生醫材料薄膜培養人類腎小管細胞之組合物

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市場及需求:

根據器官捐贈移植登入中心資料顯示，目前國內每年約有 700 人在等待適合的角膜，去年角膜捐贈人數約 500 人，並且因配對困難等因素，國內角膜需求仍然不足，許多病患等候時間過長或轉向費用昂貴的國外眼庫。捐贈角膜從捐贈者處取出至完成移植，捐贈角膜的內皮細胞會因運送時間及震盪或手術過程而減少約 20~25%，導致植入的角膜內皮細胞受損或其他不良影響，使移植成功率下降，因此發展穩定而同樣具有角膜內皮細胞功能之自體細胞生醫材料組合物是非常具有市場潛力的。

資料來源：臺灣國家眼庫、財團法人器官捐贈移植登錄中心、臺大醫院眼科部

技術摘要(含成果):

本技術係將人類自體近端腎小管細胞培養在生醫材料薄膜上，利用近端腎小管細胞之水幫浦的功能，來達到替代損傷之角膜內皮細胞層，將角膜積水排除以修復視野。

優勢:

現有的角膜內皮損傷治療仍是以捐贈角膜移植取代整個角膜為主流，然而捐贈角膜存在來源不足以及排斥反應等風險，人工角膜仍在開發階段且同樣存在排斥反應等風險。本技術係以病患自體近端腎小管細胞培養在生醫材料薄膜上，再植入角膜內皮層，無需移植整個角膜，傷口極小，且因使用自體細胞無排斥風險，可取代需換置完整角膜以修復角膜內皮層受損所致之角膜病，進而達到減少捐贈角膜的需求及改善捐贈角膜來源不足與人工角膜不穩定的情形。

競爭產品:

目前角膜內皮損傷仍以全角膜置換手術(Descemet's Stripping Automated Endothelial Keratoplasty, DSAEK)或微創角膜後彈力層內皮移植手術(Descemet Membrane Endothelial Keratoplasty, DMEK)為主要的治療方法；而人工角膜仍在研發階段， 尚未能廣泛正式應用。

專利現況:

本研究團隊具有多年開發生醫材料及組織工程之經驗，主持人近年來更積極從事專利發表與產學合作，目前已有 28 件專利，其中更有生醫材料薄膜相關的專利，如：中華民國專利號 I454291、中華民國專利號 I515024，等等。

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Combination of human renal proximal tubule cells on biomedical material

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Market Needs:

According to Taiwan Organ Registry and Sharing Center, about 700 people are waiting for a suitable cornea every year in Taiwan, whereas the number of cornea donors was about 500 in 2018. Due to pairing difficulties, domestic corneal demand is still insufficient, which leads to long waiting time or expensive foreign eye banks. The endothelial cells of the donated cornea may be reduced by 20% to25% due to factors such as transit time, poor preservation or surgery, resulting in lowering transplant success. Therefore, developing a stable biomedical material product to maintain the functions of corneal endothelial cell layer is highly necessary.

Our Technology:

The technology involves a combination product of culturing autologous human renal proximal tubule cells (hPTCs) on biomedical material membrane, which is meant to replace the damaged corneal endothelial cells in order to exclude the cornea edema through water-pumping function of renal proximal tubule cells.

Strength:

The existing treatment for corneal endothelial dysfunction is mainly DSAEK or DMEK which the whole cornea is transplanted. However, limited donor cornea and possible allograft rejection after transplantation are still an issue. Although other scientists more likely focused on the development of artificial cornea or differentiated stem cells transplantation, our technology uses combination of autologous renal proximal tubule cells (PTCs) cultured *ex vivo* on biomaterial membrane to implant onto the back of the cornea. This technology minimizes the cut as it does not require whole cornea transplantation. Moreover, autologous cell transplantation does not require immunosuppression treatment. Our technology has the capability to reduce the need of whole cornea transplantation, limited donor cornea and the unstable of artificial cornea for corneal endothelial dysfunction while being an alternative clinical use.

Competing Products:

At present, Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK) or Descemet Membrane Endothelial Keratoplasty (DMEK) are still the major treatment for corneal endothelial dysfunction. Artificial cornea is still in developing or clinical trial state, which are not yet formally used.

Intellectual Properties:

The research team possesses many years of experience in the development of biomaterials and tissue engineering. The host has been actively engaged in patent publication and industry-university cooperation in recent years, and 28 patents, including some biomaterial membrane related patents, has been approved.

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