BMJ Open

Cohort profile: The Schulthess registries for hand implants and forearm corrective osteotomies

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-093425
Article Type:	Cohort profile
Date Submitted by the Author:	06-Sep-2024
Complete List of Authors:	Mathis, Kei; Schulthess Klinik, Teaching, Research and Development Herren, Daniel B ; Schulthess Klinik, Hand Surgery Schindele, Stephan; Schulthess Klinik, Hand Surgery Marks, M; Schulthess Klinik, Teaching,Research and Development
Keywords:	Hand & wrist < ORTHOPAEDIC & TRAUMA SURGERY, Patient Reported Outcome Measures, REGISTRIES

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Title	Cohort profile: The Schulthess registries for hand implants and forearm corrective osteotomies
Authors' names	Kei Mathis[1] (0009-0009-8348-6803), Daniel B. Herren[2] (0000-0001-6585-2341), Stephan Schindele[2] (0000-0001-6997-5162), Miriam Marks[1] (0000-0002-0623-2465)
Address for each author	[1]Department of Teaching, Research and Development, Schulthess Klinik, 8008 Zurich, Switzerland [2]Department of Hand Surgery, Schulthess Klinik, 8008 Zurich, Switzerland
Authors' names and positions	Kei Mathis MSc. Research Assistant, Daniel B. Herren MD MHA Chief Surgeon, Stephan Schindele Co-Chief Surgeon, Miriam Marks PhD Senior Research Associate
Corresponding author	Kei Mathis Department of Teaching, Research and Development, Schulthess Klinik, 8008 Zurich, Switzerland kei.mathis@kws.ch +41 44 385 79 83
Contributor and guarantor information	Kei Mathis, Daniel B. Herren, Stephan Schindele and Miriam Marks developed the protocol. Daniel B. Herren and Stephan Schindele treated the patients. Kei Mathis, Daniel B. Herren and Stephan Schindele were involved in data collection. Kei Mathis and Miriam Marks were responsible for data management. Miriam Marks was involved in gaining ethical approval. Kei Mathis analysed the data and wrote the first draft of the manuscript. All authors edited and approved the final version of the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. Kei Mathis identifies as guarantor.

	We utilized OpenAI's ChatGPT, a large language model based on the GPT-4 architecture, to assist with word processing and language refinement throughout the manuscript preparation process.
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Competing interests declaration	Daniel B. Herren and Stephan Schindele receive royalties from KLS Martin Group, Tuttlingen, Germany. Daniel B. Herren and Stephan Schindele have speaker contracts with Keri Medical, which obliges them to hold training courses on the surgical technique of the Touch® prosthesis. Thumb CMC, PIP/thumb IP and MCP registries are partly sponsored by Keri Medical. IPS registry is partly sponsored by KLS Martin Group. Miriam Marks has a consultancy agreement with KLS Martin Group. Kei Mathis declares no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.
Funding	This work was continuously supported by the Willhelm Schulthess Foundation and through nested projects with industry partners, namely KeriMedical and KLS Martin Group.

Ethics	This study was approved by the Ethical Committee of Canton Zurich (KEK-ZH-Nr. 2014-0546, 2019-02096, 2020-00143). All participants provided informed consent.
Patient and Public Involvement	Patient and public were not involved in the design and conduct of this study.

Cohort profile: The Schulthess registries for hand implants and forearm corrective osteotomies

ABSTRACT

Purpose: Our hand and forearm registries were established to evaluate safety, function, quality of life and patient satisfaction in patients undergoing thumb and finger implant arthroplasties as well as corrective osteotomy of the forearm with individual patient solution (IPS) implants.

Participants: The registries were initiated between 2010 and 2020 and include patients with implant arthroplasties of the thumb carpometacarpal (CMC) (n=486), proximal interphalangeal (PIP) or thumb interphalangeal (IP) (n=864), and metacarpophalangeal (MCP) (n=34) joints as well as 27 patients with corrective osteotomy of the distal radius or forearm using an IPS implant. All patients complete disease-specific questionnaires and are clinically assessed before surgery (baseline) and up to 10 years thereafter.

Findings to date: All operated patients (100%) were included in the registries with complete baseline data. One-year follow-up rates range between 59% to 95% and for the 5-year follow-up, between 48% to 83%. Data completeness rates (i.e. number of cases with available data divided by the expected number of cases) range between 66% to 96% and 60% to 89% for the 1- and 5-year follow-ups, respectively. Patients showed significantly improved postoperative clinical and patient-reported outcomes over baseline. The registries serve as a basis for standardised patient-monitoring quality control and answering several clinical questions. With the help of these large databases, clinical practice can be improved for the benefit of our patients.

Future plans: As first patients approach the 10-year follow-up landmark, the registry will continue providing essential data on long-term clinical and patient-reported outcomes as well as revision rates. In addition to research and quality control, the cohort data will be brought back to the patients by bolstering real-time clinical decision support.

Strengths and limitations

- Main strength is the high rates of clinical, patient-reported, and radiographic follow-ups using validated and standardised clinical and patient-reported outcome measures.
- Another major strength is that clinical questions can be quickly answered with existing data and results are transferred to daily clinical practice for the benefit of the patients.
- Limitations include the retrospective collection of some cohort data.

INTRODUCTION

Hand osteoarthritis (OA) is a major global public health issue with an estimated 142 million people living with this condition worldwide in 2019.[1-3] The hand is the second most common body region affected by OA after the knee joint, followed by the hip and other joints.[1] Due to demographic change, there will be an estimated 279 million people affected by hand OA in the year 2050.[3] Besides OA, other common reasons for joint deformity or destruction of the hand include rheumatoid arthritis and trauma. Implant arthroplasty is the surgical treatment of choice for affected joints that aims to preserve range of motion. Several implant arthroplasties are available for the thumb carpometacarpal (CMC),[4 5] thumb interphalangeal (IP),[6] proximal interphalangeal (PIP)[7-10] and metacarpophalangeal (MCP) joints,[11] all of which show good medium- and long-term outcomes. For malunited fractures of the distal radius or forearm, individual patient solution (IPS) implants comprising printed, anatomical patient-tailored plates are available for three-dimensional planned corrective osteotomy.[12]

Clinical registries have gained international recognition as a continuous monitoring system that accumulates information on clinical outcomes and patient-reported outcome measures (PROMs), which provide a valuable basis for improving hand surgery practices and patient care.[13 14] When compared with large national registries that demand complex coordination and significant resources,[15] local registries often have the advantage of better means to encourage active participation and ensure complete reporting.

While several publications on hand and wrist implant registries are available to date,[16-18] a detailed cohort description is still missing that encompasses patients with new generation thumb and finger

implant arthroplasties as well as three-dimensionally printed IPS implants for corrective osteotomies. Our local hand and wrist implant registries are based at the Schulthess Klinik, an international high-volume orthopaedic centre in Zurich, Switzerland. The registries were established to evaluate safety, function, quality of life, and satisfaction in patients undergoing implant arthroplasty for thumb CMC, thumb IP, PIP and MCP joints, and forearm osteotomy correction using IPS implants. The aim of the current cohort profile is to describe the structure and baseline characteristics of the registries, and to share the collected technical and epidemiological experience in establishing and maintaining hand and forearm implant registries with high coverage and reasonable publication output. We also present how data analysed from the registries changed our clinical practice and improved patient care.

COHORT DESCRIPTION

Setting, patients and eligibility criteria

There are four registries covering patients treated with finger and thumb implant arthroplasties and IPS implants at Schulthess Klinik in Zurich, Switzerland that are continuously funded by the Wilhelm Schulthess Foundation as well as through nested projects with industry partners. Before patients are enrolled in the registries, the responsible surgeon informs the patient during the preoperative consultation that treatment data collected for the registries will be used primarily for internal quality control. Patients are also invited to voluntarily sign a general consent form indicating agreement to using their treatment data for future scientific projects and publications.

Thumb CMC registry

Patients receiving a thumb CMC implant arthroplasty have been prospectively included in the registry since June 2018. The implants currently included in the registry are the Touch™ (KeriMedical, Geneva, Switzerland) and Maïa™ dual mobility trapeziometacarpal prostheses (Groupe Lépine, Genay, France). All surgeries were carried out using the standard dorsolateral approach technique described by Lussiez et al.[4]

PIP/thumb IP registry

The PIP/thumb IP registry includes patients with PIP or thumb IP implant arthroplasties. Patients with a CapFlex (KLS Martin Group, Tuttlingen, Germany) implant arthroplasty have been prospectively included since May 2010, while other implant arthroplasties have been retrospectively added since May 2010 as well as prospectively included since July 2019; retrospectively-included treatment data were collected from patient medical records. The implants currently included in the PIP/thumb IP registry are: KeriFlex® (KeriMedical, Geneva, Switzerland), Swanson™ (Stryker, Michigan, USA), silicone arthroplasty system (Stryker, Michigan, USA), Tactys® (Stryker, Michigan, USA), HAPTIC® (implantcast, Buxtehude, Germany) and NeuFlex® (DePuy Synthes, Warsaw, USA). For PIP implant arthroplasties, a volar, dorsal Chamay or dorsal tendon-splitting approach was used based on surgeon discretion. For thumb IP implant arthroplasties, a dorsal H-shaped approach was used as described by Schindele et al.[6]

MCP registry

Patients with a MCP implant arthroplasty at the index, middle, ring or small finger have been prospectively included in this registry since January 2020. The implants currently included in the MCP registry are: KeriFlex® (KeriMedical, Geneva, Switzerland), Swanson™ (Stryker, Michigan, USA) and Ascension® MCP pyrocarbon finger joint implants (Ascension Orthopedics Inc. Austin, USA). In general, surgeries were carried out using the dorsal transverse approach as described by Estermann et al.[19] For patients with rheumatoid arthritis or multiple MCP implant arthroplasties, surgeons used the transverse approach.

IPS registry

All patients who underwent corrective osteotomy of the distal radius or forearm using an IPS implant (KLS Martin Group, Tuttlingen, Germany) have been enrolled in this registry since March 2016. Surgeries were performed as described by Schindele et al.[12]

Measurement time points

For each registry, all measurement time points along with the designated time ranges, the number of enrolled cases, number of actual patients at each time point, data completion and follow-up rates, and the number of dropouts as well as the number of revisions from the beginning of each registry until January 2024 are outlined in Figure 1. The data completion rate is calculated by dividing the number of cases with available clinical outcomes or PROMs by the expected number of cases. The expected number of cases is determined by subtracting the cases that are not due, dropout cases, and revision cases from the total number of enrolled cases. The follow-up rate is calculated by dividing the number of cases with available clinical outcomes or PROMs by the number of cases initially due for the respective follow-up.

Data collection

One week before surgery, the study assistant sends the PROM questionnaires to patients via email or post. At all scheduled follow-ups, electronic surveys are dispatched automatically on the exact follow-up date. On the day of surgery, the study assistant examines the patient and collects clinical outcomes. Postoperative examinations are done by the surgeons. An overview of the data collection process over the different time points is illustrated in Figure 2.

For all registries, surgeons require, on average, 2 mins (median) (interquartile range= 2) to input surgical details and 1 min (interquartile range = 2) for follow-up clinical outcomes. On average, patients require 7 minutes (interquartile range = 4) to complete electronic surveys.

Before surgery and at follow-up, all patients undergo clinical and radiographic assessment as well as complete a set of PROMs. In addition, we document adverse events throughout the intra- and postoperative periods (Figure 3).

Clinical outcomes

For all four registries, grip strength is measured using a JAMAR dynamometer (SAEHAN Corporation, Masan, South Korea) in a standardised test position.[20] In addition, thumb pinch strength is examined in the thumb CMC registry patients with a pinch gauge (B&L Engineering, Santa Ana,

CA, USA). For the thumb CMC, PIP/thumb IP and MCP registries, range of motion is assessed by measuring flexion and extension of the affected joints using a goniometer. Alternately, range of motion tests for IPS registry patients involve measuring flexion, extension, pronation, and supination of the wrist with a goniometer. Axis deviation and lateral stability of the affected joints are documented in the PIP/thumb IP and MCP registries. In addition, patients in the thumb CMC registry are assessed for active thumb opposition using the Kapandji index, where scores range from 0 to 10 with higher values indicating better range of motion.[21]

Surgery details

Each surgery and its implants are documented in detail to include information about the surgical technique, name of implant, name of surgeon, initial diagnosis, and duration of surgery.

Radiographs

Standard anteroposterior radiographs of the hand and anteroposterior and lateral radiographs of the affected finger or wrist are taken. Preoperative radiographs of the thumb CMC registry patients are specifically analysed for OA severity using the Eaton classification.[22] For all registries, adverse events of implant fracture, migration, luxation, radiolucent lines, cysts, fractures, bone reactions and peritendinous calcifications are monitored on postoperative radiographs. Lastly, the following postoperative anatomical parameters of palmar and radial tilt, radial length and ulnar variance are measured according to Mann[23] and collected in the IPS registry.

PROMs

In the thumb CMC, PIP/thumb IP and MCP registries, we document hand function as measured using the brief Michigan Hand Outcomes Questionnaire (MHQ),[24-26] whereas wrist function is measured using the Patient-Rated Wrist Evaluation (PRWE) for the IPS registry.[27 28] Both PROMs are scored from 0 to 100, where 100 indicates the best score in the brief MHQ and the worst score in the PRWE. Pain at rest and during activities of daily living are measured using a numeric rating scale from 0 to 10, where 10 indicates the highest pain level. Quality of life is measured using the European Quality of Life 5-dimensions 5-level questionnaire (EQ-5D-5L),[29] which ranges in score from -0.66 to 1 (German value set), where 1 indicates the highest quality of life. In a similar manner to the patient

satisfaction questions posed by De Ridder et al.,[30] all registry patients rate their satisfaction by answering the following questions on a 5-point Likert scale: "How satisfied are you with the result of the surgery on your right thumb?", "In hindsight, would you decide to have this surgery again?", and "How is your operated right thumb in general compared to before the surgery?". The thumb CMC registry further records the number of days to return to work and the number of days for hand therapy.

Adverse events

Intra- and postoperative adverse events and the management of these reported incidents are documented according to the International Organisation for Standardisation.[31] Adverse events were defined as any untoward medical occurrence related to the primary surgery that required treatment.

Data management and monitoring

Treatment data are collected, managed, and stored in the REDCap electronic data capture system[32] which is hosted in our clinic. Sociodemographic data are automatically uploaded from the clinic information system to REDCap, where a case is created for each surgery. Since more than one implant can be applied to the different joints during any single surgery, an individual case may comprise multiple implants. Furthermore, there may be multiple cases for any given patient, assuming the patient undergoes surgery more than once or if a previous surgery requires revision. In the event of a revision, a new case is created for the revision surgery.

Data checks

The REDCap system notifies the study assistant when surveys as well as surgical and clinical follow-up outcome forms have been completed, which ensures that the data are double-checked for completeness. Additionally, the data manager independently performs data checks on the entries in surveys and surgical and clinical outcome forms for each time point and for every case in the registry. More precisely, the data manager flags missing data and potential errors, which are carefully examined and subsequently completed or corrected. Each reason for a retrospective change is documented in REDCap to ensure comprehensive tracking of data entry. Statistical analyses are carried out using

Stata (Version 17; StataCorp, College Station, TX, USA) or R (Version 4.4.1; R Core Team 2024) software.

Monitoring

To monitor patients who need to be recalled for a follow-up visit within the correct time range after surgery, the study assistant uses the FileMaker Pro Advanced (Version 20.3.1.31; Claris International, California, USA) database connected to the clinic information system via a SQL server.

Patient characteristics

Until January 2024, there were a total of 486 cases enrolled in the thumb CMC registry, 864 cases in the PIP/thumb IP registry, 34 cases in the MCP registry, and 27 cases in the IPS registry (Table 1).

Table 1: Baseline characteristics for all cases enrolled in the Schulthess hand implant and forearm osteotomy registries

Characteristic	**Registry type**			
	Thumb CMC (N=486)	**PIP/thumb IP (N=864)***	**MCP (N=34)***	**IPS (N=27)**
Age (years)	64 (8.8)	69 (9.8)	63 (14)	42 (21)
Gender (n [%])				
Female	366 (75)	627 (73)	24 (71)	17 (63)
Diagnosis (n [%])**				
Primary osteoarthritis	430 (99)	918 (90)	14 (22.2)	
Secondary osteoarthritis	1 (0.2)	43 (4.2)	2 (3.2)	
Rheumatoid arthritis	1 (0.2)	39 (3.8)	25 (39.7)	
Psoriatic arthritis			1 (1.6)	
Chondrocalcinosis			2 (3.2)	
Malunion distal radius				21 (68)
Malunion radius shaft				3 (9.7)
Malunion ulna				2 (6.5)
Other	2 (0.5)	16 (1.8)	2 (3.2)	5 (16)
Missing	*52 (11)*	*68 (1.5)*	*17 (26.9)*	*0 (0)*
Grip strength (kg) †	21 (11)	18 (9)	15 (9)	25 (12)
Missing (n [%])	*10 (2.1)*	*357 (41)*	*2 (5.9)*	*2 (7.4)*
Key pinch (kg) †	4.3 (2.3)			
Missing (n [%])	*10 (2.1)*			
Affected finger (n [%])				
I	486 (100)	32 (3.0)		
II		301 (28)	26 (41)	
III		353 (33)	19 (30)	
IV		252 (23)	9 (14)	
V		146 (13)	9 (14)	

ROM of affected MCP joint: flexion & extension (°)†				
I	60 (16)			
II			41 (23)	
III			46 (33)	
IV			42 (37)	
V			41 (42)	
Missing (n [%])	*14 (2.9)*			
ROM of affected IP/PIP joint: flexion & extension (°)†				
I	73 (20)	48 (25)		
II		44 (20)		
III		50 (21)		
IV		46 (22)		
V		44 (24)		
Missing (n [%])	*15 (3.1)*	*856 (79)*		
ROM wrist (°)†				
Flexion & extension				99 (37)
Pronation & supination				133 (37)
Missing (n [%])				*3 (11)*
Pain at rest (0, 10) †				
I	5.3 (2.5)	4.9 (3.0)		
II		4.9 (2.8)	4.9 (3.1)	
III		4.9 (2.8)	4.1 (2.9)	
IV		4.3 (3.0)	3.8 (3.0)	
V		4.7 (2.9)	4.0 (3.5)	
Forearm				1.1 (1.7)
Missing (n [%])	*39 (8.0)*	*530 (49)*	*3 (4.8)*	*5 (19)*
Pain during activities (0, 10)†				
I	7.3 (1.8)	7.1 (2.5)		
II		6.6 (2.2)	5.6 (2.8)	
III		6.8 (2.1)	5.2 (2.9)	
IV		6.3 (2.5)	5.0 (3.9)	
V		6.2 (2.5)	4.4 (3.5)	
Forearm				3.2 (2.8)
Missing (n [%])	*39 (8.0)*	*539 (50)*	*2 (3.2)*	*5 (19)*
Kapandji index (0, 10)†	8.9 (1.5)			
Missing (n [%])	*13 (2.7)*			
EQ-5D-5L (-0.66, -1)†	0.7 (0.2)	0.8 (0.17)	0.8 (0.2)	0.8 (0.1)
Missing (n [%])	*39 (8.0)*	*389 (45)*	*1 (2.9)*	*5 (16)*
Brief MHQ (0, 100)†	45 (15)	46 (16)	42 (17)	
Missing (n [%])	*41 (8.4)*	*388 (45)*	*1 (2.9)*	
PRWE (0, 100)†				39 (26)

Mean values with standard deviations are presented, unless otherwise indicated.

*1,084 and 63 implants were included in the PIP/thumb IP and MCP registries, respectively.

**More than one diagnosis can be selected for the IPS registry.

CMC: carpometacarpal; PIP: proximal interphalangeal; IP: interphalangeal; MCP: metacarpophalangeal; IPS: individual patient solution; ROM: range of motion; EQ-5D-5L: European quality of life 5-dimensions 5-level questionnaire; MHQ: Michigan hand outcomes questionnaire; PRWE: patient-rated wrist evaluation

†For pain, lower values represent less to no pain and better outcome. For grip strength, key pinch, ROM, Kapandji index (active thumb opposition), EQ-5D-5L, brief MHQ and PRWE, higher values represent better outcome/less disability.

FINDINGS TO DATE

Since their establishment, each registry has been used to address several clinical and methodological questions. In principle, the results serve to improve our daily clinical practice as well as be available for the community, as described in the following paragraphs. Furthermore, our registry data are integrated into our clinic information system that displays the information on a dashboard, which enables surgeons to assess indications and directly show surgery progress to their patients.

Thumb CMC registry

Based on data from our thumb CMC registry and a recent prospective study,[33] we could show that thumb CMC implant arthroplasty patients recover faster over those with a resection-suspension-interposition (RSI) arthroplasty. Thumb CMC implant arthroplasty patients had significantly better hand function and returned to work within a shorter period compared to RSI arthroplasty patients.[33] We further outlined the benefits of the thumb CMC implant arthroplasty with a high 2-year survival rate of 96% and promising clinical outcomes at 2 years.[34] With regard to the surgical technique, we found that the capsule can be safely resected during thumb CMC implant arthroplasty and have now changed our practice accordingly.[35] We also engage in surgeon discretion to preserve and suture the joint capsule, as our findings indicate this step as dispensable. Based on the promising results of thumb

CMC implant arthroplasty compared to RSI, we have chosen implant arthroplasty as our standard procedure of care.

PIP/thumb IP registry

Surface replacing implant arthroplasty is the most commonly recorded procedure for the PIP joint in this registry. In an analysis of 100 patients, we showed that the tendon splitting approach produced better outcomes compared to two other approaches.[36] Thus, we changed our surgical technique and now only use the tendon splitting approach. Five-year data on surface replacing implant arthroplasties reveal promising clinical outcomes and PROMs[7], even for the index finger.[37] Furthermore, surface replacing implant arthroplasties correct axis deviations significantly better than a silicone implant arthroplasty.[38] With these positive results, we now routinely apply this implant at the index and middle finger instead of silicone implants as used previously. We also showed that a surface replacing implant yields satisfactory outcomes at the thumb IP joint.[6] However, due to several reports of adverse events, thumb IP joint patients are selected more carefully with focus on those who place great importance on practising precision tasks.

We determined the minimal important change and patient acceptable symptom state for pain, the brief MHQ and range of motion in patients 1 year after PIP implant arthroplasty.[39-40] These calculated thresholds may support surgeons in the preoperative process of deciding for or against a surgical intervention and in explaining the probability of achieving sufficient postoperative symptom relief for the patient.

IPS registry

We evaluated 1-year postoperative clinical outcomes and PROMs in patients who underwent three-dimensional planned corrective osteotomy of the distal radius, radial shaft, or ulnar shaft using a printed, anatomical, patient-tailored implant to determine the feasibility and effectiveness of this methodology. Wrist-related pain and disability (indicated by a lower PRWE score) and range of motion significantly improved after 1 year.[12]

FURTHER DETAILS

Strengths and limitations

Among the main strengths of our registries are the high data completeness rates, consistent clinical outcomes and PROMs follow-up, and the use of validated and standardised outcome measures. Our follow-up rates are among the highest reported in the hand surgery literature, where follow-up rates for clinical outcomes and PROMs range from 30-40% to 38-62% in other registries.[16 18] Our strengths enable us to continuously monitor patients and analyse clinical outcomes and PROMs not only at the individual patient level, but also across the patient population. Furthermore, our cohorts have enabled us to publish relevant papers on the new generation of implant arthroplasties and IPS implants, contributing to advancing research and enhancing the quality of care in hand surgery.

The main limitation is that not all patients are prospectively included in the PIP/thumb IP registry, contributing to an incomplete dataset with missing baseline values, especially those for PROMs. Revision rates might be slightly underestimated, as we do not know whether patients who dropped out had complications treated elsewhere. Nonetheless, because of our reputable collaboration with other Swiss hand surgeons, we usually receive information about our patients treated elsewhere and can record these events in our registry.

COLLABORATION

Data are available upon reasonable request and researchers are invited to contact the first author for requests concerning statistical codes and instruments used. The participant consent forms restrict data sharing on a public repository.

ACKNOWLEDGEMENTS

The authors would like to thank Melissa Wilhelmi, PhD (Schulthess Klinik) for the copy-editing of this manuscript and the study assistants for their support in the data collection.

COMPETING INTERESTS DECLARATION

Daniel B. Herren and Stephan Schindele receive royalties from KLS Martin Group, Tuttlingen, Germany. Daniel B. Herren and Stephan Schindele have speaker contracts with Keri Medical, which obliges them to hold training courses on the surgical technique of the Touch® prosthesis. Thumb CMC, PIP/thumb IP and MCP registries are partly sponsored by Keri Medical. IPS registry is partly sponsored by KLS Martin Group. Miriam Marks has a consultancy agreement with KLS Martin Group. Kei Mathis declares no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

FUNDING

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ETHICS

This study was approved by the Ethical Committee of Canton Zurich (KEK-ZH-Nr. 2014-0546, 2019-02096, 2020-00143). All participants provided informed consent.

PATIENT AND PUBLIC INVOLVEMENT

Patient and public were not involved in the design and conduct of this study.

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FIGURE LEGENDS

Figure 1

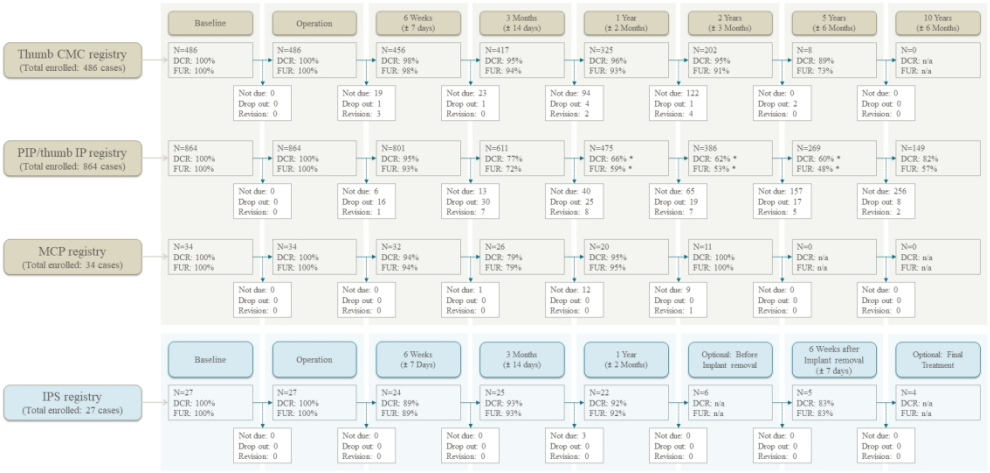
Cohort inclusion flowchart per registry including data completion and follow-up rates. For the IPS registry, implant removal and the subsequent final treatment are optional interventions that are not performed for all patients. *Smaller data completion and follow-up rates are due to a high number of missing treatment data from retrospectively enrolled cases. CMC: Carpometacarpal; DCR: Data completion rate; FUR: Follow-up rate; n/a: not applicable; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; IPS: Individual patient solution.

Figure 2

The study assistant assesses clinical outcomes at baseline, while the surgeon assesses surgical details on the day of the operation and clinical outcomes at follow-up. Patients complete surveys at baseline and follow-up. W: Weeks; Y: Year(s); PROMs: Patient-reported outcome measures.

Figure 3

Documentation of measurement procedures for the thumb CMC, PIP/thumb IP, MCP (top) and IPS (bottom) registries. *Return to work is only assessed in the thumb CMC registry. CMC: Carpometacarpal; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; M: Month(s); Y: Year(s); PROM: Patient-reported outcome measure; MHQ: Michigan hand outcomes questionnaire; EQ-5D-5L: European quality of life 5-dimensions 5-level questionnaire; IPS: Individual patient solution; W: Weeks; PRWE: Patient-rated wrist evaluation.



Cohort inclusion flowchart per registry including data completion and follow-up rates. For the IPS registry, implant removal and the subsequent final treatment are optional interventions that are not performed for all patients. *Smaller data completion and follow-up rates are due to a high number of missing treatment data from retrospectively enrolled cases. CMC: Carpometacarpal; DCR: Data completion rate; FUR: Follow-up rate; n/a: not applicable; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; IPS: Individual patient solution.

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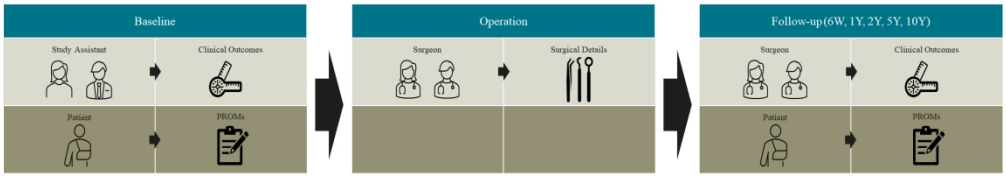

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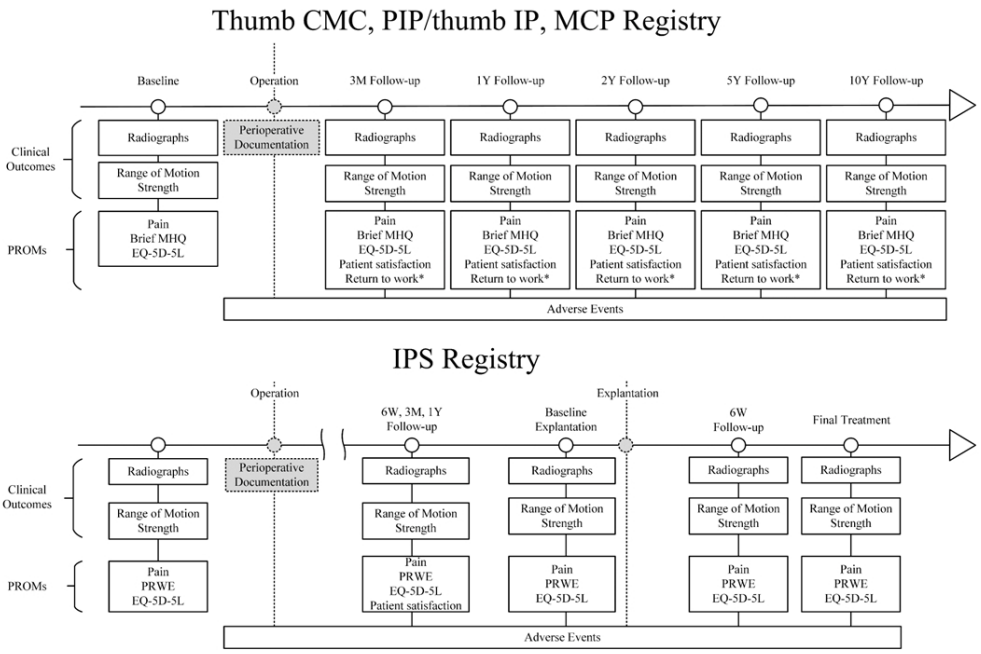
1515x481mm (38 x 38 DPI)



Documentation of measurement procedures for the thumb CMC, PIP/thumb IP, MCP (top) and IPS (bottom) registries. *Return to work is only assessed in the thumb CMC registry. CMC: Carpometacarpal; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; M: Month(s); Y: Year(s); PROM: Patient-reported outcome measure; MHQ: Michigan hand outcomes questionnaire; EQ-5D-5L: European quality of life 5-dimensions 5-level questionnaire; IPS: Individual patient solution; W: Weeks; PRWE: Patient-rated wrist evaluation.

716x481mm (38 x 38 DPI)

BMJ Open

Cohort profile: The Schulthess registries for hand implants and forearm corrective osteotomies

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-093425.R1
Article Type:	Cohort profile
Date Submitted by the Author:	18-Dec-2024
Complete List of Authors:	Mathis, Kei; Schulthess Klinik, Teaching, Research and Development Herren, Daniel B ; Schulthess Klinik, Hand Surgery Schindele, Stephan; Schulthess Klinik, Hand Surgery Marks, M; Schulthess Klinik, Teaching,Research and Development
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Surgery
Keywords:	Hand & wrist < ORTHOPAEDIC & TRAUMA SURGERY, Patient Reported Outcome Measures, REGISTRIES

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$Title	Cohort profile: The Schulthess registries for hand implants and forearm corrective osteotomies
Authors' names	Kei Mathis[1] (0009-0009-8348-6803), Daniel B. Herren[2] (0000-0001-6585-2341), Stephan Schindele[2] (0000-0001-6997-5162), Miriam Marks[1] (0000-0002-0623-2465)
Address for each author	[1]Department of Teaching, Research and Development, Schulthess Klinik, 8008 Zurich, Switzerland [2]Department of Hand Surgery, Schulthess Klinik, 8008 Zurich, Switzerland
Authors' names and positions	Kei Mathis MSc. Research Assistant, Daniel B. Herren MD MHA Chief Surgeon, Stephan Schindele Co-Chief Surgeon, Miriam Marks PhD Senior Research Associate
Corresponding author	Kei Mathis Department of Teaching, Research and Development, Schulthess Klinik, 8008 Zurich, Switzerland kei.mathis@kws.ch +41 44 385 79 83
Contributor and guarantor information	Kei Mathis, Daniel B. Herren, Stephan Schindele and Miriam Marks developed the protocol. Daniel B. Herren and Stephan Schindele treated the patients. Kei Mathis, Daniel B. Herren and Stephan Schindele were involved in data collection. Kei Mathis and Miriam Marks were responsible for data management. Miriam Marks was involved in gaining ethical approval. Kei Mathis analysed the data and wrote the first draft of the manuscript. All authors edited and approved the final version of the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. Kei Mathis identifies as guarantor.

	We utilized OpenAI's ChatGPT, a large language model based on the GPT-4 architecture, to assist with word processing and language refinement throughout the manuscript preparation process.
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Competing interests declaration	Daniel B. Herren and Stephan Schindele receive royalties from KLS Martin Group, Tuttlingen, Germany. Daniel B. Herren and Stephan Schindele have speaker contracts with Keri Medical, which obliges them to hold training courses on the surgical technique of the Touch® prosthesis. Thumb CMC, PIP/thumb IP and MCP registries are partly sponsored by Keri Medical. IPS registry is partly sponsored by KLS Martin Group. Miriam Marks has a consultancy agreement with KLS Martin Group. Kei Mathis declares no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Cohort profile: The Schulthess registries for hand implants and forearm corrective osteotomies

ABSTRACT

Purpose: Our hand and forearm registries were established to evaluate safety, function, quality of life and patient satisfaction in patients undergoing thumb and finger implant arthroplasties as well as corrective osteotomy of the forearm with individual patient solution (IPS) implants.

Participants: The four different registries were initiated between 2010 and 2020 and include patients with implant arthroplasties of the thumb carpometacarpal (CMC) (n=486), proximal interphalangeal (PIP) or thumb interphalangeal (IP) (n=864), and metacarpophalangeal (MCP) (n=34) joints as well as 27 patients with corrective osteotomy of the distal radius or forearm using an IPS implant. All patients complete disease-specific questionnaires and are clinically assessed before surgery (baseline) and up to 10 years thereafter.

Findings to date: All operated patients (100%) were included in the registries with complete baseline data. One-year follow-up rates range between 59% to 95% and for the 5-year follow-up, between 48% to 83%. Data completeness rates (i.e. number of cases with available data divided by the expected number of cases) range between 66% to 96% and 60% to 89% for the 1- and 5-year follow-ups, respectively. Patients showed significantly improved postoperative clinical and patient-reported outcomes over baseline. The registries serve as a basis for standardised patient-monitoring quality control and answering several clinical questions. With the help of these large databases, clinical practice can be improved for the benefit of our patients.

Future plans: As first patients approach the 10-year follow-up landmark, the registry will continue providing essential data on long-term clinical and patient-reported outcomes as well as revision rates. In addition to research and quality control, the cohort data will be brought back to the patients by bolstering real-time clinical decision support.

INTRODUCTION

Hand osteoarthritis (OA) is a degenerative disease that relies on surgical intervention when conservative treatment fails to control symptoms and improve function. Besides OA, other common reasons for joint deformity or destruction of the hand include rheumatoid arthritis and trauma. Implant arthroplasty, among other surgical techniques, is becoming increasingly popular as the treatment of choice for the affected joint, aiming to preserve the range of motion. Several implant arthroplasties are available for the thumb carpometacarpal (CMC),[1 2] thumb interphalangeal (IP),[3] proximal interphalangeal (PIP)[4-7] and metacarpophalangeal (MCP) joints,[8] all of which show good medium- and long-term outcomes. For malunited fractures of the distal radius or forearm, individual patient solution (IPS) implants comprising printed, anatomical patient-tailored plates are available for three-dimensional planned corrective osteotomy.[9]

Clinical registries have gained international recognition as a continuous monitoring system that accumulates information on clinical outcomes and patient-reported outcome measures (PROMs), which provide a valuable basis for improving hand surgery practices and patient care.[10 11] When compared with large national registries that demand complex coordination and significant resources,[12] local registries often have the advantage of encouraging active participation and ensuring complete reporting with fewer logistical challenges.

While several publications on hand and wrist implant registries are available to date, [13 14] a detailed description of our cohort is still missing that encompasses patients with new generation thumb and finger implant arthroplasties as well as three-dimensionally printed IPS implants for corrective osteotomies. With the publication of these cohort profiles, we aim to contribute to the existing information on establishing a local registry and the potential benefits it can bring to clinical practice. Our local hand and wrist implant registries are based at the Schulthess Klinik, an international high-volume orthopaedic centre in Zurich, Switzerland. The registries were established to evaluate safety, function, quality of life, and satisfaction in patients undergoing implant arthroplasty for thumb CMC, thumb IP, PIP and MCP joints, and forearm osteotomy correction using IPS implants. The aim of the current cohort profile is to describe the structure and baseline characteristics of the registries, and to

share the collected technical and epidemiological experience in establishing and maintaining hand and forearm implant registries with high coverage and reasonable publication output. We also present how data analysed from the registries changed our clinical practice and improved patient care.

COHORT DESCRIPTION

Setting, patients and eligibility criteria

There are four registries covering patients treated with finger and thumb implant arthroplasties and IPS implants at Schulthess Klinik in Zurich, Switzerland that are primarily funded by the Wilhelm Schulthess Foundation as well as through nested projects with industry partners. Before patients are enrolled in the registries, the responsible surgeon informs the patient during the preoperative consultation that treatment data collected for the registries will be used primarily for internal quality control. Patients are also invited to voluntarily sign a general consent form indicating agreement to using their treatment data for future scientific projects and publications.

Thumb CMC registry

Patients receiving a thumb CMC implant arthroplasty have been prospectively included in the registry since June 2018. The implants currently included in the registry are the Touch™ (KeriMedical, Geneva, Switzerland) and Maïa™ dual mobility trapeziometacarpal prostheses (Groupe Lépine, Genay, France). All surgeries were carried out using the standard dorsolateral approach technique described by Lussiez et al.[1]

PIP/thumb IP registry

The PIP/thumb IP registry includes patients with PIP or thumb IP implant arthroplasties. Patients with a CapFlex (KLS Martin Group, Tuttlingen, Germany) implant arthroplasty have been prospectively included since May 2010, while other implant arthroplasties have been retrospectively added since May 2010 as well as prospectively included since July 2019; retrospectively-included treatment data were collected from patient medical records. The implants currently included in the PIP/thumb IP registry are: KeriFlex® (KeriMedical, Geneva, Switzerland), Swanson™ (Stryker, Michigan, USA), silicone arthroplasty system (Stryker, Michigan, USA), Tactys® (Stryker, Michigan, USA),

HAPTIC® (implantcast, Buxtehude, Germany) and NeuFlex® (DePuy Synthes, Warsaw, USA). For PIP implant arthroplasties, a volar, dorsal Chamay or dorsal tendon-splitting approach was used based on surgeon discretion. For thumb IP implant arthroplasties, a dorsal H-shaped approach was used as described by Schindele et al.[3]

MCP registry

Patients with a MCP implant arthroplasty at the index, middle, ring or small finger have been prospectively included in this registry since January 2020. The implants currently included in the MCP registry are: KeriFlex® (KeriMedical, Geneva, Switzerland), Swanson™ (Stryker, Michigan, USA) and Ascension® MCP pyrocarbon finger joint implants (Ascension Orthopedics Inc. Austin, USA). In general, surgeries were carried out using the dorsal transverse approach as described by Estermann et al.[15] For patients with rheumatoid arthritis or multiple MCP implant arthroplasties, surgeons used the transverse approach.

IPS registry

All patients who underwent corrective osteotomy of the distal radius or forearm using an IPS implant (KLS Martin, Tuttlingen, Germany) have been enrolled in this registry since March 2016. Surgeries were performed as described by Schindele et al.[9]

Measurement time points

For each registry, all measurement time points along with the designated time ranges, the number of enrolled cases, number of actual patients at each time point, data completion and follow-up rates, and the number of dropouts as well as the number of revisions from the beginning of each registry until January 2024 are outlined in Figure 1. The data completion rate is calculated by dividing the number of cases with available clinical outcomes or PROMs by the expected number of cases. The expected number of cases is determined by subtracting the cases that are not due for follow-up, dropout cases, and revision cases from the total number of enrolled cases. The follow-up rate is calculated by dividing the number of cases with available clinical outcomes or PROMs by the number of cases initially due for the respective follow-up.

Data collection

One week before surgery, the study assistant sends the PROM questionnaires to patients via email or post. At all scheduled follow-ups, electronic surveys are dispatched automatically on the exact follow-up date. On the day of surgery, the study assistant examines the patient and collects clinical outcomes. Postoperative examinations are done by the surgeons. An overview of the data collection process over the different time points is illustrated in Figure 2.

For all registries, surgeons require, on average, 2 mins (median) (interquartile range= 2) to input surgical details and 1 min (interquartile range = 2) for follow-up clinical outcomes. On average, patients require 7 minutes (interquartile range = 4) to complete electronic surveys.

Before surgery and at follow-up, all patients undergo clinical and radiographic assessment as well as complete a set of PROMs. In addition, we document adverse events throughout the intra- and postoperative periods (Figure 3).

Clinical outcomes

For all four registries, grip strength is measured using a JAMAR dynamometer (SAEHAN Corporation, Masan, South Korea) in a standardised test position.[16] In addition, thumb pinch strength is examined in the thumb CMC registry patients with a pinch gauge (B&L Engineering, Santa Ana, CA, USA). For the thumb CMC, PIP/thumb IP and MCP registries, range of motion is assessed by measuring flexion and extension of the affected joints using a goniometer. Alternately, range of motion tests for IPS registry patients involve measuring flexion, extension, pronation, and supination of the wrist with a goniometer. Axis deviation and lateral stability of the affected joints are documented in the PIP/thumb IP and MCP registries. In addition, patients in the thumb CMC registry are assessed for active thumb opposition using the Kapandji index, where scores range from 0 to 10 with higher values indicating better range of motion.[17]

Surgery details

Each surgery and its implants are documented in detail to include information about the surgical technique, name of implant, name of surgeon, initial diagnosis, and duration of surgery.

Radiographs

Standard anteroposterior radiographs of the hand and anteroposterior and lateral radiographs of the affected finger or wrist are taken. Preoperative radiographs of the thumb CMC registry patients are specifically analysed for OA severity using the Eaton classification.[18] For all registries, adverse events of implant fracture, migration, luxation, radiolucent lines, cysts, fractures, bone reactions and peritendinous calcifications are monitored on postoperative radiographs. Lastly, the following postoperative anatomical parameters of palmar and radial tilt, radial length and ulnar variance are measured according to Mann[19] and collected in the IPS registry.

PROMs

In the thumb CMC, PIP/thumb IP and MCP registries, we document hand function as measured using the brief Michigan Hand Outcomes Questionnaire (MHQ),[20-22] whereas wrist function is measured using the Patient-Rated Wrist Evaluation (PRWE) for the IPS registry.[23 24] Both PROMs are scored from 0 to 100, where 100 indicates the best score in the brief MHQ and the worst score in the PRWE. Pain at rest and during activities of daily living are measured using a numeric rating scale from 0 to 10, where 10 indicates the highest pain level. Quality of life is measured using the European Quality of Life 5-dimensions 5-level questionnaire (EQ-5D-5L),[25] which ranges in score from -0.66 to 1 (German value set), where 1 indicates the highest quality of life. In a similar manner to the patient satisfaction questions posed by De Ridder et al.,[26] all registry patients rate their satisfaction by answering the following questions on a 5-point Likert scale: "How satisfied are you with the result of the surgery on your right thumb?", "In hindsight, would you decide to have this surgery again?", and "How is your operated right thumb in general compared to before the surgery?". The thumb CMC registry further records the number of days to return to work and the number of days for hand therapy.

Adverse events

Intra- and postoperative adverse events and the management of these reported incidents are documented according to the International Organisation for Standardisation.[27] Adverse events were defined as any untoward medical occurrence related to the primary surgery that required treatment.

Data management and monitoring

Treatment data are collected, managed, and stored in the REDCap electronic data capture system[28] which is hosted in our clinic. Sociodemographic data are automatically uploaded from the clinic information system to REDCap, where a case is created for each surgery. Since more than one implant can be applied to the different joints during any single surgery, an individual case may comprise multiple implants. Furthermore, there may be multiple cases for any given patient, assuming the patient undergoes surgery more than once or if a previous surgery requires revision. In the event of a revision, a new case is created for the revision surgery.

Data checks

The REDCap system notifies the study assistant when surveys as well as surgical and clinical follow-up outcome forms have been completed, which ensures that the data are double-checked for completeness. Additionally, the data manager independently performs data checks on the entries in surveys and surgical and clinical outcome forms for each time point and for every case in the registry. More precisely, the data manager flags missing data and potential errors, which are carefully examined and subsequently completed or corrected. Each reason for a retrospective change is documented in REDCap to ensure comprehensive tracking of data entry. Statistical analyses are carried out using Stata (Version 17; StataCorp, College Station, TX, USA) or R (Version 4.4.1; R Core Team 2024) software.

Monitoring

To monitor patients who need to be recalled for a follow-up visit within the correct time range after surgery, the study assistant uses the FileMaker Pro Advanced (Version 20.3.1.31; Claris International, California, USA) database connected to the clinic information system via a SQL server.

Patient characteristics

Until January 2024, there were a total of 486 cases enrolled in the thumb CMC registry, 864 cases in the PIP/thumb IP registry, 34 cases in the MCP registry, and 27 cases in the IPS registry (Table 1).

184 ***Table 1: Baseline characteristics for all cases enrolled in the Schulthess hand implant and***

185 ***forearm osteotomy registries***

Characteristic	**Registry type**			
	Thumb CMC (N=486)	**PIP/thumb IP (N=864)***	**MCP (N=34)***	**IPS (N=27)**
Age (years)	64 (8.8)	69 (9.8)	63 (14)	42 (21)
Gender (n [%])				
Female	366 (75)	627 (73)	24 (71)	17 (63)
Diagnosis (n [%])**				
Primary osteoarthritis	430 (99)	918 (90)	14 (22.2)	
Secondary osteoarthritis	1 (0.2)	43 (4.2)	2 (3.2)	
Rheumatoid arthritis	1 (0.2)	39 (3.8)	25 (39.7)	
Psoriatic arthritis			1 (1.6)	
Chondrocalcinosis			2 (3.2)	
Malunion distal radius				21 (68)
Malunion radius shaft				3 (9.7)
Malunion ulna				2 (6.5)
Other	2 (0.5)	16 (1.8)	2 (3.2)	5 (16)
Missing	*52 (11)*	*68 (1.5)*	*17 (26.9)*	*0 (0)*
Grip strength (kg) †	21 (11)	18 (9)	15 (9)	25 (12)
Missing (n [%])	*10 (2.1)*	*357 (41)*	*2 (5.9)*	*2 (7.4)*
Key pinch (kg) †	4.3 (2.3)			
Missing (n [%])	*10 (2.1)*			
Affected finger (n [%])				
I	486 (100)	32 (3.0)		
II		301 (28)	26 (41)	
III		353 (33)	19 (30)	
IV		252 (23)	9 (14)	
V		146 (13)	9 (14)	
ROM of affected MCP joint: flexion & extension (°)‡				
I	60 (16)			
II			41 (23)	
III			46 (33)	
IV			42 (37)	
V			41 (42)	
Missing (n [%])	*14 (2.9)*			
ROM of affected IP/PIP joint: flexion & extension (°)‡				
I	73 (20)	48 (25)		
II		44 (20)		
III		50 (21)		
IV		46 (22)		
V		44 (24)		
Missing (n [%])	*15 (3.1)*	*856 (79)*		
ROM wrist (°)†				
Flexion & extension				99 (37)
Pronation & supination				133 (37)
Missing (n [%])				*3 (11)*

Pain at rest (0, 10) †				
I	5.3 (2.5)	4.9 (3.0)		
II		4.9 (2.8)	4.9 (3.1)	
III		4.9 (2.8)	4.1 (2.9)	
IV		4.3 (3.0)	3.8 (3.0)	
V		4.7 (2.9)	4.0 (3.5)	
Forearm				1.1 (1.7)
Missing (n [%])	*39 (8.0)*	*530 (49)*	*3 (4.8)*	*5 (19)*
Pain during activities (0, 10)†				
I	7.3 (1.8)	7.1 (2.5)		
II		6.6 (2.2)	5.6 (2.8)	
III		6.8 (2.1)	5.2 (2.9)	
IV		6.3 (2.5)	5.0 (3.9)	
V		6.2 (2.5)	4.4 (3.5)	
Forearm				3.2 (2.8)
Missing (n [%])	*39 (8.0)*	*539 (50)*	*2 (3.2)*	*5 (19)*
Kapandji index (0, 10)†	8.9 (1.5)			
Missing (n [%])	*13 (2.7)*			
EQ-5D-5L (-0.66, -1)†	0.7 (0.2)	0.8 (0.17)	0.8 (0.2)	0.8 (0.1)
Missing (n [%])	*39 (8.0)*	*389 (45)*	*1 (2.9)*	*5 (16)*
Brief MHQ (0, 100)†	45 (15)	46 (16)	42 (17)	
Missing (n [%])	*41 (8.4)*	*388 (45)*	*1 (2.9)*	
PRWE (0, 100)†				39 (26)

Mean values with standard deviations are presented, unless otherwise indicated.

**1,084 and 63 implants were included in the PIP/thumb IP and MCP registries, respectively.*

**More than one diagnosis can be selected for the IPS registry.

CMC: carpometacarpal; PIP: proximal interphalangeal; IP: interphalangeal; MCP: metacarpophalangeal; IPS: individual patient solution; ROM: range of motion; EQ-5D-5L: European quality of life 5-dimensions 5-level questionnaire; MHQ: Michigan hand outcomes questionnaire; PRWE: patient-rated wrist evaluation

†For pain, lower values represent less to no pain and better outcome. For grip strength, key pinch, ROM, Kapandji index (active thumb opposition), EQ-5D-5L, brief MHQ and PRWE, higher values represent better outcome/less disability.

FINDINGS TO DATE

Since their establishment, each registry has been used to address several clinical and methodological questions. In principle, the results serve to improve our daily clinical practice as well as be available for the community, as described in the following paragraphs. Furthermore, our registry data are integrated into our clinic information system that displays the information on a dashboard, which enables surgeons to assess indications and directly show surgery progress to their patients.

Thumb CMC registry

Based on data from our thumb CMC registry and a recent prospective study,[29] we could show that thumb CMC implant arthroplasty patients recover faster over those with a resection-suspension-interposition (RSI) arthroplasty. Thumb CMC implant arthroplasty patients had significantly better hand function and returned to work within a shorter period compared to RSI arthroplasty patients.[29] We further outlined the benefits of the thumb CMC implant arthroplasty with a high 2-year survival rate of 96% and promising clinical outcomes at 2 years.[30] With regard to the surgical technique, we found that the capsule can be safely resected during thumb CMC implant arthroplasty and have now changed our practice accordingly.[31] We also engage in surgeon discretion to preserve and suture the joint capsule, as our findings indicate this step as dispensable. Based on the promising results of thumb CMC implant arthroplasty compared to RSI, we have chosen implant arthroplasty as our standard procedure of care.

PIP/thumb IP registry

Surface replacing implant arthroplasty is the most commonly recorded procedure for the PIP joint in this registry. In an analysis of 100 patients, we showed that the tendon splitting approach produced better outcomes compared to two other approaches.[32] Thus, we changed our surgical technique and now only use the tendon splitting approach. Five-year data on surface replacing implant arthroplasties reveal promising clinical outcomes and PROMs[4], even for the index finger.[33] Furthermore, surface replacing implant arthroplasties correct axis deviations significantly better than a silicone implant arthroplasty.[34] With these positive results, we now routinely apply this implant at the index and middle finger instead of silicone implants as used previously. We also showed that a surface replacing implant yields satisfactory outcomes at the thumb IP joint.[3] However, due to several reports of adverse events, thumb IP joint patients are selected more carefully with focus on those who place great importance on practising precision tasks.

We determined the minimal important change and patient acceptable symptom state for pain, the brief MHQ and range of motion in patients 1 year after PIP implant arthroplasty.[35 36] These calculated thresholds may support surgeons in the preoperative process of deciding for or against a surgical intervention and in explaining the probability of achieving sufficient postoperative symptom relief for the patient.

IPS registry

We evaluated 1-year postoperative clinical outcomes and PROMs in patients who underwent three-dimensional planned corrective osteotomy of the distal radius, radial shaft, or ulnar shaft using a printed, anatomical, patient-tailored implant to determine the feasibility and effectiveness of this methodology. Wrist-related pain and disability (indicated by a lower PRWE score) and range of motion significantly improved after 1 year.[9]

FURTHER DETAILS

Strengths and limitations

Among the main strengths of our registries are the high data completeness rates, consistent clinical outcomes and PROMs follow-up, and the use of validated and standardised outcome measures. Our follow-up rates are among the highest reported in the hand surgery literature, where follow-up rates for clinical outcomes and PROMs range from 30-40% to 38-62% in other registries.[37 38] Our strengths enable us to continuously monitor patients and analyse clinical outcomes and PROMs not only at the individual patient level, but also across the patient population. Furthermore, our cohorts have enabled us to publish relevant papers on the new generation of implant arthroplasties and IPS implants, contributing to advancing research and enhancing the quality of care in hand surgery.

The main limitation is that not all patients are prospectively included in the PIP/thumb IP registry, contributing to an incomplete dataset with missing baseline values, especially those for PROMs. Revision rates might be slightly underestimated, as we do not know whether patients who dropped out had complications treated elsewhere. Nonetheless, because of our reputable collaboration with other Swiss hand surgeons, we usually receive information about our patients treated elsewhere and can record these events in our registry. Furthermore, while the registries are primarily funded by the Willhelm Schulthess Foundation, we also receive funding from the industry. We are aware of the potential influence this funding might have. However, in the contracts, we secured the right to publish all results, without interference from the funding party. This reinforces our confidence that industry funding does not affect cohort, reporting, or the independence of the research.

Data availability statement

Data are available upon reasonable request and researchers are invited to contact the first author for requests concerning statistical codes and instruments used. The participant consent forms restrict data sharing on a public repository.

FIGURE LEGENDS

Figure 1

*Cohort inclusion flowchart per registry including data completion and follow-up rates. For the IPS registry, implant removal and the subsequent final treatment are optional interventions that are not performed for all patients. *Smaller data completion and follow-up rates are due to a high number of missing treatment data from retrospectively enrolled cases. CMC: Carpometacarpal; DCR: Data completion rate; FUR: Follow-up rate; n/a: not applicable; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; IPS: Individual patient solution.*

Figure 2

The study assistant assesses clinical outcomes at baseline, while the surgeon assesses surgical details on the day of the operation and clinical outcomes at follow-up. Patients complete surveys at baseline and follow-up. W: Weeks; Y: Year(s); PROMs: Patient-reported outcome measures.

Figure 3

*Documentation of measurement procedures for the thumb CMC, PIP/thumb IP, MCP (top) and IPS (bottom) registries. *Return to work is only assessed in the thumb CMC registry. CMC: Carpometacarpal; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; M: Month(s); Y: Year(s); PROM: Patient-reported outcome measure; MHQ: Michigan hand outcomes questionnaire; EQ-5D-5L: European quality of life 5-dimensions 5-level questionnaire; IPS: Individual patient solution; W: Weeks; PRWE: Patient-rated wrist evaluation.*

COLLABORATION

We invite researchers to contact the corresponding author for requests for statistical code and instruments used. Multicentre registries would overcome the limitations of single-centre data

collection, including bias, lack of generalizability, limited variability, and the inability to study rare conditions. However, cross-national multicentre trials are hampered by different national laws on data collection and protection. A possible solution is data sharing in a Common Data Model with the advantage of keeping data local and only sharing summary statistics.[39]

ACKNOWLEDGEMENTS

The authors would like to thank Melissa Wilhelmi, PhD (Schulthess Klinik) for the copy-editing of this manuscript and the study assistants for their support in the data collection.

ETHICS

This study was approved by the Ethical Committee of Canton Zurich (KEK-ZH-Nr. 2014-0546, 2019-02096, 2020-00143). Participants gave informed consent to participate in this study.

PATIENT AND PUBLIC INVOLVEMENT

Patient and public were not involved in the design and conduct of this study.

COMPETING INTERESTS

Daniel B. Herren and Stephan Schindele receive royalties from KLS Martin Group, Tuttlingen, Germany. Daniel B. Herren and Stephan Schindele have speaker contracts with Keri Medical, which obliges them to hold training courses on the surgical technique of the Touch® prosthesis. Thumb CMC, PIP/thumb IP and MCP registries are partly sponsored by Keri Medical. IPS registry is partly sponsored by KLS Martin Group. Miriam Marks has a consultancy agreement with KLS Martin Group.

Kei Mathis declares no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

FUNDING

This study is primarily funded by the Wilhelm Schulthess Foundation and partially funded by KeriMedical and the KLS Martin Group.

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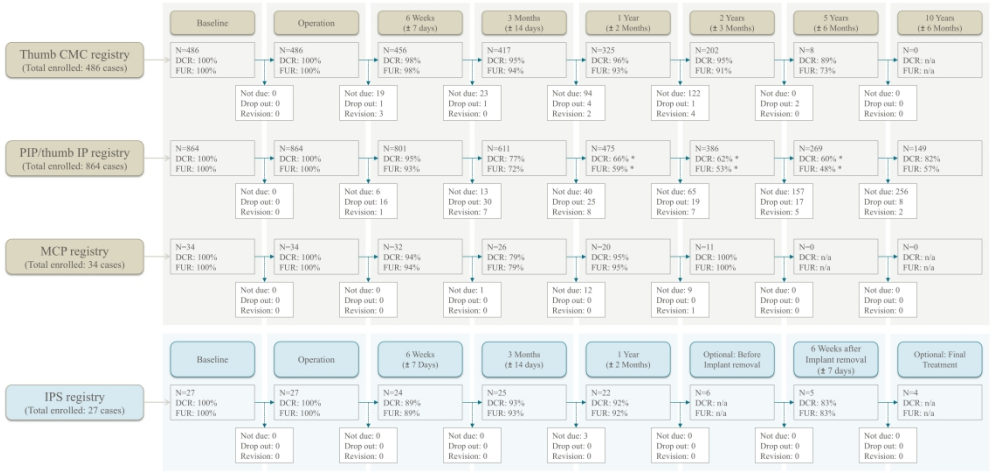

Cohort inclusion flowchart per registry including data completion and follow-up rates. For the IPS registry, implant removal and the subsequent final treatment are optional interventions that are not performed for all patients. *Smaller data completion and follow-up rates are due to a high number of missing treatment data from retrospectively enrolled cases. CMC: Carpometacarpal; DCR: Data completion rate; FUR: Follow-up rate; n/a: not applicable; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; IPS: Individual patient solution.

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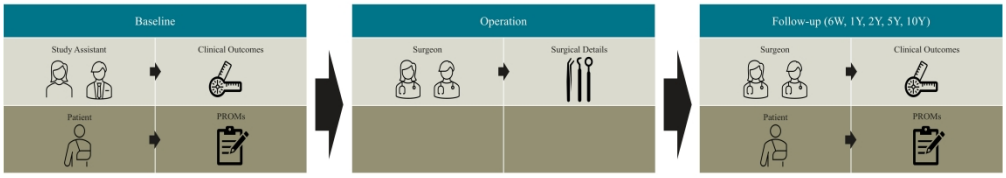
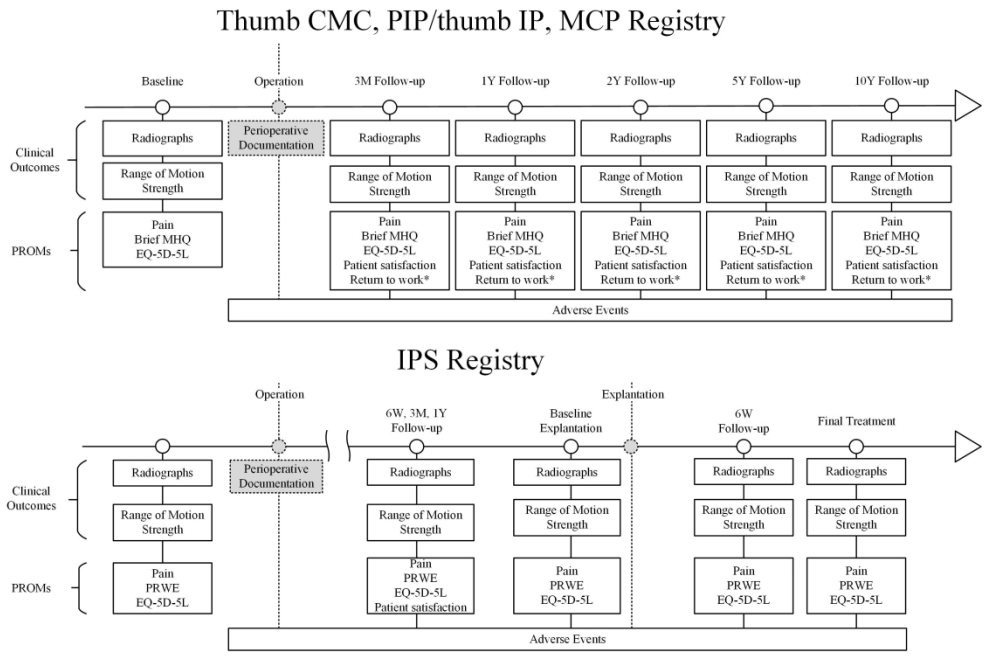


The study assistant assesses clinical outcomes at baseline, while the surgeon assesses surgical details on the day of the operation and clinical outcomes at follow-up. Patients complete surveys at baseline and follow-up. W: Weeks; Y: Year(s); PROMs: Patient-reported outcome measures.

599x190mm (300 x 300 DPI)



Documentation of measurement procedures for the thumb CMC, PIP/thumb IP, MCP (top) and IPS (bottom) registries. *Return to work is only assessed in the thumb CMC registry. CMC: Carpometacarpal; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; M: Month(s); Y: Year(s); PROM: Patient-reported outcome measure; MHQ: Michigan hand outcomes questionnaire; EQ-5D-5L: European quality of life 5-dimensions 5-level questionnaire; IPS: Individual patient solution; W: Weeks; PRWE: Patient-rated wrist evaluation.

290x195mm (300 x 300 DPI)

BMJ Open

Cohort profile: The Schulthess registries in Zurich for hand implants and forearm corrective osteotomies

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-093425.R2
Article Type:	Cohort profile
Date Submitted by the Author:	12-Feb-2025
Complete List of Authors:	Mathis, Kei; Schulthess Klinik, Teaching, Research and Development Herren, Daniel B ; Schulthess Klinik, Hand Surgery Schindele, Stephan; Schulthess Klinik, Hand Surgery Marks, M; Schulthess Klinik, Teaching,Research and Development
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Surgery
Keywords:	Hand & wrist < ORTHOPAEDIC & TRAUMA SURGERY, Patient Reported Outcome Measures, REGISTRIES

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Title	Cohort profile: The Schulthess registries in Zurich for hand implants and forearm corrective osteotomies
Authors' names	Kei Mathis[1] (0009-0009-8348-6803), Daniel B. Herren[2] (0000-0001-6585-2341), Stephan Schindele[2] (0000-0001-6997-5162), Miriam Marks[1] (0000-0002-0623-2465)
Address for each author	[1]Department of Teaching, Research and Development, Schulthess Klinik, 8008 Zurich, Switzerland [2]Department of Hand Surgery, Schulthess Klinik, 8008 Zurich, Switzerland
Authors' names and positions	Kei Mathis MSc. Research Assistant, Daniel B. Herren MD MHA Chief Surgeon, Stephan Schindele Co-Chief Surgeon, Miriam Marks PhD Senior Research Associate
Corresponding author	Kei Mathis Department of Teaching, Research and Development, Schulthess Klinik, 8008 Zurich, Switzerland kei.mathis@kws.ch +41 44 385 79 83
Contributor and guarantor information	Kei Mathis, Daniel B. Herren, Stephan Schindele and Miriam Marks developed the protocol. Daniel B. Herren and Stephan Schindele treated the patients. Kei Mathis, Daniel B. Herren and Stephan Schindele were involved in data collection. Kei Mathis and Miriam Marks were responsible for data management. Miriam Marks was involved in gaining ethical approval. Kei Mathis analysed the data and wrote the first draft of the manuscript. All authors edited and approved the final version of the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. Kei Mathis identifies as guarantor.

	We utilized OpenAI's ChatGPT, a large language model based on the GPT-4 architecture, to assist with word processing and language refinement throughout the manuscript preparation process.
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Competing interests declaration	Daniel B. Herren and Stephan Schindele receive royalties from KLS Martin Group, Tuttlingen, Germany. Daniel B. Herren and Stephan Schindele have speaker contracts with Keri Medical, which obliges them to hold training courses on the surgical technique of the Touch® prosthesis. Thumb CMC, PIP/thumb IP and MCP registries are partly sponsored by Keri Medical. IPS registry is partly sponsored by KLS Martin Group. Miriam Marks has a consultancy agreement with KLS Martin Group. Kei Mathis declares no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Cohort profile: The Schulthess registries in Zurich for hand implants and forearm corrective osteotomies

ABSTRACT

Purpose: Our hand and forearm registries were established to evaluate safety, function, quality of life and patient satisfaction in patients undergoing thumb and finger implant arthroplasties as well as corrective osteotomy of the forearm with individual patient solution (IPS) implants.

Participants: The four different registries were initiated between 2010 and 2020 and include patients with implant arthroplasties of the thumb carpometacarpal (CMC) (n=486), proximal interphalangeal (PIP) or thumb interphalangeal (IP) (n=864), and metacarpophalangeal (MCP) (n=34) joints as well as 27 patients with corrective osteotomy of the distal radius or forearm using an IPS implant. All patients complete disease-specific questionnaires and are clinically assessed before surgery (baseline) and up to 10 years thereafter.

Findings to date: All operated patients (100%) were included in the registries with complete baseline data. One-year follow-up rates range between 59% to 95% and for the 5-year follow-up, between 48% to 83%. Data completeness rates (i.e. number of cases with available data divided by the expected number of cases) range between 66% to 96% and 60% to 89% for the 1- and 5-year follow-ups, respectively. Patients showed significantly improved postoperative clinical and patient-reported outcomes over baseline. The registries serve as a basis for standardised patient-monitoring quality control and answering several clinical questions. With the help of these large databases, clinical practice can be improved for the benefit of our patients.

Future plans: As first patients approach the 10-year follow-up landmark, the registry will continue providing essential data on long-term clinical and patient-reported outcomes as well as revision rates. In addition to research and quality control, the cohort data will be brought back to the patients by bolstering real-time clinical decision support.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The strength of our hand implant registries is the prospective collection of clinical, radiological and patient-reported outcomes up to 10 years after surgery.
- Another strength is the high quality of the data through regular data checks and the high follow-up rate of more than 90% at 2 years for the prospectively enrolled patients.
- The main limitation is that part of the PIP/thumb IP cohort was added to the registry retrospectively, resulting in missing data for this cohort.

INTRODUCTION

Hand osteoarthritis (OA) is a degenerative disease that relies on surgical intervention when conservative treatment fails to control symptoms and improve function. Besides OA, other common reasons for joint deformity or destruction of the hand include rheumatoid arthritis and trauma. Implant arthroplasty, among other surgical techniques, is becoming increasingly popular as the treatment of choice for the affected joint, aiming to preserve the range of motion. Several implant arthroplasties are available for the thumb carpometacarpal (CMC),[1 2] thumb interphalangeal (IP),[3] proximal interphalangeal (PIP)[4-7] and metacarpophalangeal (MCP) joints,[8] all of which show good medium- and long-term outcomes. For malunited fractures of the distal radius or forearm, individual patient solution (IPS) implants comprising printed, anatomical patient-tailored plates are available for three-dimensional planned corrective osteotomy.[9]

Clinical registries have gained international recognition as a continuous monitoring system that accumulates information on clinical outcomes and patient-reported outcome measures (PROMs), which provide a valuable basis for improving hand surgery practices and patient care.[10 11] When compared with large national registries that demand complex coordination and significant resources,[12] local registries often have the advantage of encouraging active participation and ensuring complete reporting with fewer logistical challenges.

While several publications on hand and wrist implant registries are available to date, [13 14] a detailed description of our cohort is still missing that encompasses patients with new generation thumb and

finger implant arthroplasties as well as three-dimensionally printed IPS implants for corrective osteotomies. With the publication of these cohort profiles, we aim to contribute to the existing information on establishing a local registry and the potential benefits it can bring to clinical practice. Our local hand and wrist implant registries are based at the Schulthess Klinik, an international high-volume orthopaedic centre in Zurich, Switzerland. The registries were established to evaluate safety, function, quality of life, and satisfaction in patients undergoing implant arthroplasty for thumb CMC, thumb IP, PIP and MCP joints, and forearm osteotomy correction using IPS implants. The aim of the current cohort profile is to describe the structure and baseline characteristics of the registries, and to share the collected technical and epidemiological experience in establishing and maintaining hand and forearm implant registries with high coverage and reasonable publication output. We also present how data analysed from the registries changed our clinical practice and improved patient care.

COHORT DESCRIPTION

Setting, patients and eligibility criteria

There are four registries covering patients treated with finger and thumb implant arthroplasties and IPS implants at Schulthess Klinik in Zurich, Switzerland that are primarily funded by the Wilhelm Schulthess Foundation as well as through nested projects with industry partners. Before patients are enrolled in the registries, the responsible surgeon informs the patient during the preoperative consultation that treatment data collected for the registries will be used primarily for internal quality control. Patients are also invited to voluntarily sign a general consent form indicating agreement to using their treatment data for future scientific projects and publications.

Thumb CMC registry

Patients receiving a thumb CMC implant arthroplasty have been prospectively included in the registry since June 2018. The implants currently included in the registry are the Touch™ (KeriMedical, Geneva, Switzerland) and Maïa™ dual mobility trapeziometacarpal prostheses (Groupe Lépine, Genay, France). All surgeries were carried out using the standard dorsolateral approach technique described by Lussiez et al.[1]

PIP/thumb IP registry

The PIP/thumb IP registry includes patients with PIP or thumb IP implant arthroplasties. Patients with a CapFlex (KLS Martin Group, Tuttlingen, Germany) implant arthroplasty have been prospectively included since May 2010, while other implant arthroplasties have been retrospectively added since May 2010 as well as prospectively included since July 2019; retrospectively-included treatment data were collected from patient medical records. The implants currently included in the PIP/thumb IP registry are: KeriFlex® (KeriMedical, Geneva, Switzerland), Swanson™ (Stryker, Michigan, USA), silicone arthroplasty system (Stryker, Michigan, USA), Tactys® (Stryker, Michigan, USA), HAPTIC® (implantcast, Buxtehude, Germany) and NeuFlex® (DePuy Synthes, Warsaw, USA). For PIP implant arthroplasties, a volar, dorsal Chamay or dorsal tendon-splitting approach was used based on surgeon discretion. For thumb IP implant arthroplasties, a dorsal H-shaped approach was used as described by Schindele et al.[3]

MCP registry

Patients with a MCP implant arthroplasty at the index, middle, ring or small finger have been prospectively included in this registry since January 2020. The implants currently included in the MCP registry are: KeriFlex® (KeriMedical, Geneva, Switzerland), Swanson™ (Stryker, Michigan, USA) and Ascension® MCP pyrocarbon finger joint implants (Ascension Orthopedics Inc. Austin, USA). In general, surgeries were carried out using the dorsal transverse approach as described by Estermann et al.[15] For patients with rheumatoid arthritis or multiple MCP implant arthroplasties, surgeons used the transverse approach.

IPS registry

All patients who underwent corrective osteotomy of the distal radius or forearm using an IPS implant (KLS Martin, Tuttlingen, Germany) have been enrolled in this registry since March 2016. Surgeries were performed as described by Schindele et al.[9]

Measurement time points

For each registry, all measurement time points along with the designated time ranges, the number of enrolled cases, number of actual patients at each time point, data completion and follow-up rates from the beginning of each registry until January 2024 are outlined in Figure 1. The calculations are as follows:

Expected number of cases: Subtracting the cases that are not due for follow-up, dropout cases and revision cases occurring prior to the follow-up timepoint of interest from the total number of enrolled cases.

Data completion rate: Dividing the number of cases with available clinical outcomes or PROMs by the expected number of cases. The data collection rate quantifies our efficiency in acquiring data, excluding dropout and revision cases, which are considered outside our influence.

Follow-up rate: Dividing the number of cases with available clinical outcomes or PROMs by the number of cases initially due for the respective follow-up, without excluding the dropout patients and the revision cases. The follow-up rate reflects the proportion of data actually collected.

Data collection

Before surgery and at follow-up, all patients undergo clinical and radiographic assessment as well as complete a set of PROMs. In addition, we document adverse events throughout the intra- and postoperative periods (Figure 2).

A study assistant checks the surgery schedule each week and registers eligible patients in our database REDCap.[16] One week before surgery, the study assistant sends the PROM questionnaires to patients by email or post, depending on the patients' preferences. Using the surgical data as a basis, REDCap calculates the 6-week, 3-month, 1-, 2-, 5- and 10-year follow-ups and automatically dispatches electronic questionnaires. If the patient preferred a hard copy, the study assistant sends the questionnaire by mail. An analysis of the completion times in REDCap showed that patients require median 7 min (interquartile range [IQR]= 4) to complete electronic surveys.

The clinical assessment is done preoperatively by the study assistant at the day of the surgery and by the surgeons at each follow-up visit. Postoperative clinical examinations and radiographic analyses include the measurements that doctors would routinely take anyway.

Only the data entry into the database is an additional workload for the surgeons at the follow-up visits. For all registries, surgeons require, median 2 min (IQR= 2) to input surgical details and 1 min (IQR = 2) for follow-up clinical outcomes.

Clinical outcomes

For all four registries, grip strength is measured using a JAMAR dynamometer (SAEHAN Corporation, Masan, South Korea) in a standardised test position.[17] In addition, thumb pinch strength is examined in the thumb CMC registry patients with a pinch gauge (B&L Engineering, Santa Ana, CA, USA). For the thumb CMC, PIP/thumb IP and MCP registries, range of motion is assessed by measuring flexion and extension of the affected joints using a goniometer. Alternately, range of motion tests for IPS registry patients involve measuring flexion, extension, pronation, and supination of the wrist with a goniometer. Axis deviation and lateral stability of the affected joints are documented in the PIP/thumb IP and MCP registries. In addition, patients in the thumb CMC registry are assessed for active thumb opposition using the Kapandji index, where scores range from 0 to 10 with higher values indicating better range of motion.[18]

Surgery details

Each surgery and its implants are documented in detail to include information about the surgical technique, name of implant, name of surgeon, initial diagnosis, and duration of surgery.

Radiographs

Standard anteroposterior radiographs of the hand and anteroposterior and lateral radiographs of the affected finger or wrist are taken. Preoperative radiographs of the thumb CMC registry patients are specifically analysed for OA severity using the Eaton classification.[19] For all registries, adverse events of implant fracture, migration, luxation, radiolucent lines, cysts, fractures, bone reactions and peritendinous calcifications are monitored on postoperative radiographs. Lastly, the following

postoperative anatomical parameters of palmar and radial tilt, radial length and ulnar variance are measured according to Mann[20] and collected in the IPS registry.

PROMs

In the thumb CMC, PIP/thumb IP and MCP registries, we document hand function as measured using the brief Michigan Hand Outcomes Questionnaire (MHQ),[21-23] whereas wrist function is measured using the Patient-Rated Wrist Evaluation (PRWE) for the IPS registry.[24 25] Both PROMs are scored from 0 to 100, where 100 indicates the best score in the brief MHQ and the worst score in the PRWE. Pain at rest and during activities of daily living are measured using a numeric rating scale from 0 to 10, where 10 indicates the highest pain level. Quality of life is measured using the European Quality of Life 5-dimensions 5-level questionnaire (EQ-5D-5L),[26] which ranges in score from -0.66 to 1 (German value set), where 1 indicates the highest quality of life. In a similar manner to the patient satisfaction questions posed by De Ridder et al.,[27] all registry patients rate their satisfaction by answering the following questions on a 5-point Likert scale: "How satisfied are you with the result of the surgery on your right thumb?", "In hindsight, would you decide to have this surgery again?", and "How is your operated right thumb in general compared to before the surgery?". The thumb CMC registry further records the number of days to return to work, i.e. the number of days it takes for the patient to return to work for the first time after surgery, whether full-time or part-time, in their original job or in an adapted job. We also ask about the number of hand therapy sessions the patient had after CMC I surgery.

Adverse events

Intra- and postoperative adverse events and the management of these reported incidents are documented according to the International Organisation for Standardisation.[28] Adverse events were defined as any untoward medical occurrence related to the primary surgery that required treatment.

Data management and monitoring

Treatment data are collected, managed, and stored in the REDCap electronic data capture system, which is hosted in our clinic. Sociodemographic data are automatically uploaded from the clinic

information system to REDCap, where a case is created for each surgery. Since more than one implant can be applied to the different joints during any single surgery, an individual case may comprise multiple implants. Furthermore, there may be multiple cases for any given patient, assuming the patient undergoes surgery more than once or if a previous surgery requires revision. In the event of a revision, a new case is created for the revision surgery. All cases follow their specific follow-up schedule, with the exception of revision cases, which are terminated on the day of revision surgery. In the event of a patient receiving a new implant, the schedule will be adapted accordingly. If the implant is removed during revision surgery and not replaced (e.g. resection arthroplasty), the patient will not be followed up further.

Data checks

The REDCap system notifies the study assistant when surveys as well as surgical and clinical follow-up outcome forms have been completed, which ensures that the data are double-checked for completeness. Additionally, the data manager performs specific data checks every two weeks. Examples include to check that the age is between 18 and 99 years, that key pinch strength is less than 14 kg (the limit of the pinch gauge), and that low pain on the NRS corresponds to low pain on the brief MHQ. The study assistant then attempts to correct missing or inconsistent data by checking the patient's medical record for clinical data or by calling the patient for missing/inconsistent PROM responses. Each reason for a retrospective change is documented in REDCap to ensure comprehensive tracking of data entry. Statistical analyses are carried out using Stata (Version 17; StataCorp, College Station, TX, USA) or R (Version 4.4.1; R Core Team 2024) software.

Monitoring

To monitor patients who need to be recalled for a follow-up visit within the correct time range after surgery, the study assistant uses the FileMaker Pro Advanced (Version 20.3.1.31; Claris International, California, USA) database connected to the clinic information system via a SQL server.

Patient characteristics

Until January 2024, there were a total of 486 cases enrolled in the thumb CMC registry, 864 cases in the PIP/thumb IP registry, 34 cases in the MCP registry, and 27 cases in the IPS registry (Table 1).

Table 1: Baseline characteristics for all cases enrolled in the Schulthess hand implant and forearm osteotomy registries. All patients were prospectively enrolled in the registries, apart from patients with PIP/thumb IP prostheses other than CapFlex-PIP. These patients who underwent surgery between 2010 and 2019 were retrospectively added to the PIP/Thumb IP registry based on the patient's medical record, which explained the high number of missing values.

Characteristic	**Registry type**			
	Thumb CMC (N=486)	**PIP/thumb IP (N=864)***	**MCP (N=34)***	**IPS (N=27)**
Age (years)	64 (8.8)	69 (10)	63 (14)	42 (21)
Gender (n [%])				
Female	366 (75)	627 (73)	24 (71)	17 (63)
Affected finger (n [%])				
Total number of fingers	486 (100)	1074 (100)	63 (100)	
I	486 (100)	32 (3.0)		
II		300 (28)	26 (42)	
III		346 (32)	19 (30)	
IV		251 (23)	9 (14)	
V		145 (14)	9 (14)	
Diagnosis (n [%])**				
Primary osteoarthritis	473 (97)	926 (86)	14 (22)	
Secondary osteoarthritis	1 (0.3)	44 (4.0)	2 (3.3)	
Rheumatoid arthritis	1 (0.3)	39 (3.7)	36 (57)	
Psoriatic arthritis			1 (1.6)	
Chondrocalcinosis			2 (3.3)	
Malunion distal radius				21 (78)
Malunion radius shaft				3 (11)
Malunion ulna				2 (7.4)
Other	2 (0.5)	17 (1.7)	2 (3.3)	5 (19)
Revision	9 (1.9)	48 (4.6)	6 (9.5)	
Missing	*0 (0)*	*0 (0)*	*0 (0)*	*0 (0)*
Grip strength (kg) †	21 (11)	18 (9.3)	15 (9.0)	25 (12)
Missing (n [%])	*10 (2.1)*	*357 (41)*	*2 (5.9)*	*2 (7.4)*
Key pinch (kg) †	4.3 (2.3)			
Missing (n [%])	*10 (2.1)*			

ROM of affected MCP joint: flexion & extension (°)‡				
I	60 (16)			
II			41 (23)	
III			46 (33)	
IV			42 (37)	
V			41 (42)	
Missing (n [%])	*14 (2.9)*		0 (0)	
ROM of affected IP/PIP joint: flexion & extension (°)‡				
I	73 (20)	48 (25)		
II		44 (20)		
III		50 (21)		
IV		46 (22)		
V		44 (24)		
Missing (n [%])	*15 (3.1)*	*847 (79)*		
ROM wrist (°)†				
Flexion & extension				99 (37)
Pronation & supination				133 (37)
Missing (n [%])				*3 (11)*
Pain at rest (0, 10) †				
I	5.3 (2.5)	4.9 (3.0)		
II		4.9 (2.8)	4.9 (3.1)	
III		4.9 (2.8)	4.1 (2.9)	
IV		4.3 (3.0)	3.8 (3.0)	
V		4.7 (2.9)	4.0 (3.5)	
Forearm				1.1 (1.7)
Missing (n [%])	*39 (8.0)*	*524 (49)*	*3 (4.8)*	*5 (19)*
Pain during activities (0, 10)†				
I	7.3 (1.8)	7.1 (2.6)		
II		6.6 (2.2)	5.6 (2.8)	
III		6.8 (2.1)	5.2 (2.9)	
IV		6.3 (2.5)	5.0 (3.9)	
V		6.2 (2.6)	4.4 (3.5)	
Forearm				3.2 (2.8)
Missing (n [%])	*39 (8.0)*	*533 (50)*	*2 (3.2)*	*5 (19)*
Kapandji index (0, 10)†	8.9 (1.5)			
Missing (n [%])	*13 (2.7)*			
EQ-5D-5L (-0.66, -1)†	0.7 (0.2)	0.8 (0.2)	0.8 (0.2)	0.8 (0.1)
Missing (n [%])	*39 (8.0)*	*389 (45)*	*1 (2.9)*	*5 (19)*
Brief MHQ (0, 100)†	45 (15)	46 (16)	42 (17)	
Missing (n [%])	*41 (8.4)*	*388 (45)*	*1 (2.9)*	
PRWE (0, 100)†				39 (26)
Missing (n [%])				5 (19)

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Mean values with standard deviations are presented, unless otherwise indicated.

**1,074 and 63 implants were included in the PIP/thumb IP and MCP registries, respectively.*

*** Only diagnosis for primary surgeries are listed. More than one diagnosis can be selected for the IPS registry.*

CMC: carpometacarpal; PIP: proximal interphalangeal; IP: interphalangeal; MCP: metacarpophalangeal; IPS: individual patient solution; ROM: range of motion; EQ-5D-5L: European quality of life 5-dimensions 5-level questionnaire; MHQ: Michigan hand outcomes questionnaire; PRWE: patient-rated wrist evaluation

†For pain, lower values represent less to no pain and better outcome. For grip strength, key pinch, ROM, Kapandji index (active thumb opposition), EQ-5D-5L, brief MHQ and PRWE, higher values represent better outcome/less disability.

FINDINGS TO DATE

Since their establishment, each registry has been used to address several clinical and methodological questions. In principle, the results serve to improve our daily clinical practice as well as be available for the community, as described in the following paragraphs. Furthermore, our registry data are integrated into our clinic information system that displays the information on a dashboard (Figure 3), which enables surgeons to assess indications and directly show surgery progress to their patients.

Thumb CMC registry

Based on data from our thumb CMC registry and a recent prospective study,[29] we could show that thumb CMC implant arthroplasty patients recover faster over those with a resection-suspension-interposition (RSI) arthroplasty. Thumb CMC implant arthroplasty patients had significantly better hand function and returned to work within a shorter period compared to RSI arthroplasty patients.[29] We further outlined the benefits of the thumb CMC implant arthroplasty with a high 2-year survival rate of 96% and promising clinical outcomes at 2 years.[30] With regard to the surgical technique, we

found that the capsule can be safely resected during thumb CMC implant arthroplasty and have now changed our practice accordingly.[31] We also engage in surgeon discretion to preserve and suture the joint capsule, as our findings indicate this step as dispensable. Based on the promising results of thumb CMC implant arthroplasty compared to RSI, we have chosen implant arthroplasty as our standard procedure of care.

PIP/thumb IP registry

Surface replacing implant arthroplasty is the most commonly recorded procedure for the PIP joint in this registry. In an analysis of 100 patients, we showed that the tendon splitting approach produced better outcomes compared to two other approaches.[32] Thus, we changed our surgical technique and now only use the tendon splitting approach. Five-year data on surface replacing implant arthroplasties reveal promising clinical outcomes and PROMs[4], even for the index finger.[33] Furthermore, surface replacing implant arthroplasties correct axis deviations significantly better than a silicone implant arthroplasty.[34] With these positive results, we now routinely apply this implant at the index and middle finger instead of silicone implants as used previously. We also showed that a surface replacing implant yields satisfactory outcomes at the thumb IP joint.[3] However, due to several reports of adverse events, thumb IP joint patients are selected more carefully with focus on those who place great importance on practising precision tasks.

We determined the minimal important change and patient acceptable symptom state for pain, the brief MHQ and range of motion in patients 1 year after PIP implant arthroplasty.[35 36] These calculated thresholds may support surgeons in the preoperative process of deciding for or against a surgical intervention and in explaining the probability of achieving sufficient postoperative symptom relief for the patient.

IPS registry

We evaluated 1-year postoperative clinical outcomes and PROMs in patients who underwent three-dimensional planned corrective osteotomy of the distal radius, radial shaft, or ulnar shaft using a

printed, anatomical, patient-tailored implant to determine the feasibility and effectiveness of this methodology. Wrist-related pain and disability (indicated by a lower PRWE score) and range of motion significantly improved after 1 year.[9]

Future perspectives

We continue to monitor our arthroplasty patients up to 20 years, enabling us to analyse long-term outcomes and implant survival. A further step will be the implementation of an intake questionnaire to be sent to all patients before their first consultation. In this questionnaire, patients will be asked about their complaints and expectations. This will enable patients to more thoroughly prepare for their appointments with doctors. For the doctor, such a questionnaire will allow for more targeted and efficient organisation of the consultation. Last, but not least, we are working on improving our outcome measures by introducing algorithm-based PROMs.

COLLABORATION

We invite researchers to contact the corresponding author for requests for statistical code and instruments used. Multicentre registries would overcome the limitations of single centre data collection, including bias, lack of generalizability, limited variability, and the inability to study rare conditions. However, cross-national multicentre trials are hampered by different national laws on data collection and protection. A possible solution is data sharing in a Common Data Model with the advantage of keeping data local and only sharing summary statistics.[37]

FURTHER DETAILS

Strengths and limitations

Among the main strengths of our registries are the high data completeness rates, except for the PIP/thumb IP registry, where some patient data were collected retrospectively. Additionally, we

maintain high data quality through regular data checks , and the use of validated and standardised outcome measures. Our follow-up rates are among the highest reported in the hand surgery literature, where follow-up rates for clinical outcomes and PROMs range from 30-40% to 38-62% in other registries.[38 39] Our strengths enable us to continuously monitor patients and analyse clinical outcomes and PROMs not only at the individual patient level, but also across the patient population. Furthermore, our cohorts have enabled us to publish relevant papers on the new generation of implant arthroplasties and IPS implants, contributing to advancing research and enhancing the quality of care in hand surgery.

The main limitation is that not all patients are prospectively included in the PIP/thumb IP registry, contributing to an incomplete dataset with missing baseline values, especially those for PROMs. Revision rates might be slightly underestimated, as we do not know whether patients who dropped out had complications treated elsewhere. Nonetheless, because of our reputable collaboration with other Swiss hand surgeons, we usually receive information about our patients treated elsewhere and can record these events in our registry. Furthermore, while the registries are primarily funded by the Willhelm Schulthess Foundation, we also receive funding from the industry. We are aware of the potential influence this funding might have. However, in the contracts, we secured the right to publish all results, without interference from the funding party. This reinforces our confidence that industry funding does not affect cohort, reporting, or the independence of the research.

Data availability statement

Data are available upon reasonable request and researchers are invited to contact the first author for requests concerning statistical codes and instruments used. The participant consent forms restrict data sharing on a public repository.

FIGURE LEGENDS

Figure 1

Cohort inclusion flowchart per registry including data completion and follow-up rates. Data completion rate and follow-up rate were calculated as follows:

Data completion rate: The number of cases with available clinical outcomes or PROMs is divided by the expected number of cases. The expected number of cases is calculated by subtracting the cases that are not due for follow-up, dropout cases and revision cases occurring prior to the follow-up timepoint of interest from the total number of enrolled cases.

Follow-up rate: The number of cases with available clinical outcomes or PROMs is divided by the number of cases initially due for the respective follow-up, without excluding the dropout patients and the revision cases.

For the IPS registry, implant removal and the subsequent final treatment are optional interventions that are not performed for all patients.

*Smaller data completion and follow-up rates are due to a high number of missing treatment data from retrospectively enrolled cases. CMC: Carpometacarpal; DCR: Data completion rate; FUR: Follow-up rate; n/a: not applicable; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; IPS: Individual patient solution.

Figure 2

Documentation of measurement procedures for the thumb CMC, PIP/thumb IP, MCP (top) and IPS (bottom) registries.

*Return to work is only assessed in the thumb CMC registry. CMC: Carpometacarpal; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; M: Month(s); Y: Year(s); PROM: Patient-reported outcome measure; MHQ: Michigan hand outcomes questionnaire; EQ-5D-5L: European quality of life 5-dimensions 5-level questionnaire; IPS: Individual patient solution; W: Weeks; PRWE: Patient-rated wrist evaluation.

Figure 3

Dashboard integrated into the hospital information system showing the results of a CMC I implant arthroplasty in a male patient between the ages of 70 and 79 years. Data for key pinch (left) and the brief Michigan Hand Outcomes Questionnaire (MHQ) are shown at baseline and at the various follow-up time points. The green rectangles are the patient's data and the shaded area is the interquartile range

of data from all other patients of the same sex and age group. Various clinical and patient-reported outcomes can be displayed.

ACKNOWLEDGEMENTS

The authors would like to thank Melissa Wilhelmi, PhD (Schulthess Klinik) for the copy-editing of this manuscript and the study assistants for their support in the data collection.

ETHICS

This study was approved by the Ethical Committee of Canton Zurich (KEK-ZH-Nr. 2014-0546, 2019-02096, 2020-00143). Participants gave informed consent to participate in this study.

PATIENT AND PUBLIC INVOLVEMENT

Patient and public were not involved in the design and conduct of this study.

COMPETING INTERESTS

Daniel B. Herren and Stephan Schindele receive royalties from KLS Martin Group, Tuttlingen, Germany. Daniel B. Herren and Stephan Schindele have speaker contracts with Keri Medical, which obliges them to hold training courses on the surgical technique of the Touch® prosthesis. Thumb CMC, PIP/thumb IP and MCP registries are partly sponsored by Keri Medical. IPS registry is partly sponsored by KLS Martin Group. Miriam Marks has a consultancy agreement with KLS Martin Group.

Kei Mathis declares no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

FUNDING

This study is primarily funded by the Wilhelm Schulthess Foundation and partially funded by KeriMedical and the KLS Martin Group.

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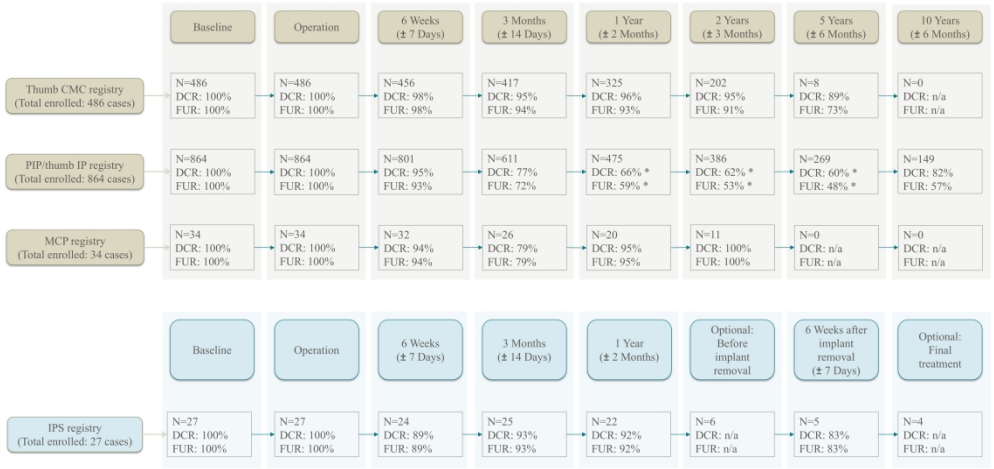
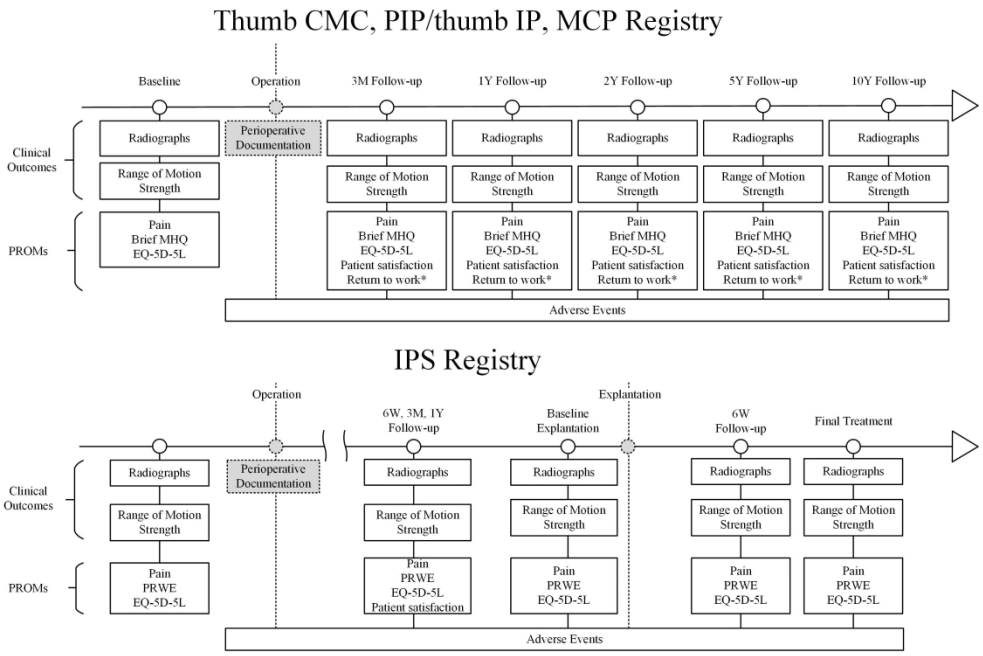


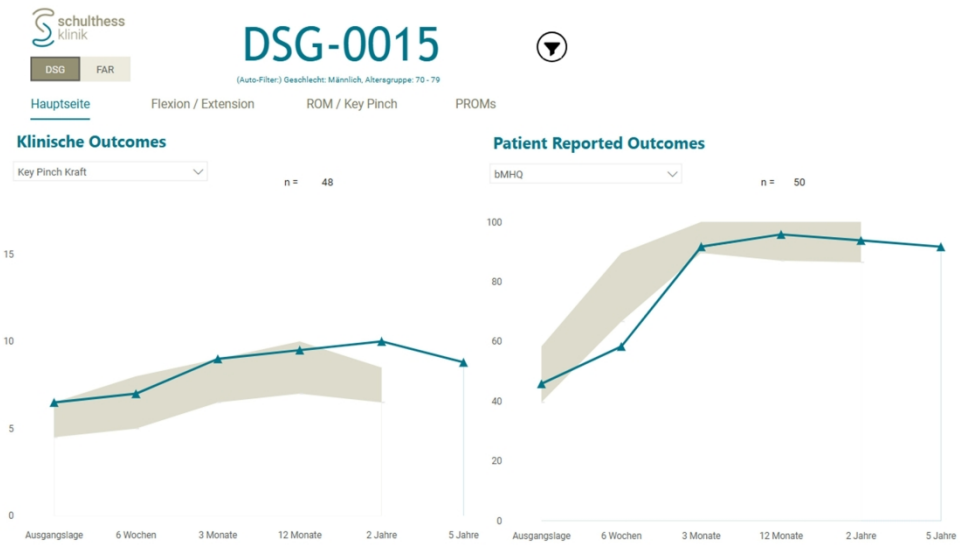
Cohort inclusion flowchart per registry including data completion and follow-up rates. Data completion rate and follow-up rate were calculated as follows:
Data completion rate: The number of cases with available clinical outcomes or PROMs is divided by the expected number of cases. The expected number of cases is calculated by subtracting the cases that are not due for follow-up, dropout cases and revision cases occurring prior to the follow-up timepoint of interest from the total number of enrolled cases.
Follow-up rate: The number of cases with available clinical outcomes or PROMs is divided by the number of cases initially due for the respective follow-up, without excluding the dropout patients and the revision cases.
For the IPS registry, implant removal and the subsequent final treatment are optional interventions that are not performed for all patients.
*Smaller data completion and follow-up rates are due to a high number of missing treatment data from retrospectively enrolled cases. CMC: Carpometacarpal; DCR: Data completion rate; FUR: Follow-up rate; n/a: not applicable; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; IPS: Individual patient solution.

500x250mm (300 x 300 DPI)



Documentation of measurement procedures for the thumb CMC, PIP/thumb IP, MCP (top) and IPS (bottom) registries.
*Return to work is only assessed in the thumb CMC registry. CMC: Carpometacarpal; PIP: Proximal interphalangeal; IP: Interphalangeal; MCP: Metacarpophalangeal; M: Month(s); Y: Year(s); PROM: Patient-reported outcome measure; MHQ: Michigan hand outcomes questionnaire; EQ-5D-5L: European quality of life 5-dimensions 5-level questionnaire; IPS: Individual patient solution; W: Weeks; PRWE: Patient-rated wrist evaluation.

290x195mm (300 x 300 DPI)



Dashboard integrated into the hospital information system showing the results of a CMC I implant arthroplasty in a male patient between the ages of 70 and 79 years. Data for key pinch (left) and the brief Michigan Hand Outcomes Questionnaire (MHQ) are shown at baseline and at the various follow-up time points. The green rectangles are the patient's data and the shaded area is the interquartile range of data from all other patients of the same sex and age group. Various clinical and patient-reported outcomes can be displayed.

338x190mm (300 x 300 DPI)