

ADVANCED TRACK

Using Diabetes Technology to Minimize Glucose Extremes



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DISCLOSURES

Research grant funding from the National Institutes of Health (NIH), Helmsley Charitable Trust (HCT), and Juvenile Diabetes Research Foundation (JDRF)

Scientific founder and shareholder in ImmunoMolecular Therapeutics, biotech company



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INTRODUCTION

- Technology is part of our daily lives. It is involved in our day-to-day activities and our many communication circles.
- Combining technology and medicine can give people with diabetes more control over their condition and improve quality of life.
- Ways to minimize blood glucose variability:
 1. Diabetes Technology
 2. Exercise
 3. Diet



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CONTINUOUS GLUCOSE MONITORS

Model	FreeStyle Libre 2	FreeStyle Libre 3	Guardian 3	Guardian 4 *	Dexcom G6	Dexcom G7 *	Eversense (E3)
							
MARD	9.5%	7.9%	8.7-9.14% in arm 9.6-10.5% in abdomen	Unknown	9%	8.1% in arm 9.1% in abdomen	8.5%
Wear Length Time	14 days	14 days	7 days	7 days	10 days	10.5 days	90 days

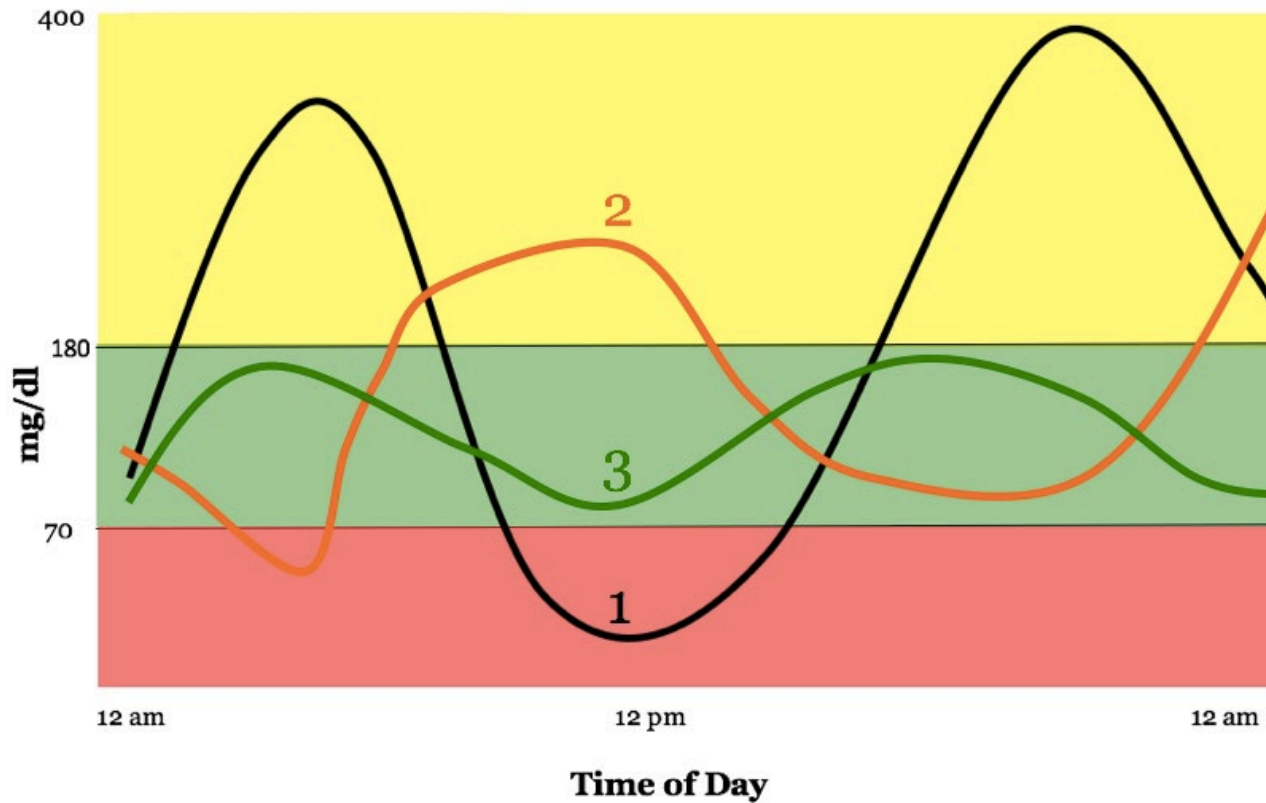


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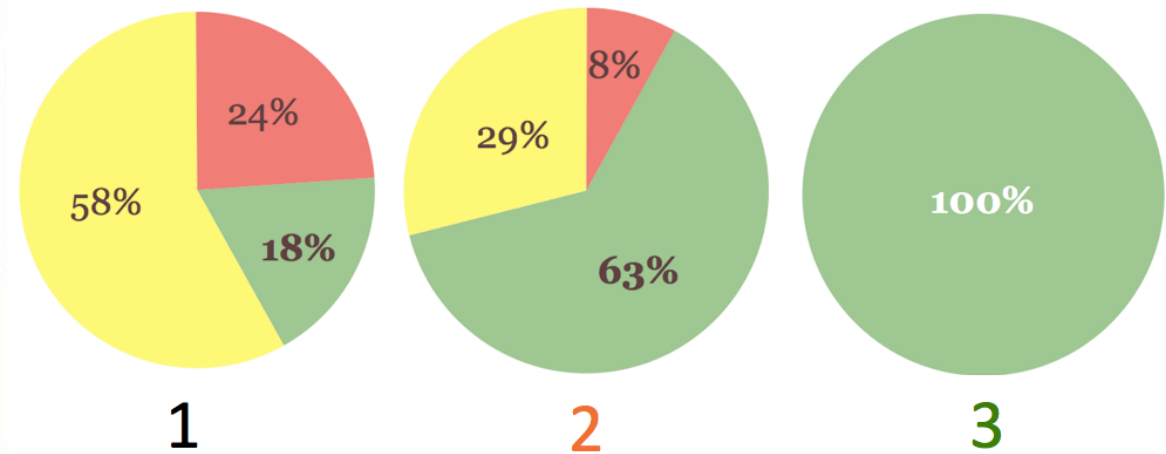


BEYOND HEMOGLOBIN A1C – TIME IN RANGE



The Many Faces of a 7% A1c

Time spent **HIGH** **IN RANGE** **LOW**

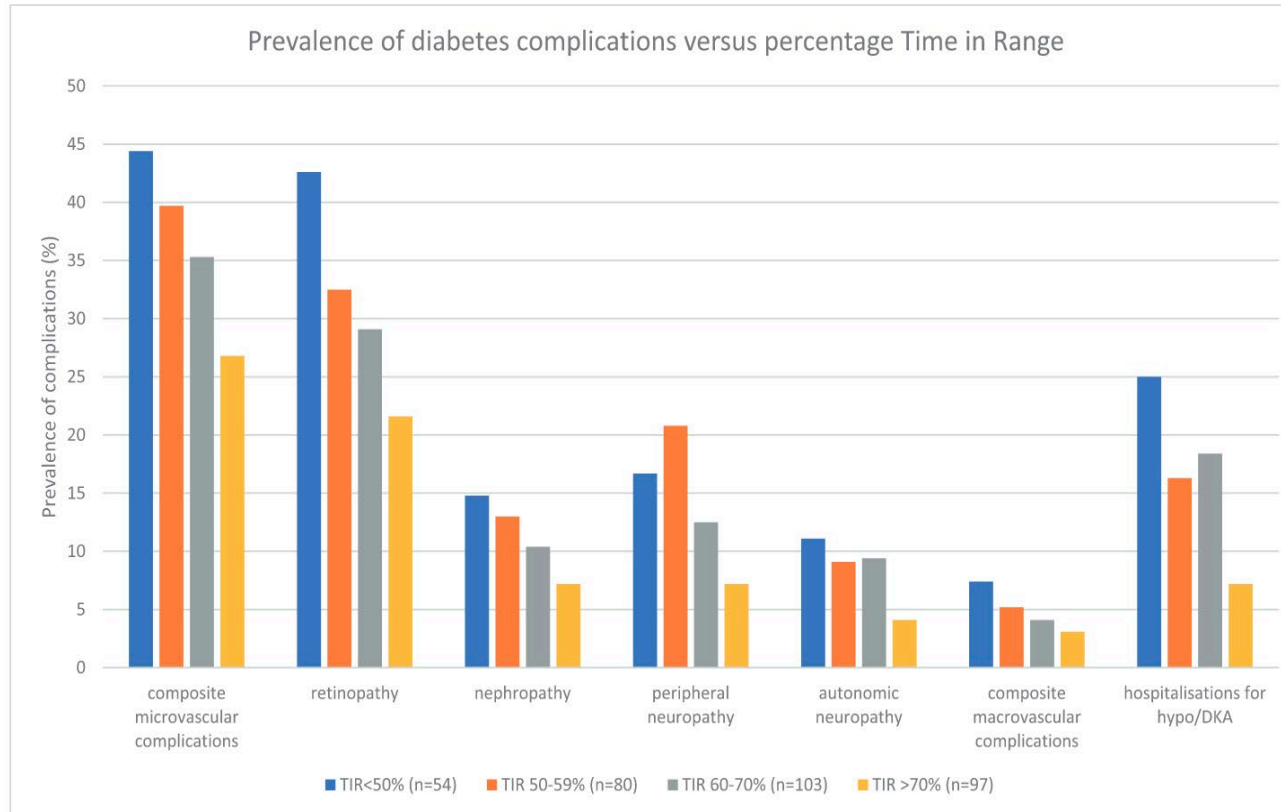


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TIME IN RANGE AND DIABETES COMPLICATIONS



El Malahi et.al: J Clin Endocrinol Metab: 2022 Jan 18;107(2):e570-e581



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AUTOMATED INSULIN DELIVERY, 'ARTIFICIAL PANCREAS'

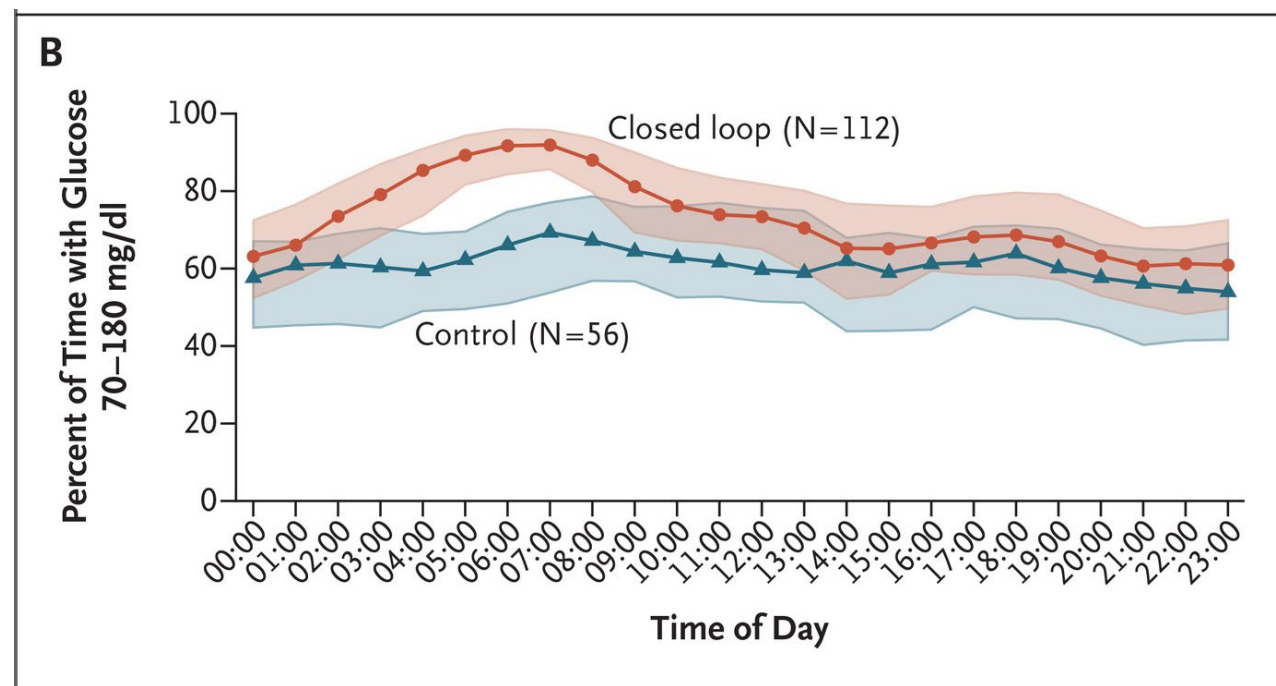
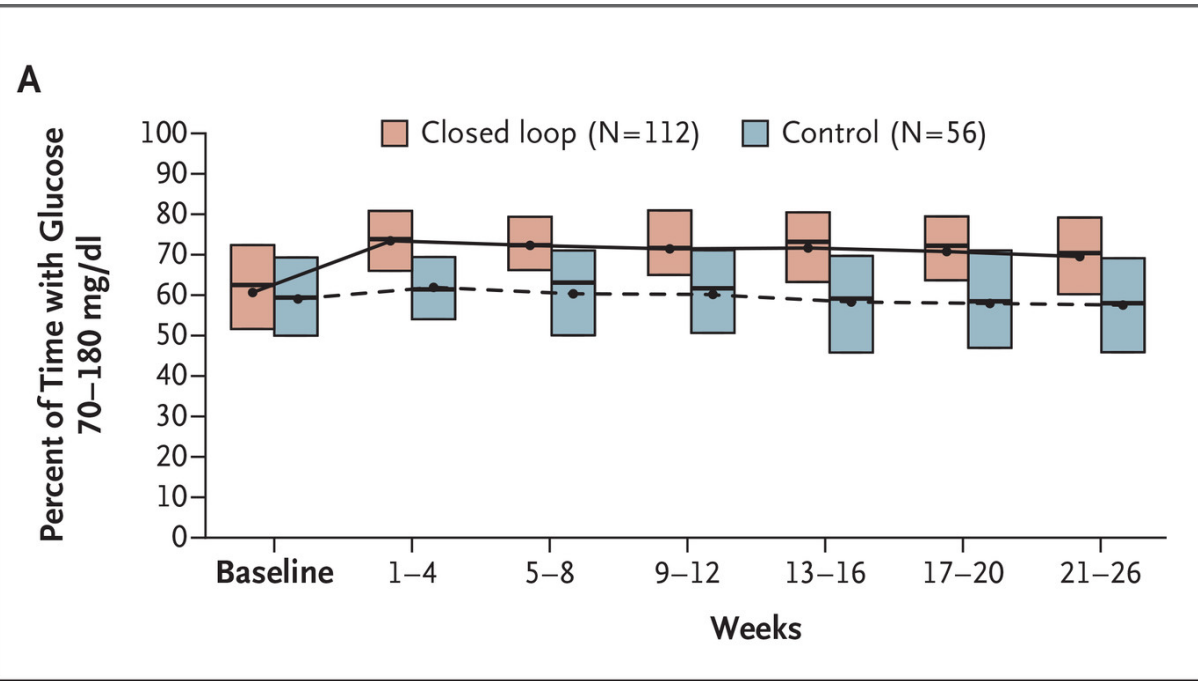


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TANDEM CONTROL IQ – TIME IN RANGE (%)



Brown et al. N Engl J Med 2019. DOI: 10.1056/NEJMoa1907863



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QUESTIONS? & DISCUSSION



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USING DIABETES TECHNOLOGY TO MINIMIZE GLUCOSE EXTREMES



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CONFLICT OF INTEREST

- Research support from: Medtronic, Dexcom, Abbott, Tandem, Insulet, Beta Bionics, and Lilly
- Speaker, Consultant, Ad/Board Member for: Medtronic, Dexcom, Abbott, Tandem, Insulet, Beta Bionics, and Lilly



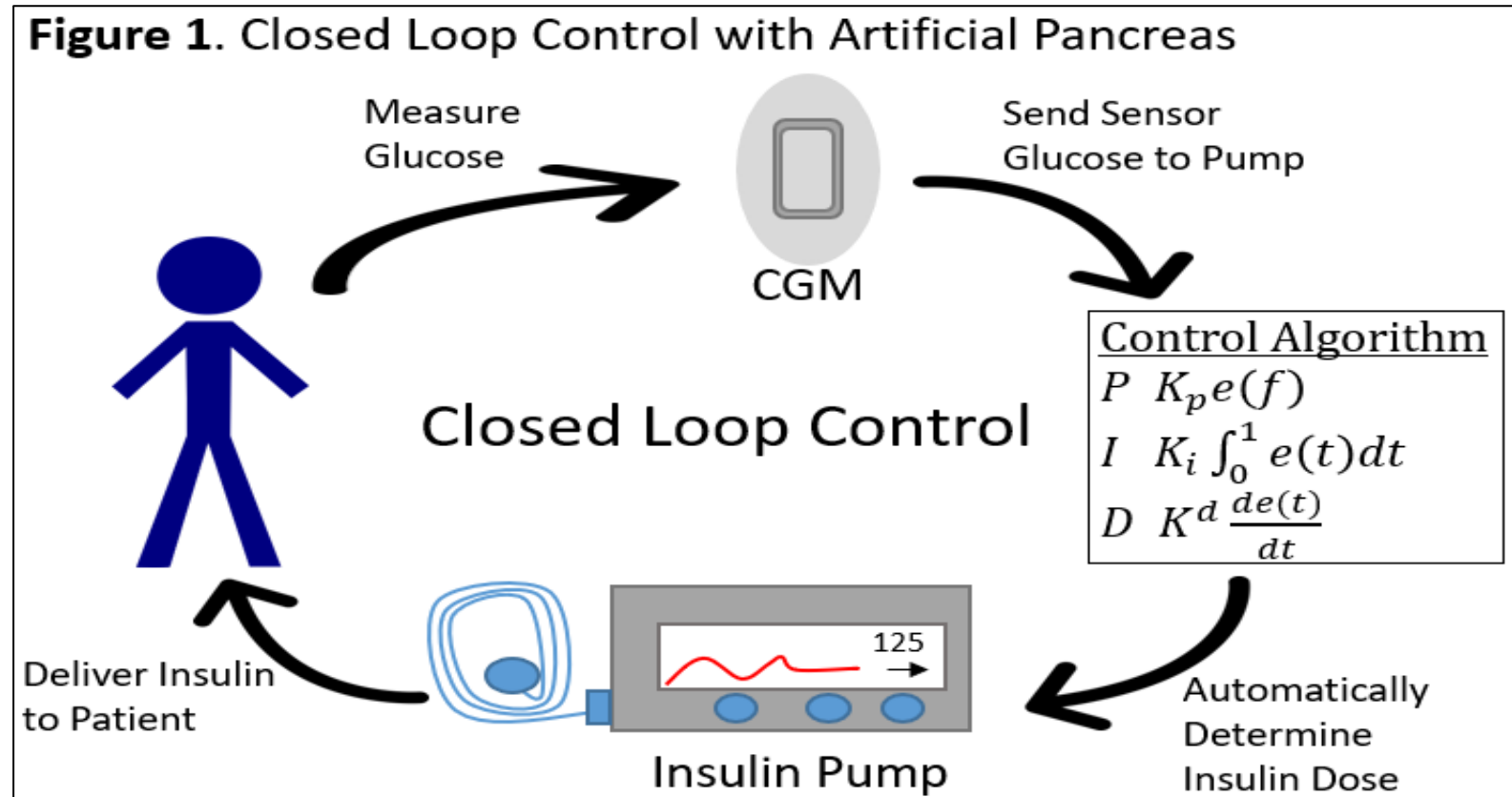
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BACKGROUND

- **Automated Insulin Delivery:** any automation of basal and/or bolus insulin.
- **Hybrid Closed Loop:** Full automation of basal insulin with required meal boluses.
- **Fully Closed Loop:** Full automation of both basal and bolus insulin.
- **Artificial Pancreas:** Outdated term we still use. Essentially synonymous with AID.
- **Dual Hormone:** Could be either HCL or FCL
 - Generally means Insulin and glucagon, but could be insulin and another counter-regulatory hormone



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BDC DIABETES CONTROL 2018-2020

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

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DIABETES TECHNOLOGY & THERAPEUTICS
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TABLE 3. COMPARISON OF HEMOGLOBIN A1C BETWEEN NONHYBRID CLOSED-LOOP USERS AND HYBRID CLOSED-LOOP USERS AMONG PUMP AND CGM COMBINED USERS

Age group (n)	Pump/CGM without HCL (n=1287)	Pump/CGM with HCL (n=706)	np/CGM, 93 (49.8%)
Mean HbA1c [SD]	8.3 [1.8]	7.6 [1.2]****	[1.6]****
Met goal HbA1c %	19.4	29.9***	3.1***
<6 (106)	7.5 [1.2]	7.1 [0.7]	[1.1]****
6 to <12 (554)	8.0 [1.4]	7.5 [0.9]****	2.1 [1.3]****
12 to <18 (939)	8.5 [1.9]	7.8 [1.3]****	3.6* [1.7]****
18 to <22 (394)	8.6 [2.1]	7.4 [1.2]****	0.9** [2.0]****
	18.4	38.4***	5.4***

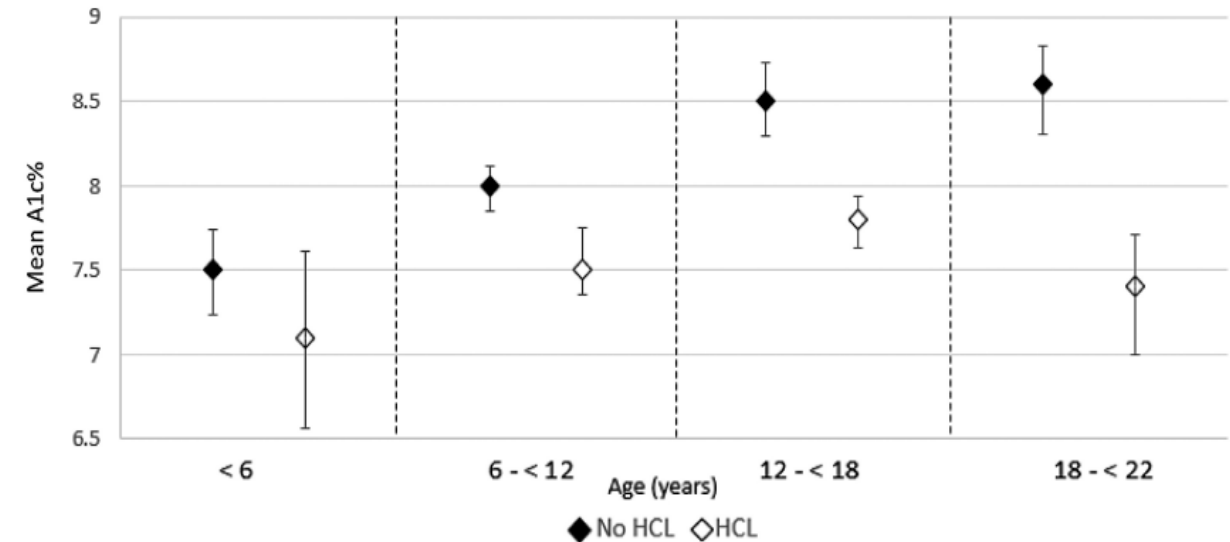


FIG. 2. Mean HbA1c compared between pump/CGM users without HCL and pump/CGM users with HCL using ANCOVA and controlling for diabetes duration, race, and insurance (Medicaid/not). *P*-value is <0.0001 for comparisons within the 6 to <12, 12 to <18, and 18 to <22 years groups, but >0.05 in the <6-year age group. Error bars represent 95% CI. HCL, hybrid closed-loop.

MDI/BGM, MDI with BGM; MDI/CGM, MDI with CGM; Pump/BGM, pump with BGM; Pump/CGM, pump with CGM.



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Existing Commercial Automated Insulin Delivery 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. Medtronic AHCL 780G FDA approved April 2023.
- **Tandem (T:slim):** Approved 14+ y/o in December 2019. Approved 6-13 y/o in June 2020. Trial for 2-5 y/o completed in 2022 and under review.
- **Insulet (OmniPod):** Approved January 2022 (6+ y/o). Approved for 2-5 y/o in August 2022.



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Emerging Commercial Automated Insulin Delivery Systems

- **Tidepool Loop:** FDA approved commercial build of the DIY Loop algorithm. Works with a phone and a watch. Works with Dexcom G6 CGM. Does not yet have a pump partner for commercialization. Studies likely to be required with new pump partner(s).
- **Beta Bionics (iLet):** Designed to be single or dual-hormone. Single Hormone (insulin only) studies completed and under FDA review. Anticipate FDA approval in 2023.



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GLYCEMIC CONTROL IN MAJOR STUDIES

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	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 *	22.8 / 30.0	3.4 / 2.8	0.6 / 0.5 *	30.3 / 32.2	Forlenza - DTT - 2018	65	162	7.5	10.3	32	3	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	Gil-Poch - Abstract - 2023**	77.4	144	6.7	3.4	17.1	1.6	0.4	32.4
Tandem Control IQ	Brown - NEJM - 2019	71	156	7.06	5.2	27	1.58	0.29	34	Breton - NEJM - 2020	67	162	7	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	160	6.99	9.6	30.2	1.78	0.32	37
Beta Bionics iLet1	Russell - NEJM - 2022	65	164	7.3	8.5	33	1.8	0.3	36	Included in the adult/adolescent data								
Tidepool Loop	Lum - DTT - 2021	73	147	6.5	5	24	2.8	0.4	37	Included in the adult/adolescent data								

* The Garg 670G trial reported TBR <50 mg/dL instead of <54 mg/dL and TAR >300 mg/dL instead of >250 mg/dL

** The Gil-Poch data is from a conference abstract, not the pivotal trial



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