Development of Ampoule Opener Machine Adapted to Hospital Environments Using Fused Deposition Modeling

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***Abstract*—In hospital settings, healthcare personnel are exposed to cuts and ergonomic injuries when opening ampoules. In this study, an Ampoule Opener Machine was developed using Fused Deposition Modeling (FDM) technology, adapted to hospital activities, affordable, and safeguarding the safety of healthcare personnel. To achieve this objective, Hospital III Goyeneche in Arequipa was used as a case study, where the requirements of nursing staff were compiled. An Ampoule Opener Machine adapted to the previous requirements was then designed using 3D modeling software and manufactured using 3D printing with locally available materials, achieving an affordable manufacturing cost of less than 100 USD. The machine consists of a portable design with a crank mechanism and is powered by a gear motor, which even allows for simultaneous ampoule opening. In tests, it was evaluated with different types of 20 ml ampoules, demonstrating a preliminary opening effectiveness of up to 83.29%. The machine has also demonstrated biosafety capabilities by trapping most glass fragments and opening ampoules with blunt edges (3.85 mm). These results indicate that the Ampoule Opener Machine developed with FDM technology is safe, affordable, and adaptable to the work of healthcare personnel in hospital settings.**

***Keywords*—ampoule, hospital, design, machine, Fused Deposition Modeling (FDM), 3D printing, opening**

I. INTRODUCTION

Currently, in hospitals and health centers, sharps injuries account for approximately 90.3% of injuries to nursing staff, with the most common being those caused by manually opening glass ampoules [1]. In a study conducted by Lien *et al.* [2], 32.9% of cut injuries were recorded among nursing staff during the opening of glass ampoules. Similarly, in the study conducted by Garus-Pakowska *et al.* [3], 25.92% of injuries were reported as cuts. In addition, this procedure causes ergonomic injuries due to repetitive and irregular movements of the arm and wrist, adding to the force applied to open the ampoules [2, 4]. Glass particles were also observed in medications from ampoules opened by this procedure, which is a risk to patient safety when receiving treatment [5, 6]. On the other hand, in Latin America, the lack of resources means that healthcare personnel do not have the supplies and devices to open ampoules safely, increasing the risk for both staff and patients [7].

In response to this situation, various research groups and institutions have developed protocols and designed tools and prototypes for opening ampoules. Masako *et al.* [8] have developed a new procedure that improves staff technique for opening ampoules. On the other hand, in some hospitals and health centers, healthcare personnel have adapted available tools such as emery sheets attached with rubber rings [9] and disposable syringe tubes [10] to achieve safer ampoule opening, highlighting their low cost and simplicity. Other research has led to the design of tools called "ampoule openers", which offer greater safety to the user [11] and reduce contamination with glass fragments [12, 13]. Luo [14] has developed a novel device with dual functionality: opening ampoules and crushing residual fragments. Duan *et al.* [15] implemented a novel ampoule box design in a hospital that reduces contamination from glass particles and minimizes injuries to healthcare personnel. As seen above, the development and incorporation of new protocols and tools have reduced the risks of cuts [16, 17] and ergonomic injuries among healthcare personnel [18], and contamination from glass fragments in patients' medications has also been controlled [19]. However, the risk of cuts and ergonomic injuries to healthcare personnel persists, since these are manual devices and still require their intervention to open. Technological advances have also driven the development of machines capable of opening ampoules without human intervention, such as the research by Yuqing and Hu [20],

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who designed a novel semi-automatic single-ampoule opener. Wang *et al.* [21] designed an ampoule opener with a cyclic mechanism that allows multiple ampoules to be opened. These studies have succeeded in reducing the involvement of healthcare personnel in opening ampoules, eliminating the risks of cuts and ergonomic injuries, as well as improving opening times [22], which is crucial in emergency rooms. Despite the optimistic outlook for these designs, they still have technical problems that prevent them from being efficiently adapted to hospital environments. Advanced robotic systems have also been developed and implemented in clinics and pharmaceutical centers, which have multiple functions, including opening ampoules [23], as is the case with the CytoCare and I.V.STATION robots [24, 25]. However, these systems are not only incompatible with the work pace of nursing staff, but are also inaccessible due to their high costs for low-income hospitals and health centers.

On the other hand, Fused Deposition Modeling (FDM) technology, also known as 3D printing, has evolved in recent years in the industry, allowing complex devices to be manufactured at an affordable cost [26]. Similarly, it has been implemented in the biomedical sector, enabling the development of devices, tools, or machines in different specialties [27, 28]. Jeffer *et al.* [29] developed and validated a low-cost prosthetic device using 3D printing, similarly to Abel *et al.* [30], who developed a lower limb prosthesis by evaluating different 3D printing patterns. Urendes *et al.* [31] presented a limb exoskeleton with a simple design for rapid adaptation by staff and patients in pediatric physiotherapy. Benhrens *et al.* [32] designed a peristaltic pump for drug administration using 3D printing technology. Costanza *et al.* [33] designed a medical instrument based on FDM technology for laparoscopic surgery. Longhitano *et al.* [34] manufactured ventilation valves for masks using 3D printing. As can be seen in the above studies, FDM technology is being applied with positive results in the biomedical sector, as corroborated by the use of 3D printing for the development of an ampoule opener machine adapted to the requirements of the healthcare sector.

In this article, we present a new prototype for opening ampoules using FDM technology, focused on staff biosafety, adaptable to tasks, and accessible to healthcare centers with limited resources. First, we take Hospital III Goyeneche in Arequipa as a case study. Then, requirements are compiled based on interviews with nursing staff in order to design an affordable prototype based on staff needs. Next, the ampoule opener machine is manufactured using FDM technology criteria. Finally, the efficiency, adaptability, and biosafety of the device are evaluated with ampoule opening tests using ampoules of different sizes and configurations.

II. Materials and Methods

A. Design Requirements

This section presents the design requirements for the development of an ampoule opener machine. These requirements are based on the needs and requirements obtained from interviews and surveys with nursing staff at Hopstipal III Goyeneche.

Nursing staff are responsible for administering the appropriate dose of medication according to the patient's condition. According to the staff, the most commonly used medications are presented in type I, form B glass ampoules, as shown in Fig. 1, whose dimensions comply with ISO 9187-1 [35]. They are transported around the hospital in nursing carts, as shown in Fig. 2, equipped with the necessary supplies to deal with any emergency.

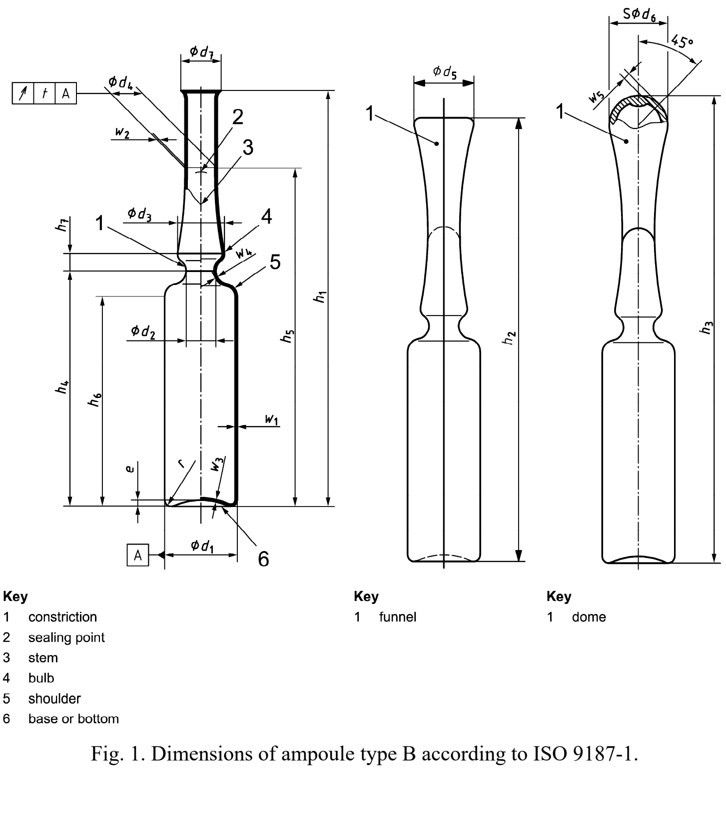
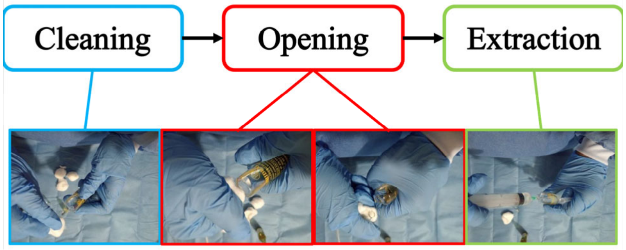


Fig. 1. Dimensions of ampoule type B according to ISO 9187-1.

Fig. 2. Nurse's cart.



(a) (b) (c) (d)

Fig. 3. Conventional procedure for opening ampoules: (a) surface cleaning; (b) thumb positioning; (c) next breaking; (d) medication extraction.

The procedure for opening ampoules performed by staff at Hospital III Goyeneche is divided into three phases, as shown in Fig. 3. In the first phase, the outer surface of the ampoule is cleaned, as shown in Fig. 3(a). In the second phase, the thumb is placed on the mark on the ampoule, as shown in Fig. 3(b), and pressure is applied to break the neck of the ampoule and open it, as shown in Fig. 3(c). Finally, in the third phase, the medication is extracted with a syringe and the appropriate dose is administered to the patient, as shown in Fig. 3(d).

It is during the second phase that most cuts and lacerations occur (Fig. 4). In response to this, nursing staff have implemented a procedure that consists of covering the head of the ampoule with gauze before beginning to open it. They have also implemented the use of commercially available protective devices for opening ampoules [36]; however, injuries to healthcare personnel persist.

Fig. 4. Cut injuries sustained when opening glass ampoules.

Next, the requirements are obtained based on the information provided above by the nursing staff. Table I shows the design requirements established and classified into three categories: biosafety, adaptability, and accessibility.

TABLE I. LIST OF DESIGN REQUIREMENTS

Category	Requirements	Description
Biosecurity	Containment fragments	Contain glass fragments when opening ampoules.
	Cut protection	Minimization of sharp edges (< 4 mm) [17].
Adaptability	Portability	Compact size and weight less than 2.5 kg.
	Ergonomic	Easy to use and convenient to transport in nursing carts.
	Opening force	Force of up to 100N according to ISO 9187-1 for opening ampoules [35].
	Aperture range	For opening type I ampoules, shape B and sizes of 20 ml.
Accessibility	Availability	Made from locally sourced materials.
	Low cost	Low manufacturing cost (<100 USD)

B. Mechanical Design

Based on the requirements in Table I, the ampoule opener machine was designed using Solidworks software. First, the ampoules were designed according to the standardized dimensions of ISO 9187-1, as shown in Fig. 5(a). Next, the adapter was designed, which has two side rails that allow entry and exit to the machine structure, as well as cavities to hold up to three ampoules, see Fig. 5(b). Next, the opening cap was designed, which has three holes aligned with the heads of the ampoules located in the adapter. Next to each hole, circular protrusions were designed, which come into contact with the ampoules when the cap is closed, generating the force necessary for opening, see Fig. 5(c). Next, the transmission system was designed, consisting of a connecting rod as shown in Fig. 5(d), a pinion as shown in Fig. 5(e), and a driven gear as shown in Fig. 5(f). This system has a transmission ratio of Rt = 3. The combination of these mechanisms converts the rotary motion from the motor into oscillating motion in the cap to open and release the ampoules. Finally, the main structure was designed, which has four strategically distributed cavities to house the various components of the system, as shown in Fig. 5(g). The first cavity allows the ampoule adapter to be inserted, next to which is the second cavity, where the glass fragments are stored after each ampoule is opened. A circular lid was designed to eject the fragments. Below this is the third cavity, which houses the motor and electronics. Finally, the fourth cavity is located on the outside of the machine and houses the transmission system.

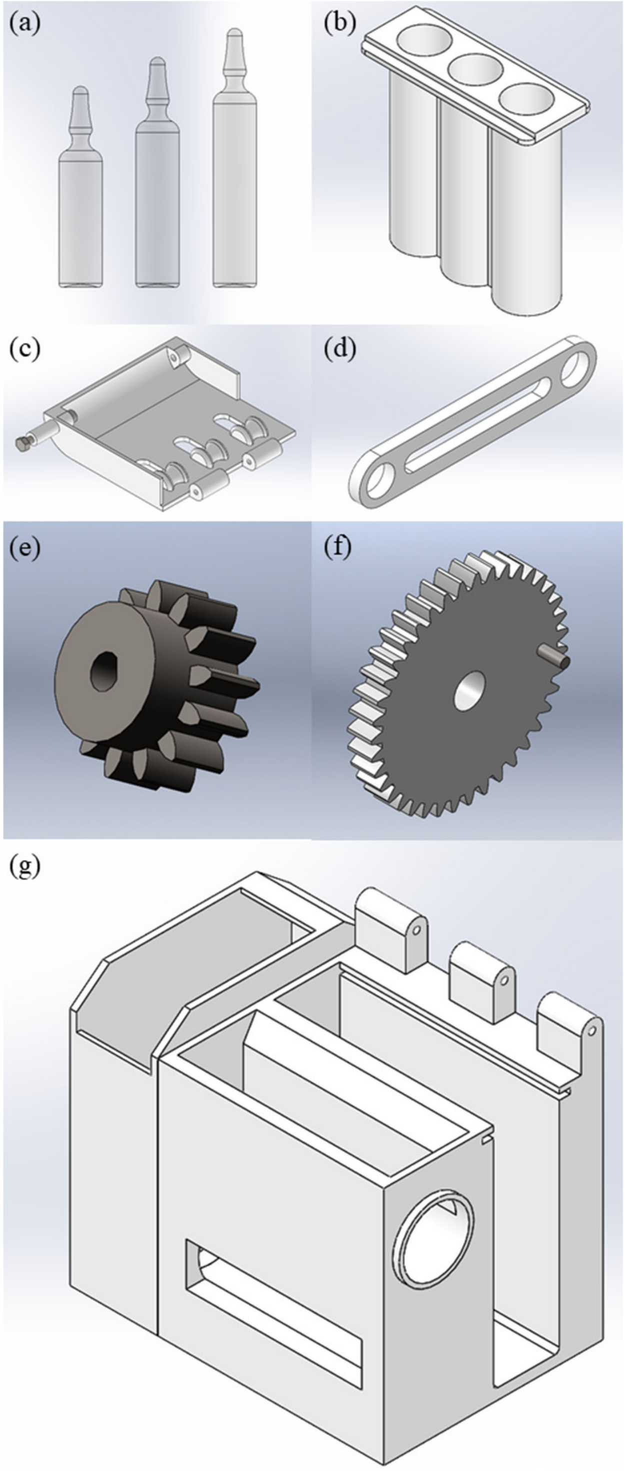


Fig. 5. Component design for ampoule opening machine: (a) reference ampoules; (b) ampoule adapter; (c) opening cap; (d) connecting rod; (e) pinion; (f) driven gear; and (g) main structure.

C. Simulation with Finite Element Analysis

This section presents the Finite Element Analysis (FEA) simulation of the components of the ampoule opener machine, in order to determine the mechanical characteristics when applying the load conditions specified in ISO 9187-1 and to ensure the safe manufacture and operation of the prototype.

First, the maximum load required to open the ampoules was determined, which depends on the volume of the ampoule according to ISO 9187-1. For 20 ml ampoules, the maximum load is 100 N [35], as shown in Table II.

TABLE II. OPENING FORCE ACCORDING TO AMPOULE VOLUME

Nominal Ampoule Volume (ml)	Opening Force	
	Minimum Force (N)	Maximum Force (N)
1 2 3 5	30	80
10	30	90
20 25 30	30	100

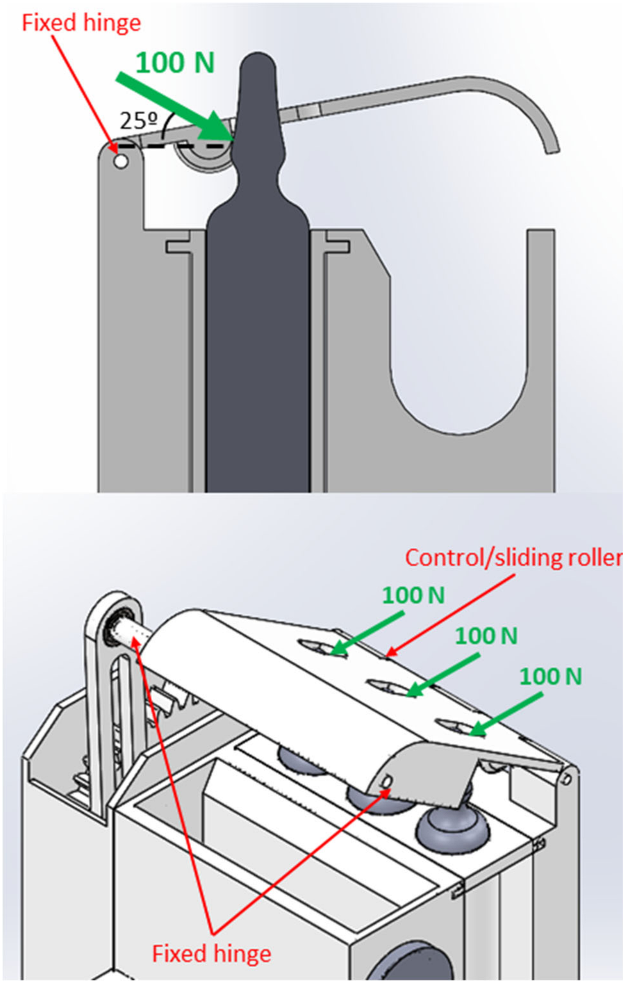
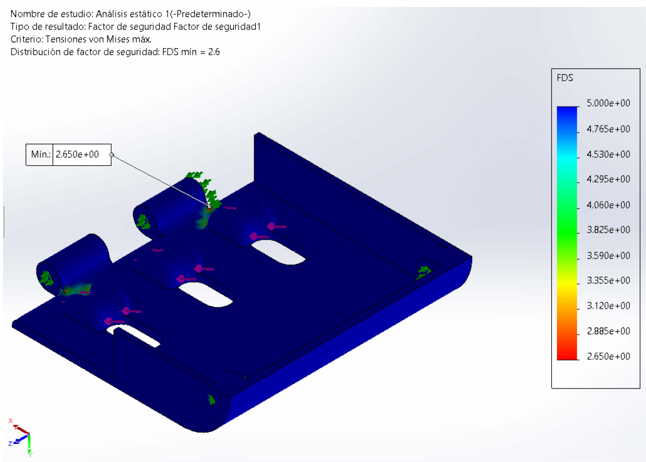


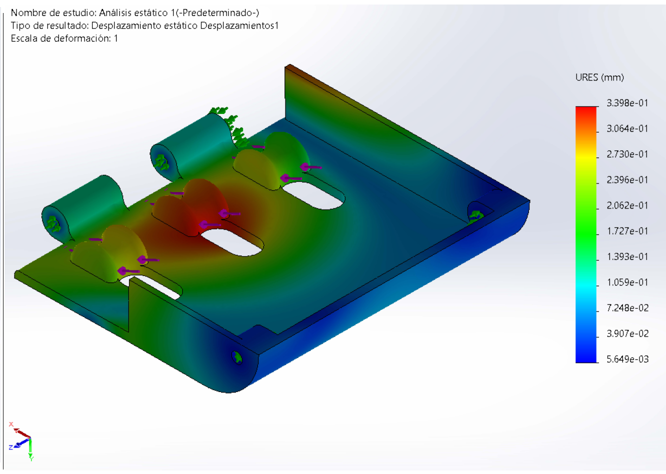
Fig. 6. Diagram of the boundary conditions and load configuration for the opening cover component.

Finite Element Analysis (FEA) allows the design of structures to be validated for optimization prior to manufacturing. To do this, the stress and deformation generated by the loads acting on the structure are determined [37]. This is why we use this analysis on the components of the ampoule opening machine to obtain an optimal design. We define the PETG material, then apply the loads in the appropriate direction to each component [38] and start the simulation in the SolidWorks Simulation tool. The analysis was performed as a static study. The PETG material was modeled in the software as a linear elastic isotropic material, with a modulus of elasticity of 2.2 GPa, a Poisson's ratio of 0.35, and a tensile strength of 55 MPa. The load of 100 N per ampoule pack is initially applied at the contact zone between the opening lid and the ampoule pack. For the case of 3 ampoules, which would be the critical scenario, the total load is 300 N. The direction of this load was determined using the SolidWorks interference detection tool, establishing an inclination angle of 25°, as shown in Fig. 6. The boundary conditions and load configuration were defined based on the function of each component of the device, using three types of constraints: "Fixed geometry", "Control/sliding roller" and "Fixed hinge". Fig. 6 presents a schematic representation of the boundary conditions and load configuration applied to the "opening cover" component, where the opening force acts directly. The boundary conditions for this case were defined as "Fixed hinge" for the bolted joints and "Control/sliding roller" constraints for the sliding contact surfaces. The same criteria were applied to the other components of the device. The mesh was generated with an average element size of 2 mm. The simulations were performed using the von Mises criterion. A convergence analysis was conducted, establishing a variation of less than 5% in the maximum stress. The components were optimized to achieve convergence in up to three design iterations, yielding the results shown in Fig. 7.

For the opening lid, the maximum stress of 21.62 MPa is generated at the hinge joints, see Fig. 7(a), and the maximum deformation of 0.0339 mm is generated at the intermediate hole, see Fig. 7(b). Next, for the ampoule adapter, the maximum stress of 6.66 MPa is generated at the upper edge of the intermediate hole, see Fig. 7(c), and the maximum deformation of 1.82 mm is generated at the bottom of the adapter, see Fig. 7(d). Next, for the connecting rod, the maximum stress of 25.12 MPa occurs on the inner side of its groove, see Fig. 7(e), and the maximum deformation of 2.397 mm is generated in the same location as the maximum stress, see Fig. 7(f). Next, for the pinion, the maximum stress of 7.51 MPa is generated on the flat part of the cavity where the motor shaft is housed, see Fig. 7(g), and the maximum deformation of 0.008 mm is generated on the upper edge of the teeth, see Fig. 7(h). Subsequently, in the driven gear, the maximum stress generated is 3.11 MPa located at the base of the teeth, see Fig. 7(i), and the maximum deformation of 0.033 mm is generated at the upper edge of the teeth, see Fig. 7(j). Finally, in the main structure, the part where the transmission system is coupled is identified as the critical area with a maximum stress of 7.29 MPa, see Fig. 7(k), and a deformation of 0.022 mm located in the cavity that houses the driven gear shaft, as shown in Fig. 7(l).



(a)



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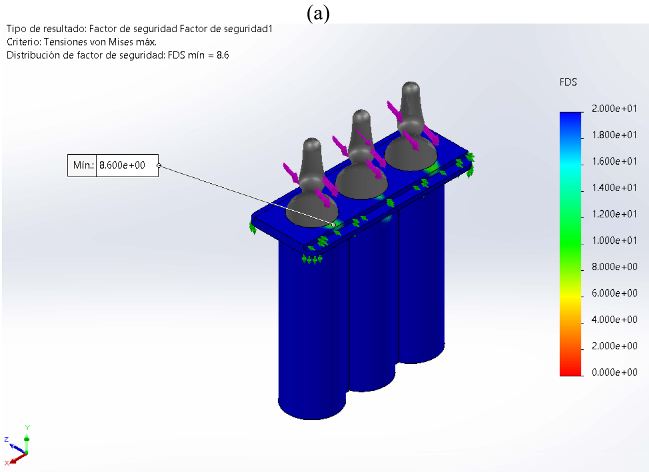
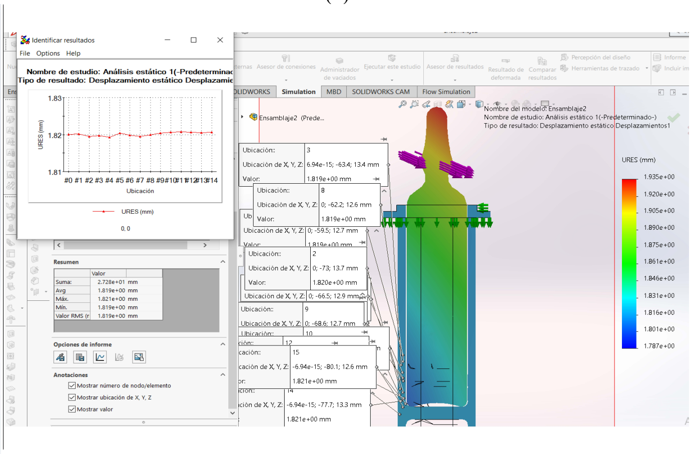


(c)



(d)

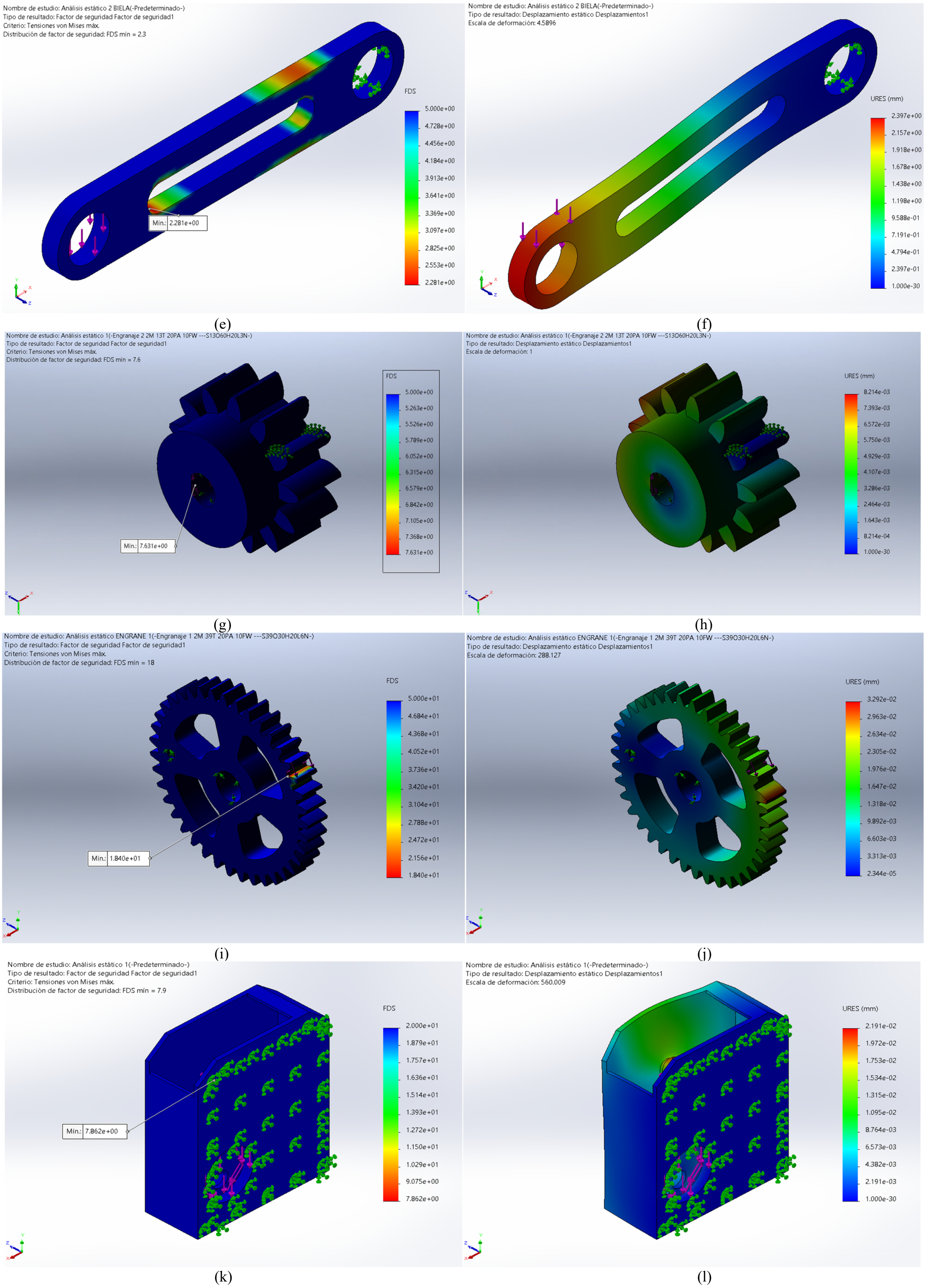


Fig. 7. Finite Element Analysis (FEA) on ampoule opening machine components: (a) stress on opening cap; (b) deformation on opening cap; (c) stress on ampoule adapter; (d) deformation on ampoule adapter; (e) stress on connecting rod; (f) deformation on connecting rod; (g) stress on pinion; (h) deformation on pinion; (i) stress on driven gear; (j) deformation on driven gear; (k) stress on structure; and (l) deformation on structure.

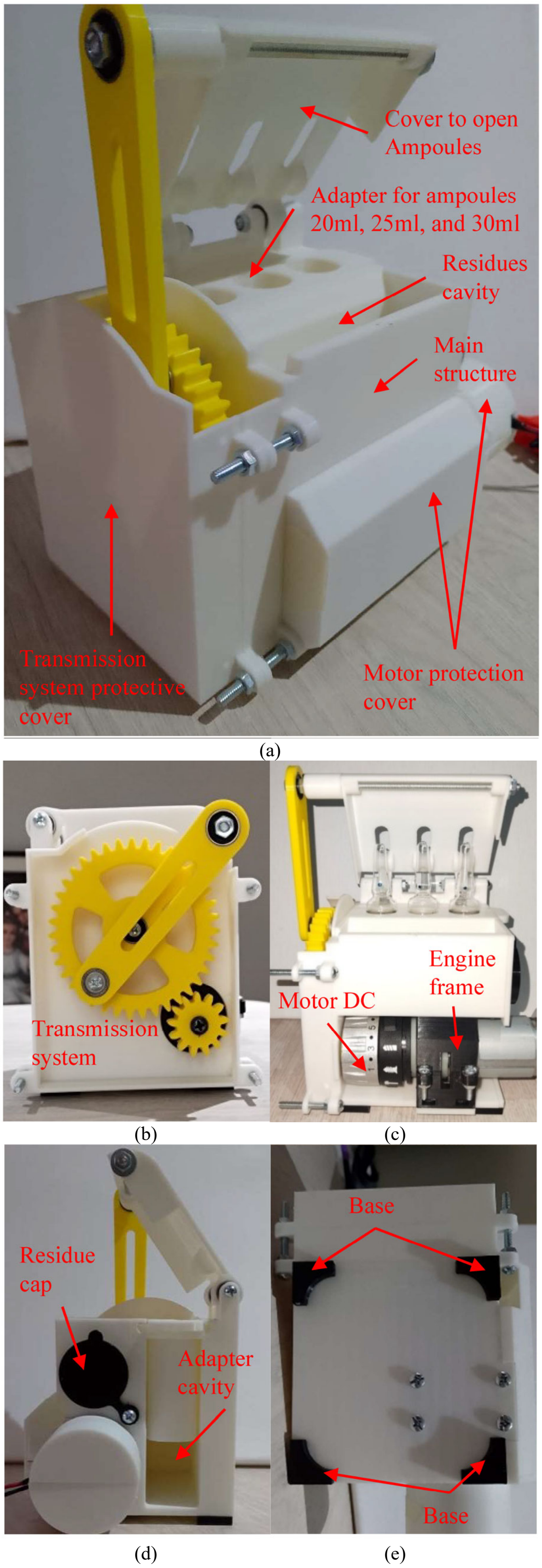


Fig. 8. Construction of ampoule opening machine: (a) components; (b) transmission system; (c) motor; (d) cavities; and (e) base.

The analysis determined that the design is safe in terms of strength and stiffness, with all components having safety factors greater than 2.0. The critical component is the connecting rod, with a safety factor of 2.28. Likewise, most components do not suffer significant deformations, with values below 0.05 mm. However, deformations of up to 1.82 mm and 2.397 mm are observed in the adapter and connecting rod, respectively. To minimize deformation, the following improvements were considered:

- Use of a larger diameter bearing and, consequently, expansion of the surrounding hole to increase rigidity in the area of greatest deformation of the connecting rod.
- Adjusting the clearance in the cavity of the main structure where the adapter is located.

D. Manufacturing with FDM Technology

Fused Deposition Modeling (FDM) technology has evolved in recent years, leading to its implementation in the medical sector with positive results. This technology allows for the development of customized devices with complex designs at an affordable cost [26]. In this section, the components of the ampoule opener machine were manufactured using FDM technology and assembled as shown in Fig. 8(a).

The machine was manufactured primarily using PETG additive material. Its structure incorporates 304 stainless steel shafts and 624 and 625 rigid ball bearings. The manufacturing cost of the machine is less than 100 USD. The weight and dimensions of the machine are 1.226 kg and 19.2 × 12.3 × 25 cm, respectively. The yellow-painted transmission system consists of a pinion, a driven gear, and a connecting rod, and has a transmission ratio of Rt = 3. The pinion is coupled to the shaft of the 12 V DC gear motor. Both the driven gear and the connecting rod move on fixed shafts with 624 bearings. The connecting rod has a 625 bearing inserted at its upper end that rotates on a shaft that couples with the ampoule opening cap, as shown in Fig. 8(b). The motor was installed in the lower cavity of the main structure with a design bolted to the base, as shown in Fig. 8(c). The machine is activated by a push button, generating the rotary movement of the pinion. The main structure has a flexible cover to purge residual glass after each operation, as shown in Fig. 8(d). Four black legs were installed at the base of the main structure for greater stability during ampoule opening operations, as shown in Fig. 8(e). This machine is modular, as the transmission system can be detached from the main structure, transforming the device into a manual ampoule opener. This feature ensures the continuity of ampoule opening operations in the event of motor or electrical system failure.

III. Results and Discussion

In this section, we present the results and discussion of the experimental validation of the ampoule opening machine. Several 20 ml glass ampoules were used, and aspects of biosafety, adaptability, and accessibility were reviewed. This validation was designed to preliminarily verify the functionality of the proposed device and its performance in different ampoule-opening configurations. Therefore, each configuration was evaluated using a controlled test (n = 1). Furthermore, this validation also aims to verify the safety of this device; since this is a parameter that poses a greater risk to personnel safety, nine independent repetitions were performed (n = 9). The experimental procedure for opening ampoules is explained below:

(1) First, place the ampoules in the adapter cavities as shown in Fig. 9(a). The ampoules can be arranged in the adapter in up to 7 position configurations, where A is the position closest to the transmission system and C is the position furthest away. Configurations A, AB, and ABC correspond to 1, 2, and 3 ampoules, respectively.
(2) Second, slide the adapter with the ampoules into the cavity of the main structure as shown in Fig. 9(b).
(3) Third, the machine is turned on and the mechanical system begins to move to push the cap against the ampoules and open them, as shown in Fig. 9(c).
(4) Finally, remove any remaining glass fragments before proceeding with the next opening operations, as shown in Fig. 9(d).

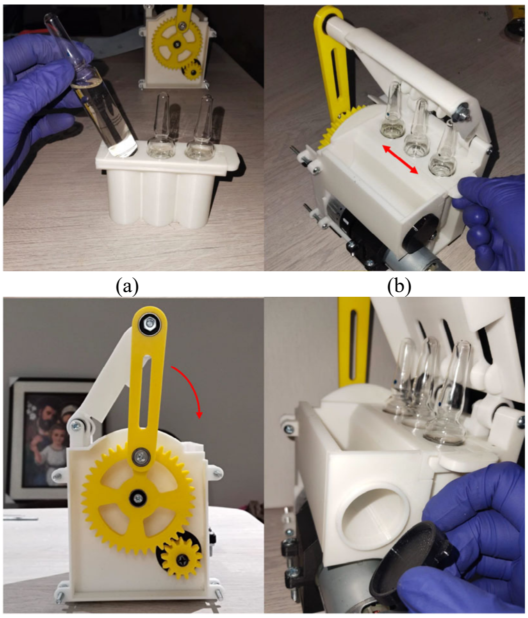


Fig. 9. Ampoule opening test procedure: (a) placing ampoules in adapter; (b) installing adapter in machine; (c) opening ampoules; and (d) removing ampoules and waste.

The evaluation criteria for experimental tests are as follows:

(1) Opening efficiency is measured as 100% if all ampoules in the configuration are open; otherwise, it is evaluated as follows: for configurations A, B, and C, if not completed, it is 0%; for configurations AB, BC, and AC, it is 0% if no ampoule is opened, 50% if at least one ampoule is opened, and 100% if both ampoules are opened. For configuration ABC, it is 0% if none of the 3 ampoules are opened, 33% if one ampoule is opened, 66% if 2 ampoules are opened, and 100% if all ampoules are opened. The calculation of the opening efficiency for each ampoule configuration "i" is determined using Eq. (1), where "$N_{opened,i}$" is the number of ampoules opened by the device and "$N_{total,i}$" is the total number of ampoules per configuration.

$$E_i(\%) = \frac{N_{opened,i}}{N_{total,i}} \times 100\% \quad (1)$$

Next, to determine the device's overall opening efficiency, the arithmetic mean of the efficiencies obtained for each configuration is calculated, as shown in Eq. (2), where "k" is the total number of configurations evaluated (k = 7). To determine the overall efficiency, all configurations are given equal weight.

$$E_{total}(\%) = \frac{1}{k}\sum_{i=1}^{k} E_i \quad (2)$$

(2) The speed at which the ampoules are opened is measured from the moment the ampoules are inserted into the adapter until they are removed from the machine in an open state.
(3) The length of the sharp edge is measured from position A to B as shown in Fig. 10 and must be less than 4 mm to be considered a blunt edge [17].

Fig. 10. Length of the sharp edge of the ampoules opened by the ampoule-breaking machine.

Based on the experimental tests carried out, the results are shown in Table III, which presents the number of ampoules per configuration, the number of ampoules opened by the device according to the configuration, and the opening efficiency for each configuration. Based on these results, the preliminary total efficiency of the device was determined using Eq. (2) to be 83.29%. In addition, the opening speeds were similar between configurations, reaching up to 8.05 s for 3 ampoules, an acceptable time according to nursing staff, considering that they are no longer exposed to cuts from glass fragments. Regarding the risk of cuts, the sharp edges of the ampoules opened during the test were analyzed in Table IV, with an average edge length of 2.59 ± 0.81 mm (n = 9) and the sharpest edge having a value of 3.85 mm. Therefore, the results in Tables III and IV demonstrate the potential of this device to replace the function of opening ampoules performed by staff, aligning with their tasks and eliminating the risk of cuts.

TABLE III. RESULTS OF EFFECTIVENESS TESTS FOR OPENING TYPE I AMPOULES, FORM B AND 20 ML

Configuration	Opening Effectiveness (%)	Opening Time (s)	Comments
A	100	6.74	Opening of ampoule with occasional release of glass fragments.
B	100	6.85	
C	100	5.81	First crack in hinge and slight buckling visible.
AB	100	7.82	Manages to open ampoules with some deformation.
BC	50	7.14	Only ampoule B is opened.
AC	100	7.04	Noticeable sagging, ampoule A opens first, followed by ampoule C.
ABC	33	8.05	Opening of ampoule A, the fissure did not progress.

TABLE IV. RESULTS OF SHARP EDGE LENGTH TESTS

Vial number	Length of the sharp edge
1	2.25
2	1.95
3	3.90
4	2.30
5	1.85
6	1.95
7	2.20
8	3.85
9	3.05

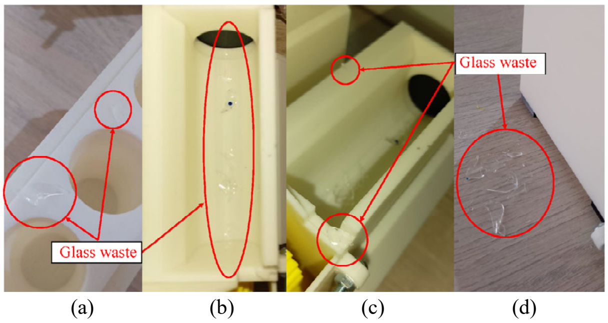


Fig. 11. Glass fragments in (a) adapter; (b) waste cavity; (c) structure edges; and (d) machine exterior.

On the other hand, cracks were observed in the hinge of the main structure during testing, suggesting that this area needs to be reinforced. In addition, buckling was observed, as mentioned in Table III, suggesting that the thickness of the opening cover should be increased to improve rigidity, and a second support rod should be added to the other end of the cover so that the movement is aligned and buckling on one side is reduced. Good fragment containment was also observed. Some debris was found on the top of the adapter, as shown in Fig. 11(a); most of the debris was trapped in the debris cavity, as shown in Fig. 11(b), and other debris was located at the edge of the structure as shown in Fig. 11(c). In addition, some glass fragments were identified on the outside of the machine where the adapter enters, as shown in Fig. 11(d). This event was recorded in one of the nine tests (n = 9), equivalent to an 11.11% leakage rate per opening cycle, which indicates adequate performance of the device in containing fragments; however, occasional leaks do occur. This suggests that installing a gate in the adapter cavity would improve the containment of glass fragments.

Finally, the test results were analyzed based on the characteristics of biosafety, adaptability, and accessibility:

(1) Biosafety: the machine offers a high level of safety for nursing staff during procedures that require handling ampoules, as this operation would be performed without the need for direct intervention by staff. The machine catches most of the glass fragments released when opening ampoules with a minimal fragment leakage rate of 11.11%, and the curved design of the protrusion on the side of each opening hole in the lid allows the edges of the opened ampoules to be small and less than 4 mm. From the perspective of hospital workflow, the device's design allows for an easy cleaning procedure, thanks to its curved cavities and flexible flap, facilitating the quick and safe removal of accumulated fragments after each operating cycle.

(2) Adaptability: the machine has a compact design, weighing 1.226 kg and measuring 19.2×12.3×25 cm, making it portable thanks to its size and low weight. It can be installed on nursing carts. In addition, it is easy to use and has an ergonomic design, with rounded edges that allow for comfortable grip. The opening force of the device is guaranteed by the high power of the gear motor. However, during testing, it was observed that some ampoules could not be opened. This was due to structural deformation and not a lack of force on the part of the machine. Finally, the device has been shown to open ampoules as effectively as healthcare personnel and even faster, with a total effectiveness of 83.29% and an average time of 7.06 s.

(3) Accessibility: The prototype stands out for its low cost of 100 USD compared to commercially available ampoule opening machines such as CytoCare and I.V.STATION, making it accessible to low-income healthcare workers and healthcare facilities. It was manufactured using locally available materials and FDM technology, allowing for technical support and easy maintenance.

IV. CONCLUSION

This article describes the development of an ampoule opener machine using FDM technology that demonstrates solid biosafety, adaptability, and accessibility capabilities for integration into the work of healthcare personnel in hospital settings.

The design was based on the needs of nursing staff at the III Goyeneche Hospital in Arequipa and ISO 9187-1, resulting in the requirements being classified into three groups: biosafety, adaptability, and accessibility.

Subsequently, the ampoule opener machine was designed considering FDM manufacturing criteria. The structural characteristics of the machine were then evaluated using FEA analysis prior to manufacturing, obtaining a critical safety factor of 2.28. The machine has an affordable cost of 100 USD. It is also lightweight, compact, and modular, allowing the machine to be adapted to the tasks of nursing staff.

Finally, in the results of the experimental tests showed a preliminary overall effectiveness of 83.29% in opening 20-ml Type I ampoules, and the average operating speed was 7.06 s, demonstrating the device's potential to meet the needs of healthcare personnel. In addition, most of the glass fragments were captured inside the machine, with the sharpest edges of the ampoules measuring 3.85 mm, indicating that the machine also has a high level of biosafety.

Future research will consider the following recommendations:

- The design was evaluated using PETG material; however, in the future we will evaluate various materials that offer better rigidity characteristics for opening ampoules.
- To optimize the device's biosafety, we will consider redesigning the caps and cover where glass fragments were found to have leaked. We will also evaluate materials that are compatible with the disinfection and sterilization processes used in clinical settings.
- The prototype developed in this article was evaluated with 20 ml ampoules; however, in the future, we seek to validate the prototype with a wider range of ampoule types and multiple repetitions to assess the device's long-term performance.

These recommendations will be addressed in future research to optimize the design of the ampoule opener machine.

Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

AGM and BAA performed the main designs, simulations, tests, and manuscript writing. EVF manufactured the prototype. YLS and DP reviewed and corrected the manuscript for submission. All authors have approved the final version of the manuscript.

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