

ARCR_Pred Newsletter

June 2022 | Number 4

This Newsletter is published twice a year



<http://p3.snf.ch/project-184959>



suva

Surgical safety and effectiveness in orthopedics: Swiss-wide multicenter evaluation and prediction of core outcomes in Arthroscopic Rotator Cuff Repair

Start of 2 years follow-up

Two years after the recruitment of our first patient in June 2020, we started this month the 2-year follow-up by asking patients to complete a final questionnaire. For each patient, send it just 2 years after the primary surgery date and not before. We recommend electronic data capture after invitation per email as performed in most sites, or else of course paper-based questionnaires can be used.

Status of 1 year follow-up

Follow-up documentation are performed according to plan with high level of completeness. This is supported by weekly communication with the sites including missing data reports and specific data queries

Facts

19 clinics

147 project staff

985 patients operated

974 cuff tear repairs

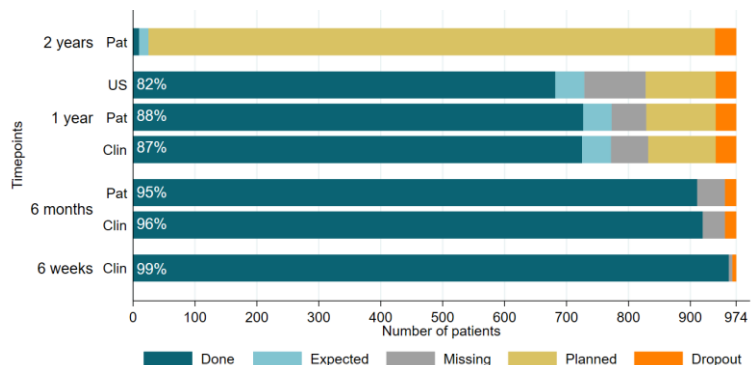
99% 6-week follow-up

96% at 6 months

88% at 12 months

34 (3.5%) dropout

98% of 9827 collected forms have no missing data



New surgery is no reason for dropout



Treating patients with a new surgery (eg. revision ARCR or arthroplasty) is not a reason for dropout from our study. We need to describe the number of patients with subsequent surgeries after the primary repair.

MRI subproject

The Cantonal Hospital of Winterthur (KSW) joined the MRI project to increase our sample size close to our target of 310 patients. So far 244 patients gave consent, and 192 MRIs were performed.

Milestones achieved:

- Publication January 2022: Prognostic factors for the occurrence of post-operative shoulder stiffness: a systematic review [BMC Musculoskeletal Disorders](#)
- Prognostic factors for improvement of shoulder function after arthroscopic rotator cuff repair: a systematic review has been submitted in February 2022

Well working processes 	Processes to be improved 
<ul style="list-style-type: none">+ Overall follow-up rates+ Motivation of project staff+ Publication management+ Electronic CRFs completeness	<ul style="list-style-type: none">- Data queries resolution (especially AE forms)- Ultrasound examinations completeness- Reason for dropouts not adequately described



Last Minute change ! Our next ARCR_Pred project meeting will take place on Friday June 24 (12:30 – Rom Guangzhou) during the coming Swiss Orthopadics (SGO) congress in Basel



Outlook:

1. **Second Delphi Process of Prognostic factors ranking for functional outcomes** [by end of Summer 2022](#)
2. **Preparation of a Study-dedicated Website** [Summer 2022](#)
3. **Description of the ARCR_Pred cohort for publication in *BMJ Open*** [Submission Q3 2022](#)
4. **6-week and 6-month database locking and preparation for analyses** [by end of Summer 2022](#)
5. **Implementation and submission of some subprojects according to publication plan** [by end of Dec 2022](#)
6. **Completion of patient recruitment and MRI capture at 12 months (SUVA project)** [by end of Dec 2022](#)

Publication plan

We have a transparent publication policy, and no data will be published without information and agreement with the project board. We started with some analyses involving baseline data, including diagnostic imaging assessments (USB / SON). We also shared selected datasets with the research team in Lugano (LUG) to initiate statistical programming.

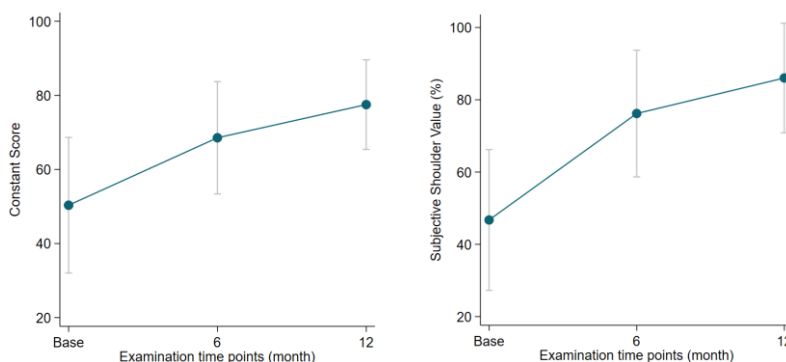
Adverse Events

We continued monitoring of AE documentation. Please, recall that all the adverse events described by patients AND/OR surgeons should be reported in specific AE forms. We will now complete this recording for all patients who completed their 2-year questionnaires, as well as ask them (and 5 selected surgeons) about the perceived severity of these events. Preliminary local AEs reporting is presented below.

Complication group and type	n	%
At least one post-operative local event	222	22.8
Persisting or worsening pain	80	8.2
Rotator cuff (re)defect	30	3.1
Deep soft tissue event	83	8.5
Capsule (stiffness)	61	6.3

Outcomes

The time has come to look at outcomes parameters and closely monitor inconsistencies. This will also help our group to consolidate the various expected analyses as documented in our publication plan. The following shows changes of mean Constant Score and Subjective Shoulder Value.



We wish you a nice summer and thank you for the fruitful collaboration over the last 2 years!

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