Application of 3D Printing to Medical Care and Rehabilitation Equipment: A Case Study of Needle Removers for Improving Medical Safety and Satisfaction

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\textbf{ABSTRACT}

According to research surveys, the patients with type 2 diabetes often lack safety protective equipment for the removal of insulin syringe needles in their home. Approximately 70\% of the patients and their families using an insulin pen have been pricked by its needle. The needle-stick not only potentially causes hepatitis, human immunodeficiency virus (HIV), and fatal diseases, but also affects psychological health. The method in this study includes the use of stereolithography (SLA) 3D printing technology for innovative research and development of an insulin-pen-needle-remover. This insulin-pen-needle can be safely removed from the remover and directly discarded into the disposal bin without recapping with both hands, so that the safety of patients/their families can be ensured, the risk of needle-stick infection reduced, and the quality of health care for the patients with diabetes improved. Therefore, with the appearance of 3D printing technology, this study was aimed to explore the innovations applicable to medical care and rehabilitation.

\textit{Keywords:} 3D printing technology, medical care & rehabilitation, satisfaction

\textbf{INTRODUCTION}

Rehabilitation for the patients with amputees can be caused by diabetes. Diabetes is a chronic disease that is widespread worldwide. An International Diabetes Federation report indicated that in 2015, up to 415 million people around the world suffered from diabetes, while more than 1.7 million people in Taiwan had diabetes (Chou, 2016). Ranking fifth among the ten leading causes of death in Taiwan, diabetes has the fastest growing mortality...
rate over the past two decades (Department of Statistics, Ministry of Health and Welfare, 2016). If diabetes is poorly controlled, it may cause systemic irreversible, large and small blood vessels and nerve lesions, such as stroke, heart disease, kidney disease, retinopathy, foot necrosis and amputation and other complications, which seriously affect the quality of life (Chuang, Tsai, & Lu, 2016). Studies have shown that the physical and mental health-related quality of life in diabetic patients is worse than those without diabetes (Chen & Chen, 2016). The more unsatisfactory the glycemic control is, the higher the depression index will be (Hassan, Loar, Anderson, & Heptulla, 2006). Therefore, it is suggested that the target for glycemic control in type 2 diabetic patients should be maintained at an HbA1c level of below 7 percent, in order to reduce the incidence of diabetes-related large and small vascular complications. When diet controlling, physical exercising, blood sugar monitoring, or the administration of various oral hypoglycemic drugs still cannot improve the blood glucose levels, a combination use of insulin injections in the treatment of type 2 diabetes is clinically effective (Guidelines on Insulin Injection in Taiwan, 2015).

According to the clinical practitioners or the health care professionals educating for the patients on insulin injection, the patients after finishing the insulin injection need to remove the needle with both hands; however, because of aging, deterioration of eyesight, retinopathy, blindness, and other factors, patients removing hypodermic needles from the syringe are often exposed to the risk of repeated punctures arising from the blur of the hole of the transparent outer cover or a hand tremor; thus, they are a group that needs special attention. Domestic data indicated that the number of insulin pen users increases gradually. The patients or their family respond that 70 percent of them have experienced needle-stick injuries in the process of injection at their home (Chang, Chiang, Su, Lin, & Liu, 2014). Studies have shown there is also a lack of safety protection equipment for insulin injection needles and blood collection needles at homes. Therefore, it is a challenge to improve the safety of needle use and disposal for the patients and families (Markkanen, Galligan, & Quinn, 2017).

Also, the medical staff at clinical practice is at high risk due to the use of a needle-stick for the injection and blood collection. The high risks include hepatitis, human immunodeficiency virus (HIV), fatal diseases, or exert psychological stress such as fear and anxiety (Lavoie, Verbeek, & Pahwa, 2014). For example, nursing staffs often experience needle-stick injuries when giving injections of insulin for the patients with diabetic. Although the insulin syringe needle is small, the damage it causes may bring possibility of infection. Therefore, the use of medical equipment with safety design can reduce the risk of injury. Both medical personnel and users need to be fully protected, including the use of protective equipment designed for safety and the attendance at education training (Costigliola, Frid, Letondeur, & Strauss, 2012).

The National Patient Safety Foundation (NPSF) defines patient safety as “avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare,” while the Joint Commission of Taiwan (JCT) interprets patient safety as “necessary measures taken in the medical process to avoid or prevent adverse effects on or harm to patients, including prevention of errors, bias, and accidents” (JCT, 2014). As a result, the promotion of patient safety
culture can enable the staff to share common attitudes, beliefs, perceptions, and values towards patient safety and quality improvement. According to the International Classification of Functioning, Disability and Health (ICF) issued by the World Health Organization (WHO) for the purpose of enhancing people's physical and mental well-being, environmental factors include three aspects: physicality, sociality, and value. The physical factor refers to the physical environment, such as aids and home living space (Liao & Hwang, 2009). Assistive devices or aids in rehabilitation can effectively improve the bodily functions of people with disabilities (Liang et al., 2004).

The advent of 3D printing has led to revolutionary changes in the traditional manufacturing industry and is setting the trend for the development of the global manufacturing sector. 3D printing is cutting-edge technology based on multiple disciplines such as information technology, precision machinery, and material science. With the maturity of 3D printing technology, 3D printing is playing an increasingly vital role in the medical market.

3D printing technology emerged in the 1980s. The principle of 3D printing is that the printed paper is stacked in layers and there is a three-dimensional shape coming out. Replace the currently-used printer ink by another material that can harden after ejection, and then switch the nozzle from the original plane to 3D movement, which is the basic principle of the current 3D printer. The 3D printing industry extends to economic systems, business models, school education, and healthcare, with many innovative applications expanding constantly. Through the 3D printing technology, the ideas that originally exist only in the mind can be prototyped and molded rapidly using the 3D printer. 3D printing generally refers to rapid prototyping which can be specimen made before formal mold making and mass production, for the purpose of verifying whether the final design is unproblematic. Currently, the common 3D printing prototyping technologies include selective laser melting (SLM), selective laser sintering (SLS), stereolithography (SLA), and fused deposition modeling (FDM) (Lo, Wu, Lin, Lin, & Wang, 2016).

**PURPOSES**

In an effort to improve patients’ understanding of insulin injection technique and safety, it was aimed to modify and develop the design of the insulin-pen-needle-remover to help patients safely remove the needle for improving their safety and satisfaction.

**METHODS**

The method of this study included innovative research and development (R&D) of an insulin pen needle remover. With the help from the company named ur3d (智邦3D生活館), the 3D model making processes includes the design of the remover, the production of a 3D file using 3D drawing software, the development of a model with a SLA 3D printer (Starmen 4535, Starmen Opto-electronics, Taiwan), and the outcome of the product appearance (see Figure 1, Table 1).

The product was produced by utilizing SLA to make the final product of a needle remover. The SLA is a manufacturing method that uses laser or ultraviolet beams to harden successive layers of liquid light-activated resins. Due to the high accuracy of molding (the precision of 0.05 to 0.15mm...
can be reached), the smoothness and fineness of the surface of the finished product is quite close to those of the injection molded plastic products. The advantages of stereolithography, such as cost, speed, accuracy, and flexibility, have been able to provide different industrial applications and play an important role in the medical field (Palaganas et al., 2017).

Thus, the above method was employed to design a safe insulin-pen needle-remover, with its 3D printing structure containing (Table 2): the needle holder includes a hole for placing the needle, which was a slant plane and elongated groove with an opening shrinking inward. After finishing the injection, the insulin-pen and its needle were inserted into the hole, and the insulin pen was combined with the transparent outer cover of the pen needle, so that the transparent outer cover was tightly joined to the inclined plane. The pen needle was unscrewed and separated from the insulin pen before the pen was drawn out. Finally, the needle could be safely removed from the remover and directly discarded into the disposal bin without recapping with both hands (Table 1).

In order to understand the usage of this product, a questionnaire survey was conducted by healthcare educators to the patients who received insulin injections, with the aim of offering a preliminary understanding regarding the patient's satisfaction with the use of the insulin-pen-needle-remover. The questionnaire survey was designed as a self report and included 5 items with a 5-point Likert scale. In addition, a questionnaire survey was carried out for ten clinical nurses to investigate their satisfaction of medical personnel for the use of the removers.

### Table 1. Needle remover usage

<table>
<thead>
<tr>
<th>Usage Method</th>
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<tr>
<td>Take off the needle's outer cover and put it into the safety removal device, carefully remove the inner cover and discard it.</td>
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<tr>
<td>Insert the insulin-pen into the removal device, and separate the pen from the needle by the principle of rotating with the friction.</td>
</tr>
<tr>
<td>Finish injection by discarding the needle into the disposal bin.</td>
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RESULTS

First of all, with innovative R&D design, the 3D printing technology was employed to devise an insulin-pen-needle-remover by which the needle can be directly discarded from the remover into the disposal bin, so that it can be safely removed without recapping with both hands. This final product of the insulin-pen-needle-remover has been patented as utility model patent No. M543704 (Figure 2).

A questionnaire survey was conducted by healthcare educators in an outpatient education room of a regional hospital. There were ten patients on insulin injections aged between 65 and 75. The results of these self-reports regarding the users’ satisfaction were briefly summarized as follows (Figure 3): By using the insulin-pen-needle-removers, (1) the 90 percent of respondents found that the needle remover was easy to operate; (2) 100 percent of respondents knew how to use it; (3) 100 percent of them thought the remover could prevent needle-stick injuries, and (4) 90 percent were aware of the importance of the prevention of needle-stick. Meanwhile, another questionnaire survey was carried out to ten clinical nursing staffs aged between 30 and 40 on the satisfaction with the insulin-pen-needle-removers. The results showed that (1) 100 percent of respondents considered that the needle remover was easy to operate; (2) 100 percent of them knew how to use it, and (3) 90 percent of them believed the remover could prevent patients from needle-stick injuries. In summary, these results of the surveys have demonstrated that prevention and promotion against needle-stick, along with tools, can create a safe environment for patients and further enhance the quality of the health service care for diabetes.

DISCUSSIONS

The main differences of the design between this insulin-pen-needle-remover and existing needle remover relies on lowering the high risk of getting pricked by the original needle; in contrast, this newly developed insulin-pen-needle-remover could be safely removed from the remover and directly discarded into the disposal bin without recapping with both hands. The great advantages of this insulin-pen-needle-remover include ease for carrying, easy for the users to operate, and preven-
tion of getting pricked and injured. Meanwhile, it is notable that this insulin-pen-needle-remover does have restrictions for the need to take time to produce a product. This requires the decision makers to take into consideration while thinking of the replacements of the original needle with this innovated insulin-pen-needle-remover.

Through the 3D printing technology, there is no need to spend huge capital on mold making and design; that is, people can efficiently make the products processed which are equivalent to plastic injection molding products in terms of fineness, match to patients’ clinical needs, and utilization of such technology to promote the innovation for healthcare in the coming years. The successful combination of 3D technology and materials will bring significant medical contributions and impacts to human health care in the future.

The main challenge encountered in the process of product development is primarily the communication with some manufacturers. Since the safe removal device is targeted at the patients with diabetics instead of the general public, the manufacturers have taken into consideration user restrictions, low production costs, low prices, and relatively small profits. As a result, it is difficult to find a cooperative manufacturer to make molds and to produce the large number of quantity for the final products developed.

APPLICATIONS TO MEDICINE
AND REHABILITATION

The advancement of medical interventions and nutritional levels significantly extend the average life expectancy of people. With the aging, many parts of the human body are prone to become malfunctions. Low-priced 3D printing technology can be applied in a variety of fields and play a vital role. For example, in the field of medicine, it can achieve remarkable feats regarding possibilities and opportunities at the application level, such as printing skulls, cells, living tissues, blood vessels, organs, and bronchi, as well as treating epilepsy and diagnosing and treating 3D printed fetuses. 3D printing technology has be-
### Table 2. Design description of the first generation of the insulin-pee-needle-remover

<table>
<thead>
<tr>
<th>Picture</th>
<th>Illustration</th>
<th>Design description</th>
</tr>
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<tbody>
<tr>
<td><img src="image1" alt="Outside view" /></td>
<td>This is a square structure of 4.3cm*4.3cm. With the groove design for the hole of needle, the pen-needle can be smoothly slid into the hole. Reasons for the square-type design: (1) it can help create a sense of orientation through four corners for users with deterioration of eyesight or blindness, and (2) it does not roll about when slipping out of elderly’ hands.</td>
<td></td>
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<tr>
<td><img src="image2" alt="Plane view" /></td>
<td>By rotating, the friction is generated between the needle and eight recesses of the assist device for needle removal to push out the needle smoothly to separate. Moreover, the downward extending depth of about 1.4mm from the plane of the removal device to the needle is devised, so as to prevent the risk of needle-stick injuries arising from the fingers accidentally touch the plane of the removal device.</td>
<td></td>
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<tr>
<td><img src="image3" alt="Sectional view" /></td>
<td>From the sectional view, it can be seen that the creation is a hollow design, with the reduction of the use of raw materials.</td>
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<tr>
<td><img src="image4" alt="Final product design" /></td>
<td>As research has indicated that the elderly are more sensitive to red and orange, vivid colors are adopted to increase the user’s sensitivity of objects.</td>
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come the darling of the orthopedics field by virtue of its excellent customization. Local medical institutions in the US are attempting to introduce the 3D skull printing into clinical treatment. Moreover, there are also 3D exoskeletons or a pair of 3D printed gloves. This pair of gloves boasts a soft robot actuator, which has the ability to move fingers to assist people who suffer from arthritis, local paralysis, and hand dysfunction with treatment, or play a supporting role in the rehabil-
itation. With the 3D printing technology, you can build a highly adaptable grasping robot, such as robots that have flexible fingers to pick up a piece of vegetable. The research teams on rehabilitation assistance, in particular, endeavor to “lower the price of rehabilitation and ancillary equipment” as one of the ultimate goals. The 3D printed-software robot for assisting the rehabilitation improved only costs 1/1000 of similar products. Therefore, 3D printing can serve an important role for the rehabilitation and medicine in the long run.

Many organizations and experts are using these technologies to make our lives more convenient. For example, Sethu Vijayakumar, the director of the robot technology center at the University of Edinburgh, in collaboration with Touch Bionics, helped to develop a bionic hand that could reduce fatigue and burden. “In order to create the bionic auxiliary system, we have called on many experts in the development of humanoid robots. In cooperation with Touch Bionics, we have developed the ability to grasp the pre-plastic, reduce user fatigue and workload of the intelligence upper limb prostheses. In addition, their researches in gait analysis and bipedal walking open up new doors for the control of exoskeletal devices so that the patients with stroke and the users with lower limb orthosis can be assisted during rehabilitation training with more personalized support”. Such researches will bring benefits to many people such as those with walking problems. In the years to come, 3D printing technology may be applied in the field of medical health to create durable prostheses for patients who lose limbs. Through individual customization, it will bring unprecedented independence and flexibility to users especially if we can provide the patient with affordable compound grasp bionic technology, and test whether this device can benefit and enhance the quality of life, satisfaction, and physical health for the patients.

3D printing can also assist the patients with stroke in home program of the rehabilitation. For example, the occupational therapist Chang Kai developed a hand spreader like "X-Men" that presented patients with stroke or brain damage with an opportunity to re-open their palms. After winning the prize, Chang hoped to find a not-for-profit cooperative manufacturer that could produce reasonably priced 3D- rehabilitation- arms to help more patients. According to his clinical experience, he found that one of the most difficult parts of rehabilitation for the patients with stroke is the hand because the fingers are unable to be opened normally. He got inspiration from the mechanical arm and combined it with 3D printing and stay cord, by which patients wear aids with hand stretching forth and fingers naturally open for rehabilitation. He was declared the winner of the social group for the creation from the “2015 3D Printing Innovation and Application Contest” organized by the National Applied Research Laboratories and other organizations in the hope of encouraging more and more young people to use 3D printing to advance the next generation of manufacturing revolution in Taiwan.

**CONCLUSION**

Through the advance of 3D technology, it can promote innovation, research, development, and application in medical care and rehabilitation-related industries. As noted in this article, the research and development of the insulin pen nee-
dle remover can start a trend of innovative R&D through the 3D printing technology and foster a improved satisfaction and better humane quality of life.

ACKNOWLEDGEMENTS

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運用3D列印於醫療護理與復健器材之創新：
以針頭卸除裝置提升醫療安全性及使用者滿意度為例

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中文摘要

根據研究調查第二型糖尿病人（家屬）居家缺乏胰島素注射針頭卸除的安全防護設備，因此使用筆型胰島素注射器約有七成病人（家屬）曾被針扎過。針扎不僅會造成肝炎、人類免疫缺陷病毒（HIV）和致命性的疾病，也會影響心理健康。本篇的方法包含運用光固化立體造型（stereolithography，SLA）3D列印技術，創新研發胰島素針頭卸除裝置，可將胰島素針頭由卸除器內直接倒入針頭棄置筒內丟棄，達到不需要雙手回套，就能夠安全卸針，營造病人（家屬）安全，降低針扎感染風險更提升糖尿病照護品質。因此，透過3D列印技術的興起，未來能夠推廣於醫療護理與復健的創新，為人類醫療保健帶來重大的醫療貢獻與影響。

關鍵字：3D列印，醫療器材創新，臨床醫護與復健，使用者滿意度

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