

Standardizing the Delivery of 20 μ L of Hapten During Patch Testing

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Background: The current method for patch test tray assembly requires hand dispensing a small volume of hapten onto chambers. Because of human error, this technique produces inaccurate and inconsistent results. The recommended volume of hapten for patch testing using Finn Chambers is 20 μ L.

Objective: The aims of this study were to create a device that standardizes the delivery of 20 μ L and to compare it with the current hand dispensing technique.

Materials and Methods: A device, named the Revolution, was created using the SolidWorks program. Five nurses in our Contact Dermatitis Clinic were asked to load 10 Finn Chambers using the current technique and also using the Revolution. Assembly time, volume of petrolatum, and accuracy of placement were measured. After the 3 trials, the nurses completed a survey on the 2 methods.

Results: The amount of petrolatum dispensed using the current technique ranged from 16 to 85 μ L, with an average amount of 41.39 μ L. The Revolution design dispensed an average of 19.78 μ L.

Conclusions: The current hand dispensing technique does not allow for accurate and consistent dispensing of 20 μ L for patch testing. In contrast, the Revolution is an accurate and consistent device that can help standardize the patch testing method.

In 2007, a study was published suggesting that 20 μ L is the optimal dose for 8-mm Finn Chambers on the basis of the chamber volume.¹ Because of human error, dispensing this specific amount is extremely challenging using the current hand dispensing technique. The varying amount of hapten dispensed is a well-documented problem with both interindividual and intraindividual differences.^{1–3} Variations in the amount of hapten used in patch testing can interfere with the validity of the test. Excess hapten has the potential to leak into adjacent chambers, causing cross-contamination of multiple allergens.⁴ An insufficient amount of hapten may lead to false-negative patch testing results. These issues demonstrate a clear need for standardization of the current hand dispensing technique (Fig. 1).

METHODS

Design of a Device

The Revolution is designed to dispense a volume of 20 μ L with each complete 360-degree revolution (Figs. 2–4). Two separate

pieces are involved in this device, including an externally threaded plunger and an internally threaded part that clips onto the barrel of a 1-mL syringe to match the external threads. The most important aspect of the design is the pitch of the threads, which determines the distance the plunger will depress. After testing the vertical distance that the 1-mL manufactured plunger depresses when dispensing 20 μ L, it was determined that the average distance was 1.14 mm, which was then translated to the pitch of the threads to equate 1 revolution to depressing 1.14 mm. This pitch was transferred onto the externally threaded plunger using the SolidWorks program. The internally threaded piece is shaped as an ellipse to sit over the wings of the barrel and snaps on top through the use of 2 clips on the underside of the part, tailored to securely fit the barrel. At the top of the plunger, there is a knob for ease of use with an arrow to properly indicate rotation of 1 revolution. Together, the 2 parts give an accurate and efficient design.

A 1-mL syringe was used because of the intricate pitch of the threads. Thus, the device requires the transfer of the allergen from the 5-mL syringe into the 1-mL syringe (Becton, Dickinson and Company). Once the transfer occurs, the device can be stored for up to 50 uses if the user dispenses 20 μ L with each delivery.

Study Method

Five nurses in our Contact Dermatitis Clinic participated in the study. Each nurse was asked to load 10 Finn Chambers using a

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Figure 1. Image taken from a typical day in our patch testing clinic showing the large variation in the amount of allergen that is dispensed.

standard 5-mL syringe filled with petrolatum. Assembly time, volume of hapten, and accuracy of placement were measured for 10 chambers on a single piece of Scanpor tape (Norgesplaster A/S, Vennesla, Norway). This trial was repeated 3 times. The process was then repeated with the Revolution device. The standard deviation between nurses and between different trials was measured.

After the 3 trials for each device, the nurses completed a survey on the current technique and the Revolution design. The survey consisted of 10 questions that were specific to the usefulness and accuracy of the device (Fig. 5).

RESULTS

There was a large variation in the amount of allergen dispensed using the current technique (Table 1). The amount dispensed ranged from 16 to 85 μL , with an average amount of 41.39 μL . The standard deviation between nurses was 8.80 μL , and the standard deviation between trials was 11.95 μL .

The Revolution design delivered an average amount of 19.78 μL . The standard deviation between trials and between nurses decreased to 2 μL (Table 1).

The average time to deliver 10 trays using the current technique was 71 seconds. The average time to deliver 10 trays using the Revolution device was 82 seconds (Table 2).

The current technique scored higher than the Revolution design in 1 question, tied in 2 questions, and scored lower than the Revolution in the other 7 questions (Fig. 5). Both methods received an overall score higher than 2.5. The Revolution design received the highest total score overall (Fig. 6).

DISCUSSION

The average amount of allergen delivered using the hand dispensing technique is more than double the amount that is recommended. The excess allergen has the potential to leak into adjacent chambers, causing confusion for the physician who reads the results, which ultimately leads to lack of standardization. The large variation between nurses and also between trials using the current hand dispensing technique highlights the difficulty the nurses had in consistently loading a specific amount of allergen. In contrast, the Revolution design delivered an accurate amount, and the standard deviation was minimal, demonstrating the nurses' ability to consistently deliver the desired amount.



Figure 2. Horizontal view of an externally threaded plunger inside of a 1-mL syringe and an internally threaded cap that clips onto the syringe.

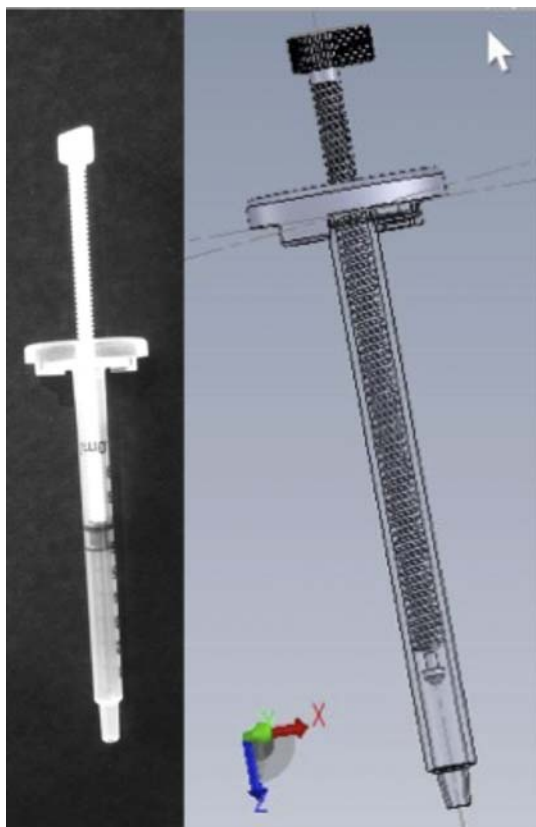


Figure 3. The 3-dimensional-printed Revolution device (left) and the SolidWorks design of the Revolution device (right).

There is an 11-second difference in loading 10 Finn Chambers between the 2 methods. Because the American Contact Dermatitis Society recommends an 80-hapten panel, this would equate to an extra 88 seconds to load a typical tray using the Revolution device.⁵ Note that this does not take into account the time it takes for the initial transfer of allergen from the 5-mL syringe into the 1-mL syringe.

The Revolution scored less than the current technique in 7 of the 10 questions that addressed the accuracy and consistency of the

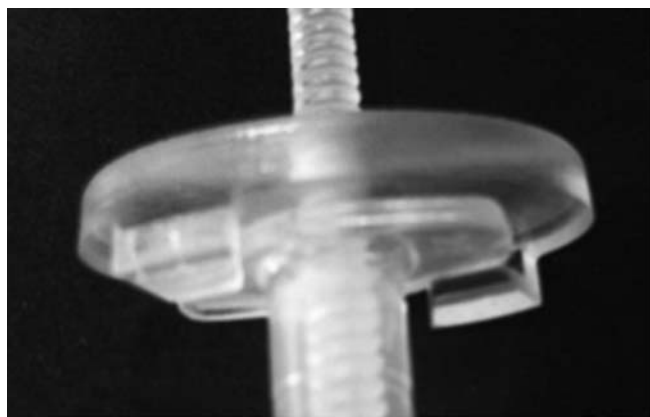


Figure 4. Internally threaded cap that clips onto the 1-mL syringe.

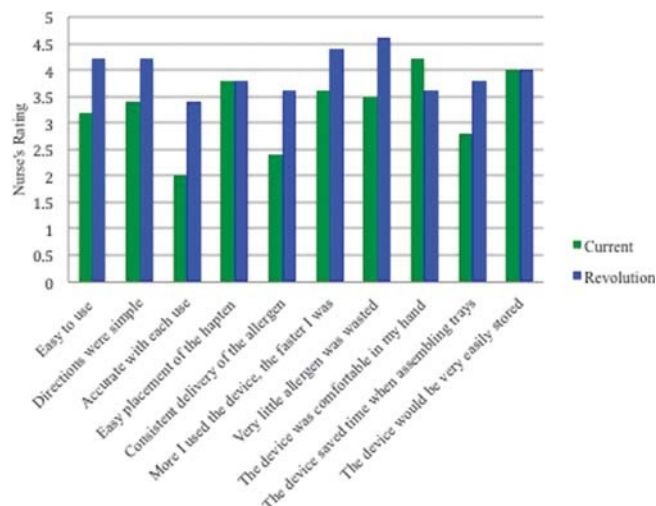


Figure 5. Average score given to each question by the 5 nurses in the clinic based on a 5-point scale, with 5 being highly agree and 1 being highly disagree.

2 methods, and overall, the Revolution scored higher than the current method for hapten loading.

CONCLUSIONS

The current hand dispensing technique is not accurate and does not allow consistent delivery of 20 μ L. The nurses at our clinic dispensed an average of 41.39 μ L with a large variation between

TABLE 1. The Average Hapten Dispensed by Device

	Current Technique, μ L	Revolution Device, μ L
Nurse 1	37.80	20.23
Nurse 2	50.59	19.69
Nurse 3	35.99	19.38
Nurse 4	33.29	19.58
Nurse 5	49.29	20.04
Average amount	41.39	19.78
Standard deviation between trials	8.80	2.19
Standard deviation between trials	11.95	2.10

Results are displayed for each nurse during the 3 trials of loading 10 Finn Chambers, with standard deviation.

TABLE 2. The Average Time It Took Each Nurse to Load 10 Finn Chambers During the 3 Trials for Each Device

	Current Technique, s	Revolution Device, s
Nurse 1	66	91
Nurse 2	92	84
Nurse 3	86	84
Nurse 4	54	82
Nurse 5	56	71
Average	71	82

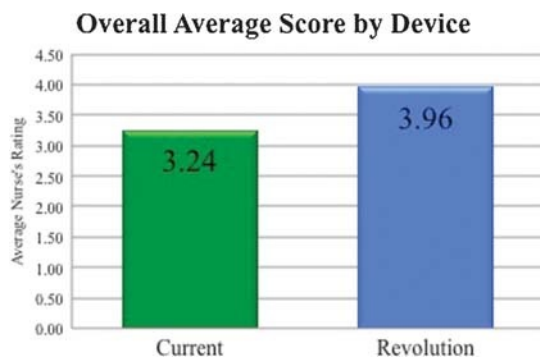


Figure 6. The overall average score given to each device by the 5 nurses in the clinic.

nurses using the hand dispensing method. The Revolution dispensed an average of 19.78 μL with a small variation between nurses. The Revolution design is accurate and consistent and

received the highest total composite survey score. The Revolution design has the potential to solve the current consistency problem in hapten delivery.

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