Liquid bandage for ocular use set to enter CE mark trials

AN INNOVATIVE polymer liquid bandage could provide an alternative to conventional sutures and cyanoacrylate adhesives for closing corneal incisions and wounds.

In addition to dressing corneal lacerations and bandaging corneal transplants, OcuSeal (HyperBranch Medical Technology, Durham, NC) may prove useful in controlling leakage and preventing infections in clear corneal incision cataract surgery, researcher Terry Kim, MD, of Duke University, Durham, US, told a symposium at the XXIV ESCRS Congress.

"We are all aware of the potential link between the increased incidence of endophthalmitis in cataract surgery and clear corneal incisions. The peer-reviewed literature suggests that endophthalmitis rates can range from three to 15 times higher for clear corneal incisions compared with scleral tunnel incisions. The ESCRS Endophthalmitis Study Group identified clear corneal incisions as a risk factor of endophthalmitis after cataract surgery with an odds ratio of 7.4," he said.

A hydrogel bandage holds promise for reducing the chances of infection by sealing the wound through which microorganisms might gain access to the anterior chamber and vitreous after surgery, without the added risk of conventional sutures, said Dr Kim. This may be especially valuable in managing eyes with poorly constructed incisions or low intraocular pressures, both of which have a higher risk for leakage anywhere from a few minutes to several hours after surgery, creating an extended opportunity for infectious agents to enter the eye, said Dr Kim, who helped to develop the product.

OcuSeal may also be used for protecting corneas from other procedures such as pars plana vitrectomy and treating complications related to LASIK surgery and filtering blebs.

Advantages seen over sutures and self-sealing
Applied to the eye as a solution consisting of a custom-designed biocompatible dendritic macromolecule and polyethylene glycol, OcuSeal forms a hydrogel that conforms precisely to the tissue surface and polymerizes into a form-fitting seal in about 30 seconds. The material cures in a mesh polymer network with pore sizes ranging from one to three microns. The set bandage is smooth, soft, flexible, low in profile and completely transparent.

In theory, this hydrogel technology offers several advantages over current surgical closure techniques. By sealing the wound, it may reduce the risk of fluid leakage and the possibility of infection present in self-sealing incisions. By sealing the wound without inducing additional perforations or introducing foreign materials onto the ocular surface, it may reduce the risk of irritation, infection or vascularisation associated with conventional sutures. HyperBranch, the company that makes OcuSeal, is developing similar materials for use in treating brain aneurysms and pleural effusions and draining fluid from wounds.

In preclinical tests on enucleated eyes, OcuSeal-treated wounds have been shown to withstand substantially higher intraocular pressures without leaking than self-sealing wounds or wounds closed with conventional sutures. In tests on rabbit eyes, OcuSeal adhered to undamaged corneas for about one day, to abraded corneas for about 1.5 days, and to scored corneas for more than six days.

The material has passed standardised FDA biocompatibility tests demonstrating that it is not an irritant, mutagenic, cytotoxic or a sensitising agent. It biodegrades as corneal tissue heals beneath it. However, the substance has not yet entered trials for FDA approval in the US.

In vitro studies presented by Dr Kim at the ESCRS Congress also showed that the material is 99 per cent effective in blocking transmission of two common endophthalmitis infectious organisms, Pseudomonas aeruginosa and Staphylococcus aureus and their by-products, for at least 24 hours. These tests involved incubating a concentrated sample of the bacteria on an OcuSeal barrier applied to agar that was treated to turn colour in the presence of the bacteria or its by-products. Of 150 samples, none showed penetration within 24 hours.

Dr Kim also presented interim results of early clinical trials on five human patients with healthy corneas. On average, the OcuSeal bandage stayed in place for a little over one day on the undamaged eyes in these early tests. The bandage caused no change in best-corrected visual acuity or intraocular pressure. Follow-up exams at one, three, seven, and 30 days showed no complications or adverse events. None of the subjects experienced any discomfort, and all eyes were quiet with no abnormal findings on slit-lamp examination.

So far, the results from early human testing have been consistent with the results found in our rabbit studies, Dr Kim said.

"It does not adhere as well to a surface with an intact epithelium. However, if there is an epithelial defect we have observed the adhesive to stay on the ocular surface longer. The bandage spontaneously detaches once the epithelium heals. The preliminary results suggest that the OcuSeal ocular bandage could be a safe and effective alternative for sealing ocular wounds," Dr Kim said.

OcuSeal is slated to begin clinical trials for the CE mark this spring in Europe. If the tests are successful, the product could be available in Europe by year's end.