Annals of Medicine and Surgery 82 (2022) 104630

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu

Perspective

"Pig skin corneal tissue: A new hope for Low Middle-Income Countries?"

More than two hundred million people suffer from visual impairment, corneal disease being among the top five causes of blindness worldwide [1]. Etiologies vary geographically and include Fuchs endothelial dystrophy, keratoconus, and infectious and non-infectious keratitis, the latter two being the most prevalent causes outside of the United States. In a pilot study published on August 11, 2022, Rafat et al. tested a bioengineered porcine construct, double crosslinked (BPCDX) which is a corneal tissue made from collagen fibers found in pig skin. This trial was carried out on twenty keratoconus patients with minimally invasive surgery to graft the BPCDX without the removal of existing tissue [2]. Previously, treatment options like Penetrating Keratoplasty (PK), Deep Anterior Lamellar Keratoplasty, and other types of transplantations were available in addition to non-surgical therapies for trachoma (the leading cause of keratitis), vitamin A, and better food and overall hygiene [1]. While the latter non-invasive options are not a cure, transplantations are subject to delays due to the shortage of cornea donors and banks, especially in Low Middle-Income Countries (LMICs). On the other hand, BPCDX suffers no such reliance and showed no side effects during the 2-year follow-up period in the feasibility study. PK and DALK have been the most popular surgeries so far because of their unparalleled improvements in the visual acuity of patients. The results of this trial suggest that BPCDX can surpass even these improvements. Furthermore, 100-percent of the blind patients enrolled in the trial were cured by the follow-up time [2].

Currently, the only treatment available for corneal blindness is a corneal transplant. Keratoconus is a condition in which a person's cornea thins and bulges outward, and while this condition rarely results in complete blindness, it can cause considerable vision impairment and partial blindness. At present, the only treatment options available for keratoconus manage symptoms and slow down its progression. For people with advanced keratoconus there was no hope, until now. BPCDX is a bioengineered corneal tissue that is acellular, transparent, implantable, and made of natural type 1 collagen that is already FDA-approved and used in the medical industry [2]. Due to the delicate nature of pure collagen and its susceptibility to deterioration, the researchers used dual chemical and photochemical crosslinking. BPCDX mimics the human cornea in its stiffness and transmission of light. It does not irritate, breed infections or cause epithelium stratification, remaining well-tolerated overall.

At present, corneal blindness is treated by corneal transplants from human donors, and while developed countries have an effective donor system, LMICs simply cannot compete [3]. Not only is it hard to get viable donors in LMICs but these human implants require personnel, buildings, and equipment for them to be harvested post-mortem, tested for pathogens, assessed for graft rejection risk and specific short-term storage. This in turn increases the possibility of them being sourced through illegal or non-consensual ways. BPCDX solves all these problems; It can be easily dispensed and stored for up to 2 years at room temperature or refrigerated without any special medium while maintaining its transparency and mechanical properties. These implants are transplanted by a minimally invasive surgical technique that does not require the removal of native corneal tissue. A single corneal incision is made that promotes rapid wound healing, normalizes refractions, and prevents stromal thickening, unlike conventional corneal transplants that require long surgeries and result in several postoperative complications like abscess formation and astigmatism [4]. The suture-free technique for transplanting BPCDX corneas requires fewer resources, reduces hospital stay and follow-up hospital visits, making it more suitable for resource-limited LMICs.

However, it should be noted that this trial was a pilot study with a small sample size and a follow-up period of only 2 years. Consequently, some drawbacks of BPCDX might have been overlooked. Additionally, LMICs being rich in culture and religion, the believers of Judaism, Islam, and Hinduism might have reservations towards these porcine transplants [5].

Ninety-eight percent of people who have corneal blindness reside outside of developed countries. Together, Africa and East Asia account for about 50% of all cases of corneal blindness worldwide [1]. Rafat et al. designed BPCDX to address this burden, and although this innovation comes with a few concerns, it cannot be denied that it also opens a lot of doors for LMICs. Randomized Controlled Trials need to be performed using a larger sample size to further evaluate its efficacy and safety for treating advanced keratoconus. Researchers also need to investigate ways to source collagen type 1 from organisms that are permissible for different religions, such as marine sources. BPCDX's effectiveness should be assessed for treating other causes of corneal blindness as well as looking into ways to make the production even more cost-friendly so that LMICs can manufacture it locally. If these measures are taken, this existing burden of corneal blindness on LMICs may finally be lifted.

Ethical Approval

N/A.

Sources of funding

No funding.

Author contributions

Naima Khan: Conceptualization, Writing - Original Draft, Writing - Review & Editing, Visualization.

Hafsah Alim Ur Rahman: Writing - Review & Editing, Visualization.

https://doi.org/10.1016/j.amsu.2022.104630
Received 26 August 2022; Accepted 4 September 2022
Available online 8 September 2022

Madiha Salman: Writing - Review & Editing, Visualization.

Trial register number

1. Name of the registry: N/A
   2.Unique Identifying number or registration ID: N/A
   3.Hyperlink to your specific registration (must be publicly accessible and will be checked): N/A

Guarantor

Naima Khan.

Consent

N/A.

Declaration of competing interest

None.

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