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ORIGINAL RESEARCH

STYLCONNECT Study: An Assessment of Automatic Data Collection Devices by People Living with Diabetes and Using an Insulin Pen

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ABSTRACT

Introduction: The use of devices to connect insulin pens could facilitate management and improve glycaemic control in people with type 1 (PwT1D) and type 2 diabetes (PwT2D). However, their acceptance seems little studied. We conducted an online survey with the main objective of assessing the level of interest among insulin-treated people with diabetes (PwD) in a device connected to a disposable pen and secondary objectives of assessing the perceived benefits and important features expected of a connected device and identifying factors associated with interest scores.

Methods: An ad-hoc questionnaire, validated by PwD, was used. Responses from 1798 PwD (975 PwT1D and 823 PwT2D) were analysed.

Results: The mean interest rating was 7.4/10 (PwT1D: 7.2 vs PwT2D: 7.7; $p < 0.001$). PwD perceived that the device would make it easier to record their diabetes-related information (7.7/10) and keep all insulin and diabetes data in a single location (7.7/10). It was particularly important for PwD that this type of device could integrate data from glucose-measuring devices (7.8/10) and could set an alarm when all insulin in the body had been metabolised (7.7/10).

Conclusion: Our study highlighted PwD's strong interest in automating the collection of their insulin therapy data, with significantly more interest among PwT2D than PwT1D, and the importance of interoperability between glucose measurement devices and interchangeability between the different brands of insulin. More generally, for the first time and on a large scale, our study provided a greater understanding of the expectations of PwD regarding these devices.

Keywords: Insulin; Connected pen; Type 1 diabetes; Type 2 diabetes; Diabetes management; Connected medicine

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Key Summary Points

Why carry out this study?

While the use of devices to connect insulin pens and automate the collection of insulin therapy data could facilitate management and improve glycaemic control in people with diabetes (PwD), their acceptance by PwD seems to be little studied

This study used an online questionnaire to assess the level of interest and perceived benefits and features users would expect among insulin-treated PwD in a device connected to a disposable pen

What was learned from the study?

Our study revealed the strong interest in a device connected to a disposable pen among PwD

Interest was significantly lower in people with type 1 diabetes than in those with type 2 diabetes, likely because the former had better knowledge of insulin therapy

It was particularly important for PwDs that this type of device could be connected to blood/interstitial glucose measuring devices and that it was compatible with the different brands of insulin

This information could be used to expand the use of this type of device and improve its features

INTRODUCTION

In France, the prevalence of pharmacologically treated people with diabetes (PwD) is estimated at 6.13% of the population; that is, > 4 million people [1]. An estimated 858,000 PwD were treated with insulin in France in 2018 [2]. It is estimated that around 12% used an insulin pump in 2019 and 88% had daily or multiple daily insulin injections [3]. Most people with type 1 diabetes (PwT1D) and approximately 20% of people with type 2 diabetes (PwT2D) are treated with insulin injections [4, 5].

Insulin treatment aims at providing the right dose of insulin at the right time to help PwD to better control their diabetes while limiting iatrogenic hypoglycaemia [6]. Beyond the short-term life-saving therapy that insulin is for PwT1D, the long-term purpose of controlling blood glucose is to limit the onset and progression of micro- and macrovascular complications [7, 8]. These complications are responsible for high levels of morbidity and mortality, lower quality of life for PwD and increased healthcare expenditure [9, 10].

Despite the development of new insulins [11], the adherence of PwD to their insulin treatment remains a key factor in optimising control of their blood glucose [12, 13]. This situation is further complicated by the many constraints associated with insulin treatments [14–16]. Several studies suggest that recording insulin injection data can improve glucose control by helping patients to lower the number of missed doses and dosing errors and by optimising the treatment provided by healthcare professionals [16, 17]. However, unlike insulin pumps, which collect administration data automatically, people treated with insulin pens need to collect their data manually in most cases [16]. Although the practice requiring patients to record data themselves helps them limit missed doses and better understand their condition, the clinical reality is that data are rarely collected manually on a long-term basis.

In this respect, the use of devices that connect insulin pens to apps for monitoring and data-sharing purposes seems promising [18, 19]. Although the clinical efficacy of several devices has been demonstrated, attracting great interest in the medical and scientific community [19–22], their acceptance by PwD has not been studied extensively. As effective as any technology may be, it will have no impact if it is not used by the intended recipients. For this reason, gaining a better understanding of the relationship that PwD have with such innovative technology is key and could be used to expand the

use of this type of device and improve its features.

METHODS

STYLCONNECT was a mixed study consisting of an initial qualitative survey followed by a quantitative, observational, cross-sectional survey carried out among PwD approached by the Fédération Française des Diabétiques (French Federation of Diabetics, FFD).

Aims and Objectives

The main objective of this study was to assess the level of interest of PwD in automating the collection of their insulin therapy data using a device connected to a disposable pen.

The secondary objectives were to:

1. Assess the perceived benefits among PwD of a device connected to a disposable pen;
2. Assess the important features for PwD of the app paired to a device connected to a disposable pen;
3. Identify expected functions and features for a device connected to a disposable pen;
4. Identify the socio-demographic and clinical factors associated with the interest score for using a device connected to a disposable pen.

Study Design

The qualitative survey was conducted between April and May 2021. Semi-structured interviews were conducted with three PwT1D and three PwT2D. This survey identified variables to be included in the quantitative survey questionnaire. The questionnaire was tested on three people who used an insulin pen.

The quantitative survey was published online from September to October 2021. To be eligible to participate, respondents had to be living with type 1 (T1D) or type 2 diabetes (T2D); be aged $\geq$ 18 years; receive treatment with basal insulin alone and/or combined with rapid/ultra-rapid insulin and be injection pen users; live in France; have given their consent (click accept system) after reading the study procedures. PwD treated with pre-mixed insulin were not eligible to participate in the study.

According to article R1121-1 of the French Public Health Code, our study was considered out of scope of the fields of medicine. Indeed, objectives relating to know-how among PwD and sociological aspects did not aim to expand biological or medical knowledge. For this reason, IRB or ethical approval for our study was not required. However, data protection is very important for the FFD. Therefore, this study was conducted in accordance with the Commission Nationale Informatique et Liberté reference methodology 004, 'Research not involving human subjects (studies and evaluations in the health field)'. This study was registered as a project in Health Data Hub (no. F20220504191522).

Endpoints

Primary Endpoint

To assess the level of interest of PwD in automating the collection of their insulin therapy data, they were presented with the main features of a Bluetooth connector attached to a disposable insulin pen that transmits information to a smartphone app. After this presentation, their interest was assessed using a Likert scale with the question: 'Generally speaking, is this device of interest to you?' A score of 0 represented a total lack of interest and a score of 10 a very strong interest.

Secondary Endpoints

Several parameters were assessed using Likert scales (a score of 0 indicated a total absence of benefits and a score of 10 very significant benefits): (1) potential benefits for PwD of using a device connected to a disposable pen; (2) important features for PwD of a device connected to a disposable pen; (3) expected functions and features of the connected device.

Socio-demographic and clinical factors associated with the interest score for a device connected to a disposable pen were identified based on declarative socio-demographic and clinical

variables such as gender, age, level of education, smartphone ownership, type of diabetes and ability to manage diabetes.

Smartphone usage skills were assessed on the basis of an average of two Likert scales (checking emails; internet browsing and use of apps) where 0 indicated major difficulties and 10 no difficulty. A score of 0 was given to PwD who did not have a smartphone.

Diabetes-related distress was measured using five items from the first dimension 'emotional burden and regimen-related distress' of the Diabetes Distress Scale (items 1, 3, 8, 11, 14) [23]. Other items were not included because of questionnaire length constraints. For each item, a score of 1 indicated that diabetes was not a problem at all and a score of 6 indicated that diabetes was a very serious problem/burden. The mean of the five items was used.

Difficulty in managing diabetes was assessed using five ordinal qualitative variables (difficulty in remembering the amount and time of the last injection, burdensome diabetes-management routine, incomplete injection of doses, data recording and discussion with their doctor). The mean of the scores of the five variables was used.

Analyses

Quantitative variables were described by their mean and standard deviation. Qualitative variables were described using frequencies and percentages.

The normality of the distributions was assessed using the Shapiro-Wilk test. The correlation between quantitative variables was measured using Pearson or Spearman coefficients according to the distribution of variables. Qualitative variables were analysed using the chi-squared or Fisher's test based on the numbers in the various categories. Links between qualitative and quantitative variables were determined using the Student's *t*-test or the Mann-Whitney-Wilcoxon test depending on the normality of the quantitative variable or using an analysis of variance or Kruskal-Wallis test where the qualitative variable had categories > 2.

The socio-demographic and clinical factors associated with the interest score for a device connected to a disposable pen were identified using a linear regression model. Bivariate analyses were performed to identify variables to be included in the model (variables with a p value ≤ 0.05). A stepwise selection of variables was used. Multicollinear variables were not included in the model. Seventeen PwD who were unsure about whether their diabetes was under control were excluded from the analysis.

Assumptions were tested bilaterally and considered significant when the p value was < 0.05. XLSTAT V2020.5.1 software was used for the statistical analyses.

RESULTS

Socio-demographic Characteristics of the Population

The socio-demographic characteristics of the population are presented in Table 1.

There were 2797 PwD included in the database. Of these, 999 were excluded as they did not meet the inclusion criteria. Responses from 1798 PwD were analysed. The majority of participants who responded to the online questionnaire originated from the FFD community, which included subscribers to the newsletter and its Facebook group.

Of the respondents, 54.2% lived with T1D and 45.8% with T2D. The mean age of the population was 57.3 years. PwT1D were significantly younger (51.5 years) than PwT2D (64.0 years). Overall, 48.8% of respondents were female, with a significantly higher proportion of PwT1D (53.8%) than PwT2D (42.9%) being female. PwT1D were more likely to have a level of education higher or equivalent to 'Baccalauréat' (French equivalent to A levels) + a 2- to 3-year university degree (61.4%) than PwT2D (43.7%). The vast majority of PwD had a smartphone (91.9%), but PwT1D were much more likely to report that they had one (94.4%) than PwT2D (89.1%). The mean score for smartphone use was 8.5/10. This score was significantly higher in PwT1D (8.9/10) than in PwT2D (8.0/10).

Table 1 Socio-demographic characteristics of the STYLCONNECT study according to type of diabetes

Socio-demographic characteristics	T1D *N* = 975	T2D *N* = 823	Total *N* = 1798	T1D vs T2D *p* value
Age in years—mean (SD)	51.5 (16.0)	64.0 (11.6)	57.3 (15.5)	< 0.0001
Gender				
Male—*N* (%)	450 (46.2)	470 (57.1)	920 (51.2)	< 0.0001
Female—*N* (%)	525 (53.8)	353 (42.9)	878 (48.8)	
Level of education				
< Baccalauréat [French equivalent to A levels]—*N* (%)	185 (19.0)	308 (37.4)	493 (27.4)	< 0.0001
Baccalauréat [French equivalent to A levels]—*N* (%)	148 (15.2)	127 (15.4)	275 (15.3)	
Baccalauréat [French equivalent to A levels] + a 2/3-year university degree—*N* (%)	294 (30.2)	229 (27.8)	523 (29.1)	
> Master's—*N* (%)	305 (31.3)	131 (15.9)	436 (24.2)	
Unknown—*N* (%)	43 (4.4)	28 (3.4)	71 (3.9)	
Smartphone				
Yes—*N* (%)	920 (94.4)	733 (89.1)	1653 (91.9)	< 0.0001
No—*N* (%)	55 (5.6)	90 (10.9)	145 (8.1)	
Smartphone usage score*—mean (SD)	8.9 (2.6)	8.0 (3.4)	8.5 (3.0)	< 0.0001

SD standard deviation, *T1D* type 1 diabetes, *T2D* type 2 diabetes
*People who did not own a smartphone were given a score of 0

Ability to Manage Diabetes

The characteristics associated with the population's ability to manage their diabetes are presented in Table 2.

PwT1D had been taking insulin for significantly longer than PwT2D (21.7 years vs 9.0 years). Of the respondents, 73.4% were treated with basal and rapid/ultra-rapid insulin (basal bolus), 16.4% were treated exclusively with basal insulin and 4.3% with rapid/ultra-rapid alone. A significantly higher proportion of PwT1D were treated with a basal bolus regimen than PwT2D (90.7% vs 52.9%). The number of daily injections was significantly higher for PwT1D than PwT2D (3.8 vs 2.5). For 45.4% of PwD, their insulin originated from a single manufacturer and for 47.0% from two manufacturers (Lilly, Novo Nordisk or Sanofi). The proportion of PwT1D using insulin from two different manufacturers was significantly higher than the proportion of PwT2D (59.9% vs 31.7%).

Most of the glucose monitoring was performed via flash glucose monitoring (FGM) (62.6%), followed by blood glucose monitoring (BGM) (29.2%) and continuous glucose monitoring (CGM) (3.8%). A significantly higher proportion of PwT1D used FGM or CGM than PwT2D (81.3% vs 48.6%). Thirty-three per cent of patients did not record any information related to their diabetes, mainly due to constraints or a perceived lack of usefulness (40.1% PwT1D vs 24.8% PwT2D). Among those recording some of their data, 49.6% used a paper notebook, 33.3% used an app (mainly an app linked to the CGM/FGM) and 17.1% used a file or other method. Just over half of PwD recorded data relating to their insulin therapy (55.2%). PwT1D were less likely than PwT2D to

Table 2 Ability to manage diabetes in the STYLCONNECT study population according to type of diabetes

Ability to manage diabetes	T1D *N* = 975	T2D *N* = 823	Total *N* = 1798	T1D vs T2D *p* value
Length of time on insulin treatment in years—mean (SD)	21.7 (16.7)	9.0 (8.4)	15.9 (14.9)	< 0.0001
Insulin regimen				
Basal only—*N* (%)	29 (3.0)	266 (32.3)	295 (16.4)	< 0.0001
Rapid/ultra-rapid—*N* (%)	45 (4.6)	32 (3.9)	77 (4.3)	
Basal + Rapid/ultra-rapid—*N* (%)	884 (90.7)	435 (52.9)	1319 (73.4)	
Unknown—*N* (%)	17 (1.7)	90 (10.9)	107 (6.0)	
Number of daily injections—mean (SD)	3.85 (0.9)	2.47 (1.5)	3.22 (1.4)	< 0,0001
Number of insulin manufacturers (basal only/and/or rapid)				
1—*N* (%)	372 (38.2)	444 (53.9)	816 (45.4)	< 0.0001
2—*N* (%)	584 (59.9)	261 (31.7)	845 (47.0)	
Unknown—*N* (%)	19 (1.9)	118 (14.3)	137 (7.6)	
Glucose monitoring technique				
BGM—*N* (%)	162 (16.6)	363 (41.1)	525 (29.2)	< 0.0001
FGM—*N* (%)	745 (76.4)	380 (46.2)	1125 (62.6)	
CGM—*N* (%)	48 (4.9)	20 (2.4)	68 (3.8)	
DNK—*N* (%)	20 (2.1)	60 (7.3)	80 (4.4)	
Regular recording of diabetes data				
Yes—*N* (%)	584 (59.9)	619 (75.2)	1203 (66.9)	< 0.0001
No—*N* (%)	391 (40.1)	204 (24.8)	595 (33.1)	
Reasons for not recording (*N* = 595)*				
Burdensome—*N* (%)	225 (57.5)	69 (33.8)	294 (49.4)	< 0.0001
Takes too long—*N* (%)	126 (32.2)	35 (17.2)	161 (27.1)	< 0.0001
Not useful—*N* (%)	143 (36.6)	97 (47.5)	240 (40.3)	< 0.0001
Method used for recording data (*N* = 1203)**				
Paper—*N* (%)	243 (41.6)	354 (57.2)	597 (49.6)	< 0.0001
App—*N* (%)	247 (42.3)	153 (24.7)	400 (33.3)	
Other—*N* (%)	94 (16.1)	112 (18.1)	206 (17.1)	
Regular recording of insulin data				
Yes—*N* (%)	506 (51.9)	487 (59.2)	993 (55.2)	0.002
No—*N* (%)	469 (48.1)	336 (40.8)	805 (44.8)	

Table 2 continued

Ability to manage diabetes	T1D $N = 975$	T2D $N = 823$	Total $N = 1798$	T1D vs T2D p value
Control over diabetes				
Not controlled at all—N (%)	41 (4.2)	49 (6.0)	90 (5.0)	< 0.0001
Not very well controlled—N (%)	232 (23.8)	260 (31.6)	492 (27.4)	
Fairly well controlled—N (%)	453 (46.5)	378 (45.9)	831 (46.2)	
Very well controlled—N (%)	241 (24.7)	127 (15.4)	368 (20.5)	
Unknown—N (%)	8 (0.8)	9 (1.1)	17 (0.9)	
Distress—mean (SD)	2.7 (1.2)	2.7 (1.1)	2.7 (1.2)	0.728
Diabetes difficulty management score—mean (SD)	2.6 (1.0)	2.3 (0.9)	2.5 (0.9)	< 0.0001

BGM blood glucose monitoring, *CGM* continuous glucose monitoring, *DNK* does not know, *FGM* flash glucose monitoring, *SD* standard deviation, *T1D* type 1 diabetes, *T2D* type 2 diabetes

*The analysis was limited to PwD who did not record diabetes data (T1D N = 391; T2D N = 204; overall N = 595); multiple answers were allowed

**The analysis was limited to PwD who recorded diabetes data (T1D N = 584; T2D N = 619; overall N = 1203)

record data (51.9% vs 59.2%). Of the respondents, 66.7% reported that their diabetes was fairly well or very well controlled. Significantly higher proportions of PwT1D made such declarations compared with PwT2D (71.2% vs 61.4%). The mean diabetes distress score was 2.7/6, and this figure was not significantly different between PwT1D and PwT2D. The mean diabetes management difficulty score was 2.5/6 and was significantly higher in PwT1D than in PwT2D (2.6 vs 2.3).

Level of Interest Among the Population in a Device Connected to a Disposable Pen

The level of interest in a device connected to a disposable pen among this population is shown in Fig. 1.

To the question 'Generally speaking, is this device of interest to you?', referring to the connected device, the population's mean interest score was 7.4 (± 3.0). Mean interest from PwT1D was significantly lower than that of PwT2D (7.2 vs 7.7; $p < 0.001$). A higher proportion of PwT1D than PwT2D gave an interest score between 0 and 5 (26.8% vs 22.6%) and an interest score between 6 and 8 (28.6% vs 20.9%). A lower proportion of PwT1D than PwT2D gave an interest score of between 9 and 10 (44.6% vs 56.5%). Chi-squared test showed that the proportions of PwT1D and PwT2D in these score classes were significantly different ($p < 0.0001$).

Perceived Potential Benefits of a Device Connected to a Disposable Pen

The perceived potential benefits of a device connected to a disposable pen are shown in Table 3.

Participants considered that the device would (1) make it easier to record information related to their diabetes (7.7/10); (2) enable them to keep all insulin and diabetes data in a single location (7.7/10); (3) facilitate medical follow-up (7.6/10); (4) make it easier to receive support from the healthcare professional most involved in monitoring their diabetes (7.6/10); (5) improve their blood glucose monitoring (7.3/10); (6) help them to better understand their diabetes (6.8/10); (7) mean they did not have to worry so much about having forgotten

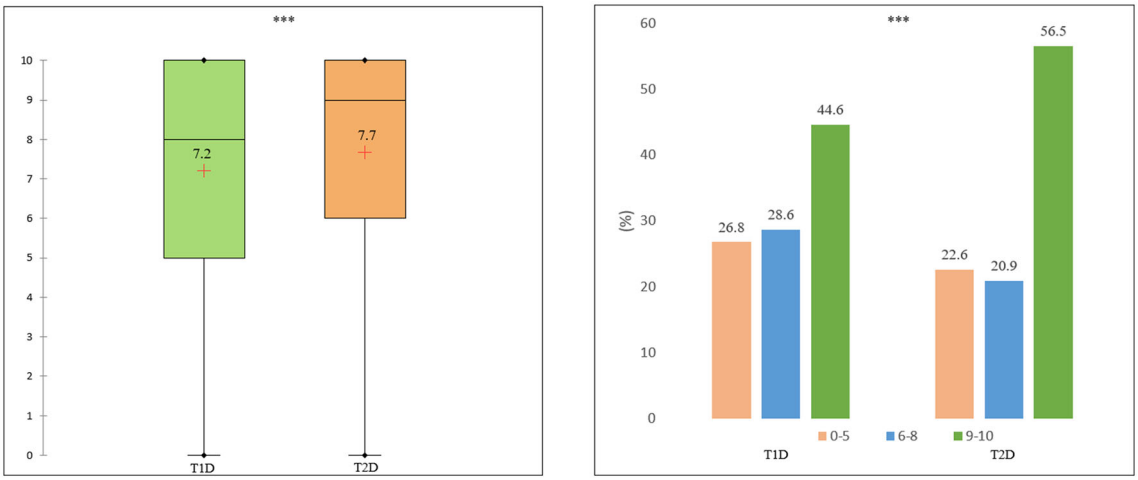

Fig. 1 Boxplot of the interest score on the left and breakdown of the interest score on the right, according to type of diabetes. *N*, PwT1D = 975; *N*, PwT2D = 823. ***$p < 0.001$. *PwT1D* people with T1D, *PwT2D* people with T2D, *T1D* type 1 diabetes, *T2D* type 2 diabetes

to inject the last dose (6.7/10); (8) limit the time spent managing their diabetes (6.4/10); (9) reduce the number of missed injections (6.1/10); (10) improve time in range (6.0/10). Most scores were significantly lower in PwT1D than in PwT2D. There was a significant correlation between the mean overall score given by PwD regarding their assessment of the potential benefits of a device connected to a disposable pen (7.0/10) and the score given to the question: 'Generally speaking, is this device of interest to you?' (coefficient = 0.810; $p < 0.0001$).

Important Features for the App Paired to a Device Connected to a Disposable Pen

The features deemed important for the app paired to a device connected to a disposable pen are shown in Table 4.

The three features with the highest scores were: (1) integrating CGM/FGM data (7.8/10), which was significantly more important for PwT1D than for PwT2D (8.0 vs 7.7; $p = 0.007$); (2) setting an alarm to alert when all insulin in the body has been metabolised (7.7/10); (3) calculating doses to be injected (7.5/10). No significant difference was observed with respect to type of diabetes for these last two features.

The three least important features were: (1) transferring data to relatives (4.1/10); (2) setting an alarm as a reminder not to forget to inject insulin (6.6/10), which was rated significantly lower in PwT1D than in PwT2D (6.3 vs 7.0; $p < 0.0001$); (3) displaying the quantity of insulin remaining in the pen (6.6/10).

The phone pedometer integration score (6.8/10) was significantly lower for PwT1D than PwT2D (6.5 vs 7.1; $p < 0.001$). Similarly, the interest score regarding transferring data to one's doctor (7.2/10) was significantly lower for PwT1D than PwT2D (6.9 vs 7.4; $p < 0.001$).

Functions and Features Expected for a Device Connected to a Disposable Pen

The expected functions and features for a device connected to a disposable pen are shown in Table 5.

All functions and features assessed were considered important (7.5/10–9.3/10). The highest scoring areas of interest related to the ease of use of the connected device (9.3/10) and the app to which it would be connected (9.2/10). Respondents also considered it important that the device could be recharged or that the batteries were easy to change (9.1/10).

Table 3 Score of potential benefits received from using this device according to the type of diabetes

Potential benefits perceived	T1D *N* = 975	T2D *N* = 823	Total *N* = 1798	*p* value
Makes it easier to record information relating to your diabetes—mean (SD)	7.6 (2.8)	7.8 (2.8)	7.7 (2.8)	0.249
Keeps all your insulin and diabetes data in one location—mean (SD)	7.5 (3.1)	7.9 (2.9)	7.7 (3.0)	< 0.001
Facilitates your medical follow-ups—mean (SD)	7.4 (2.9)	7.9 (2.7)	7.6 (2.8)	0.0001
Makes it easier to receive support from the healthcare professional—mean (SD)	7.3 (2.9)	7.9 (2.7)	7.6 (2.9)	< 0.0001
Improves your blood glucose monitoring—mean (SD)	7.0 (3.1)	7.7 (2.9)	7.3 (3.0)	< 0.0001
Helps you gain a better understanding of your diabetes—mean (SD)	6.4 (3.2)	7.3 (3.0)	6.8 (3.1)	< 0.0001
Means you don't have to worry anymore about having forgotten to inject your last dose—mean (SD)	6.6 (3.6)	6.8 (3.4)	6.7 (3.5)	0.493
Limits the time you spend managing your diabetes—mean (SD)	6.1 (3.3)	6.9 (3.2)	6.4 (3.3)	< 0.0001
Reduces the number of missed injections—mean (SD)	5.9 (3.8)	6.4 (3.7)	6.1 (3.8)	0.027
Improves your time in range*—mean (SD)	6.0 (3.5)	5.9 (3.9)	5.9 (3.7)	0.510
Mean overall potential benefits perceived interest score—mean (SD)	6.8 (2.7)	7.2 (2.6)	7.0 (2.7)	< 0.0001

PwT1D people with T1D, *PwT2D* people with T2D, *PwD* people with diabetes, *SD* standard deviation, *T1D* type 1 diabetes; T2D, type 2 diabetes

*The 230 PwD (84 PwT1D vs 146 PwT2D; $p < 0.001$) who stated that they did not know what 'time in range' means were given a score of 0. Time in range is a relatively new indicator and not always known by patients, so this question included the possibility for patients to answer 'I don't know what it is'

Variables Associated with the Interest Score for the Connected Device

Variables associated with the interest score for the connected device are shown in Table 6 and Fig. 2.

The determination coefficient (R^2) of the linear regression model was 0.117. PwT1D were more likely to give a lower interest score for the device than PwT2D (coefficient − 0.158; $p < 0.0001$). The youngest PwD were significantly more likely to award a lower interest score for the connected device than the oldest PwD (coefficient − 0.074; $p = 0.005$). PwD reporting a high smartphone usage score and those with a high score for diabetes management difficulties were more likely to give a higher interest score for the device than the other PwD (coefficient = 0.274, $p < 0.0001$ and coefficient = 0.078, $p = 0.001$, respectively). PwD who said that their diabetes was not very well controlled or was poorly controlled were more likely to give a higher interest score for the device than the other PwD (coefficient = 0.080; $p = 0.001$). PwD who did not record insulin-injection data were more likely to give a higher interest score for the device than PwD who were already recording their data (coefficient = 0.047; $p = 0.045$).

DISCUSSION

Our findings suggested that PwD have a high level of interest in automating the collection of their insulin therapy data using a device connected to a disposable pen, with a mean interest score of 7.4 (± 3.0). With data coming from both PwT1D and PwT2D, we had the possibility to compare both populations. Are PwT1D less interested in this type of device than PwT2D?

Table 4 Important features for the app paired with a device connected to a disposable insulin pen

Important features	Results $N = 1798$	T1D/T2D p-value
Integration of data from the CGM/FGM—mean (SD)	7.8 (3.0)	**0.007**
Setting an alarm when all insulin in the body has been metabolised—mean (SD)	7.7 (3.1)	0.401
Calculation of insulin doses to be injected—mean (SD)	7.5 (3.1)	0.985
Differentiation of types of insulin (slow and rapid)—mean (SD)	7.4 (3.2)	0.070
Transfer of diabetes data to my doctor—mean (SD)	7.2 (3.2)	< **0.001**
Integration of data relating to types of physical activity—mean (SD)	7.1 (3.1)	0.134
Integration of data relating to the intensity of physical activity—mean (SD)	7.0 (3.2)	0.162
Automatic integration of data from the pedometer on my phone—mean (SD)	6.8 (3.4)	< **0.001**
Integration of various brands of insulin—mean (SD)	6.7 (3.5)	0.080
Display the quantity of insulin remaining in the pen—mean (SD)	6.6 (3.5)	0.357
Setting an alarm/notification as a reminder to not forget an insulin injection—mean (SD)	6.6 (3.5)	< **0.0001**
Transfer of diabetes data to my relatives—mean (SD)	4.1 (3.5)	0.145

Bolded p-values are significant
CGM continuous glucose monitoring, *FGM* flash glucose monitoring, *SD* standard deviation, *T1D* type 1 diabetes, *T2D* type 2 diabetes

The study findings highlighted many differences between the PwT1D and PwT2D who participated in the study. In terms of demographics, PwT1D were significantly younger, had a much higher level of education and used their smartphones more proficiently than PwT2D. These differences are consistent with the data in the literature [24, 25]. In addition, and as expected, it was considered that the management of insulin therapy for PwT1D is more cumbersome than for most PwT2D; that is, the former has a more complex insulin regimen, a significantly higher number of injections and a higher diabetes management difficulty score.

Given that several studies have shown that (1) the use of connected devices and apps is more common in young people, people with a high level of education and those who know how to use their smartphones [25, 26]; (2) this type of device seems particularly aimed at people treated with multiple daily injections (MDI) of insulin (i.e. primarily PwT1D) [17], we could have expected that the interest score for this device would be higher in PwT1D than in PwT2D. Paradoxically, the study revealed that the interest score in PwT1D was significantly lower than in PwT2D (7.2 vs 7.7; $p < 0.001$). Although the difference was only 0.5/10, it is worth discussing, given that the interest in relation to eight of the ten perceived potential benefits of the device was significantly lower in PwT1D than in PwT2D.

Three assumptions may be used to interpret this paradoxical result:

1. Differences may exist between PwT1D and PwT2D in terms of their relationship to their diabetes and its management. Zowgar et al. [27] reported in a study of 744 PwT1D and PwT2D that the level of diabetes knowledge was significantly better in the youngest PwD with a higher level of education. As PwT1D were younger in our study with a higher level of education, it is likely that their knowledge of diabetes was better but also more 'intuitive' than that of PwT2D. In our study, PwT1D recorded much less information on their insulin

Table 5 Other functions and features expected when using a device connected to a disposable pen

Other functions and features expected	Results $N = 1798$	T1D/T2D p-value
The pen and its connector must be easy to use—mean (SD)	9.3 (1.7)	0.407
The app must be easy to use—mean (SD)	9.2 (1.8)	0.093
The device must be rechargeable or it must be possible to change the battery easily (reusable)—mean (SD)	9.1 (2.0)	0.511
The device must be free of charge (for me)—mean (SD)	9.1 (2.0)	**0.002**
The app must protect my personal data—mean (SD)	9.1 (2.2)	0.050
The app must be compatible with all smartphones—mean (SD)	8.9 (2.4)	**0.0001**
Using the pen and its connector must not cause me to waste time during injections—mean (SD)	8.8 (2.2)	**< 0.0001**
The connector must be able to retain information on injections for several days to make sure I do not have to connect my phone all the time—mean (SD)	8.8 (2.3)	0.420
I need a connector for each insulin pen (one for slow- and one for rapid-acting insulin)—mean (SD)	7.6 (3.1)	**< 0.0001**
There must be an option allowing the user to not send data to healthcare professionals—mean (SD)	7.4 (3.2)	0.233

Bolded p values are significant
SD standard deviation, *T1D* type 1 diabetes, *T2D* type 2 diabetes

therapy than PwT2D. Thus, it seems likely that the habitual daily management of insulin treatment of PwT1D and the very 'personal' knowledge of the often-variable nature of their diabetes make it harder for the healthcare team to adjust their therapy. A corollary of this knowledge could mean that they have a reduced need to share data with healthcare professionals and, by extension, a lower level of interest in such devices.

2. The higher level of interest in this type of device expressed by PwT2D compared with PwT1D may also be explained by the difference in the length of the diabetes treatment (PwT1D = 21.7 years vs PwT2D = 9.0 years). PwT2D not only develop diabetes later in life than PwT1D, but insulin treatment is usually only offered as a last resort, whereas it is the initial treatment for PwT1D [28, 29]. This may result in PwT2D requesting greater support, in this case electronic, than PwT1D for whom insulin injections are 'routine'. The higher proportion of PwT2D recording their insulin therapy data than PwT1D could be a sign of this difference. In addition, PwT1D often have lengthier practical experience due to their younger age at the onset of diabetes and are better trained; also, they are, for instance, more extensive users of carb counting than PwT2D, but carb counting has never been truly evaluated or used in the population of PwT2D. Unlike patients who use pumps with bolus advisors, PwT1D currently treated with MDI do not often collect data on the quantities of carbohydrates ingested. It is also difficult for the healthcare team to analyse injected insulin doses without the associated quantities of carbohydrates. As long as apps do not offer the equivalent to a bolus advisor for patients receiving MDI, this is likely to be a further limiting factor in the interest expressed by PwT1D in such devices.

Table 6 Factors associated with the interest score for the connected device

Variables	Results $N = 1798$	p value
Qualitative variables—mean (SD)		
Type of diabetes		
T1D	7.2 (3.0)	0.0001
T2D	7.7 (3.0)	
Gender		
Male	7.4 (3.0)	0.442
Female	7.5 (3.0)	
Records insulin data		
Yes	7.2 (3.1)	< 0.0001
No	7.7 (2.9)	
Control over diabetes/blood glucose		
Fairly good/good or very good/well controlled	7.2 (3.1)	0.001
Not or not at all well controlled	7.8 (2.8)	
Quantitative variables—coefficient		
Age	− 0.128	< 0.0001
Smartphone usage score	0.293	< 0.0001
Distress associated with diabetes	0.099	< 0.0001
Difficulty with diabetes	0.080	0.001
Insulin treatment time	− 0.159	< 0.0001

SD standard deviation, *T1D* type 1 diabetes, *T2D* type 2 diabetes

3. Finally, this difference in interest may have been partly induced by the PwT1D selection bias in this study, as they had to be receiving insulin by MDI to be included. The choice to be treated via MDI in 2021 in France could indicate that such patients are less 'technophile' than patients treated with an insulin pump and therefore less inclined to used connected devices. This bias is likely to be lower in PwT2D, for whom the use of an insulin pump is less common.

Multi-Compatibility/Interoperability: A Cautionary Note

One of the main expectations among PwD in terms of device benefits was the option of having all insulin and blood glucose data in a single location, and the most important feature of the paired app was its ability to integrate glucose-sensor data. As a result, multi-compatibility seems to be a crucial issue for the roll-out and adoption of this type of device.

However, two limitations have been highlighted. The first is related to the interoperability between the devices for collecting insulin data and glucose measurement devices. Although the reusable connected pens from

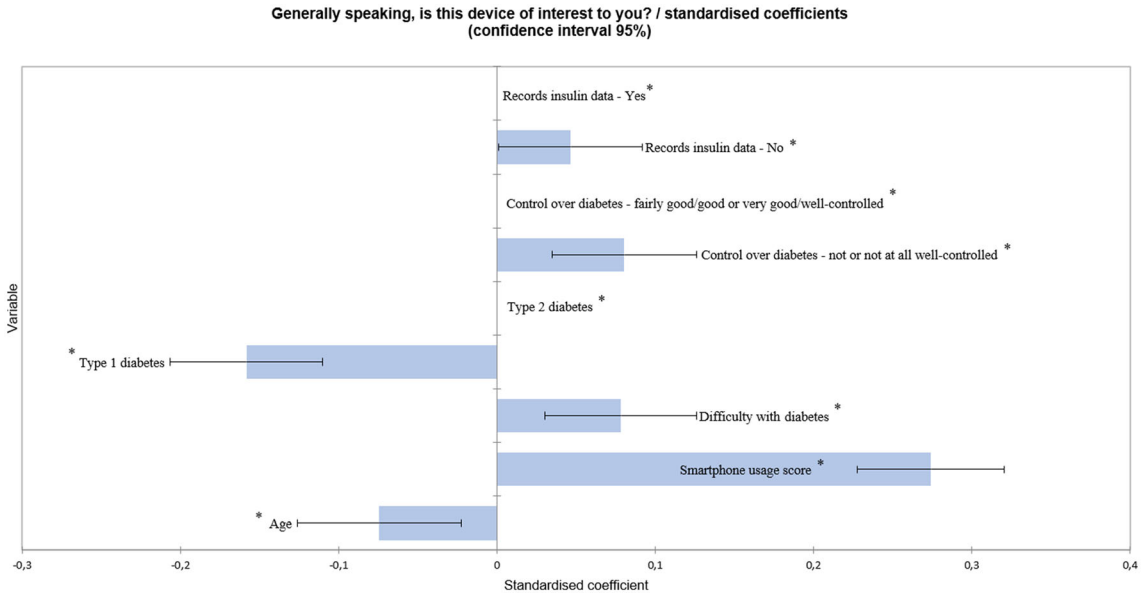

Fig. 2 Linear regression (standardised coefficients) to assess the contribution of several variables to the interest score for the connected device. $N = 1781$; $R^2 = 0.117$, $p < 0.0001$. $^*p < 0.05$. The absolute values of the standardized regression coefficients may be compared, giving a rough indication of the relative importance of the variables. This varies between − 1 and + 1 where − 1 indicates a total negative association, 0 an absence of association and + 1 a total positive association

Novo Nordisk, NovoPen™6 and NovoPen Echo™ should be able to be paired with the Freestyle Libre Link app [30]–the app dedicated to the glucose measuring device most commonly used by PwD treated with MDI in our study–as well as with the Glooko app, this is not the case for the Tempo Smart Button™ from Lilly, which can be integrated with the myDiabby™, Glooko®, Dexcom™ and mySugr™ apps, or the Mallya™ device integrated with the GluciCheck™ app [31, 32]. For these latter devices, the app feature considered most important by PwD is not available.

The second limitation is related to the compatibility between devices in terms of the automatic collection of data and the various brands of insulin. Most devices are only compatible with insulin pen or cartridge from a single manufacturer [19]. While this is not a problem for PwT2D treated with basal insulin only, this lack of compatibility can pose a major problem for PwD treated with MDI of basal insulin and rapid/ultra-rapid insulin from two different manufacturers. This was the case for 59.9% of PwT1D and 31.7% of PwT2D in our study (i.e. 47.0% of the total population surveyed). Given this situation, which assumes that almost half of the study population would have to use two automatic insulin data collection devices, it seems difficult to imagine–as things stand–that this type of device will allow all insulin and blood/interstitial glucose data to be collected in one place, as PwD would like.

The lack of interoperability and compatibility between automatic insulin data collection devices could potentially force some PwD treated with MDI using rapid/ultra-rapid insulin from one manufacturer and a basal insulin from another manufacturer to use two different automatic collection devices, and two or even three different apps (one for each device and one for blood/interstitial glucose data). Interoperability and compatibility are all the more important as they would allow PwD to maximise the benefits of all medical devices in terms of their quality of life and glucose control [33] as well as facilitate the support received from healthcare professionals.

Limitations

The main limitation of this study is its design. This study was carried out under real-world conditions; that is, a clinical research setting, which, in particular, has led to two biases. The first relates to the profile of the people included in the study–the vast majority of whom were associated with the FFD. Thus, they probably had a greater level of expertise and autonomy in managing their disease than the general population of PwD. Moreover, the fact that participants were recruited online probably implies an over-representation of PwD with a high level of e-literacy (i.e. skilled in the use of information technology tools) compared to the overall population of PwD. It is therefore highly likely that the interest score for the device for collecting insulin data has been overestimated. Finally, insofar as almost none of the respondents have ever used such devices, a usage survey must be carried out to supplement the data from this study.

CONCLUSION

Our cross-sectional study of 1798 PwD highlighted this population's strong interest in automating the collection of their insulin therapy data using a device connected to a disposable pen. Against expectations, the finding showed that this type of device garnered significantly more interest among PwT2D than PwT1D. Our study also highlighted the importance of interoperability between glucose measurement devices and interchangeability between the different brands of insulin. More generally, for the first time and on a large scale, our study provides a greater understanding of the expectations of PwD regarding these devices, thereby encouraging the development of technologies favouring their adoption.

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Compliance with Ethics. This study was conducted in accordance with reference

methodology MR-004, 'Research not involving human subjects (studies and evaluations in the health field)'.

Data Availability. The datasets generated during and/or analyzed during the current study are not publicly available due to the engagement with respondents and to avoid disclosing non-aggregated data.

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