healing process without the need for antifibrotic agents. The surgeon places the device over the scleral flap during the filtering procedure.

While antimetabolites such as MMC and 5-fluorouracil have traditionally been used to modulate wound healing in glaucoma filtering surgery, complications such as hypotony, wound leaks, and endophthalmitis are often associated with their use, said Dr Sarkisian.

Explaining the concept behind the new implant, Dr Sarkisian said that Ologen works by guiding fibroblasts to grow through the matrix scaffold in a less random fashion, thereby avoiding the ring of steel of scar tissue which limits bleb formation.

“The implant inhibits scar formation by acting as a spacer and prevents the fibroblasts from laying down in organised fashion. The implant is biodegradable in 90 to 180 days or more, leaving in its wake a porous skeleton of connective tissue, although in my experience I have seen the implant present in some fashion even after nine to 12 months,” said Dr Sarkisian.

While the implant has been shown to be efficacious in several animal studies, there are currently no published human studies using the refined version of Ologen, which uses atelocollagen obtained by pepsin treatment and is thus lower in immunogenicity than the previous version of the implant, Dr Sarkisian said.

He added, however, that a large multicentre prospective randomised comparative study of Ologen is currently under way in the US and other studies of the new collagen matrix are also expected in the near future.

“The new version is also thinner than the original Ologen which enables easier laser suture lysis after trabeculectomy,” he said.

Looking at the published data for Ologen without atelocollagen, Dr Sarkisian cited a 2011 prospective randomised study by Cillino et al comparing the safety and efficacy of Ologen as adjuvant compared with low-dosage mitomycin C in 40 patients with two-years’ follow up.

“They found that the final mean pressure was 16 mmHg in the mitomycin C group and about 16.5 mmHg in the Ologen group compared to mean preoperative IOP of 26.5 mmHg and 27.3 mmHg for MMC and Ologen respectively,” he said. There was no difference in the rate of complete and qualified success between the two groups, but there was a higher bleb height in the Ologen group,” he said.

Another study by Rosentreter et al in 2010 showed an advantage in terms of IOP lowering for MMC compared to Ologen in 10 patients. Although the complete success rate was lower for the Ologen group, the bleb morphology was significantly better for patients treated with the collagen matrix, said Dr Sarkisian.

A more recent consecutive retrospective case series by Dr Sarkisian looking at trabeculectomy with the ExPress glaucoma shunt (Alcon Laboratories) and the newer version of Ologen found a qualified success rate of 94.4 per cent at 12 months in 36 eyes.

“Five of the 36 patients were on medications, and the average pressure was 12.1 mmHg at 12 months. So it does seem that the pressure seems to be better controlled with the newer version of Ologen, although clearly this needs to be confirmed in further randomised studies with longer follow up,” he said.

Clinical experience. Dr Sarkisian also offered some pearls for getting the best from Ologen based on his own clinical experience. Patient selection is critical, he said.

“I use Ologen in about 90 per cent of my glaucoma filtering surgeries but that may differ based on your patient population. I usually do not open the Ologen until I have started the surgery and made the conjunctival incision. If the Tenon’s capsule is very thick, which is often the case in younger patients, I might use MMC instead. I do not use both, I pick one or the other,” he said.

“Patients with thicker Tenon’s capsules tend to have a lower success rate anyway with glaucoma surgery,” said Dr Sarkisian.

“I might even use MMC for three minutes in those patients or even longer. It is also important to remember that you cannot titrate Ologen as you would with MMC as the methodology of wound modulation is fundamentally different,” he said.

While some surgeons have found suture lysis problematic with Ologen due to poor visualisation through the collagen and conjunctiva, Dr Sarkisian said that using a Blumenthal suture lysis lens helps to deal with this issue.

Finally, Dr Sarkisian warned against treating Ologen patients in the same way as those being treated with mitomycin C.

“This means not using three to seven sutures in the flap and not tying the sutures too tightly. Ologen will tamponade the flap if it is placed correctly. It is also important not to wait three weeks before cutting the sutures,” he concluded.

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