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An Adapter-based Safety Injection System with Key and Keyhole Pattern for Prevention of Wrong-route and Wrong-patient Medication Errors

투약경로오류와 투약환자오류 예방을 위한
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조 용 찬

Abstract

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Wrong–route or –patient medication errors due to human mistakes have been considered difficult to resolve in clinical settings. In this study, a safety injection system is suggested, which can help to prevent an injection when a mismatch exists between the drug and route or patient. For this, two distinct adapters with key and keyhole patterns specifically assigned to a pair of drug and route or patient were prepared. When connected to a syringe tip and its counterpart, a catheter injection–port, respectively, the adapters allowed for a seamless connection only with their matching patterns. In this study, each of the adapters possessed a specific key and keyhole pattern at one end and the other end was shaped to be a universal fit for syringe tips or catheter injection–ports in clinical use. With the scheme proposed herein, this system could generate 27,000 patterns, depending on the location and shape of the key tooth in the adapters. With a rapid prototyping technique, multiple distinct pairs of adapters could be prepared in a relatively short period of time and thus, it can be envisioned that a specific adapter pair can be produced on–site after patient hospitalization, much like patient identification barcodes.

Keywords: Key and keyhole patterns, Syringe, Catheter, Rapid prototyping

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1. Introduction

1.1 Background knowledge

Medication errors are preventable events where scheduled medications fail to be completed as intended, or where wrong plans are used to deliver medication to patients (1). Patients can experience adverse drug reactions by receiving incompatible drugs under such erroneous events, which can even mean that patients face life-threatening conditions or death (2). Medication errors drew the attention of the researchers nearly two decades ago, with many studies having been conducted to prevent medication errors (3, 4). However, some critical medication errors, such as wrong-route and wrong-patient medication errors, remain unresolved.

Wrong-route or wrong-patient medication errors occur when medication is injected into a wrong injection route or patient, respectively (2, 5-7). These errors are especially dangerous to patients because a high concentration of incompatible drugs can be exposed to susceptible organs and cause serious adverse reactions (8-14). For example, many cases of wrong-route errors that resulted in patient deaths have occurred while administering vincristine to the intrathecal (IT) route or epidural analgesia to the intravenous (IV) route (8, 12, 13). Additionally, cases of transfusing ABO-incompatible red blood cells to a wrong target patient have led to serious hemolytic transfusion reactions (9). These errors occurred because of simple mistakes in identifying the correct injection route or patient at the administration stage (15-17). Medication errors that occur during prescription or preparation stages can be corrected in following drug-preparation steps. However, wrong-route errors and wrong-patient errors occur at the moment of injection. When the mistake is noticed, the drug has already been injected into the wrong target.

In an attempt to reduce the possibility of such medication errors, several strategies have been developed. Most of these strategies involve education programs for medical staff using error-prevention manuals or route-specific barcode systems (14-16, 18). Error-prevention manuals emphasize the attention of medical professionals; a medical staff should check patients' identities at every encounter, and target patient or route should be identified by more than two staff for every injection. For barcode systems, medical staff scan barcodes attached to drugs and target patients. The system alarms medical staff when a mismatch between the drug and target injection route or patient is detected. While these strategies might help staff recognize and confirm correct medication routes, they still do not address the fundamental issues of human error (19, 20). For example, even if a human mistake is discovered, the issue of the wrong drug being injected must still be addressed. For this reason, wrong-route and wrong-patient medication errors are serious ongoing problems in clinical settings (6, 14-16, 20, 21).

1.2 Strategy

When a patient is admitted to a hospital, a catheter is usually connected to the vein of the patient first, with an injection port exposed outside of the body. After establishing the required medical prescription for the patient, the medical staff injects the required drug by connecting a syringe tip to the injection–port in the catheter. Understanding this procedure and in an attempt to prevent wrong medication errors, a safety injection system is suggested, which can physically prevent the connection of a syringe tip to a catheter injection-port when there is a mismatch between a drug and patient or route. As a part of this system, a pair of adapters are installed to a syringe tip and a catheter injection–port, serving as a key and keyhole, respectively. Each pair of key and keyhole possesses a shape pattern specific to a matching pair of drug and patient or route. In this way, even when a medical staff is not aware of the medication error by mistake, a mismatch between shape patterns will be present to not allow the connection between the syringe tip and the catheter injection–port, thereby leading to automatic prevention of injection.

Producing the adapters with a specific key and keyhole immediately after patient hospitalization can be envisioned, similar to patient identification barcodes in clinical settings (20, 21). In order for such a design to be applicable to a large number of patients visiting the hospital, it would be advantageous to fabricate the adapters in a relatively short time. For this reason, additive manufacturing can be an ideal solution over other conventional fabrication methods (22-25). The additive manufacturing technique would allow for rapid, on–demand and on–site production of the adapters with various key and keyhole shape patterns, each customized to a specific patient or injection route. To test the feasibility of this strategy, a material jetting technique was employed to fabricate the adapters in this work (26). Considering their medical use, the adapters herein were printed with a biocompatible material that is known to meet the United State Pharmacopeia (USP) Class VI biocompatibility test (27, 28).

2. Materials and Methods

2.1 Adapter design

The safety injection system consists of two distinct adapters, i.e., the syringe and catheter adapters, to be connected to a syringe tip and catheter injection–port, respectively (Figure 1A). The syringe and catheter adapters was designed to be equipped with a key and keyhole, respectively. For a syringe adapter, a specific male key pattern is embossed at one end, while the other end is shaped to allow for seamless fitting to the syringe tip. The catheter adapter is designed to have a female keyhole pattern at one end to be matched with a pairing syringe adapter while the other end is shaped to allow for seamless fitting to the catheter injection–port. The syringe tip and catheter injection–port with luer lock was used as exemplary devices in clinical use (Norm-ject® 10 mL disposable luer lock syringe, Henke Sass Wolf, Tuttlingen, Germany; and Q-Syte™ catheter extension set, Becton, Dickinson and Company, Franklin Lakes, NJ, USA), where the adapters are shaped accordingly. For both adapters, a marker is prepared as a reference for their alignment.

The operation scheme of the safety injection system is depicted in Figure 1B. At the time of injection, the two adapters are aligned using the reference markers and insertion is attempted. When the drug matches the patient or route, the adapters have the corresponding shape patterns as key and keyhole, allowing the syringe tip to be inserted, forming a proper luer

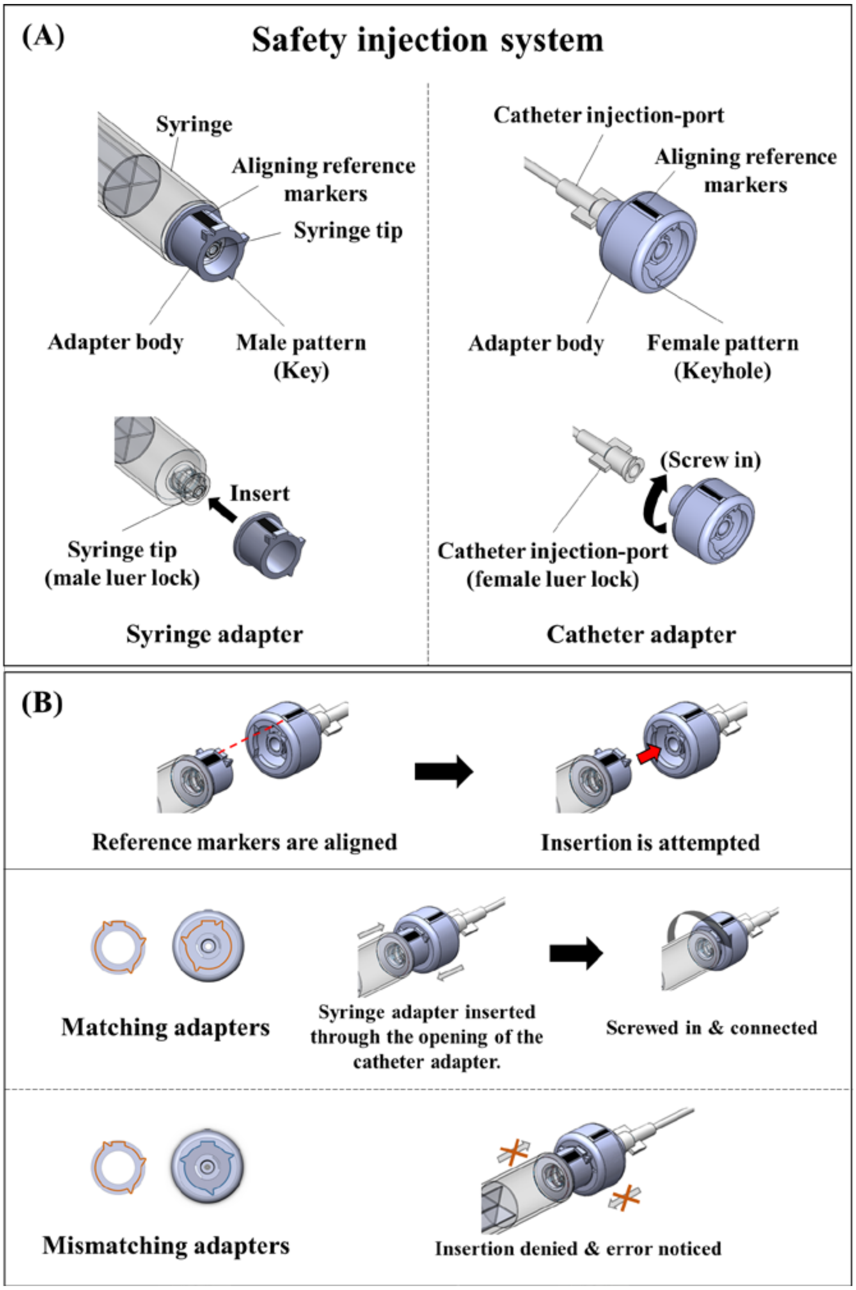

Figure 1. Safety injection system. (A) Detailed schematic of safety injection system (B) Operational schematic of safety injection system.

lock connection with the catheter adapter to allow for a seamless flow–path towards the catheter injection-port. When there is a mismatch, the adapters cannot be properly coupled, which physically hinders the luer lock connection between the syringe tip and catheter adapter, denying the flow–path towards the catheter injection–port.

In order to realize this, the following design is suggested as shown in Figure 2. The syringe adapter is in shape of a cylinder with a key pattern, 2 mm in height, which is embossed at one end. The inner diameter of the syringe adapter is 9.8 mm for its slip fitting to the syringe tip. The wall thickness of the cylindrical syringe adapter is 1.9 mm, giving it an outer diameter of 13.6 mm (Figure 2A). The catheter adapter is in the shape of a cylindrical barrel with a keyhole pattern, 2 mm in height, that is engraved at one end. To allow for the smooth slip insertion of the syringe adapter, the inner diameter of the catheter adapter is made to be 14.2 mm, which is slightly larger than the outer diameter of the syringe adapter (13.6 mm). The outer diameter of the catheter adapter is 22 mm, which includes the keyhole pattern height and wall thickness. When a key and keyhole match, the catheter adapter allows for seamless fitting to the syringe tip and thus, a female luer lock copied from the catheter injection-port is prepared at the end. At the opposing end, a male luer lock copied from the syringe tip is prepared to be fitted to the catheter injection–port (Figure 2B).

Each adapter includes a safety gap (2.5 mm) made at the end where the key and keyhole patterns are present (Figure 2A and 2B). This feature allows

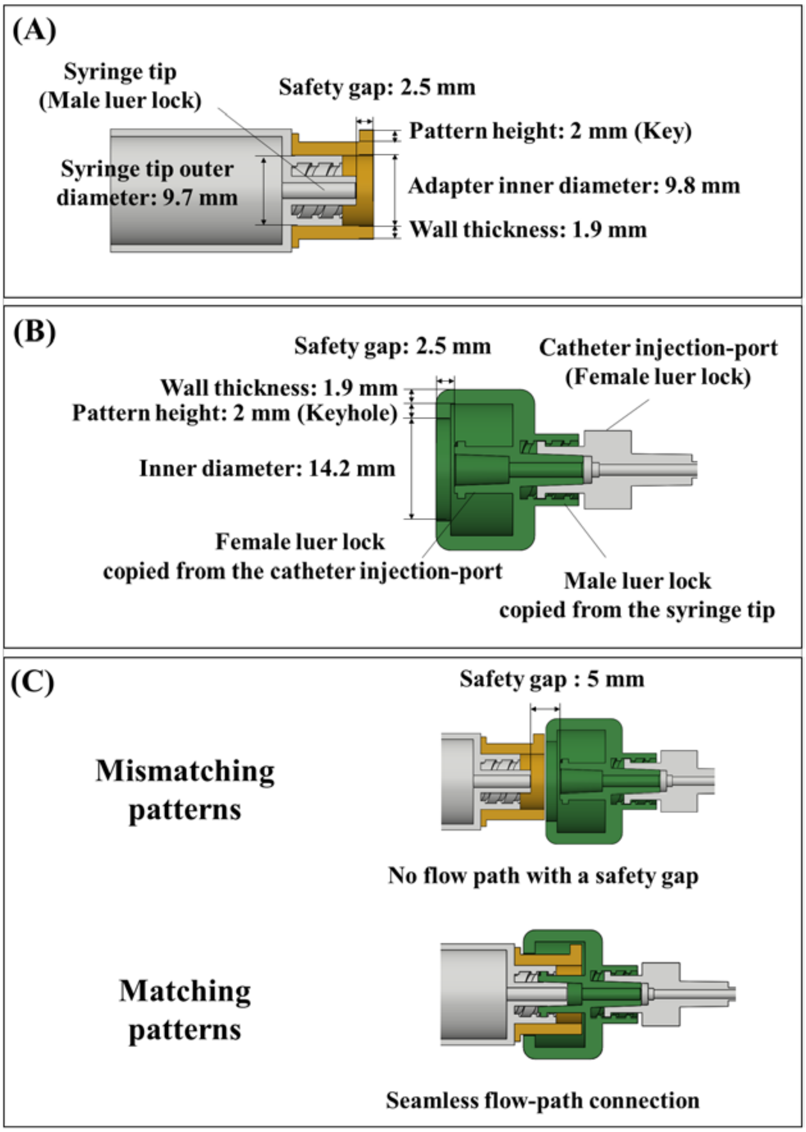

Figure 2. Adapter design for safety injection system. (A) A syringe adapter, (B) a catheter adapter, and (C) their connections under the matching and mismatching conditions.

the male luer lock of the syringe tip and the female luer lock of the catheter adapter to remain 5 mm apart, even when a forceful attempt is made to connect a mismatching pair of adapters. This safety gap denies a flow–path to be made between the syringe and the catheter injection–port. Yet, when the key and keyhole patterns match, the syringe adapter can easily be slipped into the catheter adapter, allowing the syringe tip to screw into the female luer lock made in the catheter adapter (Figure 2C).

2.2 3D scanning of syringe tip and catheter injection–port

In this work, the syringe adapter was designed to be connected to the syringe tip via a simple slip fitting. The syringe adapter was designed in the shape of a cylinder, having an inner diameter similar to the outer diameter of the syringe tip (Figure 3). Yet, in the case of the catheter adapter, accurate shapes and dimensions were needed for the luer locks of the syringe tip and the catheter injection–port. To accomplish this, both the luer locks of the syringe tip and the catheter injection–port was imaged using a 3D scanner (Ultra HD, Next Engine, USA). In order to scan the inside of the syringe tip, the tip was first cut to expose its cross-section, showing the internal thread and slip tip (Figure 4A). During scanning, the syringe tip and catheter injection–port were each placed on a turntable to be rotated 360° in front of the scanner. The scanned images obtained at each of the rotating angles, in 10° increments, were stacked to reconstruct the 3D contour of the object. The images were then post–processed using Autodesk Meshmixer (Autodesk,

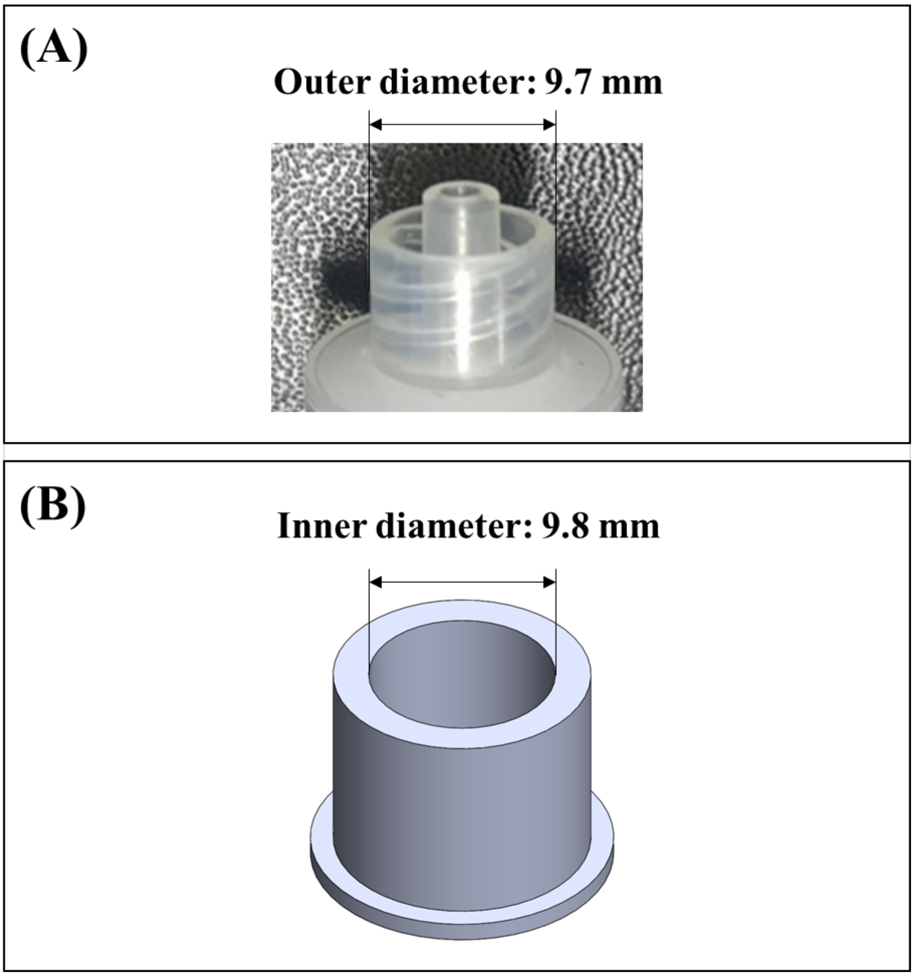

Figure 3. Design of the syringe adapter. (A) Optical image of the syringe tip and (B) the corresponding 3D model of the syringe adapter.

Mill Valley, CA, United States) and Meshlab (Slashdot Media, La Jolla, CA, United States) (Figure 4B). The resulting images were exported in stereolithography file format (.stl) and imported into SolidWorks (Dassault Système SOLIDWORKS, Waltham, MA, USA).

We then measured the dimensions of each part of the syringe tip and catheter injection–port referenced from the scanned images. For the internal thread of the syringe tip, the outer diameter, height, lead and thread thickness were measured (Figure 4C). For the slip tip, the height and outer diameters of the top and bottom were measured. For the catheter injection–port, the height, lead, inner diameters of the top and bottom, and thicknesses of the head and thread were measured (Figure 4C). Based on those dimensions, the 3D models of the syringe tip and catheter injection–port were reconstructed, as shown in Figure 4D, which were then combined to make a model for the catheter adapter, as shown in Figure 4E.

2.3 Pattern and code generation for key and keyhole

Figure 5 depicts the strategy used to generate a specific shape pattern for the key and keyhole pairs. To construct the key shape pattern, a specific code was generated based on three distinct criteria: region, position, and shape. For the region code, the periphery of the circular end of the adapter was divided into three regions of equal lengths from the location of the reference tooth (Figure 5A). At each region, ten distinct, equally spaced

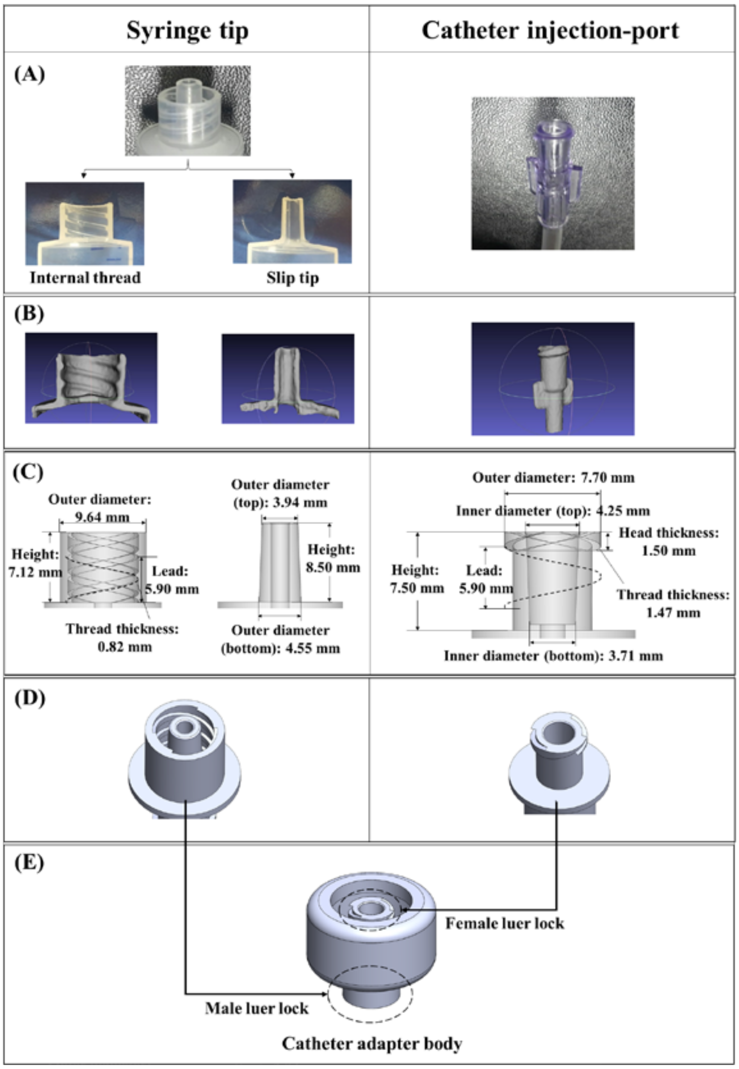

Figure 4. Design of the catheter adapter. (A) Optical images of the syringe tip and catheter injection-port, and their corresponding (B) 3D–scanned images and (C) re–drawn cross–section images showing the measured dimensions. (D) 3D–reconstructed images obtained with the syringe tip and catheter injection–port. (E) 3D model of the catheter adapter.

positions were located to generate the position codes from 0 to 9 (Figure 5B). At each position, a tooth was placed having one of three distinct shapes, i.e., the right–skewed, isosceles and left–skewed triangles representing the shape codes of R, M, and L, respectively (Figure 5C).

As shown in the example key pattern (Figure 5D), the code was composed of six discrete digits, where the first, middle and last two digits each represented the codes from regions 1, 2 and 3, respectively. For each two–digit code, the first and last digits represent the position and shape of the tooth, respectively. The key and keyhole patterns were then embedded into the 3D models of the syringe and catheter adapters, respectively. Figure 5E shows an example of the final 3D models of the syringe and catheter adapters containing the key and keyhole patterns, respectively. In order to be matched via a serial connection, a keyhole pattern for the catheter adapter was prepared by using a mirror image of the key pattern for the syringe adapter.

2.4 Adapter fabrication

The final 3D models of the adapters were converted to a stereolithography file format, and imported to a material jetting 3D printer (Projet HD 3500 Max, 3D Systems, Valencia, CA, USA). For efficient production, multiple adapters were integrated into a single file (Figure A1). Visijet M3 Crystal ® was used (3D Systems, Valencia, CA, United States) as the composing material, which is known to be highly biocompatible (United States Pharmacopeia (USP) Class VI) (27, 28).

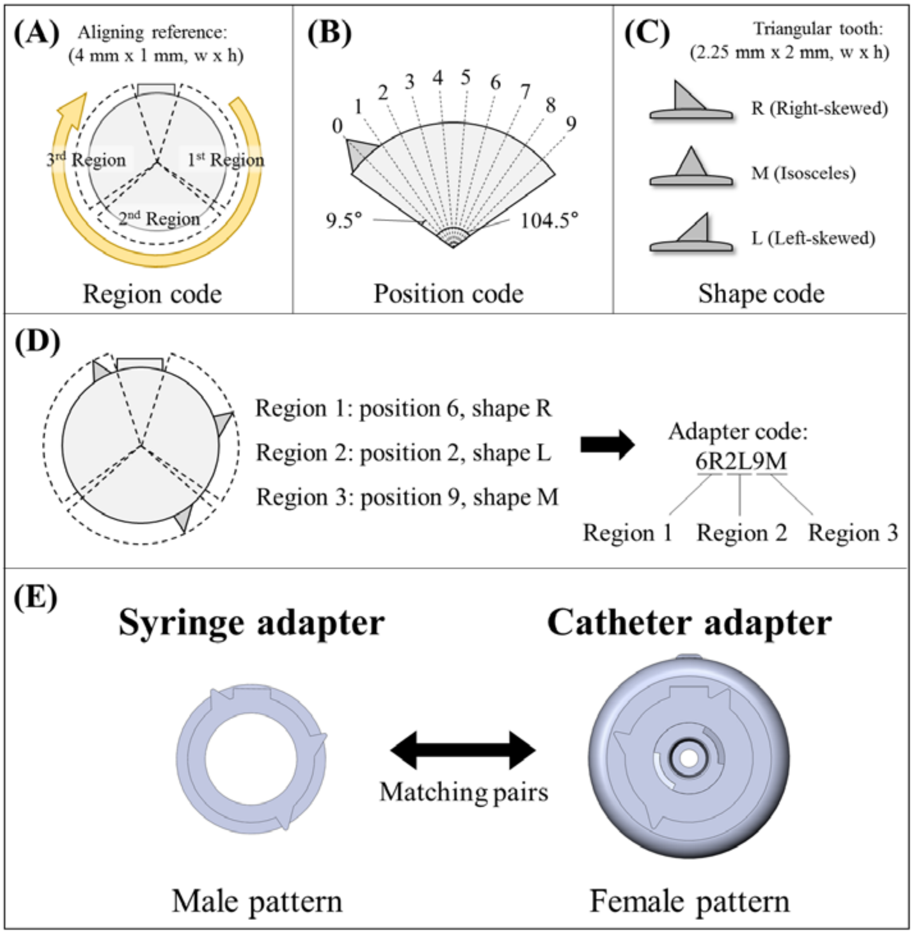

Figure 5. Scheme for pattern and code generation. (A) Region code: three regions are assigned through the periphery of the circular end of the adapter. (B) Position code: ten distinct positions are assigned in each region. (C) Shape code: three distinct shapes of a tooth are assigned to be located in each position. (D) Example pattern and its corresponding code in the syringe adapter. (E) Example matching patterns formed in the syringe and catheter adapters.

3. Results

3.1 Adapter Characterizations

Using the scheme for code generation presented in this study, there could be 27,000 distinct combinations of adapter pairs (# of combinations = (# of position X # of shape)$^{\text{\# of region}}$ = (3 X 10)^3 = 27,000), which was more than 3 times larger than the highest number of hospital beds (~ 7,000 beds) reported in the world (29). Still, the possible number of combinations herein could be easily modulated by varying the possible numbers of position, shape and region. Among those possible combinations, Figure 6 shows 36 different adapter pairs prepared in this work. The total time for their fabrication was 3.5 h. Figure 7A and 7B show the 3D models and their corresponding optical images of one of the adapter pairs herein (code: 6R2L9M), respectively. The products were fabricated following the models without noticeable defects, particularly in the cross-section of the catheter adapter, where the male and female luer locks were seen to be properly formed. In addition, it should be noted that the critical dimensions of the constituents, such as the lead and thread, were retained as constructed in the 3D models. This supports the case that the adapters could be accurately assembled with the syringe tip and catheter injection–port employed in this study with no noticeable hindrance or fracture (Figure 8).

Figure 6. Adapter pairs of 36 distinct codes prepared in this study.

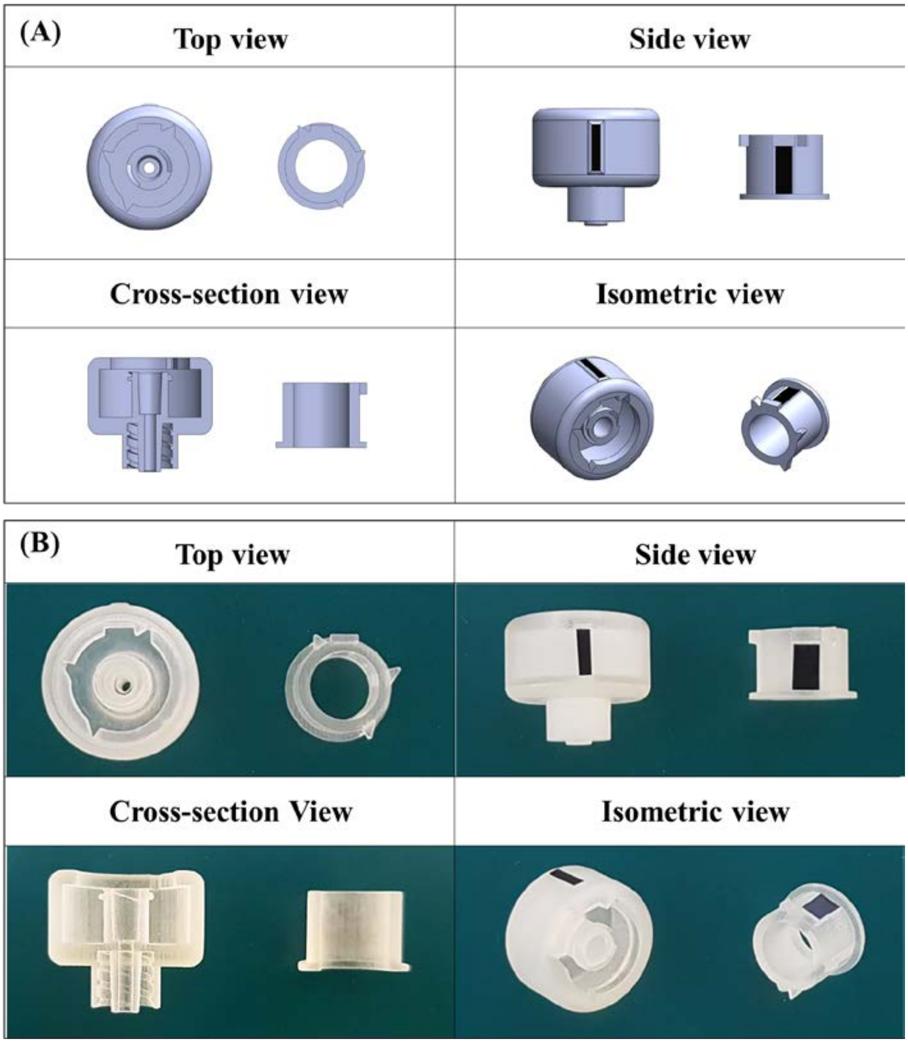

Figure 7. Adapter characterizations. (A) 3D models and (B) their corresponding optical images of the example adapter pairs (code: 6R2L9M).

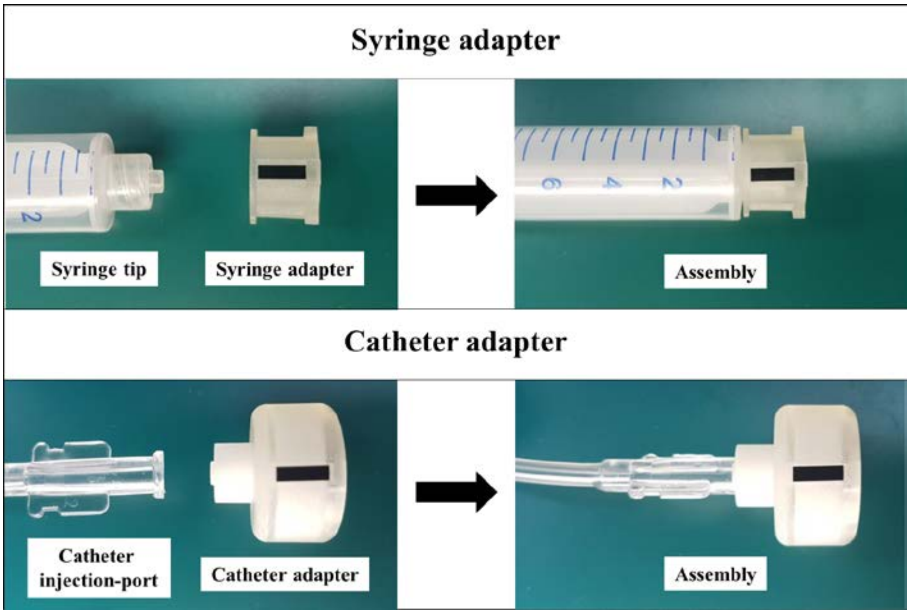

Figure 8. Assembly of the adapters with a syringe tip and catheter injection–port.

3.2 Performance of the Safety Injection System

In order to assess the performance of the safety injection system proposed herein, a matching pair of syringe and catheter adapters was used first, where the code, 6R2L9M, was simply employed as an example (Figure 9). The adapters were first assembled with a syringe tip and catheter injection–port, and the connection of both adapters was attempted as shown in Figure 1B. According to the observations, the matching key and keyhole patterns allowed for the syringe adapter to advance forward through the 5 mm safety gap, so that the syringe tip could be screwed into the male luer lock formed in the catheter adapter, as depicted in Figure 2C. To implement the scenario of the mismatched pair, syringe and catheter adapters with differing codes were used: the syringe adapter with the code, 4L5L6R and the catheter adapter with the code, 6R2L9M (Figure 9). In this exemplary case, when the connection of both adapters was attempted, the syringe adapter could not be inserted into the catheter adapter and thus, due to the presence of the safety gap, the syringe tip could not approach the male luer lock in the catheter adapter (Figure 2C).

To simulate the medication injection, the syringe was filled with an aqueous dye solution (fluorescein), which was injected under both matching and mismatching conditions (Figure 10). For the matching pairs of the adapters, it was observed that the solution could be transferred into the catheter without any apparent leak. On the other hand, when the adapter pairs mismatched and the connection was not made, the solution leaked into

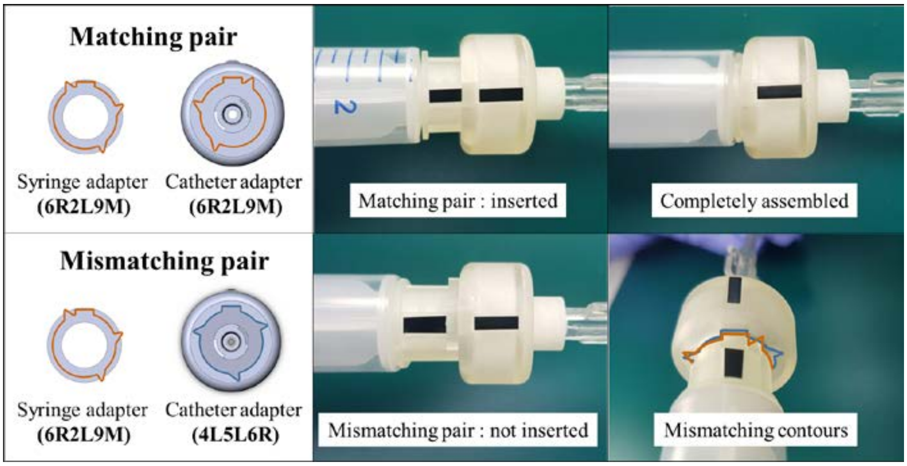

Figure 9. Connections of the adapters under the matching and mismatching conditions.

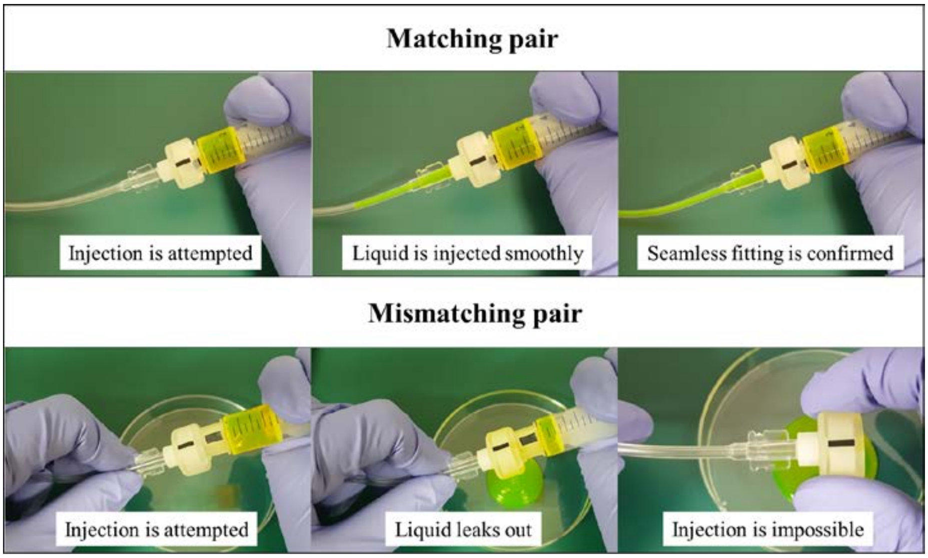

Figure 10. Liquid injection under the matching and mismatching conditions.

the gap between the two adapters and no solution was observed in the catheter. This result suggested that even when the injection was physically attempted by mistake, the medication could not be delivered into the catheter with the mismatching adapter pairs, and hence, prevention of wrong–route or –patient medication errors was achieved.

3.2 Stability of the Safety Injection System

In order to assess the mechanical rigidity of the system, the maximum pressure where the system can endure was measured (Figure 11). In clinical settings, the liquid medication is usually infused around at 300 mmHg to be higher than the systolic blood pressure of the patients (30). To test this, the male luer lock of a catheter adapter was connected to an IV solution bag loaded with an aqueous dye solution (fluorescein), and the female luer lock of the catheter adapter was stopped using a valve. Then, the IV bag was pressed in a pressure infuser bag (Pacific Hospital Supply, Taipei, Taiwan). The pressure increased from 200 mmHg at an increment of 50 mmHg until leakage was detected, where each pressure was maintained for 10 min. For all 10 tested samples, leakage was detected from 550 mmHg and during this process, no crack or fracture was observed.

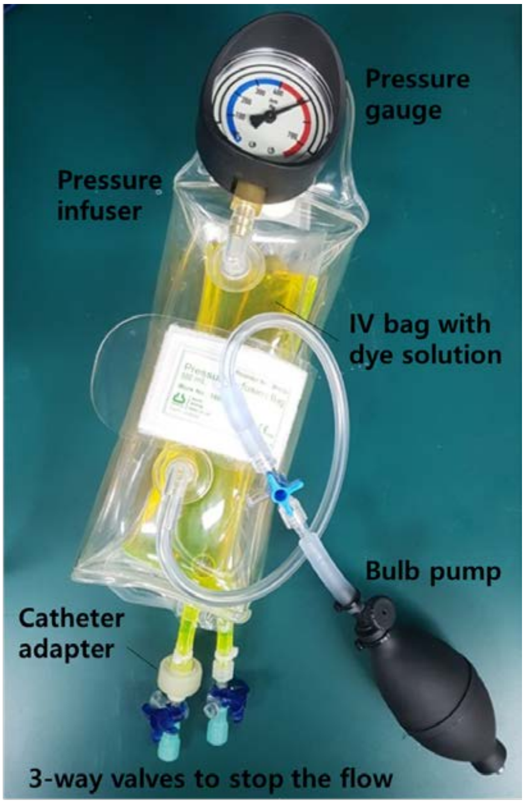

Figure 11. Experiment setup for pressure application to the catheter adapter.

4. Discussion

Wrong–route or –patient medication errors have been considered a serious issue in clinical settings (5, 7, 8, 14). Although many efforts have been made to mitigate these issues, errors from unintentional human mistakes have remained difficult to fully resolve with the suggested strategies, which are heavily based on education or visual aid to provide reassurance regarding route and patient (6, 14-16, 20, 21). In regards to human error, the safety injection system has an advantage over these other strategies, in that wrongful injections can be prevented and stopped at the source when the drug and route or patient mismatches. The adapters presented here can be prepared to possess a key and keyhole specific to the pair of medication and route or patient. In this way, a seamless connection and drug administration can be made only when the pair matches (Figure 9 and 10). Under mismatching conditions, the medical staff can immediately recognize a possible error as the adapters cannot be smoothly connected. Even when injection is still attempted, the medication is leaked excessively (Figure 10) and cannot be delivered into the catheter, which would be connected to the vein of the patient.

To reduce the chances of a wrong-route medication error, a safety connector system had been introduced previously (31), which was designed to distinguish the difference between non–luer and luer connections, using a smaller size syringe tip, needle hub and stylet nose than those of conventional luer systems. Thus, when there is a mismatch, the clinician could physically recognize the misconnect and massive leakage of medication induced by an attempt of injection. Albeit similar to the approach used in this study in some ways, this system is not able to distinguish a specific pair of medication and route or patient among many possible combinations as only size is a measure of distinction.

In this work, additive manufacturing technique is proposed for production of specific keys and keyholes for the syringe and catheter adapters, respectively. Like the generation of a barcode, it is envisioned that a key pattern specific to a pair of medication and route or patient can be generated at the time of hospital admittance. Given this, multiple distinct adapter pairs for many patients can be fabricated in a reasonable period of time (hours) with relatively low cost (Figure 6) (22-24). However, the on–site production of the adapters may not be always necessary, as the hospital may already be equipped with many pre–made adapters, each possessing a distinct key and keyhole pattern. In this scenario, however, a strategy is needed to avoid the overlapped use of the same adapter pair among many different pairs of the medication and route or patient.

This idea can be applied across many different clinical settings using syringes. The system can be specified for a patient to prevent the mistaken administration of a medicine to a different patient. This system can also be used to differentiate the specific route of injection. Beside the IV or IT routes, the system can be applied to an arterial line which is rarely used for injection of medicine (32). This system can also be used for enteral nutrients or enteral medicines to prevent IV injection of enteral nutrients or enteral medicines into the venous system (33). Issues with the clinical application of this system may be added cost and the inconvenience of injection. However, these issues should pale in comparison to the overall improvement in patient safety and the use of adapter applied prefilled syringes.

5. Conclusion

In conclusion, a safety syringe system based on adapters equipped with key and keyhole patterns specifically assigned to the pair of drug and route or patient is suggested in this study. The adapters can be connected to the syringe and catheter injection–port and thus, a seamless flow–path for injected liquid can be formed only when the key and keyhole patterns of the adapter pair match to form a secure connection. Like generating random numbers, thousands of matching patterns of key and keyhole can be generated with the strategy proposed herein. Therefore, it is concluded that the safety injection system with the adapters herein has the potential to prevent wrong–route or –patient medication errors, and potentially save lives.

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7. Appendix

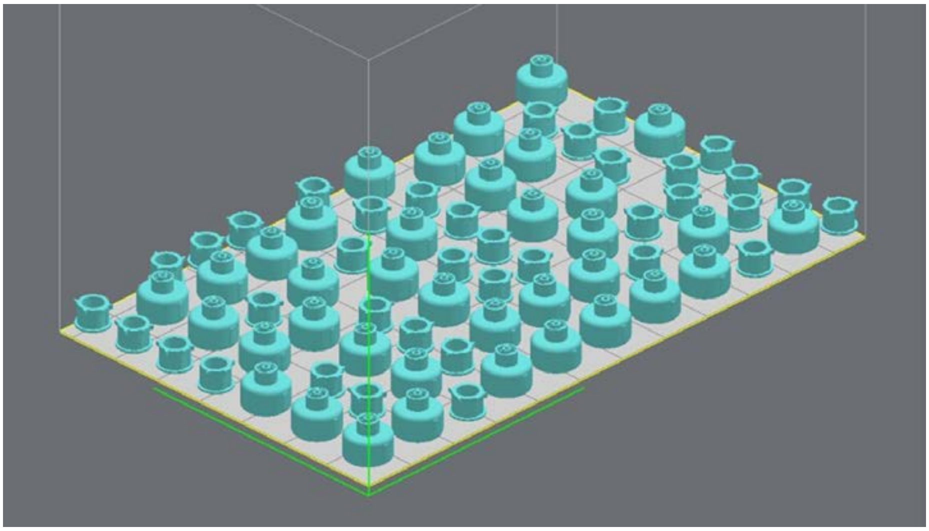

Figure A1. Multiple 3D models of the distinct pairs of the adapters integrated in a single file.

국문 초록

투약경로오류와 투약환자오류 예방을 위한 열쇠 및 열쇠구멍 패턴을 탑재하는 어댑터 기반 안전 주사기 시스템

의료진의 실수로 인해 발생되는 투약경로오류와 투약환자오류는 아직까지 해결되지 않은 문제로 남아있다. 따라서 본 연구진은 약물과 투약 경로 또는 환자 간의 불일치가 있을 경우, 주사를 방지할 수 있는 안전 주사기 시스템을 제안한다. 이 안전 주사 시스템은 열쇠와 열쇠구멍 패턴을 갖춘 한 쌍의 어댑터들로 구성되어 있으며, 특정한 한 가지 패턴을 가지는 한 쌍의 어댑터들이 하나의 투약 경로 또는 환자에게 부여되는 시스템이다. 해당 어댑터들은 각각 약물 주사기와 환자의 카테터 주입구에 부착되며, 두 어댑터 간의 열쇠와 열쇠구멍 패턴이 일치할 경우에만 서로 연결되어 약물의 전달이 가능케 한다. 각 어댑터는 한쪽에 열쇠 또는 열쇠구멍 패턴을 가지고, 반대 쪽에는 주사기와 카테터 주입구와 연결될 수 있도록 설계되었다. 열쇠와 열쇠구멍 패턴은 여러 요철로 구축되어 있으며, 요철의 위치와 모양 등의 조합으로 총 27,000 개의 패턴을 형성할 수 있다. 신속조형기술을 이용하면

여러 쌍의 어댑터들을 비교적 짧은 시간 내에 동시 제작할 수 있으므로, 바코드 시스템처럼, 환자가 병원에 입원하면 해당 환자 또는 특정 투약 경로에만 지정되는 패턴을 지니는 어댑터들을 즉석에서 제작하여 적용할 수 있을 것으로 예상된다.

주요어: 열쇠 및 열쇠 구멍 패턴, 주사기, 카테터, 신속조형기술
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