Chapter 1
An Introduction to Insulin Pump Therapy

This chapter will provide information on what insulin pump therapy is, and how insulin pumps have developed from the early models introduced in the 1970s to the sophisticated models in use today. National guidance on the use of insulin pumps in the United Kingdom will be discussed, as will alternative devices that are either being researched or are in limited use. It is likely that technological advances will result in many new devices being developed over the next decade. More detailed information on all aspects of insulin pump therapy can be found in the relevant sections throughout this book.

WHAT IS INSULIN PUMP THERAPY?

Insulin pump therapy, also known as ‘continuous subcutaneous insulin infusion’ (or CSII) therapy, is a method of giving insulin subcutaneously without the need for injections. In brief, a small needle or catheter is introduced and left in place under the skin, and the insulin pump is attached to this via a length of tubing. The needle or catheter needs to be replaced every two to three days for most people. The pump is worn 24 hours a day (although can be removed for short periods) and delivers fast-acting insulin continuously, in very small amounts, known as the ‘basal rate’. The amount of insulin being delivered is programmed by the individual pump user according to their needs. Additional insulin doses, known as ‘boluses’, are given by the pump user – for example when they are eating or if their blood glucose level is too high – by pressing buttons on the pump in sequence.
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THE DEVELOPMENT OF INSULIN PUMP THERAPY

Historically, insulin pump therapy first became an option for treating diabetes in the 1970s. Technology at that time was very limited, so, although they provided a continuous supply of insulin and provided the opportunity to give boluses without additional injections, insulin pumps lacked the sophistication of modern-day pumps, and were only capable of delivering boluses as multiples of the basal rate. Dose adjustment for many pumps could only be achieved through using a screwdriver to turn a screw head. The pumps delivered the insulin boluses slowly, over about 20 minutes. The devices were also significantly larger than today’s models and lacked adequate alarm systems to identify when they were malfunctioning or not delivering the programmed insulin, thereby increasing the risk of diabetic ketoacidosis.

In addition, health professionals lacked the knowledge and skills needed to optimise the effect of insulin delivered via a pump, and people using the pumps were not given the training and support that they needed. Pumps were used to treat people with diabetes in whom all other therapies were deemed to have failed, so the pump was viewed as a last resort rather than as a proactive management choice. No assessment of interest or enthusiasm for using a pump was made of people before pump therapy was initiated, and, together with the lack of education, this meant that in general insulin pumps were poorly managed. As one of the most common side effects was diabetic ketoacidosis, insulin pump therapy was viewed as a treatment option that carried with it more disadvantages than advantages. Even though analysis reported that insulin pumps carried no greater risk of mortality than conventional therapy (Teutsch et al., 1984), the myth that pump therapy is less reliable than injection therapy has resulted in many healthcare providers being reluctant to use it in clinical practice (Saudek, 1997), and might have contributed to the slow growth in the use of this therapy in the United Kingdom.

TODAY’S INSULIN PUMPS

Modern insulin pumps, in line with other electronic devices, have become extremely sophisticated. They deliver insulin in tiny quantities, down to as little as 0.025 units per hour, and can be programmed to deliver insulin much more physiologically than multiple-dose insulin therapy. While from a safety aspect they generally require a series of button-pressing to alter insulin doses or give additional doses, they are much more straightforward to use than their predecessors. Information about the current pumps available and their range of features is available in Chapter Four.
The improvement in technology is one aspect that makes insulin pump therapy a success today, but there are also other factors, in particular the recognition that careful assessment of individuals is required prior to their using a pump, which is discussed further in Chapter Six. The provision of intensive education and ongoing support from a specialist team is also important and helps people to optimise their diabetes management when using a pump. In the Diabetes Control and Complications Trial, carried out in the United States between 1984 and 1993, 42 per cent of those in the intensively treated group were using insulin pump therapy by the end of the trial (Diabetes Control and Complications Trial Research Group, 1993), indicating the potential it has for optimising glycaemic control.

As a result of the problems experienced in the 1970s and early 1980s, insulin pumps have been used with a great deal of caution in the United Kingdom. In addition, in the UK healthcare system, essential treatments are traditionally funded much more readily than those that are viewed to have cheaper alternatives, in this case injection therapy. The number of people in the United Kingdom who currently use insulin pumps to manage their diabetes has risen from under 200 in 1998 (Everett, 2003) to 5000–6000 in 2006 (Diabetes UK, 2006), and this number continues to rise. This means that 2 per cent or more of the UK population who have Type 1 diabetes currently use insulin pumps to manage their diabetes, compared with 15–20 per cent of people in the United States and some parts of Europe.

National guidance on insulin pump therapy

The National Institute for Health and Clinical Excellence (NICE) produced guidance in 2003 (National Institute for Health and Clinical Excellence, 2003) on the use of insulin pump therapy, outlined in Table 1.1, with a suggestion that only 1–2 per cent of people with Type 1 diabetes would need insulin pumps to manage their diabetes. Also, the therapy is not recommended at all for people with Type 2 diabetes, although small numbers of people with Type 2 diabetes use this therapy. Most of those with Type 2 diabetes had their pump initiated prior to NICE guidance being available, and anecdotally it has helped to manage severe insulin resistance.

In light of the information in the previous section of this chapter, the original NICE guidance (2003) was a large underestimation of the number of people who could benefit from this type of therapy, if the United Kingdom follows the lead from other countries, which is likely as more health professionals become confident and competent in using this therapy.

It is widely recognised that a great deal more research is required into insulin pump therapy, but it is likely to be a cost-effective treatment when measured...
Using Insulin Pumps in Diabetes

Table 1.1 Summary of 2003 NICE guidance on the use of insulin pump therapy

Insulin pump therapy is recommended in Type 1 diabetes only, where multiple-dose insulin (MDI) therapy, including using glargine\(^*\) where appropriate, has failed. People using insulin pumps should have the commitment and competence to use the therapy. The initiation should be carried out by a trained specialist team, usually a physician, diabetes specialist nurse and dietitian. There should be specific training provided for the pump user, ongoing support and a common core of advice agreed by the specialist team. Pumps can also be used in pregnancy and in children with diabetes.

Definitions:

- Failure of MDI therapy: when someone is unable to achieve HbA1c levels below 7.5% without disabling hypoglycaemia. If microalbuminuria or adverse features of the metabolic syndrome are present, the target level of HbA1c is lowered to below 6.5%.
- Disabling hypoglycaemia: repeated and unpredictable occurrence of hypoglycaemia requiring third-party assistance and causing continuing anxiety.

\(^*\) Glargine was the only long-acting insulin analogue available at the time of publication of the guidance, and substitution of other long-acting analogues prior to using pump therapy is likely to have similar effects.

against the cost of hospital admissions, the treatment of complications and time lost from work due to acute diabetes-related situations. Research indicates that the immediate financial savings, even without the reduction in long-term costs, are likely to make insulin pump therapy a cost-effective treatment (Ulahannan \textit{et al.}, 2007). Quality of life is also a major consideration, with some studies reporting major improvements in many aspects (Hoogma \textit{et al.}, 2005), but again further research is needed in this area. Chapter Three outlines some of the benefits that pump users perceive they have gained.

WHAT WILL THE FUTURE LOOK LIKE?

Current technological advances in insulin pump therapy and glucose monitoring systems indicate that this type of therapy will become increasingly sophisticated over the next decade. Many of the devices that are currently being researched, together with others available in some parts of the world, are discussed in this section. Some of these devices have been available for a number of years but have failed to meet expectations, mainly because of safety reasons, but newer models might be developed to overcome these difficulties.

Smaller pumps

One of the factors influencing pump choice for many pump users is the size of the pump they are going to use, with a preference for smaller models, and the
manufacturers are being challenged to produce pumps that are smaller than their predecessors. While there are some essential features that all pumps require, such as an insulin reservoir, it is likely that newer and smaller models will emerge.

**Disposable devices**

Disposable insulin pumps, developed in the United Kingdom, are a new innovation and are only now starting to be used. They have a reservoir of insulin and also a re-usable section that attaches to the skin, holds the battery and controls the flow of insulin. The pump user has a separate handheld programming device, rather than programming their insulin doses directly into the pump.

**Continuous glucose monitoring system linked to an insulin pump**

Continuous glucose monitoring systems, which transmit data (wirelessly) to an insulin pump, are already available. The pump user inserts a second cannula, attached to a device known as a ‘transmitter’, that measures glucose levels in interstitial fluid and then converts the measurements to correlate with blood glucose levels. The result is displayed on the insulin pump, with information on whether the blood glucose is rising or falling and whether it is changing slowly or more rapidly. The pump can provide suggestions on insulin doses to give, based on the pump user programming their target blood glucose range and their usual bolus ratios.

These devices can be funded by the NHS, but it is more common for them to be purchased by pump users themselves, together with the disposable cannulas and sensors. Cost is one of the factors that limit the wider use of these devices, but other drawbacks include wearing two devices instead of one. Also, pump users still have to carry out fingerprick blood glucose readings to both calibrate the machine and to confirm their blood glucose levels prior to giving extra insulin doses, which might affect their perception of how much benefit will be gained from using such a device.

**Insulin delivery via a pre-inserted channel**

Insulin can be infused directly into the peritoneum using a device implanted, under general anaesthetic, into the abdominal wall, with the pump tubing
subsequently being attached. This method of insulin delivery has been available for a number of years and can help people with severe insulin resistance, as it bypasses subcutaneous tissue. It does, however, have a number of drawbacks, which include: a high risk of infections and blockage of the tubing, pain at the site of entry and crystallisation of the insulin. Also, because it is more intrusive, it carries a risk of causing psychological difficulties and altered body-image perceptions. For all these reasons, it is rarely used, is likely to remain in extremely limited use in its present form and is not currently initiated in the United Kingdom.

**Wireless insulin pumps**

A wireless insulin pump that adheres to the skin as a patch, with an integral cannula, infusion set, insulin reservoir and battery, is available in the United States. It is changed every three days, and when it expires a new one is filled with insulin and applied. The programming of the pump and giving insulin doses is via a separate wireless device, which also has an integral blood glucose meter. One of the advantages of this device is that it does not have any tubing, so physical activity is made much easier, and also it does not have to be attached to clothing. This pump is not yet available in the United Kingdom.

**Implantable insulin pumps**

Implantable insulin pumps were developed in the 1970s. They are inserted under general anaesthetic and carry a reservoir of U400 strength insulin, which is four times the strength of conventional U100 insulin used in the United Kingdom. The insulin lasts between one and two months before requiring a repeat operation to refill the reservoir. The pump user has a remote control to select their insulin dose. As with insulin delivery via a pre-inserted channel, the insulin is delivered into the abdomen, thereby reducing insulin resistance and enabling people to use lower doses of insulin. They also carry an increased risk of infections and blockages. The cost of these devices is high, and currently they are not used in the United Kingdom.

**Closed loop systems**

A closed loop system of insulin delivery, where an insulin pump automatically delivers insulin at a variable rate in response to changing blood glucose levels, is often viewed as the gold standard in insulin pump therapy.
Ongoing research into this area shows promising results, but there are a number of challenges to overcome. The continuous glucose monitoring device used needs to be extremely accurate and of longer-lasting duration than those currently available, the device needs to be able to predict insulin requirements in the few minutes ahead and safety standards would need to be extremely high. It is likely to be a number of years before this type of device is available for general use.

**CONCLUSION**

This chapter has provided an introduction to insulin pump therapy and an overview of the current situation in the United Kingdom, together with information about new devices under development and those that are available but in less common use. Information about the pumps currently used in the United Kingdom can be found in Chapter Four.

**REFERENCES**


