

ANIMAL COMPOUND-FREE CORNEA STORAGE MEDIA STEM ALPHA: DATA VALIDATION OF TWO CORNEA BANKS AND PATIENTS FOLLOW-UP

Auxenfans Céline¹, Kocaba Viridiana², Febvay Camille², Burillon Carole², Muraine Marc³, Damour Odile¹

¹Banque de tissus et cellules des Hospices Civils de Lyon – Lyon, France; ²Service d'ophtalmologie, Hôpital Edouard Herriot – Lyon, France; ³Banque Française des Yeux – Paris, France

PURPOSE

The benefits of Stem Alpha (SA) corneas storage media are first to be free of animal compound and second the absence of dextran which is replaced by poloxamer 188 in the deswelling medium. These media (transport medium: Stem Alpha 1, storage medium: Stem Alpha 2 and deswelling medium: Stem Alpha 3) obtained in 2007, after validation of their quality, their safety and efficacy in vitro, a French marketing authorization Annex Therapeutics Product. However, clinical data were requested from banks wishing to use them. We present patients follow up (BTC/HCL) and the impact of using these media in two corneas bank in Lyon (BTC/HCL) and Paris (Banque Française des Yeux).

METHOD

In vivo validation, carried out in order to obtain authorization to use the stem Alpha media focused on a comparative study: for five couples of corneas collected in Lyon, one cornea was preserved in Eurobio and the other one in Stem Alpha, corneas were transplanted and patients followed for 16 months. After authorization obtention, the rate of corneas eliminated between the first (at 7 days of storage) and the second endothelial controls (48 to 72 hours before transplantation) and the rate of corneas eliminated for poor endothelial density were followed. In addition, a retrospective study included 150 patients transplanted with corneas stored in Stem Alpha was performed.

RESULTS

The preliminary clinical study showed a post operatory patient follow up in accordance with the practice. Endothelial densities measured at 16 months post-transplant were consistent with practice, given the initial condition of the patients. They are also close to the theoretical endothelial density calculated from the formula proposed by John Armittage who modeled the corneal endothelial cell loss as a decrease in two phases: an early phase related to the conservation and surgical trauma, and a late phase related to aging. This in vivo validation allowed us to obtain authorization to use Stem Alpha media. Monitoring of endothelial densities showed that only 4.6 % of corneas stored in alpha stem, validated at first endothelial control are eliminated in the second one, which is very low compared to corneas stored in our previous media (20.2% in 2011) In addition, the average density of endothelial corneal distributed is 2712 against 2520 the year before the change of storage media. The rate of eliminated corneas for poor endothelial density is, in the Banque Française des Yeux in 2012 with Stem alpha media is 16.8% versus 31% in 2010 with the previous media. Some ungrafted corneas (transplantation cancelled for clinical reasons) were recounted after 7 days in Stem Alpha 3 without endothelial cell loss. The absence of dextran could explain this good storage. We also present the results of a retrospective study included 150 transplanted patients, data being analyzed.

CONCLUSION

Stem Alpha is a medium without animal component that allows optimal preservation of endothelial cells with good tolerance and effectiveness of transplanted corneas.