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DESIGN AND TESTING OF A NEW MEDICAL RAIL-ADAPTER PRODUCT

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ABSTRACT
Injuries caused by medical device use errors were much more common than injuries resulting from medical device failures. There are many factors that contribute to device use errors such as device complexity or disorganization of the devices themselves. Rail-adapter systems are one way of helping to improve the organization and management of medical equipment. This paper discusses the current state of rail-adapter systems and the development of a new rail-adapter product based on issues in existing products. The performance of the new rail adapter is tested against other products to investigate whether the design updates contribute to real improvements in performance and efficiency for healthcare workers.

Keywords: human factors and ergonomics, product design, health care, medical rail-adapter, hand gesture cognition

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1 BACKGROUND

Working efficiency and effectiveness are important in hospital environments, especially in Intensive Care Units (ICUs). Medical errors are the eighth leading cause of death in the U.S. and injuries caused by medical device use errors were much more common than those resulting from medical device failures(Kohn, Corrigan et al. 1999). Thus medical equipment should be designed to reduce the possibility of making mistakes by nurses and other users.

There are many factors involved that contribute to medical device use errors, such as excessive complexity of the user interface or tangled cords that reduce efficiency. This paper focuses on human factors issues of medical equipment. Widely established human factors and ergonomic principles have been slow to be integrated into healthcare environments(Wears and Perry 2002). Even in well-equipped environments such as a modern ICU, the poor application of these standards can endanger patients by making equipment more difficult to use. Wears and Perry give an example of a patient taken to a Computed Tomography suite. There were many human factor problems with the equipment in the room. The organization was weakly designed, meaning that equipment was commonly placed wherever someone had used it last. This made it difficult to find particular equipment when it was needed. The operating mechanisms of some equipment were also complex. It was easy for operators to omit crucial steps while using the devices, especially in high stress situations where there are many distractions and interruptions.

Medical rail adapters can be introduced in order to manage medical equipment more easily. They have been widely used in US hospitals, especially in ICU rooms. Their main purpose is to improve the flexibility of the medical equipment. Prior to the introduction of these systems, medical equipment was typically mounted directly on a wall. This could lead to issues when either a patient needed to be moved along with devices currently in use or when devices in a fixed location needed to be brought to a patient. Finding ways to transfer medical equipment and to lock it into a certain position when needed is of vital importance. Ideally a rail-adapter system solves these problems by allowing equipment to be hung on the rail by an adapter. The adapter is usually a small mechanical mechanism that can be hung on the rail that is fixed on the wall (Figure 1). The adapter gives nurses or caregivers to easily reposition equipment to fit individual situations. Equipment can also be easily removed, added or moved by moving it from one rail system to another as needed.

Figure 1. A typical rail-adapter system

In general there are three main functions of the medical rail adapter product: mounting, sliding and removing. For a regular rail, there are two groves on the top and a bottom side (Figure 2). The adapter is locked into place when the flanges stick into the groves of the rail. This prevents the adapter from jumping out from the rail by accident. The tightness of the adapter determines whether the adapter can slide on the rail. If it is attached tightly it will not slide. If it is attached loosely then it will not maintain a stable position. To prevent the flanges from getting stuck in the rail's grove, there must be a mechanism that allows the flanges to cross the groove in the rail when making adjustments before fixing them together.

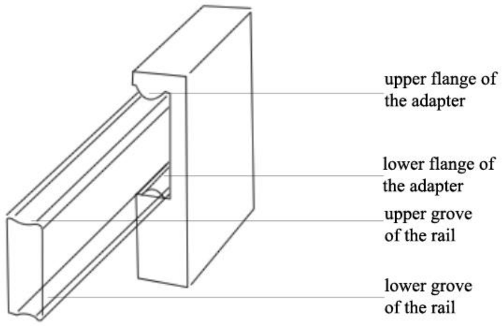

Figure 2. The detail of a rail-adapter system

Rail-adapter systems can use a variety of mechanisms to allow adjustments. One such design is an adapter with a button switch on the bottom to lock equipment on the rail (Schindele 1977). A user just needs to turn a switch to unlock the equipment to adjust or remove. A different rail-adapter system design utilizes a knob on the bottom of the adapter. The knob is rotated to lock the adapter into place after the equipment has been positioned on the rail. In either of these cases, the button or knob can be difficult to reach and operate with a hand if the mounted equipment is large or bulky. Yet another approach utilizes a pair of blocks on each end, which confines the adapter to the rail, allowing it to slide smoothly (Miller 1989). It also utilizes a knob on the bottom to allow the adapter to be locked into place once it is in the desired position. This locking mechanism can also be difficult to reach and operate if the equipment is large. Infection control can be problematic due to the difficult in cleaning the gaps between the rail and adapter. Confining the adapter to the rail can also make this approach less flexible by limiting the working area.

A system designed to improve nurses' working efficiency, utilizes a spring and nylon ball inside the adapter to replace the bottom flange (Bally, Kato et al. 2002).This mechanism allows the adapter to be adjusted without requiring any additional action on the user's part to lock it in place. A problem users may encounter with this system is that the angle between the upper flange of the adapter and upper grove of the rail can be hard to find. If the angle is not correct, it is impossible to attach the adapter to the rail. Another is that the spring locking mechanism is not as strong as the button or knob types and may not always be able to hold the adapter securely in the desired position. The spring mechanism provides good audible feedback when it is locked, however this can be too noisy for some environments.

2 DESIGN OF A NEW MEDICAL RAIL ADAPTER

To address some of these outstanding needs, a project was undertaken by two graduate industrial design students to re-design the medical rail-adapter based on the spring and nylon ball rail-adapter system. Additional needs were gathered through interviews with doctors and nurses who currently work in hospital environments:

- Moving a medical device involves performing multiple tasks, such as arranging cables and cords before removing a rail adapter. These extra steps increase the time needed to perform the task. If multiple tasks are performed together it can lead to mistakes(Owen, Fitzmaurice et al. 2005). A new rail adapter should be natural to manipulate and not add to the user's cognitive load.
- Some rail adapters lock equipment into place by using screws. This requires the assistance of maintenance people to move equipment. A new rail adapter should not require special tools to lock/unlock equipment.
- A common need is the ability to move equipment vertically to accommodate users of different heights. A new adapter should work on both vertical and horizontal rails.
- The new adapter should have as few gaps as possible to reduce the possibility of contamination.
- The operation of the new rail adapter should not fatigue a user's wrist and upper body. Repetitive actions involving wide angles of motion (Radwin and Smith 1993).

The final design of the new rail adapter is shown in Figure 3. It consists of four main parts: the back, spindle, middle and front. The back is made of aluminum and covers the inside body to prevent contamination. The spindle is made of nylon. It is contained in the middle part and is connected to the front with screws. There is one raised part on the spindle. When the adapter is not in use, this part is hidden within the adapter. The front piece is used to mount the medical equipment. When the user rotates the connected equipment by hand, the front piece of the adapter will be activated; meanwhile the spindle will rotate along with it so the raised part will rise up and prevent the adapter from falling from the rail.

To simplify the locking process and reduce cognitive load when adjusting or moving equipment, the adapter uses natural gestures instead of a button or knob, both of which require a learned mental step to ensure the adapter is locked. Specific gestures are linked to a person's cognition of a particular function. Gesture recognition is an easier and safer way to help user interact with machines (Pickering, Burnham et al. 2007). The new adapter does not require an extra step for people to lock the adapter on the rail. When a user wants to hang a medical device on the rail, the first step is to tilt the medical device clockwise about fifteen degrees then attach the adapter to the rail. Since there is no flange in the adapter it goes across the rail's grove smoothly. Once the adapter is attached a fifteen degree counter clockwise rotation to bring the medical equipment back to vertical is all that is needed to lock it in place, similar to locking a door by rotating the handle (Figure 4 and 5). By using a natural gesture to lock the adapter, the user does not risk omitting steps in a procedure (such as forgetting to lock the adapter) in stressful or distracting situations.

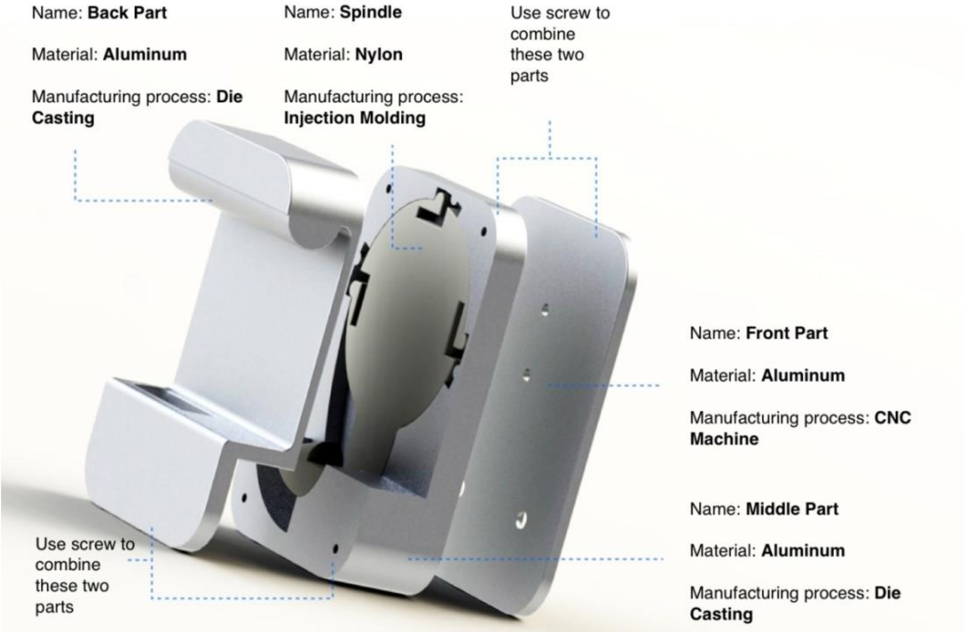

Figure 3. Exploded view of the new medical rail-adapter.

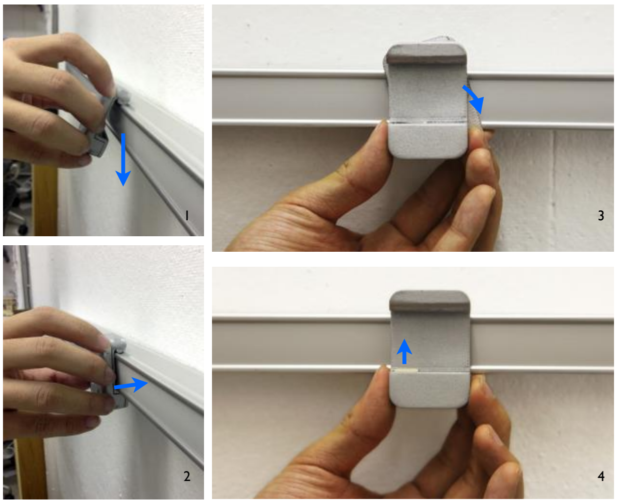

Figure 4. The operational steps of the new adapter (frame 3 and 4 show the back side of the adapter)

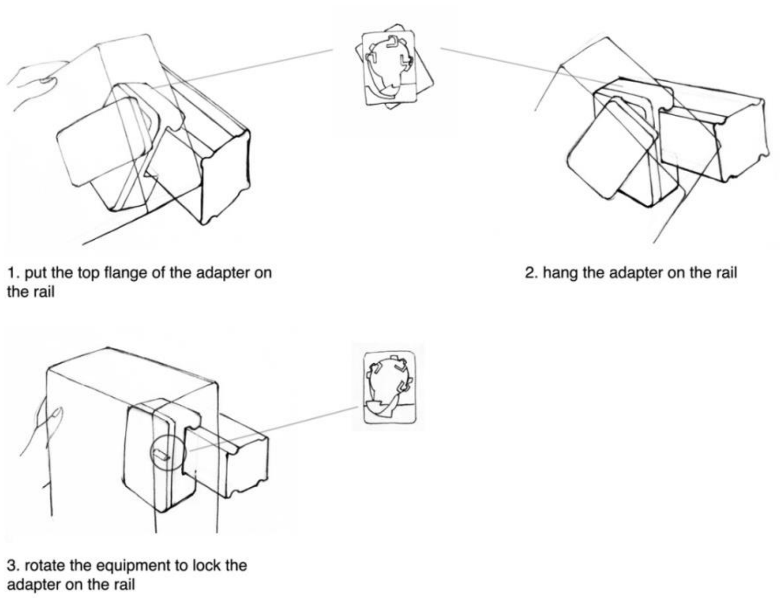

Figure 5. Illustration of the operational steps of the new adapter

The new design gives the user clear feedback about its status. Inside the adapter, there are three gears on the spindle and there are three gaps and bumps on the main body (Figure 6). When the spindle is rotated, the gears will go across the bump and go into the gap, which will gives user soft audible and a little force feedback in order to reduce sharp noise while inform that the adapter is locked on the rail.

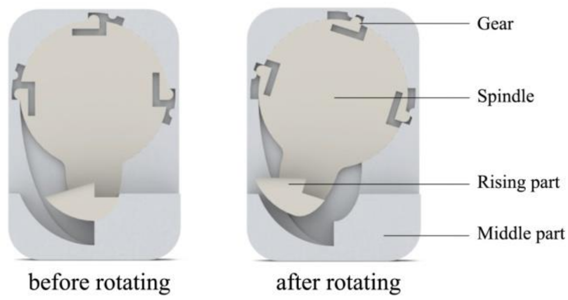

Figure 6. The spindle mechanism within the adapter

The new adapter design is suitable for both horizontal and vertical rails. Since the locking mechanism is inside the adapter, it can easily be locked on the rail in either orientation. To change location, a user simply needs to rotate the adapter a small degree to allow it to slide along the rail.

3 METHOD

A usability study was conducted to compare the newly designed adapter along with an existing adapter that incorporates a spring and nylon ball method for manipulation/adjustment. The adapters were evaluated by nurses with experience using rail adapters. Each participant independently performed a set of tasks with each of the adapter systems:

- Find the proper angle to mount the adapter on the rail.
- Judge from evidence to see whether the adapter is locked on the rail.
- Find a solution to unlock the adapter while the adapter is still on the rail.
- Attach the adapter while make as few noise as possible.
- Use one hand to take off and transfer the medical equipment with the adapter to another location.

The first task focused on the locking mechanism and whether the participants can perform the task correctly with the new adapter. The second task focused on whether the adapter provided enough feedback to the user to inform user about its status. The third one was used to test whether the user knew how to reverse action. The fourth task focused on examining whether the adapter could eliminate noise while maintain providing enough feedback. The last task was used to test whether the new natural gesture follows participants' cognition and reduces the possibility that participants make errors. Following the completion of the tasks with each adapter system, each participant completed a survey. The survey focused on aspects of consistency, visibility, memory, feedback, flexibility, errors, and control (Hildebrand, Branaghan et al. 2010).

4 RESULTS

Five participants completed the usability test and survey. All of the participants were female nurses working who currently work in an intensive care unit. All of the participants had several months to several years experience using medical rail adapters. The survey examined numerous aspects of the rail-adapter (results shown in Figures 7) including:

1) Was it easy to learn to use
2) Was it easy to use
3) Was it reliable
4) The level of satisfaction with the functional features of the adapter
5) Is the new adapter preferred over existing adapter designs

For the aspect of "easy to learn", 40% of the respondents chose the original adapter over the new design for the reason that: 1) The method of operation of the original adapter is easy to remember; 2) There are fewer steps of the original adapter than the new design. They thought the new design is hard to learn because that the locking and unlocking mechanism was complex. Meanwhile, 60% of the respondents considered that the new design is easier to learn because the shape of the new design itself was intuitive.

When participants were asked to rank the two adapters based on ease of use, 80% of the respondents preferred the new design to the original one. The main reasons cited were strength required to use the new adapter and the feeling of control. All the participants who preferred the new design thought that it requires less strength to use and that they had total control of the adapter while using it. 50% of the participants who like the new design also indicated that the new design's mechanism do not get in the way during operation. Only 20% of the participants thought the old design was easier to use than the new design. This was mainly due to familiarity with the original one.

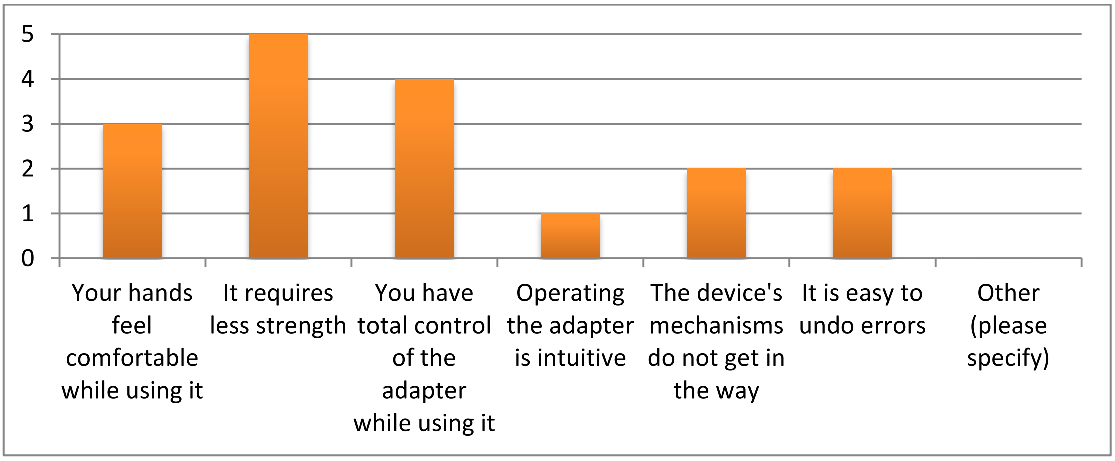

Figure 7. The aspects that make the new design easier to use

For reliability, all of the participants thought the original adapter was more reliable than the new design. 40% of the participants indicated that the operation of the new adapter did not feel reliable.

User satisfactions toward certain features were measured on the survey on a 5 point Likert scale. The original design was labeled Adapter A and the new design was labeled as Adapter B. The features included shape, operating method, locking mechanism, material and feedback. The results (Figure 8) showed that participants prefer the shape (mean: 3.80 median:4.0) and operating method (mean:4.0, median:4.0) of the new design to those of the original adapter (shape: mean: 2.8, median: 3; operating method: mean: 2.6; median: 2.0).

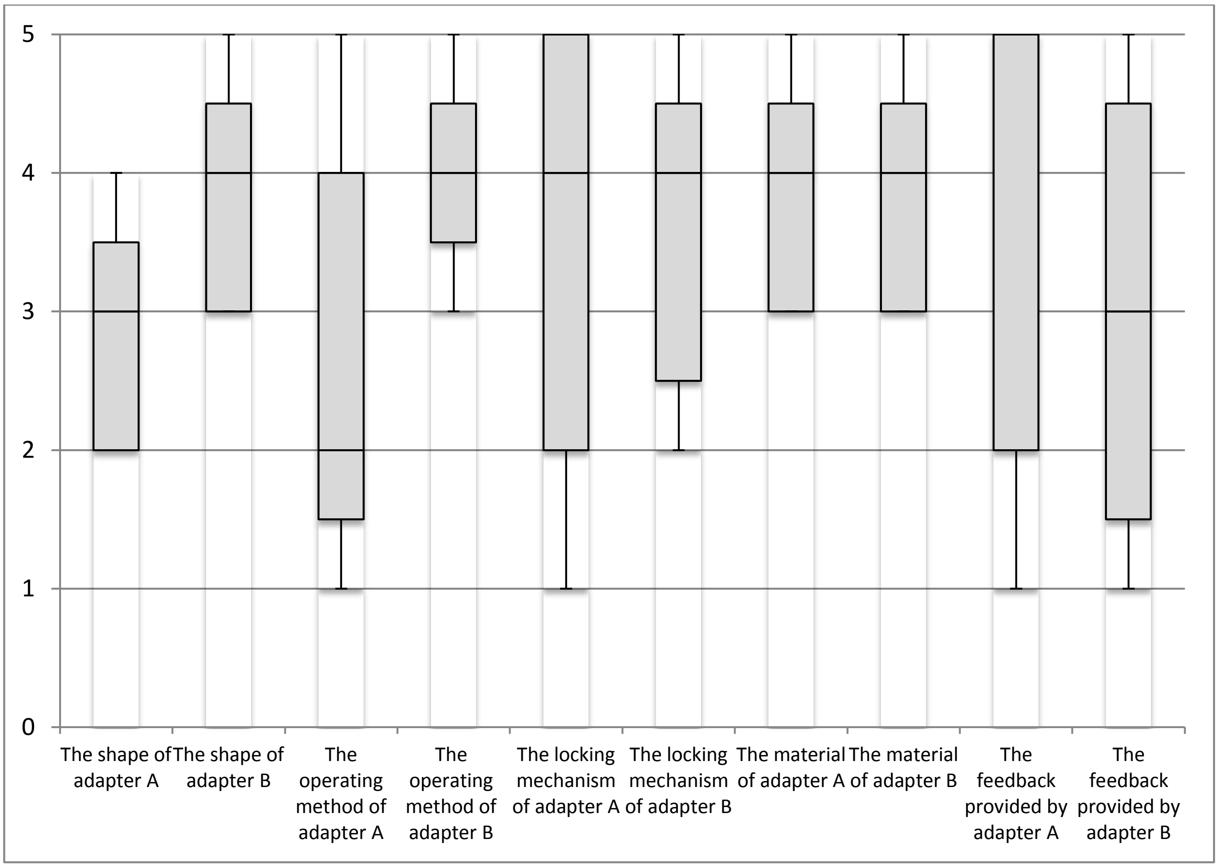

Figure 8. The mean and median value of the two adapters in several aspects. Adapter A is the original design and Adapter B is the new design.

80% of participants said that they would like to use the new design in the long term. The other 20% of the participants said that they would need to use the new design in real life for a period of time before they could make decision.

5 DISCUSSION

Since all the respondents came from the ICU nurses who have used medical adapter before, our data reflects direct user's perspective.

According to the survey result, participants thought it was easier to learn how to use the new adapter than the original one because of its intuitive shape, which indicates that the two separated pieces design provides user a good affordance so that the users know how to use it by its appearance. In this way, it can reduce user's memory load. This result also correspond with the like scale result, participants tend to rate higher score on the shape of the new design than the original one.

Moreover, respondents regarded the new design as easier to use, for the reason that the new one requires less strength and they have total control of the adapter while using it. Since our design aims at reducing the force when user are using it in the first phase, the result proved that our design accomplish this goal. The result also reflects that using a twisting mechanism instead of a total manual force provides user a better control of the device. Users can easily reverse their action and can easily find the proper angle to lock or unlock the adapter on the rail. This result is also supported by the likert scale result, which showed that participants graded higher score on the operating method of the new design than the original one.

However, even though the results support for the new design, there are some factors and issues need to be solved in the next step. All the participants have been using the medical rail adapter. It somehow affects the usability results. One participant stated that the original was easier to learn because she was more familiar with when she was asked to rank the two adapters based on "easy to learn" criteria. A group with no prior experience using medical rail adapter might be needed. Another issue has to do with the perceived reliability of the new adapter. Due to time and cost limits, the new design was a fully functional prototype but the build quality was less than that of the original adapter, which is a commercially available product. Even though some parts of the new design have been improved to allow good performance, it is not necessarily as sturdy as an existing product. This appeared to have an effect participant's judgment when comparing the two adapters.

The new design succeeded in giving users a better natural indication of how it operates. It required less strength to operate and thus enhances a user's control of the adapter. This also allows improvements in user satisfaction with the operation of the new rail system compared to the current one. Future testing will need to involve novice users with no experience with rail adapter systems to better evaluate the ease of learning with the new design. A more robust prototype will also be needed so that it more closely matches build quality of commercially available rail adapter systems.

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