MECHANICAL VERSUS ELECTRONIC SUBCUTANEOUS INFUSION SYSTEMS: PHASE I REAL-WORLD EVIDENCE ON MECHANICAL INFUSION SYSTEM USABILITY, SAFETY, AND PATIENT EXPERIENCE

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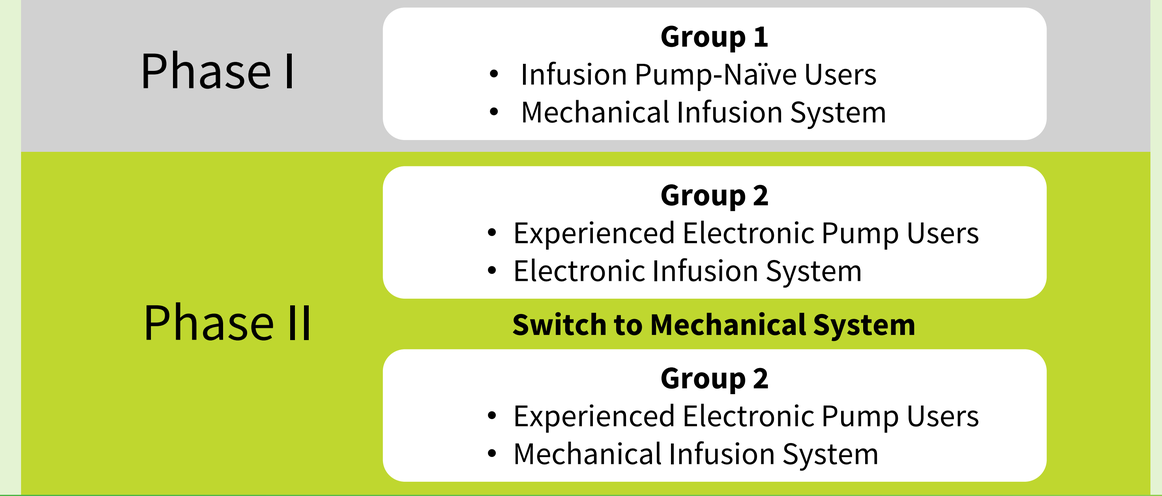
INTRODUCTION AND AIM

Subcutaneous (SC) infusion pumps are widely used for administration of high-volume therapies. The two primary infusion systems, electronic and mechanical, differ in functionality, training requirements, and user interaction. This study compares patient satisfaction between systems and evaluates ease of use, performance, and safety, including handling, instructions, troubleshooting, discomfort, and pain.

METHODOLOGY

This ongoing, multi-phase, cross-sectional study includes adult and pediatric patients across Europe receiving SC immunoglobulin (IG) therapy for primary or secondary immunodeficiency (PID or SID). Structured questionnaires using a 5-point Likert scale (1 = negative; 5 = positive) are used to collect feedback from two groups: infusion pump-naïve patients (Group 1) and experienced electronic pump users (Group 2). In Phase I, Group 1 evaluated the mechanical system; in Phase II, Group 2 will first evaluate the electronic system and then switch to the mechanical system for comparison.



RESULTS

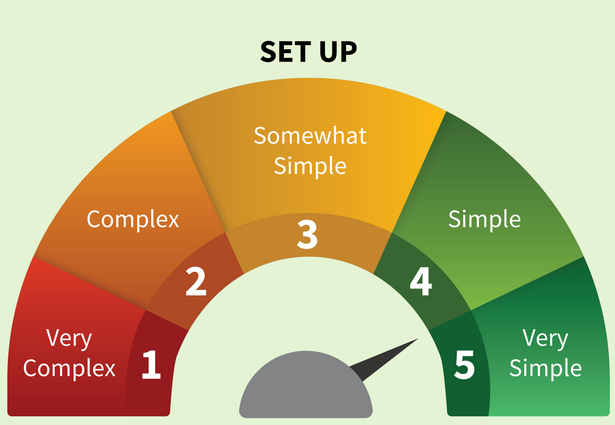
Study Participants

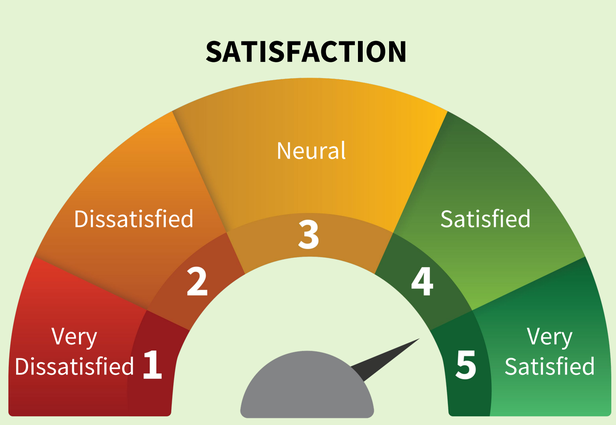
- Preliminary data from 33 infusion pump-naïve participants using the mechanical system were analyzed.
- The largest patient group was under 18 years old (39%), followed by those over 55 years old (24%).
- Out of the 33 participants, most were male (58%), and 29 were diagnosed with PID and four (4) with SID.
- Almost half of the participants were diagnosed more than five (5) years ago (49%) and 25 participants (76%) had prior intravenous IG treatment.

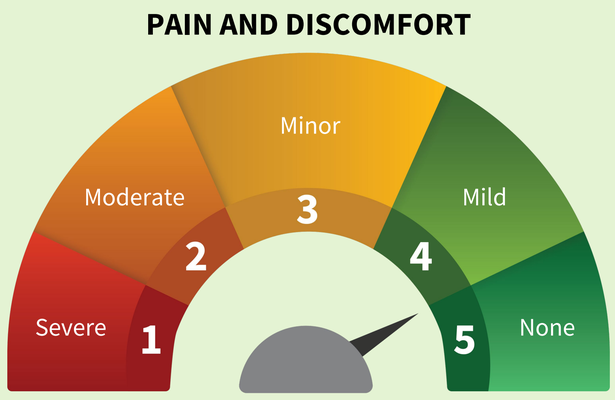
Category	Subgroup	n	%
Participants in Phase I		33	100%
Age	<18 years	13	39%
	18–55	12	37%
	>55 years	8	24%
Sex	Male	19	58%
	Female	14	42%
Diagnosis	PID	29	88%
	SID	4	12%
Time Since Diagnosis	>5 years	16	49%
Prior IVIG Treatment	Yes	25	76%

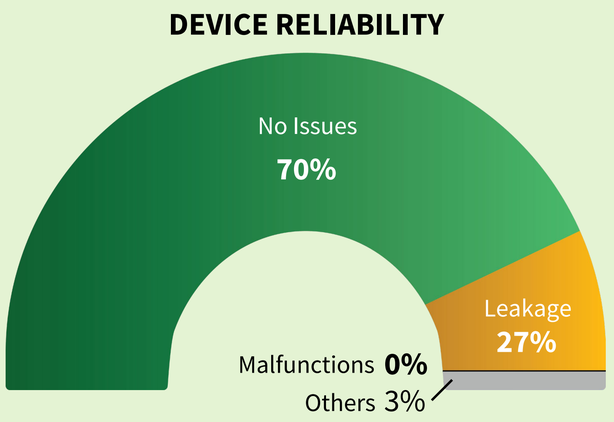
Phase I Ratings

- Ratings for set-up and ease of use ranged from 4 to 5 (e.g., simple to very simple) with narrow interquartile ranges, indicating high and consistent satisfaction.
- Device reliability was rated positively: 70% reported no issues, while 27% noted leakage. No malfunctions were reported.
- Overall satisfaction scores were strong with ratings of 4 [4, 5] or 5 [5, 5] (satisfied to very satisfied).
- When asked for suggested improvements, 13% requested simplified instructions, while another 13% reported that no improvements were needed.









Safety

Regarding safety, several questions related to pain and discomfort during the infusion were asked and median scores for pain and discomfort ranged from 4 to 5 (mild to no pain or discomfort), indicating a favorable user experience and acceptance of the mechanical pump in this population.

CONCLUSIONS

This first head-to-head, real-world comparison of electronic and mechanical SC infusion pumps provides key insights into user experience and satisfaction. Phase I results demonstrate high satisfaction and minimal issues with the mechanical pump. Results from Phase II will offer direct comparison and further inform healthcare providers and pharmaceutical manufacturers in selecting a patient-preferred, high-performing infusion system.

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