

Letter to the editor: PROKERA® slim corneal bandage now approved in Taiwan for treatment of corneal diseases

Dear Editor,

In the January–March 2020 editorial in the *Taiwan Journal of Ophthalmology*, I briefly discussed the use of PROKERA® as an amniotic membrane (AM) corneal bandage to reduce inflammation, promote healing, and restore ocular surface health in patients suffering from dry eye disease (DED) and/or neurotrophic keratitis (NK).^[1,2] PROKERA® is the only medical device designated by the U. S. Food and Drug Administration (FDA) for eye conditions involving damage to the ocular surface cells or underlying stromal inflammation or scarring. Cleared by the FDA in 2003, PROKERA® has been the U. S. market leader for >15 years and is used by thousands of eye care professionals worldwide. Herein, I wish to provide supplementary information regarding a subclass of PROKERA® called PROKERA® Slim and expand upon its use for various clinical indications.

PROKERA® Slim was recently approved for use by eye care professionals in Taiwan, expanding its commercial availability beyond the United States, Canada, and the Philippines. As a part of the PROKERA® family of products, PROKERA® Slim is a cryopreserved AM corneal bandage that is processed using the CryoTek® method, which devitalizes all living cells to eliminate the possibility of graft rejection while retaining the key components that are responsible for the tissue's anti-inflammatory and anti-scarring properties (as summarized in January–March 2020 issue by Tighe *et al.*^[3]). While PROKERA® Slim provides the same anti-inflammatory benefits as PROKERA® Classic, there are a few key differences in their design and indicated uses. PROKERA® Classic comprises two polycarbonate rings that fasten the AM tissue and act as a symblepharon ring, while PROKERA® Slim utilizes only one polycarbonate ring for a slimmer profile. The overall reduced height of PROKERA® Slim (0.7 mm compared to 1.1 mm with PROKERA® Classic) enables the device to better contour the ocular surface and move with the eye, ultimately providing better surface contact and enhanced comfort. As a result, the use of PROKERA® Slim eliminates the need for tape tarsorrhaphy in the general population, which is often implemented with the placement of PROKERA® Classic to keep the device centered and minimize discomfort.

While PROKERA® Classic is often indicated for moderate-to-severe conditions such as Stevens-Johnson syndrome and ocular burn, PROKERA® Slim is well-suited for patients with mild-to-moderate ocular surface disease such as herpetic keratitis, recurrent corneal erosions, and DED. Because PROKERA® Slim can promote corneal nerve regeneration and improve corneal topography in DED patients,^[4] it can also be beneficial in treating more advanced cases that manifest superficial punctate keratitis or even corneal ulceration (as summarized in January–March 2020 issue by Mead *et al.*^[2]). Brocks *et al.* recently demonstrated the healing of recalcitrant corneal ulcers with and without NK in a median of 14 days, which was accompanied by the significant improvement in ocular discomfort and corneal staining.^[5] PROKERA® Slim can also be used to improve postsurgical wound healing. In one study, PROKERA® Slim demonstrated superior healing outcomes compared to bandage contact lens (BCL) following superficial keratectomy.^[6] Complete re-epithelialization was achieved in 70% of eyes treated with PROKERA® Slim by postoperative day 5 compared to only 20% of eyes treated with BCL. Furthermore, 80% of eyes treated with PKS had absolute corneal clarity at 1 month, whereas all eyes treated with BCL exhibited haze and/or scarring. Overall, the availability of PROKERA® Slim in Taiwan will offer corneal specialists a slimmer profile device to treat a variety of ocular surface diseases.

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Nil.

Conflicts of interest

S.T. has obtained a patent for the method of preparation and clinical uses of amniotic membrane and has licensed the rights to TissueTech, Inc, which procures and processes, and to Bio-Tissue, Inc., which is a subsidiary of TissueTech, Inc., to distribute cryopreserved amniotic membrane for clinical and research uses.

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