ARCR_Pred: The Swiss multicenter cohort study to assess and predict key outcomes in arthroscopic rotator cuff reconstruction. Role model for orthopedic patients?

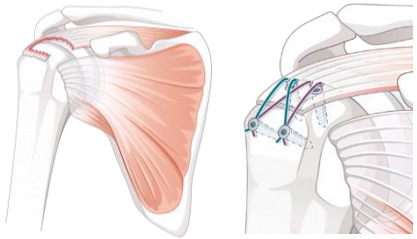
Prof Laurent Audigé

2. BEST PRACTICE IN HEALTHCARE
SCHULTHESS KLINIK ZÜRICH
September 21-22, 2023

University Hospital Basel

schulthess klinik

Background



- Need to inform patients about risks and benefits of surgical interventions, incl. arthroscopic rotator cuff repair (ARCR)
- Important core outcome measures (COS):
  - Healing process / status
  - Clinical objective outcome parameters
  - Patient-reported subjective outcome measures (PROMs)
  - Adverse Events (AE) / Complication
- Need for standardization

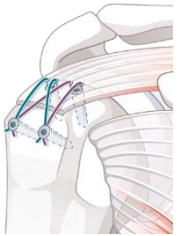
Audige et al. Orthop J Sports Med 2015
Audige et al. J Shoulder Elbow Surg 2016

- Need for representative (Swiss multicenter) documentation

Start small, get it right and grow …

Image source

Schulthess Klinik ARCR Register



Obere Extremität 2015 · 10:33–40
DOI 10.1007/s11678-014-0299-4
Received: 15 October 2014
Accepted: 19 November 2014
Published online: 23 December 2014

Matthias Flury[1] · Christoph Kolling[1] · Cécile Grobet[1] · Sebastian Niklaus Kunz[1,2] · Laurent Audigé[1]
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[2] Orthopedic Clinic, University Hospital Basel, Basel, Switzerland

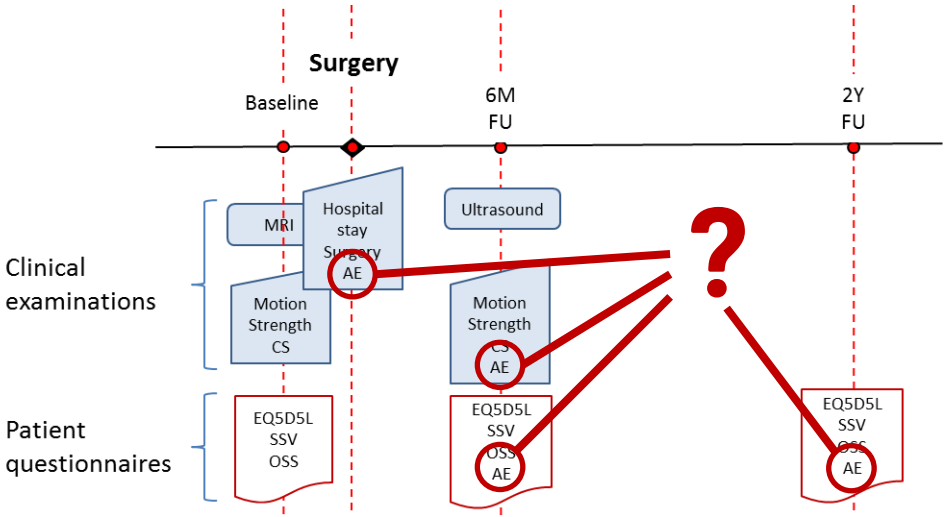
Implementation of a local outcome register for arthroscopic rotator cuff tear repair

DOI: 10.1007/s11678-014-0299-4

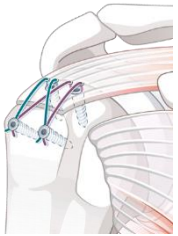
Start : 2010

N = 4998 ARCRs

Period 2016-2023
3463 ARCRs
Follow-up rate
6 months : 71%
24 months : 66%



ARCR Core Event Set (CES 1.0)



Complications associated with arthroscopic rotator cuff tear repair: definition of a core event set by Delphi consensus process

Laurent Audigé, PhD[a,b,*], Matthias Flury, MD[b], Andreas M. Müller, MD[a,c], ARCR CES Consensus Panel, Holger Durchholz, MD[b]

Journal of Shoulder and Elbow Surgery, 2016
25(12):1907–1917. DOI: 10.1016/j.jse.2016.04.036

Local event groups		
Intraoperative	Postoperative	Period
Device	Device	24 months
Osteochondral	Osteochondral	24 months
Soft tissue	Persisting or worsening pain	12 months
	Rotator cuff	12 months
	Peripheral neurological	3 months
	Vascular	30 days
	Surgical site infection	30 days (no implant) 12 months (implant)
	Superficial soft tissue	30 days to 6 months
	Deep soft tissue	12 months

Non-local event groups	
Intra / Postoperative	Period
Anaphylactic / allergic reaction	3-6 months
Neuro-psychiatric event	
Cardiovascular event	
Pulmonary event	
Urinary tract event	
Gastrointestinal event	
Musculoskeletal system	
Other non-local AE	

Can we apply this concept & proposal in practice?

Which event(s) really matter for surgeons and patients?

Analysis of local KWS ARCR Register

Safety : Risk of adverse events

Complications Within 6 Months After Arthroscopic Rotator Cuff Repair: Registry-Based Evaluation According to a Core Event Set and Severity Grading

Quinten Felsch, M.D., Victoria Mai, M.D., Holger Durchholz, M.D., Matthias Flury, M.D., Maximilian Lenz, M.D., Carl Capellen, M.D., and Laurent Audigé, D.V.M., Ph.D.

Arthroscopy, 37: 50-58. DOI: 10.1016/j.arthro.2020.08.010

Event groups	All tears (N=1661) %
At least one local event (AE)	18.5
Device	0.7
Osteochondral	0.4
Persisting or worsening pain	**3.4**
Rotator cuff – failure to repair	**3.1**
Peripheral neurological	**1.7**
Vascular	0.1
Surgical site infection	0.8
Superficial soft tissue	0.2
Deep soft tissue	**9.4**
Capsule (stiffness)	7.6

Outcome prediction

Prediction of Shoulder Stiffness After Arthroscopic Rotator Cuff Repair

Laurent Audigé,*†‡§ DVM, PhD, Soheila Aghlmandi,‡ PhD, Cécile Grobet,† MSc, Thomas Stojanov,†§ MSc, Andreas M. Müller,§ MD, Quinten Felsch,‖ MD, Johannes Gleich,‖ MD, Matthias Flury,¶ MD, and Markus Scheibel,‖ MD
Investigation performed at the Schulthess Clinic, Zurich, Switzerland

AJSM, 49:3030-3039. DOI: 10.1177/03635465211028980

Development and validation of a model predicting patient-reported shoulder function after arthroscopic rotator cuff repair in a Swiss setting.

Thomas Stojanov[1,2,3], Soheila Aghlmandi[3], Andreas Marc Müller[1], Markus Scheibel[2], Matthias Flury[4], Laurent Audigé[1,2,3]

BMC Diagnostic and Prognostic Research
Manuscript in press

ARCR_Pred project design and setting …

Image source

ARCR_Pred Project

Swiss National Science Foundation

2020-2024

swiss orthopaedics

Prospective multicenter Swiss cohort study of primary arthroscopic rotator cuff repairs (ARCR)

19 sites (CH und 1 in DE)	
151 project collaborators & partners	
973 rotator cuff tear repairs	
Follow-up timepoints	
6 weeks	961 (99%)
6 months	922 (97%)
12 months [12-2022]	877 (93%)
24 months [12-2023]	757 (87% of expected)
Overall, 98.2% of 11'055 forms are complete	

Project protocol : *Audige et al. BMJ Open DOI*: 10.1136/ bmjopen-2020-045702

University Hospital Basel

Patient population and project objectives

Swiss National Science Foundation

2020-2024

swiss orthopaedics

Patients:

- Adult patients with rotator cuff tears
- Primary arthroscopic repairs

Prediction of post-operative outcomes:

- Primary:
  - Shoulder stiffness
  - Shoulder subjective function score (PROM)
- Secondary:
  - Healing: repair integrity
  - Objective outcomes: function, motion, strength
  - PROM: pain level, quality of life, satisfaction
  - Return to work / sport
  - …

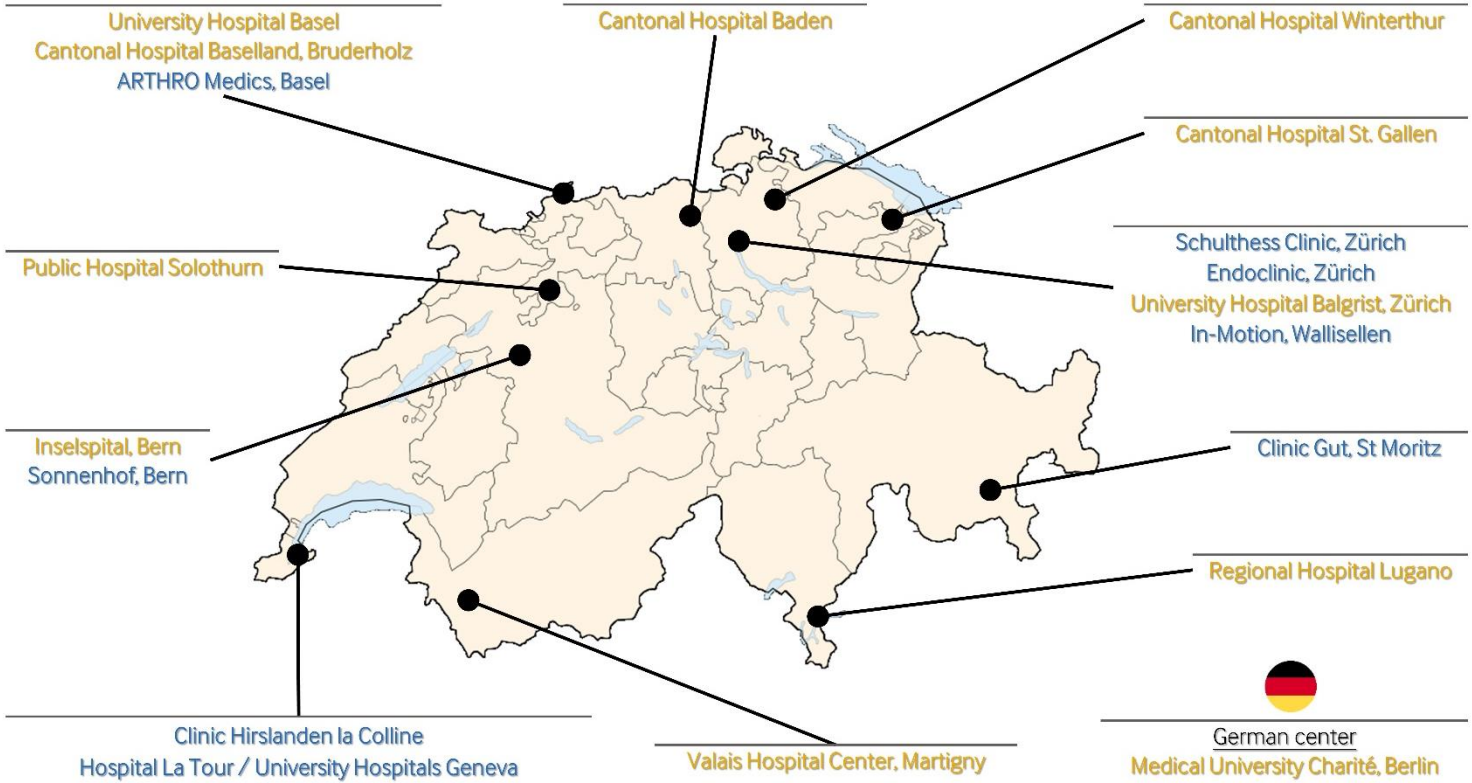
Surgical safety data:

- Standardized documentation system for adverse events (AE)
- AE severity classification
- Incidence of AE up to 24 months

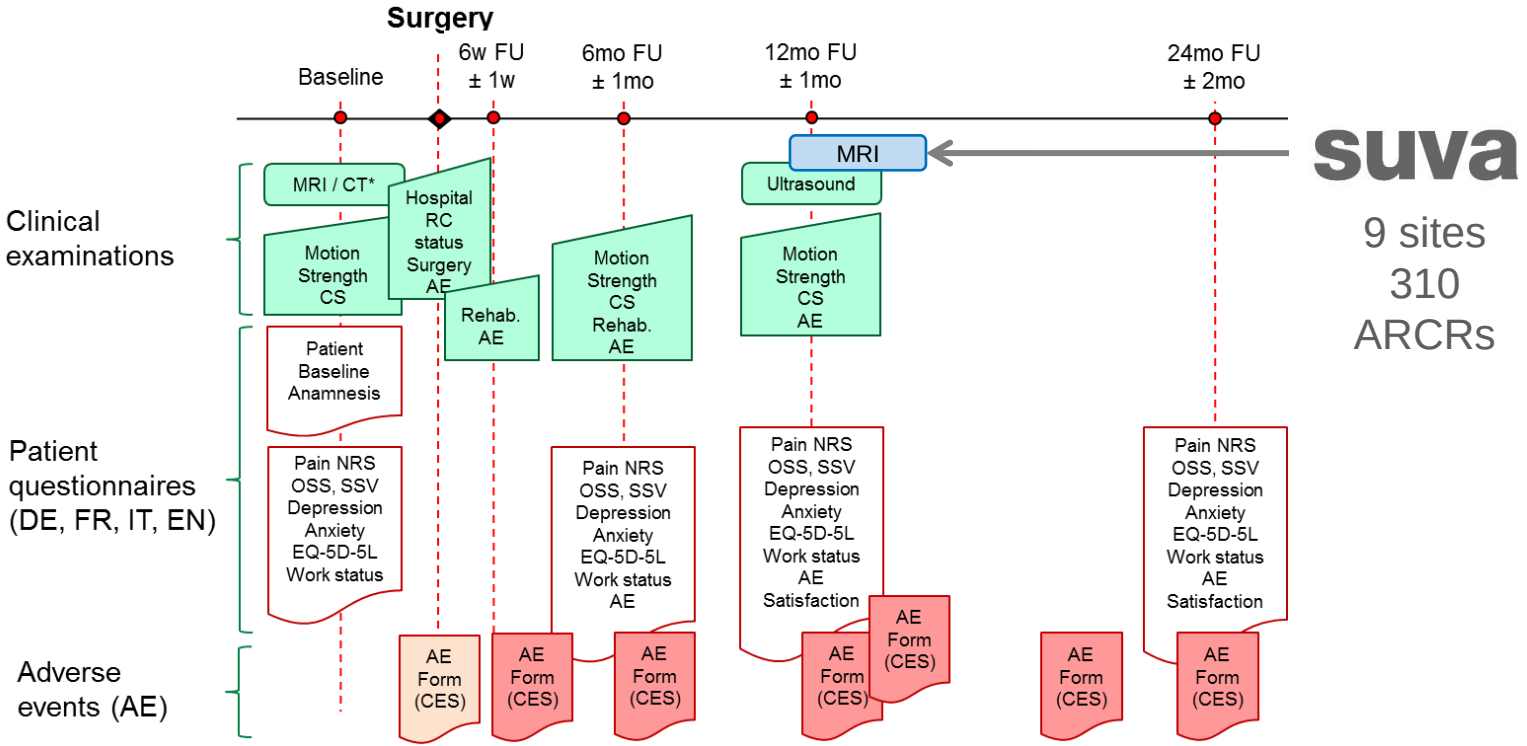
Swiss representative cohort

- Variability between clinics

Multicenter cohort



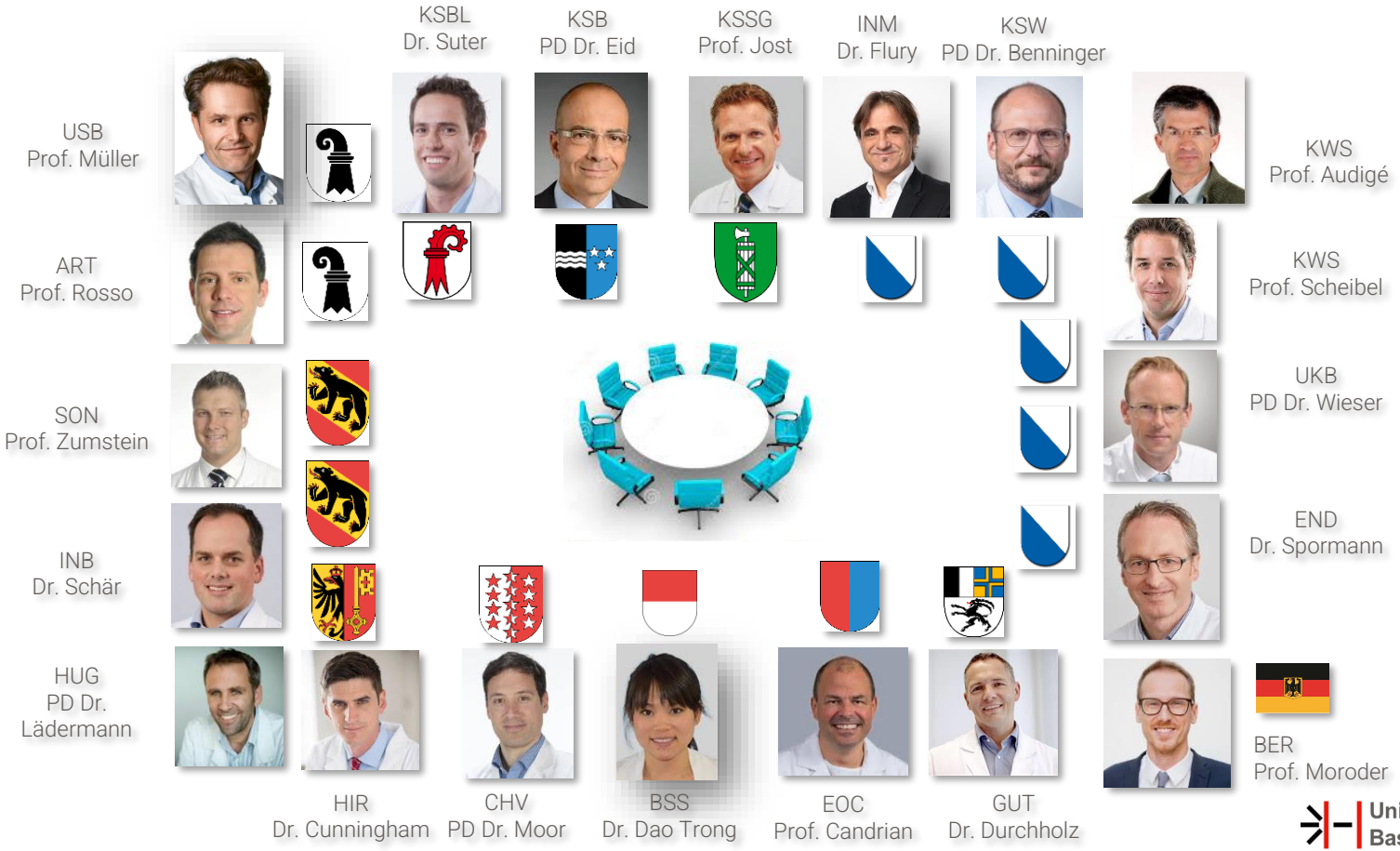
Patient documentation and time points



Organization & implementation issues …

Image source

Organization - Project Scientific Board



Organization - Team

schulthess klinik

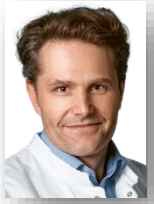
University Hospital Basel

Prof. Dr. L. Audigé

Main project coordination

Database management
Central monitoring – Data queries
Newsletter – Communication

Martina Wehrli



Prof. Dr. A.M. Müller

Main project leader (Sponsor)
Clinical expertise

Thomas Stojanov
PhD student

On-site monitoring

Prediction modelling

Dr. C. Baum
Assistant surgeon

MRI study coordinator

Ilona Ahlborn

Ethics (EKNZ)
Project documentation

Dr. S. Aghlmandi
Statistics

Prof. Dr. S. Hunziker
Psychosomatic

UNI BASEL

Dr. Ch. Appenzeller-Herzog
Literature review

KLINIKGUT
ST. MORITZ | FLÄSCH | CHUR | BUCHS | ZÜRICH | ASCONA

Dr. H. Durchholz
AE review committee

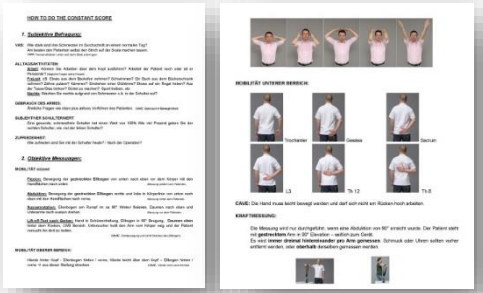
u b
UNIVERSITÄT BERN

Prof. Dr. D. Schwappach
AE review committee

Standardization of clinical measurements

Der Balgrist

Constant Score Video



Range of motion:

- Flexion, abduction
- External rotation / Neck grip
- Internal rotation

Strength:

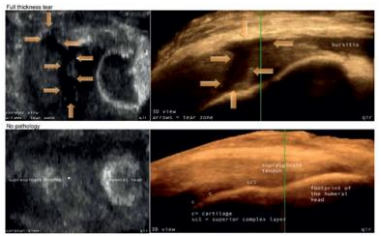
Lafayette
Dynamometer

MicroFET 2
Dynamometer

IsoForceControl® EVO2
Isobex

Mark-10
Force Gauge

Ultrasound examination @ 12 months:



KD Dr. G. Tamborrini

REDCap Electronic Data Capture System

Patient ARCR cohort number **KWS-020**
KWS

Data Collection Instrument	Baseline Enrollment	Hospital Surgery	6 W	6 Mo	12 Mo	24 Mo	+ Add new AE Adverse event(s)
Enrollment	●						
Patient Contact	●						
Dropout Form	○						
Monitoring	●	○	○	○	○	○	●
Investigator Form (survey)	●		●	●	●		
Ultrasound Form (survey)					●		
Patient Questionnaire De (survey)	✓			✓	✓	✓	
Patient Questionnaire Fr (survey)	○			○	○	○	
Patient Questionnaire It (survey)	○			○	○	○	
Patient Questionnaire En (survey)	○			○	○	○	
Operation Form (survey)		●					
Adverse Event (survey)							●

Electronic data capture
(paper-based CRF not used)

Data Access Group / Site

Structured database
- Repeated events (AE)
- Branching logic
- Languages (FR, DE, IT, EN)

Patient online questionnaires

Data query management

Monitoring


Prof. Dr. Audigé


Martina Wehrli


Marije de Jong
Patient Newsletter


Dr. K. Grezda
USB
Safety data

Central monitoring

- Recruitment statistics
- Completion of examinations and follow-ups
- Missing data reports
- Consistency checks → Data Query generation

On-site / Off-site visits

- Initiation / monitoring / closure visits → Data Query resolution


Th Stojanov


Dr. C. Baum
MRI data


Marije de Jong
Closure visits

Communication channel

- **Weekly email** : individual site information – patient listings
- 2-4-weekly **Newsflash** to all staff members
- Bi-annual **newsletter** : overall project info & statistics

Patient list and status

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
ARCR_Pred Project				Operation		6 Wochen		6 Monate				12 Monate						24 Monate	
REDCap Link	ptn	event	Clinic	sgopsurgeon	sgopsurgdt	examstatus1	examdt1	examstatus6	examdt6	promstatus6	promdt6	examstatus12	examdt12	promstatus12	promdt12	imfupstatus12	imfupdt12	promstatus24	promdt24
2023-01-20_1046	ptn	event	Clinic	sgopsurgeon	sgopsurgdt	examstatus1	examdt1	examstatus6	examdt6	promstatus6	promdt6	examstatus12	examdt12	promstatus12	promdt12	imfupstatus12	imfupdt12	promstatus24	promdt24
Patient Grid					03.08.2020	Done	01.10.2020	Done	25.02.2021	Done	25.02.2021	Verified	10.09.2021	Done	10.09.2021	Done	10.09.2021	Done	08.09.2022
Patient Grid					31.07.2020	Done	23.09.2020	Done	08.04.2021	Done	08.04.2021	Done	27.08.2021	Done	27.08.2021	Verified	27.08.2021	Missing	
Patient Grid					12.08.2020	Done	23.09.2020	Done	11.03.2021	Done	11.03.2021	Done	26.08.2021	Done	26.08.2021	MissOK		Missing	
Patient Grid					17.08.2020	Done	27.10.2020	Done	11.03.2021	Done	11.03.2021	Done	02.09.2021	Done	02.09.2021	Done	02.09.2021	Done	01.09.2022
Patient Grid					24.08.2020	Done	19.11.2020	Done	18.02.2021	Done	18.02.2021	Done	19.08.2021	Done	19.08.2021	Done	19.08.2021	Done	01.09.2022
Patient Grid					31.08.2020	Done	29.10.2020	Done	25.03.2021	Done	25.03.2021	MissOK		MissOK		MissOK		Done	22.09.2022
Patient Grid					07.09.2020	Done	29.10.2020	Done	18.05.2021	Done	18.05.2021	MissOK		MissOK		MissOK		MissOK	
Patient Grid					11.09.2020	Done	12.11.2020	Done	25.03.2021	Done	25.03.2021	Done	02.09.2021	Done	02.09.2021	Done	02.09.2021	Missing	
Patient Grid					26.10.2020	Done	17.12.2020	Done	20.05.2021	Done	20.05.2021	Done	04.11.2021	Done	04.11.2021	Done	04.11.2021	Missing	
Patient Grid					11.11.2020	Done	04.02.2021	Done	05.05.2021	Done	05.05.2021	Done	04.02.2022	Done	04.02.2022	Done	04.02.2022	Missing	
Patient Grid					17.11.2020	Done	04.02.2021	Done	24.06.2021	Done	24.06.2021	MissOK		MissOK		MissOK		Missing	
Patient Grid					02.12.2020	Done	28.01.2021	Done	01.07.2021	Done	01.07.2021	Done	24.02.2022	Done	24.02.2022	Done	24.02.2022	FupInt	
Patient Grid					25.11.2020	DropOut		DropOut		DropOut		DropOut		DropOut		DropOut		DropOut	
Patient Grid					27.11.2020	Done	27.01.2021	Done	01.07.2021	Done	01.07.2021	MissOK		MissOK		MissOK		FupInt	
Patient Grid					15.01.2021	Done	11.03.2021	Done	22.07.2021	Done	22.07.2021	MissOK		MissOK		MissOK		FupInt	
Patient Grid					05.02.2021	DropOut		DropOut		DropOut		DropOut		DropOut		DropOut		DropOut	
Patient Grid					22.03.2021	Done	27.05.2021	Done	26.08.2021	Done	26.08.2021	Done	17.03.2022	Done	17.03.2022	Done	17.03.2022	NotDue	
Patient Grid					26.03.2021	Done	02.06.2021	Verified	28.07.2021	Verified	28.07.2021	Done	06.04.2022	Done	06.04.2022	Done	06.04.2022	NotDue	

REDCap Link	ptn	alerttxt	languagepat	promdt	aepatlocyn	aepatlocb___1	aepatlocb___2	aepatlocb___9	aepatloctxt	aepatloctyn	aepatloctreat	aepatgenyn	aepatgentxt	respspain	respsfunction	respqol	passpain	passfunction	passqol	pain1wo	sleeprs	ssv	oss01	oss02	oss03	oss04	oss05	oss06	oss07	oss08	oss09	oss10	oss11	oss12
2023-01-20_1046	ptn	alerttxt	languagepat	promdt	aepatlocyn	aepatlocb___1	aepatlocb___2	aepatlocb___9	aepatloctxt	aepatloctyn	aepatloctreat	aepatgenyn	aepatgentxt	respspain	respsfunction	respqol	passpain	passfunction	passqol	pain1wo	sleeprs	ssv	oss01	oss02	oss03	oss04	oss05	oss06	oss07	oss08	oss09	oss10	oss11	oss12
REDCap Patient Questionnaire 24 months		DataQuery	1	12.12.2022	0	0	0	0				1	ssy l	5	5	5	1	1	1	2	7	85	2	2	1	1	1	1	1	2		1	1	1
REDCap Patient Questionnaire 24 months		DataQuery	1	18.11.2022	0	0	0	0				1	ttzuc	5	5	5	1	1	1	0	1	90	1	1	1	1	1	1	1	2		1	1	2

Baseline ARCR cohort description…

Image source

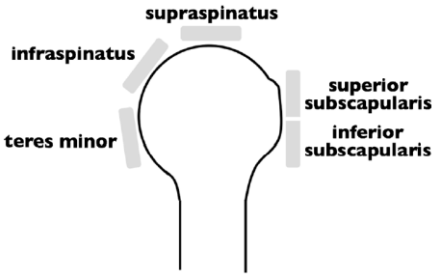
Recruitment (June 2020 – Nov 2021)

Characteristic	n (%)	Overall, N = 1,890	Not enrolled, N = 917	Enrolled, N = 973	Standardized Difference
Age (years)	Mean (SD)		58 (10)	58 (9)	0
Male sex			560 (61%)	611 (63%)	0.04
Tear severity					0.38
Partial tear			231 (25%)	147 (15%)	
Single full tear			259 (28%)	255 (26%)	
Two or three tendons (only one full)			241 (26%)	417 (43%)	
Massive tear			186 (20%)	154 (16%)	
Public hospitals			365 (40%)	565 (58%)	0.37

# RC injury profile
N=973

Injuries with at least one full-thickness tear 85%

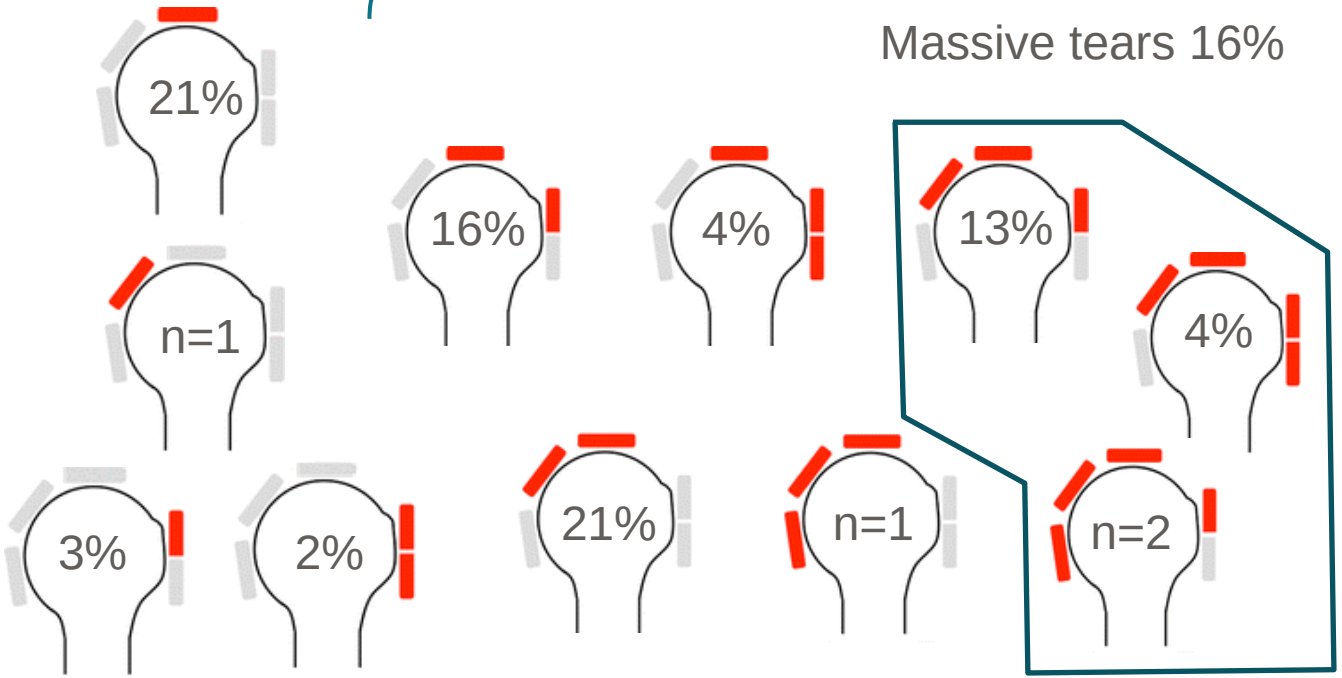
Partial tears
15%



Single 26%

2 or 3 tendons 59%

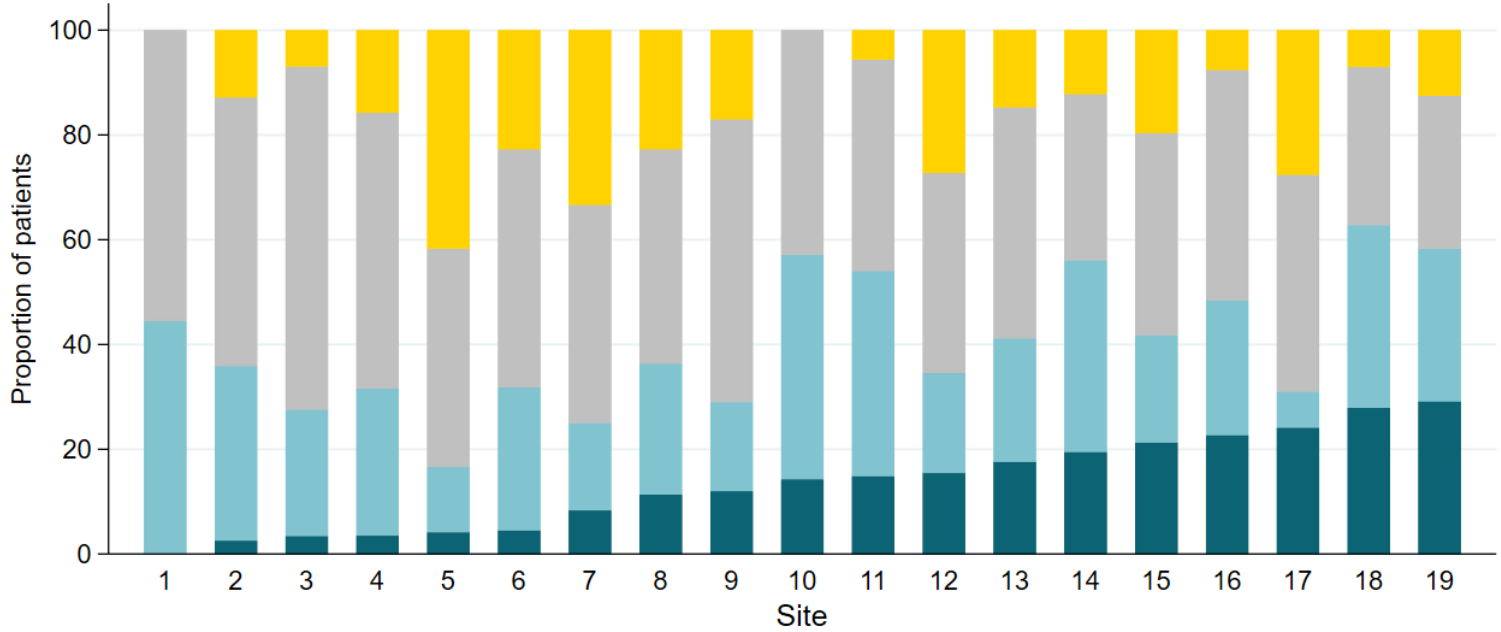
Massive tears 16%



Project case-mix (1)

RC tear severity
(intra-operative diagnosis)

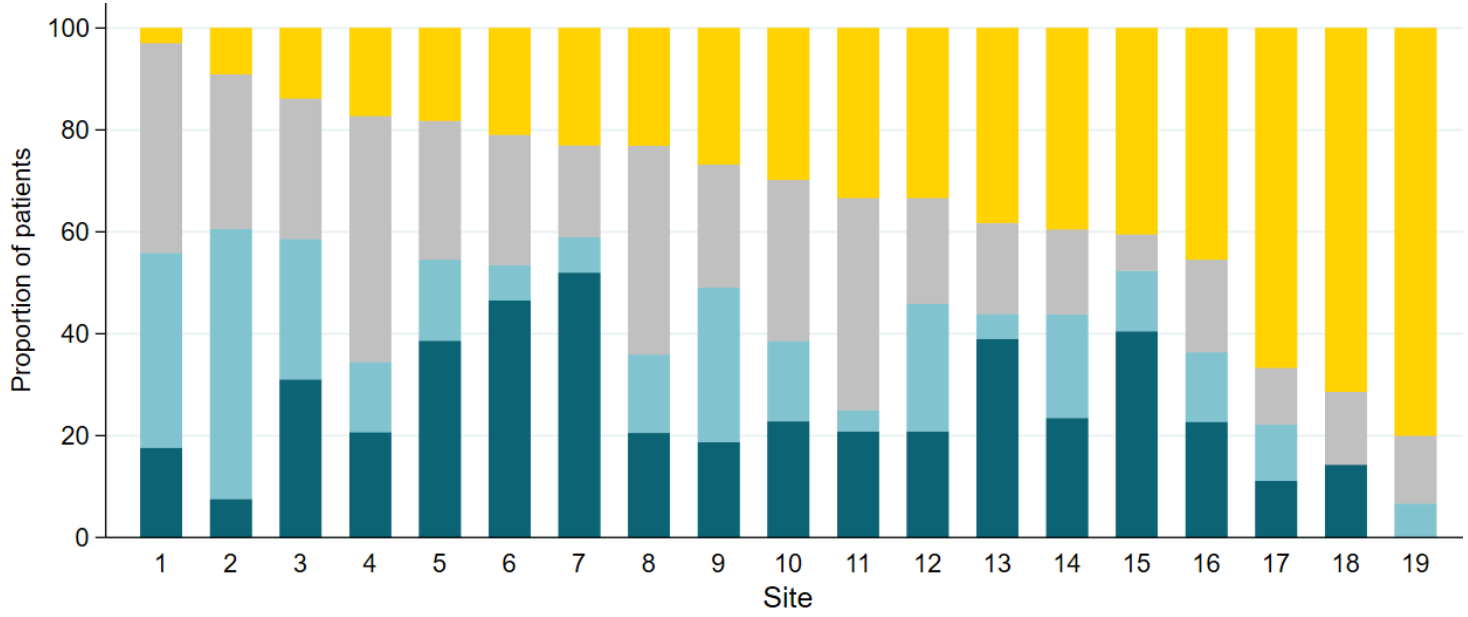
	N (%)
Massive (2+ full-tickness tears)	154 (16)
Two or three tendons (only one full)	417 (43)
Single full-tickness tear	255 (26)
Partial tear	147 (15)



Project case-mix (2)

Surgeons' judgement as to
the cause of the shoulder complaint

	N (%)
Purely traumatic	289 (29)
More traumatic than degenerative	233 (24)
More degenerative than traumatic	182 (19)
Purely degenerative	277 (28)

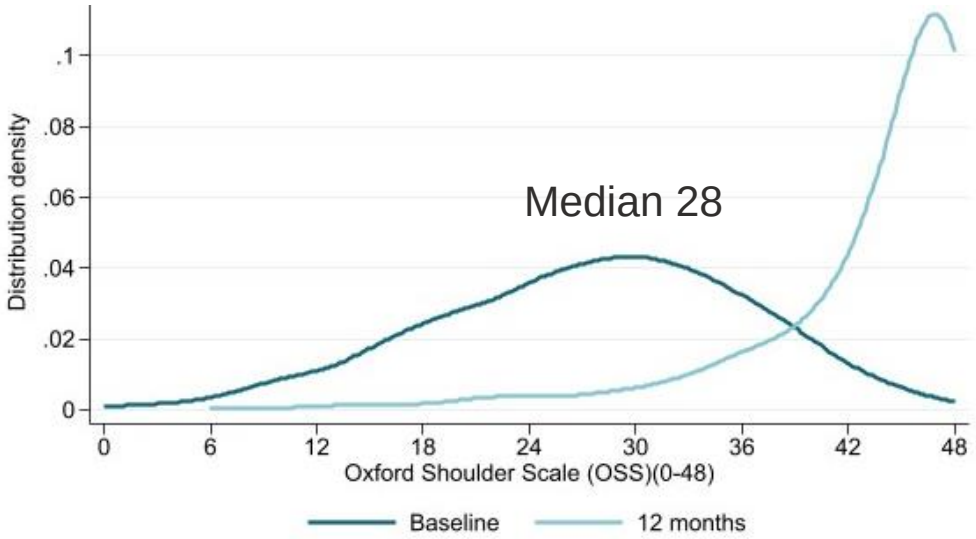


Outcome assessment …

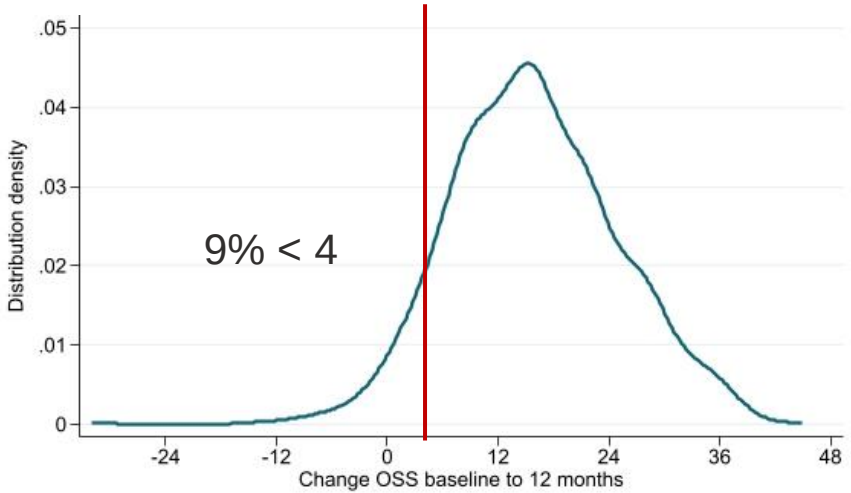
Image source

Shoulder function: change of Oxford Shoulder Score

Median 46
33% maximum score (Ceiling)

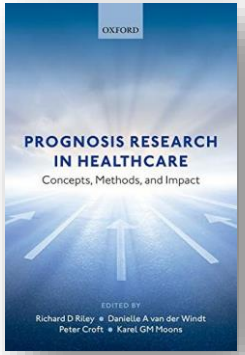


Minimum important change? (MIC)

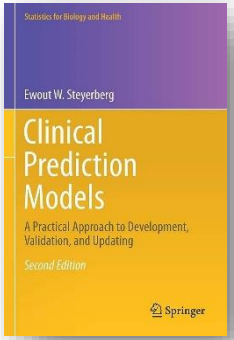


Prediction model for shoulder stiffness @6 months

Prevalence = 10.8% (105 / 941)



Riley et al., 2019



Steyerberg, 2009

Characteristic	OR	(95% CI)
Female sex	1.51	(0.96 to 2.39)
Smoking status		
— Never smoked	Reference	—
— Smoked before	1.70	(0.98 to 2.91)
— Current smoker	1.57	(0.92 to 2.63)
Traumatic onset	1.57	(0.95 to 2.61)
Symptoms duration for more than 6 months	1.80	(1.09 to 2.99)
Baseline level of external rotation	0.99	(0.97 to 1.00)
Baseline Oxford Shoulder Score	0.95	(0.93 to 0.98)
Acromiohumeral distance	0.85	(0.77 to 0.93)
Pre-operative medication	1.58	(1.03 to 2.42)
At least daily alcohol consumption	1.78	(0.93 to 3.28)
Moderate or heavy work without overhead activity	1.60	(1.03 to 2.53)

Alwin Jäger Prize 2023

klinische arthroskopische Innovation

University Hospital Basel

Next steps and future development…

Image source

Analyses and publication concept

Swiss National Science Foundation

2020-2024

swiss orthopaedics

suva

Main objectives and topics

- Baseline and operative epidemiological data
- Outcome: safety & effectiveness data
- Prognostic models

Additional analyses / nested projects (50+)

- Initiative from local project leaders
- Co-authorship of publications among centers

https://arcr-pred.ch

Publications / presentations

- Scientific articles - Congress presentations - Seminars / Webinars - Media
- Project Website

Role model project for orthopedic patients?

- Multicenter collaboration on a national level (public / private)
- Engage with professional organization
- Forster interdisciplinary collaboration
  (clinicians, clinical epidemiologists, research staff, statisticians, data scientist…)

- Structure : central organizational unit + trained local project coordinators

- Secure personnel resources and project funding
- Ensure quality through intensive cooperation and monitoring

- Maintain active communication

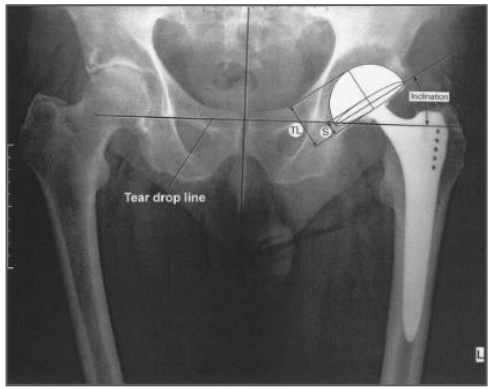
- Implement more patient and public involvement

Surgical Outcome Research Center Basel (SORC)

Register / Cohort data for frequent surgical procedures

Subjective Measurements

Objective Measurements



Biomechanics

INSELSPITAL
UNIVERSITÄTSSPITAL BERN
HOPITAL UNIVERSITAIRE DE BERNE
BERN UNIVERSITY HOSPITAL

Swiss National Science Foundation

Kantonsspital St.Gallen

Hôpitaux Universitaires Genève

Hôpital de La Tour

UNIVERSITÄT BERN

UNI BASEL

Universitätsspital Basel

Orthopädie und Traumatologie

schulthess klinik

HIRSLANDEN
CLINIQUE LA COLLINE

ORTHOPÄDIE SONNENHOF
ortho spine sport

DKF

swiss orthopaedics

Balgrist
Universitätsklinik

IN MOTION
Zentrum für Orthopädie & Neurochirurgie

ARTHROMedics
#shoulder and elbow center

Kantonsspital Baden

KSB

CHARITÉ
UNIVERSITÄTSMEDIZIN BERLIN

Bürgerspital Solothurn

solothurner spitäler soH

KSW Kantonsspital Winterthur

balgristcampus

KLINIKGUT
ST. MORITZ | FLÄSCH | CHUR | BUCHS | ZÜRICH | ASCONA

suva

Hôpital du Valais
Spital Wallis

endoclinic zürich

HIRSLANDEN
KLINIK HIRSLANDEN

eoc

Kantonsspital Baselland
ganz nah

SWISS CENTER FOR Musculoskeletal Imaging