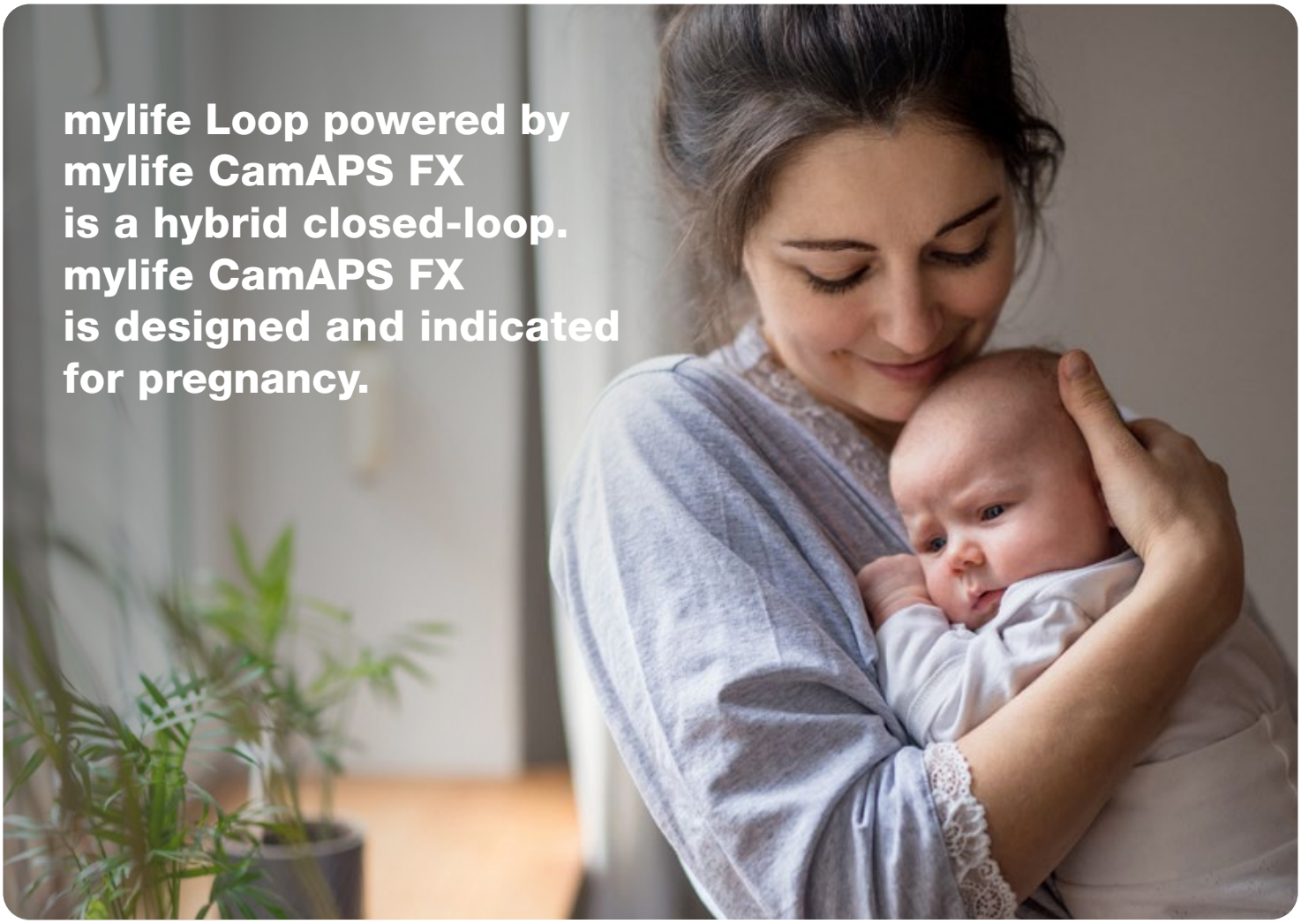
mylife Loop CamAPS FX

Clinical insights

The AiDAPT study: Automated Insulin Delivery Amongst Pregnant women with Type 1 diabetes

Take home messages

- Pregnant women using CamAPS FX improved their glycaemic control
  – 10.5 % more time spent in the pregnancy specific range of 3.5–7.8 mmol/L (63–140 mg/dL)
  – 0.3 % reduced HbA1c
  – No difference in the time spent in hypoglycaemia
- These improvements were visible immediately after initiation of CamAPS FX and were sustained throughout the pregnancy
- All women reported more enjoyable pregnancy experiences as a result of using hybrid closed-loop



Background and objective

- Pregnant women with T1D strive for tight glucose targets to minimize the risks of obstetric and neonatal complications.[1]
- Clinical studies evaluating the use of CamAPS FX in pregnant women have already shown promising results.[3-5]
- **The AiDAPT study aimed to evaluate the effectiveness of CamAPS FX in pregnant women with T1D, compared to CGM with standard insulin delivery (MDI or CSII therapy).[1]**

Recommended glycaemic target before conception[6]
HbA1c
< 6.5 % (48 mmol/mol)

Recommended glycaemic targets during pregnancy[6,7]
HbA1c
< 6.5 % (48 mmol/mol) at onset and
< 6.0 % (42 mmol/mol) as pregnancy progresses

Glucose levels[7]
Fasting: 3.9–5.3 mmol/L (70–95 mg/dL)
TIRp: 3.5–7.8 mmol/L (63–140 mg/dL): > 70 %

Methods & participants

- **124 pregnant women** across 9 clinics in the UK were randomised to either
  - **Hybrid closed-loop with CamAPS FX** (61 women, intervention group)
  - **Standard insulin therapy (MDI or CSII) with CGM** (63 women, control group)
- Participants: T1D ≥1 year, MDI or pump therapy, pregnant ≤ 13 weeks & 6 days, HbA1c between 6.5–10 %
- **Primary endpoint: TIRp 3.5–7.8 mmol/L (63–140 mg/dL) between 16 weeks gestation and delivery**
- Hybrid closed-loop (intervention group): CamAPS FX: Cambridge MPC Controller, Dana pump, Dexcom G6, CGM
  - **A personal glucose target of 5.5 mmol/L (100 mg/dL) in early pregnancy was recommended, reducing to 4.5–5.0 mmol/L (81–90 mg/dL) between 16 and 20 weeks' gestation, and continuing with the use of the lower targets until delivery.**
- Standard therapy (control group): CGM + MDI or CSII: Dexcom G6 CGM

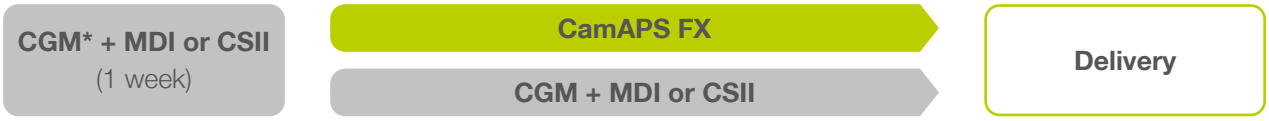


Fig. 1: AiDAPT study design

* Masked CGM is used for participants not using CGM prior to recruitment

Outcomes

The AiDAPT randomised controlled trial showed significant improvements in maternal glucose levels compared to standard insulin delivery:

- Women using CamAPS FX spent more time in the pregnancy-specific target range and had lower mean glucose and HbA1c levels compared to women in the control group.

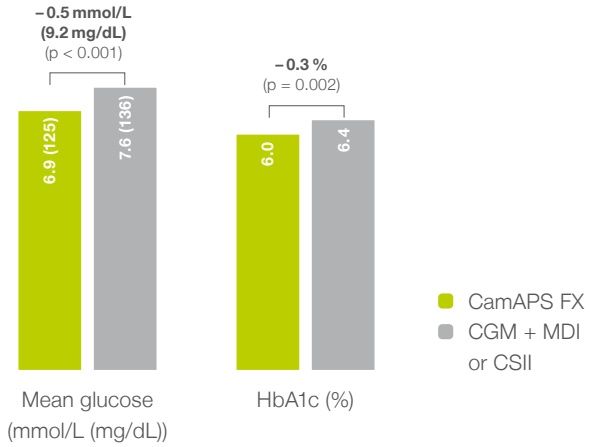


Fig. 2: Significant reduction in mean glucose and HbA1c levels in pregnant women with T1D using closed loop.

- These improvements were achieved without any difference in time spent in hypoglycaemic ranges.
- Improvements in TIRp are based on a reduction in TAR.
- There was no increase in TBR.

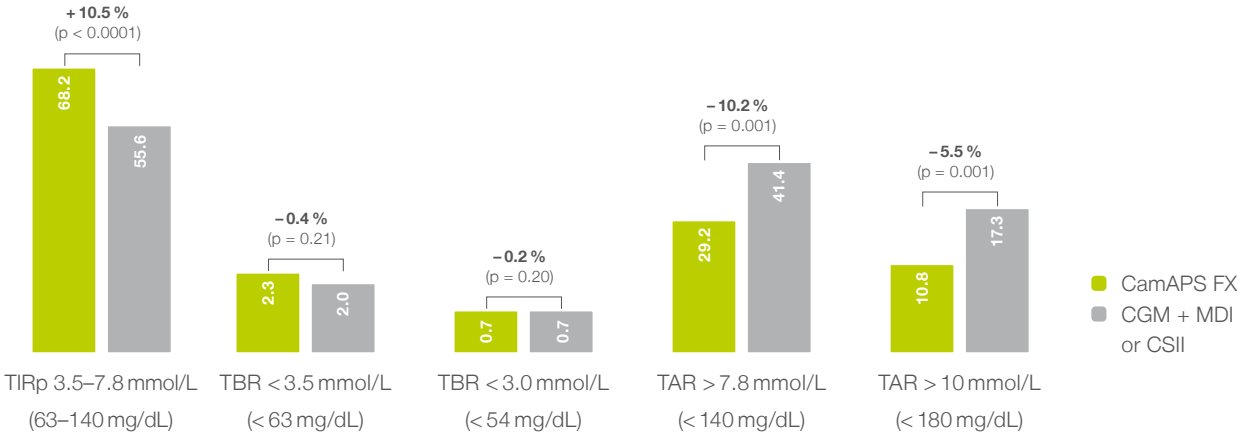


Fig. 3: Pregnancy Glucose Range during pregnancy.

- The benefits were observed immediately after starting CamAPS FX and were maintained throughout pregnancy
- No difference in TDD (0.97 and 1.06 u/kg/day) or maternal weight gain (11.1 and 14.1 kg) between the 2 groups.
- CGM was used well in both groups (97 %).
- Pregnant women spent 96 % of time in closed loop.

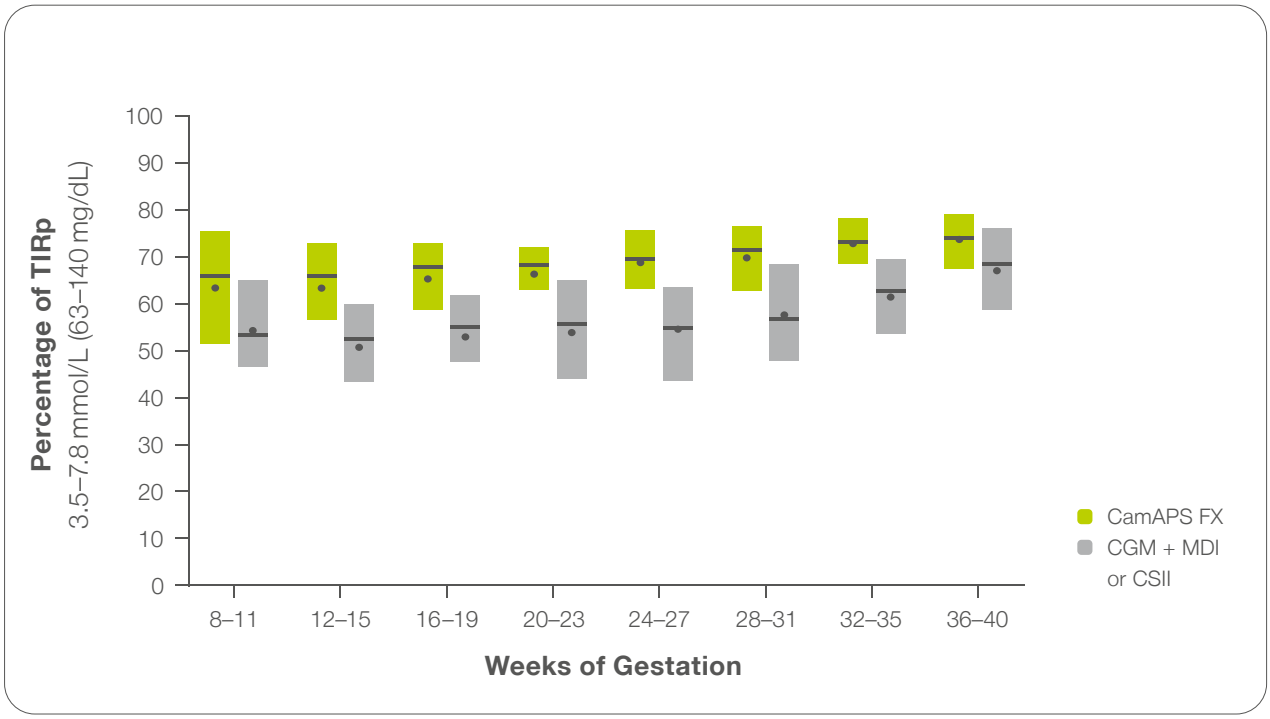


Fig: 4: Percentage of Time in the Pregnancy-Specific Target Glucose Range.

23 women using CamAPS FX were interviewed by qualitative researcher

- At randomisation: to explore their experience of managing diabetes during previous pregnancies (if relevant) and before using closed-loop.
- ~20 Weeks after randomisation: to explore their experience managing their pregnancy with CamAPS FX.

All these women reported more enjoyable pregnancy experiences as a result of using CamAPS FX hybrid closed-loop.[2]

> “Honestly, it allowed me to work. I would never be able ... to work at the job that I was doing [waitressing] at all, if I didn’t have the machine”
>
> **(participant 002)**

> “Before ... I was on it, like every couple of weeks I was having to keep changing all my basal rates and everything to try and keep up, whereas this just automatically does it, so it makes it much easier, it just takes a lot off you, like even the mental side of just constant viewing the data, it does all that for you.”
>
> **(participant 010)**

> “Sometimes I use [Boost] where I think the algorithm hasn’t been as generous as I think it needs it to be, because that’s just the algorithm still learning, because I’m extremely insulin resistant.”
>
> **(participant 022)**

> “In terms of enjoyment factor, and how I feel about the baby, and how I feel about the coming labour, and how excited I am to meet them and the bonding process and stuff like that, I’d say I’ve had a lot more time for it this time round.”
>
> **(participant 016)**

mylife Loop
CamAPS FX

mylife Loop is a hybrid closed-loop system using mylife CamAPS FX which is designed and indicated for use in pregnancy

Insulin is delivered with the mylife YpsoPump.

Glucose levels are measured by the Dexcom G6 or Abbott FreeStyle Libre 3 continuous glucose monitoring systems.

mylife CamAPS FX adjusts insulin delivery level every 8 to 12 minutes, based on the current and the predicted glucose levels.

Visit our website for detailed information about mylife Loop system: www.mylife-diabetescare.com

Abbr: CGM: Continuous glucose monitoring; **CSII:** Continuous subcutaneous insulin infusion; **MDI:** Multiple daily injection; **PGT:** Personal glucose target; **TAR:** Time above range; **TBRp:** Time below range in pregnancy; **TDD:** Total daily dose; **TIRp:** Time in range in pregnancy

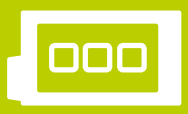
1 Lee TTM, et al. Automated Insulin Delivery in Women with Pregnancy Complicated by Type 1 Diabetes. N Engl J Med. 2023 Oct 26;389(17):1566-1578.
2 Lawton J. et al. Listening to women: experiences of using closed-loop in type 1 diabetes pregnancy. Diabetes Technol Ther. 2023 Oct 5.
3 Stewart Z. A. et al.: Closed-Loop Insulin Delivery during Pregnancy in Women with Type 1 Diabetes. N Engl J Med. 2016 Aug 18;375(7):644-54. doi: 10.1056/NEJMoa1602494
4 Stewart Z. A. et al.: Day-and-Night Closed-Loop Insulin Delivery in a Broad Population of Pregnant Women With Type 1 Diabetes: A Randomized Controlled Crossover Trial. Diabetes Care. 2018 Jul;41(7):1391-1399. DOI: 10.2337/dc17-2534
5 Stewart Z. A. et al.: Adaptability of Closed Loop During Labor, Delivery, and Postpartum: A Secondary Analysis of Data from Two Randomized Crossover Trials in Type 1 Diabetes Pregnancy. Diabetes Technol Ther. 2018 Jul; 20(7):501-505. DOI: 10.1089
6 Amercian Diabetes Association Professional Practice Committee, 15. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes-2022. Diabetes Care 2022;45(Suppl 1):S232-S243. doi: 10.2337/dc22-S015
7 Battelino T, el al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. Diabetes Care 2019;42(8):1593-1603

Disclaimer: The product images are for illustrative purposes only. // mylife and YpsoPump are registered trademarks of Ypsomed AG. // CamAPS is a registered trademark of CamDiab Ltd. // The sensor housing, FreeStyle, Libre, and related brand marks are marks of Abbott and used with permission. // Dexcom and Dexcom G6 are registered trademarks of Dexcom, Inc. in the United States and/or other countries. // The innovation described is available in selected countries and expanding to further countries soon. Expansion is contingent upon local regulatory approval. // mylife CamAPS FX is indicated for pregnancy in some countries and in the approval process in others. For specific information about your location, please contact Ypsomed Diabetes Care.

For safety information on mentioned products, see Instructions for Use or www.mylife-diabetescare.com/safety

mylife Diabetescare

More **freedom.**
More **confidence.**
With **mylife.**



Infusion systems

Blood glucose monitoring systems

Therapy management

Pen needles

With its mylife Diabetescare brand, Ypsomed offers a comprehensive portfolio of products and services for people with diabetes. This allows users easy, discreet and reliable self-treatment. With mylife Diabetescare, self-treatment becomes simpler and easier.

10382085-MSTR-en/V04

Ypsomed AG // Brunnmattstrasse 6 // 3401 Burgdorf // Switzerland //
info@ypsomed.com // www.mylife-diabetescare.com // +41 34 424 41 11

YPSOMED
SELFCARE SOLUTIONS