Durability of Insulin Pump Use in Pediatric Patients With Type 1 Diabetes

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OBJECTIVE — To examine longitudinal outcomes, rate of and reasons for discontinuation, and predictors of insulin pump success in a cohort of youth initiating pump therapy.

RESEARCH DESIGN AND METHODS — We followed a cohort of youth with type 1 diabetes ($n = 161$) starting the pump between 1998 and 2001 and recorded natural history of treatment.

RESULTS — At pump start, patients (71% female) had a mean age of 14.1 ± 3.7 years, diabetes duration of 7.1 ± 4.0 years, daily blood glucose monitoring (BGM) frequency of 4.0 ± 1.2, a daily insulin dose of 1.0 ± 0.3 units/kg, and an HbA_{1c} (A1C) of 8.4 ± 1.4%. After 1 year, mean daily BGM frequency was 4.5 ± 1.7, daily insulin dose was 0.8 ± 0.2 units/kg, and A1C was 8.1 ± 1.3% (all baseline versus 1-year data, $P < 0.01$). As of 2005, 29 patients (18%) had resumed injection therapy at a mean age of 17.0 ± 2.9 years after a mean duration of pump use of 2.1 ± 1.3 years. BGM frequency at baseline and at 1 year was significantly lower in the patients who resumed injection therapy ($P < 0.02$). In addition, patients who remained on the pump had lower A1C than those who resumed injection therapy at both 1 year ($P = 0.04$) and at the most recent clinic visit ($P = 0.01$).

CONCLUSIONS — After an average of 3.8 years, >80% of pediatric patients maintained pump therapy with preservation of baseline A1C. Patients discontinuing the pump were less adherent and did not achieve equivalent glycemic benefit compared with continued users; these patients require ongoing support aimed at improving adherence and outcomes.

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Continuous subcutaneous insulin infusion (CSII) is a safe and effective mode of insulin delivery in pediatric patients with type 1 diabetes. Several pump studies have demonstrated improved (1–5) or equivalent (6–9) glycemic control without increased hypoglycemia (1–5,7,9) and with improved quality of life (2,7). Although there are several advantages of pump therapy in the pediatric population, barriers to success remain. Furthermore, pump discontinuation rates and reasons for discontinuation have not been well described in the pediatric literature.

Health care providers strive to optimize glycemic control in patients with diabetes, and, given the benefits of pump therapy, they may consider CSII for most patients. In turn, treatment efforts should maximize success and intervene early for those individuals identified at risk for pump failure. Thus, we examined the demographic and diabetes-specific characteristics of a large group of pediatric patients with type 1 diabetes initiating pump therapy in order to determine the rate of and reasons for pump discontinuation. Next, we assessed the glycemic outcomes of those who maintained CSII therapy and those who resumed injection therapy. Finally, we compared patients who discontinued pump therapy with those who maintained pump therapy to further characterize the predictors of pump failure and identify opportunities for intervention.

RESEARCH DESIGN AND METHODS

— Participants were patients in the Pediatric, Adolescent, and Young Adult Section at the Joslin Clinic. All 161 youth who began pump therapy during the 4-year interval between 1 January 1998 and 31 December 2001 (including 4 patients beginning therapy in 1995–1996) were included in this report. All patients and families, in collaboration with their diabetes team, elected to begin pump therapy. Patients and families self-selected their pump model.

Implementation of pump therapy

Before initiating pump therapy, all patients and their families completed the clinic's standard pump assessment and education program. A multidisciplinary team of pediatric providers conducted the assessment and education; this team included a pediatric endocrinologist, a nurse educator, a registered dietitian, and a mental health clinician (psychologist or social worker). Nurse educators and dietitians provided instruction on carbohydrate counting, pump mechanics, and risks of pump therapy (e.g., site infections and risk of hyperglycemia, ketosis, and diabetic ketoacidosis with insulin omission/occlusion). Families also met with a mental health clinician to discuss patient/family motivation for initiating pump therapy, to review realistic expectations for ongoing diabetes management with pump treatment, and to assess the family's readiness for pump therapy. The purpose of this assessment was not to deny pump therapy but rather to determine whether initiation of pump therapy should be delayed to further prepare the family. The overwhelming majority of families (~90%) proceeded with pump initiation.

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Abbreviations: BGM, blood glucose monitoring; CSII, continuous subcutaneous insulin infusion.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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Table 1—*Patient characteristics*

	Baseline (prior to pump therapy)		1 year after pump start	
	Remained on pump therapy	Discontinued pump therapy	Remained on pump therapy	Discontinued pump therapy
n	132	29	132	29
Age (years)	13.9 ± 3.8	14.9 ± 2.6	14.9 ± 3.8	15.9 ± 2.6
Type 1 diabetes duration (years)	7.2 ± 4.0	6.7 ± 3.8	8.2 ± 4.0	7.7 ± 3.9
Insulin dose (units · kg^{-1} · day^{-1})	1.0 ± 0.3	1.1 ± 0.2	0.8 ± 0.2	0.9 ± 0.2
Daily BGM frequency	4.1 ± 1.3	3.6 ± 0.6*	4.7 ± 1.7	4.0 ± 1.2†
A1C (%)	8.4 ± 1.4	8.5 ± 1.4	8.0 ± 1.3	8.6 ± 1.3‡
z-BMI	0.77 ± 0.64	0.89 ± 0.6	0.73 ± 0.7	0.95 ± 0.53
BMI	22.2 ± 4.2	23.4 ± 3.5	22.8 ± 4.3	24.3 ± 3.4
Pubertal stage (%)				
Prepubertal (Tanner I)	26	38§	17	0‖
Pubertal (Tanner II–IV)	33	45	33	31
Postpubertal (Tanner V)	41	52	50	69

Data are means ± SD. *$P = 0.002$; †$P = 0.05$; ‡$P < 0.05$; §$\chi^2(2) = 6.98$, $P = 0.03$; ‖$\chi^2(2) = 6.67$, $P = 0.04$.

Following completion of the education and assessment program, patients wore a pump with saline infusing for 1 week before insulin initiation, during which time they continued injection therapy and practiced infusion set insertion, basal rate settings, and bolus dosing. With initiation of insulin therapy with the pump, families maintained daily phone contact with their diabetes team for ~1 week, followed by a third visit to review blood glucose values, basal rates, insulin-to-carbohydrate ratios, and sensitivity factors. In adherence with general clinic protocol, a follow-up visit occurred within 3–6 weeks of insulin pump initiation.

Data collection

The medical chart review and electronic laboratory system provided study data; two endocrinologists and two research assistants independently extracted the data variables. Date of pump start, HbA_{1c} (A1C), daily frequency of blood glucose monitoring (BGM), and growth parameters (i.e., height, weight, BMI, Tanner stage) were gathered from three time points: clinic visit just before insulin pump start, 1 year after initiation, and the most recent visit (as of January 2005). For patients who discontinued pump therapy before January 2005, the following data were also recorded: date of discontinuation; A1C, daily frequency of BGM, and growth parameters at discontinuation; reasons for discontinuation; and insulin regimen at discontinuation and at the most recent visit.

Outcomes of interest

Glycemic control, measured as A1C, was the primary outcome of interest. A1C results were evaluated at pump initiation, 1 year after pump start, at pump discontinuation (if applicable), and at the most recent clinic visit. A1C was measured by high-performance liquid chromatography (referance range 4.0–6.0%, Tosoh 2.2; Tosoh Bioscience, South San Francisco, CA). The patient's health care provider determined daily frequency of BGM after reviewing downloaded blood glucose data or patient logs. BMI z-scores were calculated using SAS code provided by the Centers for Disease Control and Prevention (available at http://www.cdc.gov/nccdphp/dnpa/growthcharts/sas.htm). Rates of severe hypoglycemia, defined as requiring assistance with parenteral or enteral therapy, were calculated by summing the number of events in the year pre– and post–pump start and determining events per 100 patient-years.

Statistical analyses

Continuous variables are displayed as means ± SDs; categorical variables are displayed as frequencies or percentages. *T* tests, χ^2 tests, and Fisher's exact test were used to compare groups. Paired *t* tests were used to analyze changes in continuous variables over time. All analyses were performed using SAS version 8.2 (SAS Institute, Cary, NC). An α level of 0.05 determined statistical significance.

RESULTS

— At the time of pump initiation, patients (71% female) had a mean age of 14.1 ± 3.7 years (range 3.7–21.7), diabetes duration of 7.1 ± 4.0 years (0.7–16.7), BGM frequency of 4.0 ± 1.2 times/day, a daily insulin dose of 1.0 ± 0.3 units/kg, an A1C of 8.4 ± 1.4% (5.6–14.7), and a z-score for BMI adjusted for age and sex (z-BMI) of 0.79 ± 0.63. Male and female subjects were nearly equally represented among those aged <11 years (45 and 55%, respectively), while female subjects (76%) predominated in those aged ≥11 years. One year after pump start, participants were monitoring blood glucose more frequently (4.5 ± 1.7 times/day), had lower mean daily insulin dose (0.8 ± 0.2 units/kg), and had improved glycemic control (8.1 ± 1.3% [range 5.5–12.7]) (all $P < 0.01$), while there was no significant change in z-BMI (0.77 ± 0.67, $P = 0.98$).

As of 1 January 2005, after an average of 3.8 ± 1.1 years of follow-up (range 0.6–8.8), 29 patients (18%) had discontinued pump therapy and resumed injection therapy. These patients had a mean duration of pump use of 2.1 ± 1.3 years (0.1–4.5). At discontinuation, mean age was 17.0 ± 2.9 years and mean duration of diabetes was 8.8 ± 3.6 years (2.6–16.6). After discontinuation, 10 patients (35%) began a basal-bolus insulin regimen with glargine, 18 (62%) began a regimen of modified multiple daily injections with bedtime intermediate-acting insulin, and 1 (3%) began a regimen with a premixed insulin preparation twice daily. Patients/families generally made the decision to discontinue pump treatment with support by the health care team.

We grouped primary causes for pump discontinuation into five catego-

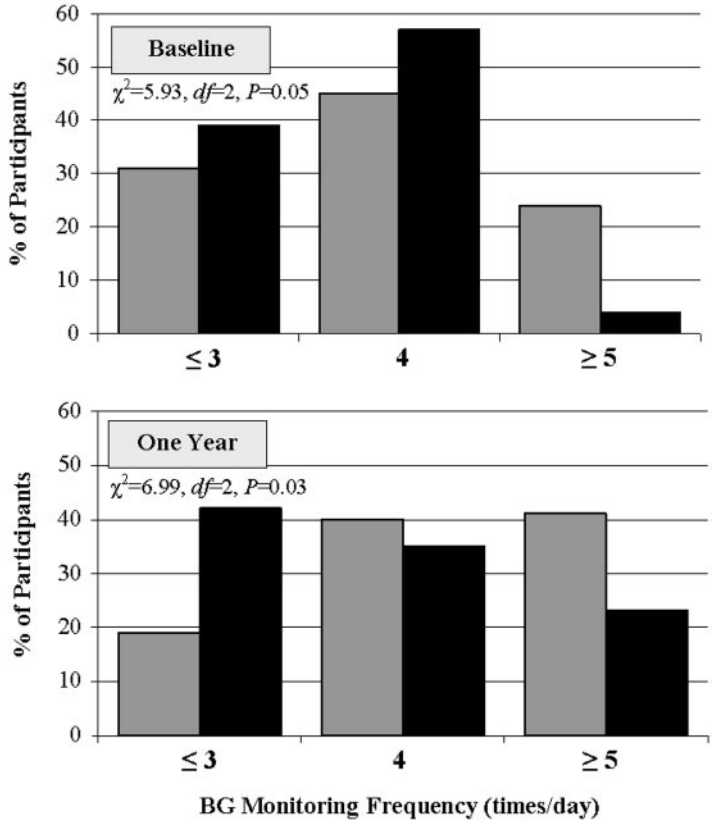

Figure 1—*Distribution of daily frequency of BGM. Youth who remained on insulin pump therapy checked blood glucose levels significantly more often, both at pump initiation (χ^2 = 5.93,* P *= 0.05) and after 1 year (χ^2 = 6.99,* P *= 0.03), compared with youth who discontinued pump therapy.* ■*, remained on pump;* ■*, discontinued therapy.*

ries. Major problems (e.g., diabetic ketoacidosis, insulin omission) accounted for discontinuation in 28% (n = 8), diabetes burnout (i.e., fatigue with infusion site changes, BGM, dietary surveillance, and/or bolus dosing) occurred in 28% (n = 8), and minor problems (e.g., infusion site issues) occurred in 21% (n = 6). Body image concerns associated with wearing the pump occurred in 14% (n = 4), and concerns about weight gain occurred in 10% (n = 3).

To understand the factors associated with pump discontinuation, we compared patients who resumed injection therapy (n = 29) with those who maintained pump use (n = 132) from baseline through follow-up (Table 1). The two groups were similar with respect to age, duration of diabetes, total daily insulin dose (units per kilogram), and z-BMI at pump initiation and 1 year later. There was no significant change in z-BMI in the year following pump initiation in either group. However, patients who resumed injection therapy were more commonly female than persistent pump users (90 vs. 67%, P = 0.02) and were older at type 1 diabetes diagnosis (8.2 ± 3.1 vs. 6.7 ± 3.5 years, P = 0.04). Pubertal status was more advanced among youth who discontinued the pump compared with those who remained on the pump (Table 1). Youth who resumed injection therapy also monitored blood glucose levels less often than persistent pump users at pump start (3.6 ± 0.6 vs. 4.1 ± 1.3, P = 0.002) and after 1 year (4.0 ± 1.2 vs. 4.7 ± 1.7, P = 0.05) (Fig. 1). Of 117 youth aged <18 years during follow-up, there was a significantly higher proportion of one-parent families among those who resumed injection therapy compared with those who remained on the pump (29 vs. 4%, P = 0.002).

In the year before pump start, the rate of severe hypoglycemia was similar between youth who resumed injections and youth who continued pump therapy (11.9 vs. 23.0 events/100 patient-years, P = 0.27). However, the group that resumed injections experienced a significantly higher rate of severe hypoglycemia in the year following pump start than the group that remained on the pump (23.2 vs. 7.4, P = 0.01). In addition, those who remained on the pump experienced a significant decrease in rate of severe hypoglycemia from the year before to the year after pump initiation (23.0 to 7.4, P = 0.001), whereas those who resumed injection therapy experienced a slight increase in rate of severe hypoglycemia (11.9–23.2, P = NS).

With respect to glycemic control, the group that resumed injection therapy and the group that continued CSII had similar A1C at initiation of pump therapy (8.5 ± 1.4% vs. 8.4 ± 1.4%, P = NS). However, those who resumed injection therapy had higher A1C compared with those who continued CSII at 1 year after pump initiation (8.6 ± 1.3% vs. 8.0 ± 1.3%, P = 0.04) and at the most recent clinic visit (9.4 ± 2% vs. 8.4 ± 1.2%, P = 0.01) (Fig. 2). Furthermore, the distribution of A1C shows a significant shift to poorer glycemic control during follow-up in the group that discontinued pump therapy. At the most recent clinic visit, >50% of those who discontinued pump therapy had an A1C ≥9.0% compared with <25% of those who remained on pump therapy [χ^2 (3) = 8.98, P = 0.03] (Fig. 3). In 29 patients who resumed injection therapy, the mean A1C at the time of pump discontin-

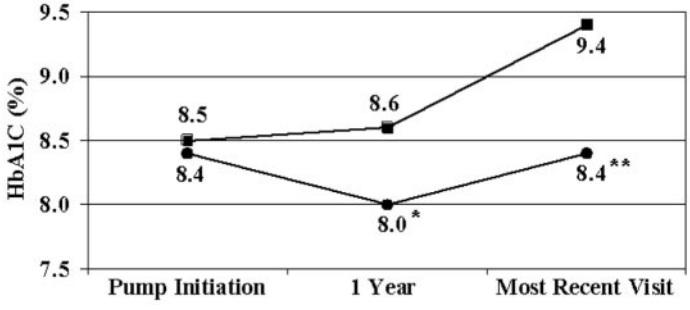

Figure 2—*Glycemic outcomes. After 1 year (*P *= 0.04) and at the most recent visit (**P = 0.01), those who remained on pump therapy had significantly lower A1C compared with those who discontinued pump therapy.* ●*, remained on pump therapy;* ■*, discontinued pump therapy.*

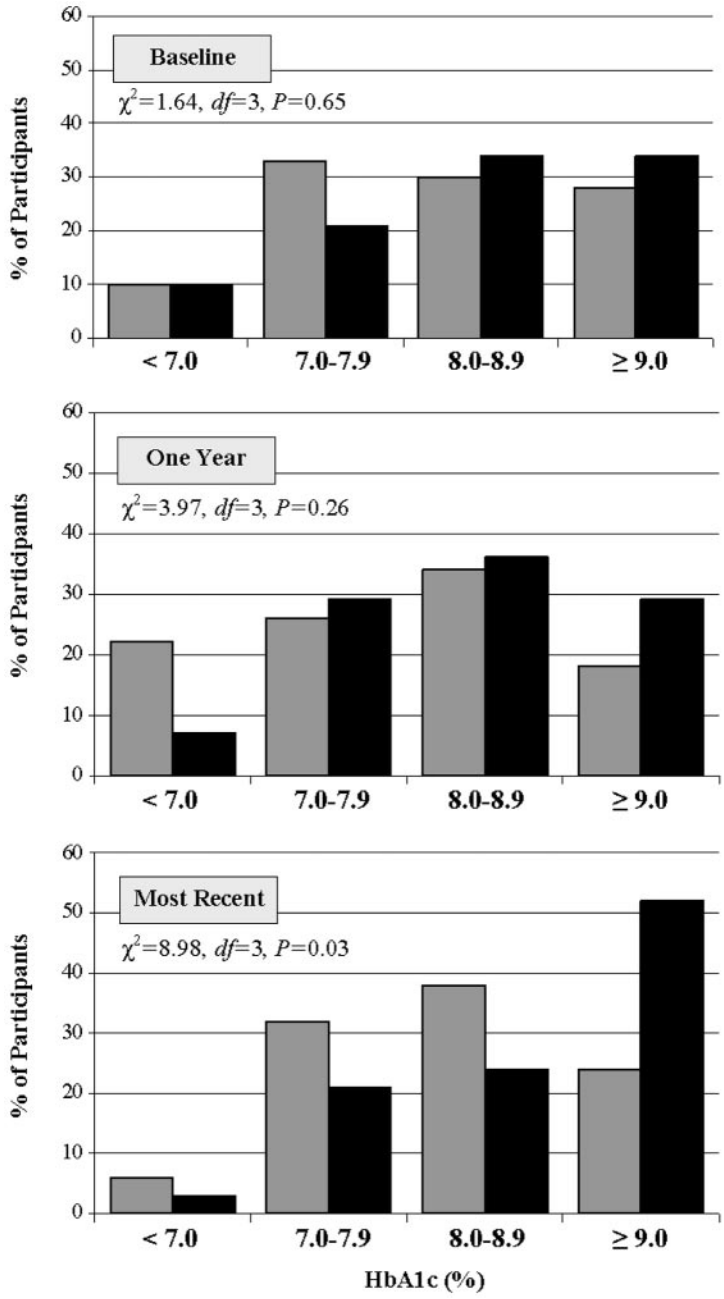

Figure 3—*Distribution of glycemic control according to time and pump status. Youth who remained on insulin pump therapy maintained their level of glycemic control during the study period, while youth who discontinued pump therapy had deterioration of glycemic control.* ■*, remained on pump therapy;* ■*, discontinued pump therapy.*

uation was 9.4 ± 1.9% (range 6.8–13.7), a significant increase from pump initiation ($P = 0.004$). The average increase in A1C was significantly greater for youth ($n = 11$) who maintained pump therapy for >2.5 years before discontinuation compared with those ($n = 18$) who discontinued the pump within 2.5 years (1.9 vs. 0.3%, $P = 0.01$).

CONCLUSIONS — Over 80% of this cohort of youth and young adults with type 1 diabetes remained on insulin pump therapy after an average of 3.8 years of follow-up; on average, <5% of pediatric patients discontinued insulin pump therapy each year. The most common reasons for discontinuation were major problems (e.g., diabetic ketoacidosis), diabetes burnout, and infusion site issues. One year after initiation of insulin pump therapy, the sample as a whole was monitoring blood glucose levels more frequently, received a lower mean daily insulin dose, and had improved glycemic control.

Upon retrospective examination, there were significant differences, even at pump initiation, between persistent pump users and those who resumed injection therapy. Youth who discontinued pump therapy monitored blood glucose levels significantly less often at pump start and during follow-up than those who remained on pump therapy. Further, those who discontinued pump therapy experienced worsening glycemic control during follow-up, whereas persistent pump users did not experience deterioration but rather improved their glycemic control during the 1st year of pump use while also experiencing a decreased rate of severe hypoglycemia.

In adult populations, there has been a wide range of rates of and reasons for insulin pump discontinuation reported. A meta-analysis by Schifferdecker et al. (10) documented CSII discontinuation rates of 0–36%, with an average of 20%. They found CSII discontinuation to be significantly correlated with metabolic control before start of pump therapy. The most common reasons for discontinuation were skin problems (22%), inconvenience (21%), and lack of metabolic improvement (10%). Weissberg-Benchell et al. (1) completed a meta-analysis of 52 studies ($n = 1,547$ children, adolescents, and adults) to evaluate the metabolic and psychosocial impact of CSII therapy. Of 400 patients from the five studies that examined discontinuation rates, 127 (32%) resumed injection therapy. However, the authors did not report what percentage of these 400 patients, if any, were children or adolescents or what the discontinuation rates were in general for the youth. Reports on CSII discontinuation in adult populations may not be applicable to youth with type 1 diabetes given the unique physiologic and psychosocial characteristics of children and adolescents, such as pubertal growth and development, reliance on family members for assistance, and the challenges of increasing autonomy during adolescence (11–13).

Our report describes the durability of insulin pump therapy in a routine clinic population of pediatric patients followed for up to 8 years. We compared our experience with pump discontinuation with that reported in the pediatric literature. An open, randomized, crossover comparison of CSII therapy and multiple daily injection regimens in youth with type 1

diabetes (aged 9.4–13.9 years) from Weintrob et al. (9) described reasons for CSII discontinuation. After 3.5 months of CSII therapy, 7 of 23 participants (30%) wanted to resume injection therapy for a variety of reasons: deteriorating glycemic control and fear of overeating and weight gain (2 boys), infusion site issues (3 girls), desire to keep diabetes a secret (1 boy), and displeasure with frequent BGM (1 boy). Although this report describes similar reasons for discontinuation to our study, the high rate of discontinuation may reflect the randomized cross over study design and may not apply to standard pediatric clinical populations.

Willi et al. (4) reported that none of 51 youth (mean age 11.2 ± 3.0 years) followed for 1 year before and after pump start discontinued pump therapy. Plotnick et al. (3) followed all 95 patients (mean age 12.0 ± 3.1 years) who began pump therapy at their center between 1990 and 2000 in order to evaluate the safety and effectiveness of pump therapy in youth. After a median follow-up period of 28 months, only 2 of 95 patients (2%) discontinued pump therapy; reasons for discontinuation were not reported. McMahon et al. (2) also assessed all patients (n = 105, mean age 12.5 ± 3.8 years) initiating pump therapy at their center between 1999 and 2002. Five patients (5%) discontinued CSII within 4 weeks of pump initiation. Reasons for discontinuation were psychiatric conditions (n = 2), a dermatological condition (n = 1), and parental/patient request (n = 2). Similar to these reports, we found that an average of 5% of our pediatric patients discontinued pump therapy yearly.

Given the advantages of insulin pump therapy with respect to flexibility, hypoglycemia prevention, and glycemic improvement, efforts are needed to identify modifiable barriers to its successful implementation in patients with type 1 diabetes. Our study highlights one such potential barrier: infrequent BGM behavior. Patients and families interested in pump therapy should be encouraged to establish consistent BGM frequency of at least four times per day (14–16). In addition, patients, and single-parent families in particular, should be offered support to both increase and maintain BGM frequency. Barriers to frequent BGM include discomfort, inconvenience, and blame/shame associated with out-of-range results (17). Emerging insulin pump technology, such as automated bolus calculators, programmable bolus reminders, and continuous BGM, may further assist patients and families with successful pump therapy.

Deterioration of blood glucose control during adolescence is not an unexpected occurrence secondary to increases in growth hormone and pubertal hormones, as well as decreased adherence associated with emerging autonomy (18,19). In our cohort, individuals who remained on pump therapy initially improved glycemic control and avoided deterioration of A1C levels during follow-up, whereas individuals who resumed injection therapy displayed deteriorating glycemic control. Patients who experience deterioration of glycemic control while on pump therapy may benefit from additional support aimed at increasing their BGM frequency. Increased BGM offers opportunities for patients/families to provide correction boluses aimed at bringing blood glucose values back in range, leading to lower A1C values. Burdick et al. (20) demonstrated that missed boluses were directly associated with higher A1C values.

In summary, insulin pump therapy provides a durable means to treat children and adolescents with type 1 diabetes. Over 80% of a large pediatric population initiating pump therapy maintained CSII for up to 8 years. Inadequate BGM frequency at pump initiation and worsening glycemic control during pump therapy may help identify youth who would benefit from additional individual and family support to maximize the benefits of pump therapy.

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