Part One: Pressure Points
Evidence-Based Insights into Lung Preservation Parameters

Advances in technology have transformed donor lung preservation, shifting practice away from traditional ice storage and towards controlled moderate hypothermic storage. However, there are persistent misconceptions that affect how organ preservation research is interpreted and applied in clinical practice. Even in the modern era, foundational research questions on preservation parameters such as temperature are frequently oversimplified. A thorough understanding of the scope, assumptions, and limitations of the current body of evidence is critical to allow for educated decision making in clinical settings.

There is no consensus on a single, specific "optimal" temperature for lung preservation, as all studies cover a range of storage temperatures.

The 2025 AATS Expert Consensus Document on Current Standards in Donor Lung Procurement and Preservation states that studies investigating static cold storage between 4°C and 10°C support the use of these warmer temperatures for safe storage of donor lungs (Co RIIa, LoE B-NR, 100% consensus).[1]

To date, FDA-regulated static controlled moderate hypothermic lung preservation systems have been studied in two main ways **(Table 1)**. The first is through a retrospective review of the GUARDIAN-Lung Registry using the LUNGguard® System, the BAROguard® System, or ice storage. Several reports of the GUARDIAN-Lung data have been presented and published, each including data collected from the embedded temperature probe that continuously measures the temperature of the preservation solution surrounding the lungs.[2-7]

The second is through an ongoing randomized controlled trial that studies lung preservation at 4°C-10°C and ice storage.[8,9] This study aims to compare extended preservation (up to 12 hours of ischemic time) at 4°C-10°C versus ice storage at 0°C-2°C (up to 6 hours of ischemic time).

As rationale for this, Ali et al. state that "preliminary studies published more than 30 years ago have suggested that 10°C is the optimal lung storage temperature."[10] However, investigation into these cited foundational studies reveals that only the temperature range of the storage environment (input) was reported, not the actual measured organ temperature (output). Wang et al. and Date et al. similarly conclude that the optimal temperature is "in the vicinity of 10°C."[11,12] The study methods by Wang et al. detail that "the storage temperature was kept constant by using a cold room at 4°C to 15°C" and that all storage environment temperatures are ±1°C (i.e., "10°C" is actually 9°C-11°C). Nakamoto et al. came to a slightly different conclusion, stating that "... the optimal temperature for lung preservation by topical cooling is 8°C to 9°C" by using segmented regression models between functional parameters and preservation temperature.[13] Similar to the clinical studies in **Table 2**, the preservation temperature in this study was equated to the refrigerator set temperature rather than an actual measured temperature.

Temperature is not consistently measured and reported in published lung preservation studies that claim a single, specific temperature ('4°C' or '10°C').

Table 1. All FDA regulated static storage lung preservation devices are labeled to operate over a range of safe temperatures.

Product	Manufacturer	Type	Storage Temperature	510(k) Number
LUNGguard® System[20]	Paragonix Technologies	Controlled Moderate Hypothermia	4°C - 8°C	K192869
BAROguard® System[21]	Paragonix Technologies	Controlled Moderate Hypothermia & Airway Pressure Control	4°C - 8°C	K223874
X°Port® System[22]	Traferox Technologies	Controlled Moderate Hypothermia	4°C - 10°C	K243870

X°PORT is a trademark of Traferox Technologies Inc.

Table 2. Examining the recent history of published "10°C" lung preservation studies from the modern era reveals that actual organ temperature has not been consistently measured or reported.

Year	Author	Model	Actual Organ Temperature	Measurement Method	Preservation Device
2025	Hoetzenecker[15]	Human	Not reported	N/A, not measured	Ice transport followed by MYTEMP 65HC Incubator set to 10°C
2024	Barturen[16]	Human	Not reported	N/A, not measured	Ice transport followed by MYTEMP 65HC Incubator set to 10°C
2023	Ali[17]	Human	Not reported	N/A, not measured	Ice transport followed by MYTEMP 65HC Incubator set to 10°C
2022	Abdelnour-Berchtold[18]	Porcine	Not reported	N/A, not measured	"4°C": ice storage "10°C": thermoelectric cooler
2021	Ali[19]	Porcine	Not reported	N/A, not measured	"4°C": walk-in cooler "10°C": thermoelectric cooler
		Human	Not reported	N/A, not measured; "Visual monitoring of the chamber temperature"	Ice transport followed by MYTEMP 65HC Incubator

Inconsistencies in temperature reporting in peer-reviewed publications have led to ongoing confusion in the lung transplant field. Historically, donor lungs were preserved on ice for transport with the intention of maintaining their temperature at approximately 4°C. Recently published work has demonstrated that this practice in fact brings the temperature down to close to 0°C, rather than the often-cited 4°C.[14] In this study of traditional static ice storage, the actual tissue temperature of the lungs was <2°C and the temperature of the Perfadex was 0°C within 3 hours of ice storage, demonstrating that the underlying assumption of ice storage at 4°C is not feasible **(Image 1)**.

Despite this evidence, recent studies of lung preservation continue to incorrectly refer to ice storage as 4°C.[15-19] Additionally, these recent studies fail to measure and report any data on the organ environment, preservation solution, or actual organ tissue temperature. All that is reported is the temperature that the storage device is set to **(Table 2)**. This gap in data incorrectly assumes that the temperature of the storage environment is equivalent to the actual temperature of the organ.[15-19] Regardless, the intervention arm of the studies is labeled as "10°C," a single temperature, despite no actual measured organ tissue or environment temperature.

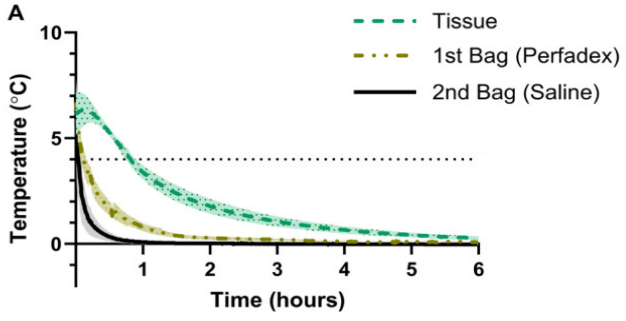

Image 1. Actual organ temperature measurement demonstrates that ice storage is not "4°C."[14]

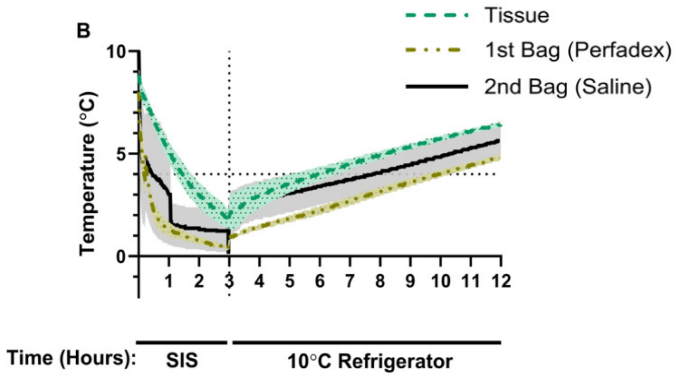

Image 2. Actual organ temperature measurement shows that the tissue temperature does not equilibrate with the set temperature of the refrigerator, even after 8 hours.[14]

Cenik et al also investigated the actual temperature dynamics of lungs stored on ice for 3 hours followed by storage in a 10°C incubator **(Image 2)**.[14] After 3 hours of ice storage, the actual tissue temperature was 1.9°C. The lungs were then placed into an incubator set to 10°C for 8 hours. The actual tissue temperature only increased by about 1°C per hour while in the incubator, never reaching an actual tissue temperature of 10°C even after 8 hours of storage in the incubator. The average tissue temperature during exposure to the 10°C environment was 6.47°C. Without measuring and reporting the actual organ preservation temperature, conclusions cannot be drawn about the "optimal" storage temperature.

The transplant field has evolved from traditional ice storage by recognizing that 'ice is not 4°C,' and for bringing greater attention to temperatures in lung preservation. However, as we move past ice, it becomes clear that the existing literature does not support a single, precise temperature for lung preservation. Across studies, temperatures are reported as ranges rather than a single digit, 'optimal' temperature, and furthermore, temperature methods are not clearly defined.

To date, the only transparently reported data comes from the GUARDIAN-Lung registry **(Table 3)**, which clearly demonstrates that preservation within the 4–8 °C range is safe and effective. Beyond this, the temperature data available in the literature lack methodological clarity and consistent temperature reporting. While the community has taken an important step past ice, it is essential to have a comprehensive understanding of the evidence supporting preservation devices through critical evaluation of new findings as they emerge.

Table 3. Presented and published temperature data from the GUARDIAN-Lung Clinical Registry.

Year	Author	Model, N	Actual Organ Temperature	Measurement Method	Preservation Device
2024	An-Lies Provoost[2]	Human N=36	6.7°C ± 1.5°C	Temperature probe in contact with organ storage bag	LUNGguard System
2024	Ceulemans[3]	Human N=13	7.3°C ± 1.4°C	Temperature probe in contact with organ storage bag	LUNGguard System
2025	Langer[4]	Human N=304	6.6°C ± 2.2°C	Temperature probe in contact with organ storage bag	LUNGguard System
2025	Hartwig[5]	Human N=80	6.1°C ± 1.6°C	Temperature probe in contact with organ storage bag	LUNGguard System
2025	Ceulemans[6]	Human N=357	6.4°C ± 2.0°C	Temperature probe in contact with organ storage bag	LUNGguard System
2025	Bush[7]	Human N=48	6.7°C ± 0.9°C	Temperature probe in contact with organ storage bag	BAROguard System

References

1. Kukreja, et al. The 2024 American Association for Thoracic Surgery expert consensus document: Current standards in donor lung procurement and preservation. JTCVS 2024.
2. Provoost, et al. Lung transplantation following controlled hypothermic storage with a portable lung preservation device: first multicenter European experience, Frontiers in Cardiovascular Medicine, (2024).
3. Ceulemans, et al. Extended Ischemic Time (> 15 Hours) Using Controlled Hypothermic Storage in Lung Transplantation: A Multicenter Experience Running head: Extended Ischemic Time in Lung Transplantation, Journal of Heart and Lung Transplantation, (2024).
4. Langer, et al. ISHLT Presentation 2025, Data on file. Real-World Outcomes Using Controlled Moderate Hypothermia at 4-8°C for Lung Transplant: An Update from the GUARDIAN-Lung Registry.
5. Hartwig, et al. ISHLT Presentation 2025, Data on file. Controlled Moderate Hypothermic Storage at 4-8°C for the Preservation of Donor Lungs from Donations after Circulatory Death.
6. Ceulemans, et al. ISHLT Presentation 2025, Data on file. Lung Preservation at Controlled 4-8°C for Extended Criteria Donors Improves Outcomes After Transplantation.
7. Bush, et al. ISHLT Presentation 2025, Data on file. Constant Airway Pressure Management System Leads to Improved Donor Lung Outcomes: Analysis of Ischemic Times >8 Hours.
8. Traferox Technologies (2025). XPort: Instructions for Use. traferox.com/wp-content/uploads/2025/07/CAR-910-0003-UM-Rev-1-XPort-Lung-Preservation-Solution-IFU.pdf.
9. https://www.clinicaltrials.gov/study/NCT05898776.
10. Ali, et al. Static lung storage at 10°C maintains mitochondrial health and preserves donor organ function. Sci Transl Med. 2021 Sep 15;13(611):eabf7601.
11. Wang, et al. The effect of ischemic time and temperature on lung preservation in a simple ex vivo rabbit model used for functional assessment. J. Thorac. Cardiovasc. Surg. 98, 333–342 (1989).
12. Date, et al. In a canine model, lung preservation at 10 degrees C is superior to that at 4 degrees C. A comparison of two preservation temperatures on lung function and on adenosine triphosphate level measured by phosphorus 31-nuclear magnetic resonance. J. Thorac. Cardiovasc. Surg. 103, 773–780 (1992).
13. Nakamoto, et al. A study on optimal temperature for isolated lung preservation. Ann. Thorac. Surg. 53, 101–108 (1992).
14. Cenik, et al. Temperature Dynamics of Porcine and Human Lungs During Static Ice Storage: Ice Is Not 4 °C. J Clin Med. 2025 Mar 20;14(6):2127.
15. Hoetzenecker, et al. Prolonged Preservation of up to 24 Hours at 10 °C Does Not Impact Outcomes after Lung Transplantation. Ann Surg. 2025 Apr 1;281(4):664-670.
16. Barturen, et al. Donor Lung Preservation at 10°C: Clinical and Logistical Impact. Arch Bronconeumol. 2024 Jun;60(6):336-343.
17. Ali, et al. Extension of Cold Static Donor Lung Preservation at 10°C. NEJM Evid. 2023 Jun;2(6):EVIDoa2300008.
18. Abdelnour-Berchtold, et al. Evaluation of 10°C as the optimal storage temperature for aspiration-injured donor lungs in a large animal transplant model. J Heart Lung Transplant. 2022 Dec;41(12):1679-1688.
19. Ali, et al. Static lung storage at 10°C maintains mitochondrial health and preserves donor organ function. Sci Transl Med. 2021 Sep 15;13(611):eabf7601.
20. LUNGguard 510k Premarket Notification. https://www.accessdata.fda.gov/CDRH510K/K192869.pdf.
21. BAROguard 510k Premarket Notification. https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223874.pdf.
22. X°Port 510k Premarket Notification. https://www.accessdata.fda.gov/cdrh_docs/pdf24/K243870.pdf.

Part Two: No Magic Number
Evidence-Based Insights into Thermodynamics

Static controlled hypothermia with FDA-cleared preservation systems remains an effective approach for donor lung storage because of its reliability, ease of use, and safe failure modes. All currently available FDA-cleared hypothermic preservation systems rely on phase-change material to maintain donor organ temperature within a safe range over a defined period of time. This is reflected both in engineering constraints and in regulatory filings: the FDA has cleared static preservation devices only for temperature ranges, specifically 4–8°C or 4–10°C.

Among these, the 4–8°C range is supported by clinical data through the GUARDIAN-Lung Registry. While the FDA cleared devices operate on similar fundamental principles, only the tighter 4–8°C range has been robustly validated in clinical practice. No currently available FDA-cleared preservation system is designed or approved to maintain a single, fixed temperature during storage.

All FDA regulated static lung preservation systems are cleared for a temperature range.

In the United States, only 3 portable preservation devices are FDA-cleared for static controlled moderate hypothermia of donor lungs intended for transplantation. All FDA regulated static hypothermic lung preservation systems are cleared to maintain temperature within a specified range, not a single temperature **(Table 1)**.

Each of these systems were FDA-cleared through the 510(k) pathway, requiring a legally marketed predicate device to which the new (subject) device can be deemed "substantially equivalent." Both the BAROguard System and the X°Port® System were determined by the FDA to be substantially equivalent to the LUNGguard System.

Thermoelectric systems have not received FDA clearance or approval for organ preservation and transport.[4-7] Their thermostat control mechanisms have not been validated to meet the rigorous standards applied to FDA cleared or approved medical devices and may subject the contents to cyclic variations in temperature. They have not been recommended by any professional societies for donor organ storage.

Passive systems, from an engineering standpoint, cannot maintain a single temperature.

All FDA-cleared portable static moderate hypothermic preservation devices are labeled for a temperature range, each achieving this through passive cooling. Passive cooling systems utilize phase change material (PCM), which operates over a temperature range. Real PCMs experience a gradual melting or solidifying of the material across several degrees, in comparison to an idealized, theoretical PCM, which would undergo an isothermal phase transition at a single temperature and does not exist in practice **(Image 3)**.[8]

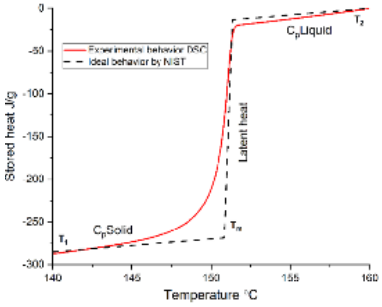

Image 3. Thermal capabilities of a real PCM versus ideal PCM, which does not exist in practice.

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X°PORT is a trademark of Traferox Technologies Inc.

This temperature range can be further understood in terms of finite heat transfer and spatial temperature gradients within the PCM. This means that different regions of the material absorb or release heat at different rates, due to finite thermal resistance, causing segments of the material to transition at slightly different temperatures causing a spatial temperature gradient.[9,10]

Additionally, variation in lung size, in-situ flush temperature and technique, and time between final breath and the start of preservation are significant contributors to the actual preservation temperature. These variables combined with a consistent energy capacity in the PCM inevitably result in variable temperature. Reporting a single characteristic temperature is insufficient, and PCMs in passive thermal systems should be described with temperature ranges.

Now that the transplant field has evolved from traditional ice storage with the recognition that ice is not 4°C, the field has turned its attention to defining the 'optimal' lung preservation temperature.

Across all hypothermic lung preservation technologies, static passive systems have few failure points, stay stable without power, and are simple for teams to use — all of which are beneficial characteristics during FDA review. The phase-change material used in Paragonix SherpaCools, the cooling technology found in both BAROguard and LUNGguard Systems, is purposely designed to hold a tight range between 4-8°C. SherpaCool was engineered this way to improve consistency and reduce temperature variability throughout transport to establish a reliable approach.

References

1. LUNGguard 510k Premarket Notification. https://www.accessdata.fda.gov/CDRH510K/K192869.pdf.
2. BAROguard 510k Premarket Notification. https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223874.pdf.
3. X°Port 510k Premarket Notification. https://www.accessdata.fda.gov/cdrh_docs/pdf24/K243870.pdf.
4. MYTEMP 65HC: https://www.gohcl.com/assets/d9/b6/d9b6b613-100d-4f53-8576-b90aa36e3108/21088_Instructions.pdf
5. Ryobi https://556aa8d9de68ea9c4f29-0a8acad11a4df5016d26c-c39a7429843.ssl.cf1.rackcdn.com/2/Pi1824BQT_015_trilingual_03.pdf
6. Lion Cooler: https://cdn.shopify.com/s/files/1/0095/7431/8146/files/PX30A_PX40A_PX50A_User_Manual.pdf
7. Dometic: https://www.dometic.com/externalassets/07-0703-070328-070328002_97000050754_123574.pdf
8. Fatahi, et al. Thermal Characterization of Phase Change Materials by Differential Scanning Calorimetry: A Review. Appl. Sci. 2022, 12(23), 12019; https://doi.org/10.3390/app122312019.
9. Ye, et al. Improved Performance of Latent Heat Energy Storage Systems in Response to Utilization of High Thermal Conductivity Fins. Energies 2023, 16(3), 1277; https://doi.org/10.3390/en16031277.
10. Günther, et al. Measurement of the enthalpy of PCM. Conference: 11th International Conference on Thermal Energy Storage At: Stockholm, Sweden. 2009.

Part Three: Narrowing Precision
Evidence-Based Insights into Pressurization

The unique characteristics of donor lungs make them sensitive to pressure changes potentially leading to over- or under-inflated lungs. Yet, current guidance on inflation pressure during packaging varies widely, making it difficult to achieve consistency. These inconsistencies are further magnified when lungs are transported in pressurized aircraft cabins, now a routine occurrence in the Composite Allocation Score era. These ideas demonstrate that discussions of 'optimal' preservation must extend beyond temperature alone. True optimization requires control of both temperature and pressure to protect the lungs throughout storage and transport.

The final airway pressure in packaged donor lungs is dependent on imprecise clinical procedures.

The resulting final airway pressure after donor lung procurement is dependent on multiple imprecise clinical procedures, with wide variability reported in practice and in the literature.[1] Procurement guidelines recommend holding lungs at a static inflation pressure of 12-15 cm H_2O to avoid over- or under-distension.[2] Other surgical protocols cite that lungs should be inflated to pressures between 15-20 cm H_2O before stapling the trachea.[3] In practice, inflation is sometimes performed using total lung capacity as guidance with the trachea being clamped while the lungs are in a partially inflated state as a means of compensating for future pressure change due to air travel.[4,5] In addition, modern air transport imposes cabin pressure variations where lungs inflated to full capacity risk barotrauma during flights, highlighted more in depth below. To account for this, recommendations have been made to extubate the patient, allowing the lungs to deflate to "around 75-80% of total capacity."[5] This adjustment to lung inflation, intended to reduce the risk of over-inflation and barotrauma during air travel, compounds the already imprecise methods of lung packaging and preservation. As a result, donor lungs are often inflated to pressures below the recommended levels. In a clinical case example, airway pressure in donor lungs was recorded at a starting pressure of 9 cm H_2O, below the guideline's minimum threshold and potentially at a higher risk for atelectasis due to pressure changes during preservation.[6] This highlights not only the challenge of achieving and maintaining the recommended inflation state, but also the variability and subjectivity employed while packaging donor lungs.

Commercial and private aircraft cabins are not pressurized to sea level.

Beyond the variation in airway pressures due to imprecise clinical procedures and ongoing metabolism, these effects are magnified by pressure changes due to air travel. The US Federal Aviation Regulations 914 CFR 25.841 require that under normal operating conditions, cabin pressure altitude cannot exceed 8,000 ft at the aircraft's maximum operating altitude. Going beyond this cabin pressure introduces structural stress on the airframe due to the pressure differential between the inside and outside of the fuselage.[7]

For this reason, both commercial and private aircraft cabins are not pressurized to sea level conditions. They are instead pressurized to a lower atmospheric pressure, characteristic of higher elevation. Private aircrafts offer cabin pressurization roughly equivalent to altitudes between 3,000 and 5,000 ft, while direct measurements aboard Boeing 747-400 flights showed average cabin pressure of 863 cm H_2O, corresponding to an altitude of 5,000-8,000 ft.[8-10] Reference standards for aircraft show that cabin pressurization systems are designed to balance the structural limits of the fuselage with human tolerance, resulting in a cabin pressure equivalent to moderate altitude, but not sea level.[11] From a physiological standpoint, studies have shown that drops in arterial oxygen saturation (SpO_2) during flight can be linked to a decrease in ambient pressure. A study of commercial airline travel recorded a decline of 3-4% SpO_2 after several hours in flight as cabin pressure decreased, tolerable for most healthy humans.[12]

Ambient pressure data from nearly 100 clinical lung transplant cases has also been collected using a mobile device's onboard barometric sensor and the Paragonix digital application.[6] Donor lungs experienced an average ambient pressure decrease of 198 cm H_2O as a result of increasing altitudes during air transport. Ambient pressure remained reduced for an average

duration of 4.7 hours before returning to near sea-level conditions, accounting for different flight lengths. The average minimum ambient pressure experienced by lungs during transport was 838 cm H_2O. Across all cases, the lowest recorded ambient pressure was 767 cm H_2O, consistent with the minimum cabin pressurization required for commercial aircraft (8,000 ft). The highest recorded ambient pressure was 1052 cm H_2O. Despite these fluctuations in ambient pressure, the BAROguard System controlled the internal airway pressure of all donor lungs within consensus range to an average of 14 ± 0.47 cm H_2O for the duration of preservation.

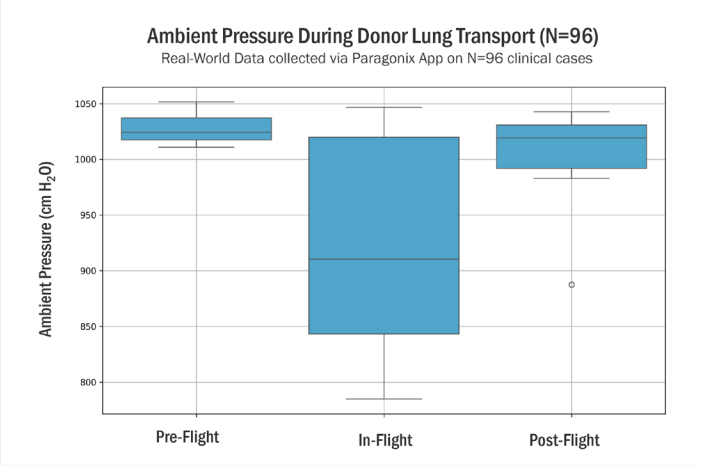

Image 4. The ambient pressure of 96 clinical lungs were measured during real-world flights.

Donor lungs are exposed to a wide range of pressure environments during transport from donor to recipient. Although clear protocols exist for protective ventilation at both the donor and recipient stages, pressure control during preservation and transport is often overlooked, potentially unraveling the careful work done on either end of the process. This variability is what prompted the addition of pressure control to the BAROguard System. The internal, automated pressure system brings stability to an otherwise variable process, keeping lungs within the ISHLT-recommended inflation range throughout transport despite commonly expected fluctuations in ambient conditions. The result is better alveolar protection, combined with a consistent, standardized means of hypothermic preservation, regardless of procurement conditions or travel method.

As the field of lung preservation continues to advance, it is critical that discussions of 'optimal' preservation address not only temperature control but also pressure control because we can all agree that donor lungs should be cold and inflated.

References

1. De Perrot, et al. Strategies to optimize the use of currently available lung donors. JHLT 2004.
2. Copeland, et al. Donor heart and lung procurement: A consensus statement. JHLT 2020.
3. Kukreja, et al. The 2024 American Association for Thoracic Surgery expert consensus document: Current standards in donor lung procurement and preservation. JHLT 2025.
4. Cantu, et al. Evaluation and Management of the Potential Lung Donor. Clin Chest Med 2018.
5. Krishnan, et al. Procurement of lungs from brain-dead donors. Indian J Thorac Cardiovasc Surg 2021.
6. Langer. AATS MCS Industry Symposium 2025, Data on file. Delivering Textbook Outcomes in Lung Transplantation. September 5, 2025.
7. Greenwald, et al. Cabin pressurization characteristics of USAF and commercial transport aircraft. Aeromed Rev., 1967.
8. Falcon 10X Aircraft. (6 May, 2021). https://www.dassaultfalcon.com/news/falcon-10x-2/#:~:text=Healthy%20cabin%20features:%20Cabin%20pressurization,for%20an%20even%20temperature%20throughout.
9. Private Jet Charter. Gulfstream G650. https://privatejetcharter.com/aircraft/gulfstream-g650/#:~:text=Welcome%20to%20Private%20Jet%20Charter,an%20abundance%20of%20natural%20light.
10. Kelly, et al. Directly measured cabin pressure conditions during Boeing 747-400 commercial aircraft flights. Respirology 2007.
11. Federal Aviation Administration. (2004). Pressurized compartment loads: General Structures Harmonization Working Group (Report No. ARAC TAEIG L-350-04-112). U.S. Department of Transportation. https://www.faa.gov/media/31686
12. Geertsema, et al. Effect of commercial airline travel on oxygen saturation in athletes. Br J Sports Med. 2008 Nov;42(11):877-81.

Part Four: The Right Combination

Evidence-Based Insights into the Dynamic of Cold and Inflated Conditions

The modern era of donor lung preservation has seen numerous benefits in terms of post-transplant outcomes, owing to the elimination of freezing injury when utilizing controlled moderate hypothermia. However, the physiological characteristics of lungs make them uniquely sensitive to pressure changes and freezing temperatures, due to their delicate alveolar structure and reliance on pressure gradients for gas exchange. For decades, the lung's inflation pressure had not been actively controlled or monitored during traditional static storage. Preclinical research has demonstrated that airway pressure in donor lungs decreases over time due to ongoing aerobic metabolism, with the rate of oxygen consumption increasing at the upper end of the "moderate hypothermic" range. Years of preclinical research have shown that pressure decreases over time due to ongoing aerobic metabolism. Literature has proven that this point holds true even under hypothermic conditions where metabolism is seen to slow down but not completely stop. Therefore, it is essential to keep donor lungs cold and inflated during preservation.

The initial airway pressure of packaged donor lungs is not maintained throughout preservation.

Published data indicate that donor lungs do not maintain their initial inflation pressure during static hypothermic preservation. Preclinical literature shows that airway pressure decreases to about 60% of its starting pressure by about 7 hours, the average ischemic time in the Composite Allocation Score era.[1,2] This suggests that lungs do not maintain their starting pressure as time elapses, likely resulting in under-pressurized lungs upon arrival. Studies measuring gas concentration in stored lungs report decreasing oxygen concentration while carbon dioxide concentration increases due to potential metabolism by the terminal alveoli. **(Image 5).** These trends in oxygen consumption and carbon dioxide production increase with temperature, indicating that although hypothermic conditions slow down metabolic activity, it does not completely stop.[3] It is important to note that as temperature increases, this point becomes more exaggerated. This demonstrates the importance of controlling lung pressure when considering warmer preservation temperatures.

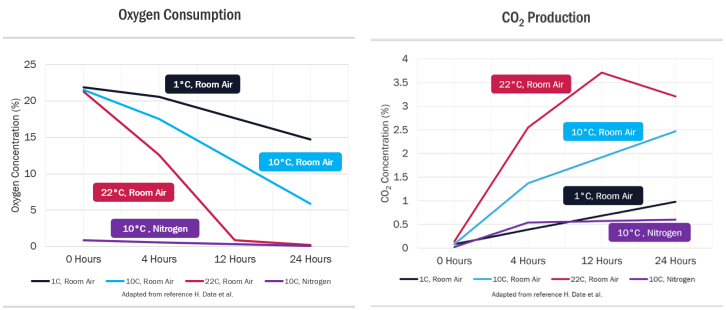

Image 5. Metabolic demand increases with rising temperatures.

Taken together, these data argue that lungs maintain metabolic activity even during hypothermic preservation, likely resulting in declining airway pressures. Without active airway pressure control, there is a higher risk of delivering under inflated grafts. When this idea is compounded with imprecise packing procedures, an initially under inflated lung is at risk of dropping pressure even further during preservation due to the lungs' aerobic state.

When discussing optimal preservation conditions for donor lungs, it is essential that pressure control is included in the conversation. The literature demonstrates that donor lungs continue to undergo metabolic activity during preservation, even under hypothermic conditions. To support these ongoing metabolic demands, the BAROguard System is designed to maintain airway pressure by drawing in fresh room air as needed, a feature specifically addressing the variabilities in donor lung inflation and helping to preserve inflation throughout transport. By adding a mechanically controlled feature, the device is able to achieve consistent and controlled airway pressures, as well as maintain higher levels of oxygen than in a statically stored lung. As the field of preservation continues to advance, future research should focus on how best to sustain the continued metabolic needs of donor lungs during hypothermic storage, especially if considering warmer preservation temperatures.

References

1. De Perrot, et al. Strategies to optimize the use of currently available lung donors. JHLT 2004.
2. Copeland, et al. Donor heart and lung procurement: A consensus statement. JHLT 2020.
3. Kukreja, et al. The 2024 American Association for Thoracic Surgery expert consensus document: Current standards in donor lung procurement and preservation. JHLT 2025.