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RESEARCH AND DEVELOPMENT OF A LOW–COST PROTOTYPE MEDICAL DELIVERY DEVICE: A CASE STUDY ON THE INSULIN PEN

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Abstract: This study explores the evolution, design considerations, and challenges associated with insulin delivery devices, with a particular focus on the development of a prototype insulin pen to address existing limitations. Material selection, including considerations such as durability, friction properties, and compatibility with insulin formulations, is crucial in insulin pen design. Common materials such as medical–grade plastics, metals, and glass are discussed, along with design considerations aimed at enhancing user–friendliness and safety. Key components of insulin pens, including the button, plunger, needle, and cap, are examined in detail, highlighting their roles in accurate insulin dosage and patient safety. Despite technological advancements, challenges such as user interface complexity, needle–related injuries, and cost constraints persist. Future directions in insulin delivery device development, including the integration of emerging technologies and innovations, are also discussed. By addressing these challenges and leveraging advancements in material science and design optimization, we can further enhance the efficiency and usability of insulin delivery devices, ultimately improving diabetes management outcomes and patient quality of life.

Keywords: insulin delivery, prototype, medical device, ergonomics, dose accuracy, usability testing

INTRODUCTION

In the realm of medical devices, the evolution of insulin delivery systems stands as a testament to relentless innovation in addressing the complex needs of individuals managing diabetes (Gillian and McCarthy, 2017; Garg and McVean, 2024). Since the groundbreaking discovery of insulin in 1920, the landscape of insulin administration has undergone remarkable advancements, aiming to optimize blood sugar regulation and mitigate the risk of associated health complications (Kesavadev et al., 2020). From humble beginnings marked by basic vial and syringe setups to the contemporary era characterized by disposable pens and sophisticated closed–loop systems, the trajectory of insulin delivery devices reflects a convergence of patient–centric design, technological prowess, and safety imperatives (Rima and Shah, 2016; Krishna, 2020; Harper et al., 2021). Notably, the integration of ergonomic principles has played a pivotal role in refining these devices, fostering user–friendliness and accessibility, particularly for individuals with impairments (Gillian and McCarthy, 2017; Kar et al., 2022).

Among these innovations, insulin pens have emerged as a cornerstone in the management of both type 1 and type 2 diabetes mellitus (T1DM and T2DM), revolutionizing insulin therapy with their simplicity and convenience (Hyllested–Winge, 2016; Lilly et al., 2019; Masierek et al., 2022). Yet, amidst the remarkable progress, persistent challenges loom, spanning from user interface complexities to needle–related injuries, portability constraints, and cost considerations (Rini et al., 2019; Krishna, 2020). It is within this context that this study embarks on the design journey of a prototype insulin pen, with a focused mission to confront these challenges head–on and elevate device efficiency to new heights. Through a comprehensive examination of user needs, technological capabilities, and safety imperatives, this case study endeavors to contribute to the ongoing evolution of medical delivery devices, with insulin pens serving as a compelling focal point for innovation and advancement

MATERIALS AND METHODS

Material selection for insulin pen design is critical, with considerations such as durability, friction properties, and compatibility with insulin. Common materials include plastics like Delrin and Zytel nylon resin, known for their strength and low friction, as well as metals like stainless steel for components requiring durability and corrosion resistance (Schneider and Lange, 2018; Watterson et al., 2022). Glass is often used for insulin cartridges due to its inert properties, ensuring compatibility with insulin formulations (Economidou et al., 2021). Bio–compatible coatings may be applied to ensure safety during contact with insulin and the patient's skin. Various components, such as the button, ratchet rotor, and plunger, play crucial roles in insulin pen functionality and are designed with user–friendliness and durability in mind.

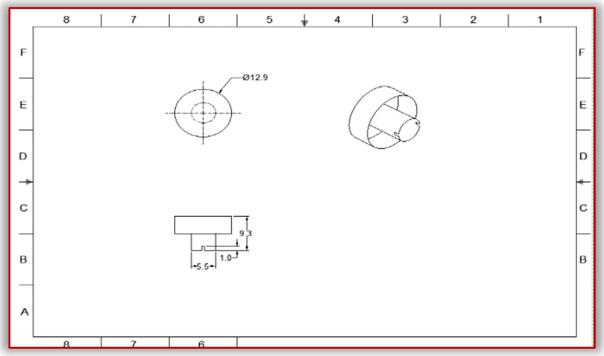

Figure 1: Insulin pen button

The specific material used for the button on an insulin pen can vary depending on the design (Harper et al., 2021). Commonly, the pen button (figure 1), are constructed from medical–grade plastics that are safe for use in healthcare settings. These materials combination is chosen for their ability to withstand the mechanical requirements of the device, resist wear and tear, and maintain the sterility required for medical devices

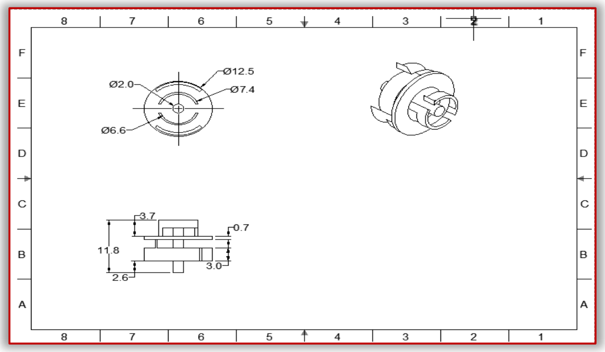

Figure 2: Ratchet Rotor

Hence, ratchet rotor (figure 2) is an important component of the insulin pen. The function of the ratchet rotor is that it serves as the control for the dose of the insulin. It may also serve has the lock for the button, the lock prevents accidentally dosing.

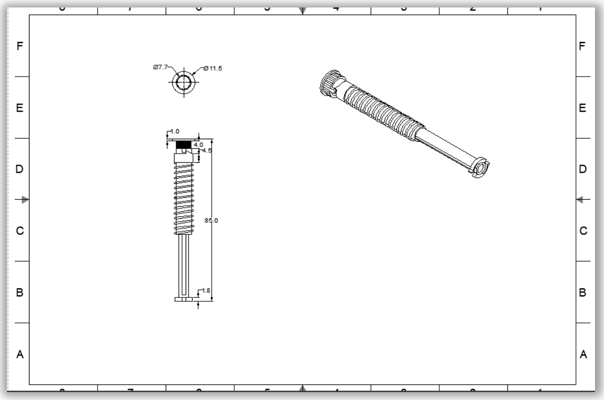

Figure 3: Control cylinder of an insulin pen

However, control cylinder (figure 3) of an insulin pen functions as the dose control mechanism. The dosing mechanism is a critical part responsible for accurately setting and delivering the prescribed dose of insulin. Control cylinder is part of this mechanism, the role of the control cylinder is regulating and controlling the movement of internal components to ensure precise insulin dosage.

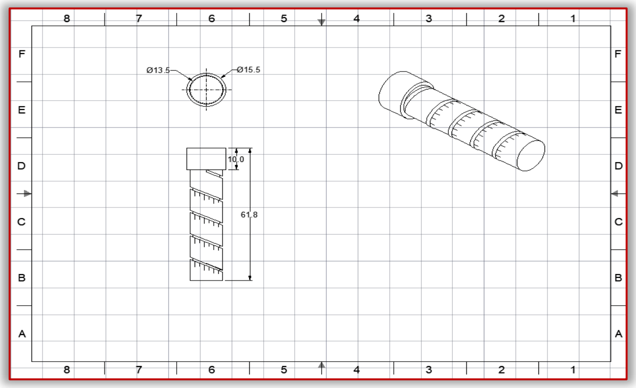

Figure 4: Plunger of the insulin pen.

Furthermore, insulin pen's plunger (Figure 4) is also an important component for precise insulin delivery. The plunger is within the pen barrel or cartridge. The plunger functions as a piston. During the injection process, the desired insulin dose is set and the injection button is pressed, the plunger moves within the cartridge, displacing insulin to ensure accurate administration. The plunger is designed to maintain the insulin pen's integrity, preventing leaks, and ensuring a smooth injection experience. The insulin pen's plunger works with the dosing mechanism. The reliable performance of the plunger is essential for individuals with diabetes in achieving accurate and effective self–administration of insulin (Paun et al., 2019)

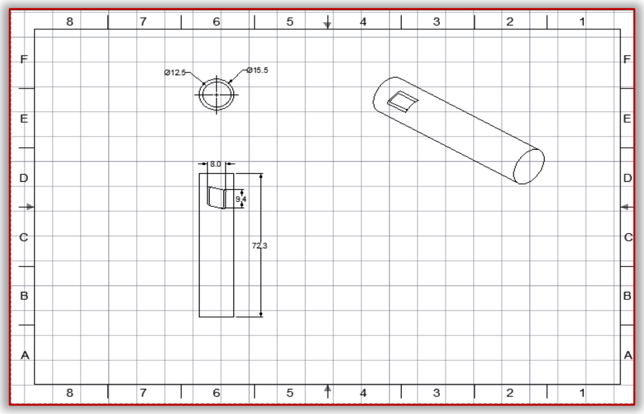

Figure 5: Cover of the insulin pen

Similarly, the covering of an insulin pen (figure 5) refers to the external casing or housing that encases the internal components of the pen. This covering is a crucial aspect of the pen's design, providing protection, durability, and often ergonomic features for ease of use. The covering is typically made from medical–grade plastics or other materials that meet safety and hygiene standards. These materials ensure the pen's integrity, durability, and compatibility with medical use. The covering serves as a protective layer, safeguarding the insulin cartridge, dosing mechanism, and other internal components from external elements, contamination, and damage. It helps maintain the sterility of the insulin delivery system. The shape, size, and texture are often optimized for easy handling, allowing individuals with diabetes to comfortably grip and manipulate the pen during dose selection and administration. The covering of an insulin pen plays a crucial role in ensuring the functionality, safety, and user–friendliness of the device. It reflects the careful consideration given to both the practical and aesthetic aspects of insulin pen design to meet the needs of individuals managing diabetes.

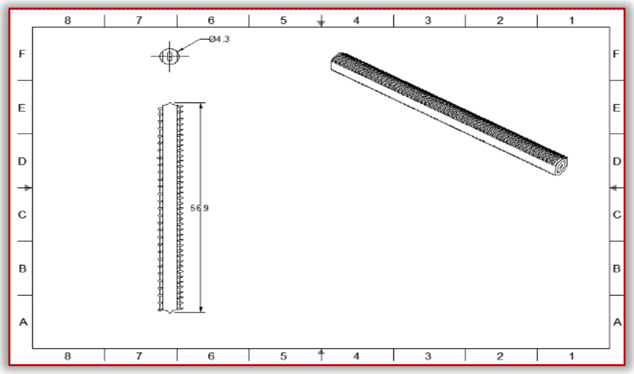

Figure 6: Jack screw of the insulin pen

In insulin pens, the dosing mechanism is crucial for accurately selecting and delivering the prescribed dose of insulin. It often involves components such as a dose dial, gears, and possibly a ratchet system. The jack screw (figure 6) is part of this mechanism, and it plays an important role in facilitating the controlled movement of internal components to ensure precision in setting and administering insulin doses. The major function of the pawl in an insulin (figure 7) is to lock and hold the container and the cartridge of the insulin pen for smooth delivery of the insulin into the body.

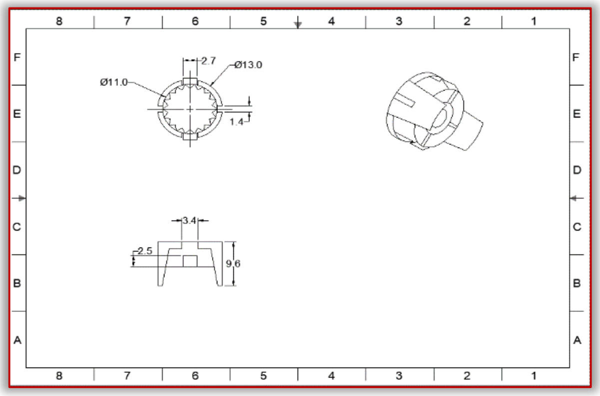

Figure 7: Pawl of the insulin pen.

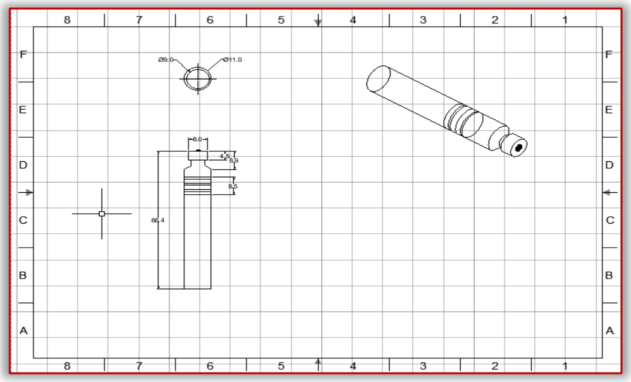

Figure 8: Container of the insulin pen

The container and the cartridge of an insulin pen (figure 8) refers to the external casing or housing that encases the internal components of the pen. This cartridge is a crucial aspect of the pen's design, providing protection, durability, and often ergonomic features for ease of use. The container is typically made from medical–grade plastics or other materials that meet safety and hygiene standards. These materials ensure the pen's integrity, durability, and compatibility with medical use. The container serves as a protective layer, safeguarding the insulin cartridge, dosing mechanism, and other internal components from external elements, contamination, and damage. It helps maintain the sterility of the insulin delivery system. The shape, size, and texture are often optimized for easy handling, allowing individuals with diabetes to comfortably grip and manipulate the pen during dose selection and administration.

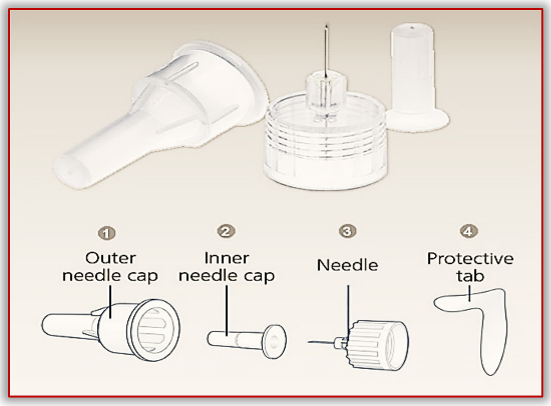

Figure 9: Needle of the insulin pen.

Moreso, the needle of an insulin pen (figure 9) is also a crucial component responsible for delivering insulin subcutaneously. Insulin pen needles are typically made of high–quality, medical–grade stainless steel. This material ensures strength, sharpness, and bio–compatibility, meeting the necessary safety standards for medical devices. Insulin pen needles come in various sizes, including different lengths and gauges (thickness). The choice of needle size depends on factors such as individual patient needs, insulin type, and injection technique (Rini et al., 2019; Economidou et al., 2021). The tip of the needle can have different designs, such as beveled or straight. Beveled tips are common and allow for a smoother entry into the skin, reducing discomfort during injections. While many insulin pen needles are designed to be universally compatible with various insulin pens, users should verify compatibility with their specific pen model to ensure proper functioning. Some insulin pen needles incorporate technologies aimed at reducing pain during injections, such as ultra–thin needles or features to minimize skin trauma. Proper needle selection and technique are essential for successful and comfortable insulin administration. Users should follow the guidance provided by healthcare professionals and the manufacturer's instructions for their specific insulin pen and needle (Sparre et al., 2022).

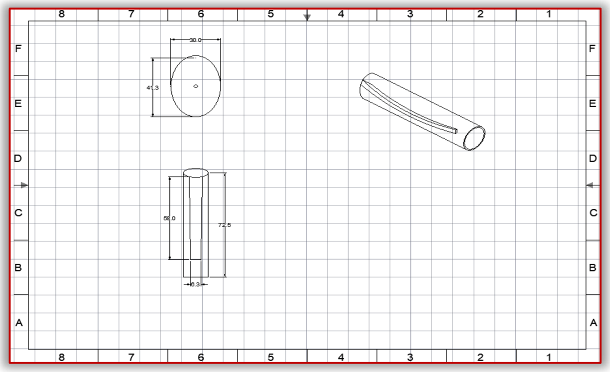

Figure 10: Cap of the insulin pen

The cap of an insulin pen (figure 10) is a protective covering for the needle, ensuring its sterility and preventing accidental needle pricks before use. The primary function of the cap is to safeguard the needle from contamination and maintain its sterility (Pillalamarri et al., 2018). It serves as a barrier that shields the needle from external elements, ensuring a clean and safe injection. Insulin pen needle caps are typically made of medical–grade plastic. This material is selected for its durability, lightweight nature, and compatibility with healthcare standards. Like the needle, the cap is designed for single–use only. After the cap is removed for an injection, it should not be reapplied, and it is discarded along with the used needle in an appropriate container. In addition to protecting the needle, some insulin pen needle caps may have additional safety features, such as tamper–evident seals or locking mechanisms, to enhance user safety. The cap of the insulin pen plays a crucial role in maintaining the integrity of the needle and ensuring a hygienic injection process. Users should always follow proper procedures for removing and disposing of the cap as part of their insulin administration routine (Pillalamarri et al., 2018; Sparre et al., 2022).

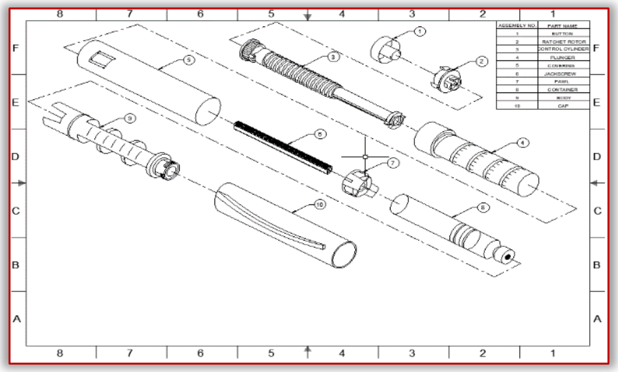

Figure 11: Components diagram of insulin pen

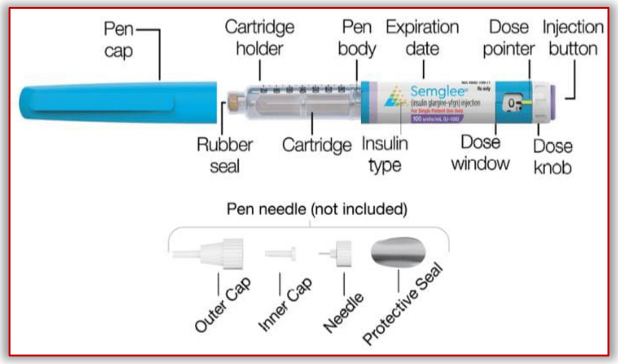

Figure 12: Coupled diagram of insulin pen

RESULT AND DISCUSSION

Figure 12 shows clearly delineates each component of the insulin pen, including the pen body, cartridge, needle, needle cap, dose dial, and dose display window. This clarity ensures that users can easily identify and understand the function of each part of the device. The diagram (figure 12) illustrates the sequential process of assembling the insulin pen, starting with the insertion of the cartridge into the pen body, followed by the attachment of the needle. The dose dial is then used to set the desired insulin dose, and the dose button is pressed to release the insulin. This step–by–step depiction helps users understand the proper assembly procedure and ensures accurate dosing.

Figure 12 further illustrates the mechanical interactions between the components of the insulin pen, such as how turning the dose dial adjusts the insulin dose and how pressing the dose button releases the insulin. These mechanical features are essential for facilitating the precise delivery of insulin and ensuring user confidence in the device's functionality. Safety features, such as the needle cap, are clearly depicted in the assembly diagram. The needle cap serves to protect the needle when not in use, reducing the risk of accidental needlesticks and enhancing user safety. Additionally, the diagram may include features for preventing the reuse of needles, further reducing the risk of contamination.

The design of the insulin pen components reflects high–quality materials and construction, ensuring durability and reliability (figure 11). Components such as the pen body and cartridge are constructed from sturdy materials that can withstand repeated use, while the needle is designed for smooth insertion and minimal discomfort. These quality considerations contribute to the overall reliability and longevity of the insulin pen. Similarly, the ergonomic design of the insulin pen is evident in the assembly diagram, with features such as a comfortable grip and intuitive controls. The pen body is designed to fit comfortably in the user's hand, facilitating easy manipulation of the dose dial and dose button. These ergonomic considerations enhance the overall user experience, making the insulin pen accessible and user–friendly for individuals managing diabetes.

Testing insulin pen effectiveness involves assessing dose accuracy, usability, safety features, durability, and regulatory compliance (Sharp and Ives, 2021). Tests include laboratory studies, clinical trials, human factors testing, and post–market surveillance to ensure safe and accurate insulin delivery (Krishna, 2020; Payne et al., 2021). Dose accuracy testing involves evaluating the pen's ability to deliver precise doses across different volumes, considering factors like temperature variations and injection speed.

The equation for dose accuracy is often expressed as a percentage of the intended dose.

$$\text{Dose Accuracy} = \frac{\text{DELIVERED DOSE}}{\text{INTENDED DOSE}} \times 100 \qquad (1)$$

In the above equation the following value to calculate dose accuracy. Dose Accuracy (%): The percentage of the intended dose that is actually delivered. Delivered Dose: The actual amount of insulin delivered by the pen, measured in units or another appropriate unit of measurement. The prescribed or set dose that the user intended to administer, also measured in units or the relevant unit of measurement. This equation gives a percentage that represents how close the delivered dose is to the intended dose. Ideally, the dose accuracy should be as close to 100% as possible, indicating that the delivered dose matches the intended dose precisely. Statistical analyses help interpret results and ensure compliance with regulatory standards. Incorporating healthcare professionals and end–users in the testing process is essential for gathering comprehensive feedback and addressing real–world challenges (Rima and Shah, 2016; Kesavadev et al., 2020).

Despite technological progress, challenges persist in insulin delivery devices. These include issues such as user interface complexity, needle–related injuries, portability concerns, and cost constraints. Addressing these challenges is crucial to further enhance the efficiency and usability of insulin delivery devices, ultimately improving diabetes management outcomes (Watterson et al., 2022).

Material selection is a critical aspect of insulin pen design, with considerations such as durability, friction properties, and compatibility with insulin formulations. Common materials used include medical–grade plastics, metals like stainless steel, and glass for insulin cartridges (Gillian and McCarthy, 2017.; Watterson et al., 2022). Bio–compatible coatings are applied to ensure safety during contact with insulin and the patient's skin. Design considerations focus on user–friendliness, durability, and compatibility with medical standards (Kyfonidis and Lennon, 2019). Insulin pens consist of various components, each playing a crucial role in insulin administration. These include the button, ratchet rotor, control cylinder, plunger, covering, jack screw, pawl, cartridge, needle, and cap. Each component is designed with precision and safety in mind, ensuring accurate insulin dosage, sterility, and protection against contamination and needle–related injuries.

Looking ahead, future directions in insulin delivery device development may involve the integration of emerging technologies and innovations. This could include advancements in smart insulin pens with digital connectivity for enhanced monitoring and dosage tracking. Additionally, further research into materials and design optimization could lead to even more user–friendly and efficient insulin delivery devices, ultimately improving diabetes management outcomes and patient quality of life.

CONCLUSIONS

The study highlights the continuous evolution and design considerations of insulin delivery devices, with a focus on developing a prototype insulin pen to address existing challenges. By understanding the historical progression, current challenges, and future directions in insulin delivery device development, we can work towards improving diabetes management outcomes and enhancing the quality of life for individuals with diabetes.

The assembly diagram of the insulin pen reflects a well–engineered design that prioritizes user safety, ease of use, and manufacture–ability. By integrating ergonomic principles, mechanical precision, and clear user instructions, the insulin pen offers a reliable and user–friendly solution for individuals managing diabetes, contributing to improved health outcomes and quality of life. The designing and prototyping insulin delivery devices are crucial for improving healthcare efficiency and patient outcomes. Interdisciplinary collaboration, incorporating feedback loops, and leveraging emerging technologies are recommended for optimizing device design and functionality. Regular usability testing and validation with healthcare practitioners ensure that devices meet user needs and integrate seamlessly into healthcare workflows. By prioritizing these strategies, we can continue advancing medical device innovation and enhancing the quality of diabetes care.

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