Expanding the Horizons of Automated Insulin Delivery: a Pilot Study Bringing AID to Primary Care

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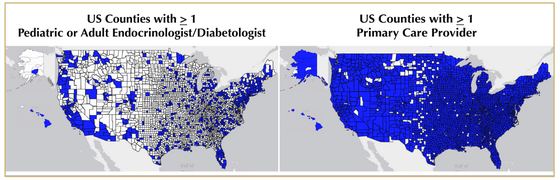
Background



Approximately 90% of diabetes care is delivered in primary care, including half of adult type 1 diabetes care. Yet technologies like automated insulin delivery (AID) systems have typically been managed by endocrinology, potentially limiting access.

AID systems are becoming more advanced and automated, and the iLet requires only weight for initialization. These advances present opportunities to potentially expand delivery of AID systems through both endocrinology and primary care, which could help decrease disparities in access to evidence-based diabetes technologies. We completed a pilot study to evaluate the initiation and management of the iLet bionic pancreas AID system in both primary care and endocrinology settings, both in person and via telehealth, to determine estimated effect size for sample size calculations for a larger scale, randomized controlled trial evaluating the iLet in primary care.

Objective

To pilot test feasibility, safety, and initial performance of use of the iLet by primary care patients on MDI compared to endocrinology patients already on an insulin pump, via in-person care or telehealth.

Settings

(1) Primary Care: University of Colorado School of Medicine, Aurora, Colorado
(2) Academic Endocrinology: Diabetes Research Center, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts

GO BIONIC!

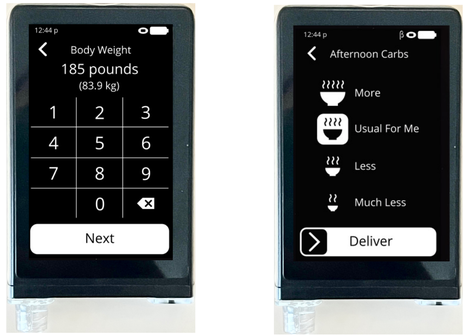


Figure 1. The iLet® Bionic Pancreas is initiated by inputting only the participant's weight. The user triggers mealtime insulin making a rough comparison of the coming meal's carbohydrate content to the carbohydrate of a usual meal for them (Usual for Me, More, or Less).

Population

40 adults with type 1 diabetes: 20 multiple daily injection users recruited through primary care; 20 insulin pump users recruited through endocrinology

10 participants in each of 4 cohorts: (1) Primary Care In-Person; (2) Primary Care Telehealth; (3) Endocrinology In-Person; (4) Endocrinology Telehealth

Table 1. Characteristics of Participants at Baseline

Characteristics	CU-Primary Care (n=20)	MGH-Endocrinology (n=20)
Age – yr.		
Mean ± SD	43.6 ± 15.0	45.1 ± 13.5
Range	23-74	24-65
Glycated Hemoglobin – %		
Mean ± SD	6.6 ± 1.8	7.1 ± 0.8
Range	5.9-8.6	5.5-8.6
Female sex – no. (%)	7 (35)	10 (50)
Race or ethnic group – no. (%)		
White, non-Hispanic	12 (65)	19 (95)
Black, non-Hispanic	0	1 (5)
Hispanic	3 (15)	0
Asian	0	0
American Indian or Alaskan Native	1 (5)	0
Multiple	2 (10)	0
Other	1 (5)	0
Unknown or not reported	1 (5)	0
Insulin-delivery method – no. (%)		
Multiple daily injections	20 (100)	0
Pump without automation	0	2 (10)
Pump with predictive low-glucose suspension	0	0
Hybrid closed-loop system	0	18 (90)
Use of continuous glucose-monitoring system – no. (%)	19 (95)	20 (100)

Figure 2. Schematic of Study Design

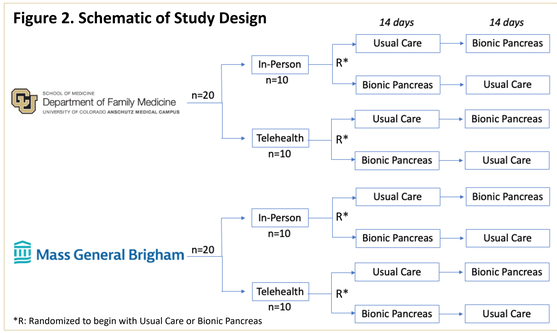
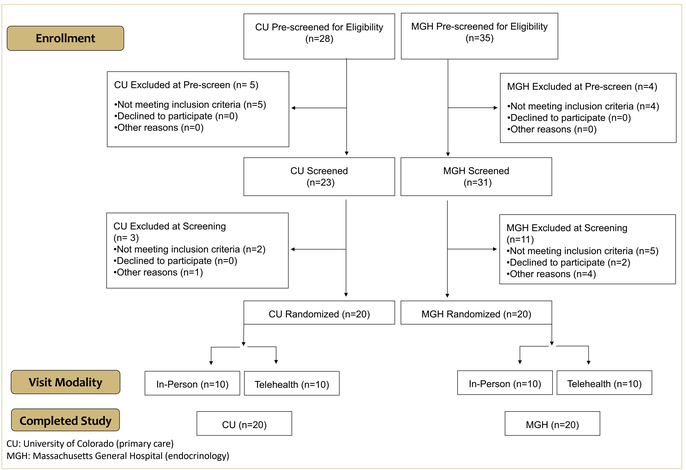


Figure 3. Participant Enrollment and Randomization



Outcome Measures

Primary: % of participants with mean glucose <183 mg/dL (corresponding to estimated HbA1c <8.0%) on days 3-14, by group.

Secondary:
- Mean CGM glucose
- % of time with CGM glucose <54 mg/dL
- % of time with CGM glucose 70-180 mg/dL
- % of participants with mean CGM glucose <154 mg/dL (corresponding to estimated HbA1c <7.0%)

Safety Endpoints
- Frequency of Adverse Events
- Frequency of Severe Hypoglycemia
- Frequency of Diabetic Ketoacidosis

Anticipated Results

We hypothesize that: (1) primary care can successfully start pump naïve participants on the iLet bionic pancreas system in-person and via telehealth; and (2) we will see similar glucose management by the iLet in the primary care and academic endocrinology groups and in the telehealth and in-person groups.

Demographic data demonstrates a more diverse primary care patient sample.

Data collection is now complete, and analysis is currently pending.

Conclusion

Primary care patients represented broader race/ethnicity demographics, which **may** imply that AID access to these populations could expand with use of AID in primary care. Results of this trial will inform protocol refinement, estimates of effect size, power calculation, and planning for a larger randomized controlled trial to include a broader geographical range of primary care clinicians and participants, to include type 1 diabetes and type 2 diabetes.

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