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CLINICAL APPLICATIONS

The Implantable Peritoneal Pump—A Patient's Perspective

Christopher J. Witkowski, J.D.,[1] and Christopher Saudek, M.D.[2]

Abstract

A participant in a study of implantable insulin pump therapy recounts his experiences with on-and-off use of the pump over the past 18 years. Christopher Witkowski, 55, first had a pump implanted in 1990. Despite occasional difficulties over the years, Witkowski reports that his overall experience has been extremely positive. With delivery of insulin directly into the peritoneal cavity, he feels better, has more flexibility in eating, and experiences fewer insulin reactions. Witkowski expresses disappointment that the manufacturer of the pump, Medtronic, no longer plans to seek Food and Drug Administration approval for this therapy. Witkowski expresses his hope that research on the device will continue, believing that this therapy could be of benefit to millions of diabetes patients. This article is accompanied by a detailed description of the pump refill procedure by Dr. Christopher Saudek of Johns Hopkins University, current leader of the ongoing research study.

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Introduction

I was diagnosed with diabetes at 14 years old. I can still remember coming home from high school one day and collapsing on the couch, wondering why I felt so awful. Once we figured out what was wrong, I learned to manage the inevitable roller coaster of high and low blood sugars as best I could with a never-ending cycle of insulin injections. Over the past four-plus decades, I've probably given myself more than 40,000 insulin injections. Now that I think about it, that's an awful lot of shots.

I'm 55 now, and I still have diabetes. But in recent years, I've been getting about four injections *a year* instead of four or more *a day*, thanks to the insulin pump that is implanted in my abdomen as part of an ongoing research study being conducted by researchers at Johns Hopkins University. Unlike the external insulin pumps that are now widely in use, there's nothing sticking into my body, no tubes or attachments to worry about, and no wondering when the insulin will actually reach its destination. I'm not tethered to anything. For someone

Author Affiliations: [1]Association of Flight Attendants-CWA, Washington, DC, and [2]Johns Hopkins University, Baltimore, Maryland

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Corresponding Author: Christopher J. Witkowski, Director of Air Safety, Health and Security, Association of Flight Attendants-CWA, 501 3rd Street, NW, Washington, DC 20001; email address cwitkowski@live.com

who hates to wear even a watch, the difference is monumental.

My implanted pump is a battery-powered device that looks a lot like a metal hockey puck. It is stitched into a pocket of tissue directly under my skin and has a catheter that pokes through the peritoneal wall to deliver a constant stream of insulin directly into my body cavity. It's like having a titanium pancreas that provides a basal amount of insulin 24/7. At mealtimes, I just punch a few buttons on a hand-held communicator, instructing the pump to deliver a bolus of insulin.

Four times a year, I return to Johns Hopkins Hospital to have the pump refilled with a highly concentrated form of insulin. The first step in the insulin refill process is preparing the syringe **(Table 1)**.

Table 1.
Syringe Preparation

25-cc syringes, with special clips that allow them to be opened against a pressure gradient, are prepared beforehand, each with a two-way stopcock between the syringe and a special long withdrawal needle. One "withdrawal syringe" with approximately 5 cc of a buffer solution One syringe with approximately 20 cc of U-400 insulin
The barrel of the "withdrawal syringe," with the stopcock closed, is pulled open to create a vacuum within the syringe.
The new insulin syringe, with its approximately 20 cc of insulin, also has a vacuum pulled and is shaken vigorously to "degas" the insulin solution. This is done several times, reducing the partial pressure of air dissolved in the insulin. The stopcock remains closed to preserve the degassing.
Both the withdrawal and the insulin syringes are carefully weighed on a balance.

The second step is cleaning the implant area and numbing the area with a local anesthetic **(Table 2)**.

The third step is the withdrawal of leftover insulin from the pump **(Table 3)**.

Table 2.
Subject Preparation

The subject lies down on an examination table and frees the abdomen of clothing.
The skin is scrubbed with betadyne and alcohol in an area about 6 inches around the center of the pump. This area is draped with a sterile cloth.
Approximately 0.1 cc of xylocaine is put into the skin in the area to be entered with the needle, making the procedure painless.
The health care professional uses sterile gloves.

Table 3.
Withdrawal of Insulin

A "guide needle," an 18-gauge pink needle, is placed through the skin into the refill cone in the center of the pump. This does not enter the pump; it just serves as a guide for the withdrawal needle.
Through that guide needle, the withdrawal needle (attached to the 25-cc syringe with approximately 5 cc of buffer, weighed carefully) is inserted into the reservoir of the pump.
The stopcock is opened so that the reservoir is exposed to the vacuum in the syringe, and "old" insulin is withdrawn into the syringe.
After withdrawal is complete, the stopcock is again closed, and the syringe with the "old" insulin is again weighed carefully, documenting how much insulin was left in the reservoir after the approximate 3 months of use.
The "actual" figure for how much insulin was left in the reservoir is compared to the amount of insulin that was nominally delivered based on the total basal and bolus dosing over those 3 months. A "refill error" is calculated, which normally is about 1–10% accurate.

The fourth is filling the pump with fresh insulin **(Table 4)**.

Table 4.
Filling the Pump with "New" Insulin

The carefully weighed and carefully degassed syringe with approximately 20 cc of fresh U-400 insulin is then inserted through the guide needle to the pump reservoir.
The stopcock is opened, and because the reservoir has a *permanently negative pressure relative to atmosphere,* the insulin is slowly drawn into the reservoir if the needle is placed properly. There is no need to exert positive pressure on the syringe, which could be dangerous if the refill needle were not placed properly.
After approximately 15 cc of insulin is drawn into the reservoir, the reservoir is full and no more is drawn in. About 1 cc is withdrawn in order to reestablish negative pressure in the reservoir.
The refill needle and syringe are withdrawn and weighed carefully to calculate exactly how much insulin was dispensed into the pump reservoir.
The guide needle is withdrawn, a bandage is put over the needle sites, and the procedure is complete.

A few additional features of the insulin refilling process should also be considered for optimal performance of an intraperitoneal pump **(Table 5)**.

It's a far cry from early teenage days when I used to hum verse after verse of Credence Clearwater Revival's "Rollin' on a River," waving my syringe to the beat as I tried to muster the nerve to jab the needle into my thigh. It's hard to describe the huge improvement in my quality of life with the implanted pump. I feel better. I have more energy. It's easier to stay focused. I don't have severe insulin reactions anymore. My weight stays down because I don't find myself eating simply to "feed" the latest shot of insulin.

I have greater flexibility at home and on the job. If I'm tied up in a meeting or if a conference call runs late, I don't have to stop for a meal or risk an insulin reaction. When I travel to meetings overseas, adjusting to several time zone changes is much easier. The pump's steady basal rate helps me maintain normal blood glucose levels throughout. In essence, it provides the ability to live as close to a "normal," nondiabetic life as possible.

I've been a part of this research protocol for more than 15 years and, over that time span, I've had four different insulin pumps implanted, one replacing another as the pumps' batteries died. However, I'm disappointed to report that, despite the promise that I think this technology still offers, the pump's manufacturer, Medtronic, has served notice that it plans to discontinue the research program. It is unclear how Medtronic will deal with participants whose pumps continue to function well. My hope is that that the company will not completely cut off support to participants such as me, forcing us to explant a valuable, functional pump.

My participation in the implantable insulin pump therapy study began nearly two decades ago when my doctor at the Washington Hospital Center, Robert Tanenberg, told me that he had the opportunity to form a group of patients who would be subjects in an implantable pump study that was being spearheaded by Dr. Christopher Saudek at Johns Hopkins. What attracted me to the program was the ease of the device and the opportunity to participate in a study that had the potential to offer an improved quality of life to millions of people with diabetes. The hope was that after a few years of study,

Table 5.
Notes on the Refill Procedure

Pump refills are scheduled routinely every 3 months.
The total time from preparation to completion is normally ~15–20 minutes.
No significant pain is experienced by the subject other than placement of the xylocaine.
The negative pressure reservoir precludes the need to push insulin and is a major safety feature, as insulin is not infused unless the needle is placed properly.
This procedure has been performed by physicians, trainees, and, on occasion, nurses.
Other more elaborate procedures are done in order to troubleshoot or correct underdelivery situations.

the manufacturer would file an application to have it approved by the Food and Drug Administration (FDA) for use by diabetes patients in the general public.

Implanting my first pump in 1990 was a fairly simple procedure from a patient's standpoint, involving a 2-day stay at the hospital. The surgeon made a 4-inch horizontal incision just to the left and above my navel, slipped the pump into place, and then stitched it to surrounding tissue to keep it anchored. Except for a small bulge in my abdomen and a telltale scar, you can hardly tell it's there. (However, it does set off airport metal detectors.) To me, one of the most significant differences from the external pump is that the implanted pump delivers insulin directly into the peritoneal cavity, similar to the delivery of insulin from the pancreas. There's no delay in absorption of insulin into the bloodstream and no wondering how long it will take for the insulin to make its way through fat and muscle tissue, as with external pumps. Over the years, with the thousands of injections, fibrous tissue and mounds of fat have replaced normal skin. The implanted pump, by delivering directly into the "peritoneal space," deep in the abdomen, bypasses all of that, giving more consistent absorption.

Quality of life improvements were evident as soon as I had the surgery. My blood sugars were under better control. Administering mealtime boluses was simple. No more cowering in a corner at the airport, hunting around for a private place to shoot up. No more worrying about whether a restaurant meal would arrive in time to counteract the insulin shot I'd already taken. I could pull out my hand-held communicator and program a bolus without attracting any more attention than would someone pulling out a calculator or a Blackberry. As an unexpected bonus, my weight decreased steadily by 15–20 pounds as I stopped eating simply to offset insulin injections.

The pump felt like a natural part of my body. I quickly stopped even noticing it. Psychologically, I felt confident in my ability to control my blood sugars, free from the burdens associated with insulin delivery and potential infection. I felt less sluggish, more alert, and more focused. One thing the pump didn't change was the need to test my blood sugar regularly. In order to time and calculate boluses correctly, regular testing still is crucial.

The pump experience has not been without its complications. We were told prior to implantation that the pump batteries could last up to 4 years. But with my first implanted model, after 2 years my blood sugars started creeping up and it became clear that the pump battery was dying. In addition, a number of us in the study had problems with insulin crystallizing around the port where the insulin is released into the catheter. This meant that the full dose of insulin wasn't delivered, resulting in unexpectedly high blood sugars. A nonsurgical pump rinse procedure was developed to clear the blockage, which soon became part of routine maintenance of the pump. Some other patients experienced problems when tissue growth blocked the ends of their catheters. Despite these complications, I feel that the many benefits of the pump far outweigh any difficulties.

After my first pump's battery died, a replacement was implanted in 1993. This was a fairly simple undertaking, as the surgeon could slip the new pump into the same tissue pocket formed by the first one. The second pump gave way to a third in 1999. Along the way, when Dr. Tanenberg left the Washington area to take a fulltime medical school teaching position, Dr. Saudek agreed to fold Dr. Tanenberg's pump patients interested in continuing with the study into his group at Johns Hopkins.

The program hit a long bump in the road sometime after that. Because of environmental concerns related to the manufacture of the pump's specialized insulin in Germany, Medtronic deactivated all of the pumps indefinitely while it worked to reformulate the insulin. We patients had the choice to have our inert pumps removed or to leave them in place while the problem was resolved. I chose to keep my pump in place, hoping that the hiatus wouldn't be too long and reasoning that the existing pump would maintain the tissue pocket for the new one. Little did I know the hiatus would last several years.

As a result, it was back to shots, which was a rude awakening. There was the inconvenience factor. I had wider swings in my blood glucose levels. My weight steadily began to creep up again. It was more of a challenge to stay focused and maintain attention. Finally, in May 2004, my old, inert pump was swapped out for a new, functioning one. Again, I felt healthier, more alert, and my weight came down.

The latest wrinkle in the pump study came last year when I learned that Medtronic no longer planned to seek FDA approval for the pump and planned to halt the research program this summer. This is a decision that I still am hoping to see reversed. It doesn't make sense to me to halt a program that offers people with diabetes around the world the hope of a steady insulin source unencumbered by external pumps or other paraphernalia.