Insulin Pump Settings
A Major Source For Insulin Dose Errors

John Walsh PA, CDE[1], Dariusz Wroblewski, PhD[2], and Timothy S. Bailey MD, FACE, CPI[1]
[1]Advanced Metabolic Care + Research and [2]BioFormatix Inc, Escondido, CA
jwalsh@diabetesnet.com dariusz@bioformatix.com tbailey@AMCRclinic.com

Introduction

Today's insulin pumps assist in bolus calculations for carbs and high glucose levels. Clinicians hoped this would help normalize A1c levels. However, average A1c values for pump wearers have not reached recommended goals. Failure to reach goals has been attributed to inaccurate carb counting, missed boluses, fear of hypoglycemia, inaccurate meter readings, and lack of diabetes education.

This poster explores other reasons not previously addressed: the non-physiologic nature of pump settings and the imprecision inherent in pump settings.

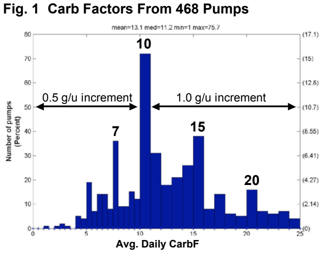
Methods

Anonymous data from 541 Cozmo insulin pumps were downloaded in 2005 from pumps used in clinical setting throughout the U.S. Some of these pumps were returned for routine maintenance and others for functional problems that were often not verified on subsequent inspection. Despite being a non-random dataset with, the data here is believed to represent widespread pump use. A subsequent, random dataset will be analyzed to verify these findings.

Results

Fig. 1 shows average carb factor (CarbF) values for 468 pumps in which carb counting was used to calculate meal boluses.

Fig. 1 Carb Factors From 468 Pumps

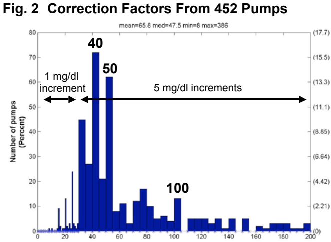


The height of bars in Figs. 1 & 2 is significant, their width is not.

CarbFs are ultimately derived from TDD, carb intake, and insulin sensitivity which all have a bell-shaped type distribution. CarbFs would be expected to have a similar distribution without spiking, but the CarbFs above show distinct spikes with a discontinuous bell-shaped distribution. Certain numbers – 7, 10, 15, and 20 – are favored for unclear reasons, while 8, 9, 12, 13, and 16-19 are less popular than a bell-shaped distribution with a negative skew to the right would anticipate.

Fig. 2 shows correction factors (CorF) in 452 pumps where corrections were used.

Fig. 2 Correction Factors From 452 Pumps



CorFs also display a non-physiologic distribution with gaps between preferred factors and spikes at 40, 50, and 100 mg/dl per unit. For CorFs, increments of 1 mg/dl per unit are available below 30u, but Fig. 2 shows that almost all CorFs were either 15, 20, or 25 mg/dl per unit in this area, a percentage change of 20 to 33%.

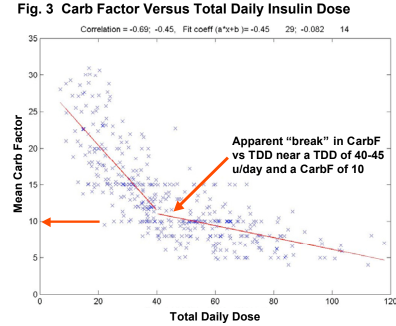
To demonstrate whether non-physiologic factors affect doses, consider someone who physiologically requires a CorF of 19 mg/dl per unit but uses 15 or 25 instead (target = 100 mg/dl). For a BG of 366, the pump will recommend a correction bolus of 17.7 u or 10.6 u, respectively rather than 14 u, resulting in a glucose as much as 70 mg/dl below or 65 mg/dl higher than their desired target.

For CarbFs, if someone physiologically requires a carb factor of 8.5 grams per unit (a TDD of about 70 u/day), but uses 7 or 10 grams instead because the number seems better, the pump will give bolus recommendations of 12.1 or 8.5 units respectively, rather than 10 units. The seemingly small change in CarbF changes the recommended carb bolus by + 2.1 or - 1.5 units, sufficient to cause hypo or hyperglycemia with an approx. fall of 63 mg/dl or rise of 45 mg/dl in the BG.

48.9% of pumps used a CarbF of 10 or less, so precision in this lower CarbF area is important for insulin dosing in a large number of pumps. The Cozmo pump currently provides increments of 0.5 gram per unit below 10 grams per unit.

Figure 3 displays the relation between avg. CarbF and TDD.

Fig. 3 Carb Factor Versus Total Daily Insulin Dose



This relationship is best approximated by a piece-wise linear function with a break near a CarbF of 10 grams per unit. Two formulas were required to represent the data, shown as two thin red lines in Fig. 3. It is not clear that there is a physiological reason for this breaking point.

Though not shown, a similar relationship between the CorF and the TDD was found with a break near a CorF of 50 mg/dl per unit, again near a TDD of 45 units.

Table 1 displays the avg. CarbFs and avg. CarbF Rule Number (CarbFRN = CarbF x TDD, often referred to as the 450 or 500 Rule) for 200 pumps with avg. BGs lower than 209 mg/dl in the middle green columns, and a similar number with avg. BGs higher than 209 in the right blue columns.

Table 1: CarbFs and CarbFRNs For Lower & Higher Avg. BGs

	Lower Avg BG		Higher Avg BG	
TDD	**CarbF**	**CarbFRN**	**CarbF**	**CarbFRN**
20.0	20.6	412.0	22.6	452
25.0	18.3	456.3	19.5	488
30.0	15.9	477.0	16.4	492
35.0	13.6	474.3	13.3	466
40.0	11.2	448.0	10.2	408
45.0	10.5	474.0	11.1	500
50.0	10.2	508.0	10.8	540
60.0	9.4	563.0	10.2	610
70.0	8.6	603.0	9.5	666
80.0	7.8	627.0	8.9	710
90.0	7.1	636.0	8.2	742
100.0	6.3	630.0	7.6	760

Lower BG CarbFRNs: 412-630

Higher BG CarbFRNs: 452-760

The CarbFRN and CorF Rule Number (CorFRN = CorF x TDD, often referred to as the 1800 or 2000 Rule) both rise as the TDD rises. Although there are exceptions in the higher avg. BG group, most CarbFs and CarbFRNs are 10% to 20% higher (less aggressive) on average in the higher avg. BG group.

For the CarbF, a rise in CarbFRNs as the TDD rises suggests there may be hesitation to appropriately lower CarbFs below 10 as the TDD rises above 45 units. Metabolic factors may be responsible for this, but the etiology is unclear.

Fig. 4 Average Daily Basal Total Versus TDD

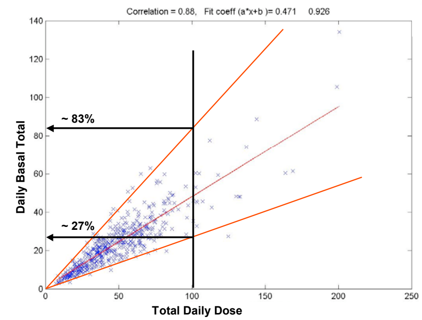


Fig. 4 shows avg. daily basal totals relative to avg. TDDs for each pump. Averaging close to 50% for the entire group, individual basal percentages varied widely between approximately 27% and 83% of the TDD. It is not clear that dietary variations would explain this degree of variation. The poorly-tuned CarbFs may influence basal percentages and vice versa. Regardless, Fig. 4 suggests that many pump wearers use basal rates outside their ideal physiologic range.

Discussion

Pump settings chosen by clinicians and users appear to contain many non-physiologic settings. A significant number of pump wearers appear to be using poorly-tuned settings that are likely to introduce significant dosing errors.

Errors in selection of carb and correction factors may result from:

- a lack of understanding of the significance of precise bolus calculations,
- an emotional attachment to certain numbers,
- hesitation to lower factor numbers below certain values,
- or hesitation to lower factor numbers to increase bolus doses.

The large gaps or jumps seen between factor numbers in Figs. 1 & 2 indicate that clinicians and users use broad strokes for these settings and do not realize that setting changes of the degree seen in the graphic may dramatically affect control.

Although not as clear, the wide distribution of basal rate percentages relative to TDD suggests that basal rates are also poorly tuned for many pump users.

Conclusions

Our findings suggest the presence of widespread errors in accuracy of carb factor, correction factor, and basal rate settings, as well as potentially insufficient precision in some setting increments. Therefore, we recommend efforts be taken to minimize potential pump setting errors:

1. Reinforce current recommendations that all pump settings be first selected from standard formulas and readjusted through testing.
2. Improve precision in insulin pumps with dose increments of 5% or less in both carb and correction bolus factors. For instance, provide carb factors of 0.5 gram/unit below 20 gram/unit and 0.25 gram/unit below 10 gram/unit.
3. Guide the user when carb and correction factors are being changed. For example, show their average carb intake per day divided by current and new CarbFs to demonstate how the change will impact their daily insulin doses.
4. Allow users to compare their current factors and basal rates with a comparable set from pump users who are in good control and have a similar TDD by provision of a "best practices" page in the insulin pump.