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Development of Auto-Injection Systems through the TRIZ Problem-Solving Method

Desarrollo de sistemas de autoinyección mediante el método de resolución de problemas TRIZ

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ABSTRACT

This study presents a comprehensive approach to the redesign of auto-injection syringe systems, employing the TRIZ problem-solving framework along with Ishikawa analysis. The proposed design aims to address common challenges, including usability issues, high production costs, complex assembly procedures, and hygiene considerations. By leveraging the TRIZ methodology, this work successfully identified and addressed technical contradictions, leading to the development of an innovative auto-injection syringe. This design incorporates a recyclable polypropylene random copolymer, which not only reduces manufacturing costs but also promotes environmental sustainability. Replacing flexible springs with inexpensive rubber bands enhances the design's affordability and usability. This change lowers costs and improves user-friendliness, allowing patients to operate the system more easily while upholding performance standards. According to engineering validations carried out through static and dynamic simulations in NX Nastran, the design safely withstands up to 10 N of applied force, with its maximum stress levels remaining below 5.2 MPa, well within the material's 27.5 MPa yield strength. While prior studies have reported ergonomic or functional improvements, they often lack a systematic engineering approach to address design contradictions. This study fills that gap by uniquely integrating the TRIZ and Ishikawa approaches to develop an optimized, user-friendly, and sustainable autoinjector. As a result, our new design meets user needs and adheres to the industry's safety and efficacy standards. This research underscores the effectiveness of integrating the aforementioned methodologies to create practical and efficient solutions for patients requiring regular self-injection, thereby contributing to improved healthcare outcomes and a more sustainable medical device industry.

Keywords: syringe design, Ishikawa diagram, mechanical design and analysis, recyclable materials and sustainability, medical device innovation

RESUMEN

Este estudio presenta un enfoque integral para el rediseño de sistemas de jeringas autoinyectables, empleando el marco de resolución de problemas TRIZ junto con el análisis Ishikawa. El diseño propuesto busca abordar desafíos comunes, incluidos problemas de usabilidad, altos costos de producción, procedimientos de ensamblaje complejos y consideraciones de higiene. Aprovechando la metodología TRIZ, este trabajo logró identificar y resolver contradicciones técnicas, lo que condujo al desarrollo de una innovadora jeringa autoinyectable. Este diseño incorpora un copolímero aleatorio de polipropileno reciclable, lo cual no solo reduce los costos de fabricación, sino que también promueve la sostenibilidad ambiental. La sustitución de resortes flexibles por bandas elásticas económicas mejora la asequibilidad y la facilidad de uso del diseño. Este cambio reduce los costos y mejora la usabilidad, permitiendo que los pacientes operen el sistema con mayor facilidad sin comprometer los estándares de rendimiento. Según validaciones de ingeniería realizadas mediante simulaciones estáticas y dinámicas en NX Nastran, el diseño soporta hasta 10 N de fuerza aplicada de manera segura, con niveles máximos de tensión que se mantienen por debajo de los 5.2 MPa, muy por debajo del límite elástico del material, que es de 27.5 MPa. Si bien han reportado mejoras ergonómicas o funcionales, los estudios anteriores a menudo carecen de un enfoque sistemático de ingeniería para abordar contradicciones de diseño. Este estudio llena ese vacío al integrar de manera única los enfoques TRIZ e Ishikawa para desarrollar un autoinyector optimizado, fácil de usar y sostenible. Como resultado, nuestro nuevo diseño satisface las necesidades del usuario y cumple con los estándares de seguridad y eficacia de la industria. Esta investigación subraya la eficacia de integrar las metodologías mencionadas para crear soluciones prácticas y eficientes para pacientes que requieren autoinyecciones regulares, contribuyendo así a mejorar los resultados sanitarios y a una industria de dispositivos médicos más sostenible.

Palabras clave: diseño de jeringas, diagrama de Ishikawa, diseño y análisis mecánico, materiales reciclables y sostenibilidad, innovación en dispositivos médicos

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Introduction

The effective handling of various medical conditions often necessitates the use of injectable medications, which have become increasingly vital in modern healthcare. Pre-filled syringes are disposable plastic devices designed for the administration of single-dose vaccines and parenteral medications, specifically engineered to prevent needle reuse. The transition from metal or glass syringes to plastic has resulted in an increased demand for these syringes in the medical field [1]. As advancements in medical technology continue to evolve, a growing number of patients are opting to self-administer this type of treatment, resulting in a significant transformation in medication delivery methods [2]. Automated injection syringe systems have emerged as essential tools that not only enhance the convenience of self-administration but also improve the safety of these processes. The use of autoinjectors has been observed to significantly reduce pain at the injection site, with a substantial majority of patients favoring this method as a more satisfactory option [3]. By empowering patients to independently manage their treatment regimens, these systems can lead to improved adherence to prescribed therapies and, consequently, better therapeutic outcomes [4]. The applications of autoinjectors tested for patient use have been widely favored due to their ease of use and reduced discomfort [5]. Studies have also looked into the reliability of auto-injectors, exploring the frequent reasons for their failure. The findings indicate that these devices have a low failure rate, underscoring their benefits in terms of usability and maintenance, which positions them as highly dependable tools [6].

However, despite the numerous advantages offered by contemporary automatic injection systems, several challenges persist which can hinder their widespread adoption and effectiveness. Usability remains a prominent concern, as some devices are overly complex and difficult for patients to operate, which can lead to frustration and decreased compliance with treatment protocols [7]. In the literature, several studies have emphasized the increasing prevalence of autoinjectors, attributing this trend to their convenience and dependability. However, it has been noted that the high costs of these advanced systems may hinder widespread accessibility [8] and could create barriers for patients who would greatly benefit from the ability to self-administer their medications. In addition, certain products pose significant hygiene risks, particularly those that require the manual transfer of medication from disposable syringes to automatic devices. On the other hand, reusable devices pose a risk of infection and tend to be more expensive for manufacturing companies [9]. This process can introduce contamination, jeopardizing patient safety and undermining the very benefits these systems are designed to provide [10].

Medical devices also have significant adverse effects on the environment; disposable devices contribute to the increase in medical waste and are largely responsible for the inventory costs incurred by hospitals. The development of biodegradable alternatives or the utilization of recyclable materials is crucial for mitigating the environmental impacts of single-use, non-recyclable, and non-biodegradable plastics within the healthcare sector [11]. Polymers (plastics) possess unique characteristics that allow for a wide range of applications in medical device technology, constituting the majority of single-use medical devices [12]. Additionally, the use of recyclable materials in medical device designs promotes sustainability and aligns with current environmental considerations, which are becoming increasingly important in today's healthcare landscape [13]. Studies have shown that the use of recyclable medical devices can boost environmental sustainability and increase efficiency in healthcare services [14].

Electromechanical autoinjectors have also been developed as suitable alternatives. These systems offer benefits such as customizable injection speeds, reliable medication delivery, and electronic record-keeping, which enhance adherence and sustainability through reusability. They can also reduce discomfort and anxiety during injections, improving the patient's experience [15]. Recent developments in autoinjector technology have integrated advantageous features such as precise dosing and user-friendly operation [16].

Research has also shown that integrating sustainability into medical device development has led to the creation of several approaches for assessing sustainability criteria. These approaches are designed to evaluate design concepts and improve the process overall [17].

Various methodologies are widely used in this style of product development. For example, utilizing the Ishikawa diagram for root cause analysis enables the systematic identification of the various problem factors contributing to the limitations of current devices. Furthermore, the TRIZ (theory of creative problem solving) supports systematic innovation, facilitating the development of creative and effective solutions to these challenges [18].

In the product development process, various creative problem-solving techniques are employed, such as brainstorming, design thinking, six sigma [19], PDCA (plan-do-check-act) [20], DMADV (define, measure, analyze, design, and verify) [21], 5M (machinery, manpower, material, measurement, method) [22], and morphological analysis. However, these methods often fall short in providing structured mechanisms to resolve specific contradictions, particularly within the engineering domain. While design thinking and brainstorming are fundamentally user-centered, they heavily rely on iteration and experiential learning. Moreover, DMAIC (define, measure, analyze, control) emphasizes statistical improvement over innovation. In contrast, TRIZ offers a solution-oriented and algorithmic framework based on inventive principle patterns, proving highly effective in addressing technical conflicts. The Ishikawa diagram complements this process by systematically identifying root causes and key focus areas across multiple domains.

The integration of the TRIZ and Ishikawa methods fills a significant gap in the literature by providing analytical depth and creative solutions. This integration is particularly crucial in the complex development of automatic injection systems, where safety, usability, cost, and sustainability intersect.

This study identifies shortcomings in current auto-injection systems which necessitate further investigation and innovation. Many systems lack intuitive design, making them challenging for users, especially for those with limited technical skills or anxiety. Research is needed to create more ergonomic designs and user interfaces for diverse populations, including children and the elderly. High production costs also restrict access to life-saving treatments. Exploring alternative materials, innovative manufacturing methods, and optimizing supply chains could yield more affordable solutions without sacrificing quality or safety. In addition, collaboration with manufacturers may enhance production efficiency and reduce costs.

The assembly of auto-injection systems is complex and labor-intensive, increasing production costs and the risk of human error. Streamlining this process through modular designs or automation could enhance efficiency and reliability. Hygiene is also a critical concern, as existing designs may not adequately address contamination risks. Investigating antimicrobial or self-sanitizing materials and packaging solutions that maintain sterility until use is essential for improving safety and reducing infection risks.

Our research hypothesis posits that the combination between the TRIZ problem-solving methodology and Ishikawa analysis can significantly enhance the development of an advanced auto-injection system, effectively addressing a series of existing challenges in this field. This research aims to systematically identify and address the shortcomings of existing auto-injection systems through the aforementioned approaches while also focusing on sustainability through the incorporation of recyclable materials.

Method

In this research, the Ishikawa method was used to identify problems, and TRIZ was employed to find their ideal solution. Furthermore, the NX software was used to design new CAD data, as well as NX Nastran to analyze the model and 3D printing technology to produce prototypes. These methods and tools are detailed in this section.

Ishikawa diagram method

Ishikawa is a prominent figure in quality management, best known for his development of the Ishikawa diagram, a tool for root cause analysis. This diagram categorizes the potential causes of a problem, providing a systematic approach to problem-solving. [23]. This type of diagram is also known as the *fishbone method*, and it is depicted in Fig. 2 [24].

TRIZ

TRIZ was initially developed by Genrich Altshuller and his colleagues in the mid-1940s. It is a systematic and practical methodology for designers/engineers to analyze inventive problems and further resolve them in a strategy-driven manner [25], and it is much less experience-dependent than many existing design methods, which rely too heavily on specific previous experience and thus limit potential innovation [26], [27], [28]. During the application of this method, while one desired product feature is improved, a different feature is bound to deteriorate in response. Altshuller developed a 40 x 40 matrix that describes the relationship between these features. TRIZ is a method that allows solving problems using this matrix. It is a logical and practical in comparison with other methods, as illustrated in Fig. 1.

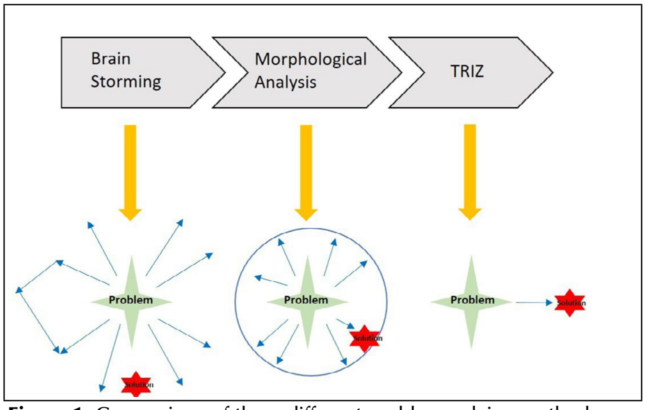

Figure 1. Comparison of three different problem-solving methods
Source: Authors

TRIZ is a convenient method to be used together with the Ishikawa diagram. This integration is depicted in Fig. 2.

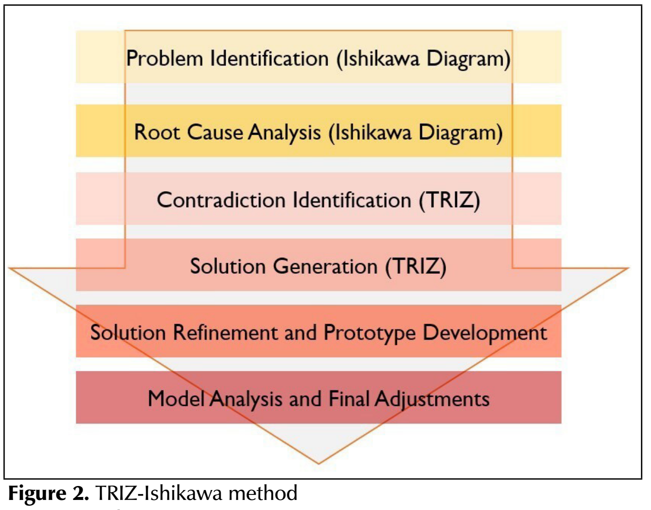

Figure 2. TRIZ-Ishikawa method
Source: Authors

In our approach, the application of the Ishikawa diagram and the TRIZ methodology is structured in a series of clear steps that ensure systematic problem identification and innovative solution development. The following steps outline the framework used in this study:

1. Problem identification (Ishikawa diagram). The initial phase aims to pinpoint and classify the fundamental causes of the challenges faced by the auto-injection system. Utilizing the Ishikawa diagram, the problem is dissected into essential categories, including design, materials, processes, user interaction, and safety, thereby offering a comprehensive view of the factors at play.
2. Root cause analysis (Ishikawa diagram). During this stage, the previously identified causes are assessed and ranked according to their importance. This targeted analysis sheds light on the most pressing issues, paving the way for the subsequent phases of the process.
3. Identification of contradictions (TRIZ). The TRIZ approach is employed to uncover the contradictions present in the system, *e.g.*, the challenge of balancing usability with cost or enhancing functionality without exacerbating environmental concerns. The TRIZ matrix serves as a tool to map these contradictions, facilitating the creation of innovative solutions.
4. Solution generation (TRIZ). In this stage, creative solutions are formulated by applying the 40 inventive principles of TRIZ in order to solve the identified contradictions. The emphasis is on improving the design while preserving critical factors such as safety and cost efficiency.
5. Solution refinement and prototype development. The proposed solutions are polished and converted into detailed designs using CAD software (NX), followed by the creation of prototypes through 3D printing. This process enables swift testing and iterative enhancements based on user feedback.
6. Model analysis and final adjustments. The prototypes are subjected to performance evaluations using NX Nastran to verify compliance with engineering and safety standards. Necessary modifications are implemented, culminating in a fully optimized auto-injection system.

Problems and solutions

It is known that, in current practice, patients pay high costs to purchase autoinjectors. Therefore, one of the most important associated parameters is the need to ensure an engineering development that allows producing the product at a lower cost. To this effect, emphasis was placed on the use of cheaper materials in the design, on less costly and easier production methods, and on the use of minimum parts.

The main goal should be to design the most comfortable version possible for the user. In this context, another problem that we identified was the assembly of the product. In addition to being easy to assemble the product, for the sake of reusability, it is important for users to be able to perform re-assembly on their own. In this regard, the design must be reusable, in addition to complying with engineering tolerance calculations.

Since user comfort is the primary objective, an ergonomic design should be achieved wherein users will have no difficulties in applying the product themselves. They should be able to comfortably grasp the product and apply it with one hand, for which the location and shape of the trigger area is also important.

Since the market that the product appeals to is the healthcare sector, it is important for the designed product to meet hygiene standards in order to avoid any complications. In addition, the fact that the syringes used for treatment differ in size and are disposable represents hygiene issues for general-purpose productsIn order for the design to be translated into practice, it must comply with certain engineering rules. In this regard, the static displacement of the main body, the properties of the materials with which the product will be designed, some dynamic calculations for the moving area, and the design parameters should not pose an issue in terms of engineering.

Finally, given the mounting environmental pollution issues, we aimed to make the product environmentally friendly. To this effect, we used a recyclable material and carried out the necessary medical certification procedures [29] to release the product to the market.

The Ishikawa diagram shown in Fig. 3 was used to identify the main problems.

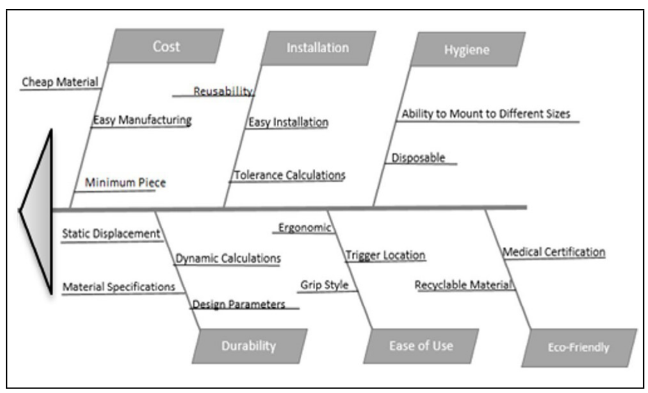

Figure 3. Ishikawa diagram
Source: Authors

In the matrix, note that there are six main problems, with their corresponding solution alternatives (Fig. 3). To find the best way to solve these problems, we used the TRIZ matrix, which is presented in Fig. 4.

Cost

As mentioned in the introduction, it is difficult to cover the cost of alternative devices that serve the studied purpose. Ahead of price hikes, three options have been identified among the procedures that need to be implemented for a satisfactory outcome: changing the device material for a cheaper one, making production easier and cheaper by using fewer parts, and adopting a design that can be

TRIZ Matrix									
Problems	Worsening Feature / Improving Feature	15-Duration of Action of Moving Objects	16-Duration of Action by Stationary Objects	21- Power	26-Quantity of substance / the matter	32-Ease of Manufacture	33-Ease of Operation	39- Productivity	Ideal Final Solution & How it is applied to the design / Integration
Durability	16-Duration of Action by Stationary Objects				3 31 35				**Parameter Change** - The material and the design was changed acc. to durability analyses
Cost	26-Quantity of substance / the matter	3 10 35 40	3 31 35						**Partial Quality:** Minimum number of parts is targeted.
Ease of Use	33-Ease of Operation			2 10 34 35					**Prior Action:** Prototyped and had been tried by a user.
Eco-Friendly (Recyclable)	34-Ease of Repair					1 10 11 35			**Parameter Change:** Materials were selected to be suitable for recycling
Hygiene	35-Adaptability or Versatility		2 16				1 15 16 34		**Partial or Overwork:** Extra ribs added.
Installation	38-Extent of Automation							5 12 26 35	**Combining:** Easy assembly and ergonomics are targeted.

Figure 4. TRIZ matrix
Source: Authors

produced at a lower cost. In this way, the cost of the product can be reduced, as well as its prices. These solutions are suggestions provided by the morphological analysis, but the TRIZ matrix was used to find the most appropriate of them. When using TRIZ, one feature improves while another deteriorates. Within the scope of the cost problem, the quantity of substance was chosen as the feature to be improved. In addition, the duration of object movement and the duration of the stationary objects' action were selected as the deteriorating features. In the examined 39 x 39 TRIZ matrix, solution number 3 (partial quality), located at the intersection of the mentioned features, was found to be the most suitable alternative. It was concluded that a model with fewer parts should be designed.

Installation

Another problem is the assembly of the product. Designs that are not user-friendly and are extremely complex cause difficulties for the user in terms of cost and application. Current products are either complex or can be used only once. To avoid this, the design must be easy to assemble and suitable for multiple uses. In order to find a specific solution, we used the TRIZ matrix again. Here, increasing the level of automation entailed a loss in terms of productivity. As shown in Fig. 4, the most suitable solution is the combined method (number 5), which targets easy assembly and ergonomics are targeted.

Hygiene

The product type under study has been used for treating various diseases. In this context, hygiene is important for preventing undesirable complications. Nevertheless, the use of some current devices causes serious hygiene issues, as it includes a transfer process. To prevent these issues, disposable needles have been used, but they complicate self-administration. Therefore, we designed a system where disposable needles can easily fit, aiming for compatibility with different syringe sizes. When we analyzed the features in the matrix, we concluded that the best alternative was solution 16, bearing in mind that, if it is difficult to fully obtain 100% a desired effect, one should seek to simplify the problem [30]. In this vein, by adding more than one rib to the system, it became possible to adapt to different syringe sizes, thereby ensuring the product's compliance with hygiene rules. The application of this solution is depicted in Fig. 5.

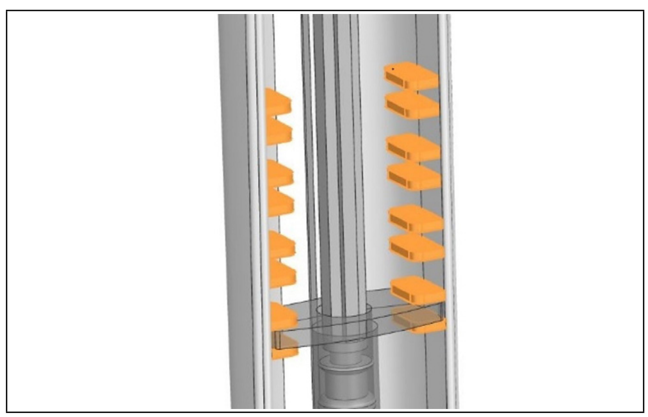

Figure 5. Rib region
Source: Authors

Durability

Durability (or strength) is one of the most important factors to consider when designing a new product, as it is important for the product to be usable in practice as well as in theory. To predict the strength of a product, static displacement, dynamic calculations, material specifications, and design parameters must be taken into account. These parameters are analyzed in detail in the solution section. With the help of the TRIZ matrix, we decided that the material's mechanical properties should be set according to durability analyses in order to increase product strength.

Ease of use

As mentioned in the previous sections, user-friendliness is one of the desired features of this product. To this effect, an ergonomic design was elaborated. The system was designed to allow for easy installation and application. Its innovations are examined in three subsections. For a better understanding, a model of the design is provided in Fig. 6.

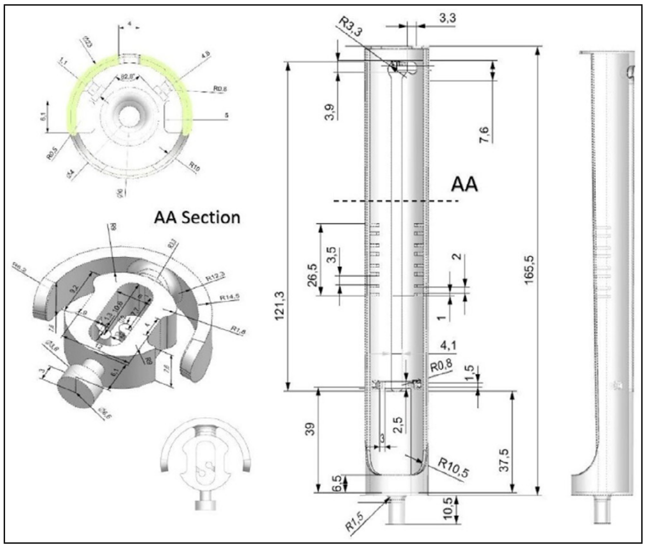

Figure 6. Model of the design and its dimensions (mm)
Source: Authors

Inserting the syringe

The syringe tip is pushed into the hole in Fig. 7. The assembly of the syringe is completed by placing its tabs into the designated fixing areas (number 7).

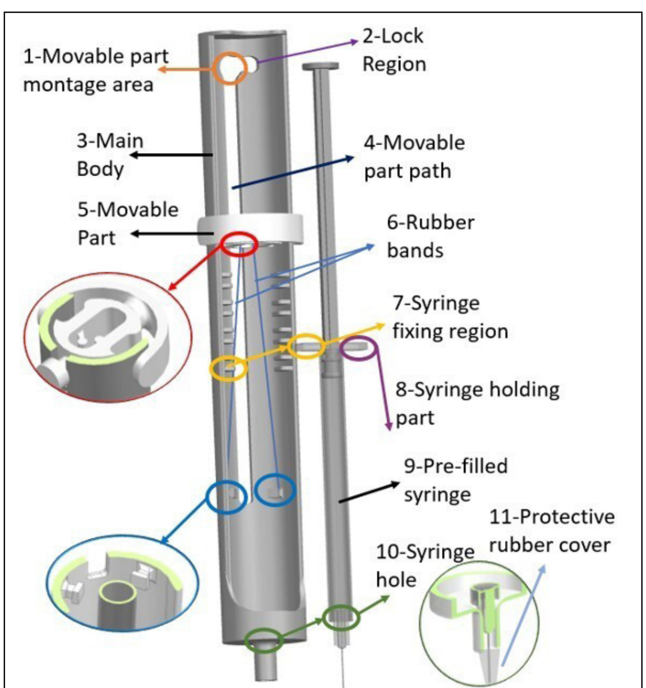

Figure 7. Detailed model of the design
Source: Authors

Installation

After the syringe is placed, the device is held with one hand in order to make the system operational, and, with the help of the other hand, movable part number 5 is pulled and slid towards part number 1, and it is locked in region number 2. Elastic potential energy is introduced into the system with the help of rubber bands (number 6).

Grip style and trigger location

Since the user must use the needle on their own, the device is designed to be controlled with one hand. After grasping the apparatus with four fingers and inserting the needle under the skin, the user moves part number 5 (which is locked in number 2) with their thumb. Part number 5 moves along path number 4 thanks to the potential energy accumulated in the rubber band, releasing the syringe. This creates pressure on the piston. With the effect of the applied force, the piston of the syringe moves inward and sends the medicine under the skin, driven by the internal pressure. The grip model is shown in Fig. 8.

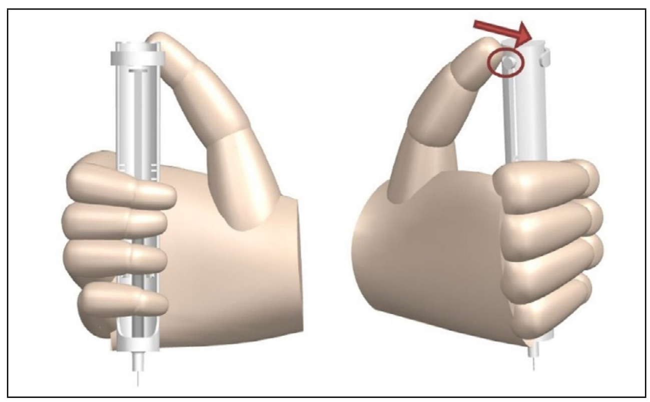

Figure 8. Grip model
Source: Authors

Eco-friendliness

A significant portion of biomedical engineering deals with implants, scaffolds, wound dressings, biosensors, and various matrices for drug delivery applications. However, due to the potential negative impacts of these materials, scientists are focusing their efforts on utilizing more sophisticated, non-toxic materials. Right now, the focus of manufacturers and researchers is on renewable resources [31]. Therefore, making our biomedical product from a recyclable material helped to reduce the harm made to the environment, which is not only beneficial but also reduces costs. One of the key points in this regard was the use of rubber bands instead of the spring mechanisms found in equivalent products.

Results

To address the issues outlined above, several analyses were conducted, leading to the data presented in this section. This study focused on optimizing the design for ease of use, production efficiency, and recyclability. Mathematical and static analyses were performed to assess the strength and deformation of key components under operational forces, with calculations considering syringe and needle specifications. The results indicated that the spring and syringe retention areas could withstand forces of 10 N without structural failure, and that torsional and tensile loading up to 50 Nm and 20 N did not lead to plastic deformation. Additionally, the moving part of the system demonstrated elastic deformation within the material's limits. These findings confirm that the design, which includes fewer components and uses recyclable materials, is both functional and feasible for real-life applications, as demonstrated by the successful production of a prototype.

The solution found for the problems mentioned in methods section was to create a design with fewer parts that was easy to assemble and recyclable. Said design consisted of four parts: a main body, a moving part, a protective rubber cover, and a syringe.

In order to make the product easier to use, the design was made for the user to grasp and apply the product with one hand. This issue is of extra importance for self-treatment, especially in applications involving the arm. By placing the holding parts of the syringe (part number 8 in Fig. 6) in the compartments labeled as number 7, we aimed to accommodate syringes of different lengths and widths, with the help of the material used in production and the slit that forms the path of the part in motion (number 4).

Since syringes of different sizes can be mounted into the device, the user does not need to transfer any product, thus preventing the hygiene complications that may arise during this process. In addition, a protective rubber cover (number 11) was added to keep the tip of the needle sterile.

During the production of the model, polypropylene random copolymer (Bormed RG835MO) [32] was used to create a cheaper and recyclable design compared to other materials. The fact that the design consists of fewer parts not only facilitates production, it also makes assembly and application easier.

For increased recyclability, the entire main body of the product was made of a recyclable flexible plastic material. In addition, rubber bands were used – which are easier to recycle – instead of flexible springs, which are used by alternatives on the market. This led to more environmentally friendly and cheaper product. Since rubber bands are easier to access, they can be purchased at a lower cost than their counterparts in the market.

In order to increase the strength of the design, the parts with potential strength issues were mathematically and statically analyzed to observe their deformation under specific forces. For the corresponding calculations, the dimensions of the most commonly used syringes and needles were taken as reference [33]:

- Needle length: 4, 5, 6, 8, 10, and 12 mm
- Needle tip inner diameter: 29, 30, 31, and 32 G ≈ 0.286, 0.255, 0.227, and 0.202 mm
- Syringe capacity: 0.3, 0.5, 1.0, and 2.0 ml
- Minimum needle inner diameter according to ISO standards (9626:2016) [34]: 0.114 and 0.125 mm for 31G; 0.089 and 0.105 mm for 32 G
- Rubber bands:
    - Length: 79 ± 1 mm
    - Hight: 10 ± 1 mm
    - Width: 10 ± 1 mm [35]
    - Minimum tensile strength: 15.5 MPa
    - Minimum elongation at break: 650% [36]
- Density of insulin: 1.09 g/cm^3

Calculations

Calculations were made based on the average values specified in the previous sections and using the law of conservation of energy, the final speed of the moving part when it hits the piston was found. A pressure value was found using terminal velocity and Bernoulli's principle. Using the pressure value found and Poiseuille's law for laminar flow formula, the net force applied on the piston was calculated.

Bernoulli equation (*1*)

$$P_1/\rho + (V_1^2)/2 + G_{z1} = P_2/\rho + (V_2^2)/2 + G_{z2} = const.$$

$$P_1 = 101.325 \text{ kPa}$$

$$\rho = 1.09 \ g/m^3$$

$$V_1 = 0$$

$$G = 9.81 \text{ m/s}^2$$

$$z_1 = 0.55 \text{ mm}$$

$$\rho = 1.09 \ g/m^3$$

$$V_2 = 15.66 \ [37]$$

$$G = 9.81 \text{ m/s}^2$$

$$z_2 = 0$$

$$101.325 \text{ kPa}/(1.09 \text{ g/m}^3) + 0^2/2 + 9.81 \text{ m/s}^2 \times 0.055 \text{ m} = P_2/(1.09 \text{ g/m}^3) + \{(15.66 \text{ m/s})\}^2/2 + 9.81 \text{ m/s}^2 \times 0$$

$$P_2 = 133 \text{ Pa}$$

Poiseuille's law for laminar flow (2)

$$P = F/(n \times \pi \times (D/2)^2)$$

$$F = P \times n \times \pi \times (D/2)^2$$

$$\pi = 3.14$$

$$P_2 = 133 \text{ Pa}$$

$$D = 0.255 \text{ mm}$$

$$n = 1 \; [34]$$

$$z_2 = 0$$

$$F = 6.66 \text{ N}$$

With a safety factor $S = 1.5$

$$F^*S = 6.6^*1.5 = 10 \text{ N}$$

Needle forces must be at least 10 N

Force provided by rubber bands (3)

$$F = k \times \Delta x$$

$$\Delta x = x_2 - x_1$$

$$k = 38.8 \text{ N/m}$$

Based on the results, we concluded that the net force that should be applied to the piston should be 10 N, as a consequence of the tensile forces exerted by the rubber bands. Since two rubber bands were used to this effect, we sought to calculate the load per rubber band and the distance between the corresponding connection points. This was done using the elastic potential energy formula.

$$2 \times F = 10 \text{ N}$$

$$F = 5 \text{ N}$$

$$5 \text{ N} = 38.8 \text{ N/m} \times \Delta x \rightarrow \Delta x \approx 0.13 \; m$$

The rubber bands were arranged in double layers. Moreover, the length loss at the connection points was considered.

Connection points: 2×0.008 m

$$0.065 \text{ m} - 0.008 \text{ m} = 0.057 \text{ m}$$

Considering these results, the distance between the connection points is 0.06 m.

Computer-aided analysis

In line with the calculated mathematical values, the parts that could experience strength issues were statically analyzed using NX Nastran. The mesh quality was calculated via the tunnel elastic and elasto-plastic deformation approach [38]. This study used the CTERA10 mesh type, with a standard element size of 1 mm. A maximum surface growth rate of 1.3 was selected, for a total of 1626 mesh elements across all components.

Analyzing the spring retention area: force = 10 N

Firstly, a static analysis of the spring retention area was performed. Since this area supports the rubber bands, its durability is very important. Considering the calculations presented in the previous section, when the system experiences 10 N of applied force, the maximum stress is 3.1 MPa. Since the strength of the material used in the design is 27.5 MPa [39], the spring retention area can withstand a force of 10 N. The analysis for this section is presented in Fig. 9.

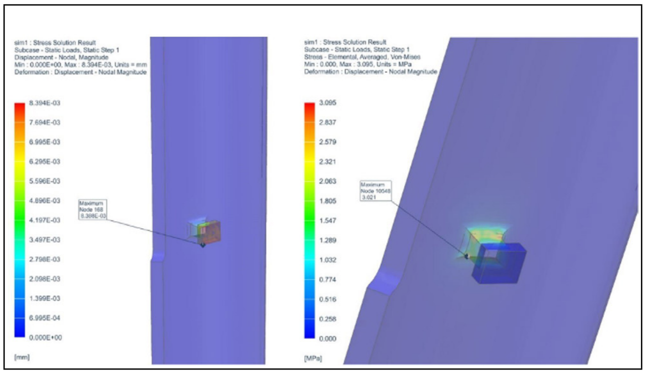

Figure 9. Static analysis of the spring retention area under a 10 N force
Source: Authors

Syringe retention (rib) area analysis: force = 10 N

Another area where the applied force is likely to have a negative effect on the product is the syringe retention (rib) area. As seen in Fig. 10, the 10 N deformation analysis yields a maximum value of 5.2 MPa. This is the maximum level of deformation that the material can withstand. It was determined that the rib region will not generate strength issues under the influence of a 10 N force, since the value obtained is below 27.5 MPa.

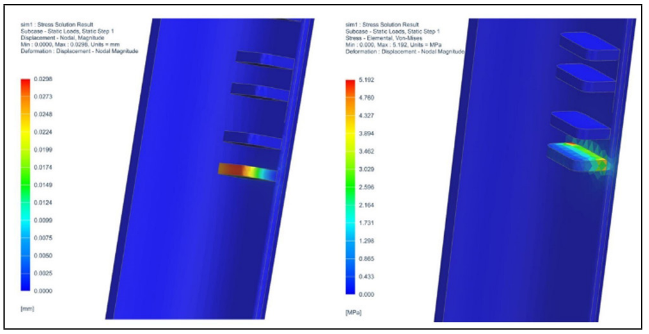

Figure 10. Static analysis of the syringe retention (rib) area under a 10 N force
Source: Authors

Syringe torsional analysis: torque = 50 Nm

When a torsional force of 50 Nm was applied to the model while considering the safety factor, the maximum stress level was 1.4 MPa (Fig. 11). Given the properties of the material used, the part will not undergo plastic deformation under 50 Nm of torsional force.

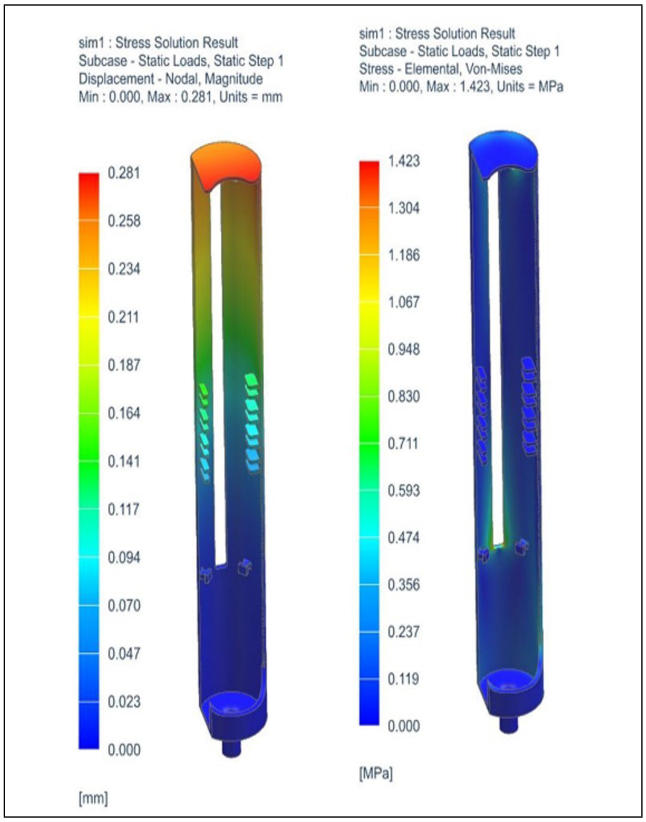

Figure 11. Static torsion analysis of the syringe under a 50 N torque
Source: Authors

Effect of rubber forces: force = 20 N

In order to determine the potential deformation effects arising from the tensile forces exerted by the rubber band, the analysis shown in Fig. 12 was conducted. According to the results, the model experiences 11.4 MPa under 20 N of tensile force. This value can be withstood by the material used.

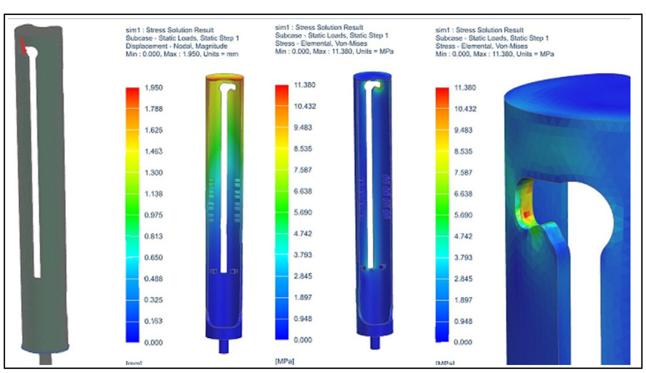

Figure 12. Static analysis of the effect of rubber forces (20 N)
Source: Authors

Moving parts analysis: force = 10 N

Finally, we analyzed the moving part, which was subjected to a maximum deformation of 10.3 MPa (under a 10 N force), as seen in Fig. 13. Considering the mechanical properties of the material used, this part remained within the elastic deformation zone and was an obstacle for the prototype.

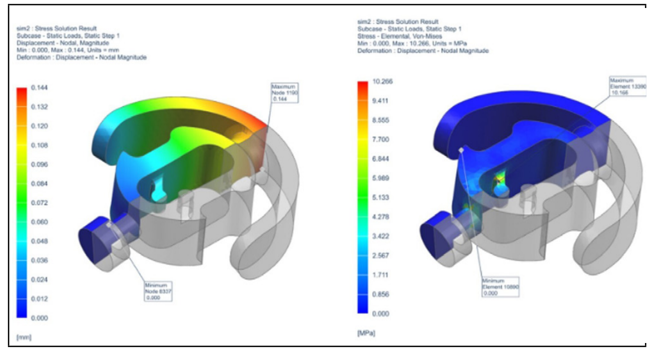

Figure 13. Static analysis of the moving part under a 10N force
Source: Authors

As a result of the solution suggestions and engineering calculations made in this research, a prototype of the design that is applicable in real life was produced. This prototype is presented in Figs. 14 and 15.

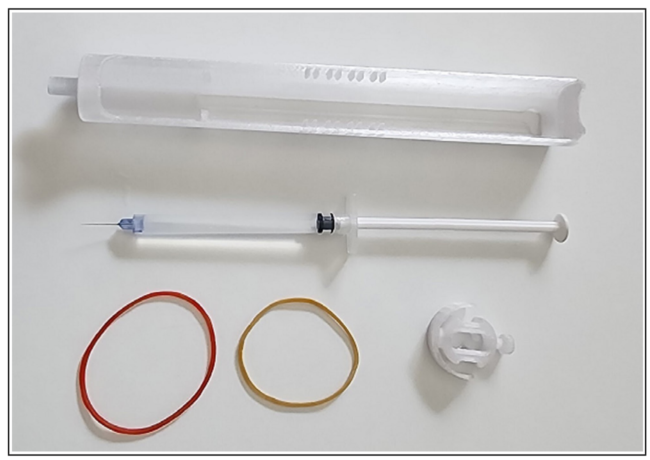

Figure 14. Unassembled prototype
Source: Authors

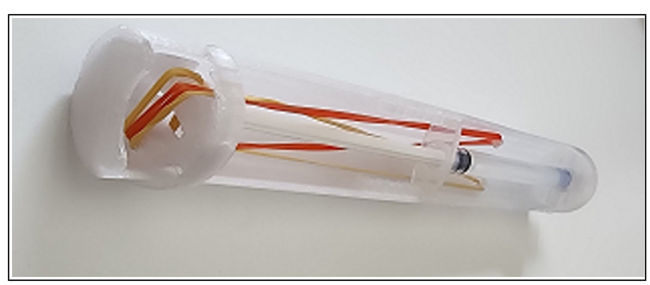

Figure 15. Assembled prototype
Source: Authors

Discussion

This research created an advanced auto-injection system by employing the TRIZ problem-solving methodology in conjunction with Ishikawa analysis to tackle issues related to usability, cost, assembly complexity, and hygiene. The proposed design incorporates polypropylene random copolymer (Bormed RG835MO), which not only offers cost efficiency but also promotes recyclability, distinguishing it from the conventional materials typically utilized in similar devices.

A key benefit of this design is its significantly reduced number of components, which simplifies the manufacturing process and facilitates both assembly and application. This improvement is akin to other developments that advocate for streamlined designs to minimize complexity and enhance user experience [40]. The substitution of flexible springs with rubber bands further contributes to the design's environmental sustainability and cost-effectiveness, as rubber bands are more accessible and affordable than other alternatives on the market.

The literature has discussed some of the frequent mistakes made when using auto-injectors. These mistakes include not applying pressure to the injection site, overlooking the expiration date, failing to check the medication window, and not rotating the injection site for a second injection [41]. In this work, static and dynamic analyses performed using NX Nastran confirmed that our reengineered auto-injection system maintains adequate structural integrity. The analysis of the spring retention area indicated that the design can endure a force of 10 N, with a maximum deformation of 3.1 MPa, which is significantly below the material's strength threshold of 27.5 MPa. Additionally, evaluations of the syringe's retention area and torsional properties demonstrated that the system can withstand applied forces without experiencing plastic deformation, corroborating the findings of related studies on the mechanical characteristics of injection systems.

The emphasis on recyclability and environmental considerations in the field of medical devices reflects a growing commitment to sustainability. Studies have emphasized the need to incorporate environmentally friendly materials into the design of medical devices to support public health and reduce ecological damage [10]. The substitution of rubber bands for conventional springs not only advances this sustainability objective but also lowers manufacturing costs, thereby enhancing accessibility for a broader patient demographic.

Throughout the evolution of engineering systems, the advantages of employing the TRIZ methodology in crafting innovative solutions that simultaneously tackle various design challenges has become evident [16]. The methodical implementation of TRIZ principles in this work led to a design that fulfills functional specifications while also improving user convenience and promoting environmental sustainability.

Studies examining the use of various drugs have shown that autoinjectors facilitate faster injection times and minimal tissue effects, especially when dealing with higher-viscosity formulations [42].

It has been observed that the triggering of autoinjectors varies in terms of comfort and maximum force depending on the age and dexterity of the user. In addition, the applied forces are affected by the geometry of the device, as well as by the way it is held [43]. However, difficulties such as limited dexterity and anxiety related to injection may hinder an adequate application [44]. In this regard, it should be noted that this study did not test the system in groups of subjects in different age ranges.

Autoinjectors play an important role in the self-administration of drugs. However, the EU's understanding of a specific medical device development tool (MDDT) may cause inconsistencies regarding quality and regulatory compliance. Therefore, it is essential to conduct studies aimed at ensuring compliance with the standards set within this framework [45], [46].

Studies have shown that integrating sustainability into medical device development results in various useful approaches to evaluate sustainability criteria. These approaches help to evaluate design concepts and improve the overall design [47]. Various sustainability problems have been partially solved in this study.

The concept of *quality* should be understood in a broad context that includes factors such as material purity, biocompatibility, device reliability, recall rates, and acceptability for patients. Social, demographic, and economic factors also play an important role in determining the sustainability of medical devices. Careful selection, use, and waste management positively affect sustainability when environmental impacts are considered throughout the lifecycle of the device, which includes design, production, clinical application, and final disposal [12]. Studying the use of environmentally recyclable materials and the sustainability of waste management will contribute to addressing product development issues in the medical sector.

Despite the fact that the design was developed through the TRIZ methodology with a focus on customer requirements, concerns regarding the durability and long-term usability of our proposal may arise. From this viewpoint, the use of rubber bands could lead to a decline in functionality over time, necessitating user replacement. Additionally, the predominance of plastic in the structure increases the risk of breakage or deformation under unforeseen circumstances, such as impacts from falls or excessive weight. Future research aimed at establishing the minimum lifespan of the device through durability, storage conditions, and usage assessments will significantly contribute to advancements in the medical field. Furthermore, investigating the target demographic in relation to user experiences and preferences as well as market performance could provide valuable insights.

The results suggest that integrating the TRIZ and Ishikawa methodologies can substantially enhance both the design and operational efficacy of medical devices. Future works should focus on assessing the long-term performance and user satisfaction associated with our revamped auto-injection system within clinical environments. Furthermore, applying these approaches to various medical device categories may result in widespread advancements throughout the healthcare sector.

Conclusion

This article provides a comprehensive investigation aimed at enhancing user experience in a cost-effective and practical way through two prominent methodologies: TRIZ and Ishikawa analysis. By leveraging these methodologies, our research established a robust framework for identifying specific improvement areas. In summary, after identifying the issues associated with using auto-injectors in the medical field through Ishikawa analysis, the TRIZ approach was employed to develop a matrix that served as a strategic problem-solving instrument.

The design process, guided by TRIZ to tackle the aforementioned issues, was marked by iterative improvements that incorporated feedback and insights from initial analyses. Rubber bands were selected as an alternative to metal springs, promoting both environmental sustainability and cost-efficiency, while thermoplastic materials were utilized for the main body of the device. To assess the practicality and reliability of the proposed design, static analyses were conducted through a series of engineering calculations. Both the static and dynamic analyses, which employed using NX Nastran, confirmed that the design maintains a sufficient structural integrity, with its spring retention area, syringe retention area, and torsional properties validating the system's capacity to endure applied forces without experiencing plastic deformation. Engineering validations through static and dynamic simulations showed that the design safely withstands up to 10 N of applied force, with the maximum stress levels remaining below 5.2 MPa, well within the material's 27.5 MPa yield strength. This provided essential insights into the structural integrity and operational capabilities of the proposed product, thereby affirming its viability for practical application.

The emphasis on utilizing recyclable materials highlights an increasing commitment to sustainability within the medical device sector. This design approach is in harmony with contemporary healthcare objectives, as it seeks to reduce both environmental impact and production expenses. The implementation of the TRIZ methodology played a crucial role in fostering innovative solutions that tackled various design obstacles, thereby improving functional attributes and user comfort. Additionally, it streamlined the assembly process by reducing the number of components involved, leading to enhancements in both cost efficiency and usability.

Nevertheless, some concerns persist regarding the system's durability, long-term usability, and overall lifespan. Although the economic benefits are clear, the dependence on rubber bands necessitates frequent replacements, and the extensive use of plastic materials raises the potential for breakage or deformation under unforeseen circumstances. Future investigations should aim to establish the minimum lifespan of the device through rigorous durability testing, as well as to analyze user experiences and preferences to further optimize the design.

The proposed design offers notable enhancements in terms of user experience, sustainability, and cost-effectiveness, but it also has significant limitations. As mentioned above, the reliance on rubber bands, while economical and environmentally friendly, raises durability issues due to the need for frequent replacements. Additionally, the extensive use of thermoplastic materials, beneficial for manufacturing and recyclability, may lead to breakage or deformation under unexpected stress. Although static and dynamic analyses confirm structural integrity, these tests were conducted under controlled conditions, and real-world performance may involve unforeseen variables. Moreover, the long-term usability and lifespan of the device are still unverified, necessitating further durability assessments and user feedback in order to ensure reliability and practicality. These limitations underscore the need for continued research to enhance the design and evaluate its long-term effectiveness in diverse healthcare settings.

Future research should concentrate on assessing the long-term efficacy of the redesigned automated injection system in clinical environments, in addition to considering the application of these methodologies across a wider array of medical devices, facilitating substantial progress within the healthcare field. The results indicate that, by prioritizing user-centered solutions and employing systematic problem-solving techniques, effective treatment instruments can be developed which significantly enhance patient outcomes and satisfaction.

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CRediT author statement

The author handled the entire conceptualization process, from idea generation and research to workflow formulation and assessment. He also designed the component, wrote the manuscript, and conducted structural analyses, calculations, and prototype development.

Conflicts of interest

The author has no conflicts of interest to declare.

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