

PEDIATRIC TRACK

PEDIATRIC DIABETES TECHNOLOGIES



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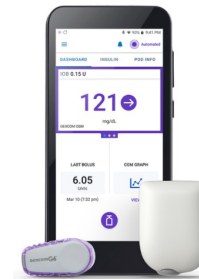
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Existing Commercial Artificial Pancreas Systems

- **Medtronic: 670G** Approved Fall 2016 (14+ y/o), started to ship April 2017. Approved in June 2018 for 7-13 years old. Approved June 2020 2-6 y/o. Medtronic 770G FDA approved June 2020. Hope to see AHCL 780G in mid 2022.
- **Tandem (T:slim):** Approved 14+ y/o in December 2019. Approved 6-13 y/o in June 2020. Trial for 2-5 y/o is now running in 2021.
- **Insulet (Omnipod):** Approved January 2022 (6+ y/o). Trial for 2-5 y/o completed March 2021.



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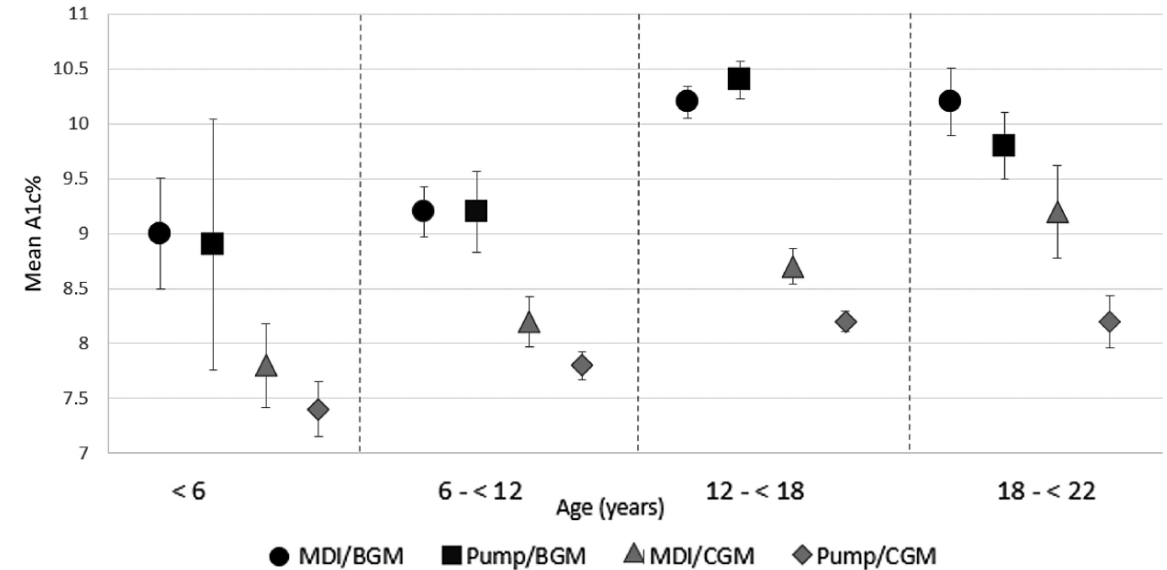
GLUCOSE IMPROVEMENTS WITH TECHNOLOGY USE

- Recently published data from >4000 kids at BDC demonstrates significant improvements in A1c across all ages with use of CGM and use of CGM + Insulin Pump.

Glycemic Control in Relation to Technology Use in a Single-Center Cohort of Children with Type 1 Diabetes

Alexandra Sawyer, MD, MPH,¹ Marisa Sobczak, BA,²
Gregory P. Forlenza, MD,³ and Guy Todd Alonso, MD³

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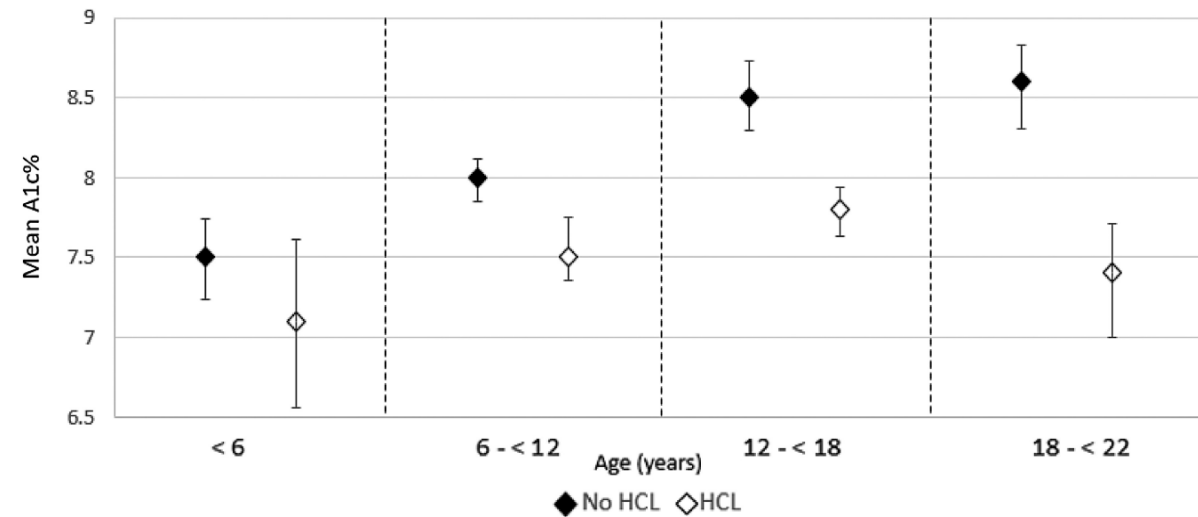
GLUCOSE IMPROVEMENTS WITH AUTOMATION

- As of December 2020, BDC has >700 children using some form of Automated Insulin Delivery or Hybrid Closed Loop System.
- Average A1c in those using a HCL system is 7.6% whereas national averages for A1c in the pediatric age group range from 8.5 to 9.5% prior to HCL therapy.

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HCL PERFORMANCE ACROSS DEVICES

Current Status and Emerging Options for Automated Insulin Delivery Systems

Gregory P. Forlenza, MD¹ and Rayhan A. Lal, MD²

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TABLE 1. SELECT METRICS FROM DEVICE PIVOTAL TRIALS

Device	Source	Adults or adults/adolescents								Children								
		TIR 70–180 mg/dL (%)	Mean SG (mg/dL)	HbA1c (%)	TAR >250 mg/dL (%)	TAR >180 mg/dL (%)	TBR <70 mg/dL (%)	TBR <54 mg/dL (%)	%CV	Source	TIR 70–180 mg/dL (%)	Mean SG (mg/dL)	HbA1c (%)	TAR >250 mg/dL (%)	TAR >180 mg/dL (%)	TBR <70 mg/dL (%)	TBR <54 mg/dL (%)	%CV
Medtronic 670G	Garg—DTT, 2017	68.8/67.2	148.3/158.5	6.8/7.1	1.3/2.8 ^a	22.8/30.0	3.4/2.8	0.6/0.5 ^a	30.3/32.2	Forlenza—DTT, 2018	65.0	162	7.5	10.3	32.0	3.0	0.8	33.7
Medtronic 780G	Carlson—DTT, 2021	75.1/72.7	147/150	7.0/7.1	4.3/5.6	22.6/24.9	2.3/2.4	0.5/0.6	33.7/35.7	Not yet reported								
Tandem Control IQ	Brown—NEJM, 2019	71	156	7.06	5.2	27	1.58	0.29	34	Breton—NEJM, 2020	67	162	7.0	7.8	31	1.6	0.2	38
Insulet OP5	Brown—DC, 2021	73.9	154	6.78	5.8	24.7	1.32	0.23	31.7	Brown—DC, 2021	68.0	160	6.99	9.6	30.2	1.78	0.32	37.0
CamAPS FX	Tauschmann—Lancet, 2018	65	160.2	7.4	3.5 ^b	32	2.6	0.3 ^b	40	Included in the adult/adolescent data								
Diabeloop	Benhamou—Lancet Digital Health, 2019	68.5	156.6	7.3	7.4	29.5	2.0	0.2	31.0	Not yet reported								



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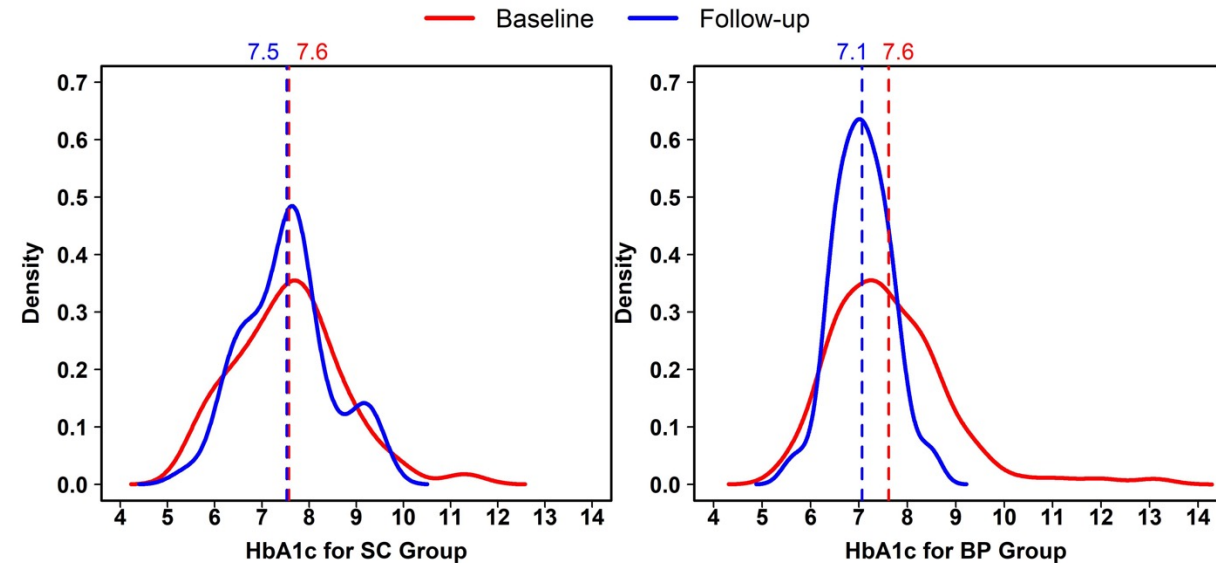


BETA BIONICS ILET

- FDA approval trial of the Beta Bionics iLet demonstrated safety and efficacy of this system.
- The device is started with only the patient's weight.
- Meals are announced with only concept (usual, large, or small).
- System under FDA Review.

Presented by Steven Russell, MD at ATTD 2022

Distribution of HbA1c



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FULLY CLOSED LOOP DEVELOPMENT

Advanced Closed-Loop Control System Improves Postprandial Glycemic Control Compared With a Hybrid Closed-Loop System Following Unannounced Meal

Jose Garcia-Tirado,¹ Jenny L. Diaz,¹ Rebeca Esquivel-Zuniga,² Chaitanya L.K. Koravi,¹ John P. Corbett,¹ Martha Dawson,¹ Christian Wakeman,¹ Charlotte L. Barnett,¹ Mary C. Oliveri,¹ Helen Myers,¹ Katie Krauthouse, Marc D. Breton,¹ and Mark D. DeBoer^{1,2}

Diabetes Care

Table 1—Glycemic outcomes during unannounced and announced dinners, 1800–0000 h

	Unannounced dinner (primary outcome)			Announced dinner (secondary outcome)		
	USS	RCKT	P value	USS	RCKT	P value
Glycemic metrics						
CGM glucose (mg/dL)	166 ± 26	141 ± 21	0.001^a	114 ± 26	114 ± 11	0.45
Percentage of CGM time						
<50 mg/dL (<2.8 mmol/L)	0 (0–0)	0 (0–0)	1	0 (0–0)	0 (0–0)	1
<60 mg/dL (<3.3 mmol/L)	0 (0–0)	0 (0–0)	0.5	0 (0–0)	0 (0–0)	0.08
<70 mg/dL (<3.9 mmol/L)	0 (0–0)	0 (0–1)	0.2	0.7 (0–8)	0 (0–0)	0.04^b
70–140 mg/dL (3.9–7.8 mmol/L)	27 (22–36)	49 (41–59)	0.002^b	82 (57–89)	86 (69–94)	0.13
70–180 mg/dL (3.9–10.0 mmol/L)	53 (40–71)	83 (64–93)	0.004^b	93 (85–99)	100 (99–100)	0.004^b
>180 mg/dL (>10.0 mmol/L)	47 (28–60)	17 (1.3–34)	0.01^b	0 (0–1)	0 (0–0)	0.10
>250 mg/dL (>13.9 mmol/L)	0 (0–0)	0 (0–0)	1	0 (0–0)	0 (0–0)	1
>300 mg/dL (>16.7 mmol/L)	0 (0–0)	0 (0–0)	1	0 (0–0)	0 (0–0)	1
CGM SD (mg/dL)	40 ± 13	37 ± 17	0.2	20 ± 8.5	23 ± 7	0.11
CGM coefficient of variation (%)	24 ± 9	26 ± 9	0.4	17.5 ± 7.1	20 ± 6	0.10
Safety metrics						
Severe hypoglycemia (<i>n</i> events)	0 (0–0)	0 (0–0)	1 ^b	0 (0–0)	0 (0–0)	1 ^b
Diabetes ketoacidosis (<i>n</i> events)	0 (0–0)	0 (0–0)	1 ^b	0 (0–0)	0 (0–0)	1 ^b
Technical performance metrics						
Time in CLC (%)	95 ± 15	100 ± 1	0.16	92 ± 17	99 ± 2	0.16
Total injected insulin (IU)	14 ± 4	15 ± 5	0.21	14 ± 4	15 ± 7	0.22

Data are presented as mean ± SD or median (IQR). Significance levels <0.05 are presented in bold. ^aOne-sided paired *t* test. ^bWilcoxon signed rank test.

<https://doi.org/10.2337/dc21-0932>



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