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Araştırma Makalesi

Design Error and Solution in Dry Powder Inhalers

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Abstract: In this study, the design errors of dry powder inhaler devices that have been used for many years, and their solutions depending on these errors were investigated. For this study, the most recommended inhaler devices by doctors, and the most frequently used by patients are provided. The effective use of the device and the problems that arise during its use have been observed on many patients, and a newly designed inhaler device has been developed considering the emerging problems. Observations have revealed hesitations for patients to switch to the newly designed device due to old habits. However, in the studies conducted on patients who switched to the new design device, it is seen that there is a serious time reduction in the treatment processes if the device is used correctly.

Key words: Powder inhaler, Respiratory system, Capsule blasting, Oral cavity, Patient

Kuru Toz İnhalerlerinde Tasarım Hatası ve Çözümü

Öz: Bu çalışma da, uzun yıllardır kullanılan kuru toz inhaler cihazların tasarımsal olarak hataları ve bu hatalara bağlı olarak çözümleri araştırılmıştır. Bunun için doktorlar tarafından en çok tavsiye edilen ve hastalar tarafından en sık kullanılan inhaler cihazları temin edilmiştir. Cihazın etkin kullanımı ve kullanım esnasında ortaya çıkan sorunlar bir çok hasta üzerinde gözlemlenmiş ve ortaya çıkan sorunlar dikkate alınarak yeni dizayn bir inhaler cihazı geliştirilmiştir. Yapılan gözlemler, alışkanlıklardan dolayı hastaların yeni dizayn edilen cihaza geçmelerinde tereddütler ortaya çıkarmıştır. Ancak, yeni dizayn cihaza geçen hastalar üzerinde yapılan araştırmalarda, cihazın doğru biçimde kullanılması halinde tedavi süreçlerinde ciddi bir azalmanın oluştuğu görülmektedir.

Anahtar kelimeler: Toz inhaler, Solunum sistemi, Kapsül püskürtme, Ağız boşluğu, Hasta

1. Introduction

Today, active substances suitable for inhalation are applied in the treatment of many respiratory diseases, especially asthma and chronic obstructive pulmonary diseases [1-3]. Various inhalation devices have been designed to ensure adequate delivery of these active substances to the patient. Inhalation devices in which the drug in dry powder form is contained in a capsule generally consist of a mouthpiece, body, and capsule piercing parts [4]. The dry powder inhaler (DPI) has been used commercially since 1971

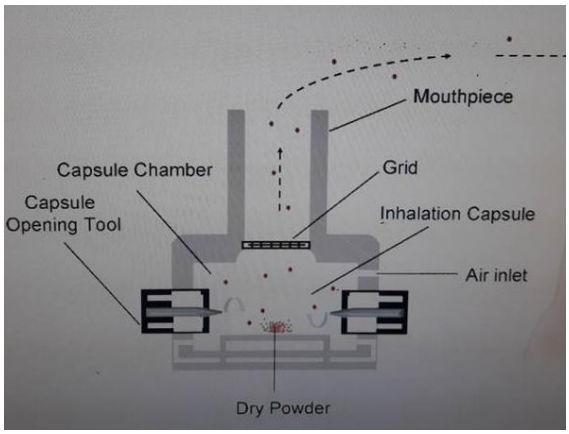
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and is continuously being improved and updated with new models [5,6]. Corresponding to this, Matida et al. [7] showed that the motion of the emitted particles and their deposition in the respiratory tract depends on their velocity, position, and size at the mouthpiece outflow. In addition, studies showed that not using an inhaler optimally (poor device compatibility) can result in very low drug delivery to the lungs, resulting in failure of drug delivery [8,9]. On the other hand, not providing enough or no inhaler device training to patients, cognitive or physical disability of the patient, not choosing the appropriate device for the patient, or misuse are very common among patients [10].

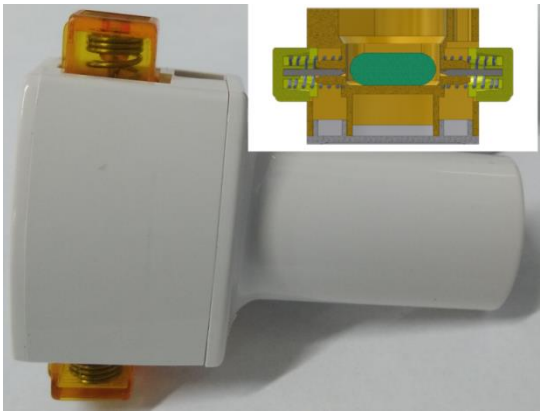
DPIs are the most widely used devices. The common feature of these devices is that they always spray the same amount of medicine with a single push or pull. For this reason, a very good patient cooperation is required for it to be effective. Studies showed that as a result of the low force application of the patient, the capsule does not burst and the drug cannot be used properly [11,12]. Thus, in order to eliminate these disadvantages, one-button detonation device should be developed and new structures should be made. In the present study, the results of an economical new inhaler device that increases the effect of the drug and minimizes patient-related misuse by opening opposing holes with a single button were investigated. In other words, this study investigates the effect of modifying the design of a dry powder inhaler on the device performance.

2. Materials and Method

In order to prepare the drug for inhalation in inhalation devices, the capsule is pierced with piercing tools and the dry powder drug contained in the capsule is inhaled through one or more holes in the capsule. In addition, in this device, the capsule piercing process is carried out with double compression (double spring). However, since many patients cannot press the double-press keys equally, the capsule cannot be properly pierced with two holes. Fig.1 shows the most widely used double-push model in our country.



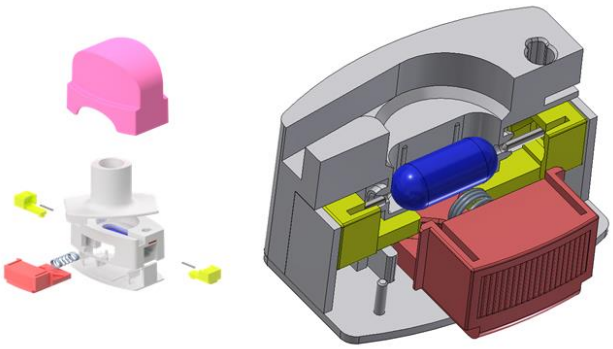
(a)



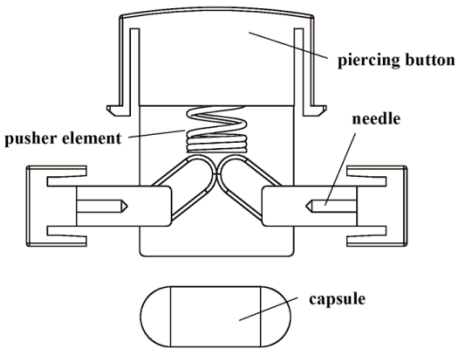
(b)

Figure 1. Double-button dry powder inhaler, (a) schematic view, (b) general view of device

Studies show that the capsule is not punctured properly because the applied force is not sufficient and appropriate at this double-push model. As a result, the drug is not taken at an adequate level and the device is far from being economical. To eliminate these drawbacks, in the our research laboratory (BIMED), we have improved it by adding a new part to the existing device used double-push model in our country so that the capsule can be pierced more effectively with low force (Fig. 2).



(a)



(b)

Figure 2. Modified one-button dry powder inhaler, (a) general view, (b) components of device

As seen from Fig. 2, the device turned into a one-button punching device. In the new device, with a new movable part created using a single spring, the two piercing needles of the two-button device pierce the capsule by moving simultaneously and evenly. Finally, by equalizing the force on the piercing needles, the capsule is pierced with a suitable and lower force.

3. Results and Discussion

Recently, intensive studies have been carried out on the performance of dry powder inhaler device [13-15]. Corresponding to this, Ding et al. [16] showed that there is a correlation between capsule material properties, powder formulation properties, and device engineering and design which might have a direct impact on the product performance and hence, the therapeutic effect. In addition, it has been shown that the piercing profile of the capsule in the device depends on ambient moisture content and storage temperature [17, 18]. Figure 3 shows capsules punctured by plastiape, panthero dry powder inhaler (double button), and our modified dry powder inhaler by BIMED (one button device).

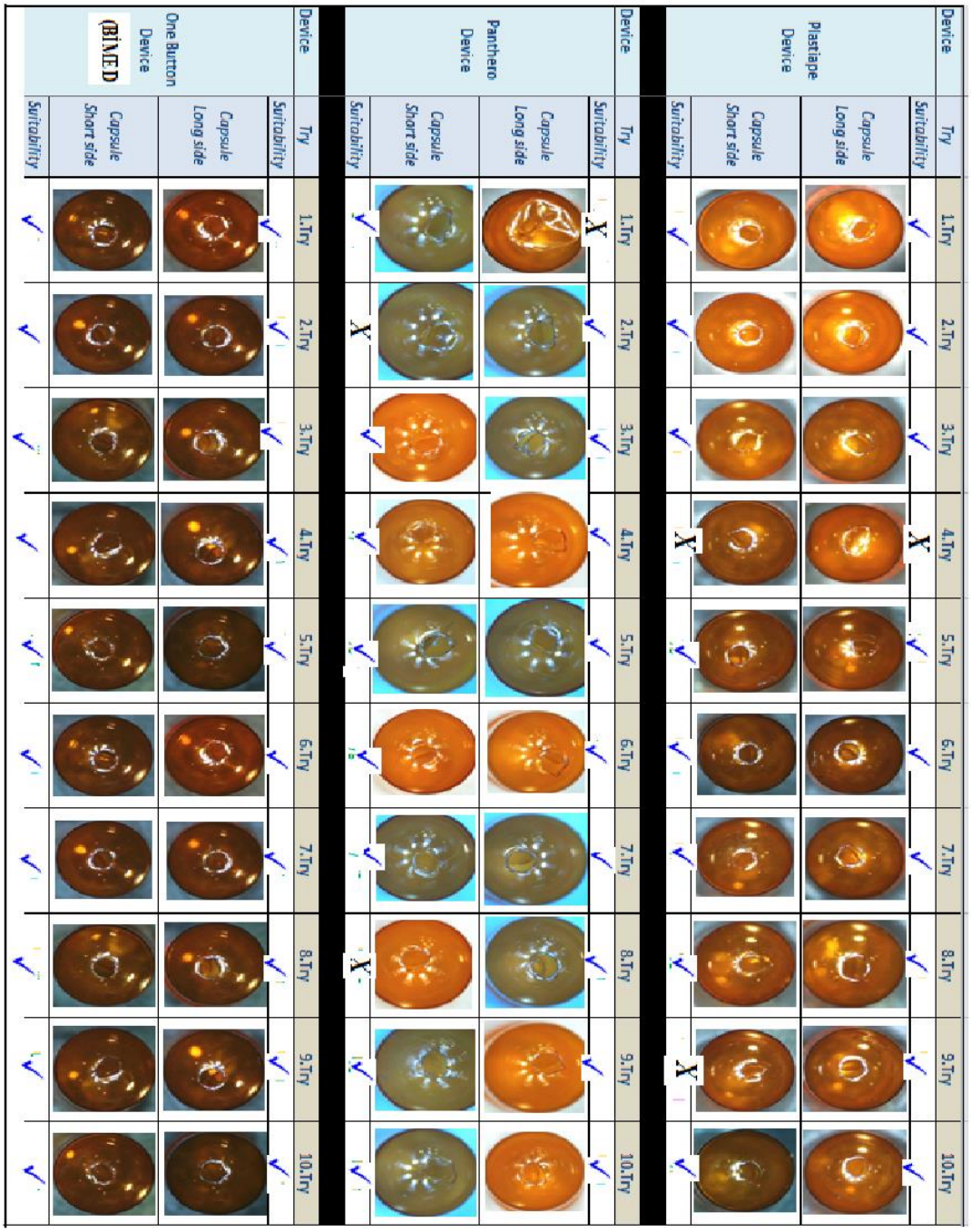


Figure 3. The view of punctured capsules of different dry powder inhalers

As can be partially seen in Figure 3, after hundreds of trials, we came to the conclusion that some capsules were not properly pierced plastiape, panthero dry powder inhaler, but all capsules were properly pierced when our modified device was used. This result shows that our modified one button dry powder inhaler device is more efficient and more economical than others. To sum up, one can conclude that the performance of a dry powder inhaler depends on properly drilled as well as the air and particle flows in the device. In other words, errors caused by the user (such as a finger showing little pressure) are eliminated by modified one-button dry powder inhaler are eliminated.

In the preset study, the force measurements required to pierce a capsule were performed with the Zwick/Roell universal testing machine up to 500 N. The force required to

pierce a capsule with plastiape, panthero dry powder inhalers was 11.14 and 13.28 N, respectively. In addition, with these plastiape and panthero dry powder inhalers, the needle needs to travel 7.90 and 9.14 mm to pierce a suitable capsule (Fig. 4). These values are 8.72 N and 3.78 mm for our modified dry powder inhaler device, respectively. Kuentz et al. showed that increasing the force required to pierce a capsule may have negative influences on aerosol performance [17].

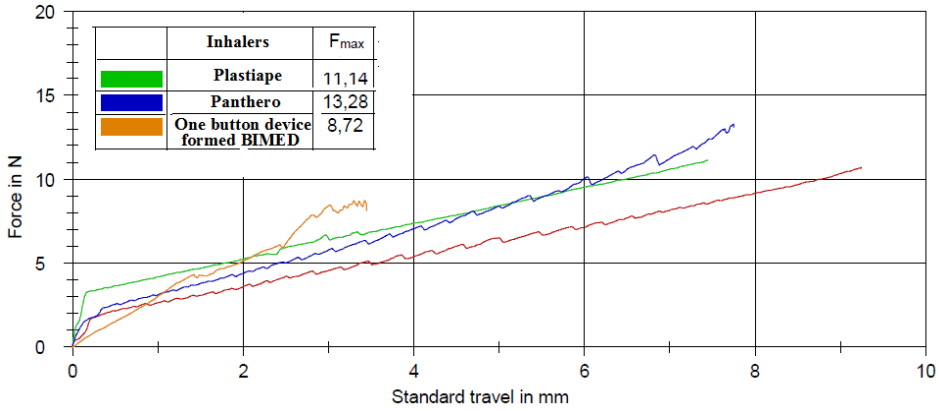


Figure 4. Force and needle travel required to puncture the capsule

Moreover, the measuring the inhaled airflow through the inhaler allows information on whether the drug was released within the optimal window of the inhalation cycle to be accurately. In this study, the airflow volumes of the plastiape dry powder inhaler (double button) for the inhaler of the domestic market and our modified dry powder inhaler (one button) were measured visually. These measurements were performed with a device developed by BIMED (Fig. 5).

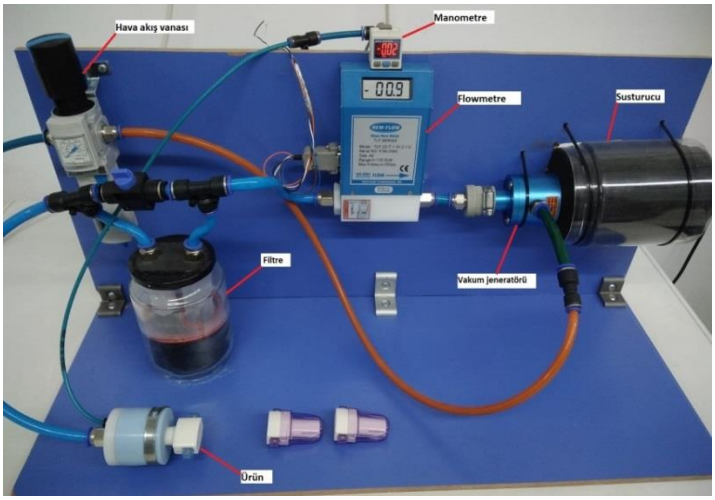


Figure 5. Air flow tester developed by Bimed

In literature, device resistance measurements indicated that the type of films, type of device geometry, and specific device dimensions significantly affect the airflow resistance of the device [19]. In this work, while the flow rate of the air passing through the flow volume under 4 kPa pressure of the original products (double button-plastiape dry powder inhaler) with a flow rate of 100 liters per minute (l/min) is 96.9 l/min, this value is an average of 95.1 l/min for the device modified dry powder inhaler (one button

dry powder inhaler). The results showed that there is no significant difference in airflow volumes in between one and double button dry powder inhalers.

4. Conclusion

Based on the experimental results, the following main conclusions can be drawn:

- With our modified dry powder inhaler device, the effect of the drug can be increased by performing a much more convenient drilling process compared to the others.
- It can be easily used by every patient due to its single-push function.
- The device can properly pierce the capsule with a much lower force.
- There is no significant difference in airflow volumes.
- This work will allow the production of more advanced dry powder inhaler devices.

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Author Statement

Adnan Çalık: Conceptualization, Methodology, Resource, Material, Instrument Supply.
Nazim Uçar: Writing, Reviewing and Editing
Yalçın Can: Investigation

Conflict of Interest

As the authors of this study, we declare that we do not have any conflict of interest statement.

Ethics Committee Approval and Informed Consent

As the authors of this study, we declare that we do not have any ethics committee approval and/or informed consent statement.

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