

ABSTRACT

Objective:

To collect real-world feedback on patient user experience, treatment satisfaction and adoption barriers with a novel bolus Patch insulin delivery system in diabetes patients requiring rapid-acting insulin (RAI).

Method:

This was a US-based, user evaluation of an FDA cleared, bolus Patch insulin delivery system (Calibra Medical, Inc.). A total of 44 adult diabetes patients (40 T2D and 4 T1D), median age 57 years (range 22-75), mean A1C 8.5%, and on meal-time RAI regimen, used bolus Patch in lieu of their current bolus injection device (75% pen & 25% syringe users; mean duration of use: 6 years) for a period of 60 days. Patients responded to insulin usage questionnaires at baseline, and after 1, 4, & 8 weeks of bolus Patch usage. Responses were coded on a scale of 1-5 (1=not at all likely/satisfied; 5=extremely likely/satisfied). No clinical endpoints were specified.

Results:

After 60-day usage, 86% of patients were extremely/ very satisfied with the bolus Patch system, 79% were extremely/ very likely to ask their HCP for a prescription, and 74% were likely to use bolus Patch as a replacement (60%) or in addition to (14%) their current delivery device. More than half the patients claimed that they would dose with the bolus Patch more often than with their previous device, and >50% of patients also cited instances where they dosed with bolus Patch and probably would not have dosed using their pen/syringe; most often noted were occasions outside the home. The bolus Patch let patients dose discreetly in public (98%), made it easier to dose insulin (95%), do a better job following insulin regimen (88%), worry less about forgetting insulin (88%), have a less stressful life (88%), and avoid painful mealtime injections (76%). Most patients reported a short learning curve and used the device without difficulties. While there were some reported initial adoption issues related to preparation of the device for use, wearability, skin sensitivity, and/or mechanical issues, these improved with ongoing patient education and experience.

Conclusion:

Overall, the bolus Patch usage led to high patient satisfaction, and helped overcome usage barriers associated with multiple daily insulin injections.

BACKGROUND



Figure 1 – Calibra Patch. A novel on-demand insulin delivery system that is easy to use, discreet & eliminates the need for mealtime injections. The Patch delivers 2 units RAI with each actuation of the buttons via a cannula and can be worn continuously for up to 3 days, complementing the continued use of existing basal therapy.

METHODS AND MATERIALS

A total of 8 Healthcare Professionals (HCPs)(4 PCPs and 4 Endocrinologists) were recruited in 3 US States (California, Pennsylvania, Florida) to identify/enroll/train 44 patients currently using 2+ injections of RAI (Humalog® or NovoLog®) via pen or syringe. Patient and HCP feedback generated via a series of online and telephone interviews.

RESULTS

- Baseline Patient Characteristics and Behaviors:
 - 40 T2D and 4 T1D, 55% female, median age 57 years, mean A1C 8.5%, mean BMI 36.2 kg/m², 48% < \$50K annual income, 17% some high school, 33% high school graduates, 22% some college, 26% college graduates and above
 - 93% take 3 or more injections per day.
 - Prefer being alone when injecting at home (41%) and away (71%).
 - 55% do not prime their pen before each use.
 - 61% of patients report not carrying their insulin away from home.
- Patient Training Calibra Patch
 - In 52% of the patients, ½ hour or less was spent on initial product training.
 - 84% reported the Patch was easy to learn to use.
 - 88% were fully comfortable using the Patch after 1-3 device experiences.

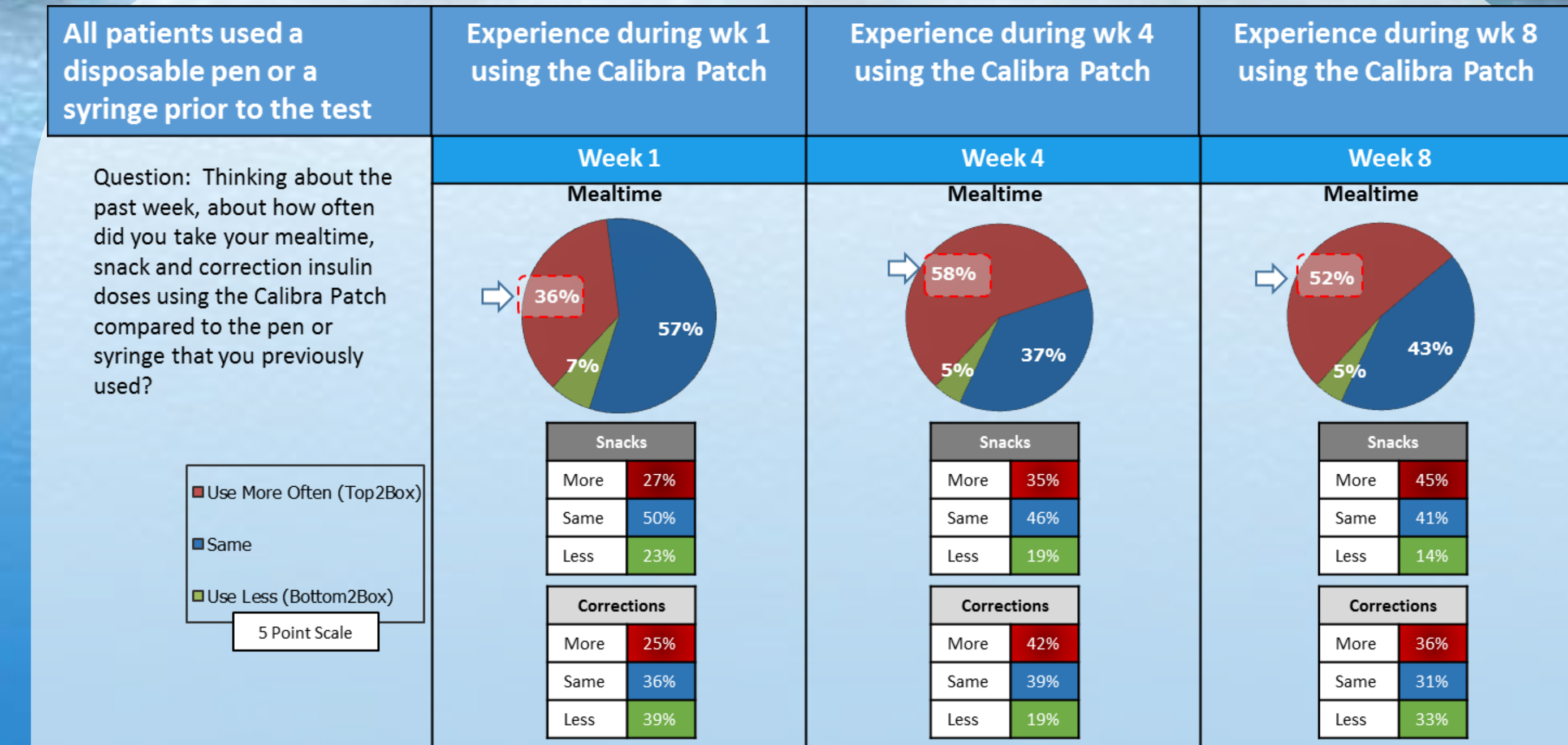


Figure 2 - Usage of the Calibra Patch vs. Pen or Syringe. Patients claim to dose more often with the Patch vs pen or syringe.

- Mealtime: By weeks 4 and 8, > 50% claim to dose more often with the Patch.
- Snacks: Increased bolus usage for snacks over time.
- Correction: Increased correction doses from week 1 to week 4 and week 8.

HCP Feedback

- HCPs (100%) satisfied at the end of 8-week usage period and likely to recommend.
- HCPs indicate: preference over pens (75%) and syringes (100%), easy to train (75%), patient satisfaction (100%), likely to start RAI sooner (75%); suitable for patients not at A1C goal (88%), at A1C goal (63%) and new to RAI (75%).

CONCLUSION

- The Calibra on-demand insulin delivery Patch is easy to train and easy to learn to use.
- With the Patch, patients report increased dosing at mealtime, snacks and for corrections.
- The Patch may be beneficial for patient adherence in patients on RAI or potentially new to RAI therapy.