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TECHNOLOGY REPORT

Comparative Dose Accuracy of Durable and Patch Insulin Infusion Pumps

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Abstract

Background:

As all major insulin pump manufacturers comply with the international infusion pump standard EN 60601-2-24:1998, there may be a general assumption that all pumps are equal in insulin-delivery accuracy. This research investigates single-dose and averaged-dose accuracy of incremental basal deliveries for one patch model and three durable models of insulin pumps.

Method:

For each pump model, discrete single doses delivered during 0.5 U/h basal rate infusion over a 20 h period were measured using a time-stamped microgravimetric system. Dose accuracy was analyzed by comparing single doses and time-averaged doses to specific accuracy thresholds (±5% to ±30%).

Results:

The percentage of single doses delivered outside accuracy thresholds of ±5%, ±10%, and ±20% were as follows: Animas OneTouch® Ping® (43.2%, 14.3%, and 1.8%, respectively), Roche Accu-Chek® Combo (50.6%, 24.4%, and 5.5%), Medtronic Paradigm® Revel™/Veo™ (54.2%, 26.7%, and 6.6%), and Insulet OmniPod® (79.1%, 60.5%, and 34.9%). For 30 min, 1 h, and 2 h averaging windows, the percentage of doses delivered outside a ±15% accuracy were as follows: OneTouch Ping (1.0%, 0.4%, and 0%, respectively), Accu-Chek Combo (4.2%, 3.5%, and 3.1%), Paradigm Revel/Veo (3.9%, 3.1%, and 2.2%), and OmniPod (33.9%, 19.9%, and 10.3%).

Conclusions:

This technical evaluation demonstrates significant differences in single-dose and averaged-dose accuracy among the insulin pumps tested. Differences in dose accuracy were most evident between the patch pump model and the group of durable pump models. Of the pumps studied, the Animas OneTouch Ping demonstrated the best single-dose and averaged-dose accuracy. Further research on the clinical relevance of these findings is warranted.

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Abbreviations: (PEEK) polyetheretherketone

Keywords: accuracy, dose, glycemic, insulin, pump, variability

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Introduction

Various studies have demonstrated that patients who intensively treat their diabetes have a lower rate of diabetes-associated complications.[1,2] One way to better achieve intensive insulin therapy is through the use of continuous subcutaneous insulin infusion pumps. These devices can deliver insulin in accordance with a preprogrammed schedule that is synchronized to a 24 h clock (basal rate) while also delivering insulin on demand (bolus) to compensate for elevated blood glucose levels or carbohydrate consumption from a meal.

While not specifically required by the Food and Drug Administration, insulin pump manufacturers specify a ±5% delivery accuracy using methods established by the international standard EN 60601-2-24:1998.[3] The basal accuracy method specified by EN 60601-2-24:1998 calls for a 24 h delivery stabilization period followed by the measurement and calculation of flow accuracy averaged over 100 consecutive basal deliveries. In addition, the maximum and minimum percentage deviations from these 100 deliveries are calculated across various averaging observation windows to assess accuracy over periods of time (trumpet curves). These average measurement methodologies can mask pump dose-to-dose variability and accuracy deviations, especially during the first 24 h after start of insulin delivery, which, in most cases, accounts for a substantial portion of the time the pump is in use. The 100 basal incremental dose measurements required by EN 60601-2-24:1998 can take significant time to acquire. At a basal rate of 0.5 U/h, 100 deliveries can take between 5 h for the durable pumps tested (a delivery of 0.025 U occurs every 3 min) and 10 h for the patch pumps (a delivery of 0.05 U occurs every 6 min).

The averaged measurement over such a long period of time provides limited information about the single-dose accuracy. The slow absorption rate of subcutaneously injected insulin provides a delay that can obscure the impact of individual dose inaccuracies. As such, an argument can be made that individual dose accuracy may not be as clinically meaningful as the 1 h average dose, which is the approximate time it takes rapid-acting insulin to reach peak concentration in the blood.[4–8] However, as ultra-rapid-acting insulins become available in the future, individual dose accuracy may prove to become more relevant to improved glycemic control.

This technical evaluation was conducted to assess accuracy of insulin infusion pumps over individual doses as well as over times relevant to the pharmacokinetic profile of fast-acting insulin for three durable pumps, the Animas OneTouch® Ping®, the Roche Accu-Chek® Combo, and the Medtronic Paradigm® Revel™/Veo™, and one patch pump, the Insulet OmniPod®.

Materials and Methods

Accuracy Evaluation

This study evaluated three durable pumps [OneTouch Ping (Animas Corp., West Chester, PA), Accu-Chek Combo (Roche Diabetes Care AG, Burgdorf, Switzerland), and Paradigm Revel/Veo (Medtronic Minimed Inc., Northridge, CA)] and one patch pump [OmniPod (Insulet Corp., Bedford, MA)].

Different testing methods have been used in the past to assess pump accuracy.[9,10] In this study, pumps were tested using a time-stamped microgravimetric system (Sartorius ME-5 microbalance with a load limit of 5 g and resolution of 0.000001 g) at room temperature. The microgravimetric system was calibrated with weights traceable to the National Institute of Standards and Technology per Animas calibration schedule. The microbalance was placed on vibration-isolating tables inside a vented enclosure to prevent weighing fluctuations from ambient airflows.

Purified water was used as the neutral fluid representing various rapid-acting insulin mixtures. Insulin analogs consist of 96–98% water and have a density comparable to that of water.[5] The use of purified water also complies with a requirement in the EN 60601-2-24 international standard that calls for the use of a liquid that provides similar results as the intended liquid for use.[3] In addition, purified water was degassed to reduce bubble formation. A thin layer of paraffin oil was applied over the purified water layer in the weighing vial to minimize evaporation. In this setup, a dose of 0.250 µl water (equivalent to 0.025 U insulin volume) could be measured with an uncertainty of ±0.4%.

Durable and patch pumps were loaded, primed, and programmed as specified by manufacturer's instructions. Each pump type required a slightly different experimental setup to accommodate its recommended operation condition. For the durable pumps, infusion sets were cut 10 cm from the tip of the cannula (including connector and infusion site) and attached to guiding fitting connectors (Upchurch Scientific, Oak Harbor, WA) with a 10 cm polyetheretherketone (PEEK) tube with a similar inner diameter as the cannula. The PEEK tubing allowed for fitting of the cannula with the microfluidic connectors outside the draft shield, improving stability of the infusion set. The length of the tubing used was similar for all sets. A glass vial of purified water was placed on the weighing pan of the balance, and the distal tip of the PEEK tube was immersed in the water. Paraffin oil was applied over the purified water layer and the pump was adjusted to a height where the cartridge center tip and the meniscus of the oil layer in the vial were at the same level (**Figure 1A**). The OneTouch Ping setup included a 2.0 ml cartridge and 23" Unomedical Comfort infusion set (Unomedical, Lejre, Denmark). The Accu-Chek Combo setup included an Accu-Chek Spirit 3.15 ml cartridge and 60 cm Accu-Chek Flexlink tubing. The Paradigm Revel/Veo setup included a 1.8 ml or 3.0 ml Paradigm reservoir and 23" Paradigm Silhouette infusion sets. For the OmniPod patch pump, the cannula was deployed and the needle retracted per manufacturer's instructions. Since this pump does not have an external infusion line beyond the deployed cannula, the pump was placed as close as possible to the glass vial in the microbalance weighing chamber. As such, the pump was placed on a vertical stage and proximate to the glass vial (without making contact) within the vented enclosure. The cannula was then submerged in the water and paraffin oil added (**Figure 1B**).

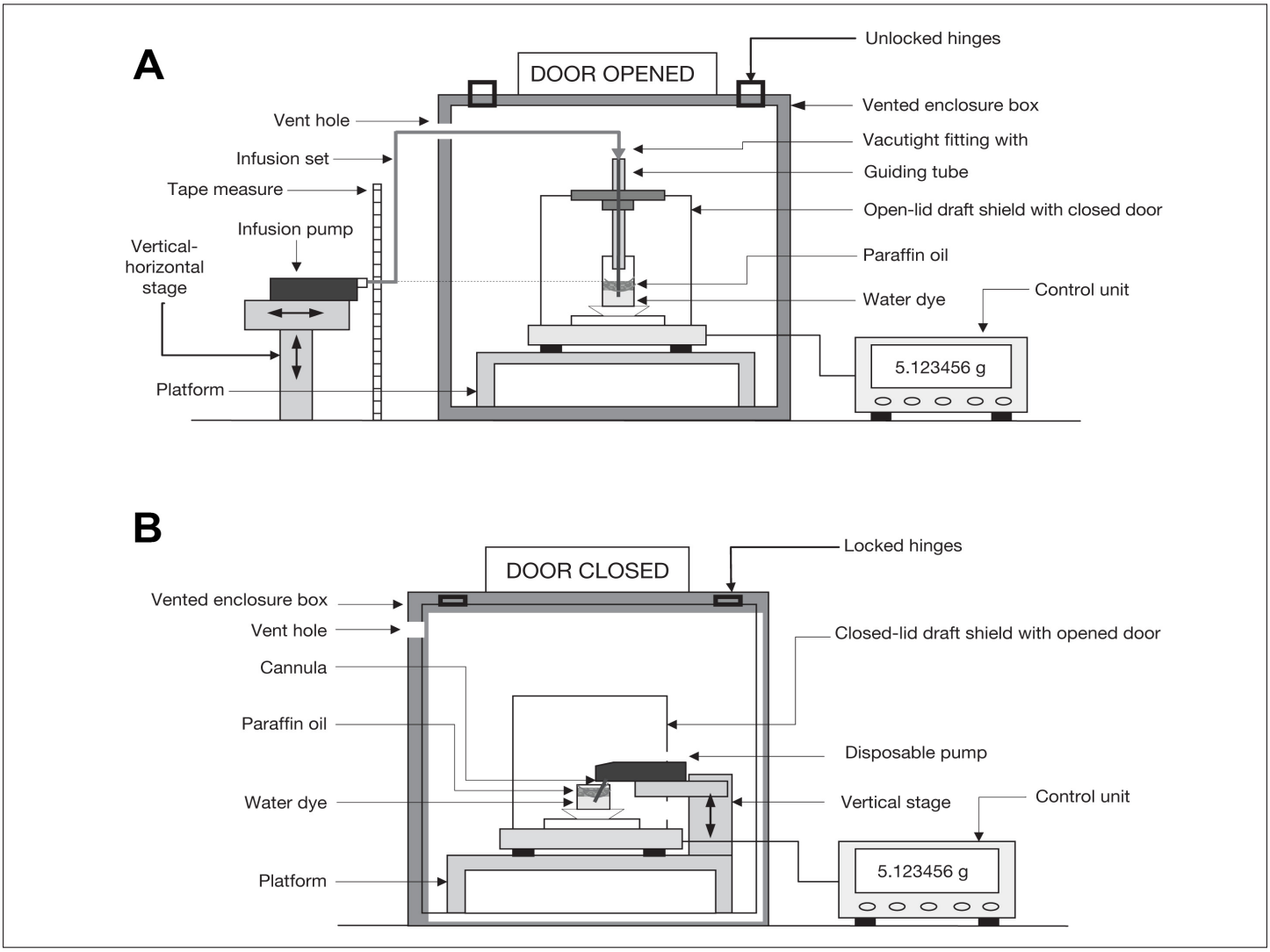

Figure 1. (A) Durable pump testing setup and **(B)** patch pump testing setup.

Pumps were characterized at a basal rate of 0.5 U/h to determine single-dose and averaged-dose accuracy. At this basal rate, each durable pump delivered a 0.025 U dose (0.250 μl) 20 times per hour (3 min intervals), while the patch pump delivered a 0.050 U dose (0.500 μl) 10 times per hour (6 min intervals).

Each test lasted 22 h, and data were collected in 10 s intervals. During the first hour (hours 0–1), the pumps were set at 0.0 U/h basal rate and the data were used to check the measurement-system stability. The initial baseline stability was maintained within a ±5% deviation threshold relative to the set basal rate of infusion. After the initial 1 h stability test, the pump's basal rate was set to 0.5 U/h for the next 20 h (hours 1–21). After 20 h at the test basal rate, the basal rate was again set to 0.0 U/h to recheck the system stability (hours 21–22). The final baseline stability was expected to be within ±5% deviation threshold as well, but without considering the effects of mechanical compliance post-basal delivery, which may result in a higher deviation. The dose data collected during the basal delivery time (hours 1–21) were compared for each pump model (n = 30 per pump model): five test repetitions for each of 6 different pumps for durable pumps and two test repetitions for each of 15 different pumps for patch pumps. A higher number of patch pumps was required due to its usage limit of 72 h, after which it becomes inoperable.

Data Analysis

Data for each discrete dose were collected and time stamped. Dose weight was calculated from the weight difference measured by the balance, and dose volumes were calculated using the density of water as follows:

$$\frac{\Delta W \text{ milligrams}}{0.99821 \text{ grams } H_2O/\text{cm}^3} \times \frac{1 \text{ gram}}{1000 \text{ milligrams}} \times \frac{1000 \text{ microliters/cm}^3}{10 \text{ microliters/U}} = \text{Units},$$

in which ΔW is the weight difference of water delivered by each dose.

The percentage error in dose volume was calculated from the set basal rate and delivery schedule as follows:

$$\frac{\text{Volume dose delivered} - \text{Volume dose set}}{\text{Volume dose set}} \times 100 = \%\ \text{Error in dose volume}$$

Because each pump's dose-delivery schedule operated asynchronously to the system sampling interval, it was necessary to analyze the data to determine the time of the pump's first (startup) dose. The initial startup dose could be determined *a priori* by using the dose delivery scheduled and the time the basal rate was switched from 0.0 to 0.5 U/h. This methodology is what the patient using the pump would expect; however, the startup dose time was determined experimentally as the point in time where a weight increase from a prior measurement was measured that was greater than 15% of the weight of the next expected dose. The startup dose delivery time with respect to the time the basal rate was changed from 0.0 to 0.5 U/h varied among all the pumps. A delay in the delivery of the startup dose reduced the overall number of doses measured during a test, which affected the total number of doses for the Accu-Chek Combo, Paradigm Revel/Veo, and OmniPod (**Table 1**). Individual dose accuracy was analyzed by counting the number of doses with percentage error larger than predetermined accuracy thresholds ranging from ±5% to ±30%. Accuracy thresholds were defined as the percentage deviation from the target dose volume. Implementation of a cumulative dose-accuracy analysis renders differences in delivery delays insignificant.

Time for insulin to reach a steady state in the body varies per insulin and per individual. As such, individual dose accuracy may be viewed as less relevant in clinical practice. To capture dose accuracy over clinically relevant periods of time, the dose percentage error was averaged over observation windows of 30 min, 1 h, and 2 h. For example, 20 consecutive dose errors were averaged to obtain the dose error over a 1 h period for pumps delivering doses every 3 min. For pumps delivering doses every 6 min, 10 consecutive dose errors were averaged to obtain the dose error over a 1 h period.

Table 1.
Cumulative Doses Outside Accuracy Threshold (0.5 U/h)

Cumulative doses outside accuracy threshold, %	OneTouch Ping (n = 12,000)	Accu-Chek Combo (n = 11,947[a])	Paradigm Revel/Veo (n = 11,987[a])	OmniPod (n = 5,977[a])
Per dose				
±5%	43.2	50.6	54.2	79.1
±10%	14.3	24.4	26.7	60.5
±15%	4.9	12.2	13.0	46.0
±20%	1.8	5.5	6.6	34.9
±25%	1.2	3.0	4.0	27.2
±30%	0.9	2.1	2.9	22.7
30 min averaging window				
±5%	22.6	24.4	35.8	72.6
±10%	7.5	10.5	15.7	49.3
±15%	1.0	4.2	3.9	33.9
±20%	0.3	1.2	0.6	23.2
±25%	0.2	1.0	0.4	16.7
±30%	0.1	0.9	0.3	11.9
1 h averaging window				
±5%	19.7	21.0	33.2	65.5
±10%	6.2	9.4	14.3	37.7
±15%	0.4	3.5	3.1	19.9
±20%	0	1.1	0.1	10.3
±25%	0	0.7	0.1	5.1
±30%	0	0.7	0.1	3.0
2 h averaging window				
±5%	15.9	17.0	30.51	53.6
±10%	5.1	8.1	13.44	25.1
±15%	0	3.1	2.18	10.3
±20%	0	0.7	0	4.4
±25%	0	0.6	0	1.3
±30%	0	0.4	0	0.1

[a] Accu-Chek Combo (10/30 sets tested), Paradigm Revel/Veo (8/30 sets tested), and OmniPod (18/30 sets tested) pumps encountered delays in their programmable delivery sequence, leading to one or more missed doses.
OneTouch Ping versus Accu-Chek Combo: $p < .0001$ for single dose at ±20%; $p < .001$ for single dose at ±15%; $p < .01$ for single dose at ±10%, ±25%, and ±30%; $p < .05$ for single dose at ±5%, for 30 min at ±15%, ±20%, and ±30%, for 1 h at ±15%, ±20%, ±25%, and ±30%, and for 2 h at ±15%.
OneTouch Ping versus Paradigm Revel/Veo: $p < .01$ for single dose at ±5%, ±10%, and ±15% and for 2 h at ±5%; $p < .05$ for single dose at ±20%, for 30 min at ±5%, ±10%, and ±15%, for 1 h at ±5%, ±10%, and ±15%, and for 2 h at ±10% and ±15%.
OneTouch Ping versus OmniPod: $p < .0001$ at all ranges for single dose and 30 min, for 1 h at ±5%, ±10%, ±15%, ±20%, and ±25%, and for 2 h at ±5% and ±15%; $p < .001$ for 1 h at ±30% and for 2 h at ±20%; $p < .01$ for 2 h at ±10%.
Accu-Chek Combo versus Paradigm Revel/Veo: $p < .05$ for 30 min at ±5%, for 1 hour at ±5% and ±20%, and for 2 h at ±5%.
Accu-Chek Combo versus OmniPod: $p < .0001$ for single dose at all ranges, for 30 min and 1 hour for ±5%, ±10%, ±15%, and ±20%; $p < .001$ for 2 h at ±5%; $p < .05$ for 1 h at ±25% and for 2 h at ±20%.
Paradigm Revel/Veo versus OmniPod: $p < .0001$ for single dose at all ranges, for 30 min at ±15%, ±20%, ±25%, and ±30%, and for 1 h at ±15%, ±20%, and ±25%; $p < .001$ for 30 min at ±10%, for 1 h at ±30%, and for 2 h at ±20%; $p < .01$ for 30 min at ±5%; $p < .05$ for 1 h at ±5% and ±10% and for 2 h at ±15%.

Typical Pump Performance

To better understand the observed differences in dose accuracy, a "typical" performer was selected for each pump model, and its delivery profile was visualized in a time graph. The typical pump was selected as the pump with the test repetition that had the median "standard deviation in dose percent error" (*STDDEV*), calculated as follows:

$$STDDEV = \sqrt{\frac{\Sigma(x - \bar{x})^2}{(n - 1)}},$$

in which x is any given value, $\bar{x}$ is the mean of all values, and n is the number of observations.

Statistical Analysis

Standard deviation was calculated for the measured percentage error in dose volume in each test repetition. Chi-square tests were conducted to compare the four pumps. A *p*-value of less than 0.05 was used to indicate that there was a statistical difference in individual dose or averaged dose accuracy between pumps.

Results

Single-Dose Accuracy

Overall pump performance is shown in **Figure 2**. The single-dose accuracy was statistically significantly different between patch and durable pumps ($p < .0001$ for thresholds up to ±30%). This result is particularly significant because the patch pump delivers a dose volume twice as large as the durable pumps. Performance of the pumps was consistent throughout the entire data set.

The percentage of doses delivered outside the specified accuracy threshold was lower for the durable pumps than the patch pump (**Figure 3A**, **Table 1**). For durable pumps, the percentage of doses delivered outside the specified accuracy threshold (±5%, ±10%, ±15%, ±20%, ±25%, ±30%, respectively) was as follows: OneTouch Ping, 43.2%, 14.3%, 4.9%, 1.8%, 1.2%, and 0.9%; Accu-Chek Combo, 50.6%, 24.4%, 12.2%, 5.5%, 3.0%, and 2.1%; and Paradigm Revel/Veo, 54.2%, 26.7%, 13.0%, 6.6%, 4.0%, and 2.9% (**Figure 3A**, **Table 1**). In contrast, the percentage of doses delivered outside the specified accuracy threshold for the OmniPod patch pump was 79.1%, 60.5%, 46.0%, 34.9%, 27.2%, and 22.7% at the accuracy thresholds of ±5%, ±10%, ±15%, ±20%, ±25%, and ±30%, respectively (**Figure 3A**, **Table 1**). Among the durable pumps, the OneTouch Ping demonstrated better accuracy on a single-dose basis when compared with the Accu-Chek Combo over accuracy thresholds ranging from ±5% to ±30% ($p < .05$) and when compared with Paradigm Revel/Veo over accuracy thresholds ranging from ±5% to ±20% ($p < .05$). There was no statistically significant difference in accuracy between the Accu-Chek Combo and Paradigm Revel/Veo pumps on a single-dose basis.

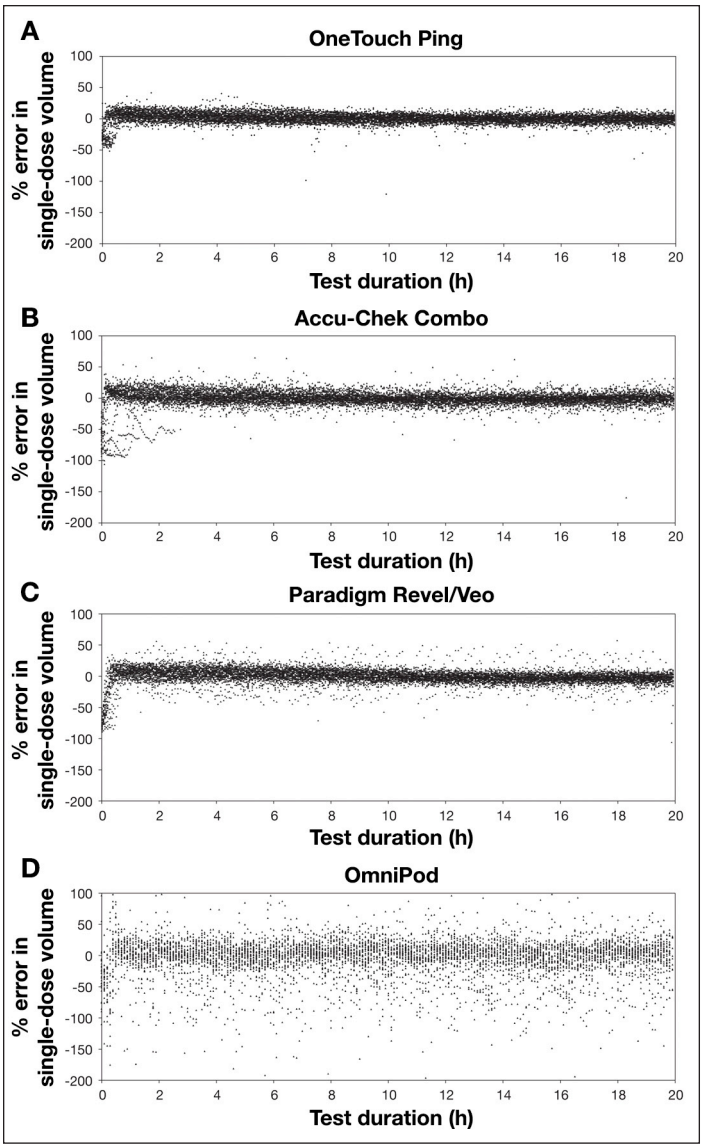

Figure 2. Single-dose accuracy. The graphs show results in terms of percentage error in dose volume with respect to the 0.5 U/h basal rate for **(A)** OneTouch Ping (n = 12,000 doses), **(B)** Accu-Chek Combo (n = 11,947), **(C)** Paradigm Revel/Veo (n = 11,987), and **(D)** OmniPod (n = 5977 doses).

Averaged-Dose Accuracy

As the slow absorption of insulin (peak plasma concentration of approximately 1 h) may obscure the need for high accuracy on a single-dose basis, the data were also analyzed to assess the effect of dose averaging on pump performance. For all pumps analyzed, the percentage of doses delivered outside the accuracy threshold decreased as the selected averaging time interval increased (**Figure 4**, **Table 1**).

The durable pumps performed better than the patch pump over all averaged dose time intervals (**Figure 4**, **Table 1**). For durable pumps, the percentage of doses

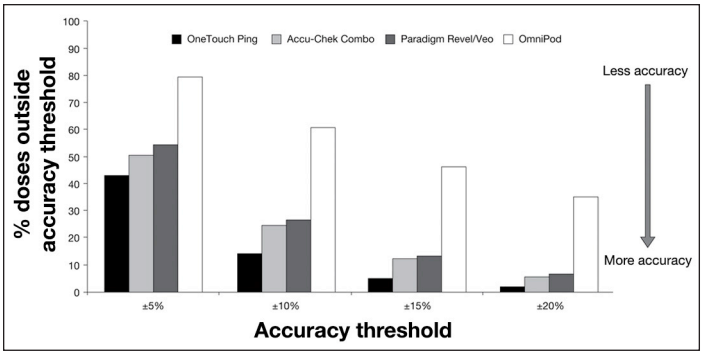

Figure 3. Single-dose accuracy. The percentage of measured deliveries (n = 12,000 for OneTouch Ping, n = 11,947 for Accu-Chek Combo, n = 11,987 for Paradigm Revel/Veo, and n = 5977 for OmniPod) that were outside the accuracy threshold of ±5%, ±10%, ±15%, and ±20% with fixed basal rate delivery. Accuracy increases with lower percentage outside threshold.

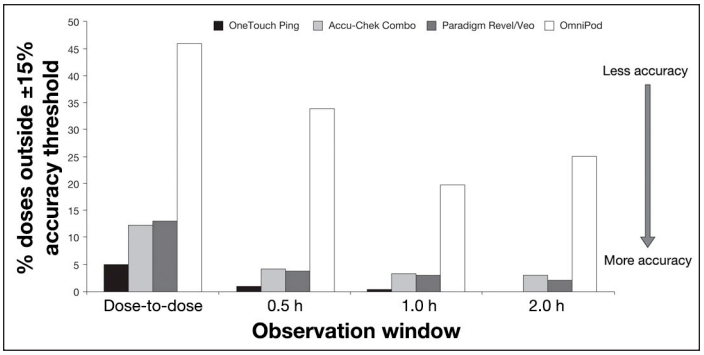

Figure 4. Averaged-dose accuracy. The graph shows the percentage of measured deliveries (n = 12,000 for OneTouch Ping, n = 11,947 for Accu-Chek Combo, n = 11,987 for Paradigm Revel/Veo, and n = 5977 for OmniPod) that were outside the accuracy threshold of ±15% averaged over the specified time interval. Accuracy increases with lower percentage outside threshold.

delivered outside the ±15% accuracy threshold for the 30 min, 1 h, and 2 h windows was as follows: OneTouch Ping, 1.0%, 0.4%, and 0%; Accu-Chek Combo, 4.2%, 3.5%, and 3.1%; and Paradigm Revel/Veo, 3.9%, 3.1%, and 2.2% (**Figure 4**, **Table 1**). In contrast, the percentage of doses delivered outside the ±15% accuracy threshold for the OmniPod patch pump was higher ($p < .05$) at 33.9%, 19.9%, and 10.3% for the 30 min, 1 h, and 2 h windows, respectively (**Figure 4**, **Table 1**).

The performance of the OneTouch Ping was significantly better than that of the Accu-Chek Combo over all time averaging windows at the accuracy threshold of ±15% ($p < .05$). Averaged-dose accuracy was also significantly better with the OneTouch Ping than with the Paradigm Revel/Veo over all time-averaging windows at accuracy thresholds ranging from ±5% to ±15% ($p < .05$). The Accu-Chek Combo performed significantly better than the Paradigm Revel/Veo over all time-averaging windows at the accuracy threshold of ±5% and over the 1 h window at the accuracy threshold of ±20% ($p < .05$).

Typical Pump Performance

Typical pump performance for each pump (the test repetition profile with the median standard deviation in percentage dose error) is shown in **Figure 5**. Even with an average time window of 2 h, a time frame longer than the average half-life of rapid-acting insulins in the patient,[5–8] the dose delivery of the patch pump remained highly variable. The graph also illustrates that the OneTouch Ping appears to be less variable than the other two durable pumps (Accu-Chek Combo and Paradigm Revel/Veo), though the times within and outside ±5% were not quantified.

Industry-Established Flow Accuracy

Flow accuracy was assessed for the last 100 deliveries in the 20 h basal delivery period using the methods established in international standard EN 60601-2-24:1998. The stabilization period for the durable pumps and patch pump was 15 and 10 h, respectively. Of the durable pumps, 30/30 test repetitions on the OneTouch Ping and Accu-Chek Combo and 29/30 of test repetitions on the Paradigm Revel/Veo pumps met the ±5% industry accuracy standard. Of the 30 test repetitions on the OmniPod patch pumps, 26 test repetitions met the ±5% industry accuracy standard.

Discussion

The results of this technical evaluation demonstrate that there are statistically significant differences in single-dose and averaged-dose accuracy among the four insulin pump models tested.

In general, the durable pumps displayed significantly better single-dose accuracy than the patch pump ($p < .0001$). Among the durable pumps, the OneTouch Ping demonstrated significantly better accuracy on a single-dose basis when

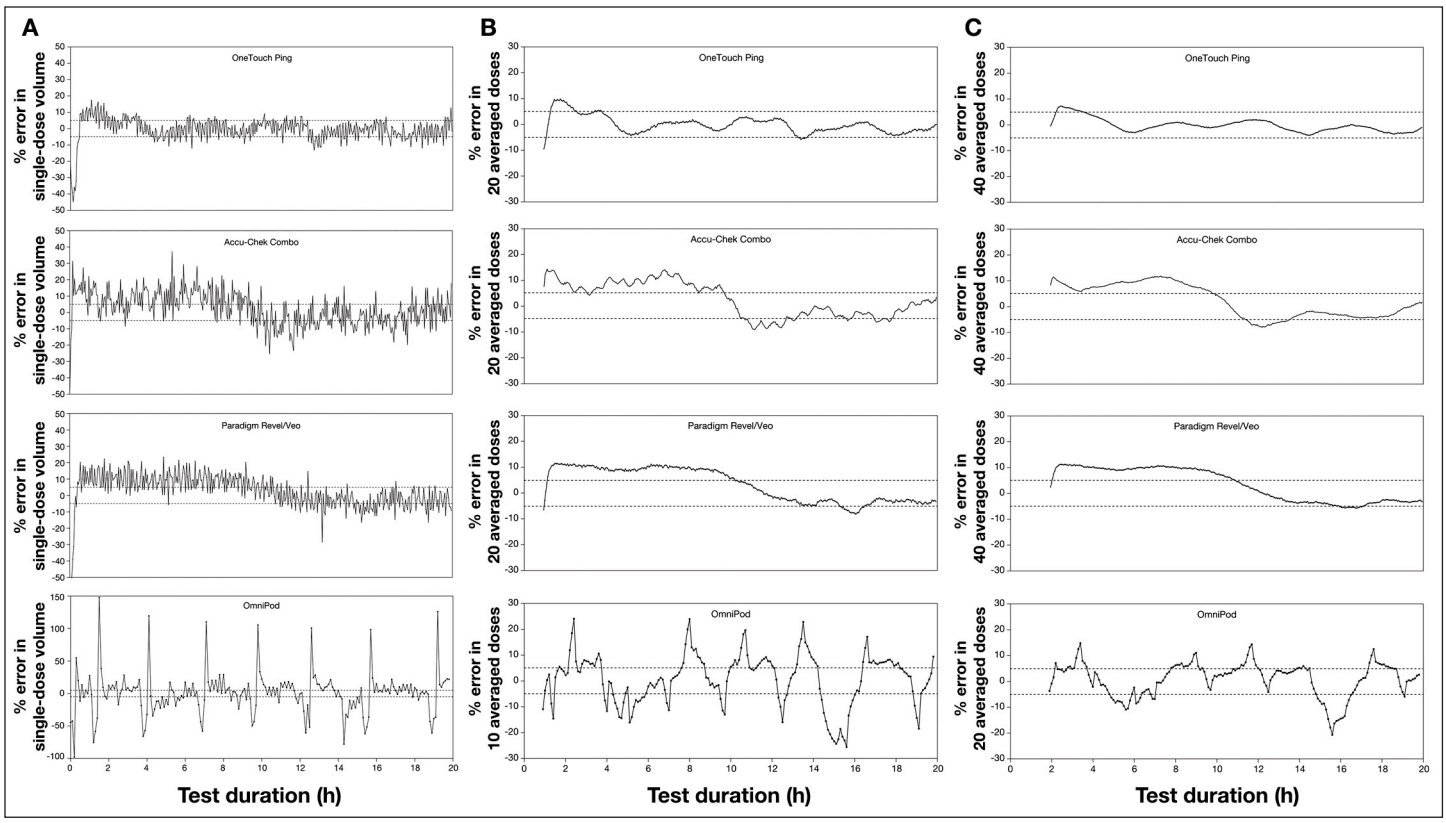

Figure 5. "Typical" pump performance (i.e., the data set with median standard deviation in percentage dose error). **(A)** Single-dose accuracy for the individual pumps. **(B)** Dose accuracy over a 1 h averaging window. **(C)** Dose accuracy over a 2 h averaging window. Dotted horizontal lines indicate the ±5% accuracy range. Please note that the durable pumps deliver 20 doses/h (0.025 U/dose) and the patch pump delivers 10 doses/h (0.05 U/dose).

compared with the other durable pumps over accuracy thresholds ranging from ±5% to ±20% ($p < .05$). Single-dose accuracy was similar for the Accu-Chek Combo and Paradigm Revel/Veo.

The durable pumps were also significantly more accurate than the patch pump when dose accuracy was assessed over 30 min, 1 h, and 2 h averaged windows ($p < .05$). Of the durable pumps, the OneTouch Ping was most accurate ($p < .05$ for all windows ±15%). The Accu-Chek Combo was more accurate than the Paradigm Revel/Veo ($p < .05$ for all windows at ±5%).

One might expect greater variability and less accuracy from a pump that delivers smaller doses, as smaller doses would seem to be more difficult to deliver given delivery systems' mechanical tolerances and constraints. However, the results presented here demonstrate otherwise. The patch pumps' doses were twice as large as the durable pumps' doses, yet the patch pump was less accurate for both single- and averaged-dose measurements.

Irrespective of the pump model tested, this investigation demonstrates that ±5% accuracy on single-dose basis is difficult to achieve when the target dose is 0.025 or 0.05 U, which is why EN 60601-2-24:1998[3] calls for the averaging of 100 doses. Nevertheless, over 45% of individual doses from the durable pumps (56.8% for OneTouch Ping, 49.4% for Accu-Chek Combo, and 45.8% for Paradigm Revel/Veo) had an error of ±5% or less at 0.025 U/dose. When assessing flow accuracy over 100 doses, all but one of the durable pumps tested met the industry accuracy standard, as did 26 out of 30 tested patch pumps.

As the relatively slow uptake of subcutaneously administered rapid-acting insulins may obscure the need for high accuracy on a single-dose basis, the effect of dose averaging on pump performance was also analyzed. The better accuracy of the durable pumps remained apparent even when time-averaging observation windows were applied to

the data. Of the durable pumps, the OneTouch Ping demonstrated significantly better average dose accuracy than the Accu-Chek Combo ($p < .05$ over all time-averaging windows at the accuracy threshold of ±15%) and the Paradigm Revel/Veo ($p < .05$ over all time windows at accuracy thresholds ranging from ±5% to ±20%). Likewise, the Accu-Chek Combo demonstrated significantly better average-dose accuracy than the Paradigm Revel/Veo ($p < .05$ over all time-averaging windows at the accuracy threshold of ±5%).

A potential limitation of this study may be the difference in setup used for the durable pumps and the patch pump. However, this was necessary to accommodate the recommended operational conditions for the two classes of pumps. Durable pumps require an infusion set for insulin delivery, whereas patch pumps do not. The tubing of the durable pumps was fully extended to prevent any disturbances due to vibrations; therefore, these pumps were placed outside the vented enclosure that held the microbalance (**Figure 1A**). As the patch pumps did not use tubing, these were placed very close to the weighing container of the microbalance inside the enclosure (**Figure 1B**). As a result, the draft door of the microbalance could not be closed in the patch pump setup. While attaching a catheter to the patch pump was attempted initially, it was found that this process potentially introduced reproducibility issues and could result in a suboptimal pump configuration compared with the configuration recommended by the manufacturer. Testing the patch pumps without additional tubing allows for a more fair comparison.

One could argue that the spikes or periodic delivery errors in the patch pump delivery duration (**Figure 5**, lower plots) could be caused by the patch pump being inside the vented enclosure or by the draft door being in an open configuration. However, the purpose of the vented enclosure was to prevent air currents that might impact the stability of the measurement system without generating any changes in temperature and pressure that could impact pump performance. In addition, pretesting assessment indicated that the difference in draft door configuration did not lead to significant drifts of the measurement system (data not shown). Periodic delivery errors were reproducible for the two repetitions of each patch pumps tested and may represent a systematic characteristic of the patch pump delivery mechanism. Thus, while experimental setup was different for durable and patch pumps, we believe that this has not significantly affected the comparison.

Conclusions

The results of this technical evaluation demonstrate significant differences in accuracy (single-dose and averaged-dose variability) among insulin pumps. The variability was greatest between the patch pump model and the durable pump models evaluated. Of the durable pumps tested, the OneTouch Ping was the most accurate per dose and over different time-averaging observation windows.

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Disclosures:

All authors are employees of Animas Corporation.

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