ORIGINAL ARTICLE

Impact of the Omnipod[®] Insulin Management System on Quality of Life: A Survey of Current Users

William H. Polonsky, PhD,^{1,2} Danielle Hessler, PhD,³ Jennifer E. Layne, PhD,⁴ and Howard Zisser, MD⁵

Abstract

Background: Few recent studies have examined the impact of continuous subcutaneous insulin infusion systems on patient-reported quality of life (QOL). We explored QOL changes resulting from treatment with the Omnipod[®] Insulin Management System (Insulet Corp., Billerica, MA).

Methods: One thousand two hundred forty-five adults (>18 years) with type 1 diabetes and current Omnipod users completed an online questionnaire examining perceived changes in QOL and glycemic control since Omnipod initiation. The QOL dimensions included overall well-being (World Health Organization-5, modified to examine changes retrospectively), diabetes distress (Type 1 Diabetes Distress Scale, current distress and a modified retrospective version), and psychosocial impact (two subscales from the Diabetes Technology Impact Measure, perceived control over diabetes, and hypoglycemic safety). Regression analyses examined associations between demographics, key psychological factors, and perceived change in glycemic control with the QOL dimensions.

Results: Broad QOL and clinical benefits associated with Omnipod use were common. The majority reported positive changes in the following: overall well-being (53.5%), perceived control over diabetes (72.5%), hypoglycemic safety (50.6%), and diabetes distress (69.6%). Worsening in any of these areas was uncommon. In addition, 64.2% of patients reported glycemic improvement post-Omnipod initiation, while 35.2% reported a decrease in severe hypoglycemic episodes. Trust in one's Omnipod, perceived improvement in glycemic control, and reductions in severe hypoglycemia independently predicted benefits in all QOL measures (all $P < 0.001$).

Conclusions: These findings suggest that Omnipod users perceived substantial QOL benefits from the device; benefits are more apparent in those who trust the device and have noted positive changes in glycemic control.

Keywords: Continuous subcutaneous insulin infusion, Quality of life, Type 1 diabetes, Glycemic control.

Introduction

FOR ADULTS WITH type 1 diabetes (T1D), anecdotal evidence suggests that continuous subcutaneous insulin infusion (CSII) may lead to an improvement in quality of life (QOL), but the available study data in this population are limited, and findings to date have been mixed and/or circumstantial. For example, among the few randomized controlled trials, significant differences in diabetes-specific QOL

(as measured by the Diabetes Quality-of-Life questionnaire) between CSII patients and multiple daily injection (MDI) patients were observed in one study,¹ but not in another.² DeVries et al. observed significant improvement in the general health and mental health components of the Short Form-36 questionnaire in the CSII group, while scores in the MDI group remained stable.³ However, this latter study was limited to adults with poor glycemic control ($A1c \geq 8.5\%$). Of note, MDI users in all three of these trials were limited to NPH

¹University of California, San Diego; ²Behavioral Diabetes Institute, San Diego, California.

³University of California, San Francisco, San Francisco, California.

⁴Insulet Corporation, Billerica, Massachusetts.

⁵University of California, Santa Barbara, Santa Barbara, California.

(Neutral Protamine Hagedorn) as their basal insulin; whether any QOL differences would have been apparent if long-acting basal insulins had been available remains unknown.

Since these studies were completed, CSII technology has advanced considerably; unfortunately, there have been no recent investigations of the potential impact of these newer CSII systems or CSII features on QOL. One of the more distinctive CSII devices is the Omnipod[®] Insulin Management System (Insulet Corp., Billerica, MA), which has a unique tubeless design. Recent evidence suggests differential patient preferences for Omnipod,⁴ although the impact on QOL has not been studied. As a first step toward addressing this gap, we conducted a comprehensive survey of a large adult population of current Omnipod users to determine the following:

1. What improvements in QOL typically occur with Omnipod use, if any, and how common are such benefits?
2. What demographic, behavioral, or attitudinal factors might predict the degree, or absence, of Omnipod-associated QOL benefits?

Research Design and Methods

Subjects

All current Omnipod patients in the Insulet registry who met the inclusion criteria (age ≥ 18 years, had T1D > 1 year, currently using Omnipod for 6–24 months, and able to read and write English without assistance) and had previously agreed to receive e-mail communications from Insulet were invited to participate in the study. A target of collecting at least 1000 completed surveys was set to ensure a large diverse patient sample.

Procedures

The e-mail inviting patients to participate in the QOL online survey study indicated that the study was being conducted in collaboration between Insulet and the Behavioral Diabetes Institute, and it was emphasized that survey responses were anonymous and participation was voluntary. Furthermore, it was explained that the online survey concerned their perception of QOL-related benefits and/or losses since Omnipod initiation, current Omnipod use, and Omnipod attitudes. Respondents were asked to complete a brief eligibility questionnaire, provide informed consent, and complete the survey, if eligible. They received a \$25 electronic gift card for participation.

The survey was conducted over a 3-week time period, and collected data were entered into a central database using a HIPAA-protected server, with no linkages to personal health information or personal identifiers. The research protocol was approved by Ethical and Independent Review Services, a community-based Institutional Review Board.

Measures

The survey instrument consisted of three major sections:

1. Demographic and clinical characteristics, including CSII experience. This section included items about personal characteristics (e.g., age, gender, ethnicity, diabetes duration, and education level), current glycemic control (last A1c value), and current and past experience with CSII. Respondents also indicated how much they trusted their Omnipod device to function as needed, via a four-

point Likert-type scale—"not at all," "a little," "moderately," "a lot."

2. Impact of Omnipod use on glycemic control. Respondents estimated how their A1c had changed since Omnipod initiation, selecting from five options: "large decrease ($\geq 0.5\%$)," "small decrease ($< 0.5\%$)," "no change," "small increase ($< 0.5\%$)," or "large increase ($\geq 0.5\%$)." They similarly estimated how the frequency of severe hypoglycemia (i.e., episodes requiring help from another person to recover) had changed over the same time period, selecting from "many fewer from before," "slightly fewer than before," "no change," "slightly more than before," or "many more than before."
3. Impact of Omnipod use on QOL outcomes. Of the validated instruments available to examine the elements of QOL, we found no adequate measures that assess the patient's perception of QOL change retrospectively. Therefore, we adapted three existing instruments for the current study:

First, to evaluate change in general well-being, a modified version of the World Health Organization-5 (WHO-5) scale, a widely used five-item instrument for the assessment of well-being, was included.⁵ In this modified version, patients were asked to indicate how Omnipod use had affected the frequency of each of the five WHO-5 items (e.g., feeling "cheerful and in good spirits") on a five-point Likert-type scale: "much less of the time" (−2), "somewhat less of the time" (−1), "no change" (0), "somewhat more of the time" (+1), or "much more of the time" (+2).

Second, to evaluate change in diabetes distress, the Diabetes Distress Scale for Type 1 Diabetes (T1-DDS) was selected. The T1-DDS is a 28-item scale that assesses current worries and concerns specifically related to diabetes and its management. It has been shown to be a good marker of diabetes-related emotional distress.⁶ Responses were given along a six-point Likert type scale, ranging from "no problem" (1) to "a very serious problem" (6). The T1-DDS includes seven subscales: powerlessness (a broad sense of feeling discouraged about diabetes), hypoglycemia distress (concerns about severe hypoglycemic events), management distress (disappointment with one's own self-care), negative social perceptions (concerns about the possible negative judgments of others), physician distress (disappointment with current healthcare professionals [HCPs]), friend/family distress (too much focus on diabetes among loved ones), and eating distress (concerns that one's eating is out of control). Respondents completed two versions of the T1-DDS. First was a modified version of the T1-DDS, asking participants to consider their level of distress before starting Omnipod therapy. They next completed the standard version, which focuses on current distress. Previous work has established a mean score of ≥ 2.0 as indicative of elevated diabetes distress,⁶ with the threshold for a minimal clinically important difference (MCID) being a mean change of $\geq \pm 0.19$.⁷

The final scale was the Diabetes Technology Impact Measure (DTIM). Originally developed to assess QOL-related benefits and losses associated with real-time continuous glucose monitoring (RT-CGM) use,⁹ the scale examines how the respondent believes that use of a specific device has affected each of 16 psychosocial issues along a five-point scale: "things became much worse" (−2), "things became slightly worse" (−1), "no change" (0), "things became slightly better" (+1), and "things became much better" (+2). In the RT-CGM study,

three key subscales were identified: perceived control over diabetes (e.g., feeling more/less confident that I can control diabetes), hypoglycemic safety (e.g., feeling much/less safe when I exercise), and interpersonal support (e.g., relationships with family and friends becoming better/worse). For the current study, the items associated with interpersonal support were not included ($n=3$), since—unlike RT-CGM—we did not expect that CSII use would have any sizable impact on this dimension, and respondents were asked to consider how Omnipod use had affected each of the remaining 13 issues.

Finally, as a potentially important moderator variable, we also included the nine-item conscientiousness subscale of the Big-Five Inventory, where each item (e.g., “I see myself as someone who perseveres until the task is finished”) was rated on a five-point Likert-type scale, from “strongly disagree” (1) to “strongly agree” (5).⁸ We hypothesized that patients scoring high on conscientiousness might be more diligent in their careful and consistent use of CSII, thereby contributing to greater QOL-associated benefits.

After assembling the draft battery, 10 T1D adults and 6 diabetes HCPs reviewed all items for completeness and clarity; no major revisions were found to be necessary.

Statistical analyses

Statistical analysis included examination of each study measure to document ranges and distributions and variables were transformed to improve skewness and kurtosis where needed. Given the adaptations to the WHO-5 and DTIM scales, the internal validity of both scales was tested by Cronbach's alpha and by conducting principal components factor analysis with Promax rotation. In line with standard factor analysis techniques, interpretation of the factors was based upon eigenvalues (>1.0), scree plots, and the rotated factor item loadings (items loading >0.60 on a given factor and <0.40 on any other factor). For each QOL outcome, mean QOL-related benefit and loss scale scores could range from -2.0 to 2.0 and were divided, only for descriptive purposes, into categories of “Broad Worsening” (mean scores from -2.00 to 0.51), “No change” (mean scores from -0.50 to 0.50), and “Broad Improvement” (mean scores from 0.51 to 2.00). The selected values for the three categories are based on the face validity of the response options (e.g., the “No change” category included mean responses equivalent to ± 0.5 the mean score of “0”).

Individual regression analyses examined the univariate associations between patient demographics, patient trust in their Omnipod device, and conscientiousness with the QOL measures and their respective subscales that emerged from the factor analyses. Stepwise multiple regression analyses were then conducted for each of the three QOL measures. Patient demographics were entered on Step 1, followed by patient trust in Omnipod and conscientiousness on Step 2, and perceived change in glycemic control (A1c and severe hypoglycemic episodes) was entered on Step 3. All univariate and multivariate regression models used continuous QOL outcome variables. All statistical analyses were performed using SPSS 23.0 (IBM Corp., Armonk, NY).

Results

In total, 1269 completed surveys were received over a 3-week time period (overall response rate was 36.8%).

Patient demographic and clinical characteristics are shown in Table 1. The majority of patients were non-Hispanic White (84.9%), relatively well-educated (59.0% had completed 4 years of college), and female (64.1%). Mean age was 40.7 ± 13.3 years, and the majority (65.7%) had been living with T1D for >15 years. Mean A1c, as reported by respondents, was $7.4\% \pm 1.0\%$. Current RT-CGM use was reported by 56.6% of respondents.

Mean duration of Omnipod use was 13.8 ± 5.2 months; 43.7% of respondents had previously used another manufacturer's CSII. The majority of subjects (71.3%) reported the highest level of trust in their Omnipod device, while 24.0% indicated moderate trust, and 4.9% noted trusting their Omnipod device only “a little” or “not at all.”

Changes in glycemic control

The majority (64.2%) of patients reported an improvement in A1c since initiating Omnipod use, with 43% of the total sample reporting an A1c decrease of $\geq 0.5\%$; 12% reported an increase in A1c since Omnipod initiation. Regarding severe hypoglycemia, 35.2% reported fewer episodes since beginning Omnipod, while 6.4% reported more episodes.

Changes in QOL

General well-being. Principal component analysis of the modified WHO-5 found one factor (eigenvalue = 3.71) that explained 74.1% of the variance. Factor loadings ranged from 0.80 to 0.90 and Cronbach's alpha was 0.91, suggesting the presence of a unidimensional scale with high internal consistency. Mean scale score was 0.66 (0.71), indicating an average small positive improvement for the overall sample. In total, we found that 53.5% reported a net improvement on general well-being (mean score ≥ 0.5), while only 2.3% indicated a net worsening (mean score ≤ -0.5).

TABLE 1. PATIENT CHARACTERISTICS

	N = 1269
Age	40.7 (13.3)
Gender, male, n (%)	456 (35.9)
Years since diagnosis	18.6 (13.2)
Ethnicity, n (%)	
Non-Hispanic White	1076 (84.9)
African American	48 (3.8)
Hispanic	61 (4.8)
Asian or Pacific Islander	16 (1.3)
Native American	7 (0.6)
Other	61 (4.6)
Education, n (%)	
High School or less	145 (11.4)
Some college	375 (29.6)
College graduate	520 (41.0)
Graduate degree	229 (18.0)
Months using Omnipod	13.9 (5.2)
RT-CGM use, n (%)	556 (43.8)
A1c	7.4 (1.0)
Trust in Omnipod	3.7 (0.6)
Conscientiousness	4.2 (0.6)

Values are expressed as mean and standard deviation, or n and percentage.

Diabetes-specific psychosocial impact. Principal component analyses of the 12 DTIM items yielded two coherent factors that cumulatively explained 52.3% of the variance (Table 2). Factor loadings ranged from 0.61 to 0.88. Factor 1 (eigenvalue=6.28) included seven items and was labeled “perceived control over diabetes” (Cronbach’s $\alpha=0.89$). Factor 2 (eigenvalue = 1.36) included five items and was labeled “hypoglycemia safety” (Cronbach’s $\alpha=0.86$). As expected, the factor structure replicates the two major DTIM subscales found in the original study.⁹ Scale scores were calculated as the mean of the items: perceived control over diabetes 0.88 ± 0.85 and hypoglycemic safety 0.61 ± 0.60 . The two scales were moderately correlated with each other ($r=0.62$, $P<0.001$). The majority of patients reported broad improvement (mean score ≥ 0.5) in perceived control over diabetes (72.5%) and hypoglycemic safety (50.6%), while broad worsening in either scale (mean score ≤ -0.5) was rare ($\leq 3\%$).

Diabetes distress. Retrospective T1-DDS total score (pre-Omnipod; Cronbach’s $\alpha=0.93$) was 2.32 ± 0.86 , pointing to at least moderate distress (i.e., above the 2.0 threshold⁶). Of the seven T1-DDS subscales, five (powerlessness, management distress, hypoglycemia distress, eating distress, and friends/family distress) were indicative of moderate or greater distress before Omnipod initiation (Fig. 1). In contrast, current T1-DDS total score (Cronbach’s $\alpha=0.93$) was significantly lower, 1.74 ± 0.64 , than the retrospective T1-DDS total score ($P<0.001$). Indeed, all T1-DDS subscales had decreased significantly from the pre-Omnipod period, with all subscales (except for powerlessness) now below the moderate distress threshold. While the majority of patients (58.6%) reported at least moderate distress at the retrospective time point (total scale score >2.0), only 25.4% reported moderate (or greater) distress at the current time. Of the total sample, 69.6% had current T1-DDS total scores that were lower than their retro-

spective scores (≥ -1.0 MCID), suggesting a clinically relevant drop in diabetes distress; 3.0% indicated current scores that were higher than their retrospective T1-DDS total score ($\geq +1.0$ MCID).

Moderate intercorrelations were observed between the modified WHO-5, the two DTIM subscales (perceived control over diabetes and hypoglycemic safety), and change in T1-DDS total score (with Pearson product moment correlations ranging from ± 0.44 to ± 0.63 ; in all cases, $P<0.001$).

Predictors of QOL changes

Univariate analyses (Table 3) revealed that positive change in each of the four QOL measures (well-being [WHO-5], diabetes distress [T1-DDS total score], perceived control over diabetes, and hypoglycemic safety [DTIM]) was significantly associated with greater trust in one’s Omnipod device, more improvement in glycemic control, and larger reductions in severe hypoglycemic episodes (in all cases, $P<0.001$), as well as with key demographic factors: shorter diabetes duration (in all cases, $P<0.001$) and fewer years of education (in all cases, $P<0.05$). Furthermore, positive change in QOL (in all of the measures except for diabetes distress) was associated with higher levels of conscientiousness (in all cases, $P<0.001$).

Multiple regression analysis generally supported the univariate findings (Table 3). Trust in one’s Omnipod device, positive change in glycemic control, and reductions in severe hypoglycemia independently predicted benefits across all four QOL measures (in all cases, $P<0.001$). In addition, for well-being and hypoglycemic safety only, shorter diabetes duration, fewer years of education, and higher levels of conscientiousness all emerged as independent predictors (in all cases, $P<0.001$). Exploratory univariate and multivariate regressions with the T1-DDS subscales (data not included) yielded virtually the same pattern of significant effects.

Discussion

In this large sample of current Omnipod users, broad clinical and QOL-related benefits associated with the use of the Omnipod system were reported to be very common. Glycemic improvement was noted by the majority (64.2%) of respondents, while 35.2% reported a drop in episodes of severe hypoglycemia. The majority of respondents also reported positive changes in overall well-being (53.5%), perceived control over diabetes (72.5%), hypoglycemic safety (50.6%), and diabetes distress (69.6%). Worsening in any of these areas was very rare. It is unknown whether similar benefits might be observed among users of more traditional CSII systems (i.e., those using tubes), since only Omnipod (a tubeless system) users were surveyed in the current study. However, consistent with the current findings, previous research has shown that CSII users—regardless of the specific system used—report less hypoglycemic fear and feeling less restricted/hassled by the demands of diabetes than MDI users.¹⁰

The key predictors of QOL-related benefits were perceived glycemic improvement, reductions in severe hypoglycemia frequency, and a sense of trust in one’s Omnipod device to function appropriately. Previous research has shown that overall glycemic improvement, reductions in glycemic variability, and fewer hypoglycemic events can each contribute to better QOL.^{11,12} This is likely due to improvement in mood

TABLE 2. FACTOR LOADINGS OF QUALITY-OF-LIFE-RELATED BENEFIT AND LOSS ITEMS

	PCOD	HS
Confident you can control your diabetes	0.824	0.049
In control of your life and your diabetes	0.810	0.087
Hopeful that you can avoid long-term complications	0.627	0.209
Motivated to keep up your diabetes management	0.714	0.072
Adjust your insulin doses correctly	0.605	0.148
Blood glucoses become more or less a “rollercoaster”	0.844	-0.072
A1c improved or worsened	0.879	-0.203
Safe when exercising	0.021	0.677
Safe about sleeping	-0.023	0.814
Fearful about hypoglycemia	-0.043	0.874
Confident you can avoid serious hypoglycemia	0.025	0.838
Safe while driving	0.019	0.813

Factor loadings represent the correlation between each item and the factor with possible values ranging from -1.00 to +1.00. Items in bold loaded ≥ 0.60 onto one factor and did not cross load (≤ 0.40) onto another factor.

HS, hypoglycemic safety; PCOD, perceived control over diabetes.

FIG. 1. Perceived change in diabetes-related distress, pre-Omnipod versus post-Omnipod. For the pre-Omnipod data, these data are retrospective (respondents completed the T1-DDS based on their remembered level of distress before initiating Omnipod). For the post-Omnipod data, respondents completed the T1-DDS based on their current level of distress. In both cases, responses were made using a six-point Likert type scale, ranging from “1=no problem” to “6=a very serious problem.” Means and standard errors are presented. All comparisons between pre- and post-Omnipod scores reached significance, *** $P < 0.001$. T1-DDS, Diabetes Distress Scale for Type 1 Diabetes.

TABLE 3. UNIVARIATE AND MULTIVARIATE REGRESSION ANALYSES FOR QUALITY-OF-LIFE CHANGE

	Univariate				Multivariate			
	Δ WHO-5 Total	Δ DTIM		Δ Diabetes distress Total	Δ WHO-5 Total	Δ DTIM		Δ Diabetes distress Total
		PCOD	HS			PCOD	HS	
Age	-0.02	0.01	0.05	0.09**	0.01	0.01	0.06	0.05
Gender (male=0, female=1)	0.09**	-0.01	-0.01	-0.06*	0.07**	-0.02	1.001	-0.06*
Education	-0.13***	-0.12***	-0.12***	0.12***	-0.09***	-0.04	-0.08**	0.04
Ethnicity (white=0, non-white=1)	0.01	-0.03	0.03	-0.01	0.01	0.01	0.04	-0.02
Years since diagnosis	-0.10***	-0.08**	-0.06*	0.10***	-0.12***	-0.09	-0.12***	0.10**
Months using Omnipod	0.01	0.02	0.01	0.01	-0.02	-0.03	-0.01	0.02
CGM use (XU=0, CU=1)	-0.04	-0.01	0.08**	0.03	-0.05	-0.02	0.07**	0.03
Trust in Omnipod	0.32***	0.41***	0.30***	-0.22***	0.25***	0.27***	0.21***	-0.14***
Conscientiousness	0.17***	0.11***	0.15***	-0.03	0.12***	0.05	0.09***	0.02
Δ HbA1c	-0.27***	-0.58***	-0.25***	0.32***	-0.19***	-0.49***	-0.16***	0.26***
Δ Serious episodes of hypoglycemia	-0.18***	-0.22***	-0.33***	0.24***	-0.14***	-0.16***	-0.30***	0.23***

Standardized regression betas from Step 3 of multivariate regression equations are presented. Step 1, patient demographics; Step 2, trust in Omnipod and conscientiousness; Step 3, perceived change in glycemic control (HbA1c, major episodes of hypoglycemia).

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.

DTIM, Diabetes Technology Impact Measure; HS, hypoglycemic safety; PCOD, perceived control over diabetes; WHO-5, World Health Organization-5.

and energy level, which may be reflected in the noted improvement in overall well-being in the current study, as well as the sense of relief or gratification that one is gaining greater personal control over diabetes, which is represented by the T1-DDS and DTIM findings. Furthermore, the impact of Omnipod trust on QOL is consistent with previous findings, where RT-CGM trust was found to be independently linked to QOL-related benefits.⁹ When patients feel confident that their personal diabetes technology is working effectively and that it will support their best efforts and will not harm them, it is understandable that they are more likely to perceive greater personal benefits. Of note, these data are cross-sectional, so great caution must be taken when considering causal relationships; still, these data suggest that helping patients to have reasonable expectations regarding the likely benefits of their CSII systems and providing them with appropriate training to use their devices most effectively (thereby building confidence and trust in their devices) will have long-lasting value.

Several negative findings are also worthy of mention. First, current RT-CGM ownership was not significantly associated with QOL benefits. This suggests that the QOL gains accruing from Omnipod use may leave little room for any additional RT-CGM benefits. Indeed, one recent investigation of QOL benefits resulting from RT-CGM use found that QOL gains were much greater among MDI users than among CSII users.⁹ Second, there was also no significant association between time since first initiating Omnipod use and QOL benefits, suggesting that maximal QOL gains may take place in a relatively short timeframe and are maintained thereafter.

There are noteworthy limitations of this study. First, although the sample is large, it may not be representative of the larger population of Omnipod users, since the survey was limited to those who could access and complete the survey online. The relatively modest acceptance rate (37% of those contacted) may have added to the selection bias. In addition, it is noteworthy that approximately two-thirds of the sample had at least 4 years of college, which may further limit generalizability of the findings. Although it was emphasized that survey responses were anonymous, respondents were aware that the study was conducted in collaboration with Insulet, which may have biased responses and/or willingness to participate. In total, this suggests that the generally positive diabetes-specific QOL-related benefits reported by these respondents may not accurately reflect the experience of many CSII users (or even Omnipod users). Finally, these data are cross-sectional; most of the critical QOL scales were modified for this study (i.e., were not formally validated) and were retrospective in nature. Patients' *actual* QOL status (as well as initial glycemic control and hypoglycemia frequency) pre-Omnipod is not known, and reported results are based on what patients may remember and perceive to be true, which are certainly limited by memory and expectations. Therefore, without a formal pre-post testing design and further instrument validation, the true impact of Omnipod use on QOL cannot be determined.

Conclusions

Omnipod use is associated with a broad number of QOL-related benefits, with the majority of patients reporting positive changes in overall well-being, perceived control over

diabetes, hypoglycemic safety, and diabetes distress. Very few patients report a worsening in QOL. The majority of patients also report marked glycemic improvement since beginning Omnipod use, and more than one-third describe a drop in severe hypoglycemic episodes. It is possible—perhaps even likely—that similar QOL gains would be reported by users of other CSII systems, but this cannot be determined from the current study. We found that the major independent predictors of QOL-related benefits are perceived glycemic improvement, reductions in severe hypoglycemia frequency, and a sense of trust in one's Omnipod device. These findings suggest that the key element may be an enhanced sense of control over one's diabetes; this includes the perception that one's diabetes is now under better control as well as the sense that one has the effective and dependable tools to help one achieve and maintain that control. Longitudinal trials are needed to better document the impact of current CSII technology on QOL and to determine whether QOL benefits may differ depending on the unique features that distinguish the currently available CSII systems.

Acknowledgment

This investigator-initiated study was supported by Insulet Corporation.

Authors' Contributions

Study conception/protocol: W.H.P.; statistical analysis: D.H.; article development: W.H.P, D.H., J.E.L., and H.Z. All authors read and approved the final article.

Author Disclosure Statement

W.H.P. has worked as a consultant for Insulet Corporation. D.H. reports no competing interest. J.E.L. is an employee at Insulet Corporation. H.Z. was an employee at Insulet Corporation while the study was conducted.

References

1. Hoogma RP, Hammond PJ, Gomis R, et al.: Comparison of the effects of continuous subcutaneous insulin infusion (CSII) and NPH-based multiple daily insulin injections (MDI) on glycaemic control and quality of life: results of the 5-nations trial. *Diabet Med* 2005;23:141–147.
2. Tsui E, Barnie A, Ross S, et al.: Intensive insulin therapy with insulin lispro, a randomised trial of continuous subcutaneous insulin infusion versus multiple daily insulin injection. *Diabetes Care* 2001;24:1722–1727.
3. DeVries JH, Snoek FJ, Kostense PJ, et al.: A randomized trial of continuous subcutaneous insulin infusion and intensive injection therapy in type 1 diabetes for patients with longstanding poor glycemic control. *Diabetes Care* 2002; 25:2074–2080.
4. Leberthal Y, Lazar L, Hadassa Benzaquen ED, et al.: Patient perceptions of using the OmniPod system compared with conventional insulin pumps in young adults with type 1 diabetes. *Diabetes Technol Ther* 2012;14:411–417.
5. Hajos TR, Pouwer F, Skovlund SE, et al.: Psychometric and screening properties of the WHO-5 well-being index in adult outpatients with type 1 or type 2 diabetes mellitus. *Diabet Med* 2013;30:63–69.

6. Fisher L, Polonsky WH, Hessler DM, et al.: Understanding the sources of diabetes distress in adults with type 1 diabetes. *J Diabetes Complications* 2015;29:572–577.
7. Fisher L, Hessler DM, Polonsky WH, et al.: Diabetes distress in adults with type 1 diabetes: prevalence, incidence and change over time. *J Diabetes Complications* 2016;30: 1123–1128.
8. John OP, Srivastava S: The Big-Five trait taxonomy: history, measurement, and theoretical perspectives. In: Pervin LA, John OP, eds. *Handbook of Personality: Theory and Research*, vol. 2. New York: Guilford Press, 1999, pp. 102–138.
9. Polonsky WH, Hessler D: What are the quality of life-related benefits and losses associated with real-time continuous glucose monitoring? A survey of current users. *Diabetes Technol Ther* 2013;15:295–301.
10. Nicolucci A, Maione A, Franciosi M, et al.: Quality of life and treatment satisfaction in adults with type 1 diabetes: a comparison between continuous subcutaneous insulin infusion and multiple daily injections. *Diabet Med* 2008;25: 213–220.
11. Peyrot M, Rubin RR, Chen X, Frias JP. Associations between improved glucose control and patient-reported outcomes after initiation of insulin pump therapy in patients with type 2 diabetes mellitus. *Diabetes Technol Ther* 2011; 13:471–476.
12. Lau CY, Qureshi AK, Scott SG. Association between glycaemic control and quality of life in diabetes mellitus. *J Postgrad Med* 2004;50:189–193.

Address correspondence to:
William H. Polonsky, PhD
Behavioral Diabetes Institute
PO Box 2148
San Diego, CA 92014

E-mail: whp@behavioraldiabetes.org