Redesign and Accuracy Improvement of Disposable Infusion Pumps

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Abstract: Nowadays, disposable injection pumps are widely used in hospitals and home care settings to provide various therapies such as chemotherapy, antimicrobial, analgesic, and anesthetic treatments, as well as for postoperative pain control and chronic pain control. Since the accuracy of the injection is very important in infusion pumps based on the flow rate, it is therefore important to reduce the error in this device. In this study, the basic design principles of these pumps and the design problems of the sample appearance available in the market were investigated. Since one of the vital problems of this type of pump is their inaccuracy, because they are unable to inject a certain amount of drug for a certain period of time, so one of the main objectives of this study is to improve the accuracy of the injection. Also, as this device is available to the patient for a long time at the time of injection, ease of use is one of the design goals. Finally, this paper ends with a design and prototype which is better in the shape of the device and a big improvement in the accuracy.

Keywords: Accuracy Improvement, Disposable Infusion Pump, Redesign

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1 INTRODUCTION

The idea of injecting fluids directly into an animal's circulatory system dates back to at least the 16th century. Sir Christopher Wren performed several experiments using a goose pen to inject fluid into a dog's forearm and observed the effects of the material on it. The effects were quite systemic, including intoxication as a result of wine consumption. Over the centuries, the combination of medical experiments and technological advances has expanded the acceptability and appropriateness of injectable therapies, and this trend continues today. The medical and technological community in this field of medicine now includes physicians, nurses, pharmacists, manufacturers, and millions of patients whose lives have been sustained or improved through injectable therapy [1]. The main purpose of injectable therapy is to insert fluid into the circulatory system to achieve an optimal physiological response in the patient. Fluids are generally classified as: 1) drugs, 2) alternative fluids, 3) nutritional compounds, 4) blood substitutes, plasma, or plasma subunits. The wide range of liquids requires specific device characteristics with a specified flow and volume. The device flow range, tank size, and pumping mechanisms, which are chemically and physically compatible with the available fluids that must be considered in each design [1]. Before the 1980s, patients were often hospitalized for treatment of diseases not responding to oral medications. Since then, the increasing use of ambulatory infusion pumps has made it possible to treat patients with intravenous injections in alternative settings, including in-home settings. Research shows that the use of ambulatory infusion pumps is becoming commonplace, and with technology advances, it continues to grow at an annual rate of approximately 9% over the next five years [2]. Further advances only continued into the twentieth century, from simple infusion pumps to chemotherapy to computer pumps, and miniature pumps were on the agenda - increasing the use of these pumps in research. In the early 21st century, we observed the development of "smart pumps" that increased adaptability to research and safety targets for patients [3].
Designing for the safe use of medical device technology is a major concern for medical device manufacturers, human factors engineers, practitioners, and regulatory agencies [4]. Most of the time, the design activity views the artifact as an object, not as a hypothesis about how the object is understood and interacted [5]. As noted by Woods, the Human Factors Standard, which is based on time and resource constraints, explains the basic concepts of how a system supports manufacturers, through the results of testing the usability of certain features and options [5].
On the contrary, the engineering of cognitive systems that helps design is not about the artifact as an object, but about how the artifact is part of the distribution of the cognitive system and eventually becomes that system [6]. Technological artifacts influence the understanding of the concept and illustrate its use. For example, just by showing the current situation, some medical devices do not show what happened before and do not indicate what to expect in the future [7]. This defect in the development of representations, which reveals the change and highlight of events in the monitoring process, has caused significant disruptions to the work of experts in the field [8].
The infusion pump is one of the most precise medical devices whose safety is very important and care must be taken in its design. In disposable and portable infusion pumps, its design is important in terms of ease of transport, patient coverability for use in public places, and relative accuracy. In general, it can be said that the design of this device is related to the health of the patient and in the event of design errors, it can endanger patients' lives. For example, from 2005 to 2009, the US Food and Drug Administration (FDA) received approximately 56,000 reports of adverse effects from the use of infusion pumps, including numerous injuries and deaths [2]. In the UK, at least 700 insecure accidents are reported with infusion pumps annually [9].
Non-electronic disposable infusion pumps have been in use for medical use for more than 20 years. There is a wide range of disposable infusion pumps. Different types of pumps use different working principles and are made from a wide range of materials. These factors strongly influence the accuracy of the device and the range of drugs injected by a particular pump. With a wide range of disposable pumps, users may find it difficult to choose a suitable injection device that meets their clinical needs [10-13].
In this article, the common appearance of these pumps was investigated, and by performing tests, the accuracy of these pumps was obtained. When a doctor prescribes a drug and determines that the drug is injected evenly over a period of time, if there is non-uniformity and variable injection rate, it will cause problems and fail to achieve the desired goal in care. Due to the fact that this inaccuracy and non-uniformity has been tested and observed in conventional pumps on the market, the improvement of this parameter is very important, which has been studied in this article. In addition, design solutions have long been applied to the product to facilitate the use of this product. Finally, the pump has been designed with a better appearance and more accuracy. Test results showed an increase in injection accuracy.

2 WORKING PRINCIPLES OF DISPOSABLE INJECTION PUMPS

All non-electric disposable pumps benefit from the same physical principle: mechanical constraint on the flow path determines the fluid velocity under pressure.

Pressure on the fluid is supplied by various mechanisms using non-electric force, such as a stretched elastomer or a compressed spring, the pressure resulting from a chemical reaction [14], and the pressure from a pressurized gas cartridge [15]. The flow restriction in all disposable pumps is due to the narrow pipes. The diameter of the pipe has a decisive influence on the flow rate of the device.

The flow rate is primarily affected by the pressure gradient along with the flow limiter as well as the viscosity of the fluid. These factors may vary in medical collections, which significantly affect the accuracy and duration of therapeutic injections. The pressure gradient may be affected by factors such as (1) the vertical displacement of the device relative to the injection site (back pressure) [10], (2) the initial volume of filling (shortage or addition of nominal volume) [16], (3) Storage conditions (e.g., refrigeration and freezing) [10], [16] and (4) atmospheric pressure changes [16-18]. Fluid viscosity is strongly influenced by temperature and is somewhat affected by drug concentration.

3 STUDYING PUMP

Non-electric Disposable infusion pumps are divided into five groups: (1) continuous injections of painkillers to treat postoperative pain [19-22], (2) patient-controlled painkillers [20], [23-26], (3) injections of chemotherapy drugs [27-30], (4) antimicrobial injections at home [16], (5) pediatric treatment programs [20], [31]. In this paper, the pumps of the first group were examined. This study was performed for appearance (ergonomics, ease of use under clothing) and from the perspective of injection accuracy.

Table 1 ergonomic and ease of use problems

No.	Description
1	Lack of hand-held space for easier carrying
2	Inadequate form for a place in clothing and use in public places
3	Fittings and pipes are cumbersome and long
4	Unattractive form for use in children's treatment programs

Specifically, in this study a disposable multi-rate infusion pump (type: SZB-CZ, Fert Medical co.) has been used. There were problems with ergonomic and ease of use of this type of pump, which is shown in “Table 1”. Then, the injection accuracy of this type of pump was tested. The appearance problems of the existing samples are presented in “Table 1”. Error percentage was too high in these types of pumps. In this study, an attempt was made to reduce the injection error rate.

4 APPEARANCE DESIGN

Medical equipment is mainly divided into four main categories: health monitoring equipment, wearable external medical equipment, internal medical equipment, and fixed medical equipment located in the network. This equipment has provided many benefits to the people and the community, including improving the quality of life, empowering patients and reducing staggering medical costs, and bringing patients closer to their goal of improving health and quality of life. Wearable equipment or in general, mobile patient equipment has several main uses:

1-Diagnosis: Remote monitoring of vital signs, sleep monitoring, neurological monitoring
2-Health: Fitness Management, Preventive Care, Elderly Care
3-Treatment: pain management, drug injection

All of these technologies and products are good, but if they are not applied to the design, thinking, feeling, and behavior of users, they will lose their importance and will not be able to communicate well with the user, they may also be considered unpleasant by the user. But designing a desirable wearable medical device, taking into account the needs of the user, should, first of all, be ergonomically well-suited to the user's body, as well as the visual interaction between the product and the user; for example, the location of the displays, the color, and overall form of the product must be in full interaction with the user.

Ergonomics should be considered when designing therapeutic wearable devices. Firstly, it should be noted that with the movement of the body throughout the day, the shape and shape of the body are constantly changing and never static, which is the most important challenge in the design of these devices. The size and dimensions are two issues that should be taken into account. First, because they can be constantly with the person, they should not occupy much space and should not disrupt the patient's daily routine. Secondly, it should be anthropometrically capable of covering from 5th to 95th percentile and usable.

Other issues to consider are the day-to-day activities of a person who may need to shower or sweat, indicating that they have to be waterproof. Each of the injection locations on the body has a unique topological surface that determines the shape and form of wearable products.

These types of pumps usually inject the drugs into upper arms so it should be considered that the product should fit on the hand. Due to the above information and non-static nature of people's bodies during the day, the designed product has become a wearable product from the carrying case inside the pocket or bag, which has made it possible to always be with the patient without any disturbance and no extra object outside the patient's body will interfere with his or her daily activities. Based on the anthropometric data in “Table 2” and according to the principles of ergonomics in product design, which aims to include the maximum number of people in the use of products, we have 95 percent of men to place the product on the arm and also 5 percent of women has been used for product dimensions.

Table 2 Anthropometric table [32]

	5th percentile (women)	95th percentile (men)
Arm height (elbow to shoulder distance)	26.4 cm	34.8 cm
Arm circumference	21.3 cm	39.7 cm

Fig. 1 Display of prototype made.

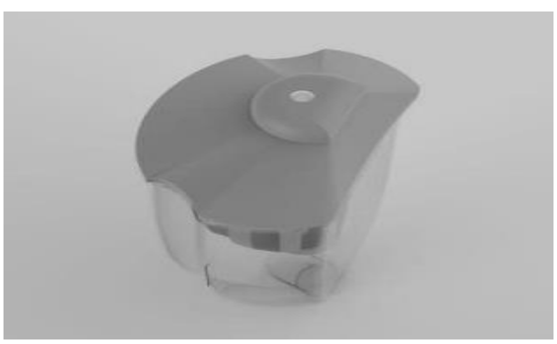

Fig. 2 Display of the designed product from the above view to show the handheld place and carve that makes it comfortable to fit on the hand.

So the product form is also designed to fit comfortably on the arm and the user will not feel uncomfortable. The shape and form of the product were designed to cover all the problems in the existing sample. As shown in “Figs. 1 and 2”, the designed product is wearable, easy to carry, with shorter tubes, and attractive for use in children's treatment programs.

5 ACCURACY IMPROVEMENT

The accuracy of the pumps available in the market makes it impossible to obtain many of the common treatment programs of these pumps. So, the existing sample has been tested and tried to improve the mechanism and accuracy of these pumps, which finally got more improvements in design and accuracy in the prototype version. The reservoir of the existing sample is such that as it fills, it has both an increase in longitudinal volume and an increase in transverse volume. It has been shown in “Fig 3”.

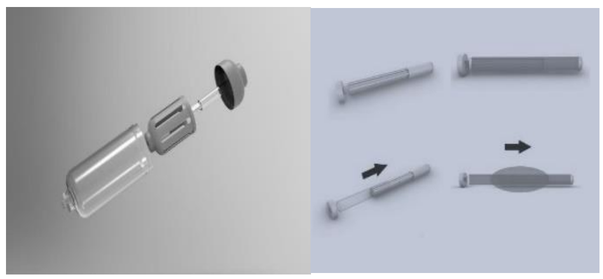

Fig. 3 Schematic view of the existing sample and how the reservoir is filled.

The test descriptions of the available sample are as follows. The test has begun in flow-rate 8 ml/h. This test has four parts, each of these four parts is a quarter of infusion time. the accuracy of infusion in each of these quarters was meant to test. To do that, four gradient containers have been provided to measure the volume of infusion in each quarter. The exact time of each quarter depends on the flow rate and the reservoir volume. In flow-rate 8 ml/h, the time of infusion in each part is exactly 187 minutes and 30 seconds. 100 ml of distilled water has been injected in the reservoir of the pump. The test was supposed to be completed in 12.5 hours. But it completed one hour and seven minutes and ten seconds earlier. The results of the test are available in “Table 3”.
Epoxy wood-glass resin has been used to make the prototype body. First, a solid MDF model was made, which was finally molded with silicone. Molds were used to make the body. For designing the injection mechanism, the injection mechanism in the original sample has been changed several times and tests were executed. finally, a mechanism that showed a small error in the tests was found. The mechanism found is shown in “Fig. 4”.

Table 3 The results of the test for studying pump

	First part	Second part	Third part	Fourth part
Estimated infusion volume(ml)	25	25	25	25
Actual infusion volume(ml)	29.6	24.6	26.2	11.6
Error percentage (%)	18.4	1.6	4.8	53.6

The test descriptions of the prototype are as follows. This test had four parts as the first test. Each of the four parts of the test is a quarter of infusion time. The accuracy of the infusion of the designed pump in each of these quarters was meant to test. The results of the test are available in “Table 4”. The time of infusion was in perfect status.

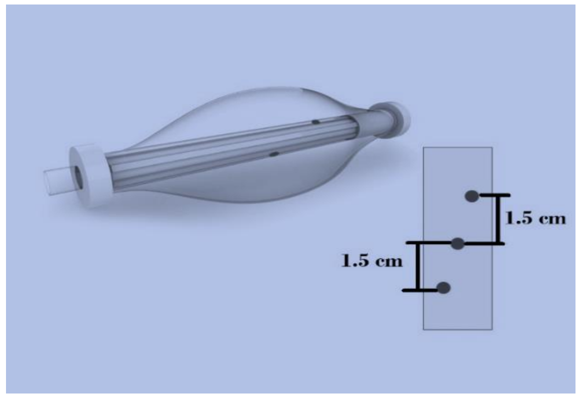

Fig. 4 Designed mechanism with small error.

Table 4 The results of the test for designed pump

	The first part (187 minutes and 30 seconds)	The second part (187 minutes and 30 seconds)	The third part (187 minutes and 30 seconds)	The fourth part (187 minutes and 30 seconds)
Estimated infusion volume(ml)	25	25	25	25
Actual infusion volume(ml)	22	25	25	20
Error percentage(%)	12	0	0	20

6 CONCLUSION

Elastomeric disposable injection pumps are one of the most common pumps in various treatment programs. The working principles of these pumps have been researched and tested over the years, and today they have reached high standards. On the other hand, in these pumps, due to the low price and simple working mechanism, the basic design of the appearance of these pumps has not been considered. In the existing sample of these pumps, problems like unattractive form and hardness of use were considered. Additionally, the infusion rate was not so accursed. In the designed form, it was tried to obtain ergonomics, ease of use, and better and more compatible interaction with the user than the previous example. By examining and making many samples and performing several tests, the accuracy of these pumps in the prototype was significantly improved. Therefore, these pumps can be used in more accurate treatment programs and reduce the cost of treatment for patients.

REFERENCES

[1] Livingston, H., Frye, K., Field, F., MiniMed Inc., Sylmar, CA, Proctective case for a Medication Infusion Pump, 1994.

[2] Global Home Infusion Therapy Market Will Reach a Valuation of US$27 billion by 2020: Persistence Market Research [news release], New York, NY: Marketers Media; July 24, 2015, www.ismp.org/sc?id=607.

[3] Rensburg, C. J. V., Medpharm Publications, Sep 26, 2018.

[4] Center for Devices and Radiological Health, U.S. Food and Drug Administration, Infusion pump Improvement Initiative; April 2010, http://www.fda.gov/.

[5] Woods, D. D., Designs Are Hypotheses About How Artifacts Shape Cognition and Collaboration, Ergonomics. Vol. 41, No. 2, 1998, pp. 168–173.

[6] Schraagen, J. M., Verhoeven, F., Methods for Studying Medical Device Technology and Practitioner Cognition: The Case of User-Interface Issues with Infusion Pumps, 2012.

[7] Nemeth, C. P., O'Connor, M., and Cook, R. I., The Infusion Device as A Source of Healthcare Resilience, In: Nemeth CP, Hollnagel E, Dekker S, Editors, Resilience Engineering Perspectives, Preparation and Restoration, Vol. 2, 2009, pp. 235–53.

[8] Woods, D. D., Dekker, S., Cook, R., Johannesen, L., and Sarter, N., Behind human error. 2nd ed. Farnham, England: Ashgate Publishing Limited, 2010.

[9] Design for Patient Safety: A Guide to The Design of Electronic Infusion Devices, National Patient Safety Agency, National Reporting and Learning Service, Edition 1, 2010.

[10] Capes, D., Asiimwe, D., Performance of Selected Flow-Restricting Infusion Devices, American Journal of Health-System Pharmacy, Vol. 55, 1998, pp. 351-3599.

[11] Chung, I. S., Cho, H. S., Kim, J. A., and Lee, K. H., The Flow Rate of the Elastomeric Balloon Infusor Is Influenced by The Internal Pressure of the Infusor, Journal of Korean Medical Science, Vol. 16, 2001, pp. 702-706.

[12] Coley, S. C., Shaw, P. K., and Leff, R. D., The Performance of Three Portable Infusion-Pump Devices Set to Deliver 2 mL/hr, American Journal of Health-System Pharmacy, Vol. 54, No. 11, 1997, pp. 1277-1280.

[13] Veal, D. F., Altman, C. E., McKinnon, B. T., Fillingim, O., Evaluation of Flow Rates for Six Disposable Infusion Devices, American Journal of Health-System Pharmacy, Vol. 52, No. 5, 1995, pp. 500-504. [Erratum, Am J Health-Syst Pharm, Vol. 52, No. 11, 1995, pp. 1233.]

[14] Bayne, C. G., Removing the Confusion About Infusion, Nurs Manage, Vol. 28, No. 2, 1997, pp. 15-18.

[15] Nowak, R., Scuba Valve Inspires Cheap Drug Delivery, New Scientist, 22 November 2004.

[16] Rich, D. S., Evaluation of Disposable, Elastomeric Infusion Device in The Home Environment, American Journal of Hospital Pharmacy, Vol. 49, No. 7, 1992, pp. 1712-1716.

[17] Mizuuchi, M., Yamakage, M., Iwasaki, S., Kimura, A., The Infusion Rate of Most Disposable, Non-Electric Infusion Pumps Decrease Under Hypobaric Conditions, Canadian Anaesthetists Society Journal, Vol. 50, No. 7, 2003, pp. 657-662.

[18] Radcliffe, J. J., Spencer, I., Performance of the Baxter Disposable Patient-Controlled Analgesia Infusor Under Hyperbaric Conditions, Anaesthesia, Vol. 49, 1994, pp. 796-797.

[19] Boada, S., Recasens, J., Papaceit, J., et al., Use of Elastomeric Pumps for Continuous Intravenous Analgesia Administration in Ambulatory Surgery Pain Management, Ambul Surg. 2002, Vol. 10, pp. 3-7.

[20] Capdevila, X., Dadure, C., Raux, O., Rochette, A., and Troncin, R., Perioperative Continuous Peripheral Nerve Blocks with Disposable Infusion Pumps in Children: A Prospective Descriptive Study, Anesthesia & Analgesia, Vol. 97, 2003, pp. 687-690.

[21] Klein, S. M., Greengrass, R. A., Gleason, D. H., Nunley, J. A., and Steele, S. M., Major Ambulatory Surgery with Continuous Regional Anesthesia and A Disposable Infusion Pump, Anesthesiology, Vol. 91, 1999, pp. 563-565.

[22] LeBlanc, K. A., Bellanger, D., Rhynes, V. K., and Hausmann, M., Evaluation of Continuous Infusion of 0.5% Bupivacaine by Elastomeric Pump for Postoperative Pain Management After Open Inguinal Hernia Repair, Journal of the American College of Surgeons, Vol. 200, 2005, pp. 198-202.

[23] Capdevila, X., Macaire, P., Aknin, P., Dadure, C., Bernard, N., and Lopez, S., Patient-Controlled Perineural Analgesia After Ambulatory Orthopedic Surgery: A Comparison of Electronic Versus Elastomeric Pumps, Anesthesia & Analgesia. Vol. 96, No. 2, 2003, pp. 414-417.

[24] Ganapathy, S., Amendola, A., Lichfield, R., Fowler, P. J., and Ling, E., Elastomeric Pumps for Ambulatory Patient Controlled Regional Analgesia, Canadian Journal of Anesthesia, Vol. 47, No. 9, 2000, pp. 897-902.

[25] Rawal, N., Axelsson, K., Hylander, J., Allvin, R., Amilon, A., Lidegran, G., and Hallén, J., Postoperative Patient-Controlled Local Anesthetic Administration at Home, Anesthesia & Analgesia. Vol. 86, No. 1, 1998, pp.86-89.

[26] Robinson, S. L., Rowbotham, D. J., and Mushambi, M., Electronic and Disposable Patientcontrolled Analgesia Systems, A Comparison of the Graseby and Baxter Systems After Major Gynaecological Surgery, Vol. 47, Anaesthesia, 1992, pp. 161-163.

[27] Ballantyne, J. C., Carr, D. B., Berkey, C. S., Chalmers, T., and Mosteller, C. F., Comparative Efficacy of Epidural, Subarachnoid, And Intracerebroventricular Opioids in Patients with Pain Due to Cancer, Regional Anesthesia, Vol. 21, No. 6, 1996, pp. 542-546.

[28] Hardy, E. M., Williamson, C., and Sewell, G. J., An Evaluation of Six Infusion Devices for The Continuous Infusion of Cytotoxic Drugs in Ambulatory Patients, Journal of Oncology Pharmacy Practice, Vol. 1, 1995, pp. 15-22.

[29] Loeffler, T. M., Weber, F. W., and Hausamen, T. U., Ambulatory High-Dose 5-Day Continuous-Infusion Ifosfamide Combination Chemotherapy in Advanced Solid Tumors: A Feasibility Study, Journal of Cancer Research and Clinical Oncology, Vol. 117, 1991, pp. 125-128.

[30] Negro, S., Azuara, M. L., Sanchez, Y., Reyes, R., and Barcia, E., Physical Compatibility and in Vivo Evaluation of Drug Mixtures for Subcutaneous Infusion to Cancer Patients in Palliative Care. Supportive Care in Cancer: Official Journal of the Multinational Association of Supportive Care in Cancer, Vol. 10, No. 1, 2002, pp. 65-70.

[31] Kaye, T., Prolonged Infusion Times with Disposable Elastomeric Infusion Devices, American Journal of Hospital Pharmacy, Vol. 51, No. 4, 1994, pp. 533-534.

[32] Irwin, M., Gillespie, J. A., and Morton, N. S., Evaluation of a Disposable Patient-Controlled Analgesia Device in Children, British Journal of Anaesthesia, Vol. 68, 1992, pp.411-413.