



# ENHANCING PUMP ADOPTION THROUGH ERGONOMIC DESIGN: FIRST USER ASSESSMENT AND APPRECIATION OF SIGI™, A NOVEL PATCH PUMP TO BE USED WITH NOVORAPID® PUMPCART®



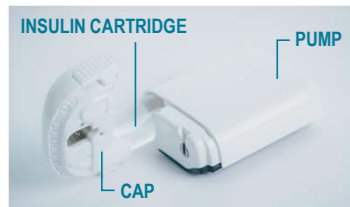
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## Background and Aims

Insulin pumps enjoy widespread appreciation, but unmet user needs remain. This end-user acceptance trial evaluated a novel patch pump (brandname Sigi™) during 7 days in daily-life situations (physical activity, water, etc.). Sigi™ is designed for improved user ergonomics, and to be used with NovoRapid® PumpCart®.

## Sigi™: description of system components



- **PUMP** reusable and rechargeable
- Readily available **prefilled cartridges**
- Disposable closure **CAP**



- Disposable **PAD** with **tubing**
- One-Click **applicator**
- PAD pre-loaded in applicator



- **Quick ON / OFF**
- Dis- and re-connection 'on the fly'



- **USB charger**
- Each user receives **2 pumps**
- **LED indicator** for charging status

Sigi™ arm wear:



Sigi™ abdominal wear:



## Methods

### Study design

- Prospective, open-label, observational usability study

### Study center

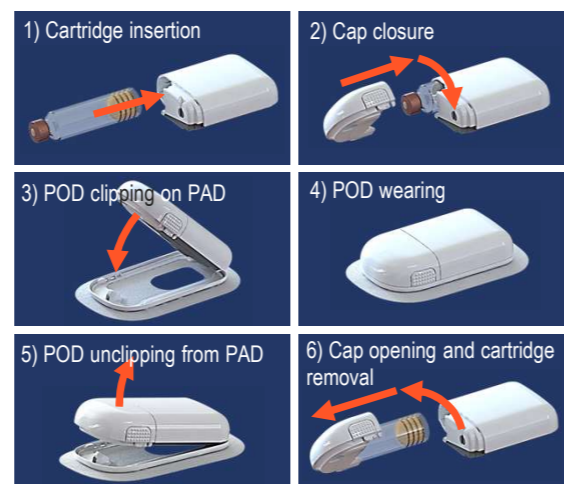
- CHUV university Hospital, Lausanne (Switzerland)
- Study conducted 22 July – 16 September 2020

### Study population

- 15 patients with type 1 diabetes
- Prior Continuous Subcutaneous Insulin Infusion (CSII) experience (patch or tethered pump users)
- Age: 35 ± 16 years old (Range 18 -70 years)
- BMI: 25 ± 3 (21 -32)
- Treatment at enrolment:
  - MDI: 2
  - Tethered pump: 8
  - Patch pump: 5

### Tasks and features evaluated

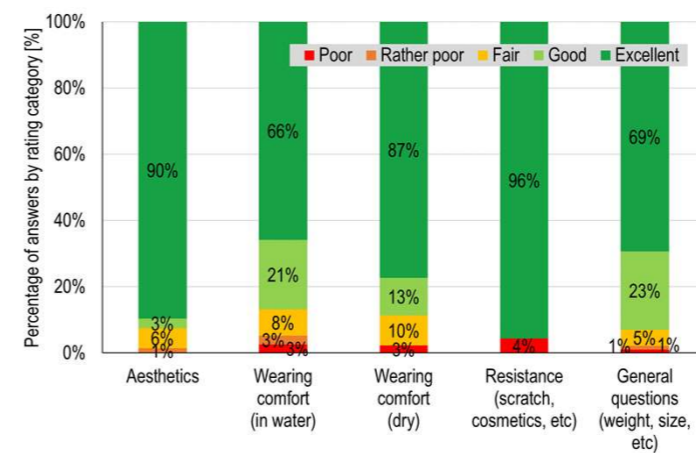
The participants evaluated Sigi™ during one week at home. The protocol defined wearing and intensive handling during 7 days. Questionnaire data was collected at days 1, 4 and 7.



## Results and Conclusions

### User ergonomics and comfort

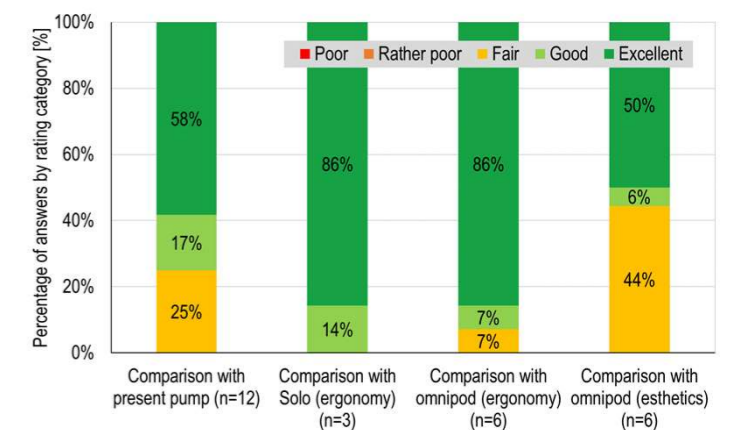
- Usability (handling of cartridge and pump) rated as "excellent", regardless of subjects' age and BMI
- High appreciation of wearing comfort in both wet (shower / bath / aquatic sport) and dry environment
- Favorable size / weight / form factor



### Comparative user preference

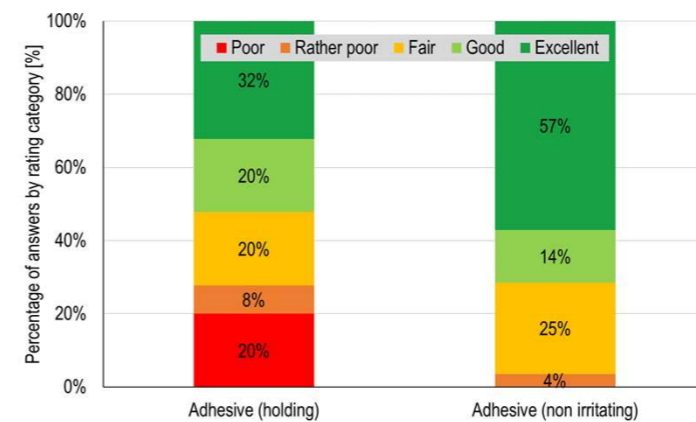
- 75% favorable vs. tethered pumps
- 100% preference vs. Solo patch pump
- 93% ergonomics preference and 56% design preference vs. Omnipod.

No significant rating differences over time: general acceptance was high from the first day to the last.



### Skin adhesion and safety feeling

- Twelve pumps (80%) held on skin for more than 3 days; 5 (33%) for 7 days or more
- First generation of PAD adhesive tape required re-design for better adhesion and skin tolerability



### Willingness to change to Sigi™

- Overall, 69% high willingness to adopt Sigi™
- Patch pump users display higher willingness to change than tethered pump users
- High MDI users willingness to adopt Sigi™

