**INTRODUCTION**

Prior adherence to treatment is common with all antidiabetic drugs (Jorgensen, 2017) and is associated with improved metabolic control, improved outcomes, and increased healthcare resource utilization (Carne et al., 2013). Differentiators (2014).

Non-adherence for twing type 2 diabetes is needed to provide adherence that is not being achieved.

ITCA 650 is an investigational drug device combination product that consists of an osmotic mini-pump that delivers exenatide (Figure 1) subcutaneously for five days. Three weekly/monthly pumps were evaluated in the ITCA 650 Phase 3 Clinical program (Figure 1).

**METHODS**

**Study Design**

- This was a Phase 2, open-label, single-site study (Figure 2).
- All subjects received an ITCA placebo osmotic mini-pump that looked identical to the ITCA 650 osmotic mini-pump used in the Phase 3 program.

**Results**

- **Primary objective:**
  - Assess the ability of the clinician to correctly place the ITCA 650 osmotic mini-pump in the abdominal wall using the Placement System.

- **Secondary objectives:**
  - Assess clinician’s ability to remove osmotic mini-pump.
  - Assess procedural feasibility.
  - For experienced clinicians, assess ease of use of the ITCA 650 Placement System based on previous experience with the Placement Tool.

**Study Population**

- All osmotic mini-pumps were placed within 17 minutes and removed within 16 minutes.

**Results**

- Mean (SD) removal time was 6.8 (3.5) and 9.9 (4.6) minutes in the Experienced and Novice groups, respectively.

**Analysis of Placement and Removal Procedures**

- Osmotic mini-pumps were correctly placed in all 20 subjects, regardless of clinician experience.

**Physician Survey Results**

- Most clinicians agreed that the Placement System was easy to use, was confident in its use, felt the instructions were more user and clinician friendly, that the time of placement was considerably easier, and that the ITCA 650 mini-pump was easier to use.

**CONCLUSIONS**

- Both Groups indicated satisfaction with their placement and had no procedural safety concerns.

- The Placement System represented the next step of the ITCA 650 placement tool.

- Based on these data the Placement System was introduced into the ITCA 650 clinical trials and has been successful at aiming the placement of osmotic subcutaneous delivery systems.

**REFERENCES**


