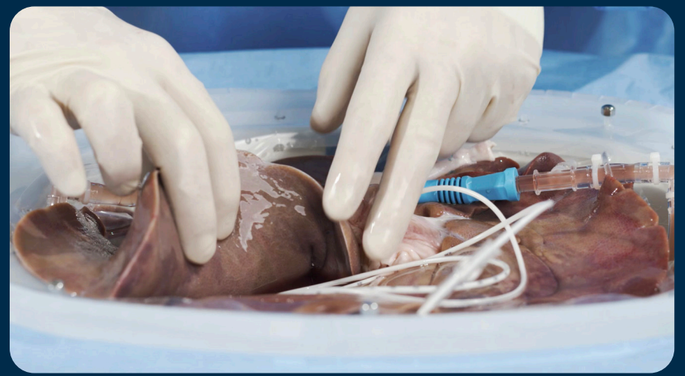
Hypothermic Oxygenated Perfusion raising HOPE for donated livers

Results from clinical trials demonstrate that hypothermic machine perfusion of livers leads to:

- Improved 5-year patient and graft survival in HOPE treated DCD livers vs untreated DCD livers[1]
- Lower biliary complications in dHOPE treated DCD livers compared to untreated DCD livers [1,2,3]
- Less ischemia reperfusion injury after oxygenated perfusion in DCD livers[2]
- Significant shorter ICU and hospital stay in ECD grafts after HOPE[4]
- End-ischemic HOPE reduces early allograft injury and improves transplant outcomes in ECD-DBD liver transplantation[5]



Normothemic ex vivo liver perfusion for increased utilization

Normothermic liver perfusion leads to increased availability by viability assessment of liver grafts. Published data suggests that normothermic ex vivo liver perfusion leads to:

- 20% increase in liver transplantation combining hypothermic and normothermic machine perfusion[6]
- Safe use of initially rejected donated livers[7,8]

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3. van Rijn R, et al. Hypothermic Machine Perfusion in Liver Transplantation — A Randomized Trial. N Engl J Med. 2021; 384:1391-1401.
4. Rayar M, et al. Hypothermic Oxygenated Perfusion Improves Extended Criteria Donor Liver Graft Function and Reduces Duration of Hospitalization Without Extra Cost: The PERPHO Study. Liver Transpl. 2021 Feb;27(3):349-362.
5. Czigany Z, et al. Hypothermic Oxygenated Machine Perfusion (HOPE) Reduces Early Allograft Injury and Improves Post-Transplant Outcomes in Extended Criteria Donation (ECD) Liver Transplantation from Donation After Brain Death (DBD): Results from a Multicenter Randomized Controlled Trial (HOPE ECD-DBD). Ann Surg. 2021 Jul 29.
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8. Mergental H, et al. Transplantation of Declined Liver Allografts Following Normothermic Ex-Situ Evaluation. Am J Transplant. 2016 Nov;16(11):3235-3245.
9. Watson C, et al. Observations on the ex situ perfusion of livers for transplantation. Am J Transplant. 2018 Aug;18(8):2005-2020.

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Liver Assist 2021.08.27 TD-11 Brochure LiA.08

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Liver Assist

The only device for ex vivo liver perfusion at temperatures ranging from hypothermic to normothermic

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Liver Assist

The most used device for ex vivo perfusion of livers

With more than 10 years of clinical application, XVIVO's Liver Assist is the most used device for ex vivo perfusion of livers. The two separately controlled pump units provide oxygenated perfusion with near physiologic settings with pulsatile perfusion of the hepatic artery and continuous flow through the portal vein.

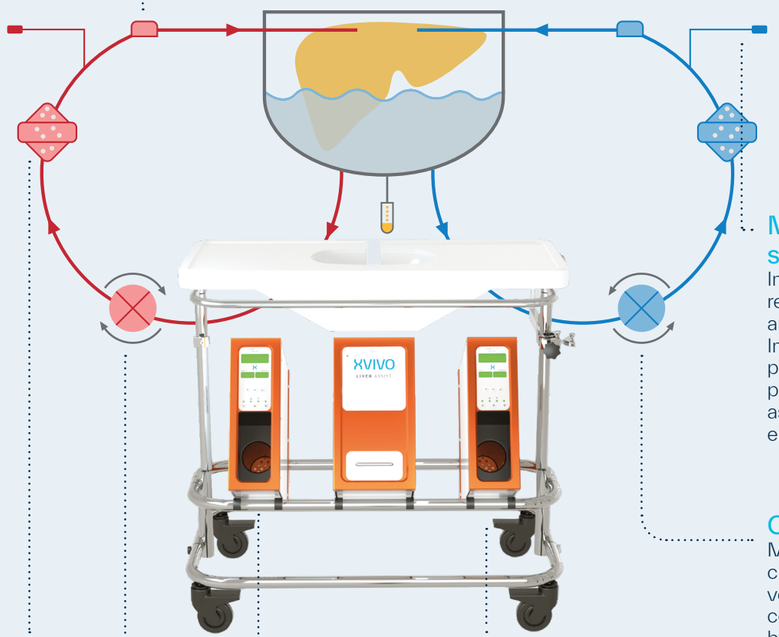
XVIVO's Liver Assist automatically adjusts the flow to the natural resistance of the organ. The heater/cooler unit enables perfusion at every temperature between hypothermic and normothermic.

With adjustable settings, XVIVO's Liver Assist allows for the clinician's choice of protocol, including HOPE, dHOPE, COR and NMP.

- O_2 Oxygenated
- Pulsatile arterial & continuous venous flow
- Flexible temperature 12°C - 37°C
- Clinically proven

Filter
Perfusate is filtered before it enters the liver.

Organ chamber
Easy to access the organ during perfusion, while ensuring a safe, sterile and humid environment. The reservoir has an integrated bile drain.



Monitoring & sampling
Integrated sensors monitor real time flows, pressures and temperatures. Incorporated sampling port allows for analysis of perfusate and bile (such as pH, lactate, glucose, enzymes and others).

Continuous
Mimicking physiological circumstances the portal vein is perfused with a continuous flow generated by a centrifugal pump.

Oxygenation
Oxygenation and/or gas exchange via two separate hollow fiber oxygenators.

Pulsatility
The hepatic artery is perfused with a 60 bpm pulse generated by a centrifugal pump.

Flexible temperature
The only device that allows perfusion within a flexible temperature range of 12-37 °C.

Ease of use
Simple user interface for easy operation. Provides an ergonomic working height.

The DHOPE-DCD trial: new hope for DCD liver perfusion[3]

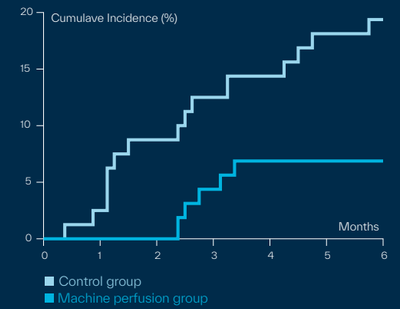
The study aimed to compare hypothermic oxygenated machine perfusion (2h, end-ischemic) to static cold preservation of livers donated after circulatory death (DCD). The study was: randomized, controlled, multicenter, n=156 (78+78).

The study showed that:

- Nonanastomotic strictures occurred in 6% of the patients in the dHOPE group and in 18% in the control group (risk ratio 0.36, P=0.03).
- The cumulative number of treatments for nonanastomotic biliary strictures was lower by a factor of nearly 4 in the dHOPE group compared to the control group.

According to the authors, the prevention of post-transplant cholangiopathy may increase the acceptance for DCD livers and make the use of machine perfusion cost-effective.

Biliary complications significantly reduced with hypothermic oxygenated machine perfsuion of DCD livers[3]



Cumulative Incidence of Symptomatic Nonanastomotic Biliary Strictures: adapted from[3] Hazard ratio, 0,32 (95% CI, 0.11 - 0.89); P=0.03

- HOPE : Hypothermic Oxygenated Perfusion
- NRP: Normothermic Regional Perfusion
- ECD: Extended Criteria Donor
- DCD: Donation after Circulatory Death

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