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RESEARCH ARTICLE

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SafeAmpCase: design and optimization of a 3D-printed solution for protecting fragile life-saving drug ampoules

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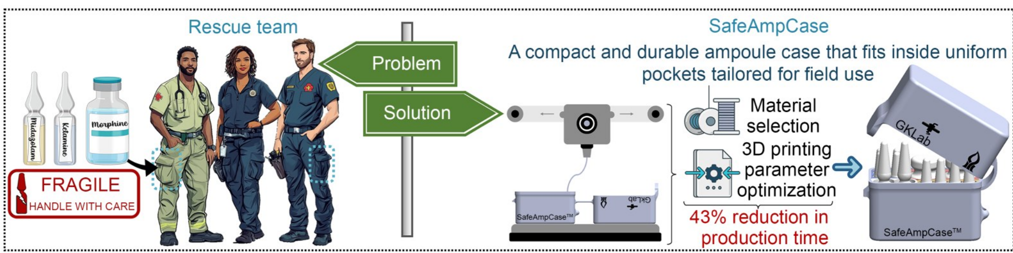
Abstract

The SafeAmpCase is an innovative 3D-printed solution developed to address critical challenges in transporting and storing fragile glass drug ampoules during emergencies. This study employs a multidisciplinary approach—integrating biomedical engineering, advanced materials science, and emergency medicine expertise—to develop a compact, durable, and user-friendly ampoule case. A key innovation lies in the strategic selection of thermoplastic polyurethane (TPU) as the material, leveraging its superior impact resistance, flexibility, and noise-damping characteristics to ensure reliability under performance in demanding real-world conditions. To optimize the 3D printing process, key parameters, including printing temperature (220–250 °C), volumetric flow rate (3 – 20 mm^3/s), retraction speed (30 – 90 mm/s), and retraction length (0.4–1.2 mm), were systematically adjusted using calibration models. The final optimized parameters (245 °C, 7 mm^3/s, 90 mm/s, and 1.2 mm) reduced production time by 43% while preserving structural integrity. American Society for Testing and Materials (ASTM) international standard drop tests confirmed the case's exceptional impact resistance, demonstrating a 90% reduction in ampoule breakage compared to polylactic acid plus. Further refinements, guided by feedback from 25 emergency professionals, resulted in medication-specific color coding and an enhanced locking mechanism for usability in high-pressure situations. The final SafeAmpCase model withstood 18 consecutive drop trials without ampoule breakage, confirming its robustness in field conditions. This research underscores the transformative potential of additive manufacturing in developing customized, high-performance solutions for critical healthcare applications, setting a new benchmark for biomedical device design and rapid prototyping.

Graphical abstract



Keywords 3D printing · Optimization of printing parameters · Fragile life-saving drug ampoules · Rapid prototyping · Thermoplastic polyurethane · Material selection

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1 Introduction

Paramedics and other rescue professionals in emergency medical services (EMS) routinely encounter considerable challenges in the transport, storage, and retrieval of life-saving medications [1]. Glass ampoules, widely used to store drugs essential for treating critical conditions such as cardiac arrest, respiratory failure, and shock, are particularly prone to breakage. This fragility poses serious risks during emergencies, where the availability of each dose might represent the difference between life and death [2, 3]. In addition to the immediate clinical consequences, broken ampoules present further concerns, including legal challenges related to regulatory compliance and logistical difficulties in inventory management. Furthermore, ampoule breakage is a frequent cause of sharps injuries among EMS and healthcare professionals, increasing their risk of exposure to bloodborne pathogens such as hepatitis B and C, as well as the human immunodeficiency virus [2–4].

Existing solutions, such as padded drug kits and foam-lined ampoule cases, provide some level of protection but often fail when subjected to accidental drops or impacts. These limitations are particularly evident in high-risk situations such as military medicine, disaster response, and remote healthcare delivery, where robust, durable, lightweight, and compact storage is essential. However, many current designs are bulky and offer limited capacity. Furthermore, ampoules stored within larger kits or modular pouches can easily become disorganized during transport or in the chaotic environment of an emergency, leading to delays in retrieving specific medications when every second counts [5, 6]. To mitigate this, some medical teams implement proactive strategies, such as prioritizing high-need ampoules or dividing medications into separate, smaller kits that contain only essential drugs. Others store critical ampoules, such as those containing Fentanyl or Morphine, in their uniform pockets for rapid access. While this method enables quick retrieval, it also increases the risk of breakage and loss of vital medications, which are often required immediately in life-threatening situations. Overcoming these limitations is crucial to improving the safety, efficiency, and reliability of drug transport and storage in demanding environments.

Additive manufacturing (AM) and computer-aided design (CAD) technologies offer a promising solution to these challenges by enabling rapid prototyping and customization of medical applications [7–10]. Among AM techniques, fused deposition modeling (FDM) has become particularly popular owing to its versatility, cost-effectiveness, and ability to quickly transition from design to prototype. FDM enables the efficient development of customized and functional components tailored to specific demands, making it an attractive option for developing medical devices [11, 12]. The success of such applications depends not only on innovative design but also on the optimization of printing parameters, which can considerably enhance production speed, material efficiency, mechanical integrity, and the overall functional performance of the final product [13, 14]. However, designing and developing solutions that are durable and efficient remains a significant challenge, particularly in applications that demand compactness and resilience.

Selecting an appropriate material is critical to ensuring mechanical durability, impact resistance, and functional reliability of 3D-printed protective cases. Common FDM filaments include polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), polyethylene terephthalate glycol (PETG), polycarbonate (PC), and thermoplastic polyurethane (TPU) [15]. Among these, TPU stands out for its optimal balance of elasticity, energy absorption, and structural integrity [16]. Its high elongation at break enables effective dissipation of impact energy, significantly reducing the risk of material failure and ampoule breakage. Additionally, TPU's biocompatibility and non-toxicity contribute to its widespread use in the medical industry. It meets key regulatory standards, including the National Sanitation Foundation Standard 61, U.S. Food and Drug Administration (FDA) 21 Code of Federal Regulations, and United States Pharmacopeia Class VI classification, ensuring its suitability for food-contact and medical applications [17]. TPU is commonly used in diagnostic devices, anesthesia and artificial respiration equipment, healthcare mattresses, dental materials, compression stockings, medical instrument cables, gel shoe orthotics, and wound dressings [18]. These attributes make TPU an ideal candidate for medical applications that require shock resistance and long-term mechanical reliability, particularly in high-stress environments where fragile ampoules must be securely protected.

This study presents the SafeAmpCase, a novel 3D-printed solution specifically designed and developed to address the critical need for a lightweight, compact, and durable ampoule case that medical professionals can carry in their uniform pockets. The SafeAmpCase combines a compact design with enhanced impact resistance and quick accessibility, making it an ideal choice for the transport and handling of glass ampoules containing life-saving medications in the field. Developed through a structured, multi-stage workflow involving iterative prototyping and feedback-driven refinement, the design was continuously optimized to address the practical requirements of EMS professionals and healthcare providers. This process relied extensively on modern 3D printing techniques and the optimization of key printing parameters to enhance production efficiency and product performance. The SafeAmpCase represents a significant step forward in leveraging AM processes to solve real-world challenges in emergency medical care.

2 Materials and methods

2.1 Workflow of the SafeAmpCase

The design process and workflow for developing the SafeAmpCase are presented in Fig. 1, following the highly iterative product development approach, adapted from the

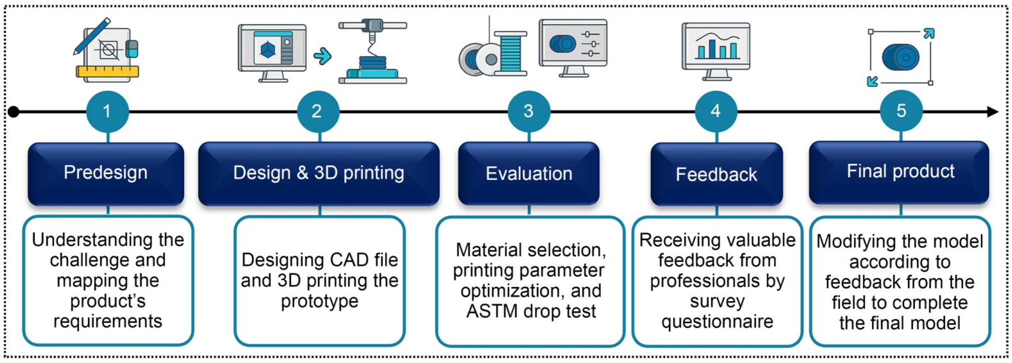

Fig. 1 Schematic representation of the design workflow and fabrication process of the SafeAmpCase. ASTM: American Society for Testing and Materials; CAD: computer-aided design

Scrum model used in software development [19, 20]. This approach is specifically designed to minimize development time and is particularly effective for refining technical specifications and production processes. The workflow consists of five key stages, each focused on streamlining the iterative design and development process to address challenges and optimize outcomes effectively.

- Predesign → This stage is dedicated to thoroughly understanding the problem and defining the product requirements. It involves identifying core challenges, such as user needs, functional objectives, and constraints specific to the product's intended use. These insights guide the development of a detailed product requirement specification, which acts as a roadmap for the design and fabrication process. This stage is essential for ensuring that the final product effectively and efficiently addresses all intended use cases.
- Design and 3D printing → In this stage, the initial concept is translated into a 3D CAD model using specialized software, such as SolidWorks. The CAD file is then converted into a 3D manufacturing format (3MF), ensuring compatibility with 3D printing systems. An iterative design process follows, where the prototype is printed, evaluated, and amended based on observations of its dimensions and performance. Each iteration refines the design, addressing any structural or functional issues. This iterative process continues until the prototype meets the fundamental requirements, providing a solid foundation for further evaluation and testing.
- Evaluation → This critical stage focuses on evaluating and optimizing the prototype for performance, reliability, and compliance with requirements. It begins with selecting appropriate materials that meet the desired mechanical and physical properties, such as strength, shock absorbance, and flexibility for the intended application. Next, adjustments to 3D printing parameters such as printing temperatures, volumetric flow rates (VFRs), and nozzle retraction settings are fine-tuned to improve printing accuracy, surface finish, and mechanical performance. A drop test assesses the prototype's performance under free-fall conditions, evaluating its ability to protect the contents during sudden impacts. The results from these tests guide further refinement, optimizing the product's design and functionality.
- Feedback → At this stage, feedback is collected from a targeted group of 25 professionals through structured survey questionnaires. The responses focus on the product's usability, functionality, and overall design. Respondents may identify areas for improvement or propose enhancements to increase the product's effectiveness. This step ensures that the design incorporates end-user perspectives and addresses their practical needs, making the product more reliable and user-friendly.
- Final product → In the final stage, the feedback received is implemented to refine the product. The CAD model is updated to include modifications based on user suggestions and testing outcomes. The revised design is then manufactured, evaluated, and validated as the final version of the SafeAmpCase. At this point, the product is ready for deployment, having met all functional, aesthetic, and usability requirements. This stage marks the completion of the development process and prepares the product for implementation or market introduction.

2.2 Designing and 3D-printing the SafeAmpCase

The SafeAmpCase models were designed and developed using SolidWorks 3D CAD software (Student Edition 2022–2023, SolidWorks Corp, USA). The designs were then exported as 3MF files, a widely accepted format for 3D printing [21]. These 3MF files were subsequently sliced and converted into G-code using Bambu Lab's software. The G-code files were uploaded to the Bambu Lab X1 Carbon printer (Bambu Lab, China), which is an FDM technique, categorized under material extrusion, one of the seven standardized AM technologies [22]. In this process, material is extruded through a nozzle and deposited layer by layer onto a build platform. Two materials were used for manufacturing: polylactic acid plus (PLA+, eSUN, China) and flexible elastomer polyurethane (eTPU-95A, eSUN). Detailed printing parameters, along with the physical and mechanical properties of the PLA+ and eTPU filaments as specified by the manufacturer, are provided in Table S1 (supplementary information).

2.3 Printing optimization using calibration models

The optimization process used the one-variable-at-a-time approach [23]. Each parameter was systematically evaluated independently to achieve optimal print quality and minimize production time. A temperature tower calibration model was utilized to determine the optimal printing temperature. This model incorporates features such as geometric elements (cones, walls, and bridges), inclined surfaces (35° and 45°), and domes to assess stringing, overhang performance, and staircase effects (Fig. 2a). Temperatures were tested in 5 °C increments, ranging from 220 to 250 °C. The results from this model were analyzed to identify the temperature range that provided the best layer adhesion, minimal defects, and precise dimensional accuracy. The optimization of the VFR involved quantitative and qualitative tests. The quantitative test model was designed to print straight lines (15 mm) and 10-mm-high material blobs at varying flow rates, with each blob consisting of 200 mm of filament (0.577 g of TPU) (Fig. 2b). Blob weights were measured to calculate under-extrusion percentages, and the test was performed across VFRs ranging from 3 to 20 mm^3/s. Each test was repeated three times (n=3) to ensure consistency and repeatability. The G-code for this test was generated using the flow test generator [24] according to the extrusion system benchmark developed by CNCKitchen [25]. The qualitative test calibration model was designed with straight lines, sharp corners, curved lines, and tips (Fig. 2c) to assess accuracy and defect prevalence at different flow rates. Optimal VFR values were determined based on print quality and extrusion consistency. The retraction settings

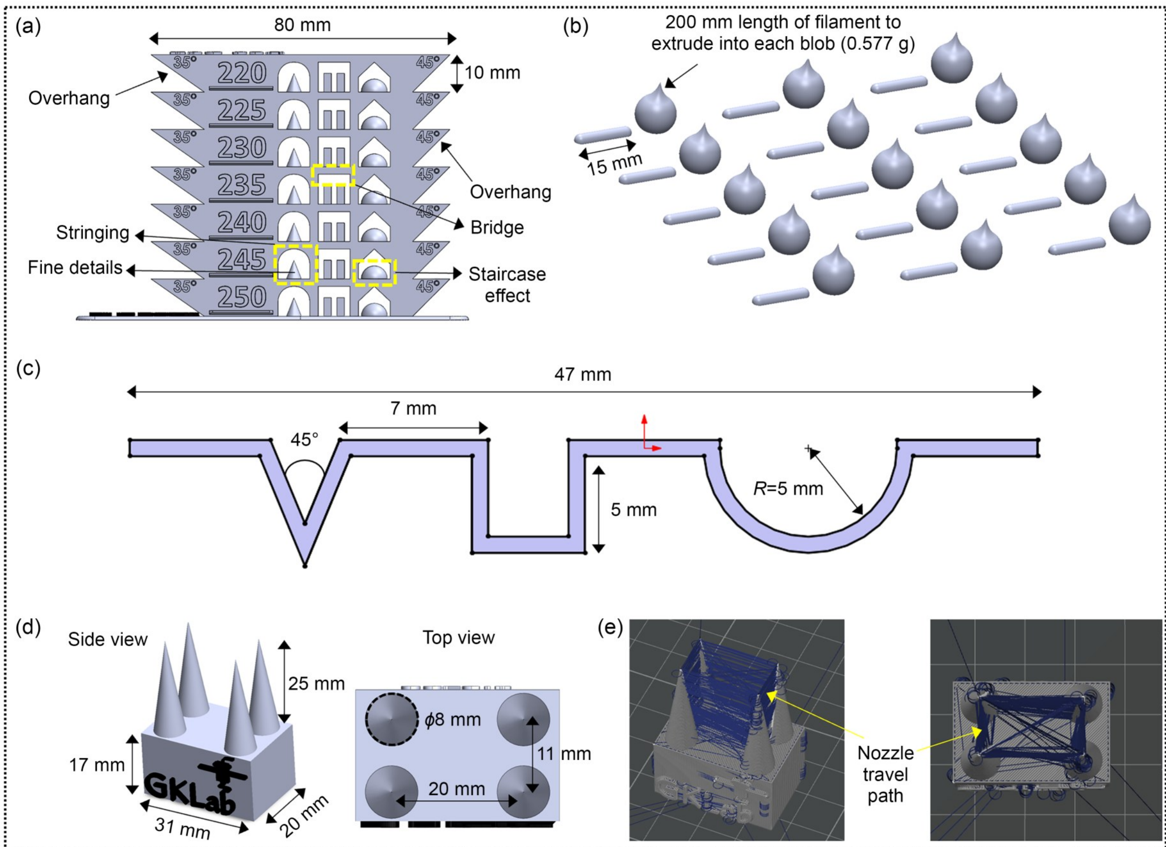

Fig. 2 Calibration models for printing optimization. (a) The temperature tower calibration model ranges from 220 to 250 °C in 5 °C increments and includes geometric shapes (cones, walls, and domes) and angled surfaces (35° and 45°) to assess stringing, overhang performance, and staircase effects. (b) Flow rate calibration test illustrated by a straight 15-mm line followed by a 10-mm-high material blob, evaluated at various flow rates. Each blob utilizes 200 mm of filament, equivalent to 0.577 g of thermoplastic polyurethane (TPU). (c) The flow rate calibration model is designed to assess accuracy across different VFRs, incorporating features such as straight lines, sharp corners, triangle apices, and curved paths. (d, e) The retraction calibration model consists of a tower with four tall cones designed to induce stringing during printing, allowing for the evaluation of retraction performance

were optimized using a tower model featuring four cones designed to induce stringing (Figs. 2d and 2e). This test evaluated retraction speeds of 30, 60, and 90 mm/s and retraction lengths of 0.4, 0.8, and 1.2 mm. Printed models were visually inspected for stringing and other extrusion-related defects to determine the optimal settings for minimizing unwanted material deposition.

2.4 Drop test of loaded containers by free fall

To evaluate the impact resistance of SafeAmpCase, drop tests of loaded containers by free fall were performed according to the American Society for Testing and Materials (ASTM) D5276-19 [26]. Each case was filled with simulated-use glass ampoules containing distilled water and dropped from a height of 1.5 m to evaluate damage thresholds and structural integrity. A standardized mechanism ensured consistent fall heights and orientations for all tests (Fig. S1 in the supplementary information). The drop test was repeated three times (n=3) for each face of the case (top, bottom, and four lateral faces), resulting in a total of 18 tests per case. High-resolution videos captured the condition of the case and ampoules before and after each drop, documenting any damage to the case, case openings, and broken ampoules.

3 Results and discussion

3.1 Stage 1: Predesign

The first stage of the development process focused on understanding the challenge and defining the product requirements. This phase relied heavily on close collaboration between the biomedical engineering laboratory and the emergency medicine unit. Their combined expertise ensured that the design addressed both technical feasibility and practical applicability in emergency situations and challenging environments.

3.1.1 Product requirements

The following requirements were identified for the SafeAmpCase:

- Capacity for different ampoules: The initial design was developed to accommodate two 10 mL Ketamine ampoules, five 1 mL Morphine ampoules, and five 1 mL Midazolam ampoules. Subsequent iterations allowed customization based on user feedback to accommodate a broader range of needs.
- Protection: The case was designed to effectively prevent ampoules from breaking during use or transport, particularly in high-stress scenarios and field operations.
- Ease of use: The design should enable quick and intuitive withdrawal of ampoules, especially in high-stress situations.
- Compact size with lightweight design: The case was designed to fit comfortably in the pocket of standard uniform trousers while minimizing additional weight for emergency responders.
- Noise minimization: The case should generate minimal noise when carried in the pocket, preventing distractions or disturbances.
- Cost-effective and rapid production: The case needed to be manufactured quickly and affordably.

3.1.2 Preliminary measurements

To initiate the design process, accurate measurements of both the uniform pockets and ampoules were taken. These measurements provided the foundation for designing a case optimally utilizing available space while ensuring accessibility and functionality. Measurements indicated that the average uniform pocket dimensions are 130 mm in width and 150 mm in length. The 1 mL ampoules, such as those for Midazolam and Morphine, measure 52 mm in length and 10.75 mm in diameter, while the 10 mL ampoules, such as those for Ketamine, are 54 mm in length and 24.15 mm in diameter.

3.2 Stage 2: Design and 3D printing

3.2.1 Design features and material selection for Prototype 1

The main goal of this stage was to produce the first prototype and deliver it to the field as quickly as possible for feedback. Using data from Stage 1, a CAD model of the case, referred to as Prototype 1 (Fig. 3), was designed in SolidWorks software. The design incorporated basic geometric shapes, such as rectangular boxes and cylinders, to form a compact two-part case with a lid and base in a 1:3 ratio. Prototype 1 featured a compact, pocket-sized design with key elements to optimize functionality and usability. The ampoules were arranged to maximize space efficiency while ensuring easy access to all necessary contents (Fig. 3a). The case's rounded box design enhanced ergonomic handling, while the prominent stripes on the lid enhanced grip, enabling one-handed opening in field conditions (Figs. 3b and 3c). To protect the ampoules during transport and handling, a protective wall was incorporated at the top section of the base, securely encasing the ampoule heads and minimizing the risk of breakage (Fig. 3c). PLA+ was chosen for this prototype because of its suitability for rapid prototyping and functional modeling. This eco-friendly material is easy to print and features a smooth surface along with a well-balanced

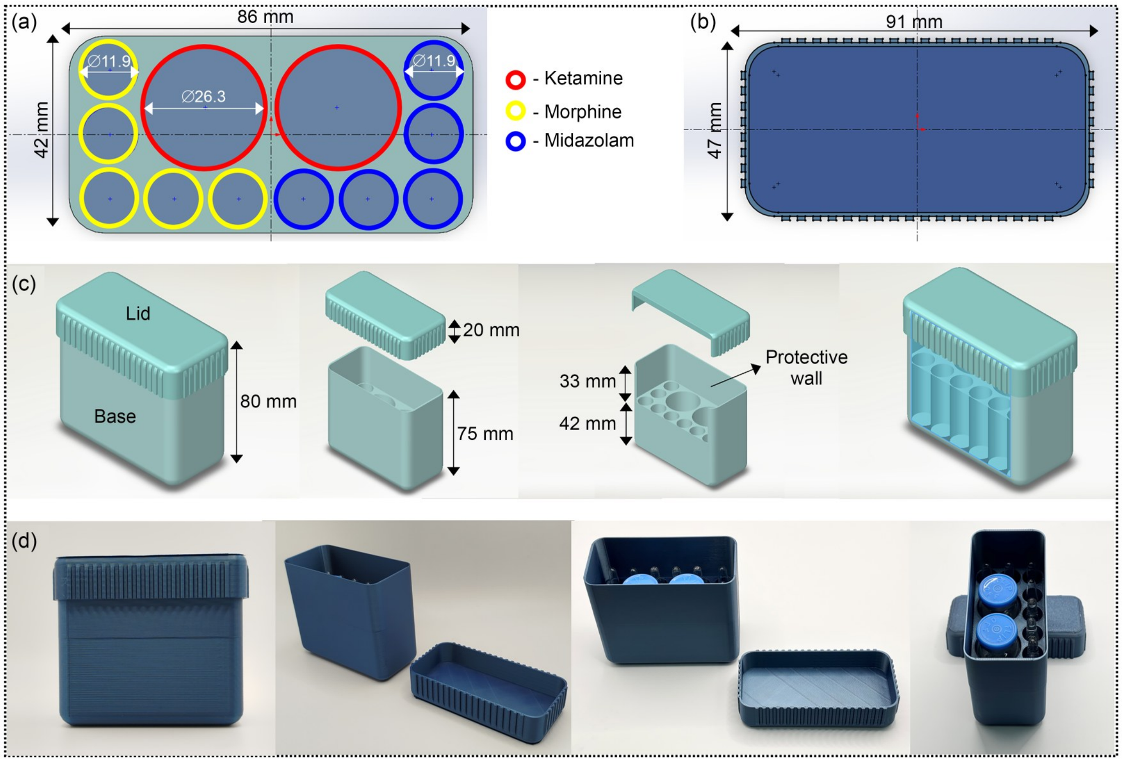

Fig. 3 Prototype 1 design and fabrication. (a) Top view of the base shows the ampoule configuration. (b) Top view of the lid highlights key design features. (c) Complete case design with labeled reference dimensions. (d) 3D-printed Prototype 1 fabricated using PLA+

combination of strength, rigidity, and toughness, making it ideal for producing functional components [27, 28]. Figure 3d presents the 3D-printed version of Prototype 1. After its fabrication, Prototype 1 was assessed based on the criteria outlined in Table 1. The main challenge identified was the difficulty in extracting ampoules from the case, which arose from the limited internal space and the design limitations of the protective wall.

3.2.2 Refinement in Prototype 2

Prototype 2 (Fig. 4) was developed to resolve the issues identified in the initial design, incorporating several key modifications. The structure was redesigned with a base and lid that intersect at the midpoint of the case, improving accessibility to the ampoules (Fig. 4c). The lid includes slots for securely holding the ampoule heads, providing better protection (Fig. 4b). Additionally, coordinating arrows were added to assist users with opening and closing the case, and a security attachment loop was included for securely fastening it to external gear, such as a paracord (Fig. 4c). The ampoule configuration from Prototype 1 was preserved, ensuring optimal organization and space efficiency (Fig. 4a). As in Prototype 1, PLA+ was used for the fabrication of Prototype 2. Figure 4d depicts the 3D-printed version of Prototype 2. After the fabrication process, the case was re-evaluated based on the criteria outlined in Table 1. Two main issues were identified: noise from the ampoules during movement and inadequate impact resistance. While walking with the case in a pocket, the ampoules moved up and down in their slots, generating significant noise. Additionally, when the case accidentally fell to the floor, several ampoules broke, indicating insufficient protection against sudden impacts.

3.2.3 Refinement in Prototype 3

To address the limitations of previous designs, the material of Prototype 3 (Fig. 5) was changed from PLA+ to TPU, which offers superior stretchability, durability, flexibility, biocompatibility, and elasticity compared to other rigid polymers [11, 12, 14]. With a hardness of 95A, TPU effectively absorbs impact forces, resists deformation and wear, and exhibits high resistance to oils and chemicals [14, 29, 30], making it an ideal choice for protecting fragile ampoules. This material facilitated the creation of components with tailored flexibility and rigidity by varying the materials' thickness. Consequently, leveraging the properties of TPU, Prototype 3 was designed and printed as a single, unified piece, incorporating a connecting strip between the base and the lid for improved functionality (Fig. 5c). This design also enabled quick opening and closing of the case, ensuring the lid remained attached during the treatment process, especially in the chaotic environment of an emergency. The ampoule configuration was redesigned for a more user-friendly

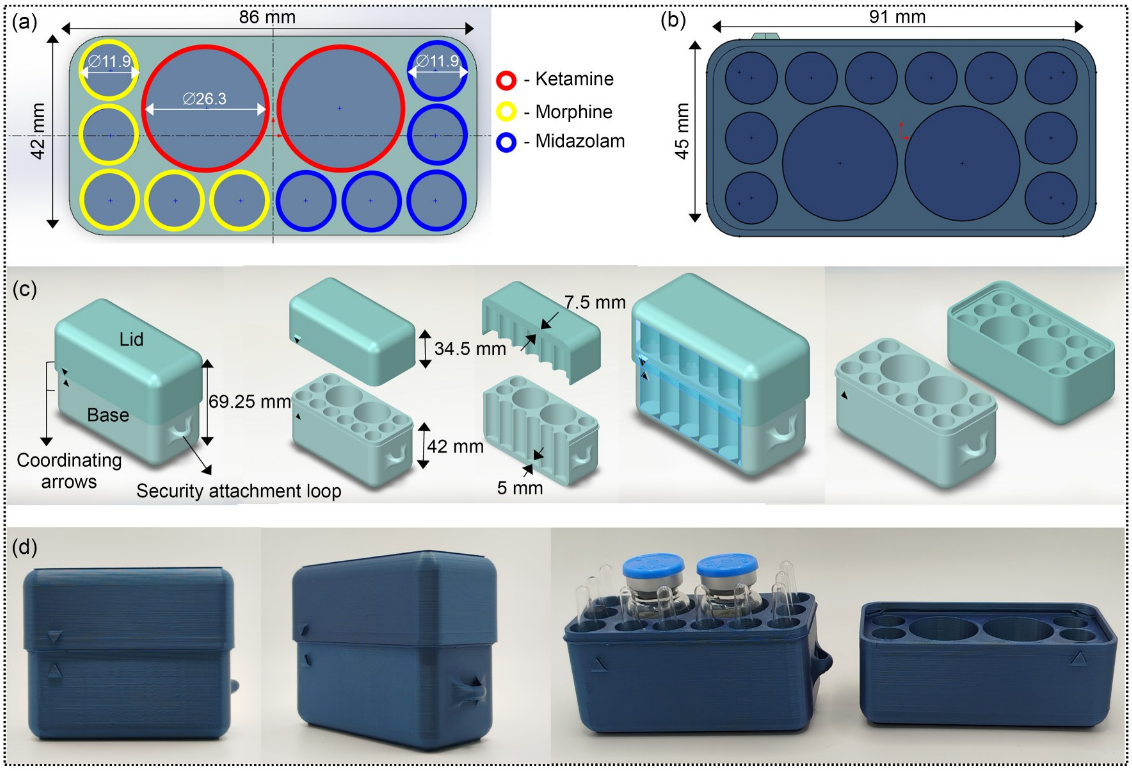

Fig. 4 Prototype 2 design and fabrication. (a) Top view of the case base shows the ampoule configuration. (b) Top view of the lid highlights slots designed to secure ampoule heads. (c) Complete case design with labeled dimensions for clarity. (d) 3D-printed Prototype 2 fabricated using PLA+

Table 1 Evaluation criteria for assessing the SafeAmpCase prototypes

Requirement	Prototype 1	Prototype 2	Prototype 3
Capacity for different ampoules	√	√	√
Fitting the size of the pocket	√	√	√
Ease of use (quick withdrawal of the ampoule)	×	√	√
Lightweight design	√	√	√
Protecting the ampoules from breaking	×	×	√
Noise minimization	×	×	√
Cost-effective and rapid production	√ (about 3 h and 10 min)	√ (about 3 h and 21 min)	× (about 7 h and 31 min)

Key performance metrics, including functionality, durability, usability, material properties, and production efficiency, used to evaluate the effectiveness of each prototype, are outlined

and ergonomic layout, enhancing accessibility and usability (Fig. 5a). Furthermore, a robust closing mechanism was incorporated, featuring a lowering latch on the top of the base and a corresponding notch on the lid. This design provided a secure closure and minimized the risk of accidental opening, thereby improving the reliability and functionality of the case (Fig. 5c). After fabrication, Prototype 3 was assessed based on the criteria outlined in Table 1. Although the case addressed key issues identified in previous prototypes, such as minimizing noise and enhancing impact resistance, one major drawback emerged: extended printing time. The transition from PLA+ to TPU considerably prolonged the fabrication process, taking more than twice as long as Prototypes 1 and 2. This increase was mainly attributed to the rubbery nature of TPU, which poses greater challenges during printing compared to other materials. According to the filament manufacturer eSUN in Table S1 (supplementary information), the printability rating for PLA+ is 9/10, while TPU is rated at 6/10.

3.3 Stage 3: Evaluation

TPU demonstrated significant advantages over PLA+ in applications that require flexibility, durability, and energy absorption. In contrast to PLA+, which is relatively brittle and rigid, TPU can absorb and dissipate energy upon impact, making it ideal for protective casings, impact-resistant

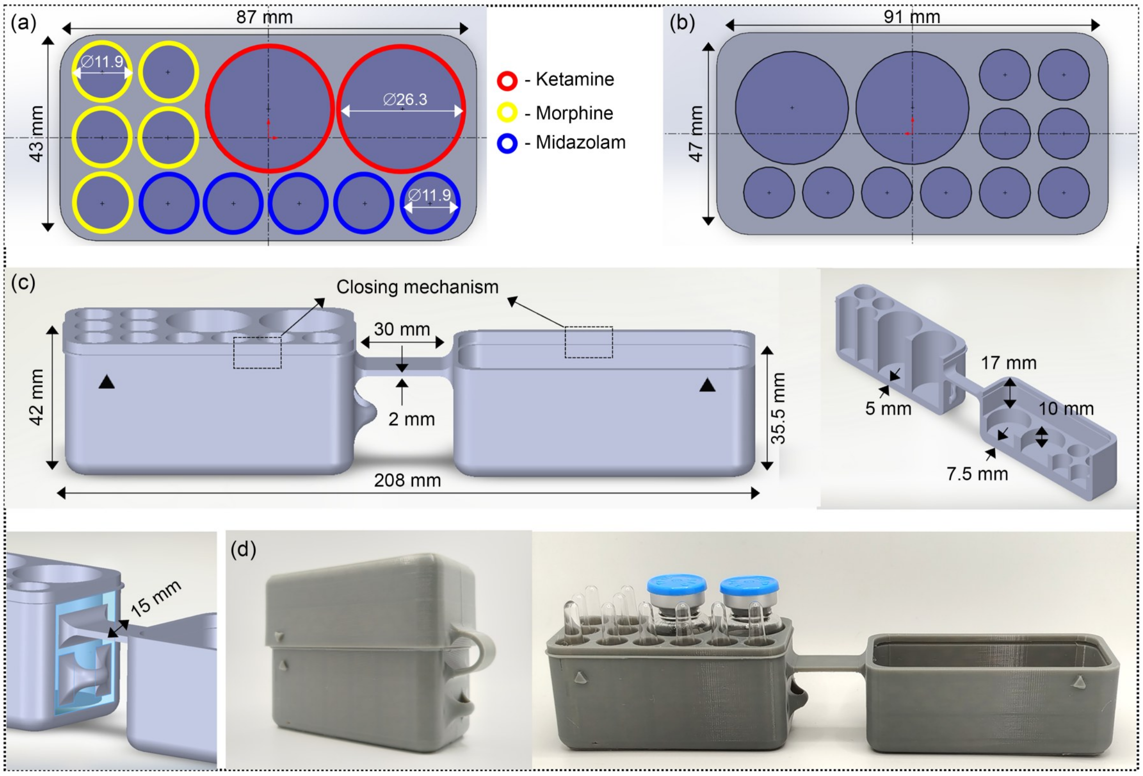

Fig. 5 Prototype 3 design and fabrication. (a) Top view of the base illustrates the updated ampoule layout for improved ergonomics. (b) The top view of the lid shows the incorporated slots for securing ampoule heads. (c) Complete case design with labeled dimensions and an integrated connecting strip between the base and lid. (d) 3D-printed Prototype 3 fabricated from eTPU for enhanced flexibility and impact resistance

components, and cushioning elements [11, 12, 14]. This characteristic minimizes the risk of breakage, ensuring superior resilience in demanding environments where durability is critical [14, 29, 30]. While PLA+ is widely used for its ease of printing and biodegradability, it lacks the necessary shock absorption, limiting its effectiveness in high-impact protection applications [14].

3.3.1 Printing parameter optimization process

Given the complexities of printing TPU and the extended time required to produce high-quality parts, optimizing the printing parameters was essential [13, 14]. The optimization process aimed to reduce overall printing time while preserving the precision and quality of the printed components. We identified three key printing parameters: printing temperature, VFR, and nozzle retraction settings (speed and length). Each parameter was adjusted independently using the one-variable-at-a-time approach [23]. Our hypothesis suggested that increasing the printing temperature would enhance material flow through the nozzle, consequently reducing production time. However, higher temperatures and elevated VFRs also introduced potential risks, such as printing defects, including stringing, overhangs, and staircase effects. Stringing refers to forming fine strands of material between printed sections [31], while overhang issues arise from structural elements that require precise orientation to avoid the need for support materials [32]. The staircase effect, characterized by a step-like pattern on the surface of a 3D-printed object, arises from the inherent layering process of FDM printing, where the edges of each layer are slightly visible on the object's surface [33]. To mitigate these challenges, it was crucial to fine-tune the retraction settings during the final optimization stage to minimize such defects and achieve a balance between production time and quality.

The first optimized parameter was the printing temperature, which refers to the specific temperature at which the thermoplastic filament is heated during the 3D printing process. This was determined using the temperature tower calibration method, an essential testing tool for calibration in open FDM systems. This model facilitates the identification of the optimal printing temperature for specific materials and printer configurations [34–36]. By systematically varying the temperature across different sections of a calibration model, this method allows for a detailed assessment of how temperature influences key print quality factors such as layer adhesion, stringing, overhang performance, and dimensional accuracy. This approach ensures that the final prints are of high quality, free from defects, and maintain precise dimensional fidelity. For this test, we designed a comprehensive temperature tower calibration model (Fig. 2a) featuring sections with temperature gradients, along with geometric elements such as cones, walls, bridges, and domes to assess stringing, overhangs, and staircase performance. Additionally, we included features of angled surfaces at 35° and 45° to evaluate the impact of temperature on overhang performance. The results, visually compared across the different floors in Fig. 6, revealed that overhang performance was optimal for 35° angles at temperatures between 235 and 245 °C, and for 45° angles between 230 and 250 °C. Stringing was observed at all temperatures, although fine details improved at higher temperatures, peaking at 245 and 250 °C. Bridges performed best at 220 and 225 °C, while the staircase effect, particularly on the tops of the domes, was considerably reduced at temperatures ranging from 235 to 250 °C. These findings provided valuable insights into the optimal temperature range for printing TPU, indicating that the best geometric outcomes occurred in the 235–245 °C range. Consequently, 235 and 245 °C were selected for further optimization.

The second optimized parameter was the VFR. In FDM, VFR refers to the volume of filament extruded per unit of time, making it a critical parameter for ensuring accurate material deposition. Precise control of VFR is vital for maintaining dimensional accuracy, layer adhesion, and overall print quality, and it plays a pivotal role in determining production speed [37]. Both quantitative and qualitative tests were performed to identify optimal VFR settings.

The quantitative test aimed to assess tendencies for under-extrusion at higher VFRs (Fig. 2b), which could occur owing to the limitations of the extruder motor in consistently feeding filament through the nozzle at elevated speeds [38–40]. Under-extrusion percentages were calculated and plotted against the tested flow rates to determine optimal settings (Fig. 7). The results indicated that under-extrusion percentages remained consistent across flow rates from 3 to 10 mm^3/s irrespective of the tested temperatures (235 and 245 °C). Based on these findings, the initial VFR of 3 mm^3/s can be successfully increased up to threefold, significantly enhancing printing efficiency without compromising quality. The qualitative test involved printing a model specifically designed to evaluate accuracy at various VFRs, featuring elements such as straight lines, sharp corners, tips, and curves to assess the printer's performance and capability in managing complex fine details and transitions (Fig. 2c). The results indicated that at 235 °C, the maximum VFR without defects was 5 mm^3/s, whereas at 245 °C, it reached 6.5 mm^3/s (Fig. 8). Considering the importance of VFR in reducing production time, where even a 1 mm^3/s change can greatly affect

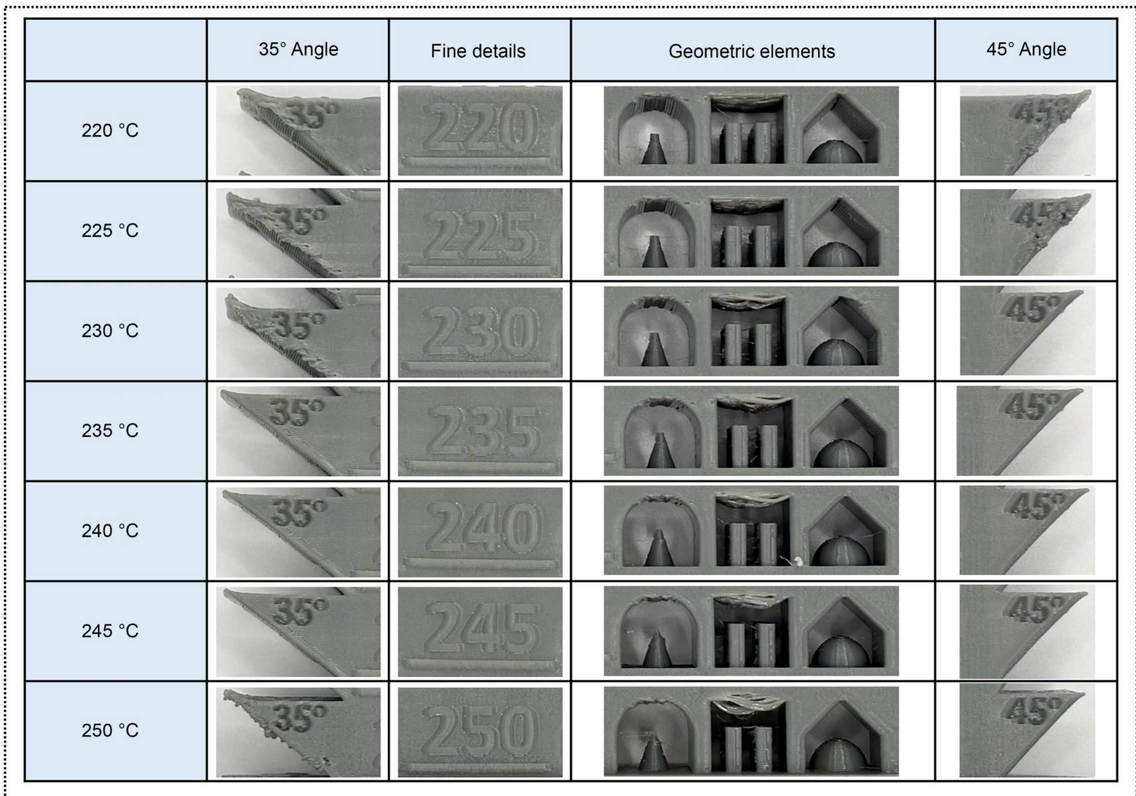

Fig. 6 TPU temperature tower calibration spanning from 220 to 250 °C in 5 °C increments. The model includes temperature-gradient sections, geometric shapes, and angled surfaces at 35° and 45° to evaluate stringing and overhang performance, and bridges to assess the effects of temperature on inclined printing. Photographic comparisons of 3D-printed features at different temperatures illustrate the impact of temperature on print quality

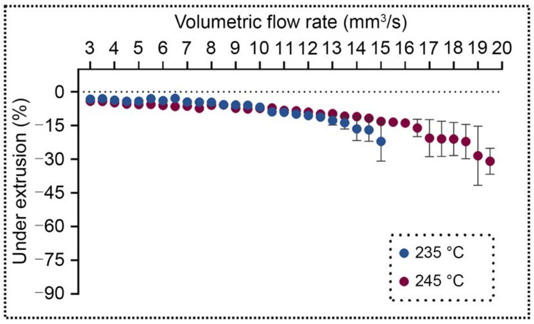

Fig. 7 Quantitative examination of TPU VFR calibration at 235 and 245 °C. Under-extrusion percentages are plotted against flow rates ranging from 3 to 20 mm^3/s in 0.5 mm^3/s increments, highlighting the relationship between flow rate and extrusion performance. Data are expressed as mean±standard deviation (n=3)

productivity, we decided to proceed with 245 °C as the printing temperature and VFRs of 6.5 and 7 mm^3/s. The VFR of 6.5 mm^3/s was chosen for its proven accuracy, while the higher value of 7 mm^3/s, which displayed some defects, was included to investigate further optimization of retraction speed and length, with the goal of improving accuracy.

The third optimized parameter was the retraction setting encompassing both retraction speed and length. During printing, as the printhead moves between points, the combination of nozzle heat and built-up pressure in the hot end can lead to the unintentional extrusion of excess material, causing stringing along the printhead's path. Retraction speed and length parameters are specifically designed to mitigate this issue by pulling back the filament when the printhead

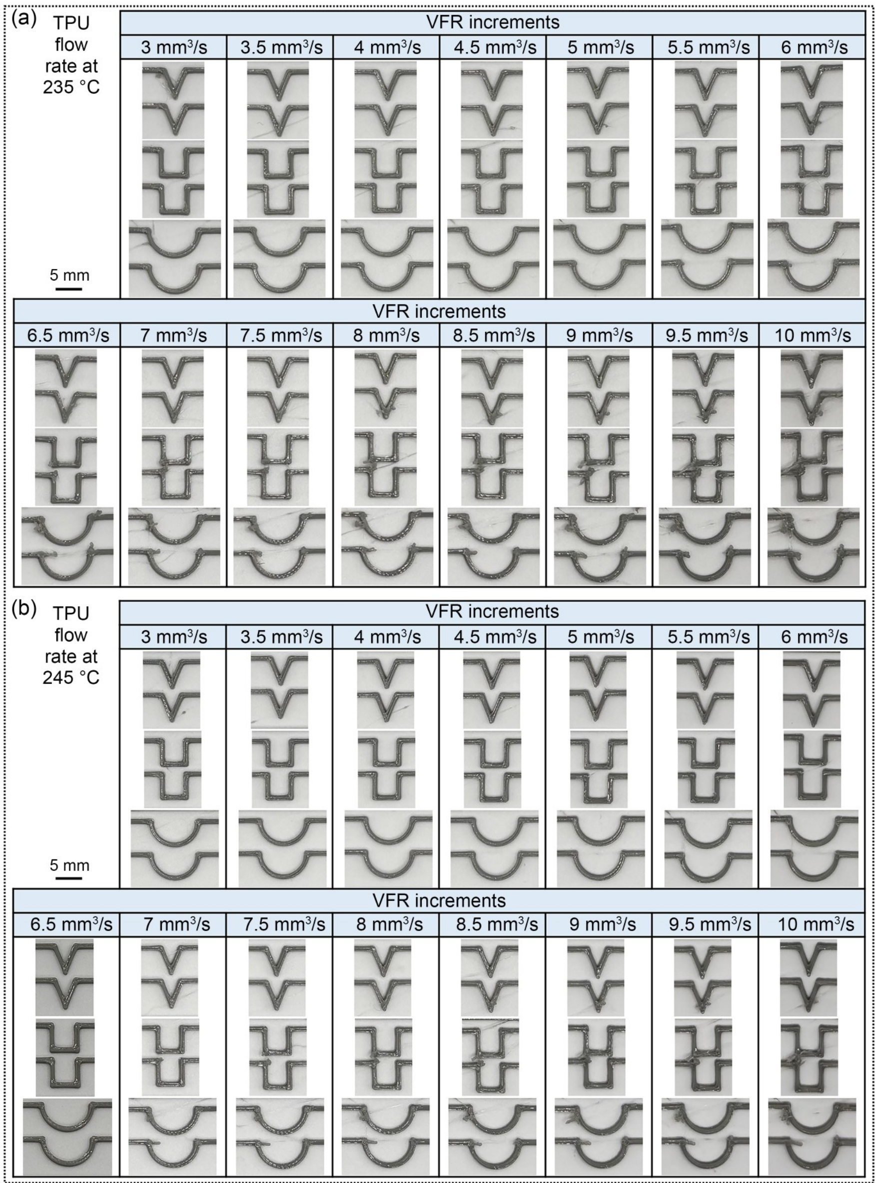

Fig. 8 Qualitative examination of TPU flow rate calibration at 235 and 245 °C. Photographic comparison of printed features at different VFRs ranging from 3 to 10 mm^3/s in 0.5 mm^3/s increments at 235 °C (a) and 245 °C (b)

moves to a new location, counteracting the pressure in the hot end and preventing unwanted extrusion. Properly calibrated retraction settings can effectively eliminate stringing, blobs, and other print quality issues related to extrusion [31]. To optimize retraction, we designed a test model consisting of a tower with four tall cones specifically structured to induce stringing during printing (Figs. 2d and 2e). A systematic evaluation was conducted using various combinations of retraction lengths (0.4, 0.8, and 1.2 mm) and speeds (30, 60, and 90 mm/s). Nine models were printed with different settings for VFRs of 6.5 and 7 mm^3/s, and the resulting print quality was assessed to determine the optimal parameters (Fig. 9). The results indicated that increasing both retraction length and speed consistently reduced stringing across both VFRs. Notably, at a VFR of 7 mm^3/s, most models exhibited defects of varying severity (highlighted in a yellow rectangle), except those printed with a retraction length of 1.2 mm at speeds of 60 and 90 mm/s. In contrast, no defects were observed at a VFR of 6.5 mm^3/s under the same conditions. Furthermore, no considerable difference was detected between the 1.2 mm retraction length at 90 mm/s across the different VFRs.

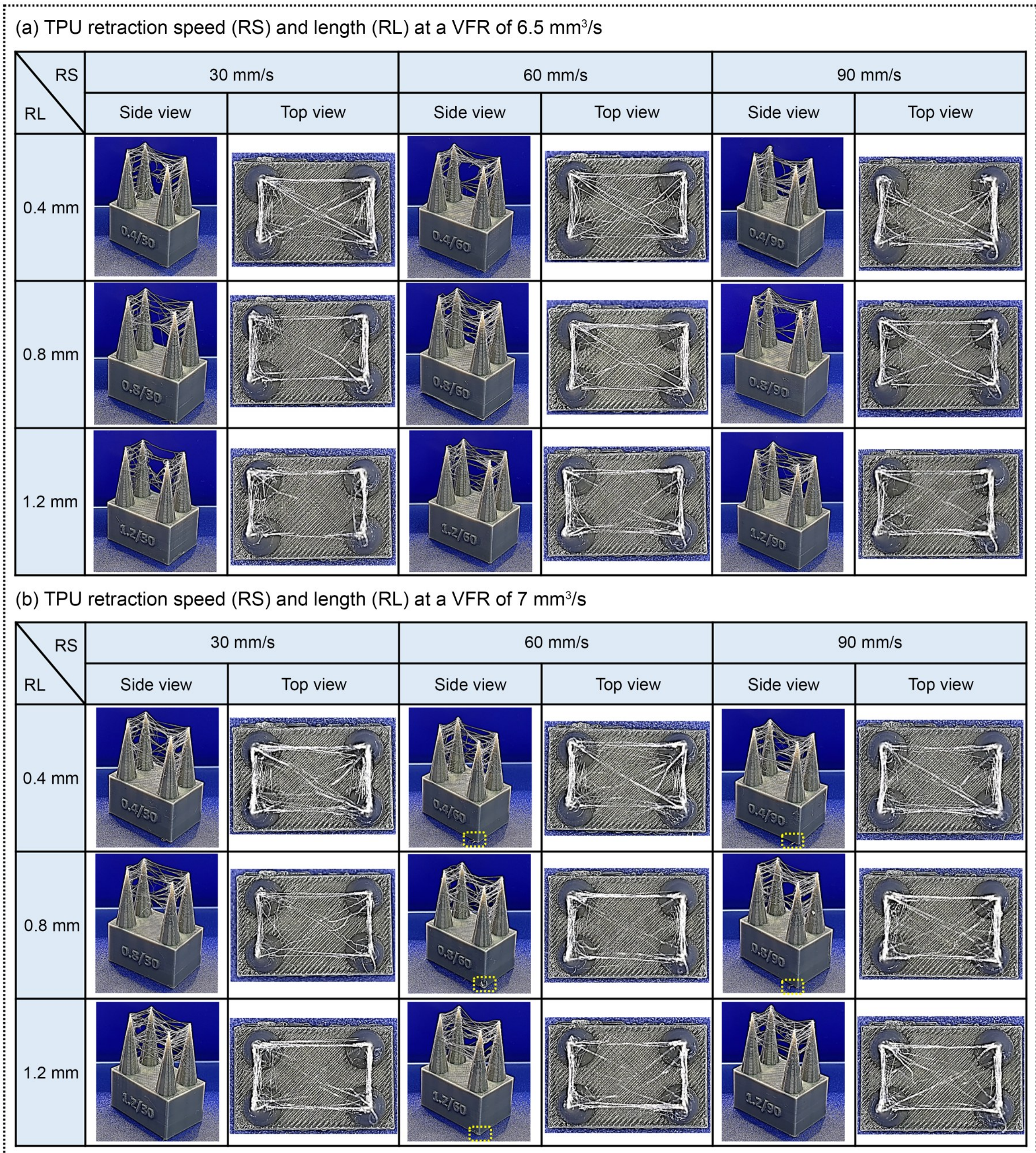

Fig. 9 TPU retraction calibration examination at 245 °C with 6.5 and 7 mm^3/s VFRs. Photographic comparison of printed features at different retraction lengths (0.4, 0.8, and 1.2 mm) and retraction speeds (30, 60, and 90 mm/s) for a VFR of 6.5 mm^3/s (a) and 7 mm^3/s (b)

Based on these findings, we printed Prototype 3 using a printing temperature of 245 °C, a VFR of 7 mm^3/s, and retraction settings of 1.2 mm at 90 mm/s. This optimization process significantly reduced the total printing time for Prototype 3 from 7 h and 31 min to 4 h and 14 min (Fig. S2b in the supplementary information), achieving a 43% decrease in production time without compromising the quality of the final product. Our optimization results underscore the importance of using calibration models and carefully selecting parameters to enhance both part quality and manufacturing efficiency. Calibration models offer a systematic framework for evaluating critical process parameters such as temperature, VFR, and retraction settings, which significantly impact the occurrence of defects such as stringing, warping, and under-extrusion. By systematically testing and identifying optimal parameter configurations, these defects can be minimized, resulting in superior mechanical properties, dimensional accuracy, and visual quality of the final product. Additionally, selecting parameters that balance performance with speed can significantly reduce fabrication time, thereby increasing productivity without compromising quality. This approach not only enhances the final product but also ensures that the manufacturing process remains efficient and cost-effective.

3.3.2 Performance assessment

To evaluate the effectiveness of TPU, the cases were subjected to drop tests in accordance with ASTM D5276-19 [26]. This test evaluates the capability of a container and its internal packing to protect its contents during the sudden shock caused by a free-fall drop impact. Videos of the drop tests, performed from a height of 1.5 m using demo glass ampoules filled with distilled water, are included (Videos S1 and S2 in the supplementary information). As expected, Prototype 2, fabricated from PLA+, failed to withstand the 1.5 m drop, resulting in the case opening upon impact and the breakage of the ampoules (Video S1 in the supplementary information). In contrast, Prototype 3, fabricated from TPU, showed significantly better performance, with the case opening in only 10 of the 18 drop tests (Video S2 in the supplementary information). Ampoule breakage occurred in only 2 of these instances. These results clearly demonstrate that the transition from PLA+ to TPU effectively mitigated the issue of ampoule breakage and significantly enhanced the durability and reliability of the product. However, additional improvements to the locking mechanism are necessary to optimize the performance of the final model.

3.4 Stage 4: Feedback

Concurrently with the case evaluation performed in Stage 3, 25 units of Prototype 3 were distributed to rescue teams comprising paramedics and doctors for initial user feedback. Each case was labeled with a unique barcode that provided direct access to an online survey upon scanning. The survey consisted of six questions using a five-point satisfaction scale, ranging from "very dissatisfied" to "very satisfied," along with one open-ended question inviting suggestions for further enhancements. The structure of the survey and its results are presented in Fig. 10. The main recommendations received from the open-ended question for improving the case design were:

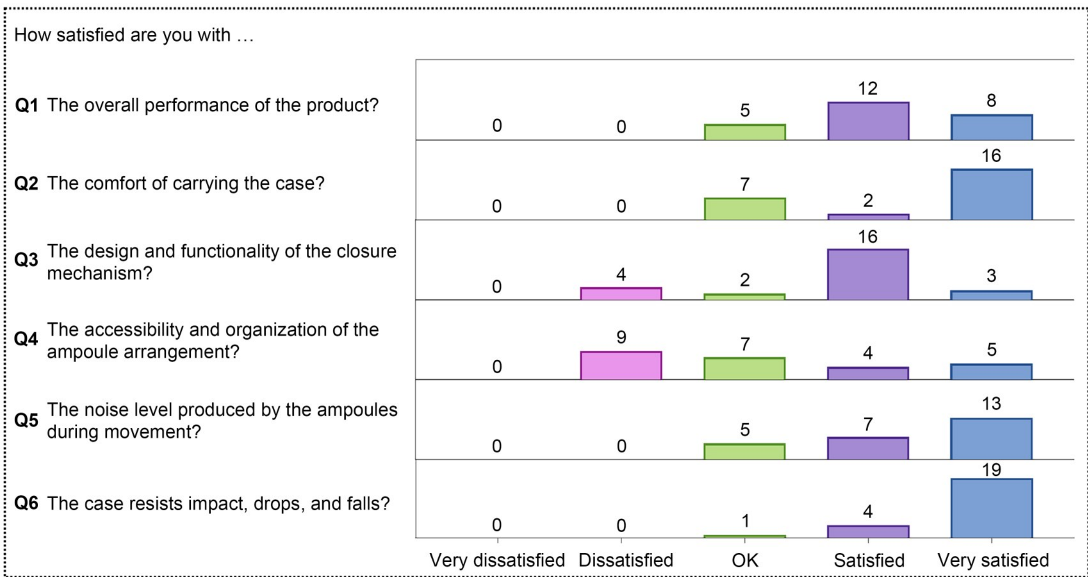

Fig. 10 Questionnaire and results from preliminary evaluations of Prototype 3 provided by paramedics and doctors, assessing the functionality, durability, usability, and overall design of the case. Satisfaction levels ranged from "very dissatisfied" to "very satisfied". Q6 received 24 valid responses, with one survey participant omitting the final question during completion

- Ampoule configuration: Incorporate two 5 mL Tranexamic acid (TXA) ampoules, potentially by reducing the numbers of the 1 mL Midazolam and Morphine ampoules in the case.
- Medication identification: Incorporating a system to distinguish between different medications enables easier identification and quicker retrieval during emergencies.
- Locking mechanism: Improving the locking mechanism ensures a more secure and reliable closure, addressing reports that the case tended to open at certain positions.

3.5 Stage 5: Final product

The following changes were implemented in the final model (Fig. 11) to address the recommendations received from the field:

- Medication set and case size: The medication set has been revised to include two 10 mL Ketamine ampoules, two 5 mL TXA ampoules, four 1 mL Morphine ampoules, and four 1 mL Midazolam ampoules (Fig. 11a). The TXA ampoules have dimensions of 73.3 mm in length and 15 mm in diameter. To accommodate these larger ampoules while maintaining a compact, pocket-friendly design, the size of the case was slightly increased. Moreover, ampoules of the same medication type were organized into shared slots, thereby minimizing the overall length and limiting the increase in case height.
- Color coding for medications: A thin, color-coded PLA+ plate was incorporated into the final model to differentiate between medications (Figs. 11a and 11b). Each medication was assigned a unique color: Ketamine is

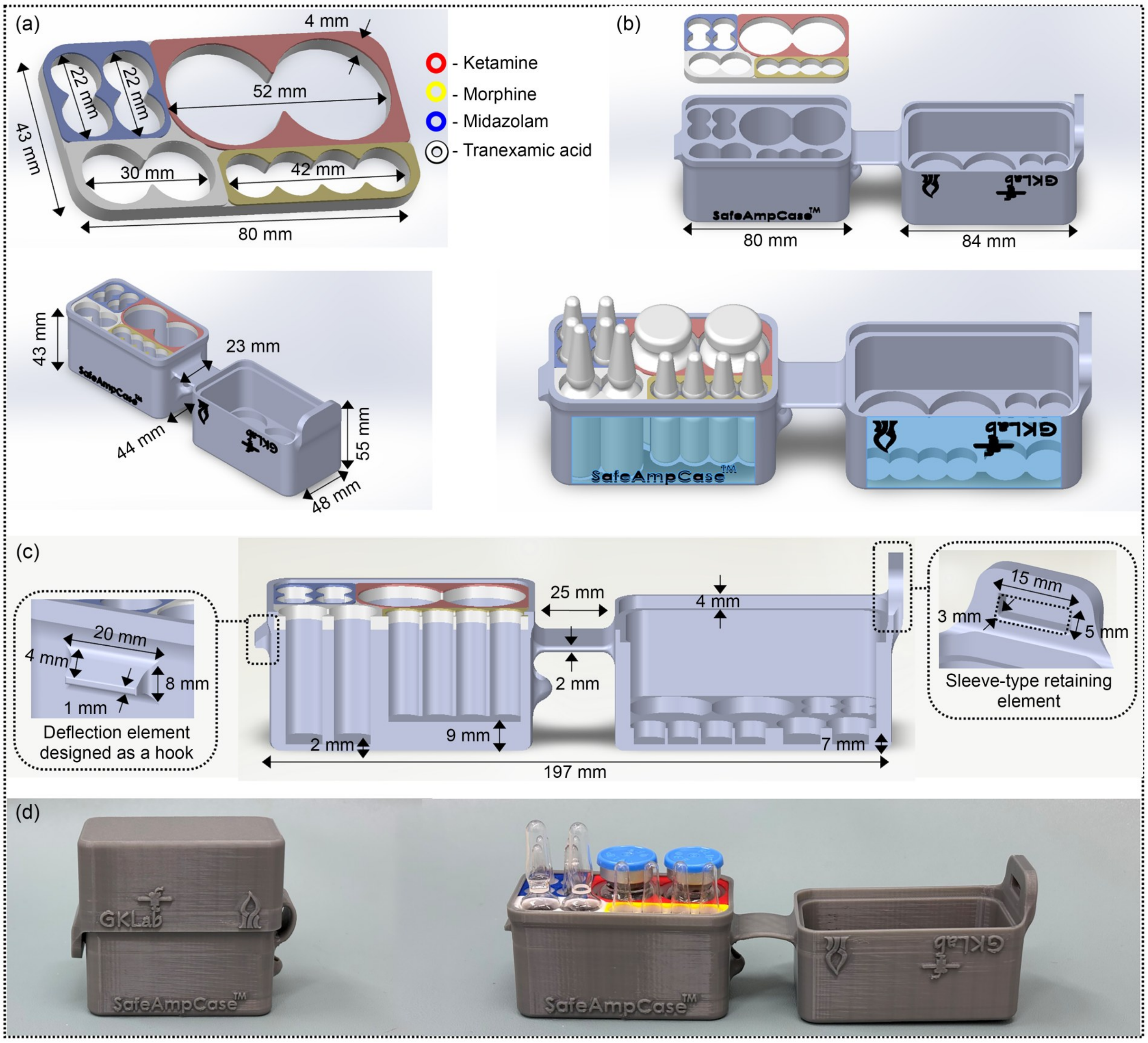

Fig. 11 The final model of the SafeAmpCase. (a) A color-coded plate displays the updated medication arrangement, with specific colors assigned to each medication type. (b) Case design, including dimensions and the integration of the color-coded plate. (c) Improved locking mechanism featuring a cantilever snap-fit design. (d) 3D-printed case fabricated from eTPU, highlighting the final adjustments and key features

represented in red, Morphine in yellow, Midazolam in blue, and TXA in white. This color-coded plate was produced using the printer's automatic material system (AMS), enabling the printing of components in four different colors.

- Improved locking mechanism: The cantilever snap-fit, the most commonly used type of locker [41], was chosen for this design (Fig. 11c). Each locker includes two primary components: the deflection element, which aids in assembly and disassembly, and the retaining element, which guarantees a secure connection with the assembly function element [42, 43]. In this design, the deflection element, located at the base of the case, is shaped like a right-angled triangle, functioning as a hook. The retaining element, located on the lid, features a sleeve-like structure designed to fit securely over the deflection element.

The final model, featuring all design modifications, was printed using optimized parameters, resulting in a fabrication time of 3 h and 43 min (Fig. S2c in the supplementary information). During drop tests, this model successfully absorbed impacts across all 18 trials, showing no case openings or damage to either the ampoules or the case (Video S3 in the supplementary information). This demonstrates its capacity to protect sensitive components under real-world conditions. The transition to TPU effectively mitigated previous issues with ampoule breakage while significantly enhancing the case's durability and reliability. Additionally, feedback from the field, collected through close collaboration between the biomedical engineering laboratory and the emergency medicine unit, facilitated iterative design modifications tailored to user needs. This underscores the critical role of multidisciplinary collaboration in developing innovative and practical solutions.

Currently, the solutions available for storing and transporting fragile drug ampoules primarily consist of generic soft cases with padded dividers or foam inserts for shock absorption [5, 6]. However, these solutions exhibit several critical limitations. First, they do not account for the precise dimensions of individual ampoules, allowing for unintended movement that exposes them to uneven mechanical stresses during transport. Second, due to the low-impact energy absorption of soft materials, these cases provide limited protection against drops or sudden impacts, increasing the risk of ampoule breakage [5, 6]. Furthermore, most existing cases are bulky and impractical for personal use, which forces EMS personnel to depend on oversized drug kits or improvised storage solutions that compromise both accessibility and protection.

The SafeAmpCase overcomes the limitations of existing solutions through material innovation, precise modeling, and enhanced usability. Unlike generic soft cases, it incorporates custom compartments designed to match the specific dimensions of each medication, thereby minimizing internal movement and ensuring mechanical stability. Using TPU enhances impact resistance and energy absorption, providing effective protection against mechanical shocks. Moreover, color-coded compartments facilitate rapid identification of medications, which is a crucial benefit in high-pressure emergency situations. Its compact and lightweight design makes it easy to carry in EMS uniform pockets, ensuring quick access to essential medications without the inconvenience of a bulky medical kit. Additionally, innovative AM techniques facilitate rapid prototyping and customization, allowing for the scalable production of tailored ampoule sets to meet specific medical requirements. These advancements position SafeAmpCase as a superior alternative, optimizing both ampoule protection and the efficiency of emergency response.

We acknowledge several limitations in the development process of the SafeAmpCase. Field evaluations were performed with a relatively small sample of 25 participants. While their feedback was invaluable, a larger and more diverse group of healthcare providers in various settings would provide a more comprehensive assessment of the case's performance and usability. Furthermore, although the case was tested for impact resistance and functionality, long-term testing in different environmental conditions (such as extreme temperatures, humidity, and frequent handling) was not performed, leaving its long-term reliability in question. To meet regulatory requirements such as FDA and Conformite Europeenne (CE) certification, the case must undergo rigorous testing in a certified laboratory to obtain the necessary approvals. Additionally, while 3D printing allows for cost-effective prototyping, it may lead to higher production costs compared to traditional manufacturing methods when scaled for mass production.

4 Conclusions

This study demonstrates the transformative potential of 3D printing technology through the development of SafeAmpCase, a custom-designed solution specifically addressing the critical challenges of transporting and storing fragile glass ampoules in emergency medical environments. The use of AM allowed rapid prototyping and iterative design enhancements, resulting in a compact, durable, and user-friendly case that meets the specific needs of paramedics and healthcare professionals. Material selection played a pivotal role in ensuring the final product's durability and functionality. The transition from PLA+ to TPU represents a significant material advancement, leveraging TPU's superior mechanical properties, such as flexibility, shock absorption, and noise reduction, to produce a robust, field-ready design capable of withstanding real-world impacts. A key novelty of this research lies in the systematic optimization of 3D printing parameters.

Using calibration models, essential factors such as printing temperature, VFR, and retraction settings were fine-tuned. The final optimized parameters (245 °C, 7 mm^3/s, 90 mm/s, and 1.2 mm) achieved a remarkable 43% reduction in production time while preserving exceptional structural integrity and print quality. The final SafeAmpCase model successfully withstood 18 consecutive ASTM-standard drop trials without any ampoule breakage, demonstrating its impact resistance and field durability. This study highlights the effective integration of advanced materials science and optimized manufacturing processes to address practical engineering challenges effectively. The multidisciplinary collaboration between biomedical engineering, materials science, and emergency medicine played a pivotal role in fostering innovation. Insights gained from field evaluations directly led to refinements in the ampoule layout, locking mechanism, and medication-specific color coding, thereby enhancing usability in high-pressure situations. The SafeAmpCase exemplifies how AM can merge innovation with functionality, providing tailored, high-performance solutions for medical applications. This approach establishes a new benchmark for the design and production of biomedical devices, paving the way for transformative advancements in healthcare technology.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study does not contain any studies with human or animal subjects performed by any of the authors.

Data availability Data will be made available on request.

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