

EXPERT OPINION

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Healthcare professional and patient perceptions of a new prefilled insulin pen versus vial and syringe

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Objective: Usability of a new prefilled insulin pen, FlexTouch[®] (FT; Novo Nordisk A/S, Bagsvaerd, Denmark), with no push-button extension and low injection force, was compared with vial and syringe (V&S).

Research design and methods: People with diabetes, and healthcare professionals with diabetes management experience conducted test injections and answered questions on preference, ease of use, confidence, ease of learning and teaching.

Results: The study involved 30 needle-naïve patients (naïve to any diabetes injection therapy), 30 V&S-experienced patients, 30 physicians and 30 nurses. In the total population, FT was preferred to V&S for teaching or learning to use (both $p < 0.001$). Nurses (100 vs. 0%) and physicians (87 vs. 7%) preferred FT to V&S for ease of teaching. V&S-experienced (73 vs. 7%) and needle-naïve patients (83 vs. 7%) preferred FT to V&S for ease of learning. The remainder chose "equally easy/difficult." More participants in each group rated FT "very/fairly easy" for ease of depressing the push-button/plunger (FT vs. V&S: physicians, 93 vs. 80%; nurses, 97 vs. 80%; V&S-experienced patients, 93 vs. 90%; needle-naïve patients, 100 vs. 77%), and injecting three doses. More participants were "very/rather confident" in managing daily injections using FT (FT vs. V&S: physicians, 100 vs. 60%; nurses, 100 vs. 70%; V&S-experienced patients, 93 vs. 90%; needle-naïve patients, 90 vs. 40%).

Conclusions: FT was rated easier to use, learn to use or teach to use than V&S by patients with or without experience of insulin injection with V&S, and by physicians and nurses with diabetes management experience.

Keywords: diabetes, ease of learning, ease of teaching, ease of use, prefilled insulin pen, vial and syringe

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1. Introduction

As the population affected with diabetes continues to increase, several professional societies including the American Diabetes Association (ADA) [1], European Association for the Study of Diabetes (EASD) [2] and American Association of Clinical Endocrinologists (AACE) [3] have recommended intensified insulin therapy to improve glycemic control, and avoid many diabetes-related complications. Interest in alternatives to the traditional insulin delivery device vial and syringe (V&S), such as insulin pens, has also become more widespread. Administering insulin using V&S requires the user to insert the needle into the vial of insulin and to hold onto the syringe while pulling the plunger to fill the syringe with insulin. In contrast, prefilled insulin pens are already filled with insulin and as such, the user only needs to dial the required dose and depress the push-button to inject. Thus, injecting using V&S involves extra steps that increase the complexity of the process,

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which may increase the potential for error in dosing and the likelihood for non-adherence to therapy. Also, the added steps may require greater manual dexterity and therefore, the ease of use of insulin pens may be especially relevant for people with diabetes who have impaired manual dexterity [4], poor hand strength or small hands. Ease of use of insulin pens may increase treatment adherence, and combined with the improved accuracy, this may reduce the risk of hospitalization and lower the overall costs of diabetes management [5-12]. However, in the USA, most patients injecting insulin use V&S, and so awareness and utilization of insulin pens remain a challenge [13-17].

Adherence to insulin regimens in diabetes management is poor. One study found insulin use was 77% of prescribed amounts [18]. Insulin injection omission was found to correlate with interference with daily activities, injection pain and embarrassment [19]. There is also resistance to initiate insulin therapy among people with diabetes who are on oral diabetes medication. Feelings of failure are a major reason why patients resist initiating insulin therapy; other factors include social embarrassment and anxiety regarding self-injection [20-25]. Several aspects of injecting insulin with the V&S method seem to contribute towards poor adherence and resistance to insulin initiation, such as the inconvenience of carrying the materials needed for V&S use, the social stigma of using such a method in public places, and concerns over correct and accurate insulin dosing and delivery with V&S [26]. Perceptions of healthcare professionals (HCPs) also contribute towards delayed initiation of insulin therapy. One of these perceptions is the belief that insulin therapy should be delayed until absolutely necessary [20], and that insulin delivery and its management are too cumbersome [25], despite the knowledge that insulin is the most efficacious treatment available and that timely initiation of insulin reduces the risk of diabetes-related complications [27,28].

The level of influence that HCPs have on patient awareness of insulin pens and their use has been demonstrated. Key predictors for initiating insulin injections with an insulin pen rather than V&S include physician encouragement for insulin pen use, the physician offering insulin pens as an option, and the knowledge that an insulin pen may facilitate self-care [29].

The potential influence of insulin injection devices on insulin initiation and/or insulin therapy adherence may be assessed from a patient-centered approach by comparing convenience and ease of use, patient lifestyle, teaching and learning to self-inject, and other factors. In conducting such assessments, it is important to consider both patients' and HCPs' experiences and opinions of insulin delivery devices, because preferences of both groups can affect initiation of, and adherence to, insulin regimens.

FlexTouch® (FT; Novo Nordisk A/S, Bagsvaerd, Denmark) is a new prefilled insulin pen with no push-button extension. The lack of push-button extension distinguishes FT from conventional prefilled pens, such as FlexPen® (FP; Novo Nordisk A/S, Bagsvaerd, Denmark), which have push-buttons

that become progressively longer as the set insulin dose increases to the maximum dose (Figure 1). Extension of the push-button increases the distance the thumb needs to stretch in order to reach the push-button and inject, and may make injecting difficult and uncomfortable for a proportion of users, especially at high doses. The spring-loaded mechanism of FT that eliminates push-button extension also significantly reduces the injection force at all doses compared with other prefilled insulin pens [30].

FT provides similar glycemic control to the widely used FP [31], and was rated higher than other prefilled pens for ease of use and confidence by people with diabetes and HCPs [31-33]. In addition, ease of use, ease of injecting, and confidence have all been rated higher for FT than V&S [34]. In this study, we examined these factors in four participant groups of this earlier study (needle-naïve [naïve to any diabetes injection therapy] and V&S-experienced people with diabetes, and physicians and nurses with diabetes management experience), as well as factors relating to ease of learning and teaching to use the device.

2. Participants and methods

2.1 Participants

This was a multicenter, open-label, crossover usability study in people with Type-1 or Type-2 diabetes (outpatients) and in physicians and nurses who had a minimum of 2 years' experience in diabetes management. Recruited patients were males and females with Type-1 or Type-2 diabetes who were ≥ 18 years of age. Only insulin pen-naïve patients were included. The patient population had to comprise a minimum of: 10% left-handed individuals; 25% with manual dexterity impairment (based on self-assessment); and 25% with a body mass index $> 30 \text{ kg/m}^2$. A maximum of 50% of the participants were to be V&S users (for at least 6 months) and the remainder were to be taking two or more oral anti-diabetes drugs for at least 2 years (and be naïve to any diabetes injection therapy). Recruited HCPs had to have at least 2 years' experience in diabetes management, and an approximate 1:1 ratio of physicians to nurses was included.

Exclusion criteria included any factor that prevented an adequate understanding or cooperation in the study, such as, unwillingness to participate, language barriers, mental or physical incapacity. Additional exclusion criteria included: any personal or family ties to a pharmaceutical or market research company; any individual who had previously tested FT; and any disease or condition that may interfere with the study.

The study was managed, conducted and analyzed by an independent clinical research organization and carried out in the USA (including at the participant's home, place of work, or other suitable venue) in accordance with the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects 2000, with amendments 2002, 2004 and 2008, and ISO/IEC 62366:2008, "Medical devices. Application of usability engineering to



Figure 1. The push-buttons of FlexTouch® (top) versus FlexPen® (bottom) when set at the maximum dose of insulin.

medical devices". All necessary institutional review board (IRB) approval was obtained for the research. In line with good medical practice procedures, informed consent and confidentiality agreements regarding test products were obtained before any test-related activities were initiated.

2.2 Materials and study design

Materials used were described in a previous publication [34].

Participants were recruited using HCP or fieldwork agency databases, or via nurses and physicians, and were pre-screened by telephone before the visit. The databases were independent of one another and the identity of all participants and their responses were confidential. The study involved a face-to-face interview of up to 60 min. Further details on the test procedure were published previously [34]. Data on the participant and their condition and treatment were collected before each participant was randomly allocated to start with either FT or V&S. After receiving instruction from a trained interviewer on how to use the injection device, the participant made several injections of test medium with FT or V&S into a foam cushion, switching between different dose sizes, including 20 international units (IU), 55 IU and 80 IU. Subsequently, participants answered written questions on ease of use and confidence in use on a 5-point rating scale (e.g., from 1 = very difficult/not at all confident to 5 = very easy/very confident). After handling the alternative injection device, participants answered the same written questions. Following the handling of both devices, questions on preference were answered either "test pen," "vial and syringe," "either/neither" or "equally easy/equally difficult." In this publication we report the results relating to ease of use, ease of teaching, ease of learning and confidence in use as reported by physicians, nurses, needle-naïve patients (naïve to any diabetes injection therapy), and V&S-experienced patients.

2.3 Statistical analysis

Endpoints for the total population included perceptions of ease of use, which was assessed on a 5-point scale. The null hypothesis was that there was no difference between answers across the 5-point scale regarding FT and V&S, and this was tested by Wilcoxon signed rank tests. Preference questions were analyzed using a one-sample binomial test using an exact method. The null hypothesis was that the preference for FT was equal to 50%, against the hypothesis that it was

different to 50%. The statistical significance level employed throughout the statistical analyses was 5%. Significance was calculated with adjustment for multiple testing (Bonferroni adjustment). All tests were conducted as two-sided tests.

The frequencies of ratings in the two most favorable categories ("very" and "fairly/rather" categories corresponding to "5" and "4" on the rating scale) were compared between FT and V&S. In addition, the frequencies of ratings in the best category ("very" category corresponding to "5" on the rating scale) were compared between FT and V&S. Due to a lack of adequate statistical power to assess potential differences in these ratings between FT and V&S within the individual groups, formal statistics were not applied to these data.

3. Results

3.1 Participant characteristics

A total of 120 individuals participated in the study. The baseline characteristics of the population were reported previously: 60 people with diabetes and 60 HCPs (30 physicians and 30 nurses) were included. Of the patients, 50% (n = 30) were injecting insulin with V&S (of these 30 patients, 8 [27%] had greater than 20 years' experience of using V&S and 24 [80%] had greater than 3 years' experience), and 50% (n = 30) had no experience of injecting insulin. All of the 30 physicians and 25 (83%) of the nurses had more than 5 years' experience of managing diabetes. Among the nurses, 24 (80%) trained patients on V&S, and 29 (97%), 27 (90%) and 25 (83%) trained on the prefilled insulin pens SoloStar® (Sanofi, Paris, France), FP and KwikPen™ (Eli Lilly & Co, Indianapolis, USA), respectively.

3.2 Device ease of use and confidence in use

3.2.1 Total population

In the total population (all 120 participants), FT was rated significantly higher than V&S (all $p < 0.001$) on all questions relating to ease of use, including: ease of depressing the push-button/plunger when injecting; ease of knowing the push-button/plunger was completely depressed; ease of reading the dose scale; ease of seeing the dose scale when injecting; ease of injecting 20 IU, 55 IU and 80 IU; ease of using the insulin delivery device; and confidence in managing daily insulin injections using the device. The results of these questions for the four individual groups are presented below.

3.2.2 Healthcare professionals

Almost all of the 60 HCPs (98%) rated FT very/fairly easy to use compared with 48% who rated V&S very/fairly easy to use (Figure 2A). Among the HCPs, all physicians rated FT very/fairly easy to use compared with 50% who rated V&S very/fairly easy to use (Figure 2B), and nurses gave similar ratings (FT = 97%; V&S = 47%) (Figure 2C). More physicians and nurses rated depressing the push-button and knowing that the push-button or plunger was completely depressed as very/fairly easy on FT compared with V&S (Figure 2A – C).

Almost all 60 HCPs (98%) rated reading the dose scale as very/fairly easy on FT compared with only 63% who gave these ratings for V&S (Figure 2A). Among these HCPs, all nurses rated reading the dose scale as very/fairly easy on FT compared with 57% who gave these ratings for V&S (Figure 2C), and physicians gave similar ratings (FT = 97%; V&S = 70%) (Figure 2B). Most of the 60 HCPs rated the dose scale on FT as very/fairly easy to see when injecting (85%), while fewer gave such ratings for V&S (52%) (Figure 2A). Within the HCP group, physicians and nurses gave similar ratings for seeing the dose scale when injecting (83 and 87%, respectively for FT and 50 and 53%, respectively for V&S; Figure 2B and C).

All HCPs were very/rather confident in FT for managing daily injections, while only 65% of HCPs were with V&S (60% of physicians and 70% of nurses) (Figure 2A – C).

More physicians and nurses rated injecting 20 IU, 55 IU and 80 IU as very/fairly easy with FT than with V&S, with a marked decline in positive ratings with V&S, but little change with FT, as the dose increased (Figure 3A – C).

3.2.3 Patients

Most of the 60 patients (95%) rated using FT as very/fairly easy, compared with 58% who gave this rating for V&S (Figure 2D). The ratings for FT were similar among needle-naïve and V&S-experienced patients (97 and 93%, respectively), and were lower for V&S in both groups (40 and 77%, respectively), but the difference in ratings were especially pronounced among needle-naïve patients (Figure 2E and F). Depressing the push-button/plunger and knowing whether the push-button/plunger was completely depressed were rated as very/fairly easy by more patients overall with FT than V&S (Figure 2D). The difference between ratings for FT and V&S was slightly larger among needle-naïve (Figure 2F) than V&S-experienced patients (Figure 2E).

Most of the 60 patients (98%) rated the dose scale on FT as very/fairly easy to read versus only 73% for V&S (Figure 2D). All patients with experience of using V&S gave very/fairly easy ratings for reading the dose scale on FT while only 77% did so for V&S (Figure 2E), and a similar result was seen with needle-naïve patients (FT = 97%; V&S = 70%) (Figure 2F). Seeing the dose scale on FT when injecting was rated as very/fairly easy by 87% of patients overall, compared with 70% who gave such ratings for V&S (Figure 2D). Needle-naïve (FT = 87%; V&S = 67%; Figure 2F) and

V&S-experienced (FT = 87%; V&S = 73%; Figure 2E) patients gave similar ratings.

Most of the 60 patients (92%) were very/rather confident in managing daily insulin injections using FT compared with 65% for V&S (Figure 2D). The difference between ratings for FT and V&S were larger among needle-naïve (FT = 90%; V&S = 40%; Figure 2F) than V&S-experienced patients (FT = 93%; V&S = 90%; Figure 2E).

More patients overall, needle-naïve patients and V&S-experienced patients rated it very/fairly easy to inject 20 IU, 55 IU and 80 IU with FT than with V&S, with a marked decline in positive ratings with V&S, but little change with FT, as the dose increased (Figure 3D – F).

3.3 Teaching and learning

3.3.1 Total population

In the total population, FT was rated significantly higher than V&S for both ease of teaching others to use and ease of learning to use (both $p < 0.001$). Considerably more participants rated FT as very/fairly easy to teach (98 vs. 63%, respectively) and to learn compared with V&S (98 vs. 75%, respectively). In addition, participants preferred FT to V&S for both teaching (88 vs. 5%, respectively; the remainder chose “equally easy/difficult”) and learning (83 vs. 5%, respectively; the remainder chose “equally easy/difficult”; both $p < 0.001$).

3.3.2 Healthcare professionals on teaching

All nurses and physicians stated that it was very/fairly easy to teach others how to use FT, compared with only 48% of HCPs (60% of physicians and 37% of nurses) who gave such ratings for V&S (Figure 4A). When asked which device they preferred for ease of teaching, most HCPs preferred FT (93%) to V&S (3%) (the remainder chose “equally easy/difficult”) (Figure 4B). All nurses preferred FT, and 87% of physicians preferred FT while 7% preferred V&S (the remainder chose “equally easy/difficult”) (Figure 4B).

3.3.3 Patients on learning

Ratings for ease of learning to use the devices were more favorable for FT than V&S among patients overall (95 vs. 78%, respectively) and needle-naïve patients (97 vs. 67%, respectively) (Figure 4A). When asked which device they preferred for ease of learning, most needle-naïve patients preferred FT to V&S (83 vs. 7%, respectively; the remainder chose “equally easy/difficult”) (Figure 4B). Similarly, most V&S-experienced patients preferred FT to V&S (73 vs. 7%, respectively; the remainder chose “equally easy/difficult”) for ease of learning (Figure 4B).

3.4 Recommendations

3.4.1 Total population

When asked if they would recommend the device, significantly more participants in the total population would recommend FT than would recommend V&S (96 vs. 57%, respectively; $p < 0.001$). If asked to choose just one device to recommend,

Healthcare professional and patient perceptions of a new prefilled insulin pen versus vial and syringe

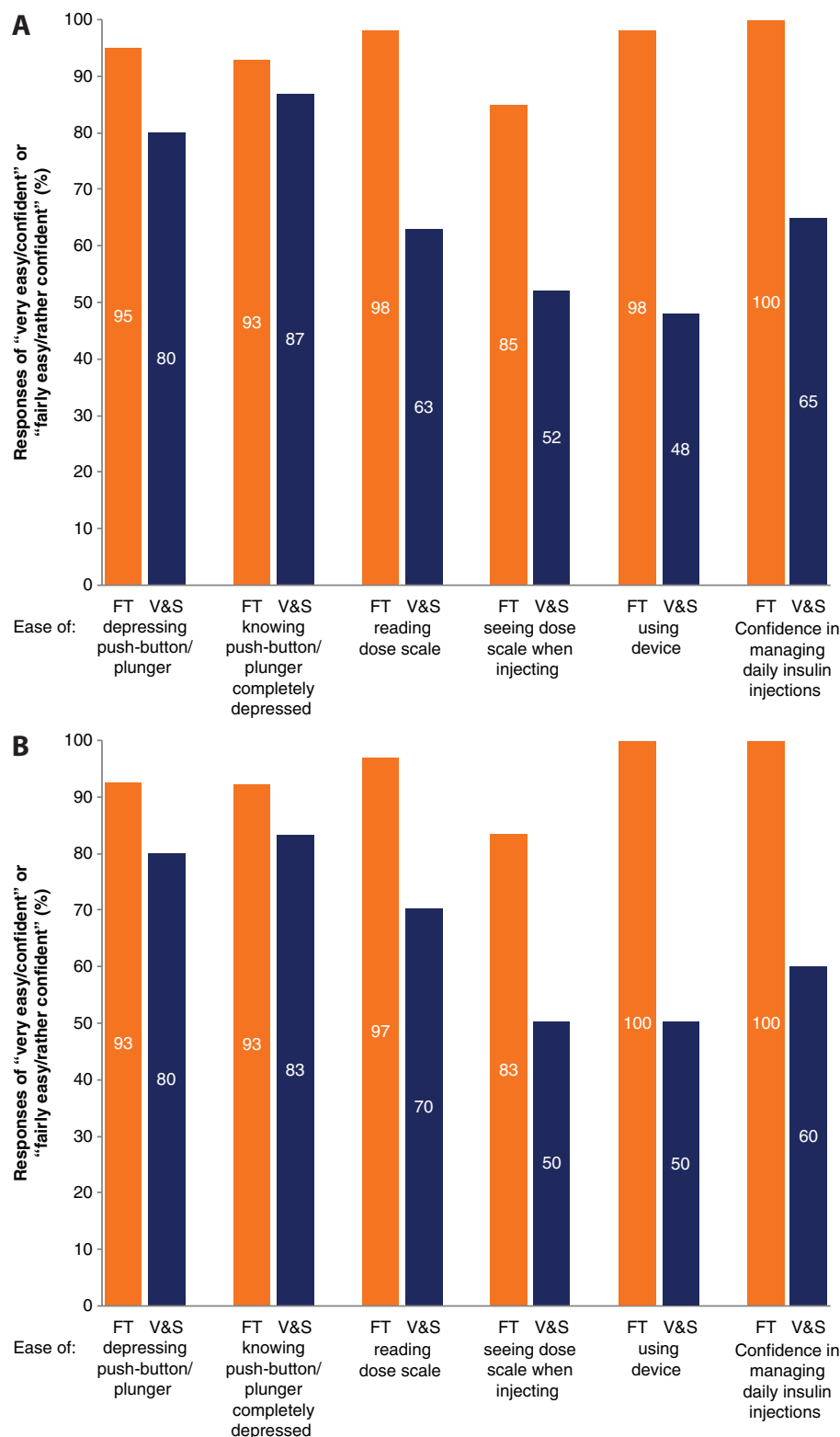


Figure 2. Percentage of participants giving scores of 5 ("very easy/confident") or 4 ("fairly easy/rather confident") combined for various questions on ease of use and confidence in managing daily insulin injections with FlexTouch® (FT) or vial and syringe (V&S). (A) All healthcare professionals (n = 60); (B) physicians (n = 30); (C) nurses (n = 30); (D) all patients (n = 60); (E) V&S-experienced patients (n = 30); and (F) needle-naïve patients (n = 30).

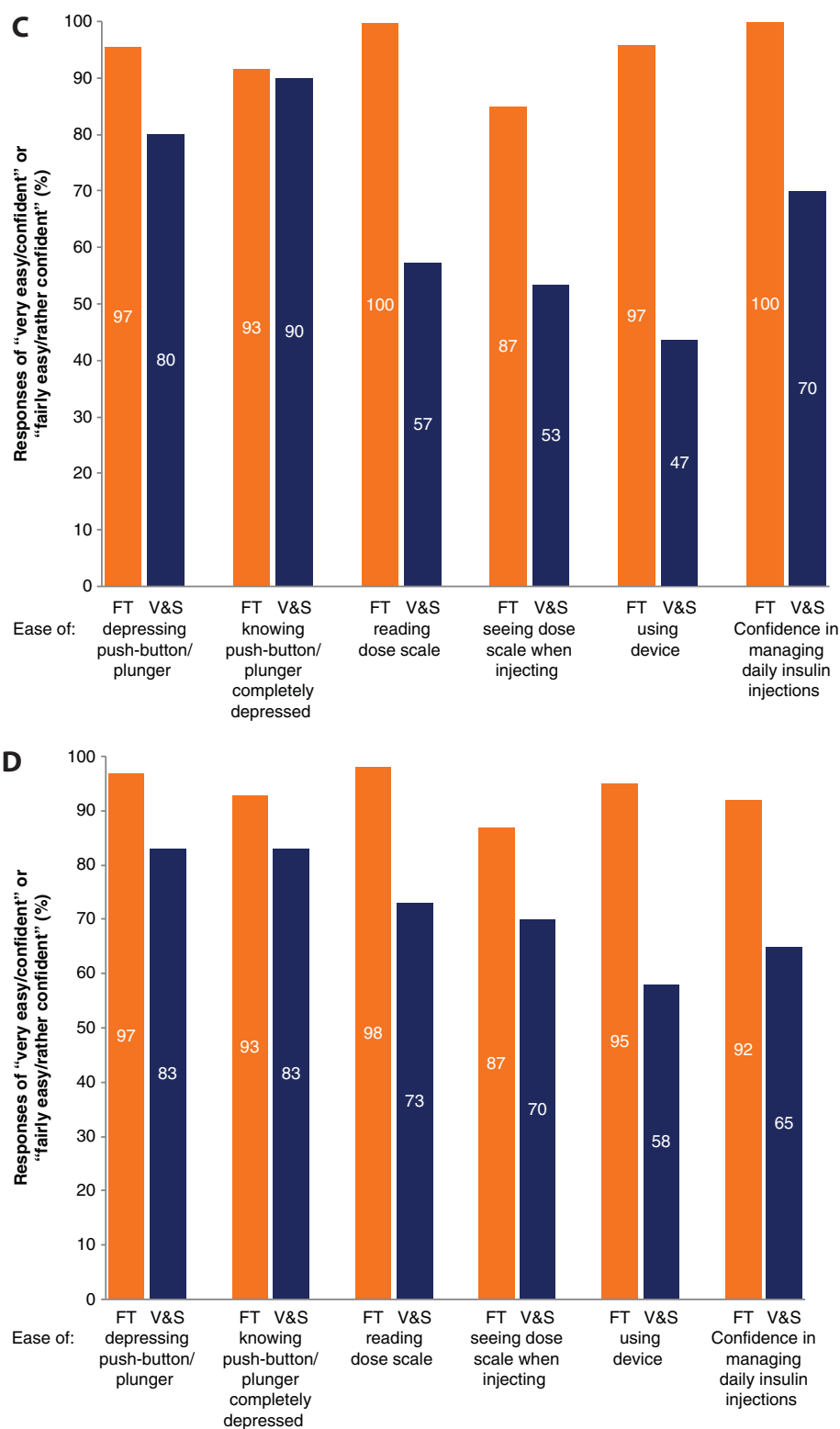


Figure 2. Percentage of participants giving scores of 5 ("very easy/confident") or 4 ("fairly easy/rather confident") combined for various questions on ease of use and confidence in managing daily insulin injections with FlexTouch® (FT) or vial and syringe (V&S) (continued). (A) All healthcare professionals (n = 60); (B) physicians (n = 30); (C) nurses (n = 30); (D) all patients (n = 60); (E) V&S-experienced patients (n = 30); and (F) needle-naïve patients (n = 30).

Healthcare professional and patient perceptions of a new prefilled insulin pen versus vial and syringe

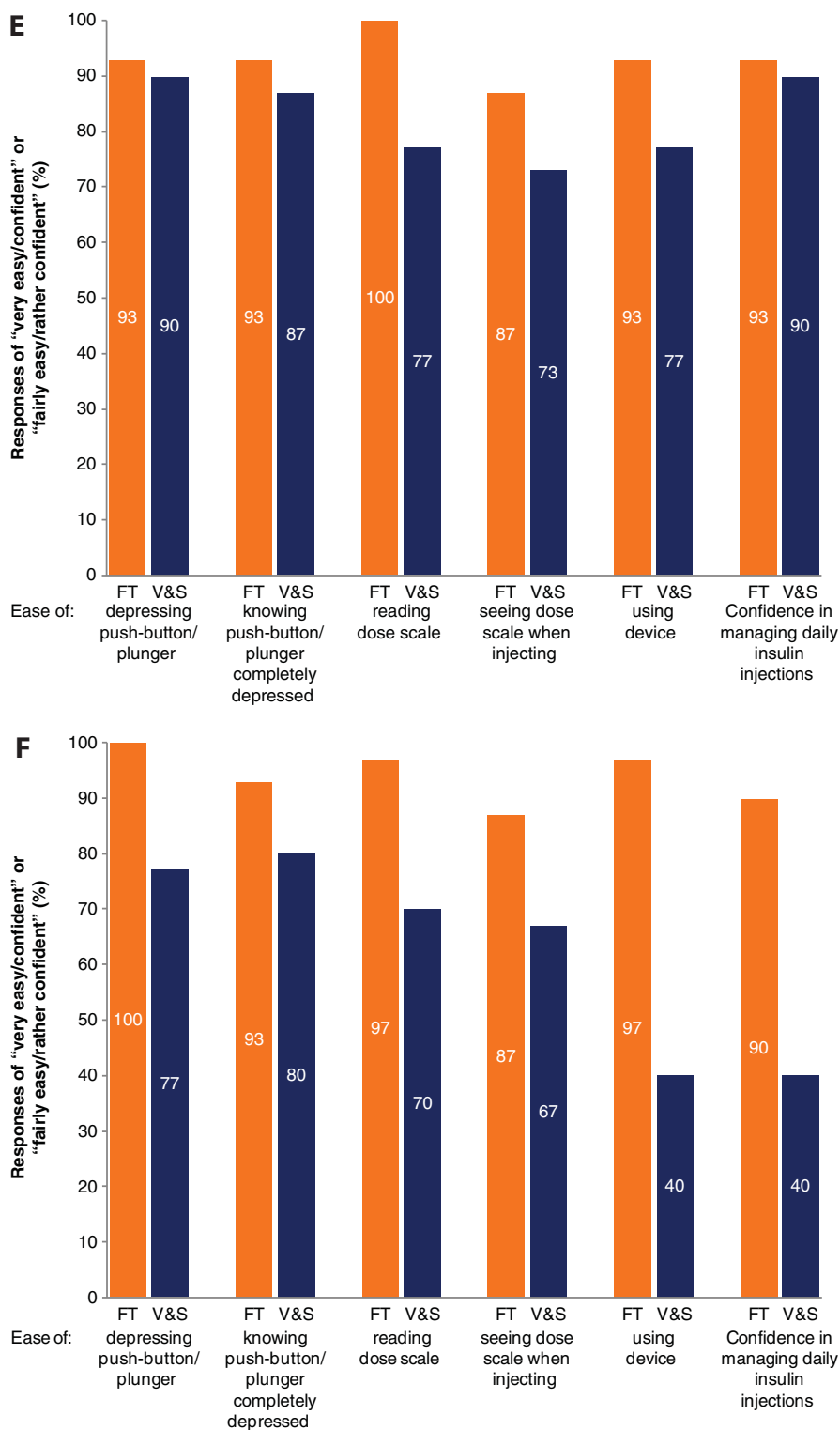


Figure 2. Percentage of participants giving scores of 5 ("very easy/confident") or 4 ("fairly easy/rather confident") combined for various questions on ease of use and confidence in managing daily insulin injections with FlexTouch® (FT) or vial and syringe (V&S) (continued). (A) All healthcare professionals (n = 60); (B) physicians (n = 30); (C) nurses (n = 30); (D) all patients (n = 60); (E) V&S-experienced patients (n = 30); and (F) needle-naïve patients (n = 30).

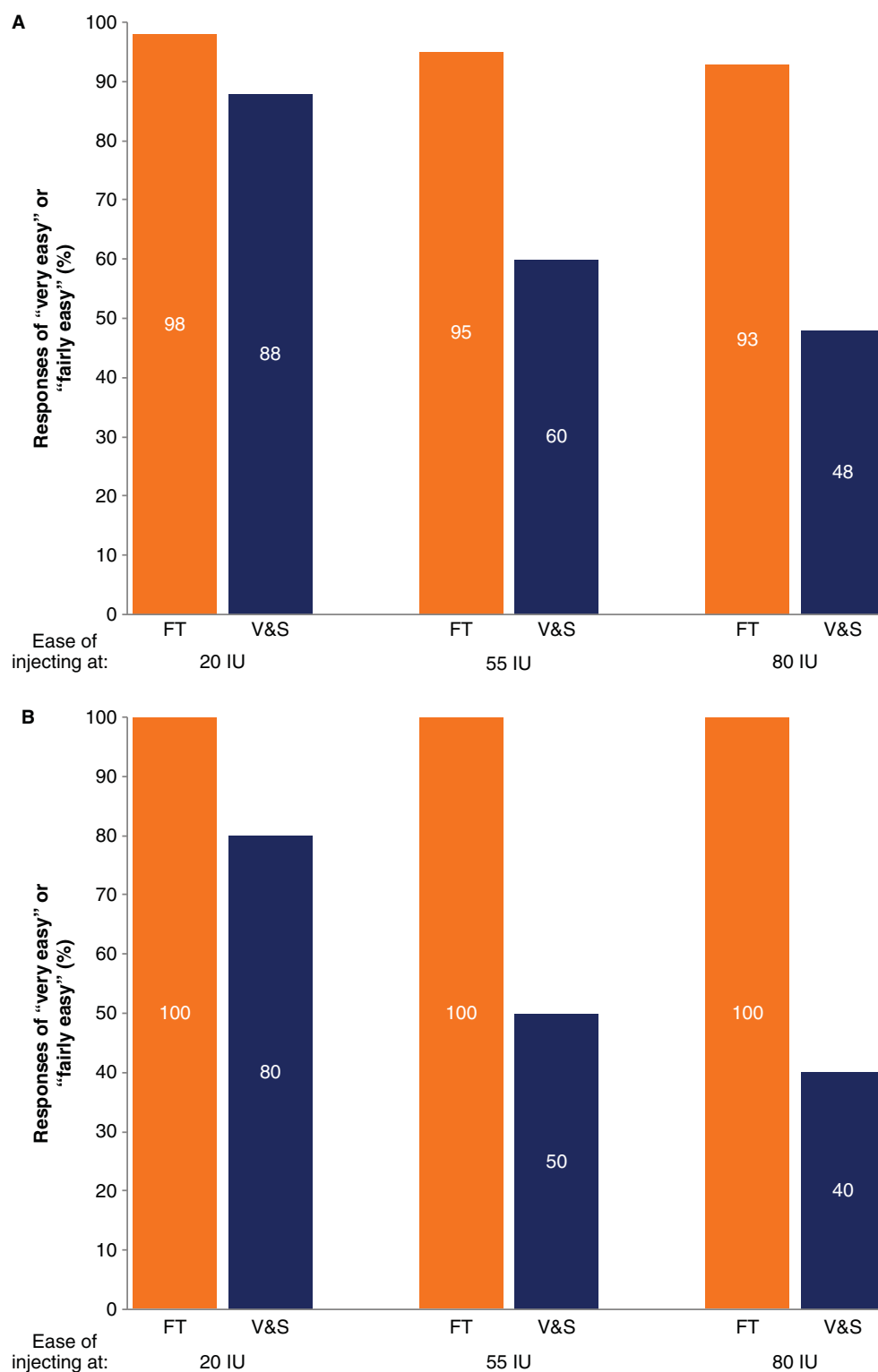


Figure 3. Percentage of participants giving scores of 5 ("very easy") or 4 ("fairly easy") combined for ease of injecting at three dose levels with FlexTouch® (FT) or vial and syringe (V&S). (A) All healthcare professionals (n = 60); (B) physicians (n = 30); (C) nurses (n = 30); (D) all patients (n = 60); (E) V&S-experienced patients (n = 30); and (F) needle-naïve patients (n = 30).

IU: International units.

Healthcare professional and patient perceptions of a new prefilled insulin pen versus vial and syringe

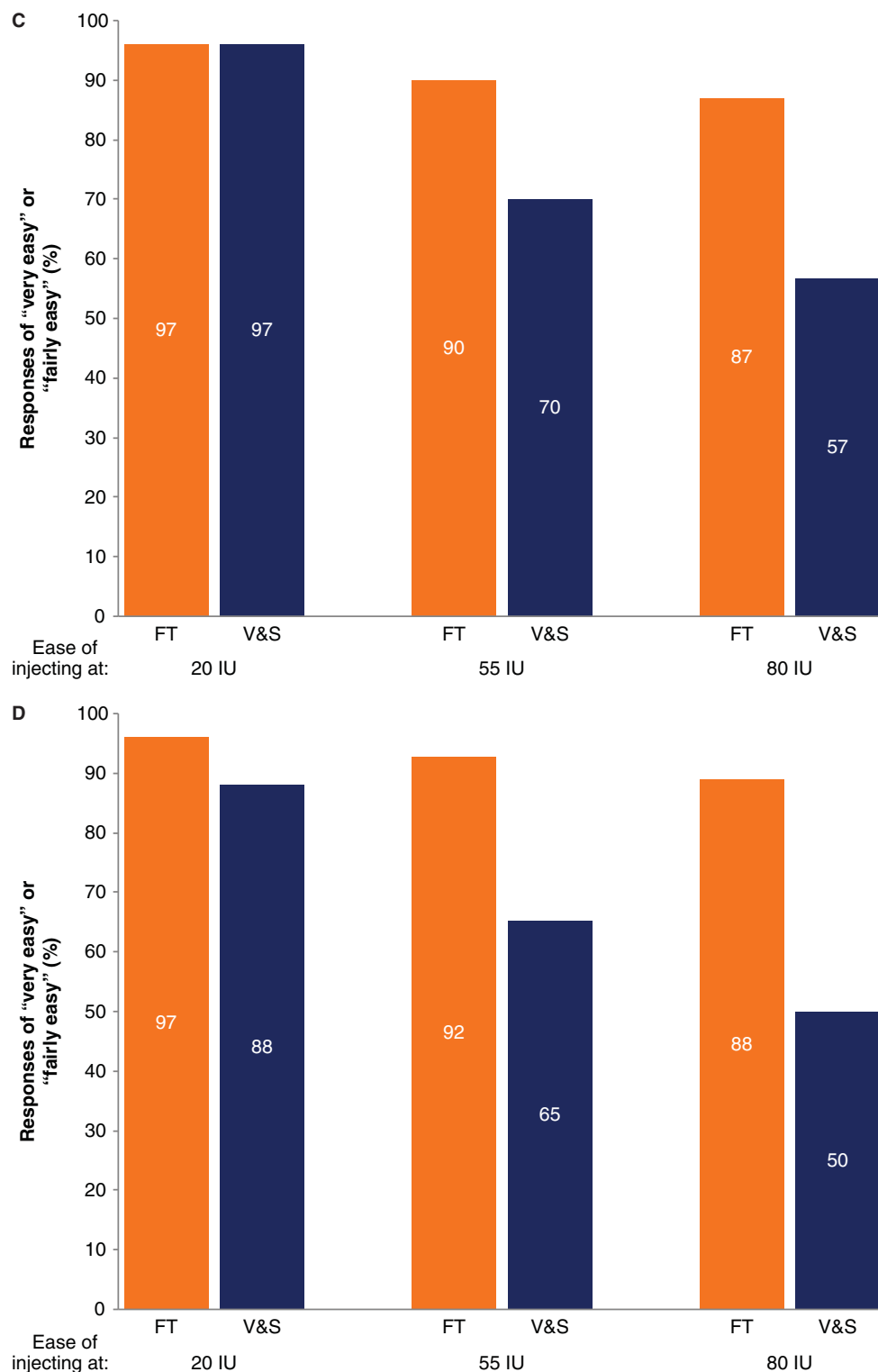


Figure 3. Percentage of participants giving scores of 5 ("very easy") or 4 ("fairly easy") combined for ease of injecting at three dose levels with FlexTouch® (FT) or vial and syringe (V&S) (continued). (A) All healthcare professionals (n = 60); (B) physicians (n = 30); (C) nurses (n = 30); (D) all patients (n = 60); (E) V&S-experienced patients (n = 30); and (F) needle-naïve patients (n = 30).

IU: International units.

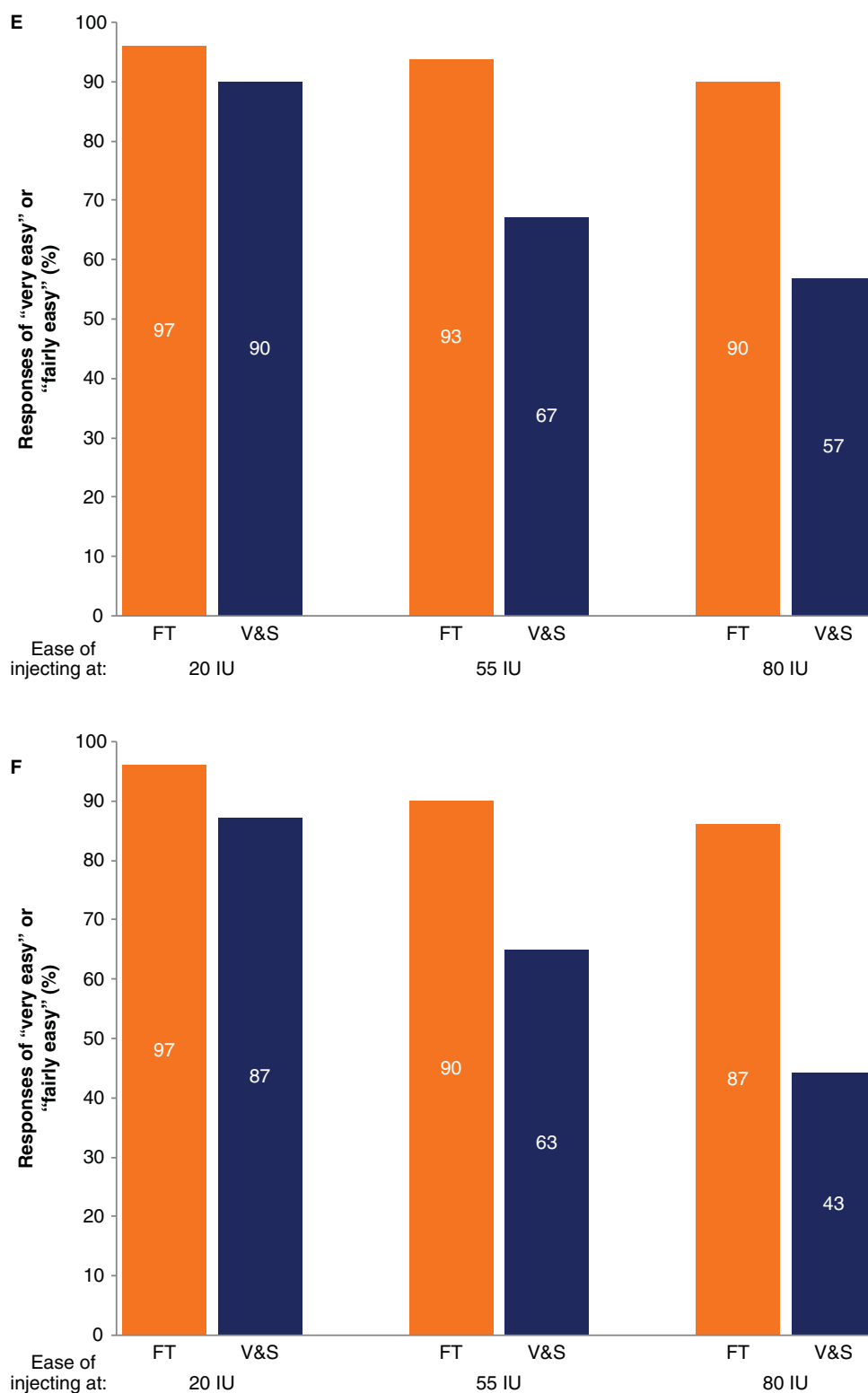


Figure 3. Percentage of participants giving scores of 5 ("very easy") or 4 ("fairly easy") combined for ease of injecting at three dose levels with FlexTouch® (FT) or vial and syringe (V&S) (continued). (A) All healthcare professionals (n = 60); (B) physicians (n = 30); (C) nurses (n = 30); (D) all patients (n = 60); (E) V&S-experienced patients (n = 30); and (F) needle-naïve patients (n = 30).

IU: International units.

Healthcare professional and patient perceptions of a new prefilled insulin pen versus vial and syringe

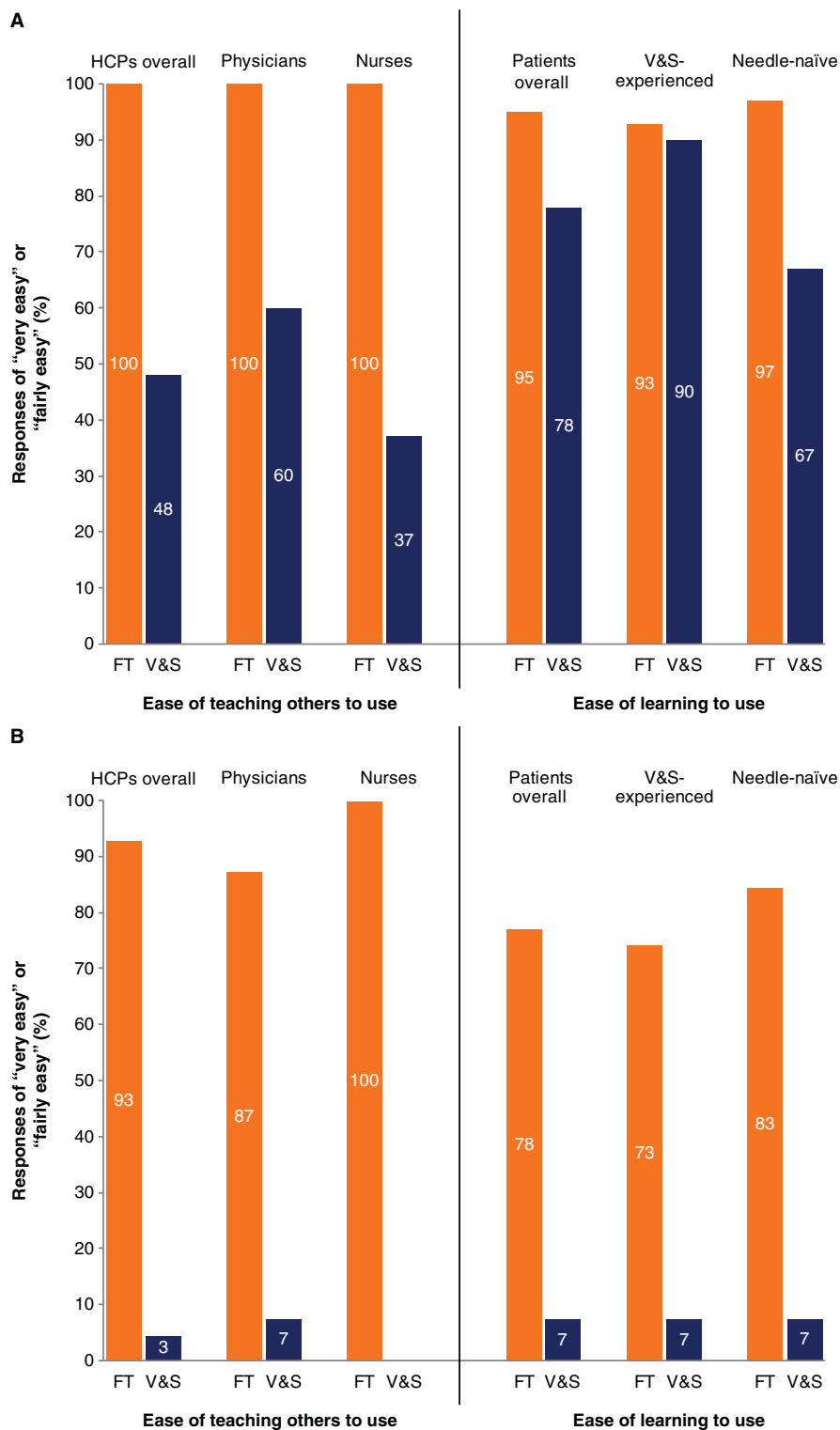


Figure 4. Ease of teaching to use and learning to use FlexTouch® (FT) and vial and syringe (V&S). (A) Percentage of participants giving scores of 5 ("very easy") or 4 ("fairly easy") combined for ease of learning to use and ease of teaching others how to use FT or V&S; and (B) percentage of participants choosing FT or V&S as the easier device to learn to use or teach others to use.

HCPs: Healthcare professionals.

significantly more participants chose FT as the device they would recommend, than chose V&S (91 vs. 3%, respectively; the remainder chose “either/neither”; $p < 0.001$).

3.4.2 Healthcare professionals

When asked if they would recommend the device, 98% of the 60 HCPs (all physicians and 97% of nurses) would recommend FT, compared with only 50% of HCPs (57% of physicians and 43% of nurses) who would recommend V&S. When asked to choose just one device to recommend, 93% of HCPs (97% of nurses and 90% of physicians) would recommend FT (the remainder chose “either/neither”), but none would recommend V&S.

3.4.3 Patients

Among patients overall, when asked if they would recommend the device, 93% (93% of needle-naïve patients and 93% of V&S-experienced patients) would recommend FT, while 63% (47% and 80% of needle-naïve patients and V&S-experienced patients, respectively) would recommend V&S. When asked to choose just one device to recommend, 88% of patients overall (97% of needle-naïve patients and 80% of V&S-experienced patients) would recommend FT, and only 13% of V&S-experienced patients and no needle-naïve patients would recommend V&S (the remainder chose “either/neither”).

3.5 “Very easy/confident” results

The percentages of participants giving FT or V&S the highest score of “5” (corresponding to “very easy/confident”) for various device operations are shown in Table 1.

4. Discussion

In this study, patients stated that FT was easier to learn to use than V&S, and HCPs stated that FT was easier to teach others to use than V&S. Higher ratings were given to FT than to V&S by HCPs (both physicians and nurses) and patients (both needle-naïve and V&S-experienced) for the following categories: ease of use, ease of injecting at three different dose settings, ease of depressing the push-button/plunger, ease of reading the dose scale, ease of seeing the dose scale when injecting, and confidence in managing daily insulin injections. Correspondingly, most HCPs and patients in this study would recommend FT rather than V&S. These findings are demonstrated by the results for ratings in the top two categories on the 5-point rating scale combined (“very” and “fairly/rather”). In addition, the strongest results were seen for ratings in the top (“very”) category alone (Table 1), also showing that a high percentage of participants rated FT very highly.

Previous studies have shown patient preference for prefilled pens over V&S. For example, in one study, more than 75% of patients stated they would continue using a pen or recommend one to others compared with V&S [35], while in

a study comparing V&S with FP, participants reported a preference for FP and considered it more discreet for use in public and easier to use than V&S [36]. However, few analyses have been conducted to assess preference among different groups of HCPs or patients.

The preference for FT compared with other *prefilled insulin pens* has been assessed among different groups of HCPs and people with diabetes. One study investigated perceptions of FT versus the prefilled pens SoloStar® and KwikPen™ among insulin pen-experienced and pen-naïve people with diabetes, physicians and nurses [37]. More people with diabetes and HCPs gave “very/fairly easy” ratings to FT than to SoloStar® or KwikPen™ for ease of use, and more participants gave “very/rather confident” ratings to FT than to SoloStar® or KwikPen™ for the ability to manage daily injections. The study also showed that patients preferred FT to SoloStar® and KwikPen™ for ease of learning to use, and HCPs preferred FT to the comparator pens for ease of teaching others to use. A similar trend in results was generally observed within the four participant groups.

Patients’ opinions and experiences should be considered when making decisions about insulin delivery devices. HCPs may expect better therapy adherence if their patients feel confident that they are using the right device for their needs, abilities and lifestyle. Although the results on ease of learning among V&S-experienced patients showed less dramatic differences between the devices (Figure 3A), 73% of those already using V&S found FT easier to learn to use than V&S (only 13% stated that V&S was easier to learn to use; Figure 3B). This result is surprising, since V&S users were already familiar with the device. As expected, V&S users gave higher ratings than needle-naïve patients for V&S in general. However, surprisingly, the differences in ratings between these two groups were not large. More patients, both V&S users and needle-naïve patients, gave “very/fairly easy” ratings for FT than for V&S on all measures. It could be speculated from the results that, if given the choice, V&S users would prefer to use an insulin pen such as FT. In addition, for V&S users who may need to change their insulin delivery system and may be resistant to new technology, FT is a good option that HCPs can recommend to make the switch easier.

In the USA, it is not unusual to prescribe high insulin doses, and for that reason it is important to test preference and ease of use of insulin pens and V&S across a range of low to high doses. Generally, most patients and HCPs rated injecting with FT “very easy” or “fairly easy,” even at 80 IU, with relatively low variation in ratings for perceived ease of injection between doses. In contrast, the “very/fairly easy” ratings declined markedly with V&S at the higher doses in all participant groups. This may be a reflection of the unique characteristics of no push-button extension and low injection force of FT. In comparison, injecting using V&S may be perceived as more difficult at high doses than low doses because of extension of the plunger, which may increase the difficulty of holding the device stable during injection (decreased

Table 1. Percentage of participants giving scores of 5 ("very easy/confident") for various device operations with FlexTouch® and vial and syringe: all healthcare professionals (n = 60); physicians (n = 30); nurses (n = 30); all patients (n = 60); vial and syringe-experienced patients (n = 30); and needle-naïve patients (n = 30).

Measure	Score of 5 ("very easy/confident")											
	HCPs overall		Physicians		Nurses		Patients overall		V&S-experienced		Needle-naïve	
	FT	V&S	FT	V&S	FT	V&S	FT	V&S	FT	V&S	FT	V&S
Using the device	83%	30%	73%	27%	93%	33%	85%	37%	83%	57%	87%	17%
Reading the dose scale	82%	35%	73%	30%	90%	40%	82%	43%	87%	53%	77%	33%
Seeing the dose scale when injecting	58%	27%	53%	27%	63%	27%	63%	42%	63%	43%	63%	40%
Depressing the push-button/plunger	75%	47%	70%	43%	80%	50%	83%	58%	83%	63%	83%	53%
Knowing if the push-button/plunger has been completely depressed	73%	50%	63%	40%	83%	60%	73%	60%	80%	70%	67%	50%
Injecting the dose of 20 IU	92%	60%	93%	43%	90%	77%	85%	57%	83%	63%	87%	50%
Injecting the dose of 55 IU	72%	33%	73%	23%	70%	43%	78%	43%	77%	53%	80%	33%
Injecting the dose of 80 IU	60%	17%	60%	10%	60%	23%	78%	38%	80%	40%	77%	37%
Teaching others to use	77%	20%	77%	23%	77%	17%	NA	NA	NA	NA	NA	NA
Learning to use	NA	NA	NA	NA	NA	NA	83%	48%	87%	63%	80%	33%
Managing your daily insulin injections using this device	90%	38%	83%	30%	97%	47%	78%	45%	83%	63%	73%	27%

HCPs: Healthcare professionals; FT: FlexTouch®; IU: International units; NA: Not applicable; V&S: Vial and syringe.

stability) [34], and the user needs to stretch the hand further on the extended plunger to inject compared with the push-button on FT. Additionally, the entire injection process with V&S, from drawing up insulin to injecting, requires additional steps that involve manual dexterity. This could be a particular issue among people with diabetes and manual dexterity impairment [4], weak hand strength (as seen in elderly patients) and/or small hands. Therefore, FT may assist these individuals with injection difficulties. A recent study has also identified an easy push-button injection to be the most important pen feature for patient satisfaction, being the feature most commonly identified by patients in their current insulin pen, and the only feature for which patients were clearly likely to switch injection devices [38].

Patients and HCPs gave relatively good ratings to some aspects of V&S use. For example, the number of positive ratings for ease of knowing if the push-button/plunger had been completely depressed with V&S was high, as may be expected because the user can see the dose leaving the syringe barrel and being injected. This is often cited as an advantage for V&S over insulin pens by patients. However, this study showed that more positive ratings were given for FT than V&S for this question and for the "seeing the dose scale when injecting" question.

A limitation of this study is that patients performed test injections with FT and V&S in an interview, and did not use the devices to administer insulin over a few days. While there are limitations to the information gathered in questionnaire studies, this information is relevant in the

current healthcare environment, where HCPs play a pivotal role in deciding the most appropriate insulin delivery system for their patients. In addition, an advantage of this study is the inclusion of different groups of HCPs and patients, which allows comparison of perceptions of insulin delivery devices between these different groups.

When recommending an insulin delivery device for a patient, HCPs need to take into account the individual's lifestyle, insulin regimen, and ability to use a particular device, which may be influenced by factors such as manual dexterity or visual acuity impairment [39]. The understanding of features on insulin pens by physicians and nurses contributes to their recommendation of the most appropriate insulin delivery device for their patients based on their individual needs. In this study, many features relating to the use of the insulin pen throughout the injection process were rated higher with FT than V&S by HCPs. When asked if they would recommend the device, 98% of the HCPs in this study stated that they would recommend FT but only 50% stated that they would recommend V&S, suggesting HCPs may be inclined to recommend FT in everyday practice. Studies show that insulin pens have superior dosing accuracy than V&S, and may be associated with lower risk of hypoglycemia, reduced healthcare resource utilization and related costs [5-9,40-44]. Despite these advantages, most patients in the USA receiving insulin therapy use V&S [13-17]. One barrier to HCPs recommending insulin pens in countries such as the USA, is the perception that there is insurance company resistance to insulin pen use. However, most insurance plans (in the USA) do

not limit the use of pens, and HCPs should be encouraged to allay these concerns and should be made aware of the clinical benefits of using insulin pens rather than V&S [4].

From a healthcare provider's perspective, the finding that FT is easier to teach others to use than V&S is important, as it suggests that a patient can be quickly taught to self-administer insulin via FT during a clinic visit, with minimal interruption in the daily schedule. By recommending an insulin delivery device such as FT over V&S, the healthcare provider may subsequently have more time to attend to other responsibilities. Interestingly, patients rated V&S easier to learn to use than HCPs rated V&S easy to teach others to use. It may be that patients over-estimated their ability to learn how to use a new device, or perhaps HCPs' general experience of teaching patients to use V&S was that they found it relatively difficult. Over 80% of nurses in this study were experienced in training patients on how to use V&S and prefilled pens—such an overwhelming response in favor of FT from these experienced nurses implies that FT could minimize the time and resources spent on patient training, which could be a benefit in the everyday management of diabetes and the interaction between HCP and patient.

5. Conclusions

Despite the challenges inherent in performing medical device usability studies, such as the validity of questionnaire-based studies on everyday clinical use, the wide range of study participants provides insight into the current needs and challenges that a variety of users, HCPs as well as people with

diabetes, face. These results demonstrate that FT is easier to use and instills greater confidence in users than V&S. Moreover, the results clearly show that patients find FT easier to learn to use and HCPs find FT easier to teach others to use compared with V&S. FT was also preferred to V&S by patients for learning to use and by HCPs for teaching others to use. A device, such as FT, that is easier to use and to learn to use than V&S may lead to less resistance from existing V&S users to transition to newer technologies and contribute to a better treatment outcome.

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