

Tandem t:slim X2 and Dexcom G6

Disclaimer

I'm not a doctor and this essay should not be taken as medical advice. It is an honest review by a type 1 diabetic, including decades of day-to-day with insulin pumps and years with Continuous Glucose Monitors (CGM). I've also worked in medical devices and digital health.

Diabetes Technology Ecosystem

Any discussion of insulin pumps owes a debt of gratitude to Dean Kamen. We are standing on the shoulders of giants. nnnn

I also owe a debt of gratitude to a number of great endocrinologists from the University of Pittsburgh and the certified diabetes educators who have helped me over the years.

CDEs, in particular, deserve thanks and a raise for stretching themselves to master such a complex device, pharmaceutical, and health insurance ecosystem that is difficult for patients to traverse alone. CDEs play a significant role in connecting the dots when patients are stuck between the prescribing doctor and the durable medical equipment provider, the pharmacy, and healthcare insurance provider without any idea where the system is failing.

Without the helpers, I'd never be able to produce the results that I demonstrate below, particularly given that I am highly active and fast regularly, meaning that my basal rates have to be finely tuned or my diet, exercise, and sleep become difficult to manage quickly. I have used 1, 2, and 3 day fasts for almost 15 years to tune my basal rates as it is an effective technique that is not difficult for me to manage, despite complaints from doctors, dieticians, and CDEs. Fasting works, as Valter Longo and others have demonstrated with fast-mimicking diets.

Before I discuss the Tandem T-Slim X2 and Dexcom G6, a little background: I was diagnosed with Type 1 diabetes as a child. While my disease is easier to manage than most, my active lifestyle makes managing diabetes challenging due to glycemic swings.

You've Lost That Cyborg Feeling

It's hard to describe the visceral feeling that comes from being device- dependent when your life depends on it and the design and manufacturing of that device is unreliable. I've had a bad experience with insulin pumps and continuous glucose monitors for the last decade and after considering going back to multiple daily injections and researching my next insulin pump and continuous glucose monitor for months I moved on. I'm glad I did the research because my experience with Tandem and Dexcom has been overwhelmingly positive, despite challenges with complex digital diabetes ecosystem and supply chain issues.

Tandem t:slim X2 and Dexcom G6

I got the Tandem t:slim X2 and Dexcom G6 on November 11, 2019, so as of Veteran's Day 2020, I've spent a year with the device managing my day-to-day blood glucose.

The timing of my purchase in the fall of 2019 meant that Tandem offered a free upgrade to its Control IQ technology when the pump shipped with Basal IQ technology installed. The long story short is that Basal IQ could prevent lows by diminishing insulin supply but it could not do what Control IQ does which is to provide increased basal rates and automatic correction boluses. I got the upgrade from Basal IQ to Control IQ around late spring 2020. It has made a difference in my control, particularly around exercise, sleep, and peace-of- mind.

Basal IQ was a leap forward given its event-driven (closed-loop) nature, since low blood sugars are high risk events that correlate with injury and death. By comparison, Control-IQ is a quantum leap, since dosing on the high side is still difficult, mostly owing to carb-to-insulin ratios and the guess work involved in calculating doses between insulin-on-board and carbohydrate-on- board. I'd like to say Control-IQ is like a 1-2 punch in diabetes control, but that's understating the difficulty of lows around intense exercise and post- prandial highs. There's more algorithmic development required to keep those totally in check. But I'm splitting hairs - the difference between 70% in range being good enough and 100% in range being perfect.

I expect the next few years will lead to algorithmic improvements that are truly mind-blowing and remove the need for David Goggins levels of self- regulation. In addition, I'm sure there are machine learning researchers looking at this data now since Dexcom and Tandem have a treasure trove of easily-anonymized data. Combine that data with data from a fitbit or

Apple Watch and you've got three pillars for significant improvement. The only thing that leaves out is precise measurement of food in grams of carbohydrate. That can be overcome with ketogenic diets as several proponents have demonstrated and I've leaned in that direction for a decade or so. I link to some of those proponents below.

Control IQ has sleep and exercise activities or modes. The exercise mode helps, but it's generally not tunable enough to completely prevent lows around exercise.

I can usually leave the pump on the default Control-IQ mode and get good but not perfect results most of the time assuming no exercise and normal diet, but the best results come from a hack that I learned watching a youtube video. That is, use sleep mode to impose a lower target and more aggressive algorithmic behavior to reach that 110 target. I leave the pump in sleep mode most of the time. I get the best results when I use sleep mode 24x7x365, even when exercising. I can go out now with a BG of 110 and run 5K at a moderate pace with little rise or fall. That was never possible prior to my switch to using sleep mode to manage exercise. It may be an outlier, but it works for me and indeed, it's a game-changer.

Reservoirs and Infusion Sets

A big difference between the Tandem/Dexcom ecosystem and Minimed/Medtronic ecosystem is disposable parts: reservoirs, infusion sets, sensors, and transmitters. I'm not going to go into every detail here but my experience with Dexcom/Tandem has been positive with few exceptions.

Before switching to Tandem/Dexcom, I'd had frequent issues with infusion site redness, dislodged cannulas, and dislodged CGM sensors, regardless of insulin, site change frequency, or location. After a year with the Tandem pump, I've had zero issues with site redness after 365 days and not a single time that the cannula dislodged from my skin in the same time period despite having dropped the pump from waist high or caught the tubing on a door handle. I use 23" tubing which puts the pump about knee high when it drops, so no damage occurs from it hitting the floor.

Software

The software ecosystem evolving around these devices is growing rapidly, as the devices have proliferated.

One thing that took me a few months to learn is that some of this software ecosystem is free, open source, and of excellent quality while improving the day-to-day disease management.

The ecosystem around DIY Artificial Pancreas Systems (APS) and Automated Insulin Delivery (AID) is beyond the scope of this document, but this activity has been evolving for several years and there is considerable tension between regulators and the open source community.

The first insight for me when I got the X2:G6 combo was that it was tiresome to reach for the pump frequently just to check my blood glucose. Getting the BG from the Dexcom G6 on my phone took more effort because I have a Google Pixel 4a, which was not supported by Dexcom at the time. Luckily, there's a very capable individual doing custom builds of the Android version of the Dexcom app on the internet. Just go through the form and you'll receive an APK build that can be loaded on an unsupported phone like my Pixel. It has worked perfectly for a year for me. That person deserves kudos!

Once I realized that checking BG on my phone was going to be nearly as tiresome as on the insulin pump itself, I decided to check out watches, reflecting that blood glucose is arguably the killer app for digital watches, especially for someone who is highly active. I quickly realized that the Dexcom supported the Apple Watch pretty well, but that wasn't an option for me having an Android phone.

I was also concerned about the cost of the Apple ecosystem having used it previously.

The real leap in learning came when I discovered an app on Github that runs on Fitbit Versa and similar devices. A quick trip to BestBuy and some configuration meant that I could track my BG on my wrist while exercising for a little over \$100. Glance has been a game changer for me since I use it daily when running or walking the dog and at-a-glance while sleeping has alerted me to problems that I otherwise would have missed. Kudos to Ryan Mason! Once you get past the excellent Dexcom Clarity app, the most well-designed of the apps available is SugarMate. I use it everyday for information-rich spot checks. Sugarmate joins the list of quick exit diabetes startups acquired by either Dexcom or Tandem, like TypeZero.

Usability

Tandem x2:slim has thoughtful design. The direct manipulation interface that Tandem presents on its main screen is intuitive since you can just tap the 3 HR indicator to toggle through the hourly graph modes and tap the status indicator to see status details.

That direct manipulation intuitiveness goes away when you descend into the options menu. Most of these functions are not frequently accessed, so probably aren't important day-to-day. However, the ones that are used more frequently do not have the at-a-glance one tap reachability that they should while discoverability is poor and menus are long and scrolling. The options menus frequently require too many taps to reach the leaf node of the options tree. When I first used the Tandem infusion sets and reservoirs, the design of the injector and reservoir seemed weird. The crinkly sound of filling the reservoirs as the bag expands with insulin and the transformer rocket launcher design of the infusion sets had me puzzled. However,

after a year of using them daily, they seem clever and reliable. I've not had an infusion set fail due to manufacturing issues.

The one issue that ignores is the sensor cost. Sensors are over \$300 per box of 3, each with a 10 day usage, with a membership and a prescription at Costco pharmacy. This is the best pricing I've found without US health insurance. There is competition in CGMs, but that competition is limited, given that integration with the insulin pump.

Results

I'm a big believer in evidence-based medicine. It's early but there's some interesting evidence available already. The easiest way to demonstrate the effectiveness of a medical device is 24x7x365 use for a year or so with results. That population survey is n of 1 or quantified self, and there's more to it than just the medical device (diet, exercise, and self-regulation); however, the medical device plays an outsized role in making good results possible, probable, and predictable, if not perfect.

The gold standard of results in diabetes control is Hemoglobin A1c. My HbA1c was 8.9 prior to acquiring the Tandem t:slim X2 in the fall of 2019, and it tested in the same lab at 6.4 in February of 2020, below the diagnostic threshold for type 1 diabetes, after only 3 months with the X2, G6, and Basal IQ. I do not have a current result after my switch to Control IQ, but I expect it to be similar since the math estimates - Dexcom's Glucose Management Indicator or GMI - essentially the variance of BG over time, show similar numbers. I've found GMI to be conservative, meaning that GMI is generally higher than my lab's HbA1c.

Regardless, the evidence speaks for itself. Prior to acquiring the X2 and G6, I had no way of approaching perfect control, where perfect control is defined as 100% in range for T1D which is generally accepted as 70-180. Today, I routinely have days where my blood sugar is 100% in control and most days are above the 70% in control benchmark, regardless of diet or exercise. I owe a debt of gratitude to Keith Runyan. His book has been helpful, though more on diet and exercise than pumps or CGMs.

I've also found Ian Lake's website and Zero Five 100 to be helpful.

Finally, Matt Vande Vegte has incredible content and led me to much of the advice and conclusions that I mention here.

Room for improvement

Digital diabetes is a complex ecosystem owing to the integration of sensors and mobile devices via bluetooth plus mobile devices and cloud systems via the 4G LTE and the internet. The devices are complex even without wireless connectivity but those things have only magnified the complexity and point to the need for human-centered design, and a non-existent last mile geek squad of technical support that is overwhelming doctors, diabetes educators, and patients.

Design problems show up despite manufacturer's best efforts to solve them and I believe this is a result of the aforementioned complexity. I have the benefit of having worked in medical devices and digital health and so I can generally intuit what's wrong when the system fails but there are at least a few cases that were difficult to debug even for someone with a shared mental model, technical depth and experience.

There are several incidents that are worth mentioning that demonstrate the challenge that these companies face in overcoming the ecosystem complexity. First, Dexcom and Tandem are not operating at NASA levels of technology delivery maturity. They are doing well enough to survive and perhaps thrive in the market, but there are cracks in the safety armor.

Almost a year ago, not long after I got the Dexcom G6, the blood glucose readouts and notifications that would typically show up on my watch or phone suddenly stopped and didn't start working for several days. This was widely reported on the internet and reached major news sites such as the Wall Street Journal.

This situation raises the need for vigilance on the part of patients, caregivers, and everyone in the technology support system to be aware that the publish-subscribe system employed by Dexcom to publish bluetooth data originating from the sensor to its subscribers (which may be everything from the patient's watch to a parent's smart phone or other app) was dependent on a single point of failure in the cloud.

I believe Dexcom learned its lesson with crisis PR, as the company now has better status mechanisms in place, but there were a tense few days, not so much for people like me - I can live without my watch displaying blood glucose - but for parents with diabetic children or the like. Second, Tandem's software quality problems have played out slightly differently. The company was slow to market with a mobile app that interfaced with the t:slim X2, but once delivered, the app seemed polished and professional.

Unfortunately, that polish was a facade. The app worked well most of the time but as I spent more time with it, I realized that there were serious latency and queuing problems plaguing the app. This latency and queuing plague is so serious that I've considered uninstalling the Tandem app from my phone. In short, what happens is that notifications from the pump are queued and not displayed on the phone until hours after the events that triggered them. This may seem like a minor annoyance until you consider that those events are important, like insulin delivery stopped and inherently timely, like receiving the insulin delivery stopped notification when insulin delivery is not actually stopped hours later or vice versa.

The implication of this is that the state machine that has to be managed by the mobile app is out-of-synch with the insulin

pump itself. The worse implication would be that there is no state machine in the design. This is a huge safety hole, one that I hope doesn't wind up causing injury or harm because it could be easily misread and lead to bad dosing decisions on the part of the patient or caregivers.

At a minimum, the app designers need to consider the cognitive dissonance that occurs when the patient receives a notification that they know is out of synch with the pump. This kind of latency may be fine in text messaging, but the design consideration in medical devices should be a serious safety concern. Third, the challenge of producing a system that is a collaborative venture between two companies such as Dexcom and Tandem, and the G6 and t:slim X2, respectively, is that the customer experience should not be concerned with crossing the chasm between Dexcom and Tandem, either legally, technically, or in terms of supply chain and support.

The past year has been challenging for everyone providing remote technical support, as many systems were not up to the challenge of scaling to support so many simultaneous connections, both human and machine.

However, where this shows up with Dexcom and Tandem is when a device or a disposable component malfunctions, it can be confusing to navigate help lines, web sites, and email addresses without a single, unified entry point into such systems. Patients deserve better. I believe Tandem and Dexcom are working hard to improve the disconnects, but it has been challenging when support needs to transit a complex ecosystem of email, web, and phone. That said, I've had a positive experience with both Tandem and Dexcom support and they've always followed through when the products and services malfunctioned. Most commonly, this has been with Dexcom's G6 transmitter batteries. They frequently failed before their 90 day expiry and this has been resolved every time with a warranty replacement, and a sensor to account for the wasted sensor owing to the transmitter change.

Summary

The following recommendations are made with a year of experience in the Dexcom G6 integrated with Tandem t:slim X2. 1. The Tandem Android app should have its latency problems fixed in a safe and reliable way. The state that the app reports should never be different than the insulin pump. The safety implications of decisions made on erroneous alerting should be obvious. 2. Brand and product support should be wholly integrated such that the customer experience has exactly one 800 number, or email, or similar - not two or more. 3. Activity modes (exercise and sleep) should be parameterized. This should include at least target BG since default targets may be too high or low for a particular user.