

**Abstract:**

**Background:** There is limited evidence supporting a replacement interval of infusion sets for continuous subcutaneous insulin infusion (CSII). The aim of this study was to investigate if steel and soft cannula infusion sets can be used in CSII therapy for up to 7 days without negative impact on infusion sites or glycemic control.

**Methods:** The insulin infusion sets YpsoPump® Orbit®micro (steel needle) and YpsoPump® Orbit®soft (soft cannula) were each used for up to 7 days by 40 adult subjects with CSII. Each subject used both infusion set types twice. Early replacement reasons were documented and glycemic control was monitored.

**Results:** Of 160 inserted insulin infusion sets, 66% were used for 7 days with no obvious difference between steel and soft infusion sets. The mean wearing time was  $6.2 \pm 1.5$  days. Main reasons for early infusion set replacements were occlusions (19%), plaster issues (4%), and accidental pull-out (4%). Comparing glycemic control during day 1-3 and 1-7, mean glucose was  $146 \pm 21$  mg/dL versus  $148 \pm 18$  mg/dL, coefficient of variation was  $34\% \pm 7\%$  versus  $33\% \pm 5\%$ , and insulin dose was  $40 \pm 11$  U versus  $41 \pm 11$  U. Only mild and nonserious infusion site reactions occurred.

**Conclusions:** In this study, 7 days indwelling time of insulin infusion sets did not show a clinically relevant impact on glycemic control or insulin requirements and the infectious risk appeared to be low. The replacement interval of infusion sets may be individualized beyond the currently labeled maximum use duration.

**Reference:**

Waldenmaier, D., Zschornack, E., Buhr, A., Pleus, S., Haug, C. and Freckmann, G. (2020) A Prospective Study of Insulin Infusion Set Use for up to 7 Days: Early Replacement Reasons and Impact on Glycemic Control. *Diabetes Technology & Therapeutics*. April 6th. doi: 10.1089/dia.2019.0445. (Epub ahead of print).