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Latin America's First Active and Intelligent Packaging for Organ Transportation

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ABSTRACT

This study aimed to present and validate the Autonomous and Intelligent Packaging for the Cold Chain in Health Systems (EMAIS-SR) for organ transport through an experimental model using porcine organs. To do so, Landrace porcine hearts, livers, pancreases and kidneys were transported using either EMAIS-SR or traditional ice-filled coolers. Following transport, organs were assessed after 2 h through collected data that included temperature monitoring, macroscopic evaluation, histological analysis and microbiological testing. Prototypes at different technology readiness levels (TRL6 and TRL7) were evaluated. Regarding the findings, EMAIS-SR maintained organ temperatures predominantly within the recommended 2°C–8°C range. In the adjusted analysis, the TRL7 prototype achieved significantly lower post-transport temperatures than TRL6 (adjusted difference: 2.91°C; 95% CI, 1.32–4.50; $p = 0.0006$), indicating improved thermal performance after system refinements. Additionally, minor macroscopic changes were observed in some samples, but without histological correlation. Histological analysis showed better tissue preservation in EMAIS-SR samples, particularly in nuclei morphology and cytoplasmic structure. Furthermore, microbiological results indicated equivalent or lower contamination in EMAIS-SR compared to the control, especially in later tests. Overall, EMAIS-SR demonstrated effective thermal control, preservation of tissue integrity and biological safety in a structured preclinical model using porcine organs. Consequently, these findings validate EMAIS-SR as a robust and clinically promising alternative to conventional organ transport systems.

1 | Introduction

Organ transport for transplantation is a highly sensitive process that demands precision, coordination and strict control over time and temperature [1]. A critical requirement is maintaining the organ within a thermal range—typically between 2°C and 8°C, with 4°C considered optimal for most organs—to preserve biological function and viability [2]. Yet, each organ also has a specific maximum preservation time, further complicating the logistics chain [3]. Although there is ongoing debate over the exact ideal temperature for each organ, it is well established that even minor deviations or prolonged exposure beyond safe limits

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can result in irreversible cellular damage and loss of transplant suitability [2, 3].

Worldwide, organ transport commonly relies on conventional coolers filled with ice. While this approach has been used for decades with acceptable outcomes, it lacks active temperature control and is associated with important limitations [4]. Variability in insulation quality, the unpredictable thermal behaviour of ice and the absence of real-time monitoring increase the risk of thermal excursions [4]. Organs transported under uncontrolled conditions are at higher risk of arriving with compromised quality, potentially rendering them unsuitable for transplantation and resulting in the loss of both the donation and the transplant opportunity. The need for reliable cold chain solutions is especially pressing, as organ transplantation remains one of the few viable treatments for end-stage organ failure [5].

Although advanced transport systems are available on the global market, their cost and infrastructure requirements often make them inaccessible in resource-limited regions [6]. To address this gap, the Autonomous and Intelligent Packaging for the Cold Chain in Health Systems (EMAIS-SR) was developed.

Therefore, this study presents the EMAIS-SR and the results of preclinical testing using porcine organs, designed to evaluate the safety and functionality of this technology for organ transportation. The objective of this research was to present and validate the EMAIS-SR for organ transport through an experimental model using porcine organs.

2 | Methods

The development of the EMAIS-SR spanned 5 years (2020–2025) and involved a multidisciplinary team from four academic and technological institutions [7]. The engineering process integrated multiple fields to incrementally advance the prototype through increasing technology readiness levels (TRLs), ultimately resulting in a system capable of maintaining organ integrity during transport.

For the EMAIS-SR validation, an adapted case–control design was chosen to compare exposure to a specific intervention—namely, the use of EMAIS-SR—with outcomes related to organ integrity. Although case–control studies are typically retrospective and observational, this adaptation was applied prospectively to evaluate a technological device rather than a biological condition, making it suitable for assessing causality between the packaging method and preservation outcomes [8, 9].

In this context, the 'exposure' of interest was the use of EMAIS-SR, a novel packaging system, while the control was a conventional cooler filled with ice, which is currently the standard for static cold storage (SCS) for organ transportation. The primary outcome variable was the maintenance of organ viability, assessed through four parameters: temperature, macroscopic organ appearance, histological structure and microbiological growth.

A randomised controlled trial deemed inappropriate for this investigation. The standard ice-filled cooler is a well-established method for SCS that generally yields satisfactory outcomes. However, it lacks real-time temperature control and consistent thermal performance due to variability in insulation and ice behaviour. In contrast, EMAIS-SR offers continuous temperature monitoring and active thermal enabling precise environmental control.

Based on this rationale, the study was structured to compare the new packaging system EMAIS-SR (case) with the conventional method (control). Before implementing the main protocol, a pilot study was conducted to refine experimental procedures and define the model used in this research. The methodology and results of the pilot study are reported separately including a detailed description of the initial data collection procedures used for validation [10]. To minimise potential sources of bias, the study protocol was rigorously standardised. Animals with comparable characteristics were used, all sourced from the same location, in order to reduce selection bias. Measurement bias was mitigated through uniform handling procedures, predefined outcome measures and the use of the same calibrated instruments across all experimental conditions. All procedures were conducted by the same trained research team to ensure consistency in execution. Potential confounding factors were controlled by maintaining constant environmental and procedural conditions throughout the study, thereby allowing isolation of the effects attributable to the packaging system.

Prior to animal experimentation, the EMAIS-SR system underwent extensive laboratory-based validation to assess its thermal stability and mechanical robustness under conditions representative of real-world organ transport. To preserve animal welfare and comply with ethical research principles, tests involving extrapolated ambient temperatures (both higher and lower than standard conditions), extended exposure times, as well as vibration and drop tests were conducted. These evaluations were performed by a specialised independent laboratory at the Packaging Technology Center (CETEA), an official Brazilian government institution responsible for the technical assessment and regulation of new packaging systems.

The thermal performance evaluation was conducted under controlled ambient temperatures of 23°C and 40°C. Prior to testing, the refrigeration system operated in transport mode for 30 min at 23°C. A 4-L water-filled plastic bag at 4°C was used as a product simulant and placed inside the package before switching the system to operation mode. Temperature monitoring was performed using three thermocouples positioned in the simulant, inside the package and externally to the package. Measurements were recorded every 15 min using a Testo 177-T4 data logger over a 24-h period, with three repetitions for each conditioning temperature. The acceptance criterion established that the simulant temperature should remain below 8°C throughout the test duration. The package demonstrated satisfactory thermal performance under both conditioning conditions, maintaining the simulant temperature within the specified limit for 24 h.

For mechanical stress testing, transport simulation tests were performed according to ASTM D4169:23, Assurance Level III, following the sequence of drop, repetitive shock, random vibration and final drop tests. The first drop sequence consisted of six free-fall drops from a height of 178 mm applied to critical

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orientations including top, edges, corners and bottom positions. Repetitive shock testing was subsequently conducted on a vibration table using a sinusoidal profile with 25.4 mm displacement, 4.65 Hz frequency and 1.10 g acceleration for 40 min.

Random vibration testing was carried out using truck and airplane vibration spectra recommended by ASTM D4169:23. For both profiles, two 1-h cycles were applied combining low, medium and high vibration intensities. Truck vibration levels ranged from 0.40 to 0.70 g, while airplane vibration levels ranged from 0.16 to 0.29 g. A second drop sequence was then performed, consisting of six drops in predefined orientations. The first five drops were conducted from 178 mm, while the final bottom drop was performed from 356 mm. At the end of the test sequence, the prototype demonstrated fully adequate mechanical resistance, with no visible damage or interruption of its operation. Additionally, the wheels and axle showed no damage after completion of the tests.

These preliminary tests informed the design of subsequent animal experiments and ensured that in vivo testing was conducted using a system with verified thermal performance.

This preclinical study involved 10 female Landrace pigs (≈25 kg), sourced from a farm affiliated with the Federal University of São Paulo without exclusion criteria. The animals were given appropriate care prior to transport and housed in ventilated wooden transport box under continuous veterinary supervision upon arrival.

The anaesthetic procedure has been described in detail elsewhere [10] and the surgery followed the human process model. Following a thoracoabdominal incision and aortic cannulation, the descending aorta was clamped. The abdominal cavity was filled with crushed ice (frozen saline solution) to induce rapid cooling. Simultaneously, 2 L of Custodiol preservation solution was infused via the aortic cannula. Organs were removed sequentially in the following order: heart, liver, pancreas, right kidney and left kidney.

Immediately after retrieval, each organ was transferred to a back table for perfusion. Cannulation was performed individually, and cold Custodiol solution was flushed through each organ until the effluent ran clear and the parenchyma showed uniform blanching. The pancreas was the only exception, as it was not perfused [11]. Following perfusion, all organs were prepared for packaging.

Each organ was packaged using a triple-layer sterile containment method, as used in human transplantation [7, 12]. The first layer consisted of a sterile plastic bag containing the organ immersed in Custodiol solution. This was enclosed within a second sterile bag filled with cold saline solution. Both bags were then placed into a third outer sterile bag to complete the containment.

The packaged organs were then placed in one of two transport systems: (1) a conventional plastic cooler filled with ice (control group), or (2) the EMAIS-SR device, which uses air cushions for shock absorption and active temperature regulation.

Following packaging, all containers were transported by car for 30 min, simulating typical urban conditions. After transport, the packages remained in the laboratory for an additional 90 min. This procedure ensured that all organs remained inside the packaging systems for at least 2 h, allowing sufficient exposure time for evaluation of preservation performance.

Data were collected at three key stages for both transport systems: immediately after organ retrieval, after perfusion and packaging on the back table and following the simulated 30-min transport and 90-min stationary period in the laboratory.

Temperature measurements were recorded at three points: H0: immediately after organ retrieval from the abdominal cavity; H1: after perfusion on the back table, prior to packaging; H2: after transport. For the pancreas, H1 was not recorded [11].

Two probe thermometers (culinary grade) were used per protocol. The probes were inserted at a 45° angle into organ parenchyma in standardised regions likely to show greater thermal variation. Readings were taken after stabilising the temperature. An infrared thermometer was also used, held 2 cm from the centre of each organ for 2–3 s per manufacturer's instructions.

Macroscopic assessments were documented using study-specific forms adapted from established protocols [13–16]. Each organ was assessed at three stages: post-retrieval, post-perfusion and post-transport with evaluations performed visually by physicians and nurses. For heart, liver and kidney, pre-transport evaluations included overall organ quality, perfusate appearance after 5 min and perfusion quality (degree of parenchymal discoloration). Post-transport evaluations focused on overall organ quality and perfusion quality. A 0–10 scale was used, with 10 indicating optimal quality. Any lesions or abnormalities identified before transport were documented for comparison.

For the pancreas, specific morphological criteria were used, including assessments of tissue injury, calcification, consistency, hematoma and edema. Colouration was recorded using predefined categories: milky white, yellow, light brown, pink, or pink-grey [11]. Consistent coloration was considered indicative of unaltered visual appearance post-transport.

Tissue samples were collected post-perfusion and post-transport fixed in 4% paraformaldehyde (phosphate buffer) for 24 h, and processed via standard histological protocols: dehydration in graded ethanol, clearing in xylene and paraffin embedding at 60°C.

Sections (4 μm thick) were cut using a Minot-type microtome (50 μm spacing) and stained with haematoxylin and eosin (H&E) for histomorphometry analysis.

Before each experiment, the interior of both packaging systems was disinfected using 70% alcohol, applied with unidirectional wiping. For the EMAIS-SR, which includes air cushions, each air cushion was disinfected individually.

Microbiological samples were collected using three sterile swabs from internal surfaces (base to lid). In the EMAIS-SR group, samples also included air cushions.

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After transport, new swabs were collected from the same regions following package opening. In the control group, ice was removed prior to sampling. In the EMAIS-SR group, only the organs were removed, and swabs were again collected from the interior surfaces, including the air cushions, to complete the post-transport microbiological analysis.

Temperature data were analysed using descriptive statistics (mean values) to evaluate thermal stability across time points. Post-transport temperature (H2) was analysed using an ANCOVA/linear regression model with group (control, TRL6, TRL7) and organ type (heart, liver, pancreas, kidney) as fixed factors and baseline temperature (H0) as a covariate (model: H2 ~ group + organ + H0). Heteroscedasticity-robust standard errors (HC3) were used due to unequal sample sizes and potential variance heterogeneity. Adjusted between-group differences are reported as estimated mean contrasts with 95% confidence intervals and two-sided *p*-values.

In macroscopic analysis, stable mean scores indicated preserved visual quality, while increases or decreases indicated improvement or deterioration, respectively. For the pancreas, lower scores indicated better quality [11]. Comparison between pre- and post-transport values indicated whether the organ's visual appearance had improved or worsened.

Parenchymal coloration was assessed for homogeneity or heterogeneity. Homogeneity was considered ideal, while heterogeneity could indicate perfusion issues.

In this study, 'overall quality' refers to the general evaluation of the organ, 'colour' pertains to parenchymal coloration and abnormalities were identified and assessed before and after transport for comparison.

Histological analysis was based on H&E staining, which allows visualisation of tissue morphology under light microscopy. Basophilic structures (e.g., nuclei containing deoxyribonucleic acid—DNA) appeared blue to purple, while acidophilic components (e.g., cytoplasm) appeared pink to red, enabling identification of structural changes in the organ tissues.

Microbiological evaluation involved swab analysis using matrix-assisted laser desorption/ionisation time-of-flight mass spectrometry (MALDI-TOF MS). The presence of microbial growth was quantified by colony-forming units (CFUs), serving as indicator of contamination before and after transport.

This study was conducted in full compliance with the Guide for the Care and Use of Laboratory Animals, as mandated by the Brazilian National Health Authority. After the collection of biological materials (organs), and while the animals remained under deep anaesthesia, euthanasia was performed by anaesthetic overdose followed by intravenous administration of potassium chloride, in accordance with established ethical and veterinary guidelines. Following euthanasia, the bodies of the pigs were individually placed in sealed white plastic bags and stored in freezers until collection by the municipal authorities of São Paulo. The organs used in the experiment were handled and disposed of according to institutional and regulatory requirements.

The experimental protocol was approved by the Ethics Committee on Animal Use of the Federal University of São Paulo (protocol number: 4197081221). All procedures were designed to minimise animal suffering.

3 | Results

Development of the EMAIS-SR was carried out in close collaboration with healthcare professionals—particularly nurses and transplant physicians—to ensure alignment with real-world clinical needs. A distinguishing feature of this approach is its user-centred strategy: design decisions were guided by the daily challenges faced by transplantation teams.

This informed design addresses essential requirements such as thermal stability, mechanical safety, ergonomic handling, data traceability and enhanced operational security via embedded digital systems. All critical events throughout the transport process are autonomously recorded, providing an additional layer of safety and accountability.

EMAIS-SR uses inverter-based active cooling and high-efficiency insulation to ensure stable internal temperatures. It includes temperature sensors that enable dynamic thermal regulation and integrates global positioning system (GPS) tracking, user-specific access control and an online platform for real-time data monitoring of temperature, location and operational status.

In addition, EMAIS-SR is equipped with autonomous features such as self-diagnostics, failure alarms, impact detection and wireless communication through Global System for Mobile Communications (GSM) networks and Wi-Fi. These capabilities enhance reliability, reduce human error and mitigate the risk of tampering or failure during transport. EMAIS-SR is the first Latin American transport packaging solution for organ transplantation with preclinical validation. It is designed as a sustainable and reusable system, adaptable for the transportation of multiple organs (Figure 1).

At this stage, we are unable to disclose technical specifications or implementation details, as these are currently subject to an active intellectual property (IP) filing process related to the EMAIS-SR system. These elements constitute confidential, patent-relevant know-how and premature public disclosure in this manuscript could compromise both the protection of the invention and the enforceability of the corresponding patent claims in certain jurisdictions. However, readers may consult the publicly available institutional page on the EMAIS-SR, which will continue to be updated as additional information is approved for release: https://saorafael.com.br/embalagem-inteligente-transporte-de-orgaos/.

Upon reaching functional maturity, a preclinical validation protocol was established to evaluate system performance in controlled experimental conditions. Prototypes at TRL6 and TRL7 were tested in distinct phases—TRL6 for early-stage identification and resolution of technical issues, and TRL7 for final performance verification.

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Ten experimental surgeries were conducted using female Landrace pigs (~25 kg, 2 months old) between 12 December 2023 and 11 June 2024. Each procedure involved a multidisciplinary team of approximately 20 professionals, including nurses, physicians graduate students, medical and nursing undergraduates, veterinarians and veterinary assistants.

Eight procedures employed the TRL6 prototype and two procedures used the TRL7 prototype, with a mean duration of 5 h per procedure. A total of five hearts were tested in each group, while the control group included four livers, four pancreases, and four pairs of kidneys (eight in total), whereas the EMAIS-SR group included six livers, six pancreases, and six pairs of kidneys (12 kidneys in total).

The time each organ remained inside the packaging systems was recorded to ensure standardisation of transport exposure. The mean, median and standard deviation of transport times for each organ, stratified by packaging type (control cooler and EMAIS-SR at TRL6 and TRL7), are detailed in Table 1.

Ambient temperature was standardised at 17°C using air conditioning. All preservation solutions and fluids were refrigerated (≈18°C) or frozen (≈−18°C) for at least 24 h prior to use.

Between TRL6 and TRL7, two key modifications were implemented to EMAIS-SR: (1) the setpoint temperature was lowered from −0.5°C to −5.0°C and following a predefined period, the temperature setpoint was adjusted to a second target value



FIGURE 1 | EMAIS-SR: Autonomous and Intelligent Packaging for the Cold Chain in Health Systems (TRL7 prototype). [Colour figure can be viewed at wileyonlinelibrary.com]

TABLE 1 | Transport time (mean, median and standard deviation) of organs in control coolers and EMAIS-SR prototypes (TRL6 and TRL7).

Organ	Packaging	Mean time	Median time	Standard deviation
Heart	Control cooler	2 h 58 min	3 h 0 min 1 s	6 s
	EMAIS-SR TRL6	3 h 0 min 5 s	3 h 0 min 9 s	14 min
	EMAIS-SR TRL7	3 h 30 min	3 h 30 min	—
Liver	Control cooler	2 h 58 min	3 h 0 min	15 min
	EMAIS-SR TRL6	2 h 47 min	2 h 44 min	6 s
	EMAIS-SR TRL7	3 h 0 min 6 s	3 h 0 min 6 s	13 min
Pancreas	Control cooler	2 h 48 min	2 h 47 min	12 min
	EMAIS-SR TRL6	2 h 36 min	2 h 33 min	6 s
	EMAIS-SR TRL7	2 h 0 min 52 s	2 h 0 min 52 s	13 min
Kidneys	Control cooler	2 h 40 min	2 h 37 min	10 min
	EMAIS-SR TRL6	2 h 23 min	2 h 28 min	21 min
	EMAIS-SR TRL7	2 h 44 min	2 h 45 min	12 min

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scpecific to each organ to enhance thermal control, and (2) internal temperature sensors were recalibrated to reflect actual chamber readings, correcting discrepancies identified during TRL6 testing.

EMAIS-SR maintained internal and surface temperatures within the recommended 2°C–8°C range for most hearts, livers and pancreases, particularly in TRL7 experiments. Only one heart transported in the control group showed an exit temperature above the recommended limit. Among livers, one control and two EMAIS-SR TRL6 samples had minor deviations slightly exceeding 8°C. For pancreases, only one control sample exceeded the temperature limit, while all EMAIS-SR samples remained within range. Initial kidney tests using EMAIS-SR TRL6 showed temperature deviations in six out of eight samples though surface readings were adequate. After adjustments implemented in the TRL7 version, all kidney samples remained within the recommended range.

Statistics (mean, median and standard deviation) of internal and surface temperatures recorded by organ and group are presented in Table 2 and summarised presentation is available in Figure 2.

In the global ANCOVA model adjusting for organ type and baseline temperature (H0), the TRL7 prototype achieved significantly lower post-transport temperatures than TRL6 (adjusted difference in H2: TRL6 − TRL7 = 2.91°C; 95% CI, 1.32–4.50, $p = 0.0006$), supporting a statistically significant improvement from TRL6 to TRL7. Relative to the control group, TRL6 had higher H2 (Control–TRL6 = 1.95°C; 95% CI, 0.19–3.71, $p = 0.031$), whereas the difference between Control and TRL7 was not statistically significant (Control–TRL7 = −0.96°C; 95% CI, −2.73 to 0.80, $p = 0.277$).

Post-transport visual assessment indicated that most hearts transported with EMAIS-SR showed stable or improved

TABLE 2 | Descriptive statistics (mean, median and standard deviation [SD]) of internal and surface temperatures for hearts, livers, pancreases and kidneys after transport ($N = 50$).

Organ	Group	Sample	Temperature	Mean (°C)	Median (°C)	SD (°C)
Heart	Control	$n = 5$	Internal	5.3	3.9	3.9
Heart	Control		Surface	4.7	4.3	2.7
Heart	TRL6	$n = 4$	Internal	5.0	4.8	1.8
Heart	TRL6		Surface	6.2	6.0	1.3
Heart	TRL7	$n = 1$	Internal	3.1	—	—
Heart	TRL7		Surface	3.8	—	—
Liver	Control	$n = 4$	Internal	5.4	4.8	2.8
Liver	Control		Surface	4.3	4.4	1.2
Liver	TRL6	$n = 4$	Internal	7.5	7.6	0.9
Liver	TRL6		Surface	5.2	5.3	2.1
Liver	TRL7	$n = 2$	Internal	6.5	6.5	1.6
Liver	TRL7		Surface	6.9	6.9	1.7
Pancreas	Control	$n = 4$	Internal	6.2	4.7	4.1
Pancreas	Control		Surface	4.2	3.7	1.3
Pancreas	TRL6	$n = 4$	Internal	5.7	6.3	1.4
Pancreas	TRL6		Surface	4.9	4.7	0.9
Pancreas	TRL7	$n = 2$	Internal	4.8	4.8	1.3
Pancreas	TRL7		Surface	2.9	2.9	1.0
Kidney	Control	$n = 8$	Internal	5.2	5.2	1.6
Kidney	Control		Surface	4.5	4.0	1.6
Kidney	TRL6	$n = 8$	Internal	9.6	10.4	2.5
Kidney	TRL6		Surface	7.9	7.9	2.0
Kidney	TRL7	$n = 4$	Internal	4.4	4.4	0.6
Kidney	TRL7		Surface	4.3	4.2	0.8

Note: No median or standard deviation values are presented for the Heart—TRL7 group because only one experiment was conducted for this condition.

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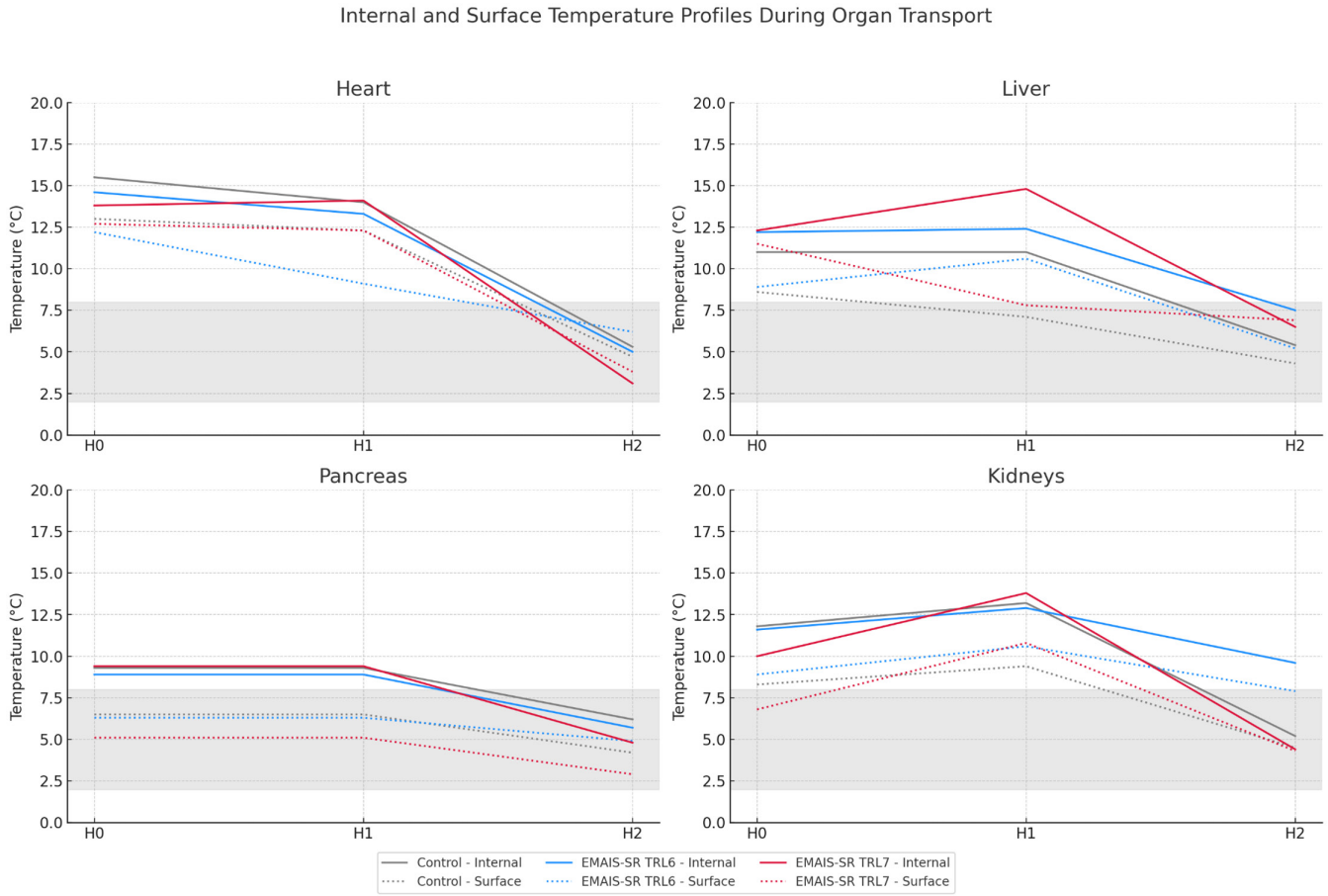


FIGURE 2 | Temperature profiles of heart, liver, pancreas and kidneys during simulated transport experiments using conventional coolers and EMAIS-SR prototypes (TRL6 and TRL7). Data represent the average of internal and surface temperatures recorded at three points: H0 (after organ retrieval), H1 (after perfusion and before packaging) and H2 (after transport). The shaded area indicates the recommended preservation range (2°C–8°C). [Colour figure can be viewed at wileyonlinelibrary.com]

appearance, comparable to control. Livers transported in EMAIS-SR TRL6 had predominantly improved macroscopic appearance, whereas livers in TRL7 and control groups showed more frequent deterioration. Pancreases transported with EMAIS-SR (both TRLs) consistently showed stable morphology, while one control sample improved in appearance. Kidneys transported with EMAIS-SR TRL6 were stable or improved, whereas TRL7 samples showed two instances of deterioration not observed in the control group. These analyses are detailed in Table 3 and summarised in Figure 3.

Samples transported using the EMAIS-SR demonstrated superior nuclear and cytoplasmic integrity compared to samples transported in the control cooler. Cardiac tissue from EMAIS-SR showed clearer nuclei and prominent nucleoli, indicating enhanced metabolic viability. Liver samples from the EMAIS-SR exhibited more uniform cytoplasm and fewer pyknotic nuclei suggesting better cellular preservation. Pancreatic samples exhibited well-defined acinar structures in the EMAIS-SR group, with both exocrine and endocrine regions preserved. Renal tissue in the EMAIS-SR samples showed better preservation of tubular structures, while control samples exhibited more frequent epithelial flattening and tubular dilation. Organs at TRL7, across all types, demonstrated superior structural integrity compared to controls. Representative histological images and organ-specific findings are presented below (Table 4).

A total of 240 swab samples were collected: 102 from the control packaging and 138 from the EMAIS-SR system (96 from TRL6 and 42 from TRL7). Table 5 details the microbial species identified before and after transport for both groups, including CFU/mL; Figure 4 illustrates the pre- and post-transport microbiological outcomes across the different packaging systems. Notably, no microbial growth was detected in EMAIS-SR TRL7 samples after transport.

4 | Discussion

This study assessed the preclinical performance of EMAIS-SR, an innovative active packaging system designed to enhance the safety of organ transportation logistics. The results consistently demonstrated the system's ability to maintain thermal stability, preserve tissue integrity and limit biological contamination across multiple organ types.

Maintaining consistent temperature control is critical for organ viability during transport. EMAIS-SR effectively stabilised both internal and surface temperatures within the

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2°C–8°C range in most cases, particularly after system refinements implemented at TRL7. These findings align with previous concerns that conventional coolers, due to passive insulation and reliance on ice, often fail to maintain stable temperatures [3, 17]. The active regulation and real-time monitoring provided by EMAIS-SR represent important advancements, mitigating risks associated with thermal excursions that could compromise transplant success. While early deviations were observed with kidneys during TRL6, these were successfully corrected, underscoring the system's capacity for iterative improvement.

Macroscopic evaluations revealed that organs transported using EMAIS-SR generally maintained or improved their visual appearance, particularly the heart and pancreas. This preservation of macroscopic integrity supports prior observations that visible tissue damage can serve as an early indicator of ischemic injury [18, 19]. Nonetheless, the deterioration observed in liver samples

TABLE 3 | Summary of macroscopic assessments of heart, liver, pancreas and kidneys transported using EMAIS-SR and conventional coolers.

Organ	Packaging	Overall quality	Colour	Abnormalities	Evaluation
Heart	Control	10/10	Homogeneous/homogeneous	Absent	Unchanged
		7.5/10	Heterogeneous/homogeneous	Absent	Improved
		9.5/9.3	Heterogeneous/homogeneous	Absent	Worsened
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		9/10	Heterogeneous/homogeneous	Absent	Improved
	TRL6	9/10	Heterogeneous/homogeneous	Absent	Improved
		9.5/10	Homogeneous/homogeneous	Absent	Improved
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		9.5/10	Homogeneous/homogeneous	Lacerations	Improved
	TRL7	9.2/10	Heterogeneous/homogeneous	Hematoma	Improved
Liver	Control	8.7/9	Homogeneous/heterogeneous	Absent	Improved
		9.5/9	Homogeneous/homogeneous	Absent	Worsened
		8.5/8	Homogeneous/homogeneous	Ischemia	Worsened
		9.5/9	Homogeneous/homogeneous	Absent	Worsened
	TRL6	7.7/10	Homogeneous/heterogeneous	Absent	Improved
		5.7/7.3	Heterogeneous/homogeneous	Absent/Lacerations	Improved
		10/9	Heterogeneous/heterogeneous	Absent	Worsened
		6.2/7	Heterogeneous/homogeneous	Absent	Improved
	TRL7	8.6/8	Heterogeneous/heterogeneous	Ischemia/Absent	Worsened
		9.5/9	Heterogeneous/heterogeneous	Absent	Worsened
Pancreas	Control	0.4/0	Milky white/milky white	—	Unchanged
		0/0	Milky white/milky white	—	Unchanged
		0/0	Milky white/milky white	—	Unchanged
		0/0	Milky white/milky white	—	Unchanged
	TRL6	0/0	Yellow/yellow	—	Unchanged
		0/0	Milky white/milky white	—	Unchanged
		0/0	Milky white/milky white	—	Unchanged
		0/0	Milky white/milky white	—	Unchanged
	TRL7	0/0	Milky white/milky white	—	Unchanged
		0/0	Milky white/milky white	—	Unchanged

(Continues)

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TABLE 3 | (Continued)

Organ	Packaging	Overall quality	Colour	Abnormalities	Evaluation
Kidney	Control	10/10	Homogeneous/homogeneous	Absent	Unchanged
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		9.5/10	Homogeneous/homogeneous	Absent	Improved
		9.2/10	Heterogeneous/homogeneous	Absent	Improved
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		10/10	Homogeneous/homogeneous	Cysts	Unchanged
		10/10	Homogeneous/homogeneous	Absent	Unchanged
	TRL6	10/10	Homogeneous/homogeneous	Absent	Unchanged
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		9.5/10	Homogeneous/homogeneous	Absent	Improved
		9.5/10	Homogeneous/homogeneous	Absent	Improved
	TRL7	10/8	Heterogeneous/heterogeneous	Absent	Worsened
		10/8	Heterogeneous/heterogeneous	Absent	Worsened
		10/10	Homogeneous/homogeneous	Absent	Unchanged
		10/10	Homogeneous/homogeneous	Absent	Unchanged

Note: Data are categorised by control and EMAIS-SR technology readiness level (TRL6 and TRL7) and include visual appearance scores post-transport compared to post-perfusion observations (pre/post).

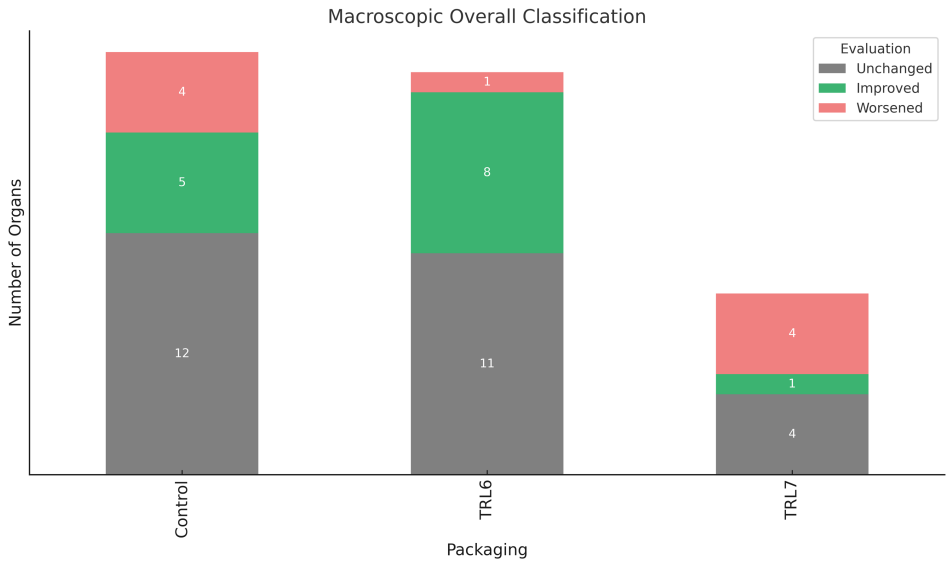


FIGURE 3 | Overall macroscopic evaluation of organs transported in conventional coolers and EMAIS-SR (TRL6 and TRL7). [Colour figure can be viewed at wileyonlinelibrary.com]

transported with both systems highlights the inherent fragility of some organ types and suggests that visual assessment alone may not fully predict tissue viability.

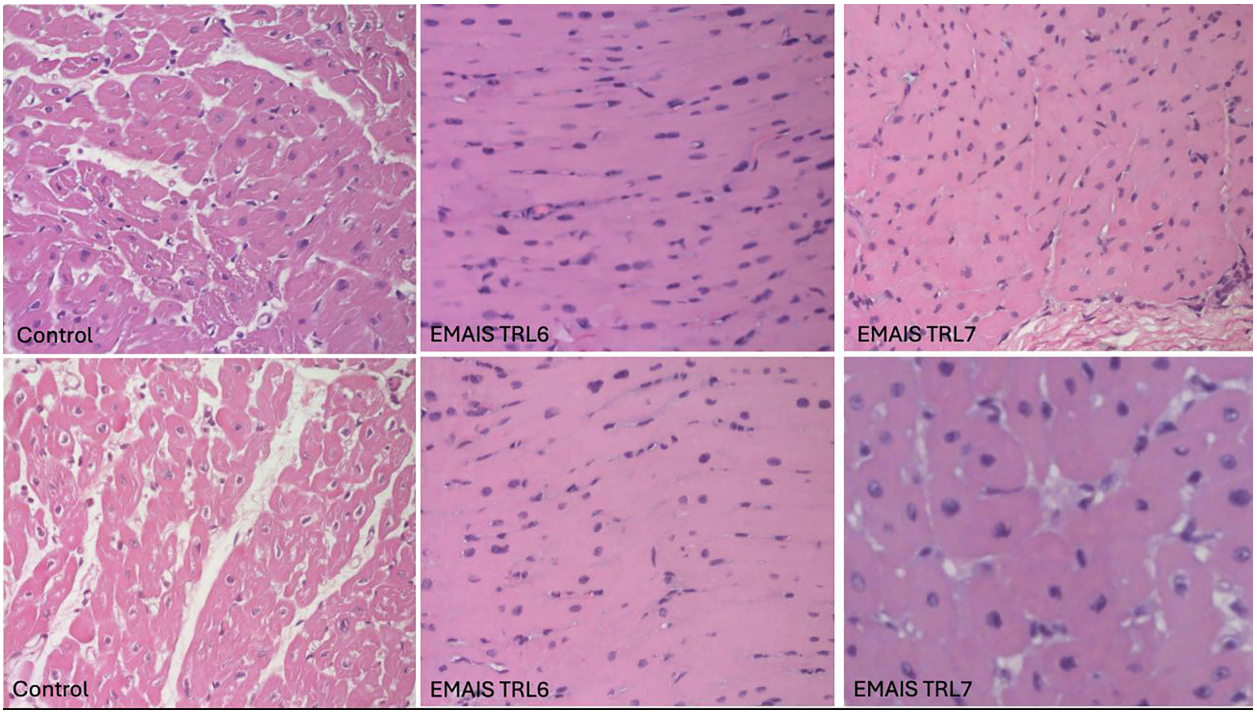
Histological analysis confirmed that EMAIS-SR provided superior preservation of cellular architecture compared to conventional methods. Samples showed clearer nuclei and more

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TABLE 4 | Representative histological images of porcine organs transported using EMAIS-SR and conventional coolers.

Heart

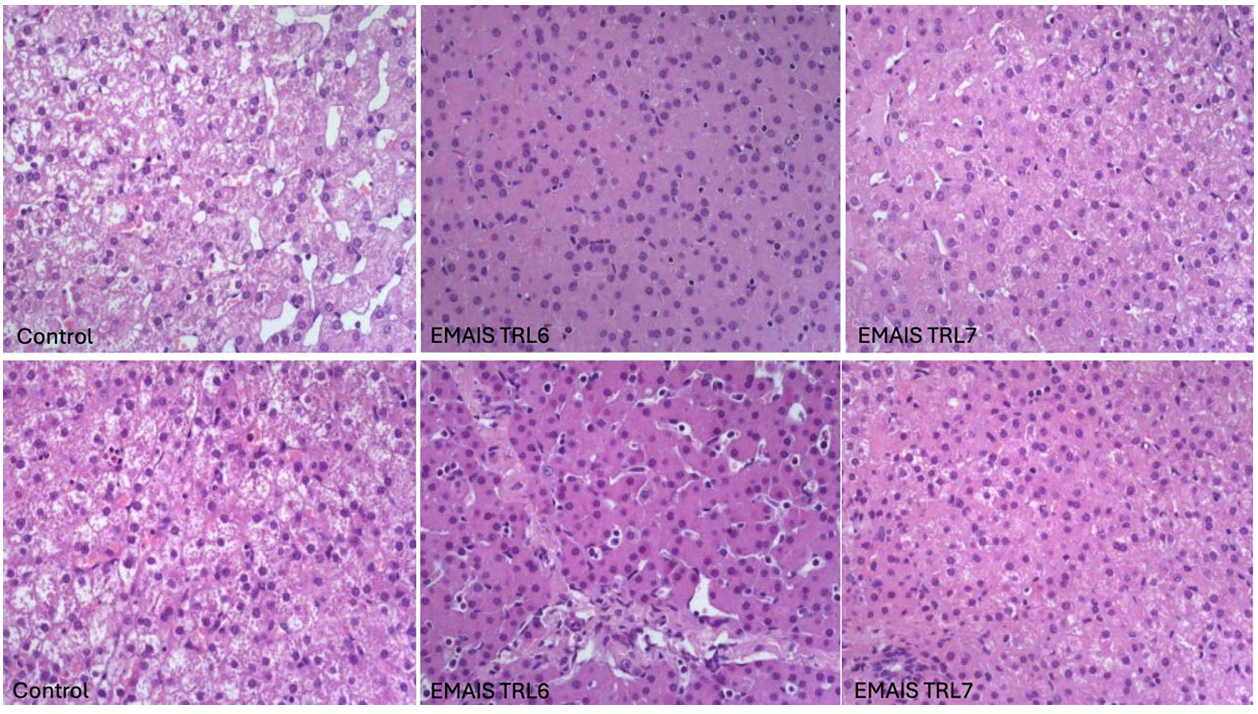
Before transport



After transport

Liver

Before transport



After transport

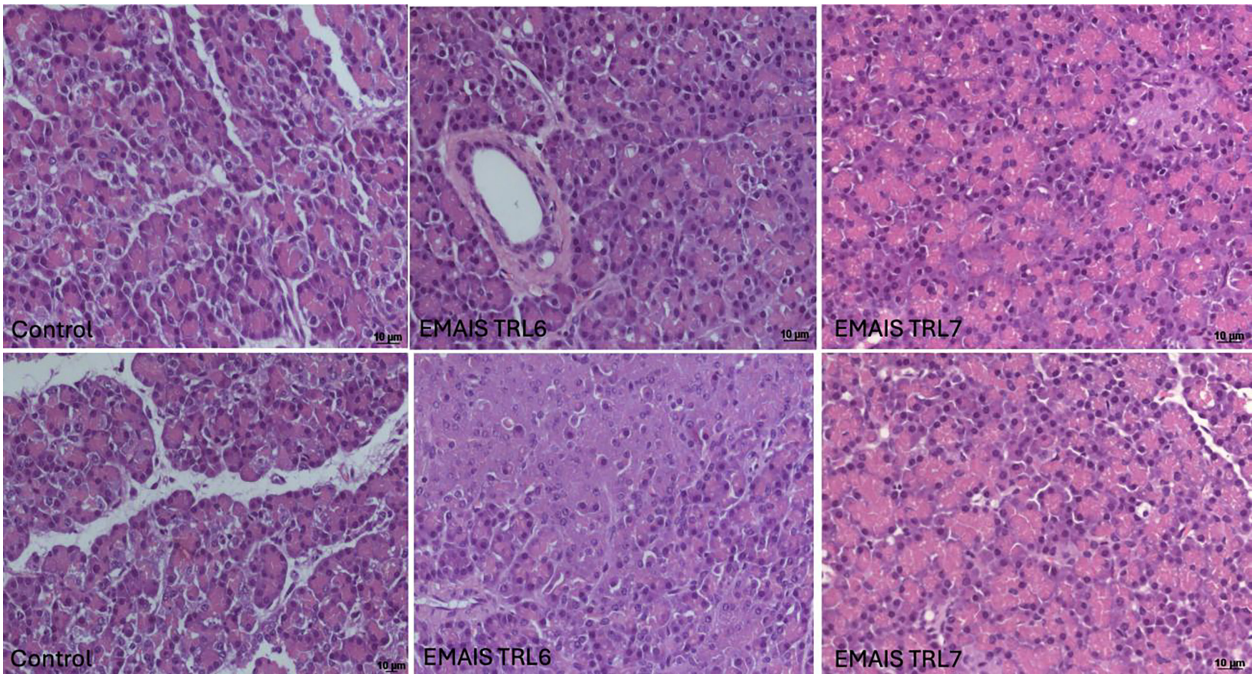
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TABLE 4 | (Continued)

Pancreas

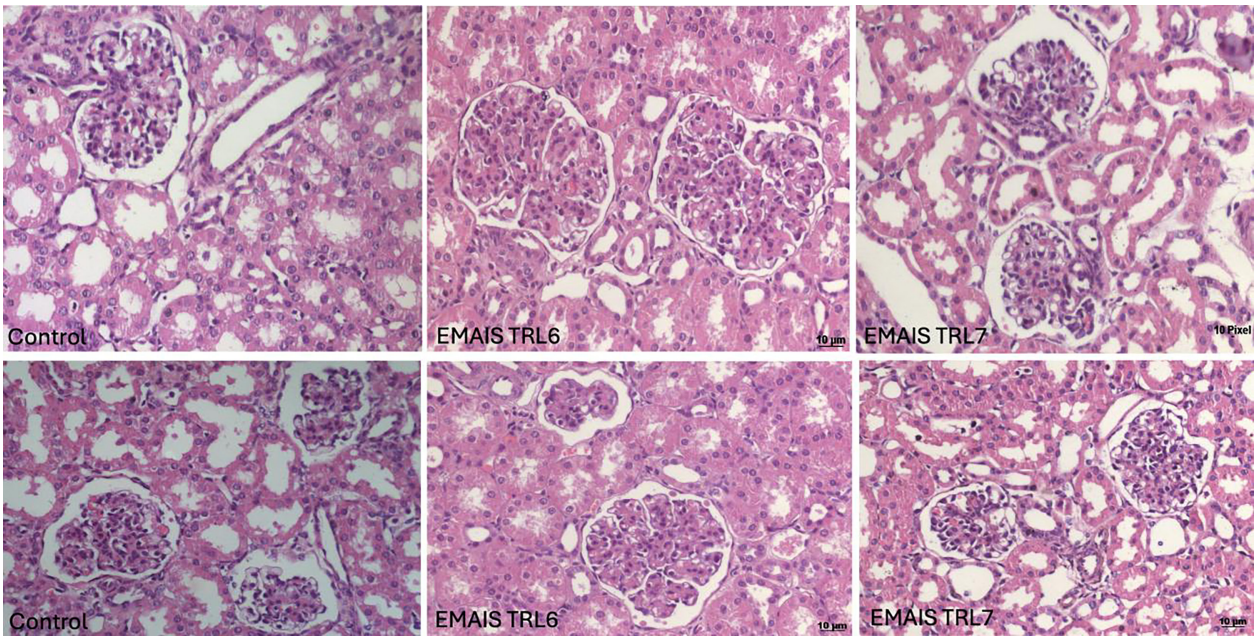
Before transport



After transport

Kidney

Before transport



After transport

Note: Slides show tissue architecture and cellular preservation after simulated transport. All samples were stained with H&E.

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TABLE 5 | Pre- and post-transport microbiological findings in packaging systems used for organ transport.

Packaging	Microorganism	Pre-transport (CFU)	Post-transport (CFU)
Control	*Staphylococcus saprophyticus*	6	No growth
	Staphylococcus epidermidis	6	4
	Micrococcus luteus	28	1
	Brevundimonas vesicularis	5	No growth
	Penicillium spp.	2	No growth
	Scopulariopsis spp.	4	5
	Fonsecaea spp.	3	3
	Bacillus halosaccharovorans	No growth	25
	Pseudarthrobacter oxydans	No growth	27
	Staphylococcus microti	No growth	5
	Staphylococcus warneri	No growth	25
	Paecilomyces variotti	No growth	1
Total (CFU)		54	96
TRL6	*Penicillium* spp.	1	No growth
	Fonsecaea spp.	1	3
	Scopulariopsis spp.	2	No growth
	Acremonium spp.	3	1
	Cladosporium spp.	4	No growth
	Staphylococcus hominis	1	3
	Staphylococcus haemolyticus	1	No growth
	Mucor spp.	1000	No growth
	S. epidermidis	No growth	7
	Curvularia spp.	No growth	4
	Enterobacter cloacae	No growth	200
	Dermacoccus nishinomiyaensis	No growth	20
	Staphylococus sciuri	No growth	5
	S. saprophyticus	No growth	30
Total (CFU)		1013	273
TRL7	*Aspergillus* spp.	2	No growth
Total (CFU)		2	0

Note: Swab results indicate bacterial and fungal growth identified through MALDI-TOF MS. Values reflect presence of microbial contamination and CFU.

homogeneous cytoplasm compared to those transported in control coolers. These microscopic findings are important, as subcellular damage often precedes gross morphological changes and can critically impact graft function [20]. EMAIS-SR's ability to preserve cellular structures reinforces its potential clinical value beyond simple thermal protection.

The histological analysis was essential because, although the macroscopic evaluation showed unsatisfactory results, the histological assessment at the cellular level demonstrated that the tissue structure remained preserved and without significant alterations. Furthermore, when comparing the results between the control and EMAIS-SR groups, better outcomes were observed in the EMAIS-SR group [11].

Biological safety was also evaluated through microbiological assessments. EMAIS-SR demonstrated comparable or lower contamination levels relative to the control, reflecting the system's effective design for internal cleanliness and controlled exposure. These results underscore the importance of strict handling protocols to optimise biological protection [21].

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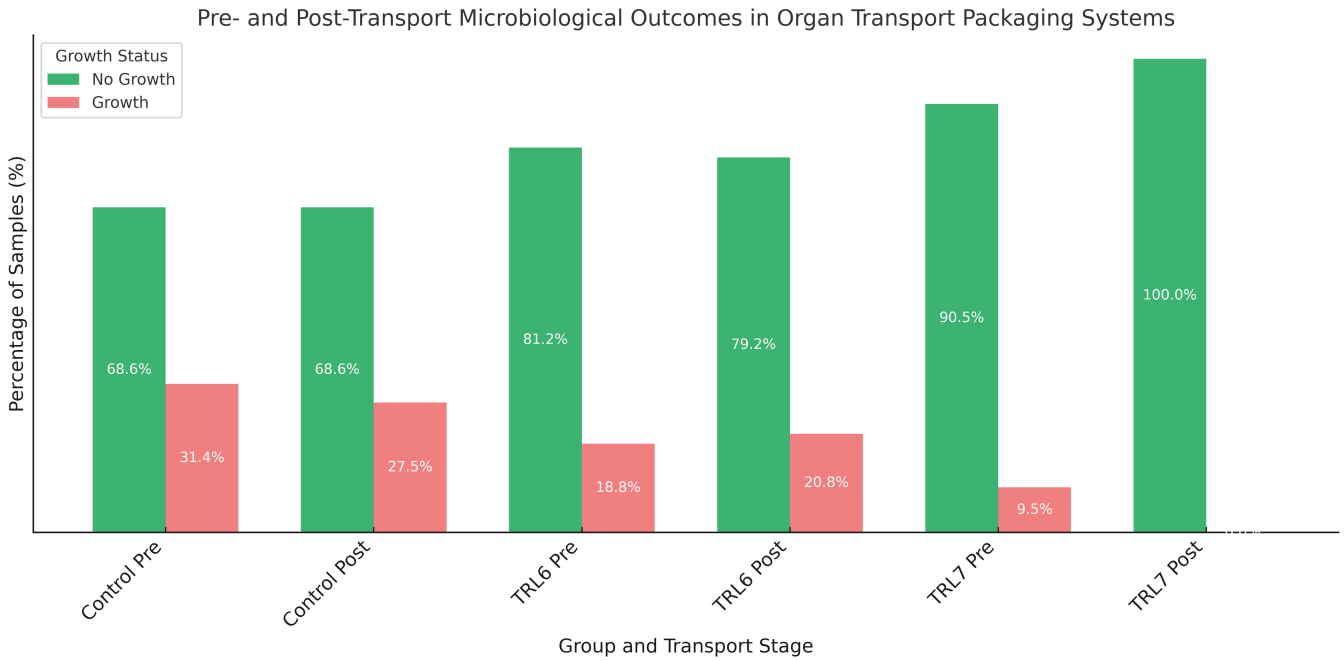


FIGURE 4 | Pre- and post-transport microbiological outcomes in organ transport packaging systems. [Colour figure can be viewed at wileyonlinelibrary.com]

Another strength of the study was the consistent transport times achieved across groups, maintaining an exposure window of approximately 2 to 3 h. This methodological rigour minimised the influence of cold ischemia on outcomes, allowing the effects of the packaging systems themselves to be isolated [22–24].

Finally, EMAIS-SR introduces several technological innovations tailored to the needs of transplantation logistics, including active temperature control, embedded data recording, shock absorption and access security features. The system is reusable and modular, capable of transporting various organs—heart, liver, pancreas and kidneys—making it a sustainable and versatile solution for clinical use. The successful validation of the TRL7 prototype positions EMAIS-SR as a clinically relevant tool for modern transplant logistics.

This study has limitations inherent to preclinical research. The number of organs per group was limited due to ethical considerations. Transport time was standardised to 2 h and may not fully represent longer or logistically complex scenarios. Additionally, although macroscopic evaluations were conducted by experienced professionals, they remain subjective and should be interpreted in conjunction with histological findings. Finally, more robust analyses, such as immunohistochemistry, will be presented in detailed studies for each organ [11].

5 | Conclusion

EMAIS-SR demonstrated effective thermal control, preservation of tissue integrity and biological safety in a structured preclinical model using porcine organs. These findings validate EMAIS-SR as a robust and clinically promising alternative to conventional organ transport systems with significant potential to enhance safety, traceability and standardisation in transplantation logistics.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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