Modification of the Insulin Pen Assistive Device to Improve the Usability and Its Evaluation

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In this study, we prepared 4 assistive devices (A–D) for Miriope® to improve the “ease of holding” and “ease of pushing” and compared their usability with that of a device provided by the pharmaceutical company (S). Fifty-five healthy volunteers in their 20s performed the self-injection maneuver using all 5 assistive devices and ranked them regarding 3 items, i.e., the “ease of holding”, “ease of pushing”, and “overall ease of administration”. In all evaluation items, C was ranked first by the largest number of subjects, and the ranking by the subjects was shown by Kendall’s coefficient of concordance to be consistent. In addition, comparison of the distance scale calculated from the ordinal scale showed significantly higher ranks of C and D compared with A, B, and S in all evaluation items. No significant difference was noted between C and D. Since C and D had shapes with concavities and convexities that fit the index, middle, and ring fingers (2nd–4th fingers), the fingers are considered to be better stabilized during the injection maneuver with consequent high ratings. Moreover, the 4 assistive devices prepared in this study were rated to be equal to or higher than S.

Key words — insulin self-injection; diabetes mellitus; assistive device

INTRODUCTION

The number of diabetic patients is rapidly increasing worldwide. The IDF Diabetes Atlas 7th edition estimates that the number in 2015 is 415 million, that the diabetes-related medical cost reaches about 81 trillion yen, and that it accounts for 5–20% of all medical costs in major countries of the world. In Japan, also, 19.5% of males and 9.2% of females aged 20 years and above were strongly suspected to have diabetes as of 2015 according to the 2015 National Health and Nutrition Survey.2

Treatments for diabetes include exercise therapy, dietary therapy, and drug therapy, and about 1 million patients are estimated to be undergoing insulin self-injection as a drug therapy.3 Since, for insulin self-injection using a pen-type injector, it is necessary to hold the injector for several seconds with the injection button pressed down during the injection procedure, a certain level of grip strength and finger dexterity is required.4 However, patients with declines in finger function, such as reduced grip strength due to aging or disease, cannot hold the injector firmly and occasionally fail to appropriately perform the injection maneuver, causing problems such as displacement of the injector to the direction of pressing of the injection button. Therefore, in Japan, pharmaceutical companies provide an assistive device to be used with each product. One of them is Miriope® assistive device. However, it has a very simple structure with a protrusion to prevent slipping of the injector and does not appear to be prepared in consideration of usability such as the ease of holding and ease of pushing the injection button.

We, therefore, prepared new assistive devices for Miriope® to improve the ease of holding and ease of pushing the injection button. In this study, we compared their usability with that of a device provided by the pharmaceutical company.

METHODS

Preparation of Assistive Devices In addition to the assistive device provided by the pharmaceutical company (S), 4 types of devices (A–D) prepared using Zortrax M200 3D Printers (Zortrax, Olsztyn) were tested (Fig. 1). A was prepared by extending the body by 2 cm compared with S, and C was prepared with concavities and convexities in the body that would fit the index, middle, and ring fingers. D was prepared with concavities and convexities half in depth or height compared with C. B was prepared by extending the handle compared with A.

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Testing Methods

This study was an exploratory study with the clinical use of improved assistive devices as the final goal. A prerequisite in the evaluation of the appropriateness of modified assistive devices is that they can be used by healthy young adults without discomfort. For these reasons, 55 healthy volunteers in their 20s were selected as the subjects.

First, to collect basic data of the subjects, the grip strength was measured using a grip dynamometer (Takei Scientific Instruments, Co., Ltd., Niigata), and the pushing strength of the thumb was measured using a modified push-pull gauge (Imada Co., Ltd., Toyohashi). Then, the tests were performed by the following procedure.

The subjects performed sham injection in the femoral region using a Miriopen® handling practice injector with an assistive device attached and an insulin self-injection practice pad (Fig. 2). The users of the devices are expected to be patients with declined finger functions. Therefore, the femoral region, in which injection can be performed without unnatural movements of the wrist, was selected as the injection site. After the subjects performed the injection maneuver using all 5 assistive devices, they ranked them regarding 3 evaluation items, i.e., the “ease of holding”, “ease of pushing”, and “overall ease of administration”. Of the evaluation items, the “ease of holding” and “ease of pushing” were evaluated by focusing on each aspect alone. The “overall ease of administration” was evaluated concerning the sequence of maneuvers from picking up the self-injector to the end of the injection maneuver using the practice pad. The order of the use of the 5 assistive devices was randomized in each subject.

Statistical Analysis

If sensory evaluation is performed using an ordinal scale by 3 or more evaluators, it is necessary to calculate Kendall’s coefficient of concordance (W) and confirm the concordance of the results among the evaluators. If the results are concordant, differences in the evaluation among the assistive devices are evaluated next. Therefore, we calculated Kendall’s coefficient of concordance (W) for each evaluation item and examined the concordance of the rankings among the evaluators. Next, since the data obtained were in the ordinal scale, they were converted to those in the distance scale by the normalized ranking method. Using the data converted to the distance scale, the significance of the differences among the assistive devices was examined by two-way analysis of variance. Moreover, to more closely examine the significance of the differences among the assistive devices, the significance was tested by calculating the minimum difference with statistical significance (least significant difference; LSD) using t-distribution. Statistical analyses were performed using IBM SPSS Statistics 22 (IBM Japan, Tokyo) and Statcel 3 software (The Publisher OMS Ltd., Saitama) at the p<0.05 level of significance.

Ethical Consideration

The tests were performed after sufficiently explaining the contents of the tests to the subjects using an explanatory docu-
ment and obtaining a signature on the consent form from those who consented. This study was carried out with approval by the Institutional Review Board of Hyogo University of Health Sciences (approval No.: 14039).

RESULTS

The subjects consisted of 21 males and 34 females. The mean grip strength was 25.6±9.2 kg, and the mean pushing strength was 79.4±20.3 N. Although we evaluated the relationships of the usability ratings with sex, grip strength, and pushing strength, no difference was observed.

Concerning the "ease of holding", C was ranked as the first, and S was ranked as the 5th, by the largest number of subjects (Fig. 3). Concerning the "ease of pushing", also, C was ranked as the first, and S was ranked as the 5th, by the largest number of subjects (Fig. 4). Concerning the "overall ease of administration", C was ranked as the first, and B and S were ranked as the 5th, by the largest number of subjects (Fig. 5).

Since Kendall’s coefficient of concordance W and the significance probability in the ease of holding were 0.284 and ≤0.01, respectively, the ranking by the subjects was considered concordant. In addition, since the distance scale showed significant differences in A, B, and S compared with C and D, they were clearly inferior in the ease of holding. D showed a slightly larger distance scale than C while the difference was not significant. Also, as there was no significant difference between A and B, S was ranked lowest (Fig. 6).

Since Kendall’s correlation of concordance W and the significance probability in the ease of pushing were 0.120 and ≤0.01, respectively, the ranking by the subjects was considered concordant. In addition, since A, B, and S showed significant differences in the distance scale compared with C and D, they were clearly inferior in the ease of pushing. In addition, D
showed a slightly larger distance scale than C while the difference was not significant. Also, while no significant difference was noted between A and B, between A and S, or between B and S, A showed a slightly larger distance scale than B and S (Fig. 7).

Since Kendall's coefficient of concordance W and the significance probability in overall ease of administration were 0.212 and ≤ 0.01, respectively, the ranking by the subjects was considered concordant. In addition, since A, B, and S showed significant differences in the distance scale compared with C and D, they were clearly inferior in the overall ease of administration. D showed a slightly larger distance scale than C while the difference was not significant. Also, while no significant difference was noted between A and B, between A and S, or between B and S, A showed a slightly larger distance scale than B and S (Fig. 8).

**DISCUSSION**

We prepared 4 new assistive devices for Miriopen to improve the ease of holding and ease of pushing of the injection button. In this study, we compared their usability with that of a device provided by the pharmaceutical company by sensory evaluation using the ranking method, which is applied when the samples are difficult to rate individually but can be ranked. The evaluation items of the usability of assistive devices such as the "ease of holding" and "ease of pushing" are considered difficult to evaluate using a scoring system. Therefore, we adopted the ranking method in this study. If sensory evaluation is performed according to an ordinal scale by 3 or more evaluators, it is necessary to calculate Kendall's coefficient of concordance W and confirm the concordance of the rankings among the evaluators. If the rankings are confirmed to be concordant, the differences in the ratings among the assistive devices are
Fig. 5. Frequency Distribution of Rankings in the Overall Ease of Administration \((n=55)\)

Fig. 6. Least Significant Difference (LSD) in the Ease of Holding \((n=55)\)

\(^*\): LSD (5%) = 0.288

\(^{**}\): LSD (1%) = 0.380
evaluated next. The ordinal scale was converted to the distance scale by the normalized ranking method, and the differences among the assistive devices were examined by two-way analysis of variance.

The improvement in the usability of the assistive devices for Miriopen® was evaluated by focusing on the “ease of holding” and “ease of pushing the injection button”. The mean minimum width of the adult hand is reported to be about 6.7 cm, but the length of the body of S is 5 cm, and it is impossible for most patients to hold it in the entire palm. In addition, when a patient with type 1 diabetes self-injects 20 units of insulin at a time using Miriopen®, the distance between the upper end of S attached to the injector to the injection button is 3 cm. However, Toraishi et al.® reported that the button can be pushed with the largest force when this distance is 2 cm. We, therefore, prepared A by extending the body by 2 cm compared with S to make the distance to the injection button about 2 cm when the device was attached to the injector. Also, part of the upper part of the device was cut off not to let the device conceal the
injection unit indicator. Next, we directed attention to the shape of the body of A, which was regarded as the basic model. The body of the device is held with the hand, but many objects designed to be held with the hand, such as the stick and bicycle handle grip, have concavities and convexities that fit the shape of the fingers for tighter and more comfortable gripping of the objects. So, we prepared C with concavities and convexities for the index, middle, and ring fingers of the body. Also, as there is individual variation in finger thickness, D was prepared by reducing the depth and height of the concavities and convexities. In this study, only the effects of the presence or absence of concavities and convexities on the usability were evaluated. The effects of the number and intervals of concavities and convexities are evaluated in a separate study. B was prepared by extending the handle of A for fixation of the entire hand.

C and D were rated higher than A, B, and S in all 3 evaluation items of the “ease of holding”, “ease of pushing the injection button”, and “overall ease of administration”. C and D are considered to have been rated high because of an improved feeling of stability during injection due to the concavities and convexities made in the body for the index, middle, and ring fingers. C and D were rated similarly with no significant difference, and there was no clear difference in their usability. The differences in their rating may be explained by the slight difference in the degree of fitting to the hand due to individual variation in finger thickness. In B with a structure that forced fixing of the entire hand, finger movements during the injection maneuver were restricted, probably resulting in a low rating. No significant difference was observed among A, B, and S in the items other than the ease of holding. However, as the distance scale was lower in S than in A and B, the 4 devices prepared in this study are considered to have been rated equally to or higher than S.

The site of insulin injection is most commonly the abdomen. In this study, however, the injectors were tested by assuming injection in the femoral region, which can be performed without unnatural movements of the wrist and fingers. There is no literature comparing the usability of insulin self-injection between the abdominal and femoral regions. However, according to a study in patients using Enbrel®, a pentype auto-injector for the treatment of rheumatoid arthritis, about 80% of the subjects felt that injection could be performed more comfortably with less failures in the femoral than abdominal region. In addition, as patients in their 60s–80s accounted for about 70% of the subjects in the above report, the results are considered to reflect the reality in elderly patients with rheumatoid arthritis. Therefore, despite the difference between diabetes and rheumatoid arthritis, the evaluation of the ease of self-injection in the femoral region is considered valid. However, the results of this study alone do not warrant the judgment that the evaluations of insulin self-injection in the femoral and abdominal regions are equivalent.

The results of this study suggest that the shape of the body and the distance to the injection button are important factors for improving the user-friendliness of self-injection assistive devices. This study was an exploratory study with the clinical use of improved assistive devices as the final goal. Therefore, healthy individuals in their 20s were selected as the subjects. Presently, we are conducting a study of the usability of the devices in patients expected to be their clinical users.

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Conflict of Interest The authors declare no conflicts of interest.

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