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Short Communication

Identifying the Mechanism of Action of Modified T-Lymphocytes in Cancer Organoids from Patients

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INTRODUCTION

Among the main causes of blindness worldwide, poor refractive function and corneal transparency loss rank first. Despite the fact that corneal blindness can be treated by transplantation, 12.7 million people are thought to be waiting for a donor cornea, with just one cornea being available for every 70 needed. With approximately 1 million new cases of corneal blindness each year, the burden of blindness is unequally distributed, primarily favoring low- and middle-income countries (LMICs) in Asia, Africa, and the Middle East. Due to the absence of infrastructure for tissue donation, harvesting, testing, and eye banking in LMICs, more than half of the world's population does not have access to corneal transplantation (Mahdavi SS et al., 2020). Economic, cultural, technological, political, and ethical constraints all play a role in the access dilemma. Further steps must be taken to assure the safety of donor tissue since infectious illnesses and pandemics effectively halt the procurement and use of donor tissue.

While keratoconus progresses, its complicated and poorly understood aetiology. Keratoconus progression can be detected and stopped in its early stages while vision is still good with appropriate screening and access to specialist care; however, if not addressed early and in LMICs where keratoconus is highly prevalent and access to healthcare is limited, the disease frequently progresses. To prevent blindness in advanced stages, transplantation is necessary (Parker JS et al., 2015). This is done through procedures like penetrating keratoplasty (PK) or deep anterior lamellar keratoplasty (DALK).

However, these procedures are constrained by the scarcity of donor corneas, the possibility of graft rejection, postoperative complications related to sutures and wound healing, the possibility of corneal neovascularization and/or infection, the need for long-term immunosuppression, and the requirement for long-term patient follow-up. Newer, less invasive procedures such stromal lenticule addition keratoplasty and Bowman layer transplantation have been developed to partially address these problems. These treatments, while promising and yet in development, stabilize the condition but only slightly enhance vision. They also rely on infrastructure for tissue banking and the availability of donor corneas, making them unavailable in many parts of the world (Geerards AJ et al., 2006).

We bioengineered a cell-free implantable medical device to replace human corneal stromal tissue in order to overcome these constraints. We employed natural type I collagen, which is the primary protein in the human cornea, as our starting material. We employed medical-grade collagen derived from swine skin, a purified byproduct from the food industry, which is already used in FDA-approved medical devices for glaucoma surgery and as a wound dressing, to create a plentiful yet affordable and cost-effective supply of collagen.

In a prior clinical study, we assessed implants made from recombinant human collagen, but these implants had a number of drawbacks: the collagen could only be produced in small amounts; the implants were mechanically feeble and needed invasive suturing; the implants had not been tested for long-term stability; and the surgery was invasive and resulted in partial implant melting. Here, we overcame these drawbacks by utilizing type I medical-grade porcine dermal collagen, creating a novel double crosslinking technique to enhance implant strength and stability, and utilizing a novel minimally invasive surgical implantation technique to encourage corneal thickening, reshaping, and quick wound healing (Mathur V et al., 2013).

Pure collagen is a delicate substance prone to deterioration, therefore we used dual chemical and photochemical crosslinking to create the bioengineered porcine construct,

a transparent implantable hydrogel (BPCDX). Compared to our previous porcine collagen-based materials29–31, BPCDX is an improvement that has also been photo chemically cross-linked using the UVA-riboflavin crosslinking method. The biocompatibility, toxicity, carcinogenicity, sensitization, and irritation of BPCDX were evaluated using in vitro and in vivo assays in mice, guinea pigs, and rabbits. It also underwent a panel of third-party certified medical device tests that were compliant with ISO standards. BPCDX was manufactured in good manufacturing practices (GMP)-certified clean room in accordance with strict quality processes.

Another difficulty is getting devices to various areas, including perhaps remote ones without bio banking, storage, or tissue processing capabilities. In order to compare the optical, mechanical, chemical, and sterility characteristics of the fully packaged BPCDX as-made and after storage for up to two years, we developed compatible packaging and sterilization processes, tested packaged devices in accelerated and real-time ISO shelf-life stability studies, and addressed this issue (Sung MS et al., 2014).

DISCUSSION

Our findings show that reversing the pathological corneal thinning and distortion in advanced keratoconus can be accomplished safely and effectively through intrastromal implantation of a cell-free bioengineered collagen-based material. Transparency was kept after BPCDX implantation without deterioration, scar formation, adverse reactions, or events necessitating hospitalization, intensive therapy, or additional surgical intervention—meeting safety criteria.

The only method that, to date, combines a chemical and photochemical technique for double crosslinking to stabilize collagen in a viscous form and avoid using a lot of harsh cross linkers while limiting cytotoxicity is called BPCDX. The BPCDX significantly differs from earlier materials tested on humans due to its high level of raw collagen purity, vacuum evaporation process that results in a high collagen content, increased chemical-cross linker-to-collagen ratio, and optimized photochemical crosslinking, in addition to other crucial biomaterial properties.

Due to these characteristics, the material is more stable after being transplanted into humans than in a prior clinical investigation, where the implanted biomaterial thinning post-operatively. Furthermore, to our knowledge, no prior study has shown the viability of a GMP-grade cornea that was bioengineered from a raw material that was sustainably derived, affordable, broadly accessible, and FDA-approved.

No other technique has ever accomplished ISO-compliant, independently third-party validated manufacturability, packaging, sterility, and long shelf life. However, these sometimes disregarded factors are crucial for practically addressing the global shortage of donor corneal tissue. In terms of safety, the majority of preclinical and clinical investigations conducted to far did not show any evidence of BPCDX causing thinning, loss of transparency, neovascularization, rejection, or other adverse events to varied degrees. From an efficacy perspective, no prior study has, to our knowledge, achieved full corneal transparency in vivo with sufficient corneal thickening and flattening, or with significant visual acuity gains as reported here; at best, modest vision gains have been achieved in prior studies, though with post-operative complications or with the use of human donor tissue; the current study, however, represents the first to achieve these results.

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