



Post ADA 2023

New technologies

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Disclosures

	Consultant	Conférencier	Membre conseil scientifique	Subvention recherche	Investigateur	Royalties	Stock options	Ownership
Medtronic		X						
Abbott					X			
Sanofi	X	X						
Novo Nordisk	X							
Lilly	X	X						
Boringer	X	X	X					
AMF microfluidics	X		X	x	X			
Astra Zeneca	X	X						
Roche		X						
Dexcom		X						
Air Liquide/Tandem		X						

Outline

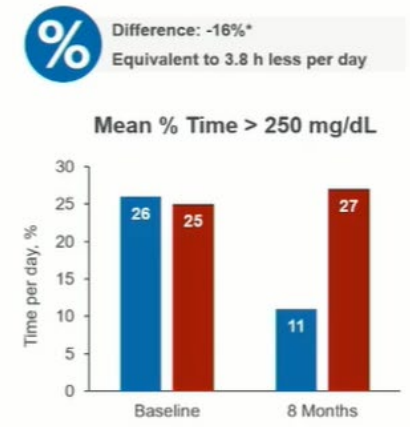
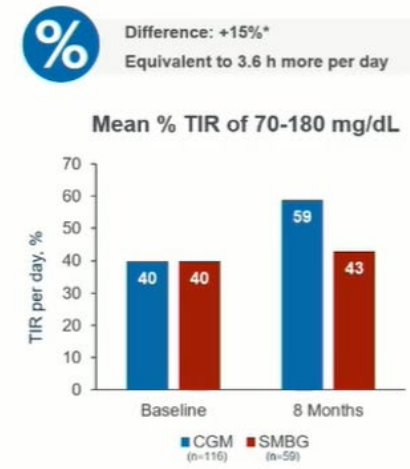
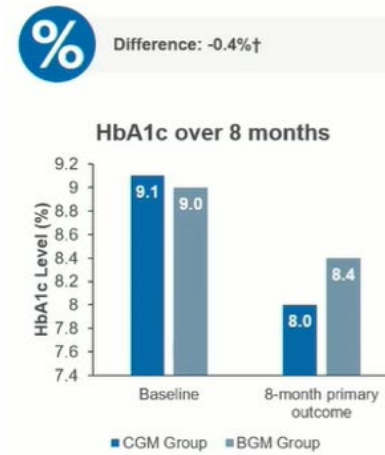
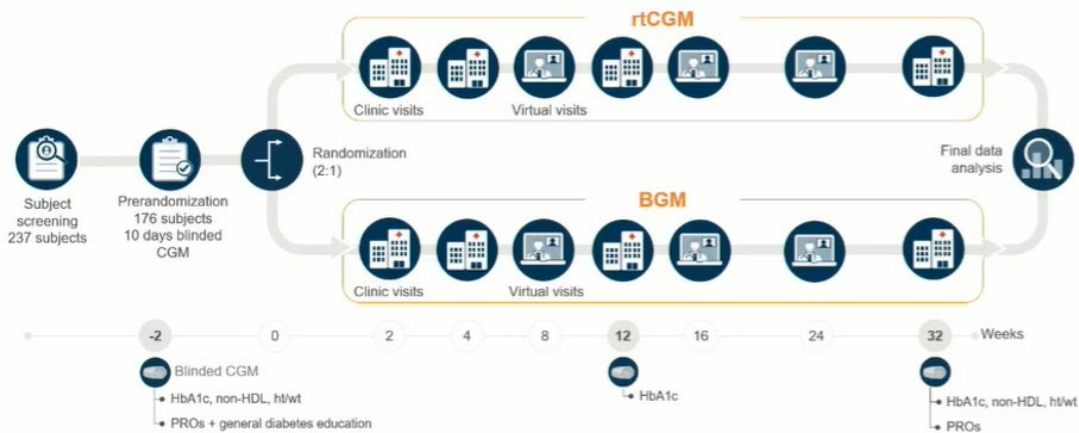
- Sensors
- Pumps
- Conclusion

Sensors

What's new on sensor use?

- New recommendation following the MOBILE Study


176 participants with T2D receiving NIIT followed by primary care clinicians, randomly assigned to rtCGM and BGM groups and followed for 8 months. CGM initiated/interpreted by diabetes specialists; management by PCPs



NIIT, nonintensive insulin therapy; PRO, patient-reported outcomes. BGM 1-3× daily. Martens T, et al. JAMA. 2021;325:2262-2272.

What's new on sensor use?

- New recommendations following the MOBILE Study



American Diabetes Association -- Standards of Care 2023
rtCGM (A) or isCGM (B) **should be offered** for diabetes management in adults with diabetes on MDI or CSII who are capable of using devices safely.
rtCGM (A) or isCGM (C) **should be offered** for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely.

As long as the beneficiary uses any insulin, the beneficiary is eligible for CGM coverage

Centers for Medicare & Medicaid Services. Accessed May 3, 2023. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822>

...therapy -- Clinical Practice
...**is recommended** for all persons with T1D regardless of insulin delivery system. (Grade A)
...**is recommended** for persons with T2D who are treated with insulin therapy, or who have high risk of hypoglycemia and/or hypoglycemia unawareness. (Grade A)

Future recommendation: Use in all patients with type 2?

- **Yes!** Symposium: Thomas Grace, Ronnie Aronson; OP-227, Robert J. Ellis

Rt-CGM

	Population & Design	Outcome
Yoo et al	RCT - 57 individuals 48 using oral therapy	A1c greater improvement of 0.7%*
Cosson et al	RCT - T2D – 25 individuals 16 using oral therapy	A1c greater gain of 0.3% (ns)
Ehrhardt et al Vigersky et al	RCT - 100 individuals – 67 using oral therapy	A1c greater gain of 0.5%*
Grace & Salyer	prospective, single arm 38 individuals – 22 using oral therapy	A1c improvement of 3.0%* TIR gain of 15.2%*
Cox et al (GEM)	RCT 30 individuals	A1c – lower by 1.1%*
Price et al COMMITTED	RCT (pilot) 70 individuals	A1c – lower by 0.2% (ns)

Is-CGM

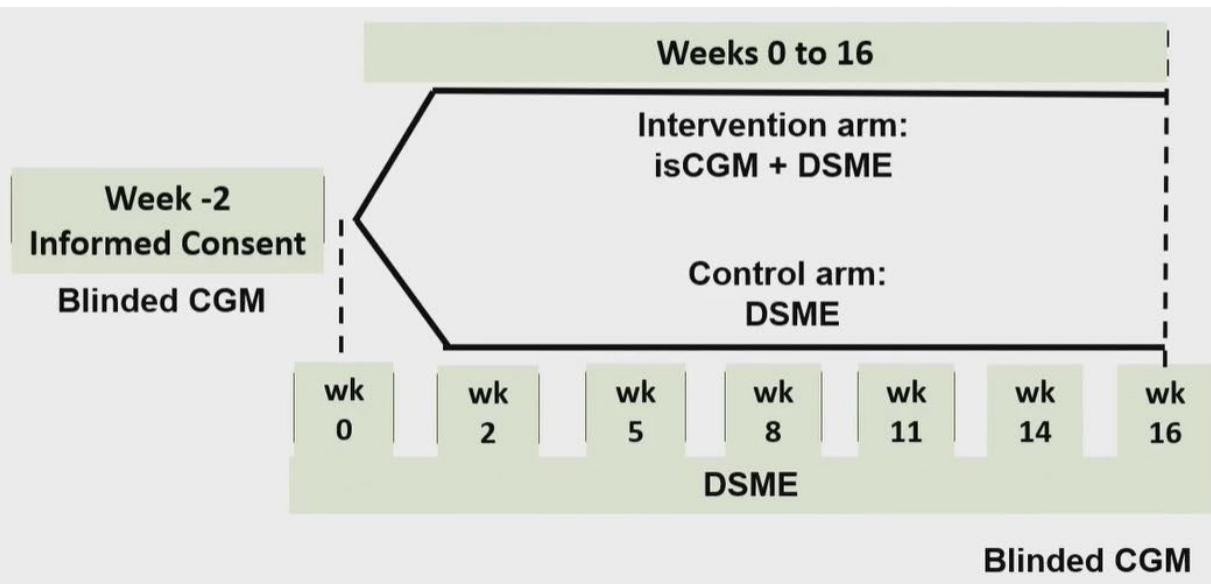
	Population	Outcome
Wada et al	RCT – 12 weeks 100 individuals	A1C lower by 0.3% (*24 weeks)
Polonsky et al AH-HA Project	Prospective, single arm 35 individuals	TIR increase by 19%*
Aronson et al IMMEDIATE	RCT 116 individuals	TIR greater by 9.9%* A1C lower by 0.3%*

Wada E et al. *BMJ Open Diab Res Care* 2020. doi:10.1136/bmjdr-2019-001115
 Polonsky et al. *DTT* 2023. DOI: 10.1089/dia.2022.0419
 Aronson et al. *DOM*. 2023. DOI: 10.1111/dom.14949

Yoo et al. *DRCP*. 2008. doi:10.1016/j.diabres.2008.06.015
 Cosson et al. *Diab & Metab* 2009. doi: 10.1016/j.diabet.2009.02.006
 Vigersky et al. *Diab Care*. 2012. doi: 10.2337/dc11-1438/-/DC1
 Ehrhardt et al. *J D Sci Tech*. 2011. doi: 10.1177/193229681100500320
 Grace T, Salyer J. *Diab Tech Ther*. 2022. doi: 10.1089/dia.2021.0212
 Cox et al. *J Endo Soc*. 2020. doi:10.1210/jendso/bvaa118
 Price D et al. *Diab Ther*. 2021. DOI: 10.1007/s13300-021-01086-y

IMMEDIATE study

- Explore the efficacy and patient 's satisfaction after is.CGM in PWT2D not under insulin
- 58 patients in each group, mean hbA1c 8.5, about 60 % under metformin, 20 % under SGLT2i or GLP1-RA, 30 % under SH or gliptins.
- 2.6 therapies



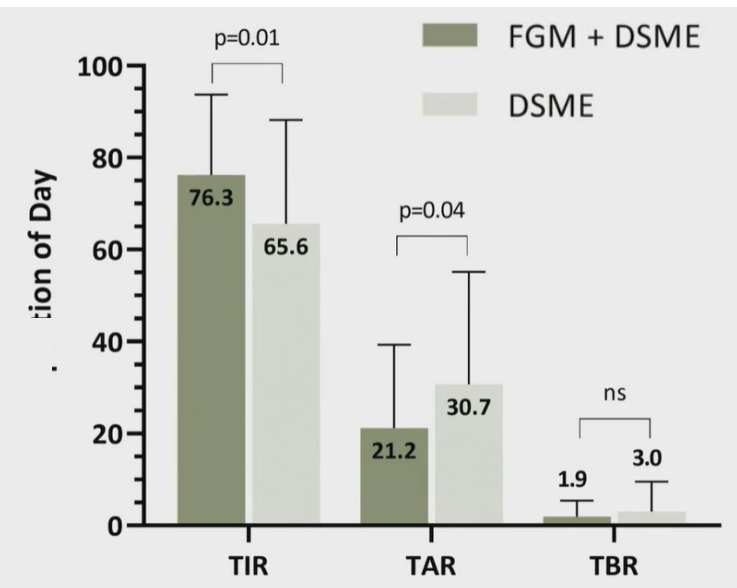
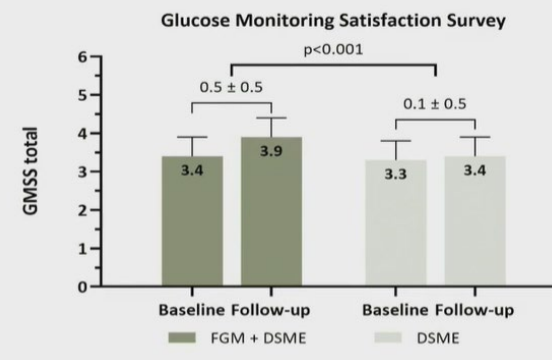
DSME. Diabetes Self Management Education

Primary Outcome:

- Time in Range

Secondary Outcomes:

- Time in Tight Glycemic Rang
- Time Above Range

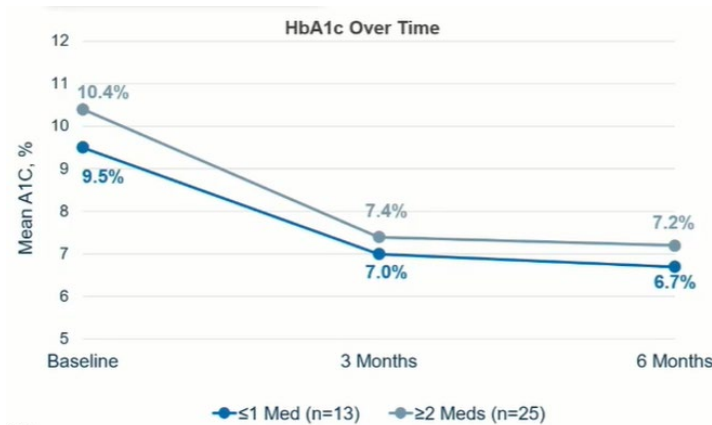


Use of Real-Time Continuous Glucose Monitoring Improves Glycemic Control and Other Clinical Outcomes in Type 2 Diabetes Patients Treated with Less Intensive Therapy

Thomas Grace, MD and Jay Salyer, CNP

Thomas Grace's study

- Explore the efficacy of rt.CGM in PWDT2 not under intensive insulin treatment
- First study: 6 months prospective, interventional, single arm study including 38 patients with HbA1c > 7.5 %
- Open to all residents of Findlay in Ohio, without insurance coverage for rt-CGM, informed by their PCP,



- Miraculous decrease of 3% in HbA1c after 3 and 6 months
- Those with Higher HbA1c experienced the most important reduction
- Same results in insulin or non insulin users.

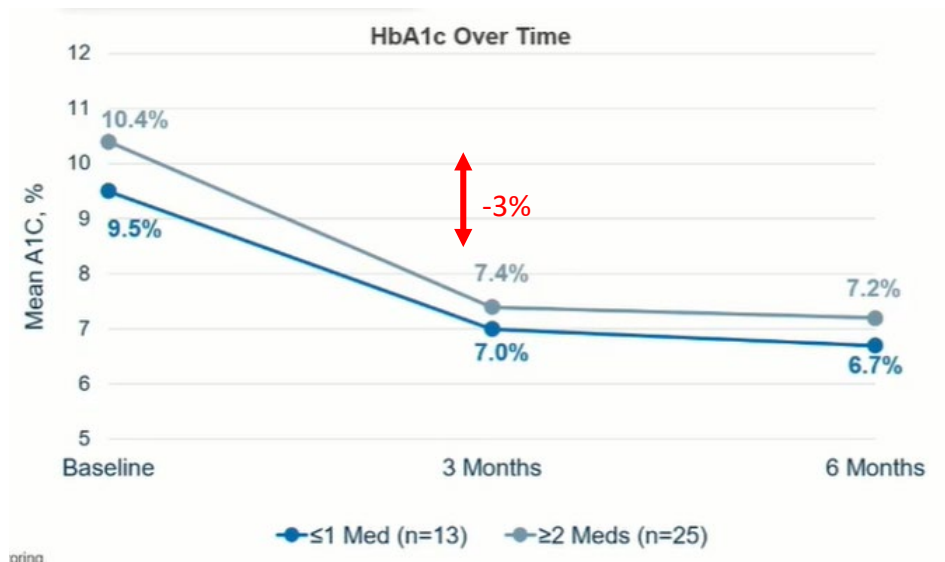
→ 227.OR : 3 to 4 wearings per year of rt-CGMs improve TIR , mean HbA1c and Glycaemia Risk index

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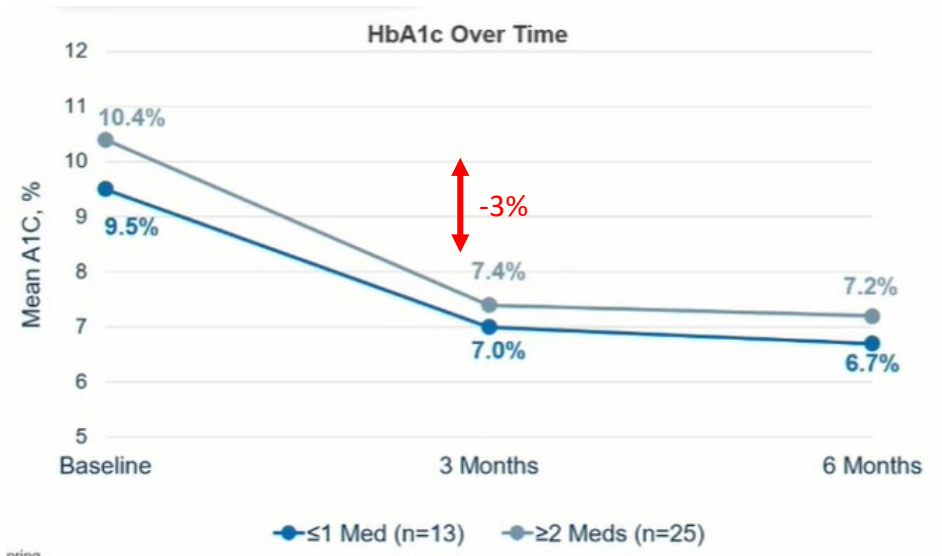
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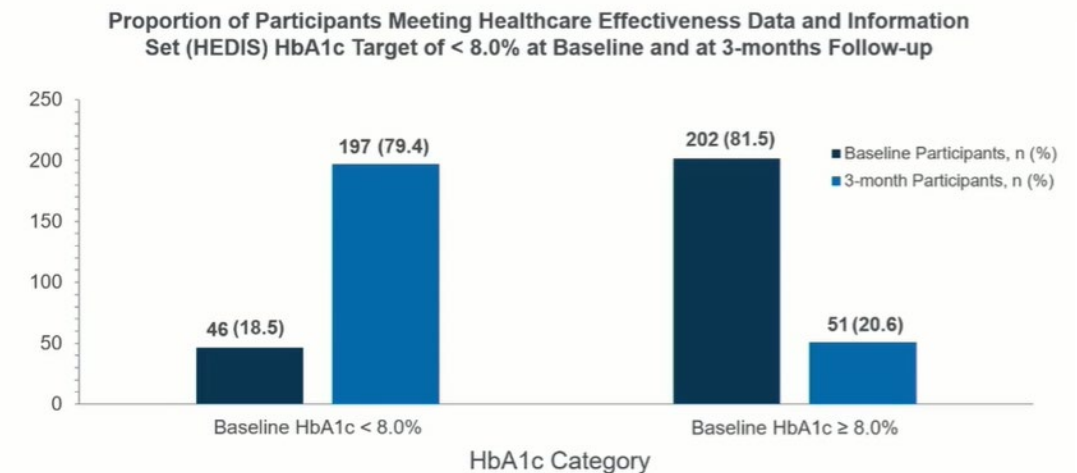
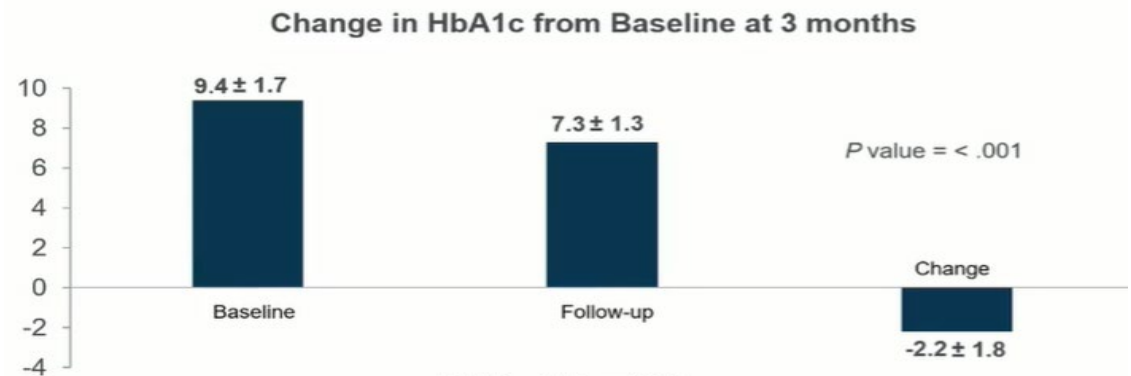
Thomas Grace, MD and Jay Salyer, CNP

Thomas Grace's study

- Explore the efficacy of rt.CGM in PWDT2 not under intensive insulin treatment
- **Extension study:** 6 months prospective, interventional, study including **248 patients** with HbA1c > 7.5 % (mean 9,4%)



- Miraculous decrease of 3% in HbA1c after 3 and 6 months
- Those with Higher HbA1c experienced the most important reduction
- Same results in insulin or non insulin users.



Future recommendation: Use in all patients with type 2?

- It is a serious option as CGM also:
 - Decreases the rate of hospitalizations, infections, ...
 - Improves diet and exercise
 - Improves health behaviours
 - Increases empowerment
 - Improves diabetes knowledge

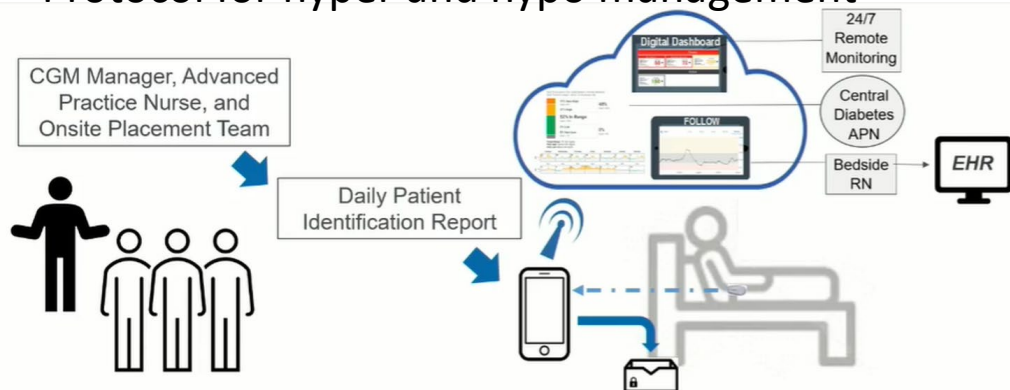
- Alternative: use of one CGM recording every 3 months
 - 227.OR : 3 to 4 wearings per year of rt-CGMs improve TIR , mean HbA1c and Glycaemia Risk index
 - Each CGMS use beyond 2/year improve
 - mean glycaemia of 11,8 mg/dl (0,6 mmol/L)
 - TIR of 7,7 %
 - TAR of 7,9%

Future recommendation: Inpatient use?

In non ICU settings

Symposium : A. Philis-Tsimikas

- ADA recommendation 2023 «CGM use for select inpatients... via an hybrid approach CGM-POC»
- CGM allows
 - Better TIR between 70-250 (3,9-14)
 - Less hypoglycemia events
- But need of staff, training, ongoing education
- Protocol for hyper and hypo management



In ICU settings

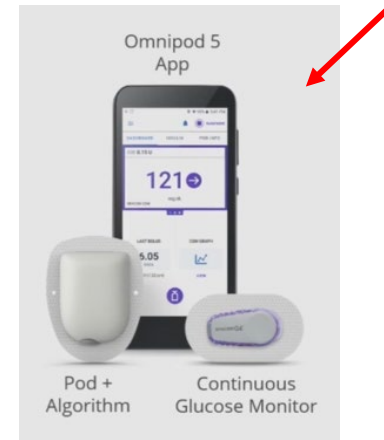
228-OR B.Hagerf; 229-OR S.Bann, 230-OR E. Faulds



- **Reliability with a MARD=9,4%** after major abdominal surgery, comprising transplantation, alternative site, blood loss, corticoids, noradrenalin...
- Confirmation of this MARD **only if calibration** (if not 13,9)
- Validation during covid pandemic but **STILL** not FDA approved

Pumps

Present closed loop systems



Possible Future Commercial Closed-Loop Systems

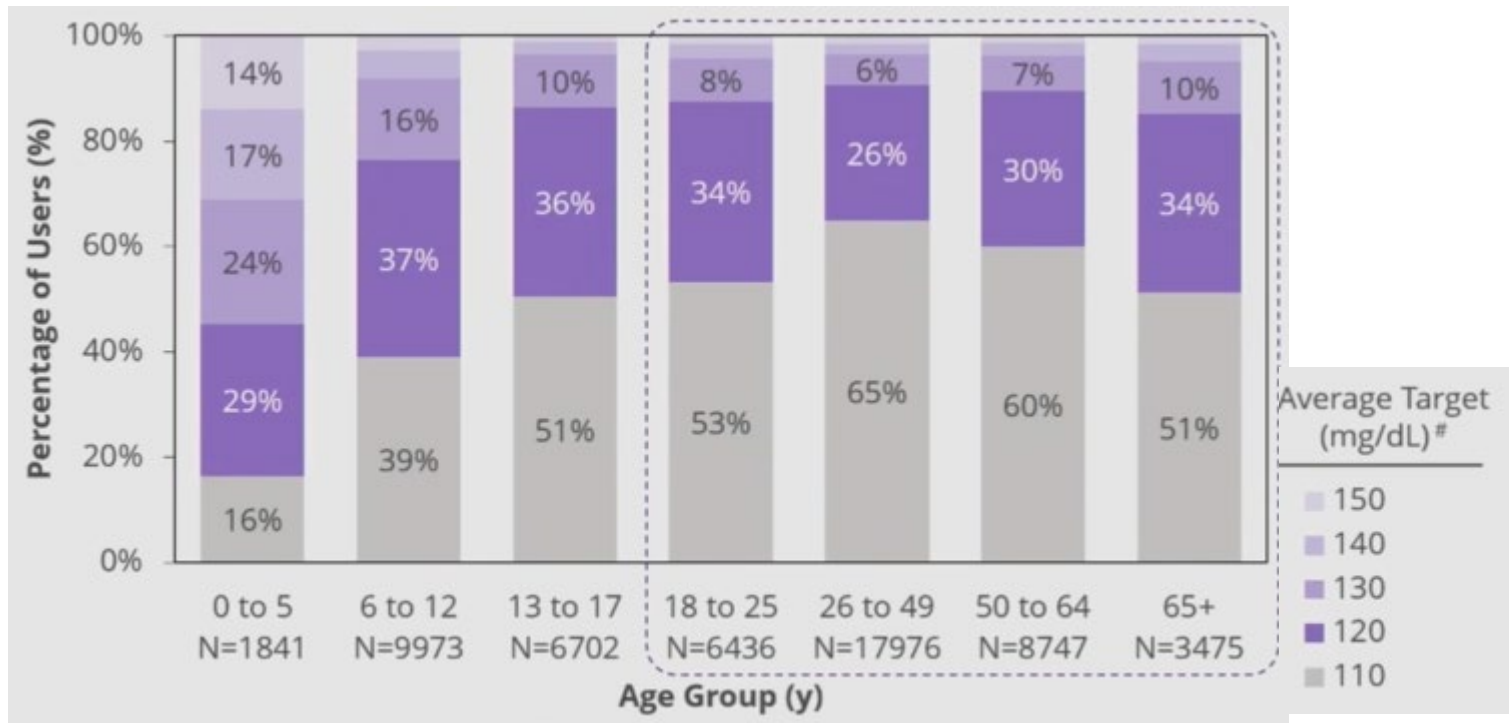
Real world setting outcome in 36634 adults using the Omnipod 5[®] AID system. Ryahan Lal et al.

- Omnipod 5[®] system
 - Is Tubeless
 - Is with an algorithm directly into the Pod
 - Proposes glucose target at 110, 120, 130, 140, 150 mg/dl are adjustable by time of day
 - Has activity feature (150 mg/dl)
 - Functions with Omnipod 5[®] application, which is only needed to switch on or off AID, deliver bolus and view data
- **Automatically upload data on insulet cloud**
- **Identification of 55150 self reported PWT1D including children**

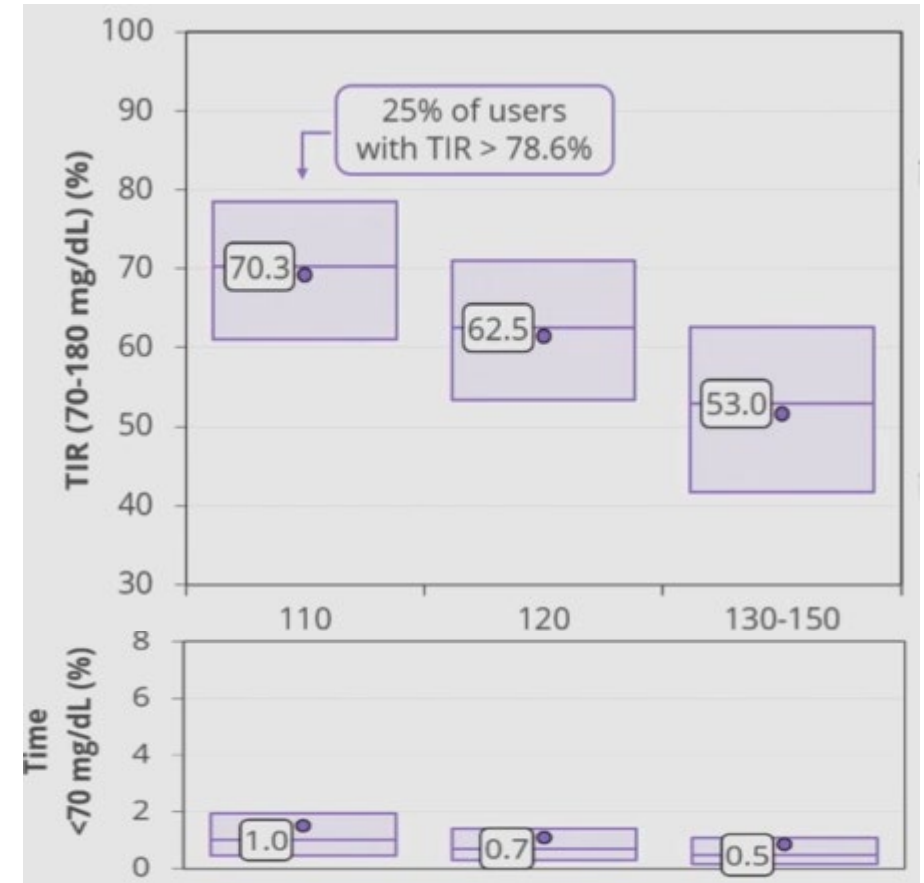


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- Target usage patterns vary with age

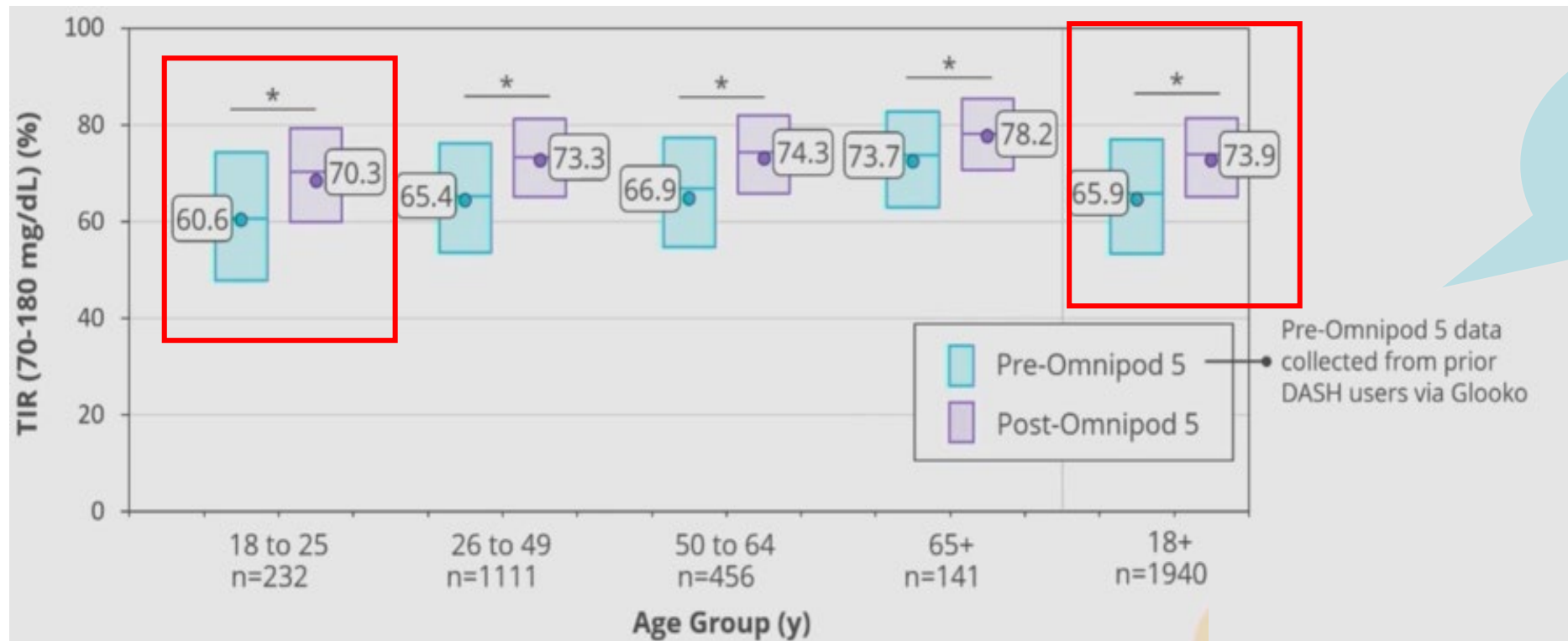


- TIR and TBR vary according to targets



Real world setting outcome in 36634 adults using the Omnipod 5[®] AID system. Ryahan Lal et al.

- Improvement using lowest target is better in younger and older adults



TIR
+4,5% to
9,7%

Present closed loop systems



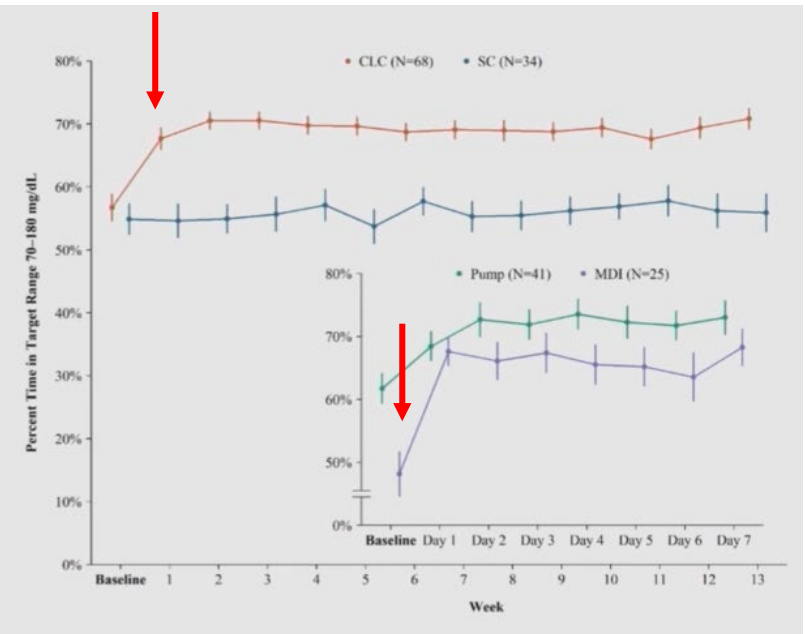
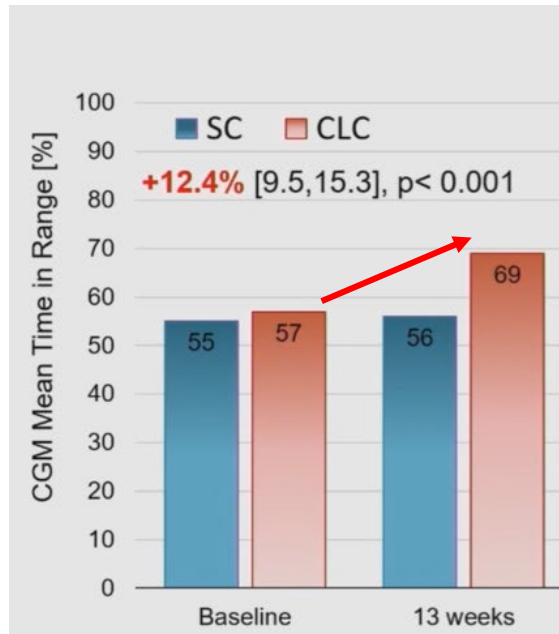
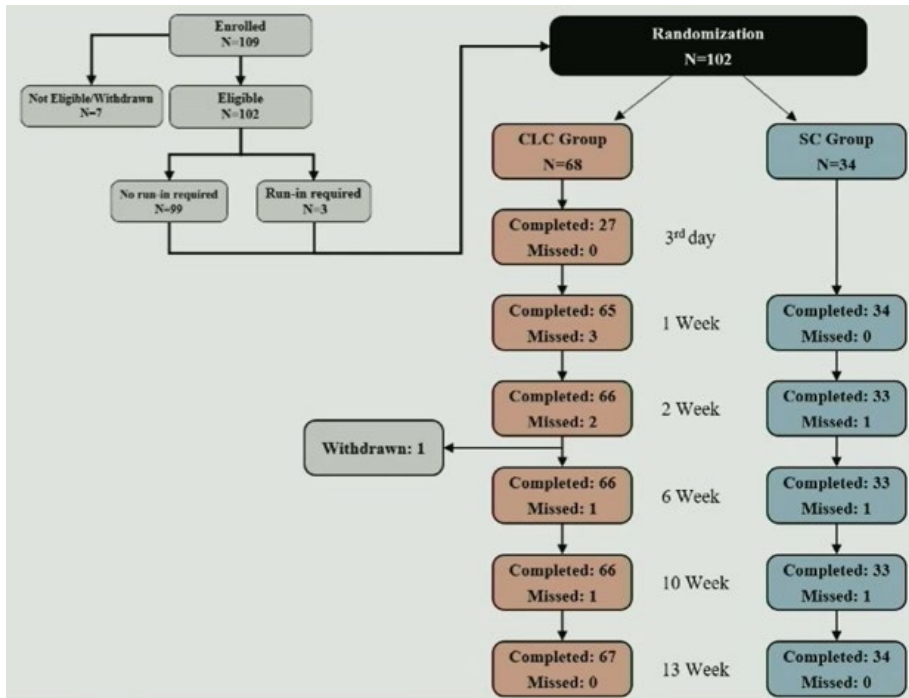
Possible Future Commercial Closed-Loop Systems

PEDAP study

Glycemic control with extended use of AID in children age 2-6 with T1D. P. Wadwa et al.

AID TIR Improvements in young MDI users with T1D are indistinguishable from pump using peers. M. Breton et al.

A 13 week RCT (2:1), with a 13 w. extension phase, including 102 patients between 2 and 6 y.o with BW > 9kg and TDD > 5 UI/day in 3 centers in US, during covid pandemic, without run-in period



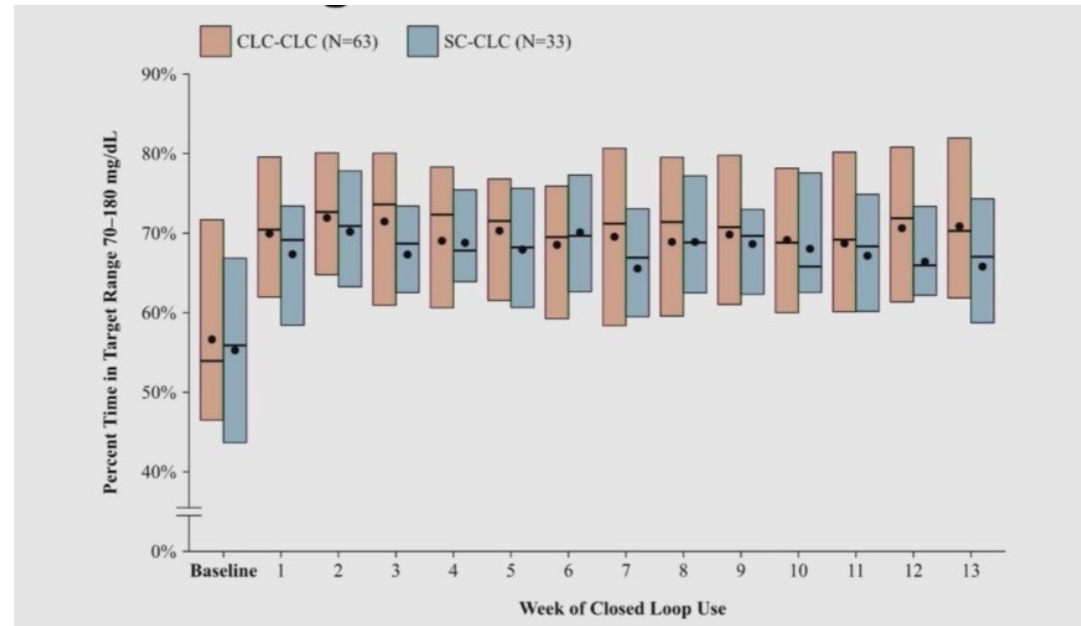
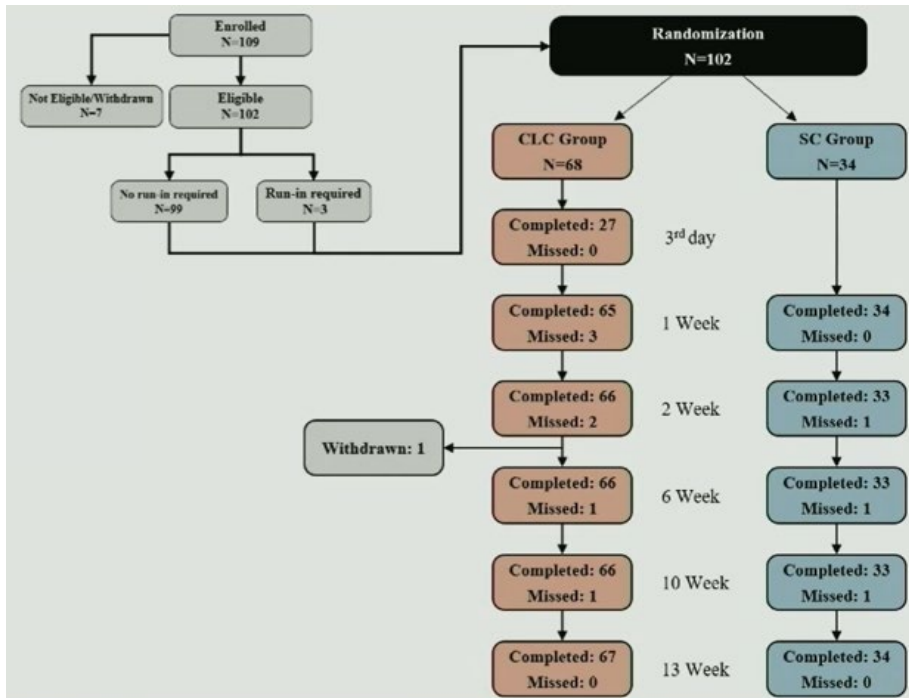
TIR increased of 12,4%, with a major increased in previous MDI users (1/3 of patients)

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During extension phase, SC-CLC had a TIR increased while CLC-CLC remained stable

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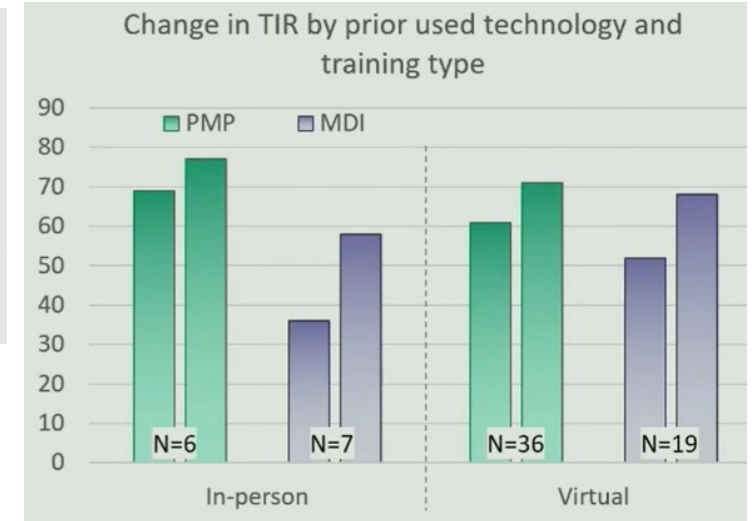
93% of teachings were virtual :

- 86% for prior pump users,
- 73% for prior MDI users

Improvement possible and similar even if not face to face teaching

Virtual Visits

CLC Training	
Primary study phase (CLC-CLC)	81%
Extension phase (SC-CLC)	82%
Trial Visits	
Primary study phase	93%
Extension phase	95%

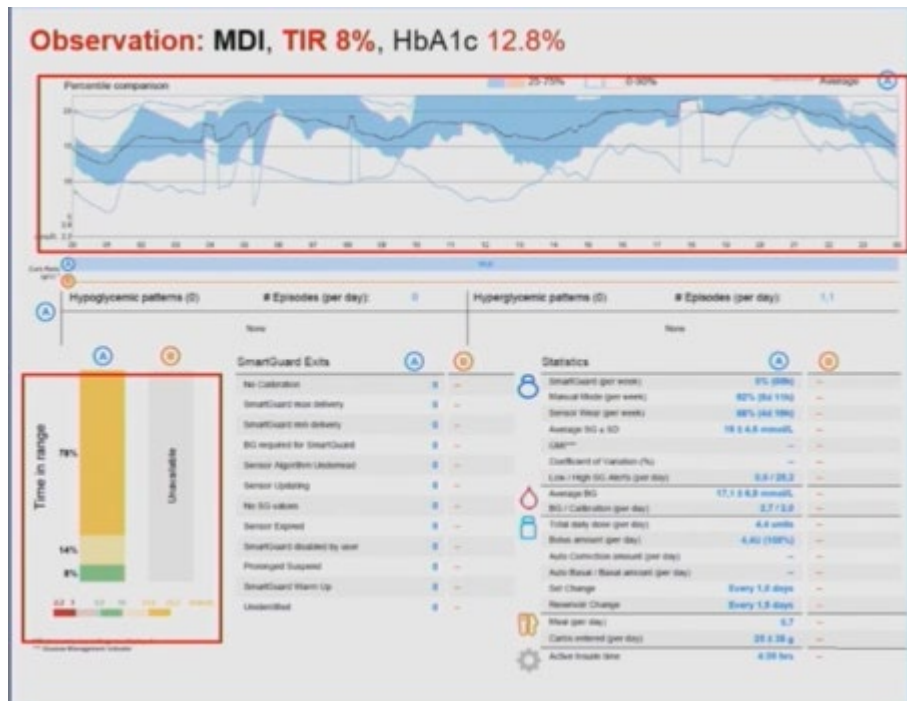


Present closed loop systems



Possible Future Commercial Closed-Loop Systems

Six months experience on meal announcement with a 3 prespecified preset of CH counting versus precise counting in adolescents using 780G. Goran Petrovski



Help with a preset of CH counting .:

Hypothesis: 60 -70% of CH in main meals,
30-40 % in snacks

7 days logbook for total daily carbs (TDC)
calculation

Three type of meal :

- regular: TDC X 0,6 /3
- Large meal: TDC X 0,6/3 X 1,5
- Snack: TDC X 0,6/3 X 0,5

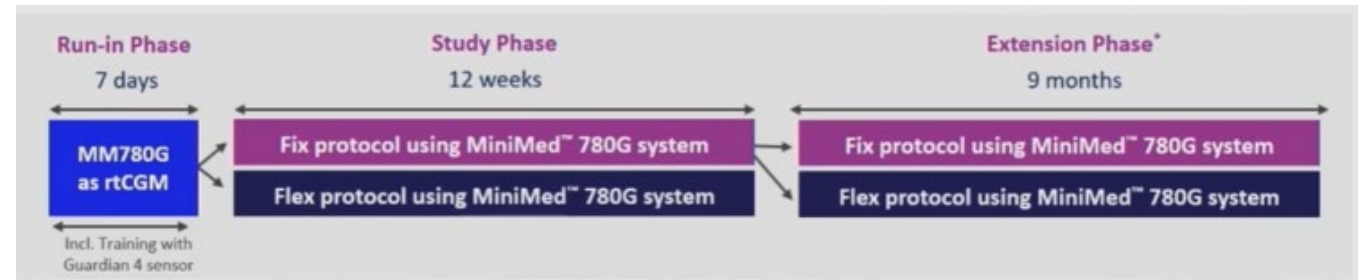
We all still have this kind of pattern if patient do not enter CH counting

Six months experience on meal announcement with a 3 prespecified preset of CH counting versus precise counting in adolescents using 780G. Goran Petrovski

RCT with 17 patients in each groups, Mean age 14 y.o.; Mean HbA1c 8%

Glucose target au 5,5 mmol/L
 active insulin time of 2hrs
 autocorrections ON

Fix protocol with regular/large meals and snacks
 Flex protocol with precise carb counting



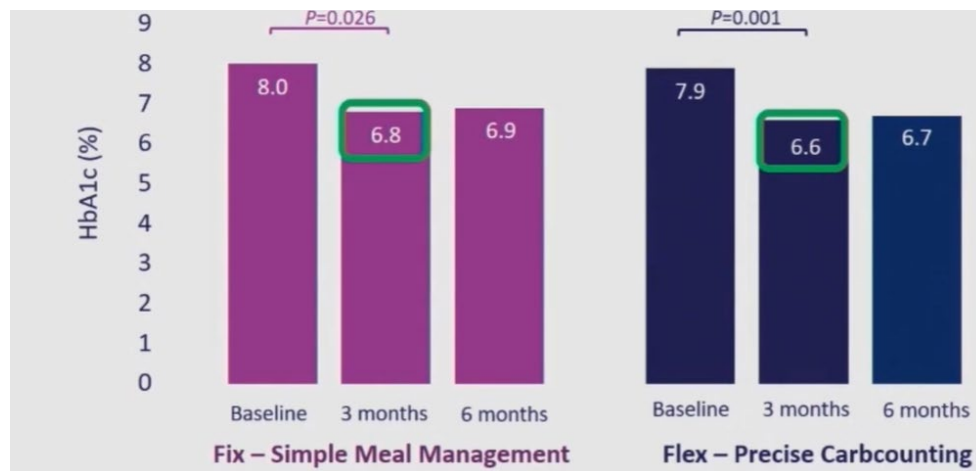
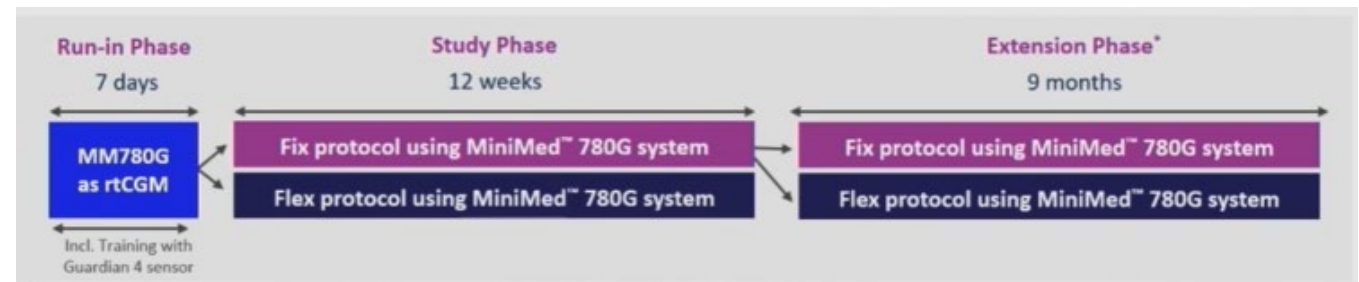
- CV, TBR and TIR were significantly better in flex protocol
- BUT both groups achieves TIR > 70 % and a great improvement in data

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active insulin time of 2hrs
autocorrections ON

Fix protocol with regular/large meals and snacks
Flex protocol with precise carb counting



- HbA1c improvement was not different between groups
- Both groups achieves HbA1c < 7%
- Lower precision overcome by automated insulin delivery and autobolus!

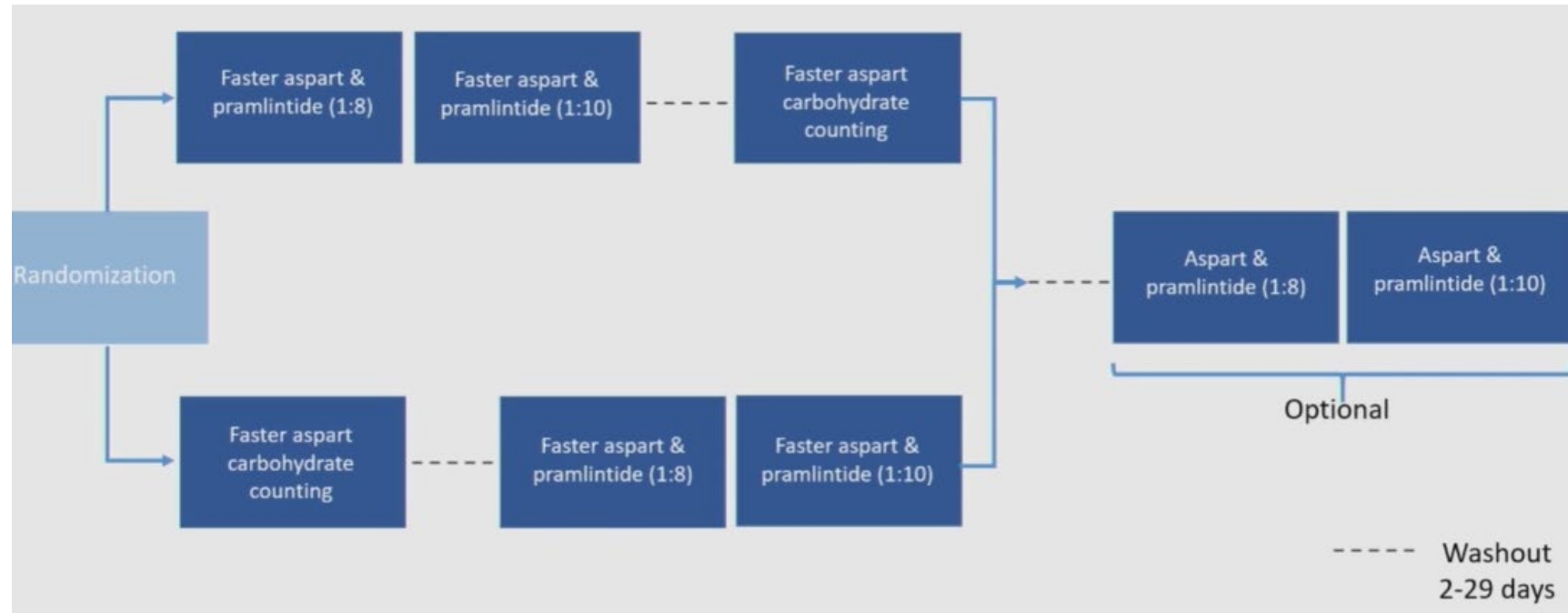
Fully closed loop?

- A pilot , randomized, controlled, crossover trial assessing a fully automated insulin and pramlintideclosed loop system in type 1 diabetes. M. Odabassian et al.
- Background:
 - CH counting is a great source of error
 - Amylin is co-secreted with insulin from beta cells
 - Pramlintide (amylin analogue) delays gastric emptying, regulates glucagon and increases satiety

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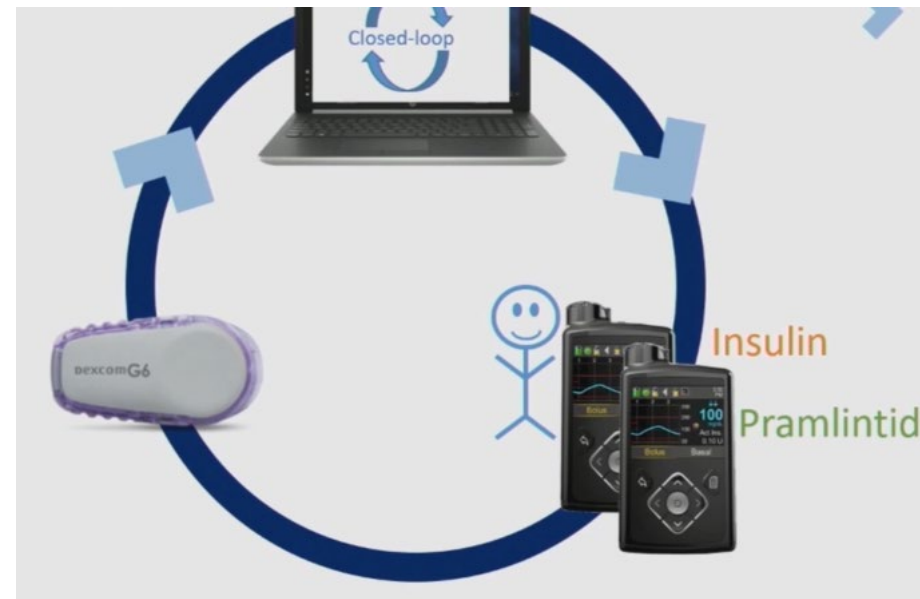
- Control group: carbohydrate counting with Hybrid closed loop
- Experimental group:
 - FIASP + Pr: 1U:8mcg
 - FIASP + Pr: 1U:10mcg
 - Aspart + Pr 1:8
 - Aspart + Pr 1:10
- N=12



Fully closed loop?

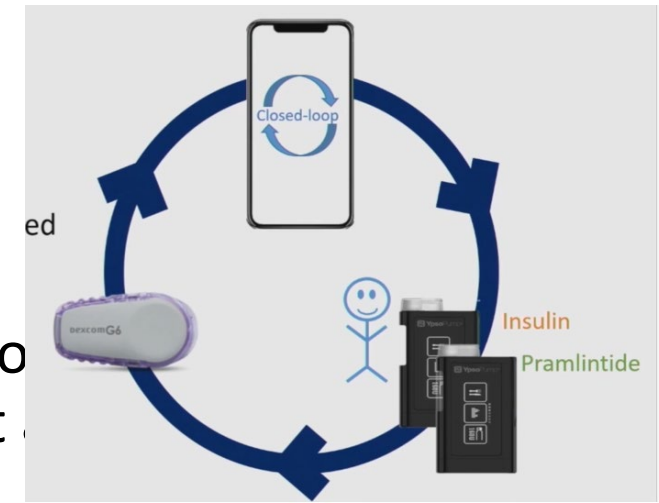
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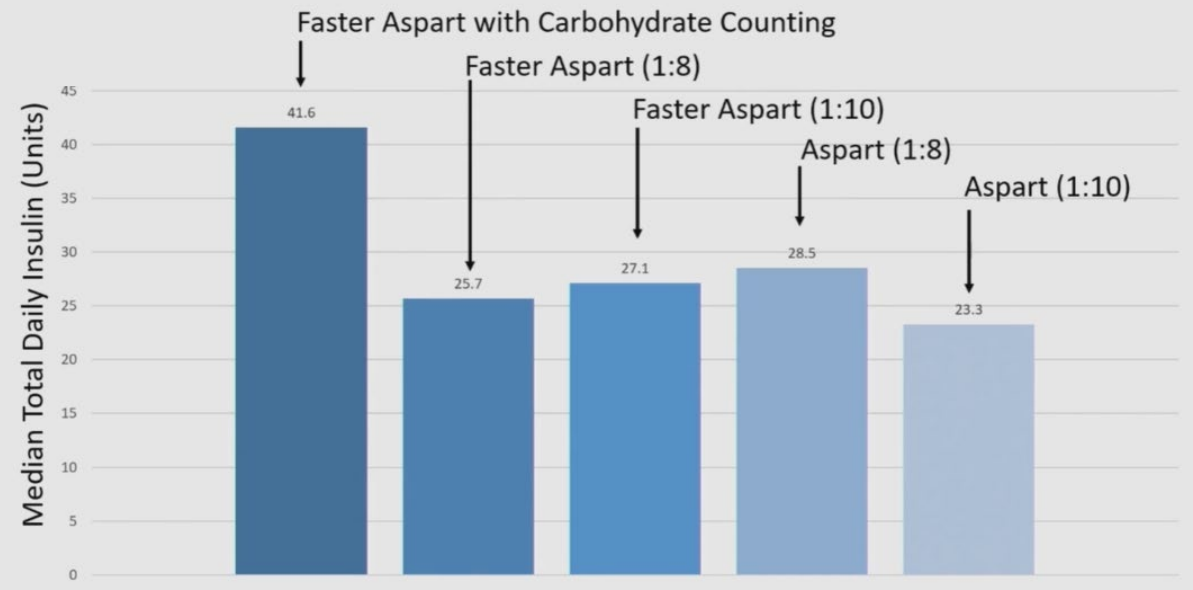
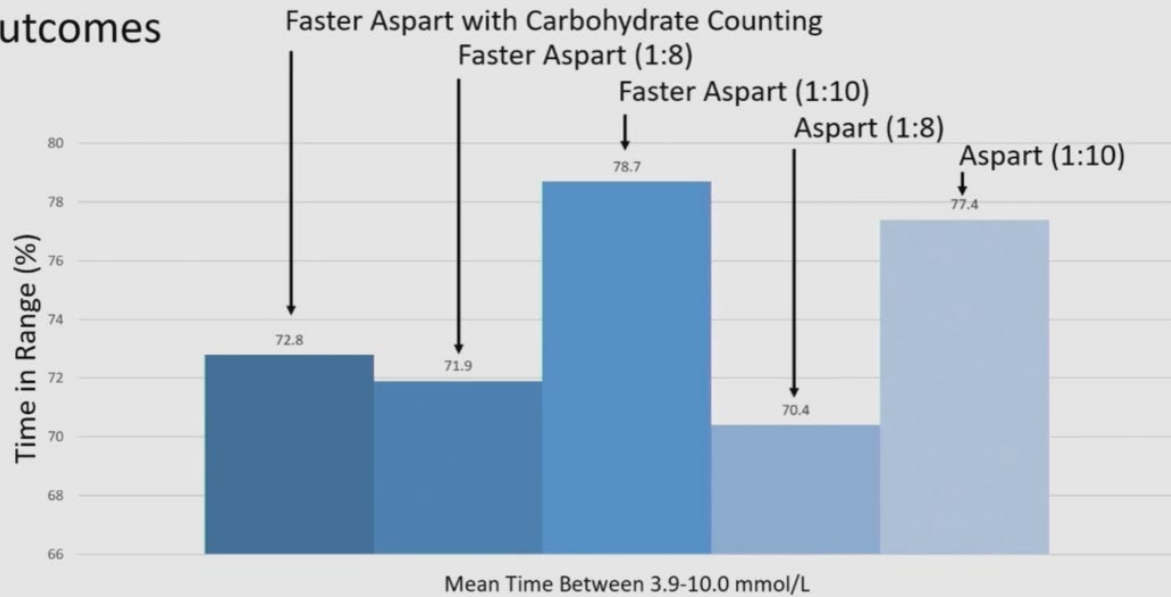


Fully closed loop?

A pilot, randomized, controlled, crossover trial assessing a fully automated closed loop system in type 1 diabetes. M. Odabassian et al.



Outcomes



TIR seems to be at least equal in this fully closed loop compared with HCL with CH counting.
Insulin doses were lower

Possible future closed loop systems

Towards miniaturization of pumps and sensors
Towards full closed loop



Conclusion

- Sensors:
 - Soon in all our patients
 - Soon at the hospital with dedicated protocols
 - Multiple sensing ongoing: ketosis, cortisol...
- Pumps:
 - Fully close loop is coming : iLet, pramlintide
 - Is becoming the gold standard for all type 1 patients even the youngest, the one who do no count CH