

# Investigation of Injector Usability following a Switch from NovoPen 300<sup>®</sup> to FlexPen<sup>®</sup>

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**Summary.** The present study examined whether quality of life (QOL) in type 2 diabetic patients is improved by switching from NovoPen 300<sup>®</sup> (cartridge injector) to FlexPen<sup>®</sup> (FLX) (prefilled injector). A self-administered questionnaire survey was conducted for 105 outpatients with type 2 diabetes in our hospital at approximately one month after switching from a cartridge injector to FLX. Before this study, all patients had used a cartridge injector for more than three months or as many. Combining “very good” and “good” responses, almost all items were assessed to be favorable by more than 60% of patients regarding the usability of FLX in comparison with a cartridge injector. In particular, 79% and 73% of patients favorably assessed “ease of reading unit numbers” and “ease of adjusting dosage”, respectively. In addition, 80.6% of patients answered that they became accustomed to using FLX “very quickly” after switching. On the contrary, 38% of patients negatively assessed “ease of pushing the injection button”, and some disadvantages were identified. Overall, switching from a cartridge injector to FLX was smoothly achieved with some degree of improvement in patient QOL.

**Key words**— prefilled preparation, cartridge-type insulin preparation, type-2 diabetes.

## INTRODUCTION

Pen-type insulin-cartridge injectors were introduced to Japan in 1988. Since then, quality of life (QOL) in diabetic patients has been markedly improved. With most injectors, however, cartridges must be exchanged. To overcome this disadvantage, prefilled injectors have been introduced in recent years. While the manufacturer has reported that prefilled injectors offer numerous advantages over existing injectors, few studies appear to have investigated their utility from the perspective of patients.

The present study conducted an injector usability survey of diabetic patients following a switch from the NovoPen 300 cartridge injector (cartridge injector) to the FlexPen prefilled injector (FLX).

## RESEARCH DESIGN AND METHODS

Subjects in the present study comprised 105 patients with type 2 diabetes who visited the diabetic outpatient clinic of our hospital and had used NovoPen 300<sup>®</sup> for more than three months or as many.

A self-administered questionnaire survey was provided to patients who visited the clinic after February 25, 2005, asking that they make a switch from their previous cartridge injector to FLX, and then, revisit the clinic about one month later. Informed consent to participate in this study was obtained from each patient. All study protocols were approved by independent local institutional review boards. The questionnaire is presented in Fig. 1.

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**Abbreviations**— NovoPen 300<sup>®</sup>, cartridge injector; FLX, FlexPen<sup>®</sup> (prefilled injector); QOL, quality of life.

## RESULTS

Valid responses were obtained from 102 patients (two patients refused, and one patient did not complete the questionnaire). Patients comprised 55 men and 47 women. Four patients were over the age of 39 years, eight patients were in their 40s, 22 patients were in their 50s, 30 patients were in their 60s, and 39 patients were over the age of 70 years.

First, background information for patients on insulin injection therapy at our clinic was ascertained (Fig. 2). Question 3 dealt with visual acuity, and 50.4% of the patients stated that they had trouble reading newspapers or could not read them at all. Question 4 dealt with hand and finger function, for which 20.4% stated that they sometimes experienced hand tremors. Question 5 dealt with the psychological, physical, economical, and social impacts of insulin therapy. About half of the patients reported that they felt burdened by insulin therapy to some degree. Question 6 dealt with compliance, and 8.8% of the patients stated that they sometimes forgot to inject insulin (Fig. 3). Question 7 dealt with situations in which patients forgot to inject insulin, and various responses could be obtained (Fig. 3).

Next, changes after making the switch from NovoPen 300® to FLX were ascertained. Question 8 dealt with the transition, and most patients made a smooth transition to FLX (Fig. 3). Question 10 dealt with various aspects of FLX (Fig. 4). Combining "very good" and "good" responses, almost all items were assessed to be favorable by more than 60% of the patients. In particular, "ease of reading unit numbers" and "ease of adjusting dosage" were assessed favorably by 79% and 73% of the patients, respectively. On the contrary, "ease of pushing the injection button" was assessed unfavorably, the most common answer being "poor" (37%). Question 9 was reassessed among patients who answered that they became used to using FLX "very quickly", but results were the same (data not shown). Question 11 dealt with the positive points of FLX, and the most common answer being "there is no need to exchange cartridges", followed by "a unit dial that can be turned in both directions" and "lightweight", in that order. Thus, patients positively assessed the unique characteristics of FLX (Fig. 5). Question 12 dealt with the negative points of FLX, and environmental issues were identified: "increased trash" (24%); and "disposable injectors are wasteful" (24%)(Fig. 5). Some patients claimed on difficulties pushing the injection button, and one patient stated that the hospital should collect and dispose of FLX injectors after use, as with used needles and tips (Fig. 6).

## DISCUSSION

### Background information for patients on insulin injection therapy

When selecting an injector, the mental and physical skill levels of each patient must be considered. In other words, the following factors are important and must be considered: 1) visual acuity; 2) hand and finger function; 3) patient resistance to device usage; and 4) family collaboration. The survey first ascertained background information for subjects. In the present study, 60% of the patients were over the age of 60 years, about half of the patients indicated difficulties in reading small letters (the size of fonts used in newspapers), and 20% of the patients described hand tremors. In addition, more than 40% of the patients felt that insulin injection therapy was burdensome.

### Assessment of usability

#### *Advantages of FlexPen*

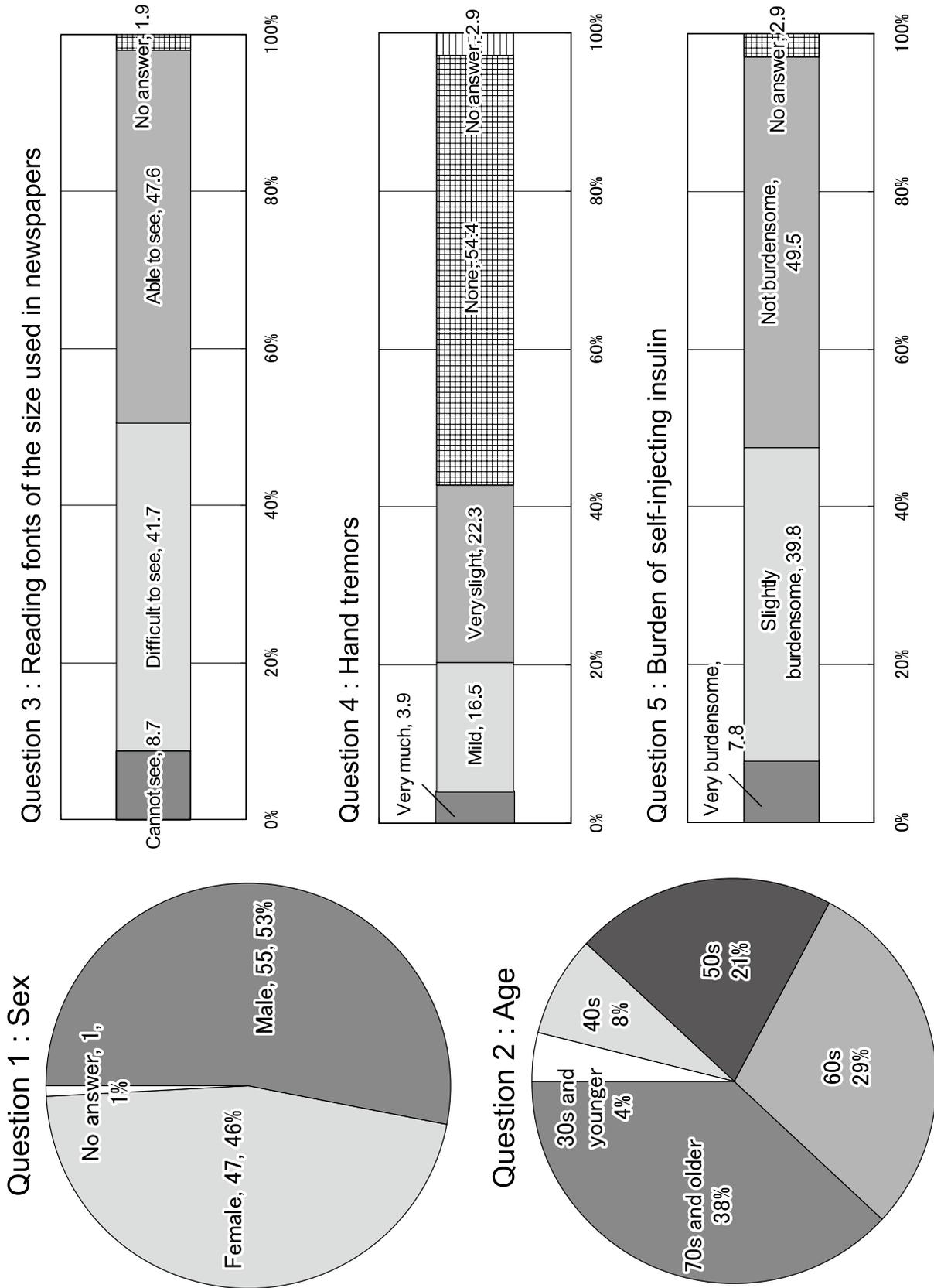
The majority of patients (80.6%) answered that they became accustomed to using FLX very quickly. The transition from a cartridge injector to FLX was smooth, as the use of FLX is comparable or easier than that of a cartridge injector.

In addition to the ease of use of the FLX, approximately 70% of the patients answered in the affirmative for the "ease of reading numbers", "ease of adjusting dosage", and "ease of turning dosage dial". Patients who entered this study were typically of advanced ages and had tremors of the hand with decreased visual activity, and the present results suggest satisfaction with the features of FLX. In contrast, "difficulty pushing the injection button" was assessed unfavorably and was therefore considered a limitation of FLX. "Ease of pushing the injection button" represents an extremely important point for patients with hand tremors (20% of the patients in the present study), as appropriate amounts of insulin cannot be injected if the injection button is not completely pressed. One study showed that failing to push the injection button to the end could exacerbate or destabilize glycemic control.<sup>1)</sup> The present results showed that about 40% of the patients assessed this item as "poor". Asakura et al.<sup>2)</sup> reported that, while resistance amplitude during injection was greater for a cartridge injector than for FLX, mean maximum injection pressure was larger for FLX than for a cartridge injector, supporting the above finding. In one study, seeking to minimize injection resistance for FLX, a piece of tape to prevent rotation was mounted on the FLX device. As a result of this procedure, the sense

**Questionnaire for patients who use FlexPen®**

1. Gender :  Male  Female
  2. Age :  30s and younger  40s  50s  60s  70s
  3. Reading fonts of the size used in newspapers :  
 Cannot see  Difficult to see  Able to see
  4. Hand tremor :  Very much  Mild  Very slight  None
  5. Burden of self-injecting insulin  
 Very burdensome  Slightly burdensome  Not burdensome
  6. Compliance  
 Often forget  Occasionally forget  Rarely forget  
 Never forget
  7. When do you forget to self-inject insulin?  
 (excluding patients who never forget to self-inject insulin)  
 When busy  
 Travel/Out of town  
 When having company  
 Inconvenience  
 Simply forget  
 Others ( )
  8. Did you still forget to self-inject after switching to FlexPen®?  
 No-longer forget  Less frequent  No change
  9. How long did it take for you to get used to using FlexPen®?  
 Very quickly  
 Took time  
 Still having trouble  
 No answer  
 Others ( )
- Thank you for your answer to the questionnaire.
10. Usability of FlexPen® (comparison to NovoPen®)
    - ① Confirmation of remaining amount :  Very good  Good  Unchanged  Poor
    - ② Ease of reading number :  Very good  Good  Unchanged  Poor
    - ③ Ease of adjusting dosage :  Very good  Good  Unchanged  Poor
    - ④ Ease of turning dosage dial :  Very good  Good  Unchanged  Poor
    - ⑤ Clicking sound for dosage adjustment :  Very good  Good  Unchanged  Poor
    - ⑥ Ease of gripping injector :  Very good  Good  Unchanged  Poor
    - ⑦ Ease of pushing injection button :  Very good  Good  Unchanged  Poor
    - ⑧ Ease of remembering operating procedures :  Very good  Good  Unchanged  Poor
    - ⑨ Injector weight :  Very good  Good  Unchanged  Poor
    - ⑩ Portability :  Very good  Good  Unchanged  Poor
    - ⑪ Appearance :  Very good  Good  Unchanged  Poor
  11. Advantage of FlexPen®
    - Same usage as NovoPen®
    - Easier to use than NovoPen®
    - No need to exchange cartridges
    - Can be turned in both directions
    - Light weight
    - Others ( )
  12. Disadvantage of FlexPen®
    - Same usage as NovoPen®
    - High cost
    - More trash
    - Disposable injectors are wasteful
    - Others ( )
  13. Comments and view for FlexPen®

**Fig. 1.** Questionnaire for patients who use FlexPen®.



**Fig. 2.** Comments on questionnaire for patients who use FlexPen® (Questions 1-5: patient background information)

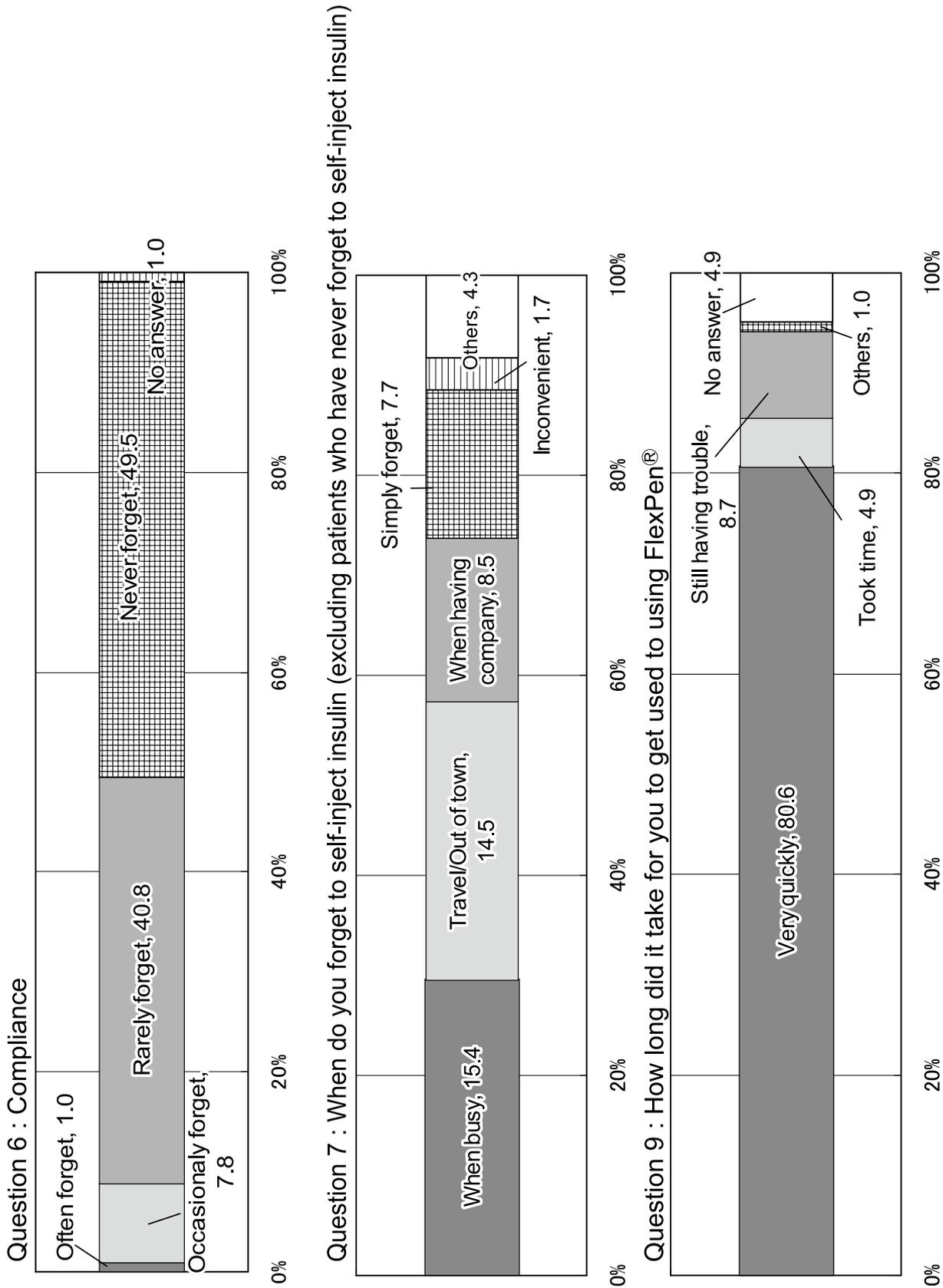


Fig. 3. Comments on questionnaire for patients who use FlexPen® (Questions 6-9)

Question 10 : \*Numbers in figure indicate number of respondents

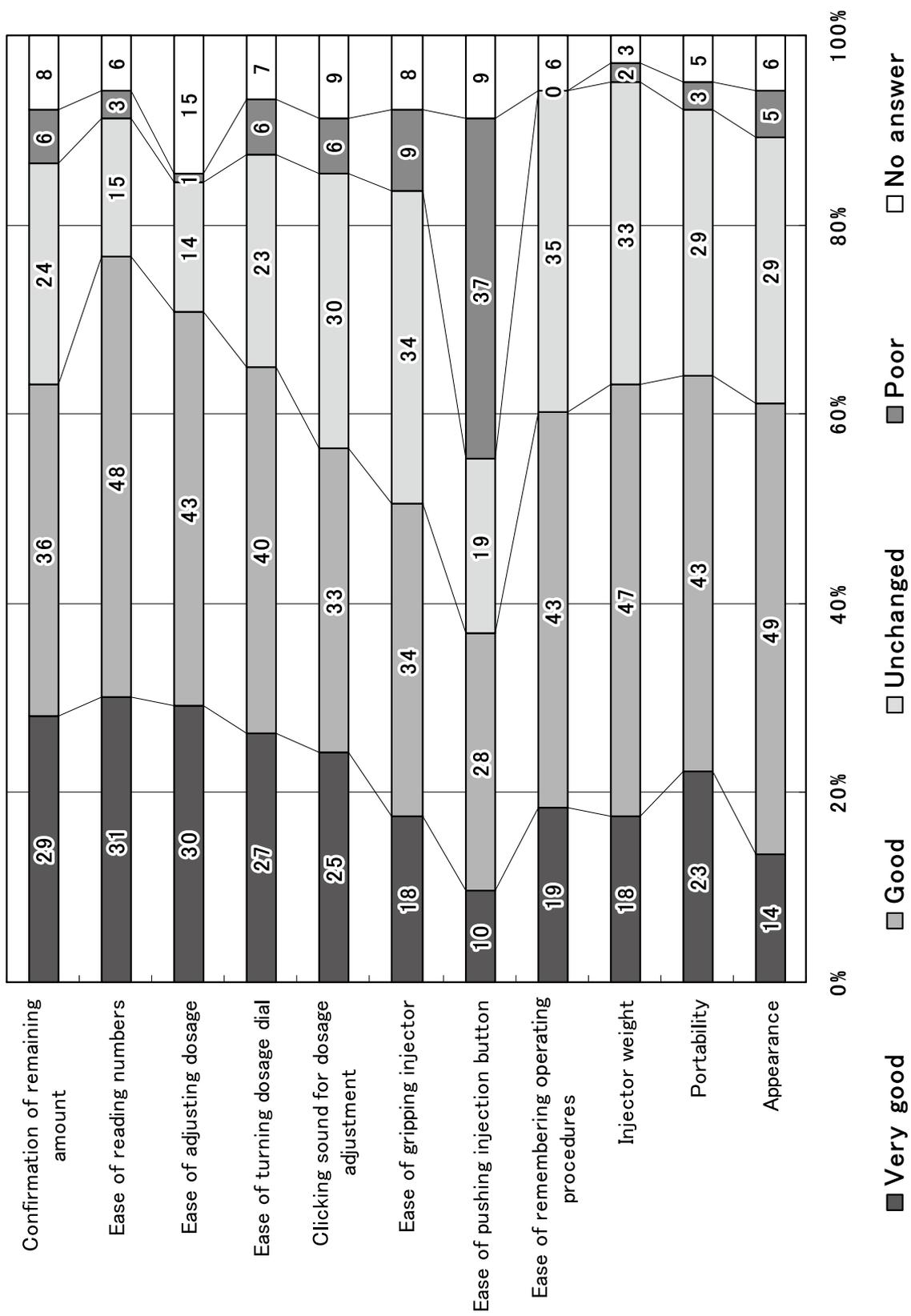
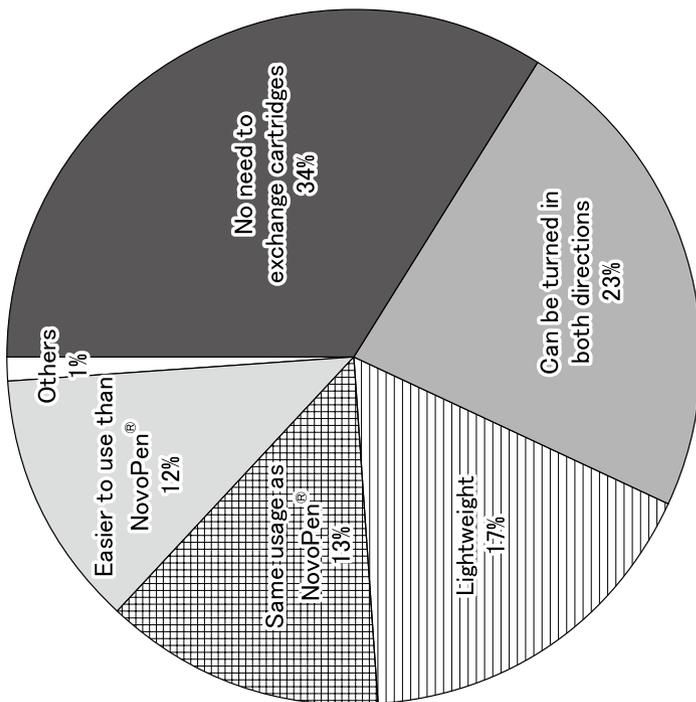


Fig. 4. Comments on questionnaire for patients who use FlexPen® (Question 10: Usability of FlexPen® (comparison to NovoPen®))

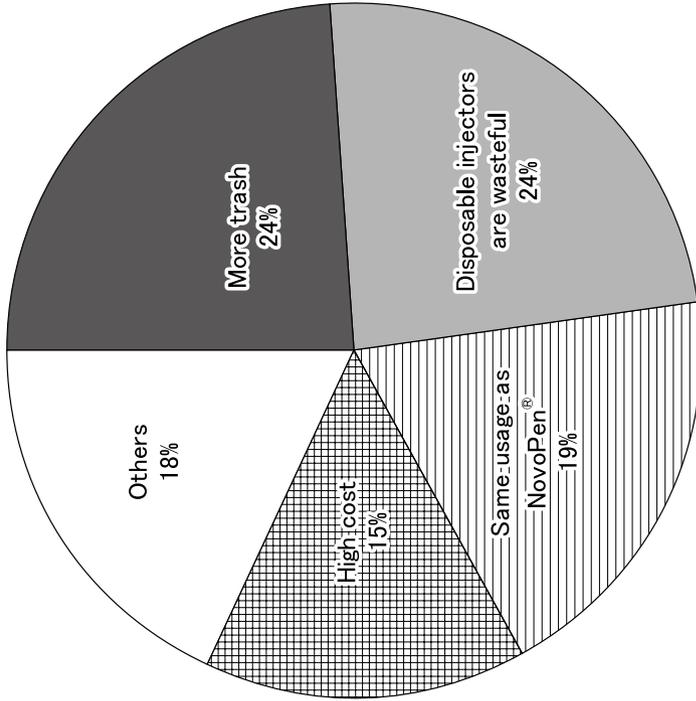
Question 11 :



Others:

- Easy to grip
- Makes clicking noise when injecting
- Unit dial stops at the end of injection
- Takes less time

Question 12 :



Others:

- Difficult to push the injection button (n = 6)
- Difficult to inject insulin (n = 2)
- Too light (n = 2)
- Need to carry more than one injector (n = 2)

Fig. 5. Comments on questionnaire for patients who use FlexPen® (Question 11: Advantages of FlexPen®; Question 12: Disadvantages of FlexPen®)

## Question 13 :

Questionnaire form No.	Comments (views and opinions)
4	The injection button feels awkward
6	The rotation during injection catches, and is not smooth
7	Particularly good
12	High resistance while pressing the injection button
16	Bigger unit numbers are easier to see
16	The larger number "0" makes it is easier to ascertain the end of injection
29	Not having to exchange cartridges saves time
36	Disposable containers are wasteful
38	Very good
41	It is somewhat difficult to ascertain remaining quantity
43	It is difficult to push the injection button
46	A portable case is needed
60	The existing product has a better tactile sensation
69	I think it is easy-to-use and good
70	I can only travel to certain foreign countries with FlexPen
71	The hospital should collect used FlexPens, just like used needles and tips
80	The area that injects insulin became stuck. I am back to using NovoPen.
97	It is much more convenient
98	I like NovoPen better

Fig. 6. Comments on questionnaire for patients who use FlexPen® (Question 13: Comments and views for FlexPen®)

of injection was improved because the sense of grip increased.<sup>3)</sup> This method may be useful for patients who experience difficulty pushing the injection button to the required extent.

### **Three advantages**

The characteristics of FLX are as follows: 1) FLX is less troublesome, as cartridges do not need to be exchanged; 2) even if dosage is set incorrectly, dosage adjustments are easy because the dosage dial can be turned in both directions; and 3) the dial display is relatively large, improving the ease of reading. In the present study, 34% of the patients stated that FLX was less cumbersome because there was no need to exchange cartridges. Regarding the "ease of adjusting dosage", 23% of the patients responded favorably to this item. This feature of FLX matched the advantages for the patients listed concerning FLX. In this study, about half of the patients had visual impairment. In general, the presence of large-sized numbers, dial clicking sounds, and tactile sensations are desirable for such persons.<sup>4)</sup> However, 30% of the patients assessed the ease of reading unit numbers as "poor". The letters on FLX are larger than those on a cartridge injector, but many patients still experienced difficulties. Further improvements are thus needed.

### **Disadvantages**

Half of the patients stated that the amount of trash was increased and disposable containers were wasteful. These

problems are not unique to FLX, but apply to all prefilled injectors. In the future, an injector may be developed to cope with these problems.

### **CONCLUSIONS**

At our hospital, the transition from a cartridge injector to FLX was smooth, and the patients QOL improved. For patients self-injecting insulin, injectors are just as important as insulin preparations. Injectors play a large role in the introduction and maintenance of insulin therapy. Selecting an injector that is suited to each patient is thus important in improving compliance and establishing an environment where the necessary therapy is administered as smoothly as possible.

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