INTRODUCTION

Current FDA guidelines for nasal spray products recommend the use of automated actuation systems that replicate actual patient actuation parameters in vitro testing of similar characteristics. Risk and industry research indicates a strong correlation between the parameters used to control automated actuation systems and the in-vitro performance of nasal spray products. The user’s age and physical challenges are likely to be determining factors in the usability and performance of these products. The current study shows how high-resolution measurements of human usage (“ergonomic data”) of a commercially available nasal spray pump device vary between different age groups of people, including the effect of dominant vs. non-dominant hand, and how these ergonomic data are related to in-vitro performance.

METHODS

Study Design:
Rheum healthy adult volunteers (described in Table 1), covering young (post-teen), middle-age and senior groups, actuated to nasal spray using their dominant and non-dominant hand (20 times each) into a spray collector; the spray collector was weighed before and after each spray using an analytical balance. Each volunteer’s dynamic actuation was measured automatically in 60 s sampling frequency using the patented ErgoSensor (Proven Scientific Corporation, Marlborough, MA) shown in Figure 1. The Ergo-generated data (ergonomic data) includes the real-time position, velocity and acceleration levels applied by the volunteers to actuate the device. The ergonomic data were statistically analyzed using the ANOVA and Tukey-Kramer test (Table 2). The Otoscope and SprayPattern data were recorded (Table 3).

RESULTS AND DISCUSSION

Determination of Actuation Parameters:
All 15 male and female volunteers were able to use the device as intended. The largest differences between the dominant and non-dominant hand actuations were in the case of velocity for users aged 46-59 years old and acceleration for users less than 40 years old. The resulting flow rates were (1) 20% in all age groups, the non-dominant hand required more actuations to prime the device; (2) the largest difference in droplet size distribution between the dominant and non-dominant hand actuations came from the middle-age group; and (3) the spray pattern data did not show major differences between any of the data sets.

The results from the dialing studies for dose weight, droplet size distribution and spray pattern are shown in Figures 5 and 6 and Table 3. (The error bars in Figure 5 and 4 represent the range of results obtained.)

CONCLUSIONS

Although differences were seen in the plume data between the different test groups, these differences were minimal. For all age groups, the non-dominant hand required more actuations to prime the device.

REFERENCES


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