

# Interim Analysis of a Prospective Study Investigating User Satisfaction and Metabolic Outcome of People with T1D Using an Innovative Modular Micropump System

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## Background and Aims

People with type 1 diabetes (T1D) can administer insulin by multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII). Despite proven clinical benefits, the uptake of CSII is still low. Thus, this study investigates the change in treatment satisfaction and metabolic outcome of people with T1D switching from MDI to CSII therapy using an innovative modular micropump system.

## Materials and Methods

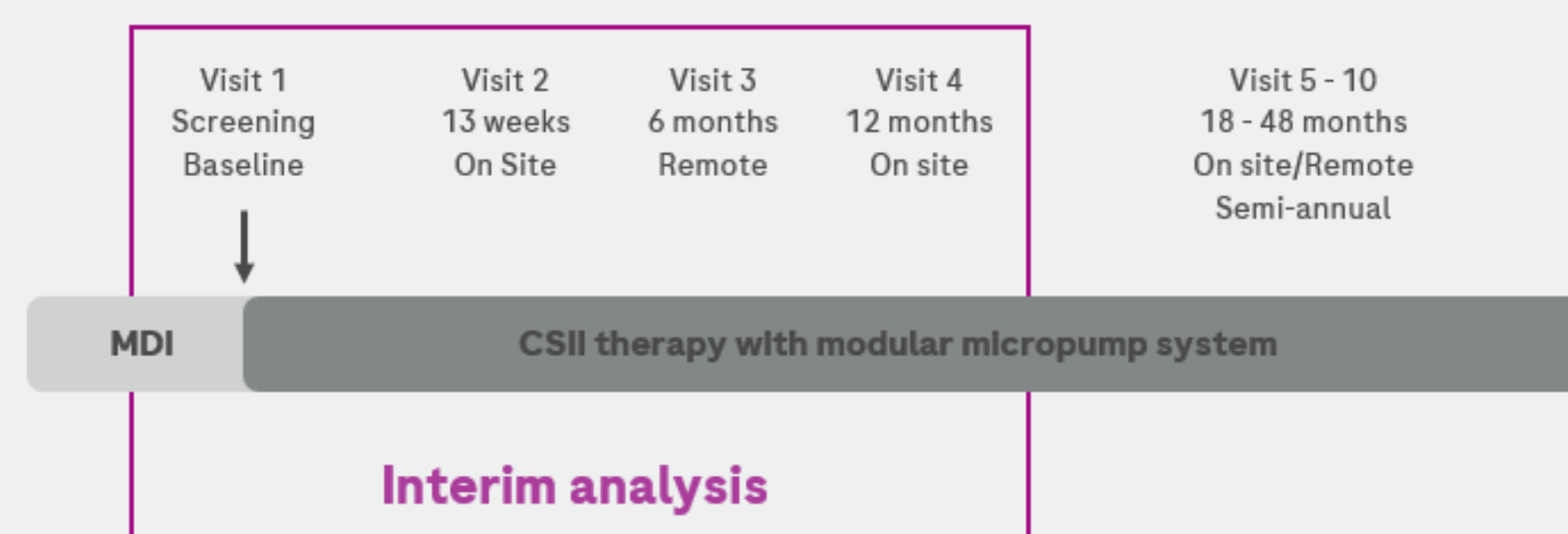
A total of 50 CSII-naive adults with T1D from Argentina were enrolled in a multi-center, prospective, single-armed study for the Accu-Chek® Solo micropump system (Figure 1) with a total study duration of 4 years (Figure 2). As an interim analysis\*, the change in diabetes treatment satisfaction was assessed after 13 weeks (mean 108, min 83, max 176 days) by the "Impact and Satisfaction" section of the Diabetes Technology Questionnaire (DTQ) as primary outcome. In addition, changes in the DTQ after 1 year, overall satisfaction measured by a micropump questionnaire created by Roche Diabetes Care as well as the HbA1c and the occurrence of incidents as e.g. severe hypoglycemia and diabetic ketoacidosis were reported.

## The Accu-Chek Solo® micropump system



**Figure 1: The Accu-Chek® Solo micropump system.** The modular micropump system is either controlled remotely via the diabetes manager (shown on the left side) or allows bolusing directly on the pump (shown on the right side). Due to the modular design including a reusable pump base (lower part) and disposables (upper part) the components can be replaced independently from each other. For a better comprehensiveness, the components of the pump are illustrated disassembled. A more detailed description of the system can be found in (1).

## The study design



**Figure 2: Study design.** Participants were screened and baseline information was collected at the first visit. Subsequently, participants switched from MDI to CSII using the Accu-Chek Solo® micropump system. Consecutive visits, alternating on site and remote, were performed after 13 weeks as well as semi-annually beginning with 6 months. As this study is ongoing, an interim analysis was performed including data up to 12 months.

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\*The data sweep for this interim analysis was performed on 10 January 2023

## Results

- The mean HbA1c decreased from 8.20% ± 1.34 to 7.92% ± 1.18 (-0.28%pt, p = 0.034) after 13 weeks and 7.87% ± 1.26 (-0.37%pt, p = 0.047) after 1 year with one event of severe hypoglycemia and diabetic ketoacidosis (DKA) being reported during 17520 device days (Figure 3).
- The mean DTQ "now" score improved from 93.28 ± 15.11 to 102.63 ± 19.00 (p = 0.021) after 13 weeks and to 102.38 ± 19.51 after 1 year (p=0.049).
- The mean DTQ "change" score, was 113.37 ± 16.74 (p < 0.0001) after 13 weeks and 111.42 ± 14.42 (p < 0.0001) after 1 year.
- Based on pre-defined sub-categories, the following mean DTQ "change" scores were measured after 13 weeks and 1 year (with a score > 3 indicating a positive change, Figure 4):
  - "Diabetes distress and burden": 3.81 ± 0.61 and 3.79 ± 0.52
  - "Hypoglycemia fear, worry and behavior": 3.96 ± 0.68 and 3.98 ± 0.60
  - "Device acceptance and satisfaction": 3.56 ± 0.71 and 3.53 ± 0.52
  - "Other": 3.90 ± 0.63 and 3.97 ± 0.62
- 13 weeks and 1 year after the switch to the Accu-Chek Solo micropump system, a mean of 80%, respectively 76%, of participants showed a positive overall system satisfaction (agreed or agreed somewhat) as measured using a micropump questionnaire created by Roche Diabetes Care (Table 2)

## The Demographics

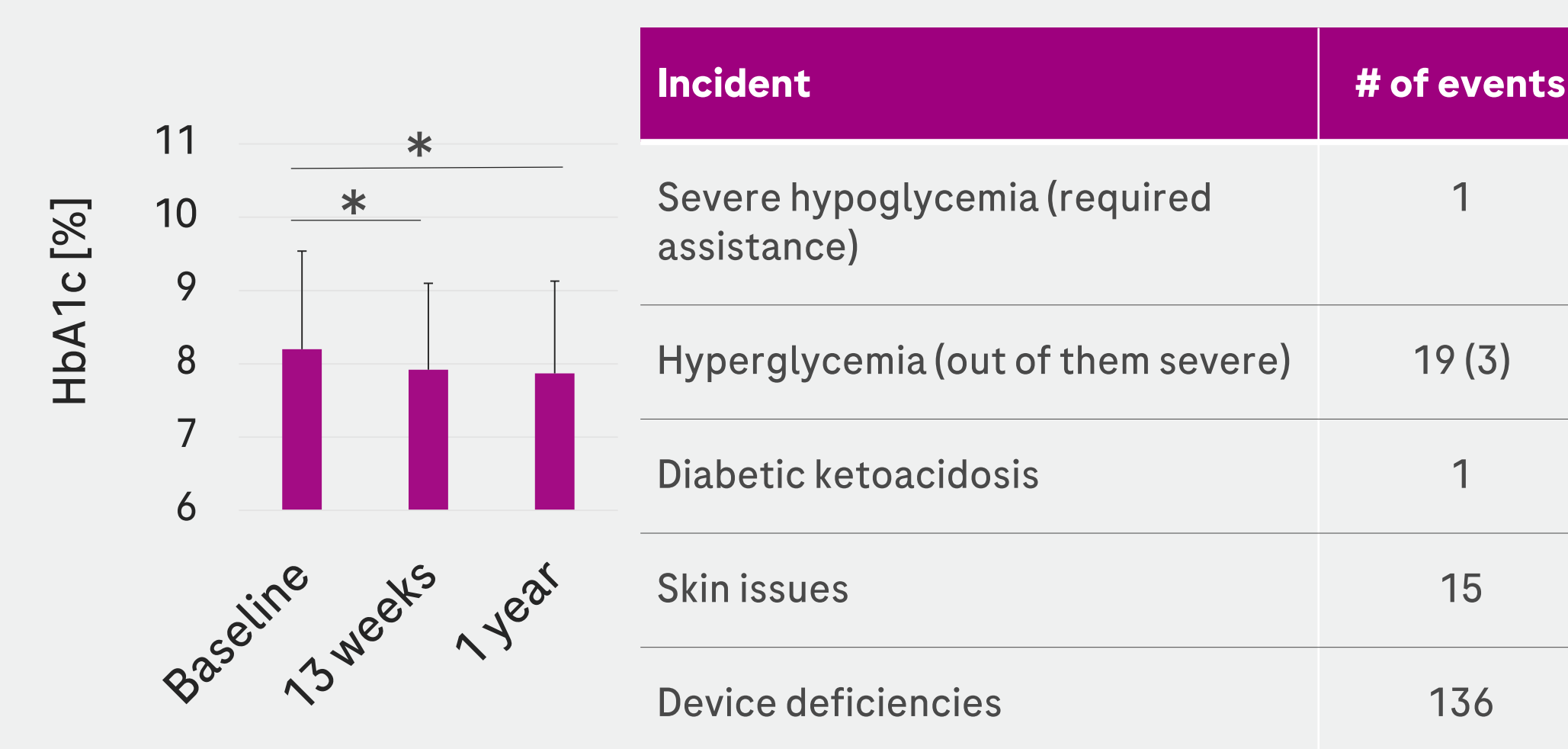
Demographics	N (%)	Mean (SD)
<b>Sex Female</b>	28 (56.0)	
<b>Race (self-reported)*</b>		
White	46 (92.0)	
Native American/ Alaska Native	1 (2.0)	
Native American/ Alaska Native, white	1 (2.0)	
Latin	1 (2.0)	
Latino	1 (2.0)	
<b>Age [years]</b>		34.80 (13.47)
<b>Height [cm]</b>		165.86 (9.32)
<b>Weight [kg]</b>		70.40 (11.37)
<b>BMI</b>		25.54 (3.25)
<b>Duration of diabetes [years]</b>		14.88 (11.02)

**Table 1: Demographics.** n = 50. \*No participant reported as Asian, Black/African-American or Native Hawaiian/Pacific Islander as race. Latin and Latino were descriptions specified by participants for the chosen category « other ». Regarding ethnicity, all participants declared to be Hispanic, Latino/a, or Spanish origin.

### Author affiliations

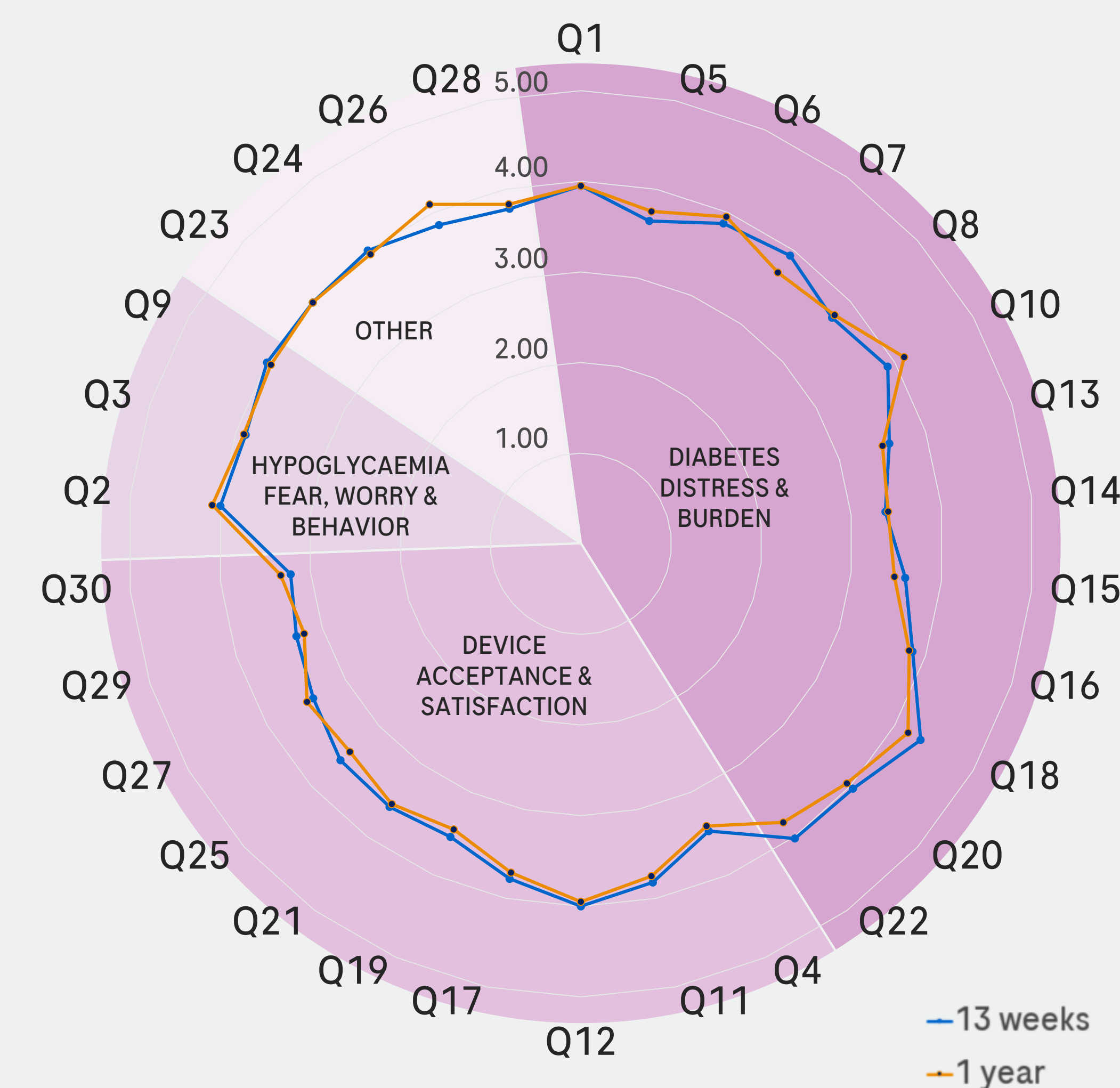
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## Changes in HbA1c and safety reports



**Figure 3: Glycemic changes and safety reports.** Left) Using the Accu-Chek Solo micropump system significantly reduced the HbA1c after 13 weeks and 1 year. \*indicates p ≤ 0.05, mixed model analysis, n = 45 - 50. Right) Number of incidents after 1 year of using the Accu-Chek Solo micropump system.

## Diabetes Technology Questionnaire



**Figure 4: Change values of the DTQ after 13 weeks and 1 year.** The change scores (mean values) of the first 30 questions of the DTQ (measuring « Impact and Satisfaction ») were clustered according to psychosocial constructs and visualized using a radial graph ranging from 1 (« much worse ») to 5 (« much better ») as previously published (2). All questions displayed a change score > 3 (=improvement) after 13 weeks or 1 year. Q = question, n = 50.

### References

(1) Ulbrich, S., et al., *Concept and Implementation of a Novel Patch Pump for Insulin Delivery*. J Diabetes Sci Technol. 2020. 14 (2); p. 324-327. (2) 56thEASD Annual Meeting of the European Association for the Study of Diabetes. Diabetologia, 2020. 63(1); p. 1-485. Abstract 708.

## Overall system satisfaction

Question	Agree <sup>5</sup> (%) after 13 weeks	Agree <sup>5</sup> (%) after 1 year
I trust that I can keep my diabetes under control with the insulin pump system	86	84
On the whole, I think the insulin pump system can be operated intuitively	70	66
I can operate the system discreetly, without drawing attention to the fact that I have diabetes.	68	66
I hardly notice the insulin pump in everyday life.	76	68
The insulin pump system gives me more flexibility in my everyday activities	84	80
On the whole I am satisfied with the insulin pump system	88	84
I would recommend the insulin pump system	88	84
<b>Mean over all questions</b>	80	76

**Table 2: Overall system satisfaction of participants.** Overall system satisfaction, evaluated using a micropump questionnaire created by Roche Diabetes Care, showed a positive reaction (agree or agree somewhat) of a minimum of 66 % of participants for the respective questions after 13 weeks and 1 year of using the Accu-Chek Solo micropump system. n = 50.

## Conclusion

The switch from MDI to CSII using the Accu-Chek Solo micropump system led to a significant improvement of participants' treatment satisfaction and HbA1c. Effects were already measurable after 13 weeks and continued through 1 year indicating that using the Accu-Chek Solo micropump system reduces disease burden among people with T1D.

**This poster is presented on behalf of all study investigators.**

**Accu-Chek Solo is a CE-marked and ANMAT-registered device, that is not available nor FDA-cleared in the US.**

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