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Amniotic membranes can ease the eye pain

The cornea is one of the most innervated tissues in the body. When the corneal nerves undergo damage from various causes (such as refractory dry eye, corneal burns and infections, refractive surgery, among others), abnormal nerve regeneration along with pain signals may be triggered and, therefore, neuropathic corneal pain (NCP) can result. Symptoms typically include chronic sensations of pain, which can be spontaneous or particularly triggered by wind and light, and are often disproportionate to the eye exam observations.

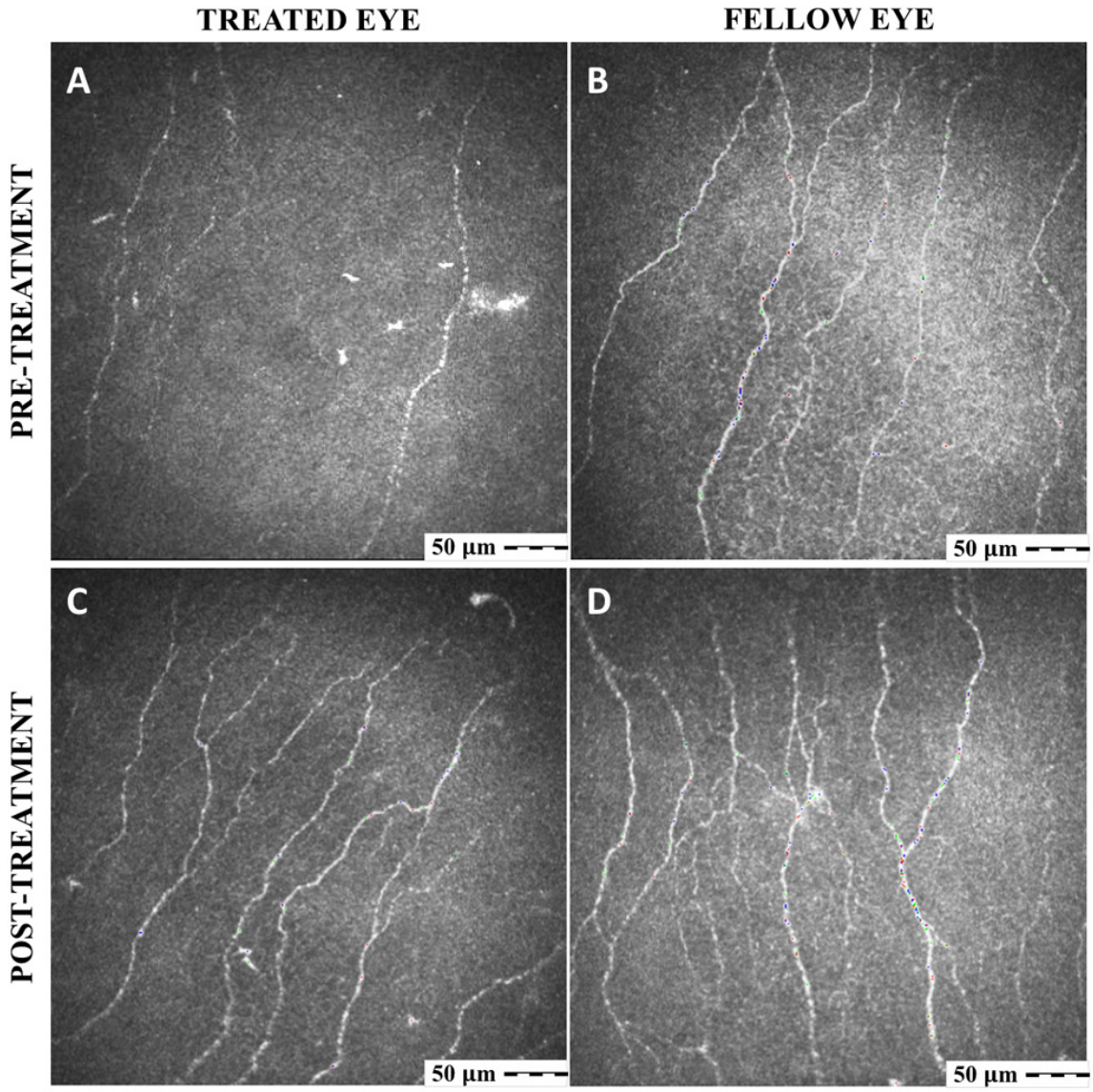

Fig. 1. Representative IVCM images before (A, B) and 63 days after Prokera placement (C, D) of treated and untreated eyes, respectively.

The lack of distinct clinical findings has posed a great diagnostic and therapeutic challenge to eye care community, but recent advances in the understanding of the pathophysiology of neuropathic pain have fortunately shed light on its diagnosis and management.

One of the most significant diagnostic advances has been the identification of abnormal morphological nerve changes by *in vivo* confocal microscopy (or IVCM, an in-office non-invasive ‘‘optical biopsy’’), which demonstrates decreased corneal nerve density, microneuromas (abrupt and engorged nerve endings), nerve tortuosity and beading (small beads along the nerves), as well as different degrees of inflammation, confirming the presence of the neuropathy.

Treatment remains intricate. Since there is no single therapeutic agent found to date that fully suppresses neuropathic symptoms, a combination of multiple therapeutic agents is usually necessary. This includes neuro-regenerative therapies intended to restore neuronal integrity and functionality (such as autologous serum tears), anti-inflammatory agents that minimize nerve degeneration from uncontrolled inflammation, and systemic pharmacotherapy, which consists in antidepressants (nortriptyline and duloxetine), alpha 2 delta ligand anti-epileptics (gabapentin and pregabalin), anticonvulsants (carbamazepine), and opioid-antagonist and opiate analgesic (low dose naltrexone and tramadol). Given the potential side-effects of these systemic medications, there is strong interest in developing new low-risk treatment modalities, as well as quick-acting options for patients in need of acute pain control.

The sutureless amniotic membrane implant Prokera (Bio-Tissue, Miami, FL) consists in a cryopreserved amniotic membrane attached to a supporting polycarbonate ring. It has been utilized with positive results in multiple ocular surface disorders, such as neurotrophic ulcers, presumably from its neuro-regenerative and anti-inflammatory effects. This rationale motivated us to evaluate the efficacy, safety, and tolerability of Prokera in the treatment of neuropathic corneal pain.

We placed Prokeras in 10 eyes of 9 patients. Baseline treatments were unchanged. Pain severity improved by 73% after an average retention time of 6.4 days. Ring intolerance and earlier removal after an average of 4 days was seen in 5 eyes, with nevertheless still significant pain reduction by 63%. IVCM showed a 36% increase in total nerve density and a 30% decrease in inflammatory cells (see example images in the Fig. 1). In 80% of the treated eyes, pain control was sustained for more than 9 months.

This is, to our knowledge, the first study to describe encouraging findings after Prokera placement in patients with NCP, based on rapid and sustained improvement of pain severity, and increase in corneal nerve density and decrease in inflammatory cells as shown by IVCM.

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