Original Contribution

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Establishing an institutional reverse total shoulder arthroplasty registry

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Abstract

Background: The number of implanted reverse total shoulder arthroplasties (RTSA) is increasing worldwide. To improve patient care, institutional and national arthroplasty registries are being established worldwide to record outcome data. This article aims to describe the setup of an RTSA database in a high-volume university orthopedic hospital.

Methods: All patients who received an RTSA at the authors' tertiary referral hospital have been followed and individual datasets have been systematically recorded in a REDCap database since 2005. The data are captured longitudinally as a primary preoperative survey and as a regular or irregular postoperative follow-up. All baseline demographic data, patient history, surgical details, arthroplasty details, adverse events, and radiographic and clinical outcome scores (Constant–Murley score, Subjective Shoulder Value, range of motion) are recorded.

Results: A total of 1433 RTSA were implanted between January 2005 and December 2020. Of these, 1184 (83%) were primary implantations and 249 (17%) were secondary cases. The cohort had a mean age of 70 ± 10 years, was 39% male, and was classified ASA II in 59%. The lost to follow-up rate was 18% after 2 years, 22% after 5 years, and 53% after 10 years. The overall complication rate with 2 years minimum follow-up was 18% (156/854 shoulders) with reintervention in 10% (82/854 shoulders). **Conclusion:** A well-managed institutional arthroplasty registry, including structured

clinical and radiological follow-up assessments, offers the opportunity for high-quality long-term patient and arthroplasty outcome analysis. Such data are not only helpful for analyzing patient outcome and implant survival, but will be increasingly important to justify our daily clinical practice against different stakeholders in the various health care systems.

Keywords

Rotator cuff injuries \cdot Quality of health care \cdot Database \cdot Postoperative complications \cdot Treatment outcome

Supplementary Information

The online version of this article (https:// doi.org/10.1007/s11678-021-00659-4) contains supplementary material, which is available to authorized users.



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With an expanding number of implanted reverse shoulder arthroplasties (RTSA) worldwide, a systematic collection of baseline data and outcome parameters is essential to improve the quality of patient care. Institutional arthroplasty registries are helpful for standardized data collection and analysis. Since the setup of an arthroplasty registry is laborious, the number of large databases is limited worldwide. This article presents the development of an RTSA database containing currently 1433 shoulders, and is intended to provide sufficient informa-

tion to build a standardized institutional registry.

In 1987, reverse total shoulder arthroplasty (RTSA) with a distalized and medialized center of rotation was introduced by Grammont to treat cuff tear arthropathy [13]. The satisfying clinical results led to widespread use of RTSAs, with an increasing expansion of indications [2, 9]. In addition to the initial indication for cuff tear arthropathy, RTSAs are now used to treat massive rotator cuff tears, primary osteoarthritis, humeral

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head necrosis, shoulder instability, primary and secondary humeral fractures, rheumatoid arthritis, and serve as a reliable revision option. The wide range of applications and an aging population have led to a tremendous increase in implanted RTSAs worldwide [17]. The number of implanted reverse arthroplasties now exceeds the number of anatomical arthroplasties in most countries [6]. Despite increasing implantation numbers and various arthroplasty designs, a relatively high complication rate of up to 24% has been reported in the literature [29].

These adverse events significantly influence patients' outcomes and safety. A thorough evaluation of outcomes, complications, reoperations, and implant survival is essential for patient care quality.

Monocentric and multicentric databases as well as national registries have been established to collect outcome data, but they vary widely in terms of the quality and quantity of collected data. Databases will become increasingly important in the future to improve patient care. However, only a few studies exist on the development, design, and requirements of reverse shoulder arthroplasty registries [22].

The following article presents the setup of an institutional RTSA database using REDCap [14, 15] in a tertiary referral, highvolume orthopedic university hospital in Europe. This article aims to describe the standardized design, the different strategies for data collection, and some exemplary outcome data illustrating the scientific potential of such a database.

Methods

Ethical approval

The anonymous data collection and the study publication were approved by the cantonal ethics committee of the University of Zurich (ID 2018-01494) and conducted following the Helsinki Declaration. Each patient treated at the clinic signed consent for further use of data for research following a detailed explanation.

Inclusion criteria

All patients who received RTSA at the authors' tertiary referral center Balgrist University Hospital as of January 2005 were potentially included in the database. Inclusion criteria were informed consent, patient age over 18 years, no pregnancy, and physical and mental ability to receive the follow-up examinations. Inclusion in the arthroplasty register could be withdrawn at any time.

Surgery

All arthroplasty-related information was captured. The main implant used was the Anatomical/Reverse RTSA manufactured by Zimmer/Biomet (Warsaw, IN, USA) as introduced in 2005 in the institution. Total joint replacement was performed by fellowship-trained staff shoulder surgeons of the authors' academic unit. The surgical procedures were standardized, with patients mostly receiving general or regional anesthesia with an additional interscalene catheter. The patients were placed in a beach chair position, antibiotic prophylaxis with cefuroxime (Fresenius Kabi, Switzerland) was administered 30 min before skin incision, and draping was performed using three rectangular drapes.

A deltopectoral approach was used in the vast majority of patients, leaving the cephalic vein laterally.

For primary RTSA implantation, the humeral head was resected, and for revision surgery, the prosthesis was removed if necessary. Well-fixed humeral stems allowing conversion to RTSA remained in situ whenever possible. The humeral stem was prepared to fit the planned implant size in 0 to 20° of retroversion. The glenoid was reamed to create a flat surface. In revision cases of anatomical shoulder arthroplasties, previous removal of the components was primarily necessary. The baseplate was implanted with a neutral version and neutral to slight inferior inclination not exceeding 10°. If possible, transosseous subscapularis refixation using No. 2 FiberWire (Arthrex, Naples, FL, USA) was carried out. Aftercare consisted of wearing a sling for 6 weeks, allowing passive mobilization and minimal active use of the arm. Active range of motion exercises were carried out without weight through weeks 7 to 12.

Clinical and radiographic follow-up examination

All patients underwent a standardized preoperative examination by the treating surgeon and an orthopedic resident. The preoperative data assessment included medical history, previous surgeries and comorbidities, standardized assessment of shoulder motion, the absolute and relative Constant–Murley score, and the Subjective Shoulder Value (SSV) [5, 10]. The preoperative radiologic examination included three standardized planes (anteroposterior, Neer view, and lateral axillary view) in the standing position and supine computed tomography, including the medial border of the scapula. Stem size was preoperatively planned on plain radiographs using dedicated software and glenoid orientation (version and inclination) was planned on the CT scan (mediCAD[®] Hectec GmbH, Altdorf, Germany).

The patients were followed up at 6 weeks, 18 weeks, 1 year, 2 years, and every 2 to 3 years thereafter. The followup was conducted by a study nurse under the supervision of an orthopedic staff member specializing in shoulder surgery. All patients underwent clinical examination using the absolute and relative Constant-Murley score [5, 10], including full assessments of range of motion and abduction strength using a validated dynamometer. Furthermore, the SSV [10] was assessed and patients were asked to rate their satisfaction with the outcome of the procedure. The radiological examination included standardized X-rays in three planes.

Data collection

All data were captured in the clinical information system and REDCap (Research Electronic Data Capture; Vanderbilt University, Nashville, TN, USA). REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with

Data Collection Instrument	basisdata	Revision Surgery	Follow-up unregular	¥1	¥2	Y3	Y4	Y5	Y10	Y15
My First Instrument										
BASE	\bigcirc									
Primary Base (Study Nurse)										
Secondary Base (Research Fellow)	\bigcirc									
FOLLOW-UP										
Outpatient Clinic Report	0	0	0	\bigcirc						
Constant Score				\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc		
Lost to follow-up	\bigcirc									
Complication										
Radiographic follow-up	\bigcirc	\bigcirc	\bigcirc			\bigcirc		\bigcirc		
REINTERVENTION	0									
Revision Surgery		\bigcirc								

Fig. 1 REDCap data capture form. The longitudinal course is arranged horizontally, which allows entering of the annual controls and unplanned events in unlimited numbers. Vertically, the different events are listed. Some of them are repeated according to the annual follow-up (outpatient clinic report, Constant score, etc.). (With kind permission from https://projectredcap.org). Y year(s)

external sources. Study data were collected and managed using REDCap electronic data capture tools hosted at Balgrist University Hospital. At the time of this article's preparation, 5006 institutions from 141 countries were registered as REDCap users [14, 15].

Patients have been systematically recorded in the clinical information system at the timepoints defined above since 2005. Data collection is based on standardized recommendations [1, 23]. The exact database design is documented below.

Database design

Each operated shoulder was assigned a unique ID; thus, patients operated on both sides received two IDs. The database was set up longitudinally with the possibility of recording all annual controls as well as the preoperative examination. In addition to regular annual controls, there was the possibility to include unplanned events and reinterventions in unlimited numbers (**©** Fig. 1).

Follow-up includes the complete consultation report with diagnosis list, the total Constant–Murley scores including the range of motion and pain, the SSV, selected radiological parameters (e.g., notching, loosening, fractures) from continuously collected x-rays at each consultation, the follow-up status (lost, death, next appointment), complications, and reinterventions.

The preoperative baseline data are more comprehensive and divided into primary and secondary (advanced) data. Basic data include gender, year of birth, body weight, height, body mass index, American Society of Anesthesiologists (ASA) classification, study participation agreement, and a few surgical details—date, indication, side, diagnosis, name of the procedure, implant manufacturer, type of stem, cementation, full surgical report.

The secondary baseline data are more extensive and are provided by shoulder research fellows. They include an exact breakdown of the surgical details as well as the prosthetic components including all sizes, accurate patient history, and radiological (x-ray and computed tomography) and laboratory chemical data. All data are provided in the Supplementary Material.

Results

Basic characteristics

Between January 2005 and December 2020, a total of 1449 RTSA were implanted in the authors' tertiary referral center and followed up continuously. Sixteen patients disagreed with undergoing analysis for studies, leaving a total of 1433 patients for further investigation. Patient characteristics and arthroplasty data are displayed in **Tables 1 and 2**.

Follow-up and mortality

Of 1433 shoulders included in the database, 1212 received the arthroplasty 2 or more years ago (before December 31, 2018) with a mean follow-up of 59 ± 35 (24; 183) months.

An overall lost to follow-up rate of the cohort was reported in 390 patients (27%) at a mean of 40 ± 36 (0; 169) months.

Death was the reason in 126 patients (140 shoulders, 36%) after at a mean time of 60 ± 37 (3; 170) months postoperatively. The mean age at death was 79 ± 10 (41; 97) years.

The period-specific lost to follow-up rate was 18% after 2 years, 22% after 5 years, and 53% after 10 years.

Complications and reinterventions in primary RTSA

As an example of the database's usability, the complication rate of primary implanted arthroplasties (without prior arthroplasty or surgical fracture treatment using plates) before August 2018 was analyzed. A total of 188 complications occurred (22%) in 156 shoulders (18%) and led to reintervention in 82 shoulders (10%). These were distributed into 41% revisions (with a change of prosthetic components) and 59% reoperations (without change of prosthetic components). The main complications were acromial fractures (5.3%), glenoid loosening (4.3%), and RTSA instability (2.7%). The main indications for reintervention surgery were glenoid loosening (2.7%), instability (1.8%), and acromial fractures (1.3%).

After breakdown of the complications, clinical outcomes were compared with the rest of the primary RTSA cohort. Patients without a complication (n = 620) showed significantly better outcomes compared patients who sustained a complication, as reflected in the absolute Constant score (67 ± 14 points vs. 45 ± 20 points, p = 0.00), relative Constant score ($81 \pm 16\%$ vs. $57 \pm 24\%$, p = 0.00), SSV ($80 \pm 20\%$ vs. $53 \pm 27\%$, p = 0.00), and constant pain

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Table 1 Basic demographic data of the cohort						
	All RTSA	Primary RTSA	Secondary RTSA			
Total shoulders	1433	1184 (83%)	249 (17%)			
Total patients	1322	1094	242			
Age at surgery	70±10 (24; 94)	72±10 (30; 94)	65±10 (24; 88)			
Gender						
Male	561 (39%)	449 (38%)	112 (45%)			
Female	872 (61%)	735 (62%)	137 (55%)			
Side						
Right	851 (59%)	706 (60%)	144 (58%)			
Left	582 (41%)	478 (40%)	105 (42%)			
BMI (kg/m²)	28±5(14;63)	27±5(14;63)	28±5 (16; 44)			
Weight (kg)	76±17 (32;159)	75±17 (32; 159)	80±18 (43; 154)			
Height (m)	166±10 (134; 200)	165±10 (134; 200)	168±9(143;197)			
ASA		I				
ASAT	87 (6%)	71 (6%)	16 (6%)			
ASA II	836 (59%)	676 (57%)	160 (65%)			
ASA III	485 (34%)	417 (35%)	68 (27%)			
ASA IV	17 (1%)	13 (1%)	4 (2%)			
ASA V	1 (0.1%)	1 (0.1%)	0 (0%)			
Smoking						
Yes	207 (14%)	159 (13%)	48 (19%)			
Stopped	157 (11%)	136 (12%)	21 (8%)			
Never	1017 (71%)	854 (72%)	163 (66%)			
Unknown	52 (4%)	35 (3%)	17 (7%)			
No. of previous surgeries	1 ± 1 (0; 12)	0.6±1 (0; 11)	2±2(1;12)			
No. previous surgeries	771 patients (54%)	771 (65%)	0 (0%)			
Primary RTSA was defined as all primary implantations without previous arthroplasty-related surg-						

eries. The values are expressed as mean ± standard deviation (minimum; maximum) **ASA** surgical risk classification of the American Society of Anesthesiologists, **BMI** body mass index,

PY pack years, RTSA reverse total shoulder arthroplasty

score (14±3 vs. 11±4, p=0.00; 15 as best value). The range of motion yielded significantly better values for flexion (122±24° vs. 88±38°, p=0.00), abduction (131±33° vs. 89±43°, p=0.00), and external rotation (27±18° vs. 21±21°, p=0.00).

Discussion

This study describes the setup of an RTSA database at a high-volume, tertiary referral orthopedic university hospital in Europe. RTSA patients have been followed up since 2005 and data recorded in the clinical information system. Since 2018, these data have been systematically transferred to REDCap to allow quick and standardized analysis. Currently, 1433 RTSA implantations are available for evaluation, of which 83% represent primary implantations without prior prosthetic surgery. All patients were followed up at regular intervals with clinical examination (including Constant–Murley score, SSV, range of motion) and standard radiographs. The mean follow-up of the cohort after a minimum of 2 years was 59 ± 35 months. Exemplary analysis of the complication rate of 18% and the reintervention rate of 10% emphasizes the importance of databases. Although these rates appear to be high, they are comparable with the current literature [29]. Specific follow-up studies should be conducted to identify possible causes and therapeutic algorithms.

Establishment of registries is an important tool in medicine for assessing patient care [21, 22]. In addition to databases for hip and knee arthroplasties, which have been established for many years, the widespread, systematic recording of RTSAs was started around the turn or the millennium. Comparable monocentric registries also have case numbers close to 1500 arthroplasties [7, 11, 12]. The monocentric design has the advantage of a relatively standardized surgical technique, often with only a few different implants. This homogeneous patient care and uniform data measurement allows—beside a rather general implant survivorship analysis—a thorough outcome analysis and can be used to answer specific scientific questions.

Generalization of the data can be achieved by multicentric data collection or national registries (**Table 3**; [20, 27]). Currently, the largest multicentric database includes more than 5000 RTSA implants from 40 different orthopedic surgeons investigating various questions [27]. Data quality in multicentric studies is highly dependent on the participating centers and can vary significantly in quality.

In contrast to local mono- and multicentric databases, national and international registries provide a significantly higher number of patients (**Table 3**; [21]). Currently, the Australian registry includes the highest number of patients, with nearly 30,330 implanted primary RTSAs. However, in contrast to institutional databases, national registries record significantly fewer or even no clinical outcome parameters, as mainly only prosthetic survivorship and reintervention rates are assessed [21]. Standardized annual clinical and radiological follow-ups are usually reserved for local databases.

The current monocentric registry is one of the largest and enabled various analyses [3, 16, 17]. It is essential to highlight the additional expense of setting up a database for an institution, especially when a clinical examination is part of the follow-up assessment. Our patients are regularly monitored, which is time and resource consuming and might not be possible in every institutional setup and insurance system. A designated study nurse collects a concise set of data at every follow-up visit. Additional recorded clinical and radiographic data are contained in a standardized way by research fellows and are additionally gathered on a studyspecific basis. Once collected in REDCap, all data are available for any further study analysis. The data were therefore recorded

Table 2 Specific data of reverse total shoulder arthroplasty				
Total	1433	-		
Surgical indication				
Primary implantation	1184	100%		
Rotator cuff tear without osteoarthritis	356	30%		
Rotator cuff tear with osteoarthritis	297	21%		
Osteoarthritis	177	15%		
Following ORIF	113	10%		
Cuff tear arthropathy	93	8%		
Fracture	86	7%		
Instability	35	3%		
Humeral head necrosis	22	2%		
Other	5	0.5%		
Secondary implantation	249	100%		
Conversion of hemiarthroplasty	114	46%		
Conversion of TSA	87	35%		
Revision of RTSA	42	17%		
Other	6	2%		
Approach deltopectoral	1401	98%		
No. of surgeons	18	-		
Manufacturer Zimmer/Biomet	1401	98%		
Humeral shaft type				
Standard stem	1244	87%		
Fracture stem	155	11%		
Revision stem	23	2%		
Cementation used	623	44%		

Primary RTSA—no previous arthroplasty implantation

Anatomical anatomical shoulder arthroplasty, ORIF open reduction and internal fixation, (R)TSA (reverse) total shoulder arthroplasty

Table 3 Major databases and registries for reverse total shoulder arthroplasty						
	RTSAs	Period	Database design	Parameters		
This study	1449	2005–2020	Monocenter	^b , ROM, CS, SSV, x-ray		
Schulthess Regis- ter [11, 22]	1480	2006–2017	Monocenter	^b , ROM, CS, SPADI, EQ-5D, x-ray		
Frankle et al. [12]	1525	2004–2014	Monocenter	^b , ROM, ASES, x-ray		
Mayo Clinic [7]	1666	2007–2015	Monocenter	^b , ROM, ASES, x-ray		
Walch et al [19, 20]	1953	1991–2010	Multicenter, 6 sites	^b , ROM, CS, SSV, x-ray		
Equinoxe/Exatec [27]	5007	2007–2018	Multicenter 40 surgeons	^b , ROM, SST, UCLA, ASES, CS, SPADI, x-ray		
NARA (Scandi- navia) [18, 24]	8938	2004–2016	Multinational registry	b		
NJR (UK) [<mark>26</mark>]	19300	2003–2019	National registry	b		
AOANJRR [25] (Australia)	30330ª	2004–2019	National registry	b		

AOANJRR Australian National Joint Registry, **CS** Constant-Murley score, **EQ-5D** EuroQoL 5-dimension 5-level, **NARA** Nordic Arthroplasty Registry Association, **SPADI** Shoulder Pain and Disability Index, **SST** Simple Shoulder Test, **UCLA** Score of University of California Los Angeles

^aOnly primary arthroplasty

^bAll registries evaluate revision rate and survival

in a standardized way to enable potential analysis in cooperation with other centers.

Only a few studies reporting on the setup of institutional RTSA databases exist in the literature. In 2020, the design of another monocentric shoulder prosthesis registry with nearly 1480 RTSAs was described [22]. Like our database setup, a normalized international consensus was used to classify adverse events [1] and radiological image data [8].

The authors are convinced that the collection of subjective and objective outcome parameters following surgical care will continue to gain importance in the future. There are several reasons for this. First, the treating surgeons should be able to objectively review the outcome of their patients and adapt the daily practice if necessary. The vast majority of surgeries are, however, nowadays still performed without an accurate breakdown of the quality of patient care for the individual surgeon [29]. Second, surgeons are obliged to inform the patients about benefits and surgical risks, especially if joint replacement is considered. The local arthroplasty data can be used to inform the patients on the basis of available objective data [4]. Third, some stakeholders express incremental interest in analyzing the value and benefits of different treatment modalities [28]. Governments and health care insurance providers start to challenge surgeon's indications, clearly showing the need for more high-level evidence to justify our daily clinical practice [28].

Conclusion

A well-managed institutional arthroplasty registry, including structured clinical and radiological follow-up assessments, offers the opportunity for high-quality long-term patient and arthroplasty outcome analysis. Such data are not only helpful to analyze the patient outcomes and implant survival, but will be increasingly important to justify our daily clinical practice against different stakeholders in the various health care systems.

Practical conclusion

- The number of implanted RTSAs is increasing worldwide and requires a structured outcome analysis to optimize patient care.
- Local arthroplasty registries are a valuable tool for structured collection and compelling patient outcome data analysis.
- Local registries often allow a more focused analysis of the outcome of specific questions compared to national registries.
- REDCap is a valuable and effective tool for establishing an institutional registry.
- Categorization of data collection according to the necessary workload (basic and advanced data) has proven successful in clinical practice.
- An internationally standardized approach is recommended to achieve a high degree of comparability.



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Declarations

Conflict of interest. P. Kriechling, M. Waltenspül, S. Bouaicha, and K. Wieser declare that they have no competing interests.

All procedures performed in studies involving human participants or on human tissue were in accordance with the ethical standards of the institutional and/or national research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards (Cantonal Ethics Committee Zurich, ID 2018-01494). Informed consent was obtained from all individual participants included in the study.

Ethical approval The anonymous data collection and the study publication were approved by the cantonal ethics committee of the University of Zurich (ID 2018-01494) and conducted following the Helsinki Declara-

Zusammenfassung

Einrichtung eines institutionellen Registers für inverse Schultertotalendoprothesen

Hintergrund: Die Zahl implantierter inverser Schultertotalprothesen (RTSA) ist international steigend. Um die Patientenversorgung zu verbessern, werden weltweit institutionelle und nationale Prothesenregister etabliert. Die vorliegende Arbeit beschreibt den Aufbau einer RTSA-Datenbank in einer orthopädischen Universitätsklinik mit hoher Fallzahl.

Methoden: Alle Patienten, welche eine RTSA an unserer Klinik erhielten, wurden seit 2005 nachkontrolliert und systematisch in einer REDCap-Datenbank erfasst. Die Übertragung erfolgt longitudinal als präoperative Erhebung und als reguläre oder irreguläre Verlaufskontrolle. Erfasst werden alle demographischen Basisdaten, die Patientenanamnese, die Operationsdetails, Prothesendetails, Komplikationen, radiologische und klinische Outcome-Scores (Constant-Murley-Score, Subjective Shoulder Value, Bewegungsmaße).

Ergebnisse: Im Zeitraum von Januar 2005 bis Dezember 2020 wurden insgesamt 1433 RTSA implantiert. Von diesen waren 1184 (83 %) primäre Implantationen und 249 (25 %) sekundäre Implantationen. Die Kohorte war im Mittel 70±10 Jahre alt, zu 39% männlich und zu 59% als ASA II klassifiziert. Die Lost-to-follow-up-Rate betrug 18% nach 2 Jahren, 22% nach 5 Jahren und 53% nach 10 Jahren. Die generelle Komplikationsrate nach einem Mindest-Follow-up von 2 Jahren betrug 18% (156/854 Schultern) mit notwendiger Revisionsoperation bei 10% (82/854 Schultern). **Schlussfolgerung:** Ein sorgfältig geführtes lokales Endoprothesenregister mit strukturierten klinischen und radiologischen Nachuntersuchungen bietet die Möglichkeit einer qualitativ hochwertigen Langzeitanalyse der Patienten- und Endoprothesenergebnisse. Solche Daten sind nicht nur hilfreich für die Analyse des Patientenergebnisses und des Implantatüberlebens, sondern werden auch immer wichtiger in der Rechtfertigung unserer täglichen klinischen Praxis gegenüber verschiedenen Kostenträgern im Gesundheitssystem.

Schlüsselwörter

Rotatorenmanschettenverletzungen · Qualität der Gesundheitsversorgung · Datenbank · Postoperative Komplikationen · Behandlungsergebnisse

tion. Each patient treated at the clinic signed consent for further use of data for research following a detailed explanation.

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