EVLP

A BRIEF GUIDE

What is it? 02

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Learning about new technologies can be a challenging task. The aim of this guide is to help you start this process and build a foundation for better understanding EVLP and how it may help you.

Lung transplantation is often the only treatment option for patients with end-stage lung disease. Despite significant advancements since the first clinically successful lung transplant in 1983, transplant physicians still face many challenges.

Now, however, the advancing technology of ex vivo normothermic machine perfusion (NMP) holds promise for improved preservation, better assessment and even reconditioning of organs before transplant. While many questions are still to be resolved regarding the implementation of this still-young technology, NMP has already had an important impact on transplant medicine in the U.S. (and globally), expanding the donor pool by allowing surgeons to assess and successfully transplant organs that once would have gone unused.

ASSESS

PRESERVE

WHAT IS EX VIVO LUNG PERFUSION (EVLP)?

Ex vivo lung perfusion (EVLP) is a special technique used by physicians to assess, ventilate, warm, nourish and re-evaluate donor lungs outside of the human body.

EVLP has emerged as an essential tool for transplant physicians to assess donor lungs that initially did not meet standard direct to transplant criteria.

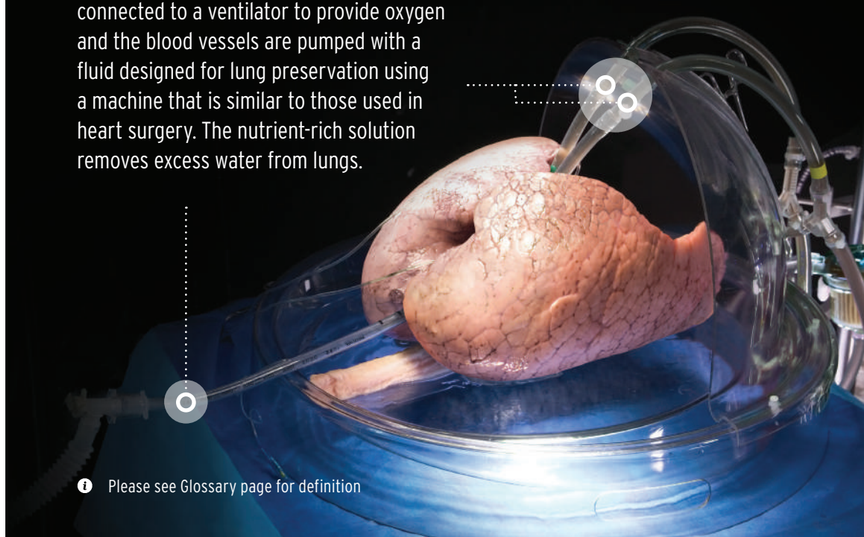
It took over half a century for the technique to evolve from a basic theory to the semi-automated circuits fit for clinical use that are now being adopted in transplant centers across the world.

With the help of EVLP, lungs that previously may have been discarded can now be re-evaluated outside of the donor's body for transplant suitability.

HOW IS IT DONE?

The EVLP system is designed to provide the lungs with an environment similar to being in the body: the lungs are warmed up to normothermic ⓘ temperature while being perfused. The lungs are then ventilated to gather data on how well the lung is performing outside of the donor's body.

During the EVLP process, donor lungs are placed inside a protective dome. They are connected to a ventilator to provide oxygen and the blood vessels are pumped with a fluid designed for lung preservation using a machine that is similar to those used in heart surgery. The nutrient-rich solution removes excess water from lungs.



ⓘ Please see Glossary page for definition

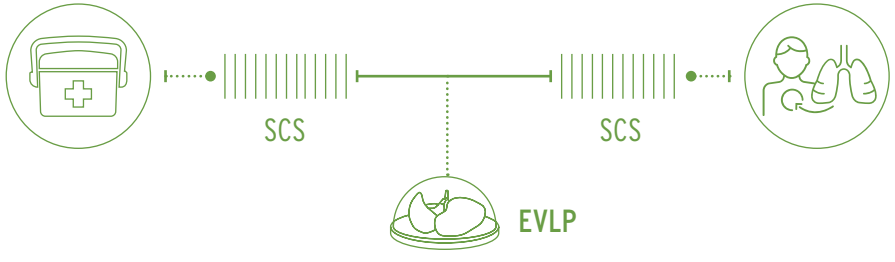
HOW DOES EVLP DIFFER FROM STANDARD TRANSPLANTATION PRACTICES?

In the past, there was only one path to transplantation called static cold storage (SCS): taking lungs that were deemed suitable for transplant, flushing them with cold preservation solution, and transporting them to the transplant center within a limited time frame. Today, we are able to extend that time frame by taking lungs that would not be suitable for transplant, flushing them with cold preservation solution, and transporting them for EVLP to re-evaluate the lungs. After the EVLP process, the lungs are cooled down again, flushed with cold preservation solution, and shipped to a transplant center on ice.

ORGAN PROCUREMENT — TRANSPLANTATION

SCS

EVLP



	SCS	EVLP
Preservation method	**Static cold storage**: cell activity is slowed down and requirements for oxygen and essential nutrients is reduced to prevent organ deterioration.	**Static cold storage**: donor lungs are preserved with static cold storage method from procurement to start of the EVLP, and from the end of EVLP to transplantation. **EVLP**: under normal conditions lung cells and tissues remain viable for several hours.
Assessment time	LIMITED	EXTENDED
Preservation time	Maximum 4-6 HR	Up to 20 HR

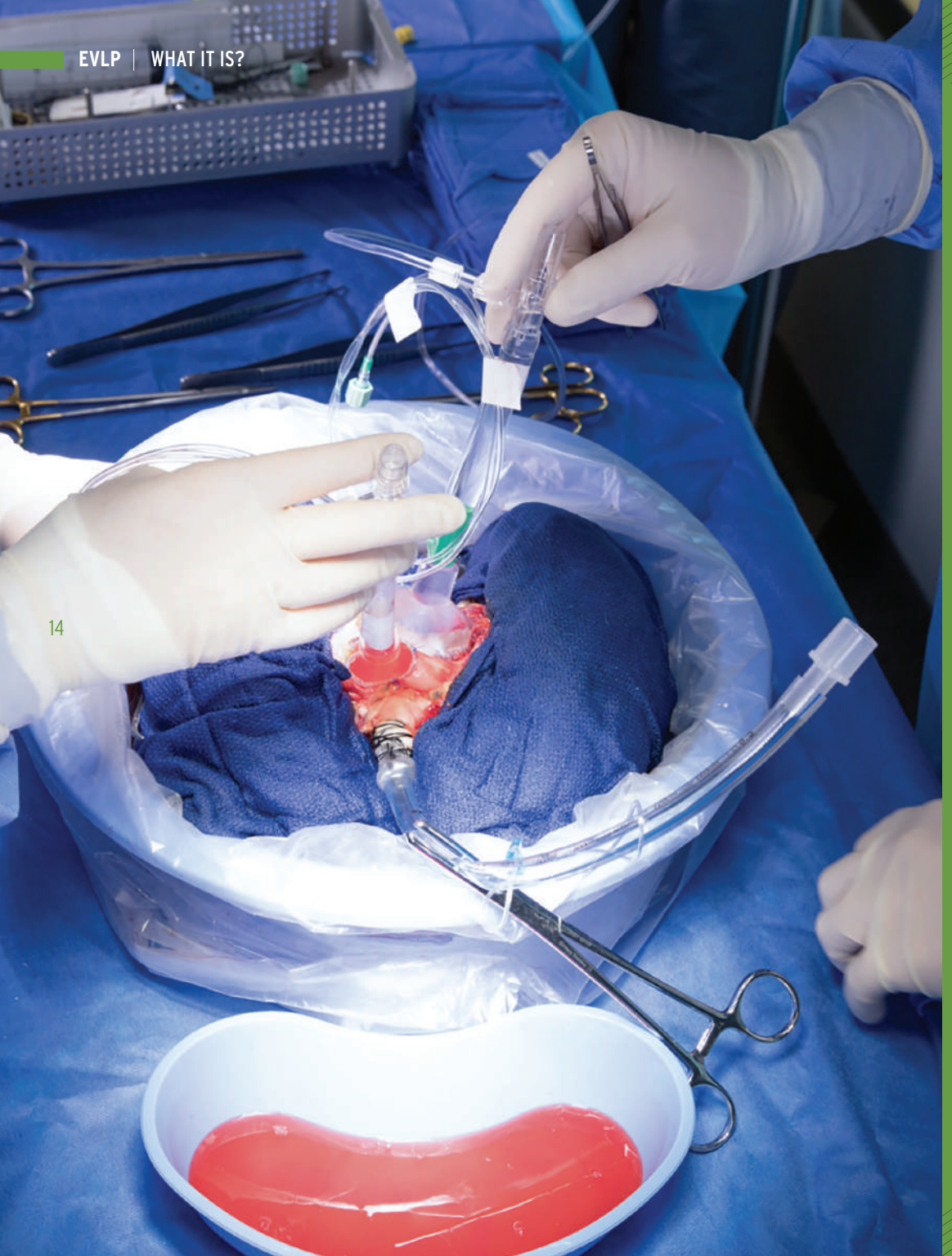
EVLP POTENTIAL

"[With EVLP] we have been able to utilize some lungs that otherwise would not have been used for transplant."

Dr. Matthew Hartwig
Transplant Surgeon
Duke University

"Extending preservation time is a clear benefit, and that is solid and well-established."

David Klassen, M.D.
UNOS Chief Medical Officer

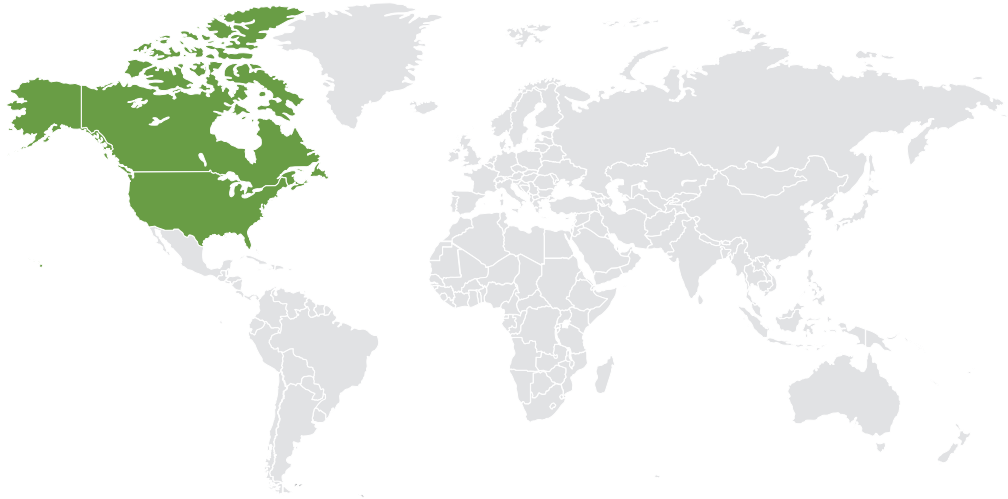


EVLP HAS CONTRIBUTED TO
AN INCREASE IN
TRANSPLANTABLE LUNGS OF
15%-20%
AT SOME TRANSPLANT CENTERS
DESPITE A LIMITED DONOR POOL[1]

1. Ex Vivo Lung Perfusion: A Key Tool for Translational Science in the Lungs. Tane S., Noda K., Shigemura N. (2017) *Chest*, 151 (6), pp. 1220-1228.

EVLP EXPERIENCE

EVLP has been in clinical practice for 10 years and it has safely increased lung transplantation activities. Several studies have shown similar outcomes for recipients receiving donor lungs treated with EVLP compared with recipients receiving standard donor lungs. Below are selected landmark studies and summaries of their outcomes.



CANADA | HELP TRIAL

Dr. Cypel, Dr. Keshavjee and colleagues in Toronto, Canada started the first clinical trial of EVLP, and reported outcomes in 2011. This study had a major impact on the lung transplant community and remains the largest cohort of recipeints of EVLP-treated donor lungs with the longest follow-up reported.

FIRST EVLP TRANSPLANT	2008
NUMBER OF EVLP TRANSPLANTS	262 of 1106 lung transplants
OUTCOMES	Use of EVLP-treated lungs led to an increase in the number of patients undergoing lung transplantation, with comparable outcomes.

USA | NOVEL TRIAL & NOVEL TRIAL EXTENSION

The NOVEL and NOVEL Extension studies were the first prospective, multicenter clinical trials designed to evaluate the safety and effectiveness of ex vivo lung perfusion (EVLP) as a device to screen and identify good quality grafts from lungs that had been rejected for transplantation.

FIRST EVLP TRANSPLANT	2011
NUMBER OF EVLP TRANSPLANTS	110 of 226 lung transplants
OUTCOMES	Comparable early outcomes and 1-year survival were observed between these cases and the 116 cases in the control group.

FURTHER READING: LINKS AND RESOURCES

1 National Library of Medicine, Clinicaltrials.gov
https://clinicaltrials.gov/

A database that provides patients, their family members, and the public with easy and free access to information on clinical studies for a wide range of diseases and conditions.

2 Lung Bioengineering
http://lungbioengineering.com/

3 XVIVO Perfusion
https://www.xvivoperfusion.com/

GLOSSARY

NORMOTHERMIC MACHINE PERFUSION (NMP)	A method of organ preservation that provides oxygen and nutrition during preservation and allows aerobic metabolism.
NORMOTHERMIC TEMPERATURE	A temperature level that contributes to a normal environment for cell level activity.
STATIC COLD PRESERVATION	A preservation method that keeps donor lungs viable between the time of procurement and transplantation. It involves flushing the procured lungs with preservation solution at 0–4 °C, then immersing them into preservation solution at the same temperature until transplantation. The cold environment is responsible for decreasing cellular metabolism.
ORGAN PROCUREMENT	A surgical procedure that removes organs from a deceased donor for reuse, typically for organ transplantation.

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