11-1-2021

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Recommended Citation

Chang DD, and Han JJ. The TransMedics Organ Care System for the Liver receives FDA pre-market approval. Artif Organs 2021.

DOI: 10.1111/aor.14115

Artificial Organs WILEY

NEWS

The TransMedics Organ Care System for the liver receives FDA pre-market approval

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The Federal Drug Administration grants pre-market approval to TransMedics Organ Care System Liver, a platform designed to prolong donor organ viability via ex vivo perfusion in preparation for transplant

On September 29, 2021, the FDA granted pre-market approval to TransMedics (*Andover, MA, USA*) OCS Liver system, following the approval of the OCS Heart on September 7 and the OCS Lung in April 2018. The TransMedics OCS Liver is now the only FDA-approved ex vivo perfusion system to prolong the viability of donor livers.

Organ preservation is a critical process to ensure successful organ transplantation. Poor donor organ viability can have devastating consequences for recipients. The current standard for transporting donor organs is cold static storage (around 4°C), which bathes the organ in perfusate and cools the organ to drive down its metabolic demand and to preserve tissue viability.

However, this is only a temporary measure because organs eventually incur ischemia-mediated injury over time, with heart and lungs generally limited to a 4- to 6-h window, liver to 12 h, and kidneys to 24 h. Furthermore, cold storage transport does not allow for dynamic monitoring of the organ itself, meaning donor organ performance cannot be confirmed until after implantation.

Ex vivo perfusion systems are artificial platforms designed to mimic the physiological conditions of the organ after harvest, thereby limiting ischemic injury and simultaneously providing real-time organ performance during transport.

The FDA based its decision on the OCS PROTECT trial (NCT0252287): a multi-center, randomized controlled trial with 300 liver transplant recipients either randomized to control ischemic cold storage ($n = 147$) or OCS ($n = 153$) for donor liver preservation. The findings were presented in June of 2021 at the American Transplant Congress. The importance of their findings was recognized as they were awarded the winner of The People's Choice Award for Most Impactful Presentation at the American Transplant Congress.

The primary effectiveness endpoint was the incidence of early allograft dysfunction, and the primary safety endpoint was the number of serious adverse events related to liver grafts. OCS-preserved livers had lower rates of early allograft dysfunction compared to organs kept in ischemic cold storage (17.3% vs. 30.5%). They also observed lower rates of ischemic biliary complications using the OCS device compared to their ischemic cold storage counterparts one year after transplant (2.6% vs. 9.9%).

The utility of the OCS Liver system in expanding the donor pool was also evident as nearly twice as many donations after circulatory death (DCD) livers were able to be safely transplanted compared to the control group (45.9% vs. 24.5%).

These results, now accompanied by the FDA approval, mark a very exciting era in the field of organ transplantation. We may observe increases in transplantation volume, and outcomes, both for patients on the waiting list and those after having received a transplant. The extended "shelf life" of the organs and the ability to monitor and recover even organs that were once considered marginal or high-risk will be vital to this endeavor.

To date, there are now a total of four ex vivo perfusion systems approved by the FDA: two for lungs [XVIVO Perfusion System (XPS™) by STEEN Solution™ (*Göteborg, Sweden*) and OCS Lung by TransMedics], and for the heart (TransMedics OCS Heart), and one for liver (TransMedics OCS Liver) platforms. All of these FDA premarket approvals occurred in the past three years, highlighting the rapid pace of modern progress.

For many years, the transplant community and society at large have not been able to rescue all patients seeking organ transplantation. However, we may, at last, be entering an era where the supply curve may begin to rise to meet the demand, aided by novel ex vivo organ perfusion systems, to bring about life-changing opportunities for our patients.

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FURTHER READING

1. Senior M. Beating the organ clock. Nat Biotechnol. 2018;36:488–92.
2. Markmann J, et al. Superior post-transplant clinical outcomes using portable normothermic perfusion and assessment with the organ care system (OCS) liver system: 1-year outcomes of the OCS liver protect randomized controlled trial. Am J Transplant. 2021;21.

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