

diaTribe

research and product news for people with diabetes

test drive

T1/2 Test Driving Insulet's OmniPod System

By Kelly Close

I've said that I would sacrifice my cell phone for an OmniPod – and those who know me will tell you that is huge. For me, it's the best product that has come along in a decade. SymLin actually comes close, and then the other pumps are way up there, but the quality-of-life improvements that OmniPod offers have been enormous. It truly is a breakthrough, and really, so few breakthroughs come along in this diabetic life.

The OmniPod, of course, is by definition an insulin pump, and there are many important reasons for using a pump (see this issue's Learning Curve). As a group here at *diaTribe*, we think it's fantastic that insulin therapy can be more physiologic, or more similar to the body's natural functions. In other words, the pump, continuously supplying small amounts of insulin, approximates a functioning pancreas much more closely than do multiple daily injections of insulin. Honestly, it's crazy to me that only 20% of type 1s and a very small percentage of insulin-using type 2s are using pumps. Insulet, which makes OmniPod, was until recently a small private company; in May, it went public with the goal of expanding capacity, and I foresee OmniPod making a difference in how many diabetics use pumps.

The Device

There are two pieces to the system: one is a Personal Diabetes Manager, or "PDM," which is kind of like a Palm Pilot or a big Blackberry. This controls the other piece, the pod, which is attached to the patient. The PDM has a FreeStyle blood glucose meter built in. It's about three by four by one inch, bigger than most meters, but not significantly. When you get the PDM, you work with your healthcare team to program it.

- Basal rates (mine varied between 0.5 – 0.7 mg/hour until I got pregnant recently – then they were 1.0 – 1.5 mg/hour!)
- Target glucose levels (mine was 100 mg/dL until pregnancy, then it went to 80 mg/dL – hypoglycemia was very rare for me in pregnancy, so it was safe to reduce this)
- Insulin-to-carb ratio (mine was 14 units per carb pre-pregnancy, and five during the last few months of pregnancy!)
- Insulin sensitivity (this means how much 1 unit of insulin lowers your blood glucose – mine was over 50 mg/dL pre-pregnancy and 45 mg/dL during pregnancy)
- You can also program a bunch of other choices, like whether you want a reminder an hour (or two or three) after you eat to tell you to check your blood glucose, if you've missed a bolus dose, or whether you want any sound at all on your meter

The programming takes about 5-10 minutes, and then you're ready to start your OmniPod. When you take the pod out of the packaging, you fill it with insulin, which takes about 30 seconds. Then the PDM (it is so friendly!) asks you if you'd like to put on a pod. Why, yes! So it instructs you – just like that! – to fill the pod with insulin. You receive a syringe with every pod, and you just withdraw the amount of insulin (minimum 85 units - maximum 200 units) you require for three days and fill the pod through a fill port on the underside of the pod. Two hundred units of

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PHOTO: DANIEL BELKIN

The OmniPod

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insulin is the maximum, which is a drawback – I never used to use so much insulin, but I found in pregnancy, it barely lasted the three days, so for some type 2 patients, this wouldn't be enough. Then the PDM asks if you are ready (again, so friendly! I really get the impression, crazy as this sounds, that it cares about me...), and you take off the pod's adhesive backing and place it on your stomach, back of arm, or leg – plenty of flexibility because you aren't constrained by tubing. You can put it anywhere there is fat tissue.

Then you press "start" on the PDM – and I always do this gleefully, because I never feel it – "go!" You hear a little "click, click, click..." which I find reassuring, and then the needle goes in at 1/200 of a second and then comes right back out, leaving the cannula under your skin. I'm not sure if it is because I don't see it go in,

or because it's so fast, or because it's automated, but for such a long time, this "auto-insertion" was my favorite thing about the pod. I didn't feel it, while the insertion of my other pumps had always been my least favorite thing about them. After insertion, you're off and running with your basal insulin. You wear the pod continuously for three days (it tells you when it's time or insulin is running out) and then remove it and throw it away. Swapping to another pod only takes about 90 seconds – super fast and easy – basically just filling the new pod with insulin and saying "go." This device is very easy to maintain – you don't need to clean anything. You do get in trouble if you forget to take a pod – and you need to switch your existing one – because the alarm is very, very loud and you can only quiet the alarm intermittently, but if the pod wants to get your attention, you can't ignore it!

While you're wearing the pod, you use the wireless PDM to program doses or adjust basal rates. To program a bolus, you first take a blood glucose test, just like with a regular FreeStyle meter, and you get your result, and then press next. I love how all this works. My husband is very technical, and he was helping me and he said "Nice UI..." approvingly the first time I tried it. "Thanks!" I said, pleased with my score of 122 mg/dL. "No, sweetie," he laughed. "You're lovely, but I was talking about the PDM. Nice UI. That means nice user interface. This means I like how it's so logical. Press 'next!'" I did, and the PDM asked if I was planning on eating, which I was – enter 30 carbs! Then there appeared the bolus dose it was telling me to take. This wasn't unlike my old pumps – I also think the "bolus estimator" function on pumps has been a breakthrough – but the screen on this is pretty big, and I just liked the PDM's personality. Then I hit "go" and a wireless signal was sent to the pod, which delivered my bolus dose of insulin. Insulet is working on combining the OmniPod with FreeStyle's soon-to-be-available continuous glucose monitoring system, Navigator – I think this holds a lot of promise, but I imagine that will take a couple of years.

Even though the interface on the PDM is easy to set up and learn, the PDM still has all the sophisticated options that a serious patient would want, like a bolus wizard (which determines your bolus) and an "insulin on board" feature (which deters overdosing). The PDM also has a food database, reminders, a quiet alarm (some like it loud, but I don't); and, best of all, it doesn't need to be connected to me!

It's also worth noting that Insulet's customer service desk is excellent – perhaps because all its members are type 1 patients who also wear the pod. (Now, that's standing behind your product.) I've only had to call the desk a few times, but when I have, the reps were extremely knowledgeable and efficient.

An evolution in pumps

As I described in an interview with a top teen Web site for diabetes (diabetesteentalk.com), over the past 10 years I have worn both the MiniMed and Animas pumps. The MiniMed 507 was the first series of pumps I started on – life changing. I cringe when I think of what I did before that from the late 1980s to the mid 1990s – on a fixed insulin dose for most of that time, mainly NPH and regular. I was in and out of the emergency room for hypoglycemia at least once a year, and I can still vividly feel what it was like to wake up in the ambulance. It always felt the same – "Oh, not this again" – and I would close my eyes and hope it was a dream.

It was in the mid-1990s, when I was working on Wall Street, that I was asked to develop an opinion for investors on MiniMed as a small public company. I had been very against pump

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therapy – probably, I was just against thinking actively about my diabetes. The body-image stuff really bugged me, and I didn’t want a constant reminder of my diabetes anywhere, much less to wear. My A1c at the time was 7 percent or so, and my doctors would assure me that below 8 percent was “very good” – this was before everyone was so focused on the importance of tight control! Anyway, I said I would go on the pump for a week to determine whether MiniMed was a positive investment. Going to MiniMed to meet the leaders, I learned about the benefits of physiologic therapy – the more you can mimic an actual pancreas, the better. With a way to mimic my pancreas’ insulin secretion every minute, four shots a day suddenly seemed like a very blunt tool.

Inside a day, I vowed never to go off pump therapy. I felt so much better on it, almost immediately. Life was more flexible: I could exercise without fears of hypos, I could eat more, I could give a “shot” just by pushing a few buttons. Now, not all was rosy – I found the insertion painful, I hated when my infusion set pulled out accidentally, and sometimes I just wanted people to stop asking about it. When MiniMed was bought by Medtronic in 2002, I started having problems with customer service and stumbled upon Animas at a conference. I used Animas all through the 1200 series. I thought the pumps were sleek and worked well, and I loved the “insulin on board” and the other “smart pump” features. At this time, there seemed to be so much innovation – more than we had seen in years.

So why the move to OmniPod? When I volunteered for the clinical trial – I love clinical trials – I didn’t think anything could prompt me to change permanently from Animas. I was intrigued by the “no tubing” concept, but the idea of leaving it on for three days seemed like a deal breaker. To my surprise, I loved it. It was more discreet than other pumps, which for me was so key. It was faster and easier than my other pumps, and it really was as smart as my old pump. It was a good time for change – I had just had my daughter, Coco, who would pull out my infusion sets, which was incredibly depressing. It was nothing I couldn’t get over, but putting those in was the worst part of being on a pump, and the OmniPod’s auto-insertion is so much less stressful for me.

Because it has no tubing, it is easily hidden. I’ve worn it nearly everywhere, though I’ve noticed that my abdomen has the best absorption (this varies from person to person). Many wear it on the back of the arm, possibly the least cumbersome location. I love hiding it. Even though I’m pretty glass-half-full about my diabetes, I do get sick sometimes of telling my story whenever someone asks about my pump (before that, my pen, or syringe). I am still asked sometimes, and typically I’m pretty upbeat about it because I feel lucky, but I’m not now answering in response to my pump, because it’s never really visible. It’s small – about half the size of a regular pump – and of course I’m hoping it gets even smaller – and it’s always hidden under my clothes.

Since the OmniPod is always attached to me, some people ask whether I can suspend the flow of insulin, for exercise, for example. Yes, you can. I walk a lot and I always suspend it half an hour before my walk. If I don’t, my BG drops 50 points minimum. I would do that with any pump. The pod is waterproof, so there’s no issue with showering or swimming. Apparently, the insulin in the pod may have problems in hot tubs, but you can prepare for that by putting it in your upper arm. Technically, the company says it can only be immersed 8 feet for 30 minutes, but that’s not really very restrictive unless you’re a scuba diver, which I’m not (I made the mistake of admitting I was diabetic when going for training a couple of years back – I’ll have to not tell the truth next time!)

Issues

Of course I’ve had some issues with the OmniPod. The pod failed only once in two-and-a-half years, and when it did, I knew it right away. But the batteries wear out quickly in the PDM, for one (not in the pod, thank goodness – that’s never happened). They wear out about every two weeks for me, probably because I check my blood glucose so frequently, upwards of 10 times per day. This is annoying, but not as bad as it could be – it takes AAA batteries, which are easy to come by, not like the old days where I used 357 batteries. Initially, I thought the backlight didn’t stay on for quite long enough until I learned this is set by the user – although my long setting probably makes the batteries give out in a shorter time, I like the tradeoff. Finally, they don’t recycle the pods, so throwing out all that hardware (a pod every three days) can weigh on your conscience. I’d feel better if they provided a recycle bag, even if it was just for show!

And then of course, it’s stuck to you 24/7, which will be an issue for some. If you don’t want

to wear it for sex, swimming, or whatever else, you're out of luck. Getting used to this was not as much of an issue as I thought it would be, and I really didn't ever notice it at all. I have a supportive partner who loves anything that makes diabetes easier for me, and if I were not in that position, I might not be so comfortable. If you're concerned about body image, and having something attached to you at all, then any kind of pump may not be the best option – but I would urge you to reconsider that sentiment strongly if that's the case.

Finally, if you're disorganized or forgetful, like I am, you have a few lessons coming to you. I've climbed on two planes without my PDM. Luckily, the pod keeps going with your basal rate, but you won't be able to bolus. Since I was 18, I've always had syringes with me to prevent a disaster, and I don't think that will ever change. The other problem is that when you forget the PDM, you also forget your meter. I guess that's the negative of integrating anything – if all your keys are on one fob when John is with me, I always carry a backup meter, and he keeps trying to make sure I always do this regardless, but honestly I don't always remember.

Trying and Buying the OmniPod

A start up kit for an OmniPod costs \$800, and it comes with the Personal Diabetes Manager and two pods. The cost of the OmniPod System is less expensive initially (\$800 PDM versus \$6,000 pump) but the overall cost is comparable during a three years to four years period. It may be harder to get reimbursed as Insulet has not signed contracts with all insurance companies. Most pumps are “durable medical equipment,” and the OmniPod is disposable, so insurers sometimes get caught up in that difference. When my clinical trial ended, my insurer, Blue Cross Blue Shield, said it would cover 90 percent of the cost of the pods, but I know that all insurers and managed care plans aren't necessarily as generous.

What's great about the OmniPod is that it's very easy to try for a few days. You get to see how the PDM works in the doctor's office and then you can wear a pod home. You don't take the PDM because there is only saline in the pump, but you get to see how wearing it feels. It is harder to sample other pumps because you walk away with \$6,000 worth of equipment on your belt. Sometimes the advantages of pumps are hard to see and the barriers seem great. Wearing the pod yourself, though, gives you a much better picture of its pros and cons.

Normally, when you get a pump, you need to go through a day to a week of pump training depending on your hospital or diabetes center, which is a big hassle. With the OmniPod, however, everything is easier, and the burdens of training are much reduced. My sense is it takes about a third or half the time to learn OmniPod as opposed to other pumps, though of course “your mileage may vary” and other ones may be easier – just not in my case.

A Breakthrough for me

What I've learned working in diabetes is that there is no average patient, and generalizing is not typically productive. I would never say this is right for everyone. But the OmniPod is innovative, and I think it will – and has – driven innovation faster in the industry. The next step for Insulet is to make OmniPod available in all states and then internationally. For now, for me, I'm just grateful that I have mine.

The OmniPod characterizes what I think is undoubtedly the best era for diabetes ever. For me, OmniPod has been a breakthrough product, like the first blood glucose monitor in the late 1970s, the first pump in the 1980s, the first insulin analog Humalog in 1996, like the first smart pumps in the late 1990s, like the next generation of continuous monitors in the near future. For sure, in my view, even though I'd never choose it for someone, it's the best time ever to be a diabetic.

The logo for diaTribe, with "dia" in a light blue sans-serif font and "Tribe" in a dark brown serif font.

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