Survival assessment of the extended-wear insulin infusion set featuring lantern technology in adults with type 1 diabetes by the glucose clamp technique

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Abstract
Maintaining good glycaemic control with the same infusion set for longer than 3 days may improve the quality of life of insulin pump users. The aim of the current study was to assess the efficacy and safety of the novel, extended-wear infusion set over 7 days of wear in adults with type 1 diabetes. Sixteen participants completed three identical 8-hour euglycaemic clamp experiments on Days 1, 4 and 7 of infusion set wear. Between the experiments, the participants were discharged home for routine diabetes management while wearing the same extended-wear infusion set throughout the study. Time to reach the maximum glucose infusion rate (TGIRmax) on Day 7 was reduced by 67% compared with Day 1 (p < .001). The corresponding area under the glucose infusion rate curve (AUCGIR) was comparable for the first 2 h of the clamp (p = .891) but decreased by 28% over time (p < .008). While the extent of insulin absorption decreased with prolonged wear, it was accompanied by an increase in insulin absorption rate. The infusion set survival rate was 100% without leakages, occlusion alarms, severe hypoglycaemia or ketoacidosis. The extended-wear infusion set proved safe and effective during prolonged wear in real-life conditions.

KEYWORDS
clinical trial, CSII, insulin pump therapy, pharmacodynamics, pharmacokinetics, type 1 diabetes

INTRODUCTION

Modern insulin therapy aims to establish good glycaemic control without causing clinically relevant hypoglycaemia. Currently, continuous subcutaneous insulin infusion (CSII) therapy comes closest to achieving that goal.1–4 However, because of physiological and mechanical effects occurring at the infusion site, CSII may be associated with non-metabolic complications5,6 (i.e. local tissue inflammation, the effect of insulin solution preservatives on the infusion site, infusion set-related events) that affect insulin delivery leading to fluctuations in insulin absorption and eventually to deterioration of glycaemic control. Because the incidence and frequency of CSII complications increase over time, manufacturers of insulin pumps and infusion sets recommend changing the infusion set and rotating the infusion site every 2–3 days to ensure reliable insulin delivery.7–11 However, in practice, most individuals prefer to use one infusion set and one insertion site longer than recommended to avoid experiencing frequent insertion-related pain, but also to keep the cost of treatment down.
We investigated the efficacy and safety of the novel, extended-wear insulin infusion set featuring patented Lantern technology over 7 days of wear. The set includes a soft cannula with anti-inflammatory coating and additional openings in the form of multiple longitudinal perforations in the cannula shaft. The cannula coating is designed to suppress the foreign body response, while the shaft perforations compensate for fluctuations in insulin delivery because of kinking/crimping, or a partial/full cannula tip occlusion (Figure 1). Owing to the cannula design, the extended-wear infusion set may reduce the likelihood of non-metabolic CSII complications, thus enabling prolonged wear, consistent with patients’ wishes.

2 | METHODS

This open, single-centre, single-arm, controlled pilot study assessed the efficacy and safety of the novel, extended-wear insulin infusion set featuring Lantern technology in 16 experienced insulin pump users with type 1 diabetes over 7 days of wear. The study was approved by the Medical University of Graz ethics committee (EC number 29–566 ex 16/17) and the Austrian national health authority, and was entered into the German Clinical Trials Register (DRKS00013263). Signed informed consent was obtained prior to any study-related activities. The participants (five females and 11 males, age 44.2 ± 15.4 years, body mass index 24.5 ± 2.3 kg/m², diabetes duration 20.0 ± 9.0 years, HbA1c 7.2% ± 0.7% [55.3 ± 7.8 mmol/mol]) underwent a total of four identical 8-h long euglycaemic clamp experiments following bolus administration of 0.15 IU/kg body weight of insulin lispro (Humalog, Eli Lilly, Indianapolis, IN, USA) with the study-specific insulin pump (MiniMed 640G, Medtronic, Northridge, CA, USA). The first clamp experiment was performed with the standard infusion set (Inset II, Unomedical, Osted, Denmark) on the first day of infusion set wear to serve as baseline, while the remaining three clamp experiments were performed with the extended-wear infusion set on Days 1, 4, and 7 of infusion set wear. The participants spent the days between the experiments (Days 2, 3, 5 and 6) at home routinely managing their diabetes while wearing the same extended-wear infusion set in combination with the study-specific insulin pump and the flash glucose monitor (FGM; FreeStyle Libre, Abbott Diabetes Care, Alameda, CA, USA).

2.1 | Euglycaemic clamp experiment protocol

The participants were required to spend each clamp experiment fasting and on bed rest. Upon arrival at the research centre, they were fitted with the FGM (Day 1 only) and intravenous lines for frequent blood sampling and infusion of insulin and glucose. Prior to clamp start, the standard infusion set was primed with insulin lispro and inserted into the periumbilical subcutaneous adipose tissue to deliver insulin at a constant flow rate of 0.10 IU/h for the duration of the clamp. A variable intravenous infusion of human insulin (Actrapid, Novo Nordisk, Bagsvaerd, Denmark) in saline was started immediately thereafter and continued for 3 to 5 h to obtain a stable plasma glucose level of 5.6 ± 0.6 mmol/L 30 min prior to administering the subcutaneous insulin bolus (0.15 IU/kg body weight). Following bolus administration, the plasma glucose target concentration was maintained by tapering off the insulin infusion and discontinuing it when the plasma glucose dropped by 0.28 mmol/L relative to baseline. At this time, a variable intravenous glucose infusion (20% glucose; Fresenius Kabi, Bad Homburg, Germany) was started to maintain the plasma glucose target concentration for the rest of the clamp. The clamp was terminated 8 h after bolus administration or earlier if the plasma glucose level exceeded 8.3 mmol/L in the absence of glucose infusion. The plasma glucose concentration was determined at the bedside in 5–30-min intervals using a glucose-oxidase method (Super GL 2; Dr. Müller Gerätebau GmbH, Freital, Germany) with a coefficient of variation (CV) of less than 2%, while the plasma insulin concentration was determined as previously described,12 using radioimmunoassay (Lispro Insulin RIA, Merck Millipore, Burlington, MA, USA) with intra-assay CVs of 6.1%–19%.

Following the end of clamp, the participants switched to routinely managing their diabetes with the study-specific insulin pump while being observed overnight. The described clamp experiment was repeated the next day using the extended-wear infusion set. Upon completing the experiment, the participants were observed overnight again, and were discharged the next morning to spend the days between the remaining clamp experiments at home routinely managing their diabetes with the extended-wear infusion set while following their daily routine. While at home, the participants documented insulin doses and carbohydrate intake in a diary and frequently monitored their glucose with the FGM system along with performing seven capillary blood glucose measurements per day using the integrated blood glucose meter. If the measured blood glucose concentration consistently exceeded 16.7 mmol/L, the participants were instructed to test...
the capillary blood for ketones and administer a correction bolus with an insulin pen (Humalog KwikPen). The two remaining clamp experiments were performed with the extended-wear infusion set on Days 4 and 7 of infusion-set wear following the described clamp protocol.

2.2 | Data analysis

The data were checked for normality with the Shapiro–Wilk test. Depending on normality distribution, the variables were analysed using the mixed-effect model, the repeated measures ANOVA, or the Friedman test. In case of a significant result ($p < .05$), the data were compared by means of the paired $t$-test or the Wilcoxon signed rank test with an adjusted level of significance ($p = .0083$, for all pharmaco-dynamic endpoints, and the total daily insulin dose). All data are presented as median (25th–75th percentiles) or mean ± standard deviation.

3 | RESULTS

3.1 | Pharmacodynamics

Figure 2A shows glucose infusion rate profiles obtained following bolus administration of 0.15 IU/kg body weight of insulin lispro when using the standard and the extended-wear infusion set on Day 1 of infusion set wear. Although time to reach the maximum glucose infusion rate ($T_{GIRmax}$) was numerically considerably shorter with the standard compared with the extended-wear infusion set (67.5 [45–115] vs. 137.5 [72.5–147.5] min; $p = .046$), the numerical difference did not reach statistical significance, and the total area under the glucose infusion rate curve ($\text{AUC}_{GIR\ total}$) was similar between the sets (1042.3 [692.5–1311.5] vs. 874.2 [711.2–1130.1] mg/kg; $p = .197$) (Table 1).

Figure 2B shows glucose infusion rate profiles obtained following bolus administration of 0.15 IU/kg body weight of insulin lispro when using the extended-wear infusion set on Days 1, 4 and 7 of infusion-
set wear. While the area under the glucose infusion rate curve (AUCGIR) was comparable for the first 2 h of each clamp experiment (Day 1: 339.8 [250.9–458.5] mg/kg vs. Day 4: 458.8 [280.4–592.7] mg/kg vs. Day 7: 414.8 [228.2–540.8] mg/kg; p = .142), it significantly decreased throughout the rest of the experiment with prolonged infusion-set wear (Day 1: 874.2 [711.2–1130.1] mg/kg vs. Day 4: 856.3 [509–1074.4] mg/kg vs. Day 7: 630.3 [328.3–814] mg/kg; p = .03). The reduction in the extent of insulin effect observed on Day 7 was accompanied by a substantial increase in the insulin absorption rate, with TGIRmax reduced by 67% compared with Day 1 (Day 1: 137.5 [72.5–147.5] vs. Day 7: 45 [35–62.5] min; p < .001).

Additionally, the plasma glucose concentration variability, as expressed by the CV, did not significantly differ during the four clamp experiments (standard infusion set, Day 1: 5.7% ± 2.1%; extended-wear infusion set, Day 1: 5.0% ± 1.1%; Day 4: 5.8% ± 1.5%; Day 7: 5.2% ± 1.4%; p = .371) (Figure 3 and Table 2).

### 3.2 Pharmacokinetics

Both time to reach 50% of the maximum insulin concentration (TcINSmax50%) (Day 1: 23.3 [18.4–27.7] vs. Day 7: 12.8 [11.6–15.5] min; p = .011) and time to reach the maximum insulin concentration (TcINSmax) (Day 1: 60 [35–80] vs. Day 7: 27.5 [20–35] min; p = .016) were significantly shorter with prolonged infusion-set wear. There were no statistically significant differences in the maximum insulin concentration (CINSmax) and the area under the insulin concentration curve (AUCINS).

### TABLE 1 Summary of pharmacokinetic and pharmacodynamic variables of the standard and the extended-wear infusion set

| Variable | Standard infusion set Day 1 Median (25th–75th) | Extended-wear infusion set Day 1 Median (25th–75th) | p |
|----------|---------------------------------------------|---------------------------------------------|----|
| Pharmacodynamics | | | |
| GIRmax (mg/(kg*min)) | 7.3 (5.2–8.8) | 6.6 (4.1–8.4) | .482 |
| T GIRmax (min) | 67.5 (45–115) | 137.5 (72.5–147.5) | .046 |
| T GIRmax 10% (min) | 20 (15–25) | 20 (15–25) | .957 |
| T GIRmax 50% (min) | 32.5 (25–37.5) | 27.5 (22.5–45) | .971 |
| AUGCIR 0–60 min (mg/kg) | 152.9 (109.5–183) | 122.2 (84.5–172.7) | .276 |
| AUGCIR 0–120 min (mg/kg) | 396.7 (272.8–579.8) | 339.8 (250.9–458.5) | .279 |
| AUGCIR 0–240 min (mg/kg) | 809.5 (567.5–1140.5) | 734 (603.3–1009.1) | .377 |
| AUGCIR 0–360 min (mg/kg) | 1036 (692.5–1280.2) | 872.1 (709.1–1122.4) | .242 |
| AUGCIR total (mg/kg) | 1042.3 (692.5–1311.5) | 874.2 (711.2–1130.1) | .197 |
| Pharmacokinetics | | | |
| T INSmax 10% (min) | 8.2 (2.9–15.9) | 9.4 (6.2–18.1) | .052 |
| T INSmax 50% (min) | 28.8 (23.4–35.2) | 23.3 (18.4–27.7) | .728 |
| T INSmax (min) | 60 (40–70) | 60 (35–80) | 1.000 |
| CINSmax (pmol/L) | 461.4 (385.4–544.2) | 482.7 (384.5–561.3) | 1.000 |
| AUCINS 0–60 min (min*pmol/L) | 15,512 (9677–18,770) | 15,153 (12,901–19,803) | 1.000 |
| AUCINS 0–120 min (min*pmol/L) | 36,667 (29,719–46,196) | 36,944 (29,795–45,289) | 1.000 |
| AUCINS total (min*pmol/L) | 81,245 (49,308–96,847) | 69,063 (48,224–87,585) | .242 |

Abbreviations: AUGCIR 0-tmin, area under the GIR curve from 0 min until specified time point; AUGCIR total, area under the GIR curve from 0 min until clamp end; AUCINS 0-tmin, area under the insulin concentration curve from 0 min until specified time point; AUCINS total, area under the insulin concentration curve from 0 min until clamp end; CINSmax, maximum insulin concentration; GIRmax, maximum glucose infusion rate; T INSmax 10%, time to reach 10% of CINSmax; T INSmax 50%, time to reach 50% of CINSmax; T INSmax, time to reach CINSmax; T GIRmax, time to reach GIRmax; T GIRmax 10%, time to reach 10% of GIRmax; T GIRmax 50%, time to reach 50% of GIRmax.
In this study we assessed the efficacy and safety of the novel, extended-wear insulin infusion set featuring Lantern technology over 7 days of wear. We used the euglycaemic clamp technique to determine the pharmacokinetic and the pharmacodynamic properties of the extended-wear infusion set in adults with type 1 diabetes following subcutaneous bolus administration of 0.15 IU/kg of rapid-acting insulin on Days 1, 4 and 7 of infusion-set wear. We observed a reduction in the extent of insulin absorption that was accompanied by an increase in the insulin absorption rate with prolonged infusion-set wear. The study in humans examined the effects of prolonged infusion-set wear on insulin sensitivity in humans and swine. The study in humans investigated the effects of prolonged infusion-set wear on insulin sensitivity in humans and swine. The study in humans examined the effects of prolonged infusion-set wear on insulin sensitivity in humans and swine. The study in humans investigated the effects of prolonged infusion-set wear on insulin sensitivity in humans and swine. The study in humans examined the effects of prolonged infusion-set wear on insulin sensitivity in humans and swine. The study in humans investigated the effects of prolonged infusion-set wear on insulin sensitivity in humans and swine. The study in humans examined the effects of prolonged infusion-set wear on insulin sensitivity in humans and swine.

### 4 | DISCUSSION

In this study we assessed the efficacy and safety of the novel, extended-wear insulin infusion set featuring Lantern technology over

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**TABLE 2** Summary of pharmacokinetic and pharmacodynamic variables of the extended-wear infusion set

| Variable | Extended-wear infusion set Day 1 median (25th–75th) | Extended-wear infusion set Day 4 median (25th–75th) | Extended-wear infusion set Day 7 median (25th–75th) | p d1 vs. d4 | p d1 vs. d7 | p d4 vs. d7 |
|----------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|------------|------------|------------|
| **Pharmacodynamics** | | | | | | | |
| GIRmax [mg/(kg·min)] | 6.6 (4.1–8.4) | 7.5 (5.7–8.5) | 6.7 (4–7.2) | .151 | .595 | .065 |
| T GIRmax (min) | 137.5 (72.5–147.5) | 50 (40–80) | 45 (35–62.5) | .002 | <.001 | .215 |
| T GIRmax 10% (min) | 20 (15–25) | 20 (15–25) | 20 (15–20) | .948 | .755 | .709 |
| T GIRmax 50% (min) | 27.5 (22.5–45) | 30 (25–35) | 30 (22.5–30) | .610 | .305 | .425 |
| AUC GIR 0–60 min (mg/kg) | 122.2 (84.5–172.7) | 163.6 (136.1–210.2) | 156.6 (113.3–200.6) | .027 | .102 | .508 |
| AUC GIR 0–120 min (mg/kg) | 339.8 (250.9–458.5) | 458.8 (280.4–592.7) | 414.8 (228.2–540.8) | .060 | .891 | .223 |
| AUC GIR 0–240 min (mg/kg) | 734 (603.3–1009.1) | 815.8 (501–1017.9) | 630.3 (328.3–811) | .533 | .021 | .037 |
| AUC GIR 0–360 min (mg/kg) | 872.1 (709.1–1122.4) | 856.3 (509–1074.4) | 630.3 (328.3–814) | .173 | <.008 | .034 |
| AUC GIR total (mg/kg) | 874.2 (711.2–1130.1) | 856.3 (509–1074.4) | 630.3 (328.3–814) | .177 | <.008 | .033 |

**Pharmacokinetics**

| Variable | Extended-wear infusion set Day 1 median (25th–75th) | Extended-wear infusion set Day 4 median (25th–75th) | Extended-wear infusion set Day 7 median (25th–75th) | p d1 vs. d4 | p d1 vs. d7 | p d4 vs. d7 |
|----------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|------------|------------|------------|
| T CINSmax 10% (min) | 9.4 (6.2–18.1) | 4.5 (0–7.9) | 6.2 (5.8–7.2) | .052 | .052 | .052 |
| T CINSmax 50% (min) | 23.3 (18.4–27.7) | 14.9 (13.5–17.5) | 12.8 (11.6–15.5) | .011 | <.001 | .193 |
| T CINSmax (min) | 60 (35–80) | 35.5 (30–40) | 27.5 (20–35) | .243 | .016 | .000 |
| C INSmax (pmol/L) | 482.7 (384.4–561.3) | 553 (352–699) | 517.8 (290.7–763.8) | .521 | .000 | .000 |
| AUC INS 0–60min (min·pmol/L) | 15,153 (12,901–19,803) | 21,979 (13,580–28,960) | 21,173 (10,838–30,405) | .040 | .802 | .000 |
| AUC INS 0–120min (min·pmol/L) | 36,944 (29,795–45,289) | 40,941 (24,079–56,289) | 41,248 (14,294–48,145) | .000 | .000 | .766 |
| AUC INS total (min·pmol/L) | 69,063 (48,224–87,585) | 63,685 (43,857–86,341) | 50,770 (28,792–70,679) | .770 | .040 | .019 |

Abbreviations: AUC GIR 0–min, area under the GIR curve from 0 min until specified time point; AUC GIR total, area under the GIR curve from 0 min until clamp end; AUC INS 0–min, area under the insulin concentration curve from 0 min until specified time point; AUC INS total, area under the insulin concentration curve from 0 min until clamp end; C INSmax, maximum insulin concentration; GIRmax, maximum glucose infusion rate; T CINSmax 10%, time to reach T CINSmax 50%, time to reach TCINSmax 10% of C INSmax; T CINSmax, time to reach C INSmax; T GIRmax, time to reach GIRmax; T GIRmax 10%, time to reach 10% of GIRmax; T GIRmax 50%, time to reach 50% of GIRmax.
In summary, although this pilot study is limited because of its small population size, the non-randomized design and the lack of a control group, the data presented suggest that the novel, extended-wear insulin infusion set featuring Lantern technology safely maintains glycemic control during prolonged wear.

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**CONFLICT OF INTEREST**

PKS, MH and TS are ConvaTec employees. TRP is an advisory board member of Novo Nordisk A/S, consultant for Roche Diabetes Care, Novo Nordisk A/S, Eli Lilly & Co, Infineon, Carnegie Bank, shareholder of decide Clinical Software GmbH, and is on speaker's bureau of Novo Nordisk A/S and Astra Zeneca. JKM is an advisory board member of Abbott Diabetes Care, Boehringer Ingelheim, Becton-Dickinson, Eli Lilly, Medtronic, Merck Sharp & Dohme GesmbH, Roche Diabetes Care and Sanofi-Aventis GmbH, a shareholder of decide Clinical Software GmbH, and has received speaker honoraria from Abbott Diabetes Care, Astra Zeneca, Dexcom, Eli Lilly, Medtronic, Novo Nordisk A/S, Roche Diabetes Care, Sanofi-Aventis GmbH, Servier and Takeda. The other authors declare no competing interests.

**AUTHOR CONTRIBUTIONS**

AS, TP and DN performed the study, interpreted data, contributed to discussions. AS, JKM and TA drafted the manuscript. WR, TRP, MH, TS and PKS contributed to discussions and interpreted data. TA, AGS and AS performed statistical analysis and interpreted data. JKM designed the study, interpreted data, contributed to discussions, supervised the project and is the guarantor of this work. All the authors critically revised and approved the final version of the manuscript.

**PEER REVIEW**

The peer review history for this article is available at https://publons.com/publon/10.1111/dom.14337.

**DATA AVAILABILITY STATEMENT**

Data are available with the authors upon request.

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