ASSESSMENT OF THE SAFETY, EFFICACY AND USABILITY OF THE QUANTA SC+ HAEMODIALYSIS SYSTEM

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Introduction and Background

Ten per cent of the worldwide adult population have some form of kidney damage, and every year millions die prematurely of complications related to Chronic Kidney Disease (CKD)[1], with 2.8 million End Stage Renal Disease (ESRD) patients routinely receiving dialysis[2]. The vast majority of patients dialyse 3 times a week, in-centre with limited treatment alternatives. Quanta Dialysis Technologies has developed a high-performance, compact, easy-to-use haemodialysis (HD) system called SC+. The SC+ system is designed to bring flexibility to the dialysis community by allowing a greater choice in treatment frequency, setting location and regimen for dialysis patients. Quanta is conducting a Post Market Clinical Follow-up (PMCF) study to assess the safety, efficacy and usability of SC+. This interim analysis reports the results of the first 255 treatments completed and provides an update on the results previously reported[3].

Study Design

An anonymised open-label, single-arm, pilot study was conducted with ESRD subjects receiving regular haemodialysis, weighing 50 kg or over and aged over 18 years. Each clinic's Principal Investigator (PI) selected the patients on a volunteer basis. Each dialysis therapy was performed at an outpatient clinic using bicarbonate-buffered dialysate at a flow rate (Qd) of 500 ml/min. Vital signs were recorded, nominally every 30 minutes, and subject symptoms were monitored during every treatment and adverse events were recorded. Blood samples for clinical laboratory evaluations of chemistry and haematology were taken pre- and post-dialysis in 55 of the 255 completed dialysis sessions and subjects' mass was recorded before and after each treatment. Clinical performance of SC+ was assessed by StdKt/V and URR for the study population and usability feedback was collected.

Results

A total of 43 subjects with a mean age of 62 were evaluated as follows: 40 subjects on a 3 times weekly dialysis regimen, 1 subject on a 4 times weekly regimen and 2 subjects on a 5 times weekly regimen. 255 dialysis treatments were completed without any device-related adverse events or safety issues to report. Subjects were selected by the PI at the clinic in-line with the stated intended use of SC+, with subjects' dry weights ranging from 50 to 161.5 kg. Table 1 summarises the dialysis specification ranges across the therapies.

Number of Subjects	43
Number of Treatments	255
Date Range	30 June 2015 - 13 April 2016
Patient Age Range (years)	22 to 85
Patient Gender Split	24 Males, 19 Females
Dry Weight Range (kg)	50 to 161.5
Anti-Coagulant Type	Enoxaparin, warfarin and enoxaparin, warfarin only
Enoxaparin Total Dose (mg)	0-60
Needle Size (G)	14,15,15 buttonhole, 16
Vascular Access	Right Radial AVF Right Brachial Cephalic AVG Left Brachial Cephalic AVF Left Brachial Cephalic AVG Left Femoral Graft
Blood Pump Speed (Qb) Range (ml/min)	220 - 450
Dialyser Size Range	FX-60, FX-80, FX-100, Polyflux 210 and Polyflux 210H
Dialysate Flow Rate Qd (ml/min)	500

AVF = Arteriovenous Fistula; AVG = Arteriovenous Graft

Table 1: Dialysis specification ranges for the 255 treatments

The association between ultrafiltration (UF) target and net fluid removal (NFR) achieved was assessed and is displayed in figure 1. NFR achieved was determined by measuring the difference in patient mass before and after treatment (by using clinical scales) and corrected for priming, washback volumes and total oral intake. The mean duration of each treatment was 232.6 minutes, with a mean blood flow rate and dialysate flow rate of 356 ml/min and 500 ml/min, respectively. The range of blood pump speeds programmed on SC+ for the study population are displayed in figure 2, with a study max of 450 ml/min.

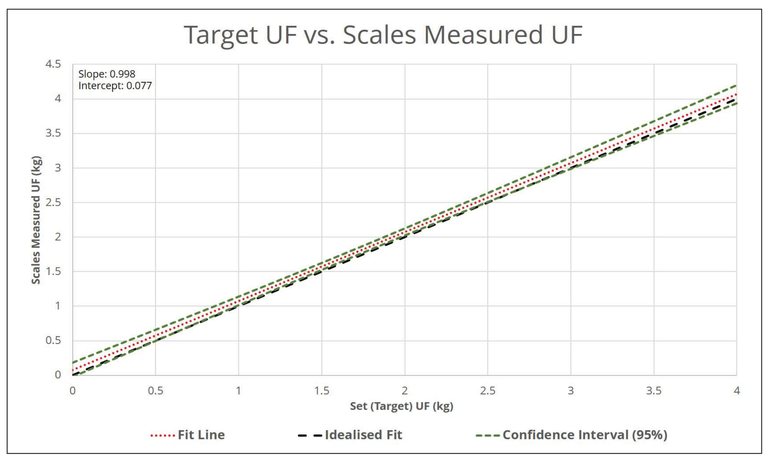

Figure 1: Target ultrafiltration on SC+ plotted against the actual fluid removed by weight change pre- and post-treatment.

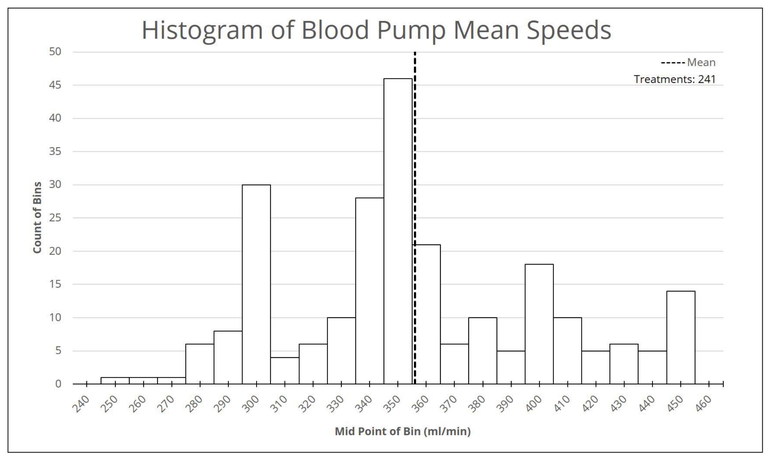

Figure 2: Blood pump mean speeds across the 255 treatments.

Standardised Kt/V

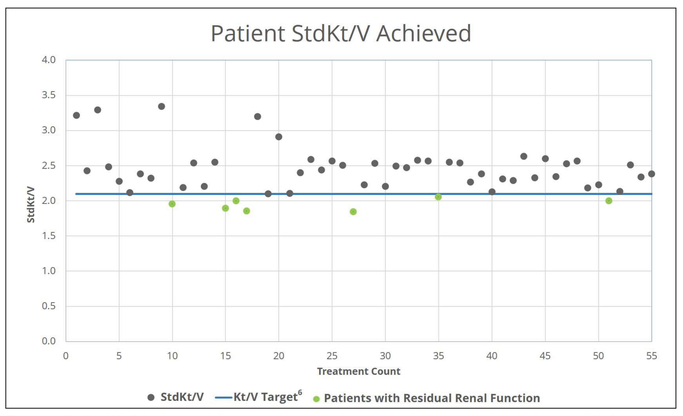

Figure 3: StdKt/V plotted for study population relative to the target of 2.1

Clinical performance of SC+ was determined by measuring the standardised weekly Kt/V for the study subjects. Dialysis dose delivered by SC+ was calculated[4] as weekly standard urea Kt/V (StdKt/V) from spKt/V as per the monthly blood collection routine at the clinic. Figure 3 plots the StdKt/V where blood samples were collected pre- and post-treatment. Subjects on a 5 times weekly dialysis regimen displayed higher clearance values, with a study maximum of 3.34. Apart from 7 values where the patient had residual renal function, all data points were above StdKt/V 2.1, as recommended by Gotch[5] as a weekly adequacy equivalence target. Clinical performance was further demonstrated by a mean urea reduction ratio (URR) of 73.3% for the study population, surpassing the recommended guidelines of 65%[6] for all treatments.

Usability Observations

SC+ usability feedback collected from nurse operators and study subjects post-treatment did not identify any significant usability issues. Below are highlights of the most common observations provided as open ended feedback:

- System size is small and compact (n = 18)
- Subjects like the simplicity of the system for potential self-care (n = 15)
- Step wise instructions on the dialysis process flow praised for ease of use (n = 15)
- Disposable dialysate cartridge reduces machine cleaning time between treatments (n = 3)

Discussion

SC+ performed consistently across the 255 treatments. Table 2 summarises the SC+ technical measurements taken for each treatment to monitor performance. UF performance was assessed by comparing UF target with NFR achieved, which was calculated based on changes in patient mass. UF performance was acceptable, with both the target UF and the actual UF achieved averaging 1.8 kg.

	Mean ± StdDev
Mean Treatment Time (min)	232.6 ± 30
Blood Pump Speed (ml/min)	356 ± 46
Dialysate Temperature (°C)	36.58 ± 0.42
Dialysate Conductivity (mS/cm)	13.79 ± 0.18
Target UF (kg)	1.80 ± 0.91
Measured NFR (kg)	1.80 ± 0.98
Arterial Pressure (mmHg)	-120 ± 36
Venous Pressure (mmHg)	175 ± 36

Table 2: Technical performance of the SC+ measured by stability of the dialysate temperature and conductivity; total therapy time and UF error within acceptable limits for study population.

Conclusions

This PMCF study supports the safety and performance of SC+ with acceptable clinical and technical performance in the dialysed ESRD subject population. There was no measured loss of therapy time, UF error was acceptable, no significant usability issues were noted, and there were no safety issues or device-related adverse events to report. Clinical performance was demonstrated by subjects attaining a weekly StdKt/V of greater than 2.1, recommended as a weekly adequacy equivalence by Gotch[5]. The maximum achieved study StdKt/V was 3.34. Clinical performance was further demonstrated by a mean study URR, of 73.3%, surpassing the recommended guidelines of 65% for 3 times weekly dialysis. Results overall demonstrate that patients dialysed with SC+ achieve adequate clearance using standard treatment regimens traditionally used in-centre.

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