



Acceptability and safety of 3D printed wrist-based splints compared to plaster casts for the treatment of non-surgical distal radius- and scaphoid fractures: feasibility study.

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Background

Splint comfort and optimal return of hand function are important issues in the rehabilitation of conservatively treated distal radius and scaphoid fractures. To date, applying a plaster cast for approximately 6 weeks of immobilization is the gold standard. However, these splints are often cumbersome, restricting hand use for light activities while wearing the splint. New 3D technologies such as the design of Patient Specific Anatomical Braces (PSAB) might, therefore, be a good alternative to immobilize such fractures. To design such PSAB, the fractured limb must be scanned, printed in a 3D printer and finally fitted to the patient's forearm ^[1].

Objective

The primary objective of this study is to assess if the patients' personal experiences and perceptions of safety and satisfaction are superior in the PSAB compared to a custom-made plaster cast while using the hand for light daily activities.

Research project

The research project is organized in two phases:

Phase I: A pre-clinical study conducted with 10 healthy volunteers testing the 3D-splint for 72h. The volunteers completed the self-designed "adult rated splint evaluation questionnaire". A splint satisfaction score of $\geq 70\%$ was a prerequisite to start with phase II:

Phase II: For the feasibility study, a criteria sample of 20 adult patients is recruited and randomly assigned to either the 3D splint or plaster cast group. The patients complete the self-designed "patient-rated splint evaluation questionnaire" (PRSE). The study duration is planned from 01/07/2021 to 31/12/2022.

Phase I: development of 3D printed wrist-based splints

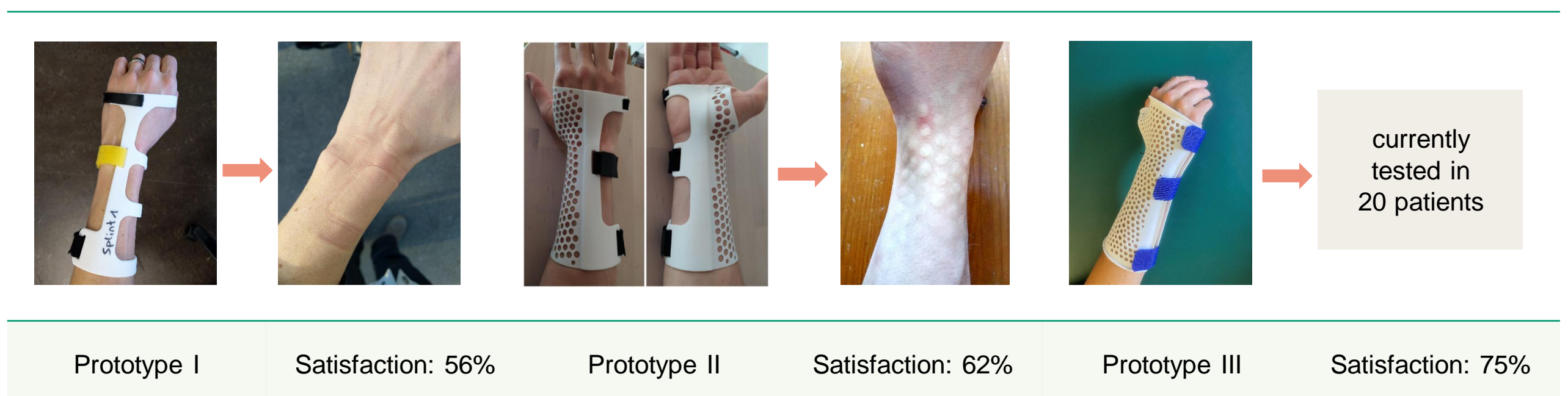


Figure 1: development of the optimal PSAB for distal radius and scaphoid fractures

In collaboration with the hand therapy and -surgery department of the University Hospital in Bern, the company Swibrace SA developed different PSAB (Figure 1).

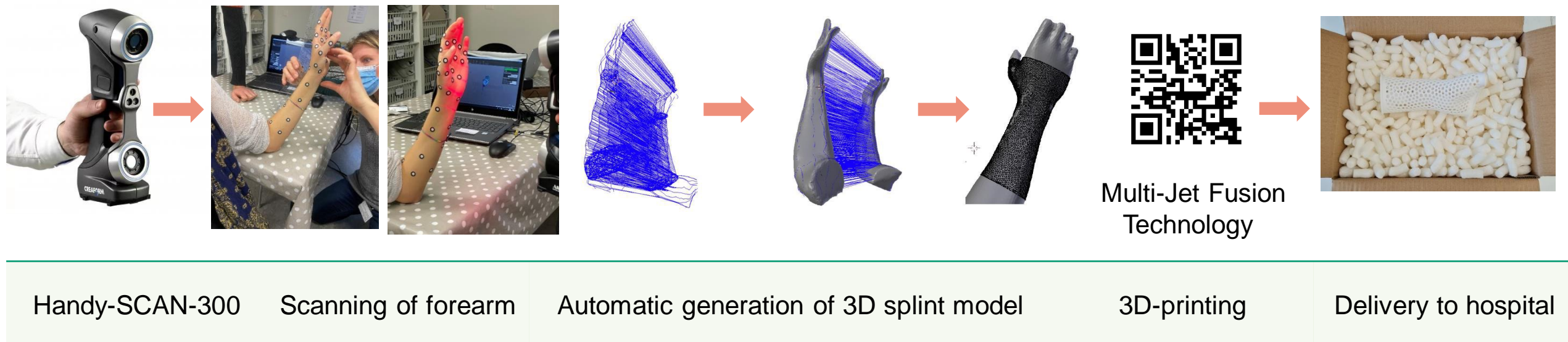
As the total satisfaction score of the 10 healthy volunteers exceeded the targeted 70% after the third pre-clinical testing round in April 2021, patient recruitment testing prototype III started in July 2021.

References

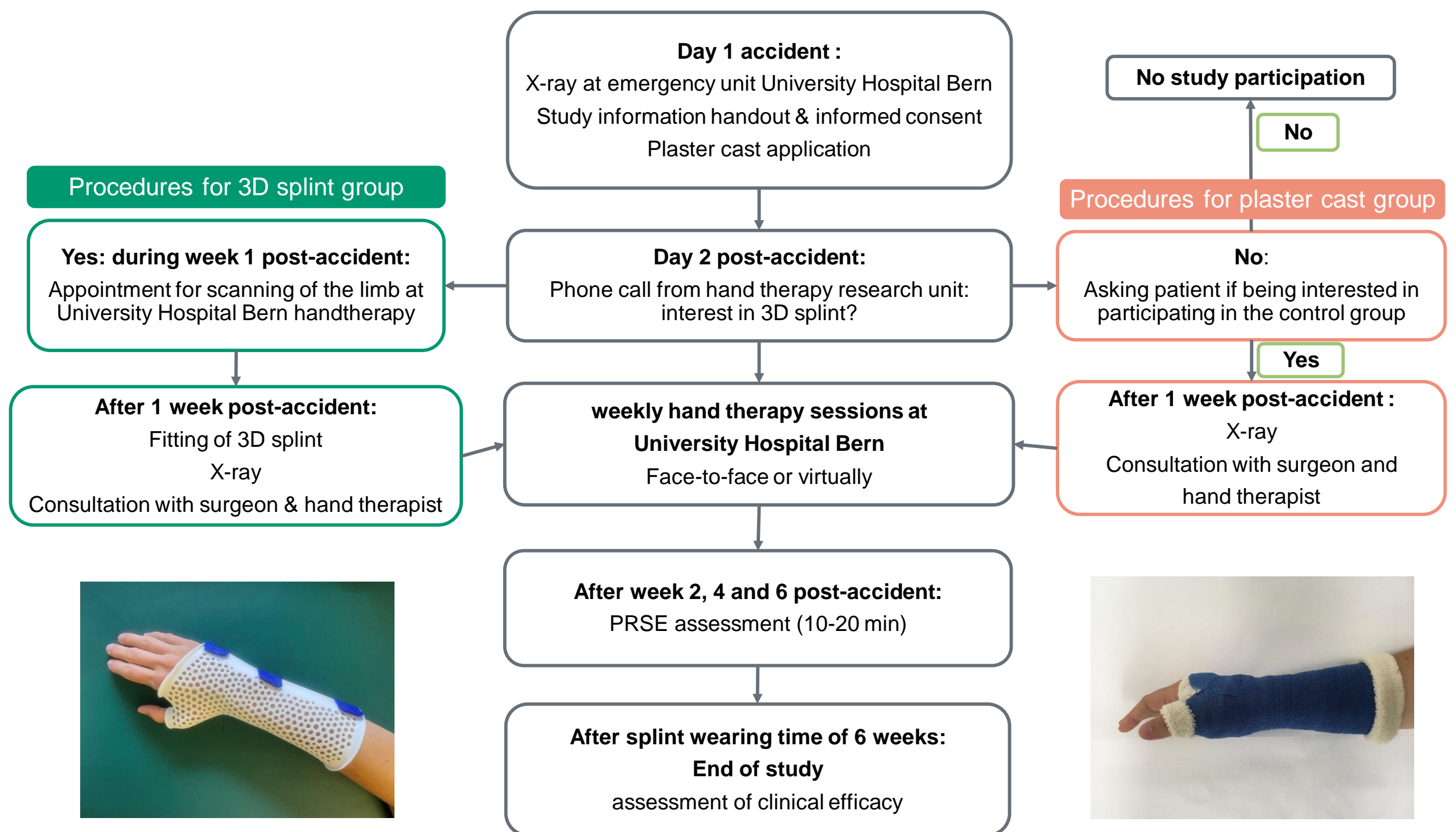
^[1] Patterson, R. M., Salatin, B., Janson, R., Salinas, S. P., & Mullins, M. J. S. (2020). A current snapshot of the state of 3D printing in hand rehabilitation. *J Hand Ther*, 33(2), 156-163.



Phase I & II: scanning procedure



Phase II: study procedure



Outcome measurements

Content

Rating

Self-designed "patient-rated splint evaluation" (PRSE) questionnaire ^[2]	Relating to the splint: pain, personal experience, safety, hand function, satisfaction	Patient-rated 11-point Likert-Scale after 2 & 4 weeks of splint wearing time and after splint removal
Assessment of patient satisfaction ^[3]	Patient comfort, patient compliance, splint odor and smell, skin itchiness	Assessed by the treating hand therapist on a 4-point Likert-Scale on a weekly basis until splint removal
Assessment of clinical effectiveness ^[3]	Stability of immobilisation, blood circulation, wear pressure-related pain, pressure sores	Assessed by the treating surgeon on a 4-Punkte Likert-Scale during splint removal

References

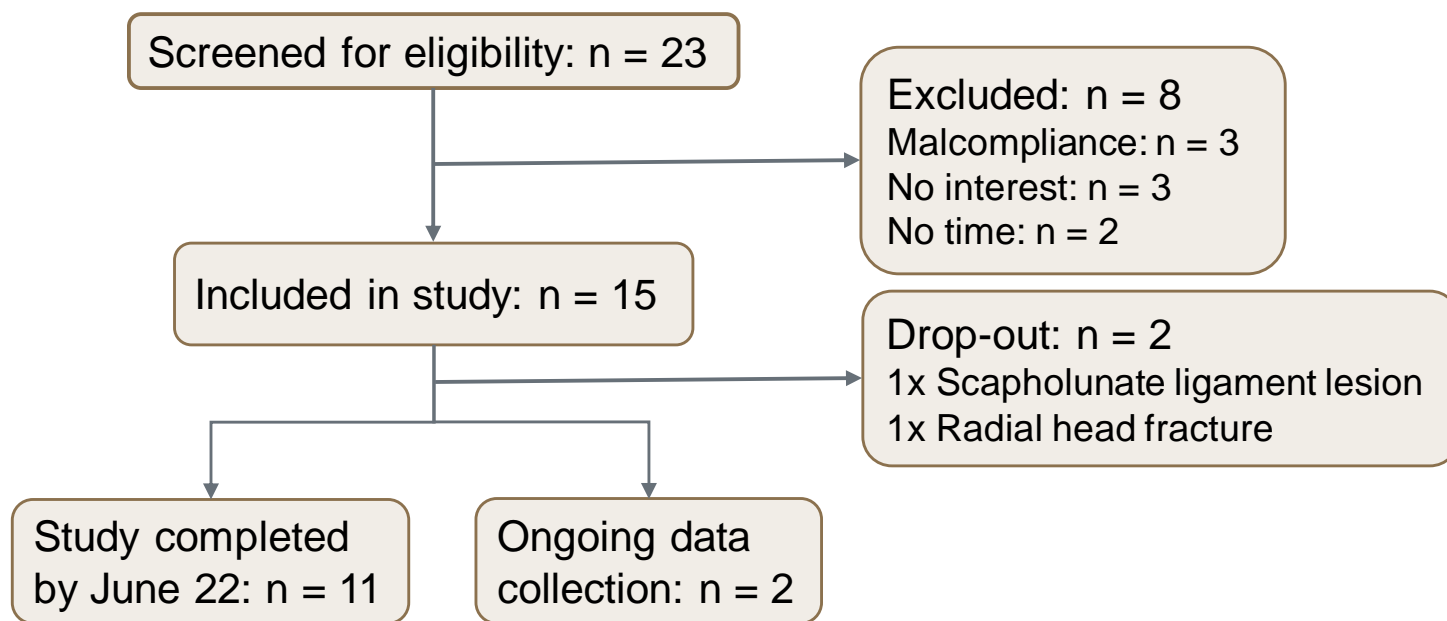
^[2] Edwards P. Questionnaires in clinical trials: guidelines for optimal design and administration. *Trials*. 2010;11:2.

^[3] Chen Y, Lin H, Yu Q, Zhang X, Wang D, Shi L, et al. Application of 3D-Printed Orthopedic Cast for the Treatment of Forearm Fractures: Finite Element Analysis and Comparative Clinical Assessment. *Biomed Res Int*. 2020; 2020:9569530



Phase II: preliminary results of feasibility study

Study flow chart



Demographics

	3D-group	Cast-group
Patients (n)	5	6
Age in years (mean)	32	31
Sex (m / f)	4 / 1	4 / 2
Handedness (r / l)	5 / 0	6 / 0
Injured forearm (r / l)	1 / 5	1 / 4
Type of splint (Scaphoid / Radius)	4 / 1	4 / 2

Patient-rated splint evaluation (PRSE) questionnaire

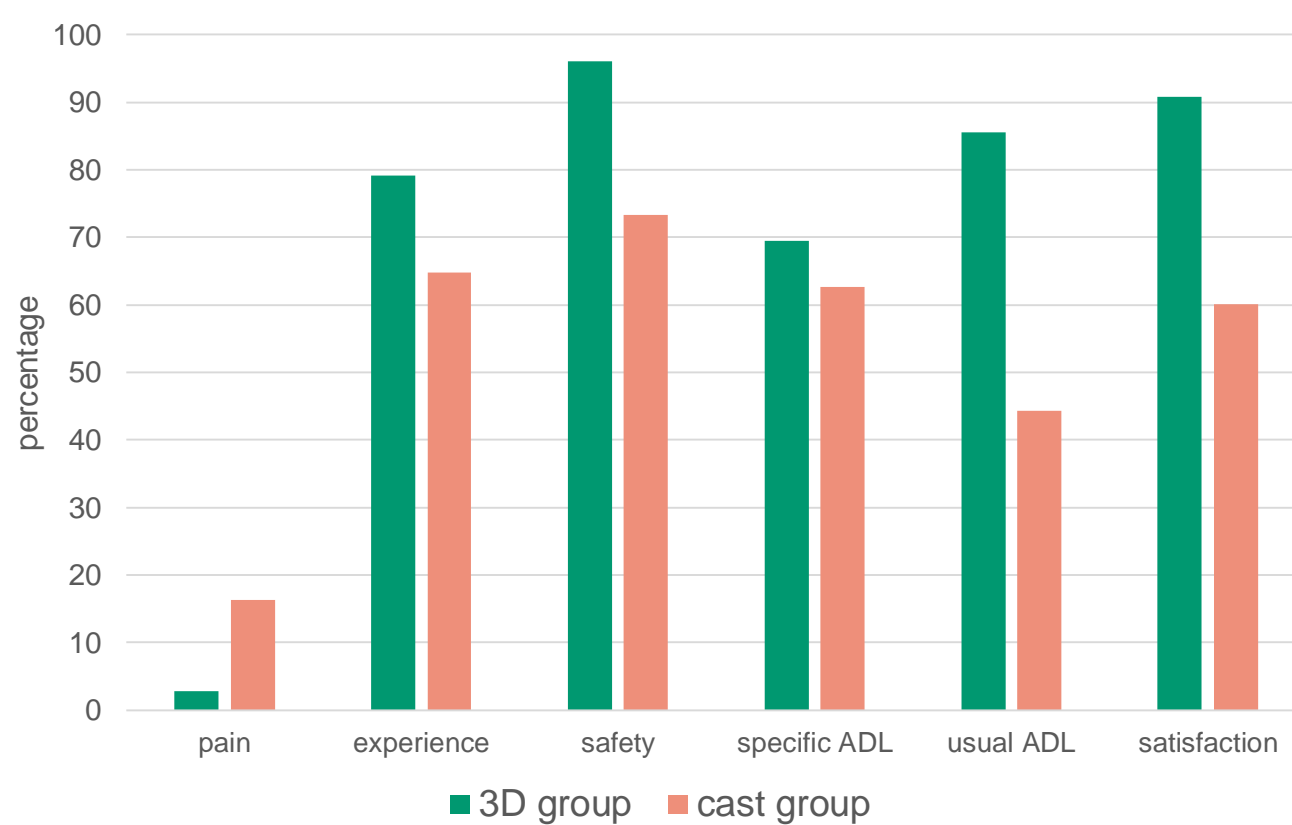
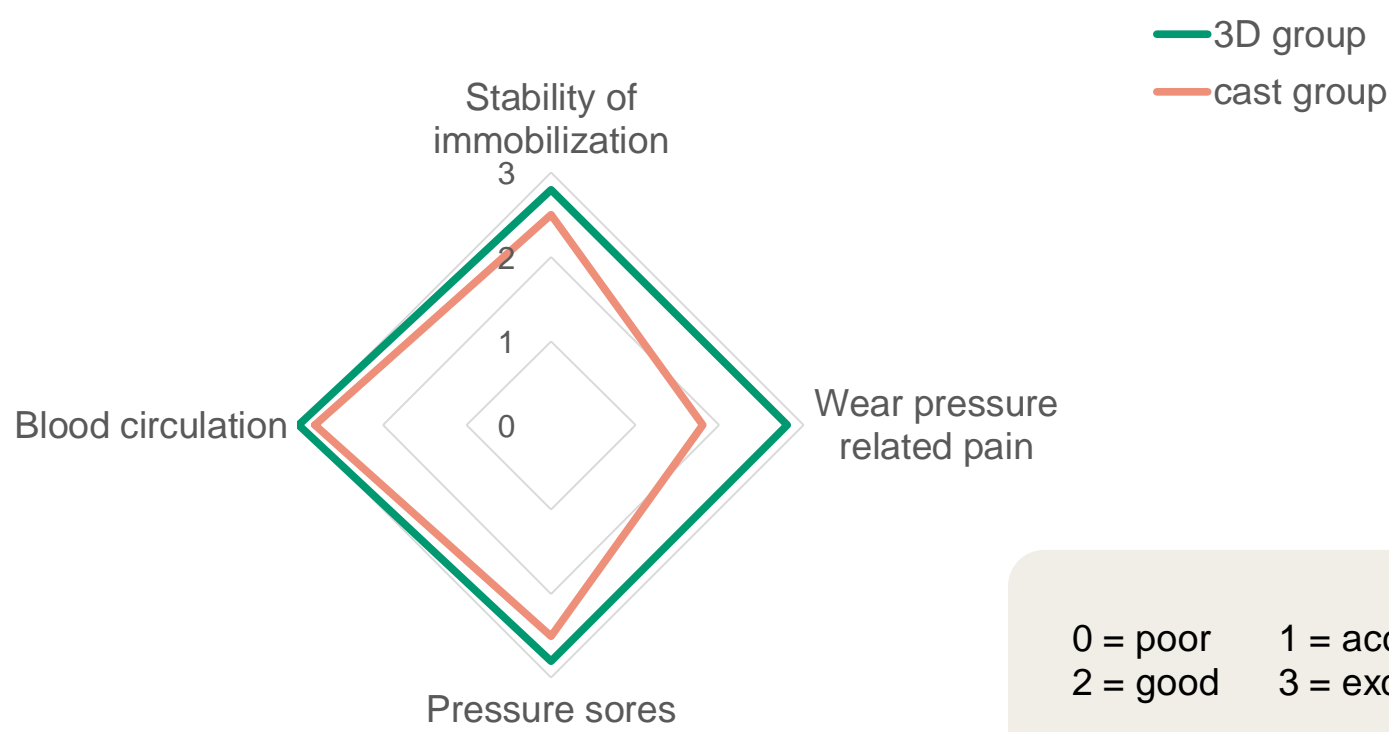
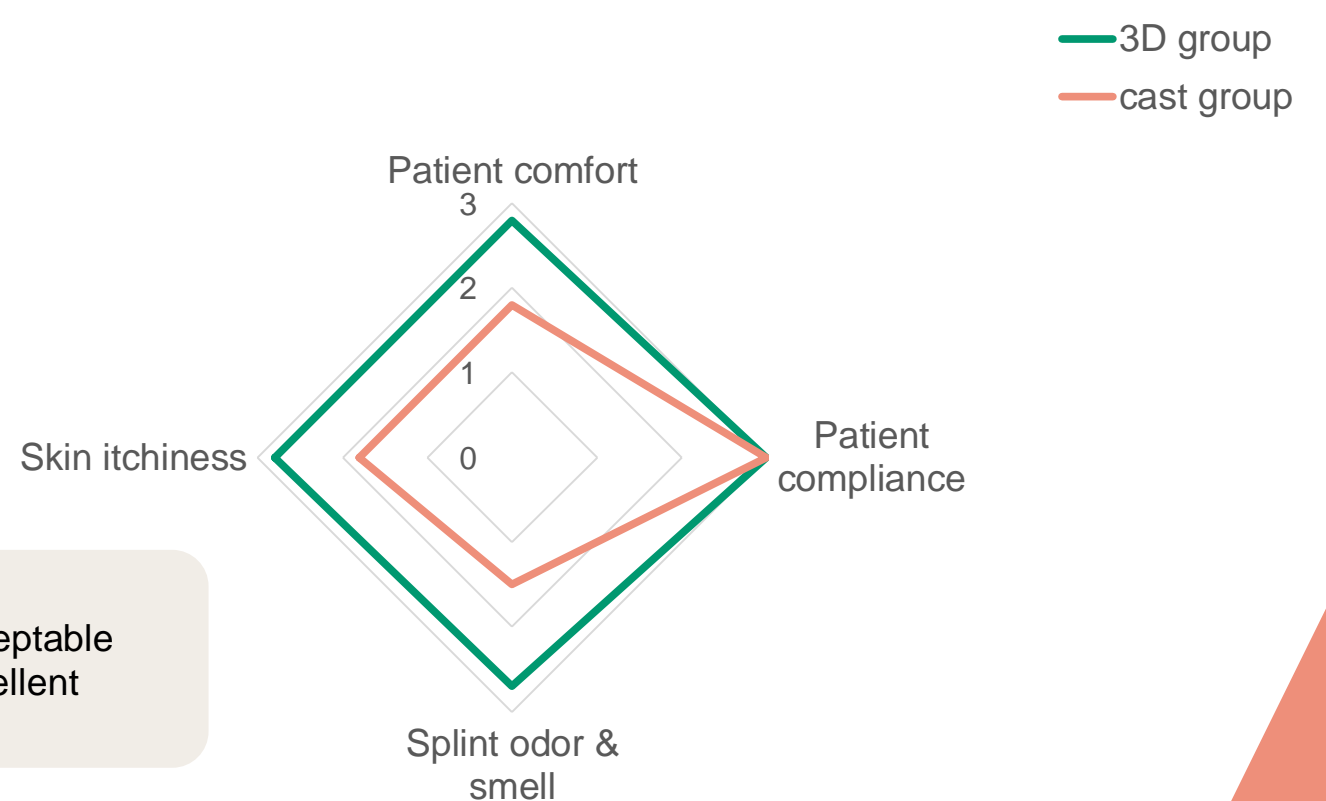


Figure 2: Patient-rated splint evaluation after splint removal
Higher scores indicate better outcomes, except for pain, where lower scores indicate better outcomes

Assessment of clinical effectiveness



Assessment of patient satisfaction



Conclusion

The preliminary study results of this feasibility study show a trend in favor of the 3D splint from the patients, hand therapists and surgeons point of view. The 3D splint seems to be more comfortable than the cast while conveying a high feeling of protection, therefore allowing better hand function during the splint wearing time. Further data collection of nine patients will confirm or challenge these preliminary findings.