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ARTICLE

Low-cost device for continuous monitoring of human organs during transportation

Dispositivo de bajo costo para el monitoreo continuo de órganos humanos durante el transporte

Daniel Armando **Aguirre Ibarra**[1], Edgar Roberto **Pérez Serrano**[2], Leonardo **Alfaro Díaz**[3], Isaac Valentín **Aguirre Manríquez**[4]

Tecnológico Nacional de México, Instituto Tecnológico Superior de Irapuato, Irapuato, MÉXICO
[1] ORCID: 0000-0001-5834-5536 | daniel.ai@irapuato.tecnm.mx
[2] ORCID: 0009-0007-8600-3745 | edgar.ps@irapuato.tecnm.mx
[3] ORCID: 0009-0006-0011-8246 | lis20110295@irapuato.tecnm.mx
[4] ORCID: 0009-0000-2349-4195 | lis20110052@irapuato.tecnm.mx

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Resumen

La investigación que se presenta es sobre el desarrollo de un prototipo para el transporte de órganos, el cual permita tener un seguimiento de la ubicación y la temperatura en tiempo real. Se hace una comparación con los prototipos y productos comerciales disponibles, teniendo como desventaja el alto costo de tales prototipos. Para realizar el dispositivo se tomó en cuenta la metodología TRIZ, que, según la literatura científica, tiene un alto valor para ahorrar tiempo en la construcción de prototipos. Se presentan los resultados la prueba del equipo con sus respectivas réplicas, por último, se añaden las recomendaciones para continuar con a la escalabilidad del prototipo.

Palabras clave: Monitoreo en tiempo real, TRIZ, transporte de órganos

Abstract

This research presents the development of a prototype for organ transport that enables real-time tracking of location and temperature. A comparison with existing prototypes and commercial products highlights the disadvantage of high costs associated with current solutions. The TRIZ methodology was employed to streamline prototype development, recognized in the scientific literature for its efficiency in accelerating prototyping processes. Results from equipment testing and their respective replicas are presented, along with recommendations for scaling the prototype further.

Index terms: Real-time tracking, TRIZ, organ transport.

I. Introduction

The process of organ transplantation increased significantly in the 1960s. Since then, the predominant method for transporting organs has been the use of a portable cooler, which, as noted in [1], is no more sophisticated or elaborate than the model commonly used for outdoor recreational activities. Even in Mexico, coolers made of expanded polystyrene are used, as illustrated in Fig. 1. Since that time, the number of transplants has steadily increased, reaching the point where demand exceeds supply. In this context, the importance of strictly adhering to the transplantation protocol, which includes the transportation of organs, is crucial. The process can be viewed from a logistics perspective, as it is a complex supply chain consisting of the following stages, as recorded by [2]:

1. Information management.
2. Planning and programming.
3. Displacement of medical teams for organ harvesting.
4. Packaging.
5. Transportation.
6. Transplant.

Fig. 1. Organ transport cooler.

In the specific case of Mexico, the transportation stage presents a challenge as there is no unified transportation system among certified transplantation hospitals. The country has a national registry of patients awaiting transplants, but each federal entity has its own organ transplant coordination team, whose main function is to notify when an organ and/or tissue is available. At that moment, a recipient is identified, and both the provider hospital and the recipient hospital agree on the mode of transportation. This information was identified through visits and interviews conducted at the State Transplant Center of Guanajuato (CETRA) [3].

Three primary concerns were identified:

1. The organ undergoes multimodal transportation in most cases (frequency not quantified, but inferred from experience), prolonging the time in transit and thereby increasing the risk of ischemia, translating to reduced functionality and durability of the organ [4], [5].
2. Due to the shifts in modes of transportation, real-time tracking of the organ's location is unavailable.
3. The third issue combines the previous two: the receiving hospital lacks real-time knowledge of the organ's status regarding temperature, humidity, and oxygenation. The only means to obtain this information is through the attending physician responsible for the cooler containing the organ, who must open the cooler and use a digital thermometer to record the temperature. However, this action compromises the cold chain [6].

The matter of mitigating the risk of ischemia during organ transplantation holds significance within the scientific community, with studies and case reports documented in the literature. On one hand, research endeavors concentrate on the utilization of clinical methodologies [7], [8], [9], which, although yielding favorable results, represent experimental techniques, even encompassing non-human organ models. The other research topic focuses on the development of technological devices that are useful during organ transportation. These devices yield positive outcomes, yet they still present a disadvantage for technology transfer to hospitals in Mexico (see Table 1).

TABLE 1
TECHNOLOGICAL DEVICES USEFUL FOR ORGAN TRANSPORTATION

Device	Disadvantage	Source
Heart-in-a-Box: battery power chamber with wireless technology that maintains the organ in functioning state, perfusing it with warm, nutrient and oxygen blood.	This device was approved by the FDA and nowadays it's only available in 20 hospitals in U.S. Furthermore, it is an expensive device with a cost over $40000 (US dollars).	[1], [10], [11]
OrganPocket: organ protector device that is made of proprietary elastomeric gel with insulating properties superior to silicone rubber. This highly elastic gel has been engineered to stretch to >1000% elongation, allowing the material to conform to the shape of transplanted organs.	It has not been tested with human organs. Researchers used an ex vivo porcine kidney, heart and pancreas models.	[12]
Paragonix: ice-free storage and transport unit that provides a controlled environment for the organ throughout the entire process, from donor extraction to recipient implantation.	It is not possible to know location of the organ in real-time. It is required a different device for each organ: lung, liver and heart.	[13]
MoTEC: mobile thermoelectric device with a two-compartment system with an outer recirculating water cooling unit.	This device requires an external car battery, making it heavy and difficult to handle.	[14]

Based on the understanding of the context in Mexico, the purpose of the research is to develop a low-cost portable device that is useful for remotely monitoring the conditions of the organ and/or tissue being transported for an organ transplant.

II. METHODOLOGY

For the prototyping process, the TRIZ method (Theory of Inventive Problem Solving) and its 39 engineering contradiction parameters were selected. This choice was predicated on the TRIZ method's recognition as one of the most potent tools for systematic innovation [15], noted for its capacity to mitigate design conflicts by means of contradiction resolution [16].

To implement the TRIZ method, the following steps were taken:

1. Problem definition.
2. Contradiction analysis.
3. Application of the TRIZ principles.
4. Idea generation.
5. Solution selection.
6. Prototype development and validation.
7. Implementation and continuous evaluation.

Table 2 shows a segment of the actions taken when evaluating the principles.

TABLE 2
TRIZ PRINCIPLES (SEGMENT)

Principle	Action
Segmentation	Divide the cooler into compartments for the organ and monitoring equipment.
Dynamicity	Implement sensors and communication devices with adjustable settings to adapt to changing conditions during transportation.
Preliminary action	Activate the monitoring system automatically upon organ insertion.
Local quality	Ensure precise temperature and humidity control within the organ compartment.
Feedback	Incorporate feedback mechanisms to adjust cooling and monitoring parameters based on real-time data.
Transition to a new dimension	Utilize miniaturized sensors and communication modules to minimize space requirements.
Equipotentiality	Ensure consistent performance across different transportation environments by optimizing cooling and communication systems.

Fig. 2 shows the connection diagram, which was created in Fritzing, and displays the connections between the elements (Arduino board, adapters and modules).

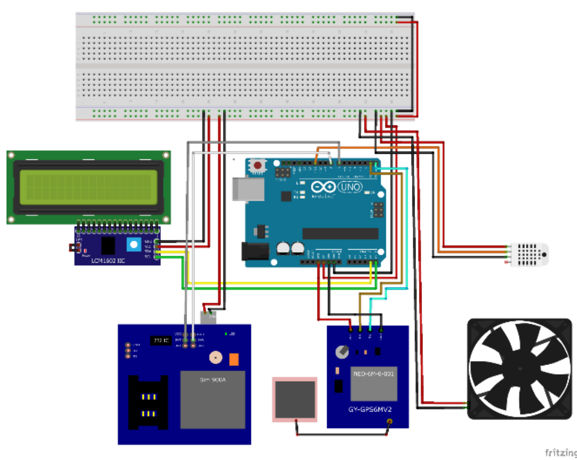

Fig. 2. Connection diagram.

The device was installed in a 28QT plastic cooler. The installation of the device is shown in Fig. 3.

The prototype utilized a conventional plastic cooler instead of one made from polystyrene. This choice offers certain advantages in terms of durability, as plastic coolers generally withstand mechanical stresses better than polystyrene, which is prone to cracking under impact. Additionally, plastic is less permeable than polystyrene, reducing the likelihood of moisture infiltration and potential contamination, which is critical for organ transport. While polystyrene provides effective thermal insulation, the more robust structural integrity of plastic can enhance the reliability of maintaining the necessary internal environment, particularly when the cooler may be subject to movement or external forces.

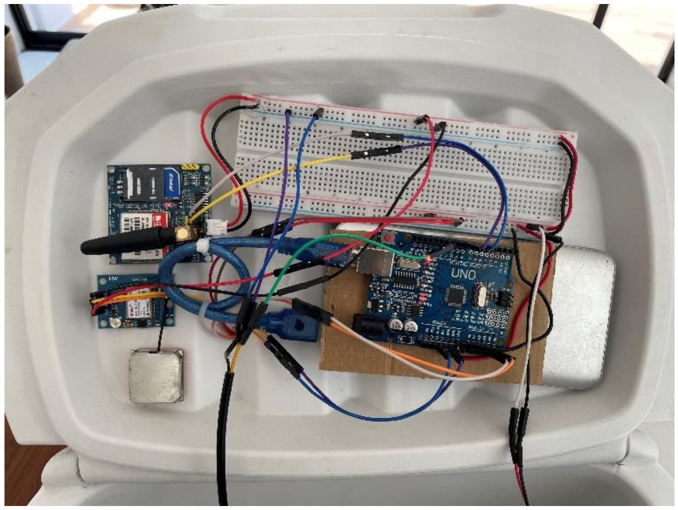

Fig. 3. Device installed in cooler.

The prototyping process, guided by the TRIZ method, effectively addressed and resolved design conflicts, ensuring the development of a robust and innovative solution. After defining the problem and analyzing contradictions, the application of TRIZ principles facilitated the generation of creative ideas that were systematically evaluated.

The solution selection process involved rigorous assessment and comparison of potential solutions to identify the most feasible and effective option. This step was crucial in ensuring that the chosen design not only met the project requirements but also leveraged the innovative potential of TRIZ principles.

Prototype development and validation followed, where the selected solution was transformed into a tangible prototype. The prototype was rigorously tested to validate its performance, ensuring that it met the desired specifications and resolved the identified contradictions. This iterative process of development and validation was critical to refining the design and ensuring its effectiveness.

III. Results

The prototype in the cooler was tested 10 times over 4-hour intervals. A control cooler was used, which did not contain sensors or the fan. Fig. 4 shows the average temperature comparison. Both coolers were filled with a cold gel pack. The organs selected for testing were pig hearts. It is important to clarify that the organs were donated by local butcher shops, so no live animals were harmed solely for the purpose of this project's research.

An analysis of variance was conducted between the two samples, and statistical evidence was found to reject the null hypothesis. Therefore, there is a significant difference between the two samples, indicating that the cooler with the device is effective in maintaining a stable temperature and humidity, at least over 4 hours (Fig 4 and Fig. 5).

In Fig. 6, the screen displays the execution of sending coordinates to a mobile device to track in real time the organ being transported, along with its temperature record.

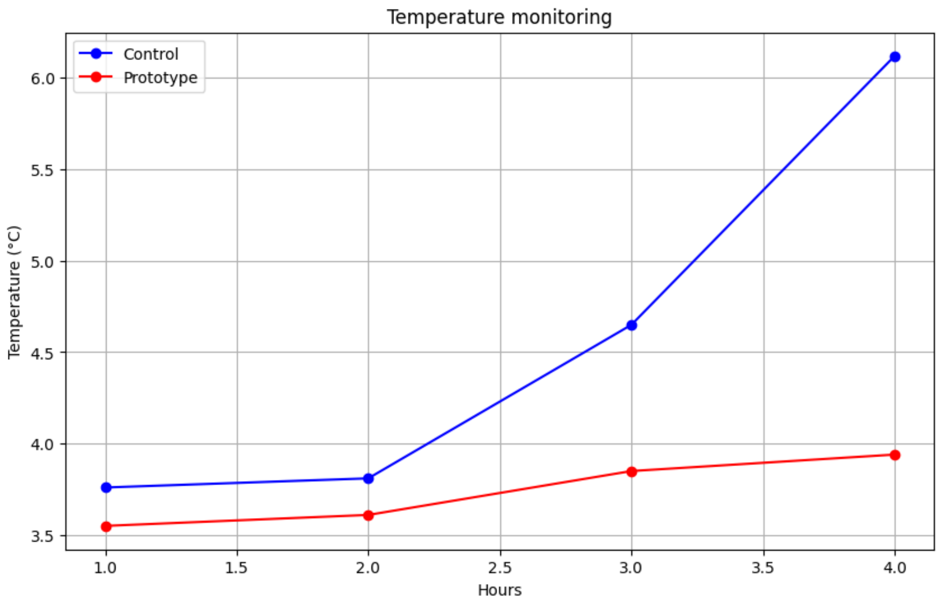

Fig. 4. Temperature monitoring.

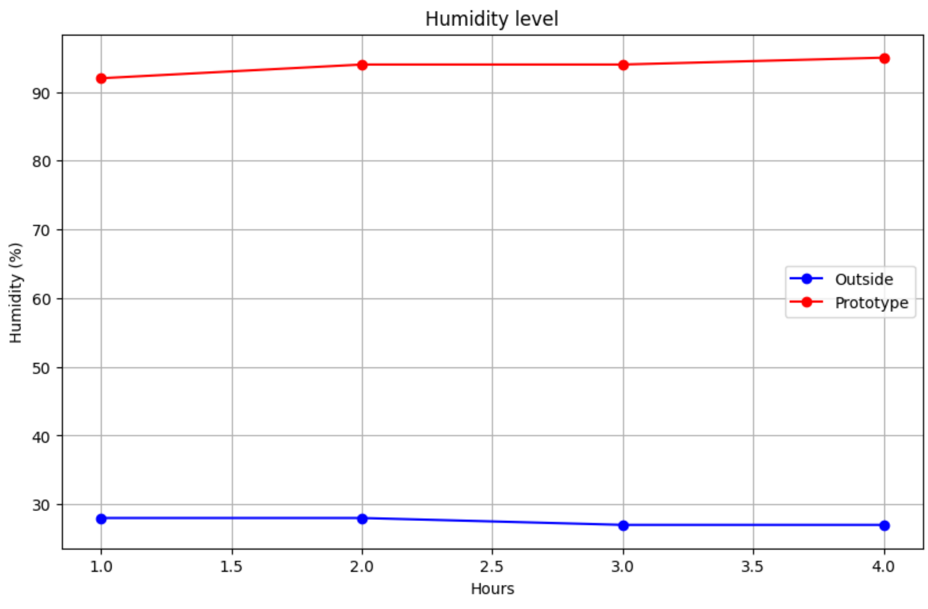

Fig. 5. Humidity monitoring.

Fig. 6. GPS display.

During prototype testing, the SMS messages programmed for automatic sending every 15 minutes were successfully received.

IV. Conclusions

The prototype meets the established objectives, providing a cooler with an integrated device that did not exceed 2000 Mexican pesos in total cost. Notably, the cooler, not being made of styrofoam, represented 53% of the total cost. Even considering labor costs, the total expenditure remains well below those indicated in Table 1.

The initial design proposed dividing the cooler into distinct compartments for the organ and monitoring equipment. However, due to cost considerations, this configuration was ultimately not implemented. Currently, sensors do not maintain either direct or indirect contact with the organ being transported. From a technical perspective, the lack of separate compartments could theoretically influence sensor accuracy due to potential signal interference from temperature fluctuations or condensation within the cooler. Nevertheless, if sensors are effectively isolated from the transported organ's immediate environment, any impact on sensor performance should be minimal, assuming adequate calibration and placement protocols. Nevertheless, there are still elements to consider for further prototype enhancement, necessitating future testing. The following elements are listed for evaluation:

1. Assessing the device with different insulating materials in the cooler.
2. Evaluating the device with styrofoam coolers to compare performance and assembly costs, particularly regarding insulation, durability, and cost-effectiveness for reliable organ transport.
3. Testing the device in areas with low cellular network connectivity.
4. Implementing a communication mode without data, specifically compliant with air travel regulations, thus requiring Wi-Fi communication.

To measure oxygenation of an organ within a cooler, non-invasive optical sensors need to be adapted. This is the next step in this project. These sensors rely on spectrophotometry, emitting specific wavelengths of light and analyzing how the organ tissue absorbs or reflects it to assess oxygen saturation levels. It is also recommended to conduct a failure analysis, for which a What-if process must be carried out and documented with the FMEA tool, detailing occurrence, severity, and detection.

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