Dissertation

IMPLANT BREAKAGE AFTER SHOULDER ARTHROPLASTY: A SYSTEMATIC REVIEW OF DATA FROM WORLDWIDE ARTHROPLASTY REGISTRIES AND CLINICAL TRIALS

submitted by

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1. ACKNOWLEDGEMENTS 4

2. STATUTORY DECLARATION 5

3. DISCLOSURES 6

4. LIST OF TABLES, FIGURES AND DIAGRAMS 7

5. LIST OF ABBREVIATIONS 10

6. ABSTRACT 11

7. INTRODUCTION 15

8. GENERAL 19

8.1. Anatomy of the shoulder joint 19

8.2. Movement of the shoulder 20

8.3. Types of shoulder prosthesis designs 22
8.3.1. Anatomical Shoulder Arthroplasty 26
8.3.2. Reverse total shoulder Arthroplasty (RSA) 28

9. STRENGTH OF MATERIALS - STRENGTH AND ALLOWABLE STRESS 32

9.1. Material testing 37
9.1.1. Characteristic values from the stress-strain diagram 39
9.1.2. Material technology in endoprosthetics – non-ferrous metals 40

9.2. Materials and Companies 42
9.2.1. Quality Management 46

10. INDICATION FOR SHOULDER ARTHROPLASTY 48

11. SPECIFIC 49

11.1. The metal – bone junction 49

11.2. Area of Implant Breakage 49
11.2.1. Glenoid/Baseplate 51
11.2.2. Glenosphere 52
11.2.3. Cage Screw 52

11.2.4. Humeral Component 53

12. MATERIALS AND METHODS 55

13. CALCULATION MODEL 59

14. RESULTS 60

14.1. Clinical Studies 60

14.2. Arthroplasty Registries 63

14.3. The Australian Arthroplasty Registry 65

15. COMPARATIVE ANALYSIS 73

16. DISCUSSION 74

16.1. THE FUTURE OF SHOULDER ARTHROPLASTY 79

16.1.1. Outpatient shoulder arthroplasty 80

16.1.2. The subscapularis sparing approach: 82

16.1.3. The pyrocarbon shoulder hemiarthroplasty 84

16.1.4. Pyrocarbon Interposition Spherical Arthroplasty 86

16.1.5. The use of Ceramic material in shoulder arthroplasty 86

16.1.6. The use of Vitamin E Polyethylene 88

16.1.7. Glenoid Component Fixation 89

16.1.8. Computer-assisted preoperative planning 91

17. CONCLUSION 92

18. REFERENCES 93

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2. Statutory Declaration

I hereby declare that this is my own original work and that I have fully acknowledged by name all of those individuals and organisations that have contributed to the research for this thesis. Due acknowledgement has been made in the text to all other material used. Throughout this thesis and in all related publications I followed the “Standards of Good Scientific Practice and Ombuds Committee at the Medical University of Graz”.

Klagenfurt, 27th May 2024

3. Disclosures

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4. List of tables, figures and diagrams

TABLE 1 DIFFERENT TYPES OF SHOULDER ARTHROPLASTY ADOPTED BY THE AUSTRALIAN ARTHROPLASTY REGISTRY [20] 25

TABLE 2 MATERIALS OF THE MEDACTA SHOULDER SYSTEM, SWITZERLAND (WWW.MEDACTA.COM) 41

TABLE 3 WORLDWIDE PRODUCING AND SELLING COMPANIES OF HUMERAL AND GLENOID COMPONENTS FOR IMPLANTATION OF A SHOULDER PROSTHESIS 43

TABLE 4 INDICATIONS FOR HEMI-, TOTAL ANATOMIC-, AND TOTAL REVERSED SHOULDER ARTHROPLASTY (SA) 48

TABLE 5 QUALITY ASSESSMENT OF INCLUDED STUDIES 55

TABLE 6 PRISMA 2020 FLOW DIAGRAM FOR NEW SYSTEMATIC REVIEWS WHICH INCLUDED SEARCHES DATABASES, REGISTRIES AND OTHER SOURCES 57

TABLE 7 INTERNET PRESENTATION OF NATIONAL ARTHROPLASTY REGISTRIES AND PUBLISHED ARTICLES 57

TABLE 8 OVERVIEW OF CHARACTERISTICS OF INCLUDED STUDIES REPORTING ON TOTAL SHOULDER ARTHROPLASTY (ATSA) WITH IMPLANT BREAKAGE 61

TABLE 9 OVERVIEW OF CHARACTERISTICS OF INCLUDED STUDIES REPORTING ON REVERSE SHOULDER ARTHROPLASTY (RSA) WITH IMPLANT BREAKAGE 62

TABLE 10 REVISIONS DUE TO IMPLANT BREAKAGE AFTER SHOULDER ARTHROPLASTY REPORTED BY THE NATIONAL ARTHROPLASTY REGISTRY OF AUSTRALIA, ITALY (RIAP), THE EMILIA-ROMAGNA REGION, NORWAY, AND DENMARK. 64

TABLE 11 ILLUSTRATION OF THE PART OF THE BROKEN IMPLANT AFTER FAILED SHOULDER ARTHROPLASTY AND ITS FREQUENCY FROM 2007 UNTIL 2021 OUT OF THE AUSTRALIAN ARTHROPLASTY REGISTER (DATA FROM ANNUAL REPORT 2022) 65

TABLE 12 DATASET OF IMPLANT BREAKAGE FROM 2015 UNTIL 2020, EXTRACTED OUT OF THE AUSTRALIAN REGISTRY OF ARTHROPLASTY 66

TABLE 13 OVERVIEW OF THE BREAKAGE INCIDENCE IN CLINICAL STUDIES IN PRIMARY TOTAL SHOULDER ARTHROPLASTY (TSA) AND REVERSED SHOULDER ARTHROPLASTY (RSA) 73

TABLE 14 DATA ON IMPLANT BREAKAGES AFTER SHOULDER ARTHROPLASTY FROM NATIONAL ARTHROPLASTY REGISTRIES AND CLINICAL STUDIES IN COMPARISON 73

FIGURE 1 RANGE OF MOTION OF THE NATIVE SHOULDER JOINT 21

FIGURE 2 ILLUSTRATION OF THE COMPONENTS OF RSA AND ATSA 23

FIGURE 3 SETUP SCHEME OF THE MODULARITY OF A MODERN SHOULDER PROSTHESIS 24

FIGURE 4 DIRECTION OF FORCES OF THE SHOULDER JOINT 26

FIGURE 5 A) COMPARISON OF A CENTERED GLENOSPHERE AND B) INFERIOR ECCENTRIC PLACEMENT. 29

FIGURE 6 A) THE VECTOR FORCE AFTER SA 30

FIGURE 7 GENERAL PROOF OF STRENGTH (CALCULATION ALGORITHM) 33

FIGURE 8 DISPLACEMENT TO GENERATE THE REQUIRED JOINT PRESSURE 36

FIGURE 9 FORCES ON THE CONE OF A PRESS FIT JUNCTION 36

Diagram 1 Stress-strain-diagram 38
Diagram 2 Comparison of breakage rate per 100.000 ocy, data extracted from clinical trials and Australian Registry 50
Diagram 3 Primary partial shoulder Replacement – Hemi Resurfacing 2015 – 2021 67
Diagram 4 Primary total shoulder replacement – Total resurfacing 2015 to 2020 68
Diagram 5 Primary total shoulder replacement – Total stemmed 2015 to 2021 69
Diagram 6 Primary total shoulder replacement – Total reverse 2015 to 2021 70
Diagram 7 Cumulative percentage of revision surgeries of all reasons minimum 10 years after primary shoulder arthroplasty until 2021 71
Diagram 8 Region of Implant breakage after shoulder arthroplasty within 22 Years 72

5. List of abbreviations

SA	Shoulder Arthroplasty
RSA	Reversed Shoulder Arthroplasty
ADL	Activities of daily live
AN	Avascular necrosis
aTSA	Anatomical Total Shoulder Arthroplasty
BMI	Body mass index
COR	Center of Rotation
FU	Follow up
IB	Implant breakage
ISP	Infraspinatus Muscle
MD	Musculus Deltoideus
MPG	Metal-backed glenoid
MDR	Medical Devices Regulation
NRSI	Non-randomized studies of intervention
OA	Osteoarthritis
QMS	Quality Management System
ocy	Observed component years
PE	Polyethylene
PJI	Periprosthetic joint infection
PMCF	Post-Market Clinical Follow-up
PROMs	Patient reported outcome measures
RA	Rheumatoid Arthritis
RC	Rotator cuff
RCA	Rotator Cuff Arthropathy
RCT	Randomized controlled trails
ROM	Range of Motion
SSC	Subscapularis Muscle
SSP	Supraspinatus Muscle
UDI	Unique product information

6. Abstract

Purpose: Implant breakage after shoulder arthroplasty is a rare complication after aseptic loosening, infection or persistent pain, resulting in malfunction of the components requiring revision surgery. This correlates with a high burden for the patient and increasing costs. Specific data of complication rates and implant breakage are available in detailed arthroplasty registries, but due to the rare occurrence and possibly underestimated value rarely described in published studies. The background of this dissertation was the evaluation of the current knowledge of shoulder prosthetics, including materials used, calculations, and production of various implants. A systematic review of this dissertation was published in the BMC Journal in autumn 2023. The aim of this systematic review was to point out the frequency of implant breakage after shoulder arthroplasty. We hypothesized that worldwide arthroplasty registry datasets record higher rates of implant breakage than clinical trials.

Methods: PubMed, MEDLINE, EMBASE, CINHAL, and the Cochrane Central Register of Controlled Trials database were utilized for this systematic review using the items "(implant fracture/complication/breakage) OR (glenoid/baseplate complication/breakage) AND (shoulder arthroplasty)" according to the PRISMA guidelines on July 3rd, 2023. Study selection, quality assessment, and data extraction were conducted according to the Cochrane standards. Case reports and experimental studies were excluded to reduce bias. The breakage rate per 100,000 observed component years was used to compare data from national arthroplasty registries and clinical trials, published in peer-reviewed journals. Relevant types of shoulder prosthetics were analysed and differences in implant breakage were considered.

Results: Data of 5 registries and 15 studies were included. Rates of implant breakage after shoulder arthroplasty were reported with 0.06-0.86% in registries versus 0.01-6.65% in clinical studies. The breakage rate per 100,000 observed component years was 10 in clinical studies and 9 in registries. There was a revision rate of 0.09% for registry data and 0.1% for clinical studies within a 10-year period. The most frequently affected component in connection with implant fracture was the glenoid insert.

Conclusion: Clinical studies revealed a similar incidence of implant failure compared to data of worldwide arthroplasty registries. These complications arise mainly due to breakage of screws and glenospheres and there seems to be a direct correlation to loosening. Periprosthetic joint infection might be associated with loosening of the prosthesis and subsequent material breakage. We believe that this analysis can help physicians to advise patients on potential risks after shoulder arthroplasty.

Level of evidence III

Keywords: Implant breakage after shoulder arthroplasty; implant fracture after shoulder arthroplasty; total shoulder arthroplasty; reversed shoulder arthroplasty.

Hintergrund: Ein Implantatbruch nach der Implantation einer Schulterendoprothese ist eine seltene Komplikation und kann durch eine Fehlfunktion zu anhaltenden Schmerzen führen und in der Folge häufig eine Revisionsoperation indizieren. Dies geht mit einer hohen Belastung für den Patienten und steigenden Kosten für das Gesundheitssystem einher. Spezifische Daten zu Komplikationsraten und Implantatbrüchen sind in detaillierten Endoprothetikregistern verfügbar, werden jedoch aufgrund des seltenen Auftretens und möglicherweise unterschätzter Wichtigkeit, in Studien selten beschrieben. Hintergrund dieser Dissertation war die Auswertung des aktuellen Wissensstandes zur Schulterprothetik, einschließlich der verwendeten Materialien, Berechnungen und Herstellung verschiedener Implantate. Ein systematisches Review dieser Dissertation wurde im Herbst 2023 im BMC Journal für muskuloskeletale Erkrankungen veröffentlicht. Ziel dieses systematischen Reviews ist es, die Häufigkeit von Implantatbrüchen nach Schulterendoprothetik aufzuzeigen. Wir stellten die Hypothese auf, dass weltweite Endoprothetik-Registerdatensätze höhere Raten an Implantatbrüchen verzeichnen als veröffentlichte klinische Studien.

Methoden: PubMed, MEDLINE, EMBASE, CINHAL und die Cochrane Central Register of Controlled Trials-Datenbank wurden für diese systematische Überprüfung unter Verwendung der Begriffe "(implant fracture/complication/breakage) OR (glenoid/baseplate complication/breakage) AND (shoulder arthroplasty)" gemäß den PRISMA-Richtlinien am 3. Juli 2023 durchsucht. Die Studienauswahl, die Qualitätsbewertung und die Datenextraktion wurde gemäß den Cochran-Standards durchgeführt. Fallberichte und experimentelle Studien wurden ausgeschlossen, um Verzerrungen zu reduzieren. Die Bruchrate pro 100.000 beobachteten Komponentenjahren wurde verwendet, um Daten aus nationalen Endoprothetikregistern und klinischen Studien zu vergleichen. Relevante Schulterprothesen wurden analysiert und die Unterschiede im Bruchverhalten herausgearbeitet.

Ergebnisse: Daten von 5 Registern und 15 Studien konnten in das systematische Review integriert werden. Die Implantatbruchrate nach Schulterendoprothetik wurde in Registern mit 0,06–0,86 % gegenüber 0,01–6,65 % in klinischen Studien angegeben. Die Bruchrate pro 100.000 beobachteten Komponentenjahren betrug in klinischen Studien 10 und in Registern 9. Innerhalb eines 10-Jahres-Zeitraums ergab sich eine Revisionsrate von 0,09 % für Registerdaten und 0,1 % für klinische Studien. Die am häufigsten betroffene Komponente im

Zusammenhang mit einer Implantatfraktur nach Schulterendoprothetik war der Glenoideinsatz.

Schlussfolgerung: Klinische Studien zeigten eine ähnliche Inzidenz von Implantatversagen im Vergleich zu Daten weltweiter Endoprothetikregister. Diese Komplikationen entstehen hauptsächlich durch Brüche von Schrauben und der Glenosphäre und scheinen in direktem Zusammenhang mit einer Prothesenlockerung zu stehen. Eine periprothetische Gelenkinfektion kann mit einer Lockerung der Prothese und anschließendem Materialbruch einhergehen. Durch diese Datenanalyse und deren Ergebnisse, können Ärzte ihre Patienten spezifischer über das mögliche Risiko eines Implantatversagen nach einer Schulterprothese aufklären.

Level of evidence III

Schlüsselwörter: Implantatbruch nach Schulterprothetik; Implantatversagen nach anatomischer totaler Schulterendoprothese; Implantatversagen nach inverser totaler Schulterprothese.

7. Introduction

The first shoulder arthroplasty was reported in the late 1800s by Themistocles Gluck [1]. Gluck, who originally grow up in Romania, studied in Germany and developed the first shoulder prosthesis made of ivory to treat the tuberculosis-associated shoulder-joint infection. A documentation of a human implantation could not be found for that time. In 1893, for the first time documented, the Paris surgeon named "Pean" replaced the shoulder joint of a patient who did not agree to amputate the arm after tuberculous associated shoulder arthropathy [2]. As an implant, he used the design of the Parisian dentist J. Porter Michaels, whereby the humeral head was made of a rubber-like substance and then boiled in paraffin to increase the degree of hardness. This was connected to a platinum shaft with a metal wire. A second metal wire was used to connect the prosthesis to the glenoid. After two years, however, the prosthesis had to be removed again because of infection [3].

The *first-generation* shoulder prosthesis was a monobloc and anatomic design, and was first announced on December 12th in 1950 by Frederick Krueger, who fabricated it out of Vitallium, in the Austionol laboratory in New York. They were non-constrained prosthesis with conforming radii of curvature and protection against dislocation. The proximal humerus of cadavers was used as a template.

It is described, that this prosthesis was also implanted in a young patient with osteonecrosis of the humeral head [4]. In the late 1950s, Charles Neer advanced shoulder prosthetics by using the same alloy (Vitallium) [3]. At this time, the implant was used as a hemiprosthesis for complex proximal humeral fractures.

Almost 20 years later, he also described the indication for implantation in cases of glenohumeral arthritis [5]. Initial design errors made the implants inherently stable and highly constraint, which resulted in numerous implant breakages (IB) and component loosening [6]. Further research, by focusing on the anatomy, biomechanics, and the use of different materials like Ti6Al-4V (titanium-aluminium-vanadium) and CoCrMo (cobalt-chromium-molybdenum), extended the durability of the implants significantly [7, 8].

The *second generation* was based on a modular concept with different head and shaft sizes as well as different radii for a physiologic rotation-translation-mechanism to offer a wider range of motion compared to earlier models, allowing users to perform more natural movements. Manufacturers used more durable materials and improved manufacturing techniques to enhance the longevity and reliability of the prosthetic device. Second-generation prosthetics were designed to better integrate with the user's remaining anatomy, resulting in a more comfortable fit and improved overall function. Despite the improved and patient-specific design, it was found that the clinical result after implantation was sometimes poor [5].

The *third generation* of humeral head prosthesis was built for an anatomic reconstruction. The inclination and the eccentric offset of the humeral head could be adjusted to restore the center of rotation. The center of rotation refers to the point around which the prosthetic shoulder joint rotates. This is a critical aspect of the design because it determines the naturalness and efficiency of movement for the user.

In a healthy human shoulder joint, the center of rotation is typically located at the center of the humeral head (the ball-shaped top of the upper arm bone). This allows for smooth and coordinated movement of the arm in various directions.

When designing a prosthetic shoulder joint, mimicking this natural center of rotation is essential for optimal functionality and comfort. Prosthetic designers aim to replicate the biomechanics of the human shoulder as closely as possible to facilitate natural movement patterns for the user. Achieving an accurate center of rotation involves precise alignment of the prosthetic components, including the socket, humeral implant, and any additional components such as bearings or articulating surfaces. Advanced imaging techniques, computer modeling, and precise surgical techniques may be used to ensure proper alignment and placement of these components during the prosthetic fitting process.

The latest development of shoulder arthroplasty maintains the possibility for a fully variable three-dimensional modularity with ability to adjust the head position regardless of the individual geometry of the shaft [9]. This is important, because a significant coherence with a

higher scapular notching rate in humeral stem designs with 155° in comparison to 135° ($P < 0.0001$, $z = -7.7107$) was shown during a systemic review in 2015 [10].

In the late 1980's, Boileau and Walch readjusted the fit of the humeral stem to accommodate several anatomical variations and developed the Sphere and the Cylinder. In addition, implant designs with different inclinations were available (anatomic neck of the humerus relative to the humeral diaphysis). The clinical results improved progressively, but complications continued to be described, which subsequently focused on the indications for a shoulder prosthesis implantation [11]. Revision surgeries are part of encountered postoperative complications in shoulder arthroplasty (SA) and range from 4 to 10% after 10 years [12-16]. Detailed information concerning the reason for revision is available in almost every arthroplasty registry [13, 17-19] and includes infection, periprosthetic fracture, dislocation and instability, loosening of components, and various rotator cuff pathologies [14, 20]. Specific reasons for revision surgeries are entitled as “other reasons for revision”, but overall there is no difference in the occurrence of dislocation and “other reasons” (0.8%) [14].

Since February 2022, the new requirements for medical implants have included the mechanical properties of the materials used, such as fracture resistance, strength and ductility [21]. Therefore, there is a need to clarify the reasons for IB in shoulder arthroplasties to reduce the number of affected patients, limit health care costs [22], and the need for revision surgeries [23, 24].

Registries and clinical studies should be analysed and compared to obtain the most probable and real incidence of various complications, such as IB, even if there are differences between registry data and clinical trials with regard to the admission criteria and the generalizability in relation to the examined population.

The aim of this dissertation was to critically analyse various registries and clinical studies in order to compare and obtain the most probable and real incidence of various complications, such as IB. We hypothesize that overall, the analysed registry datasets report higher rates of IB after SA compared to data of clinical studies.

This is the first review including the background of implant breakage after shoulder prosthetics and was already published in the BMC Journal of Musculoskeletal Disorders in 2023 [25]. Investigations of the artificial knee and hip joint have been published before [26, 27].

8. General

8.1. Anatomy of the shoulder joint

The shoulder joint consists of the glenoid of the scapula and the head of the humerus and is spherical in configuration [28, 29]. The shoulder joint (glenohumeral joint) connects the upper arm with the shoulder girdle. Stabilization and muscular support are provided by the sternum, clavicle, and spine. The scapula acts as the foundation for 17 muscles and 4 ligaments, with the glenoid of the scapula having approximately a 5° retroversion. Key anatomical landmarks of the scapula include the spina scapulae, coracoid, and acromion.

The coracoacromial ligament, coracoclavicular ligament, the conjoined tendon (coracobrachialis and short head of the biceps), and the pectoralis minor muscle attach to the coracoid. The suprascapular notch features an upper transverse band separating the suprascapular artery (superior) from the suprascapular nerve (inferior). The spinoglenoid notch guides the artery and nerve to the inferior transverse ligament. Prolonged compression of the suprascapular nerve at the spinoglenoid notch can lead to atrophy of the infraspinatus muscle. The suprascapular nerve compression syndrome is a condition where the suprascapular nerve is compressed or irritated, leading to pain, weakness, and dysfunction in the shoulder and surrounding areas. The suprascapular nerve originates from the upper trunk of the brachial plexus. Compression of the suprascapular nerve can occur at various points along its course, including:

Suprascapular Notch: The nerve may become compressed as it passes through the suprascapular notch, a bony notch on the superior border of the scapula (shoulder blade). This compression can be caused by anatomical variations, such as a thickened transverse scapular ligament or a ganglion cyst in the notch.

Spinoglenoid Notch: Another potential site of compression is the spinoglenoid notch, located on the inferior border of the scapula. Compression at this site can occur due to entrapment by the spinoglenoid ligament or a mass lesion such as a tumor or cyst.

Compression of the suprascapular nerve can result in symptoms such as:

- Shoulder pain, often radiating to the back or upper arm

- Weakness in the muscles that the suprascapular nerve innervates, particularly the supraspinatus and infraspinatus muscles
- Difficulty performing overhead activities or external rotation of the shoulder
- Atrophy (wasting) of the affected shoulder muscles in chronic cases

Diagnosis of suprascapular nerve compression syndrome typically involves a thorough clinical evaluation, including a physical examination to assess strength, range of motion, and any areas of tenderness or muscle atrophy. Imaging studies such as MRI or ultrasound may be used to visualize the anatomy of the shoulder and identify potential compressive lesions.

Treatment options for suprascapular nerve compression syndrome depend on the underlying cause and severity of symptoms. Conservative measures may include rest, activity modification, physical therapy to strengthen surrounding muscles, and corticosteroid injections to reduce inflammation. In cases where conservative treatment fails to provide relief, surgical decompression of the nerve may be considered to alleviate compression and restore function.

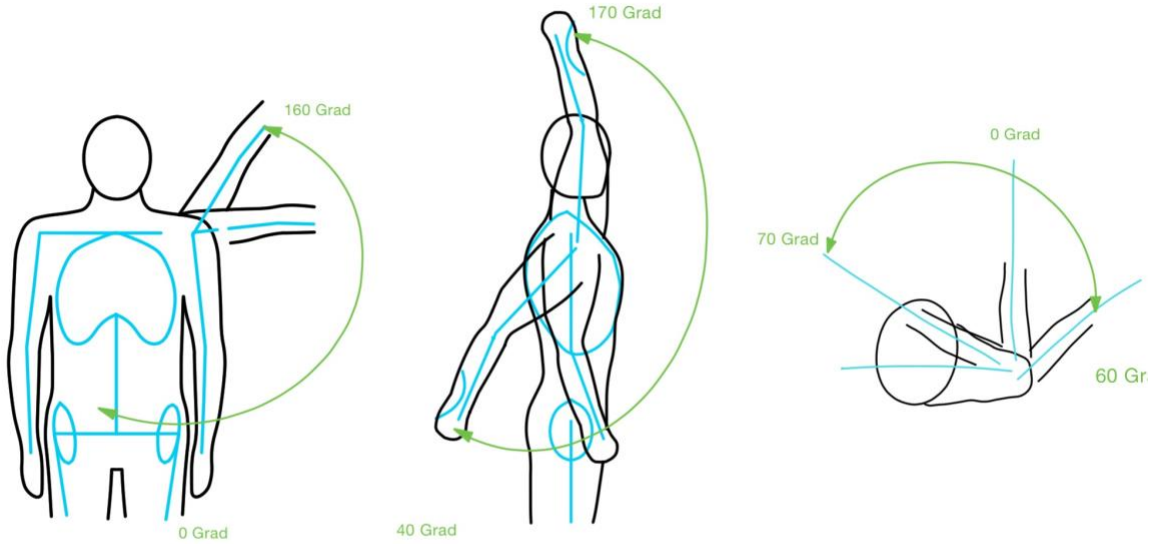
The clavicle acts as the fulcrum for lateral arm movement, displaying a double curvature (sternal-ventral, acromial-dorsal), and serves as the insertion point for the upper extremity. Remarkably, the clavicle begins to ossify as early as 5 weeks gestation, making it the first bone to initiate ossification and the last to complete fusion in the medial epiphysis, typically around 25 years of age [30]. There are a total of 5 joints on the shoulder, three of which are described as "real" and 2 as "unreal" [31].

8.2. Movement of the shoulder

As depicted in Figure 1, the directions of shoulder movement can be set in opposition:

1) Anteversion – Retroversion: In the sagittal plane around the transverse axis
2) Abduction – Adduction: In the frontal plane around the sagittal axis
3) External – Internal rotation: In the transverse plane around the longitudinal axis

Figure 1 Range of Motion of the native shoulder joint, painted by Martin Liebhauser with Concepts, TopHatch Inc.



Long and short muscle trains with sinewy attachments to the proximal humerus are responsible for shoulder movement. The muscles significantly involved in this movement include the M. pectoralis major, M. coracobrachialis, M. latissimus dorsi, M. teres major, and M. deltoideus. However, the shoulder joint is relatively unstable, relying solely on support from the rotator cuff (RC), consisting of four muscles: supraspinatus, infraspinatus, subscapularis, and teres minor.

Following the implantation of a shoulder joint prosthesis, the biomechanics of the joint undergo changes, affecting the range of motion [32]. In the development of shoulder prosthetics, the goal for anatomical shoulder prostheses is achieving the most anatomical restoration possible. With RSA (reverse shoulder arthroplasty), kinematics and the forces acting on the joint are intentionally altered, allowing the restoration of functionality even in cases where the SSP (Supraspinatus Muscle) is already pathological.

After shoulder arthroplasty (SA), most surgeons recommend immobilization for 4 to 6 weeks using a sling. In the first two weeks, this ensures support for wound healing, while in the subsequent weeks, it promotes better integration of bone and metal junctions. If the bone quality during surgery is good, early motion outside the sling may be feasible to enhance mobility. There is no one-size-fits-all rehabilitation protocol. The question of whether immediate active assisted motion after SA is possible without the occurrence of further complications was addressed by the study group of Waterman et al [33]. They found that older patients benefit more from early engagement in sports activities compared to younger patients.

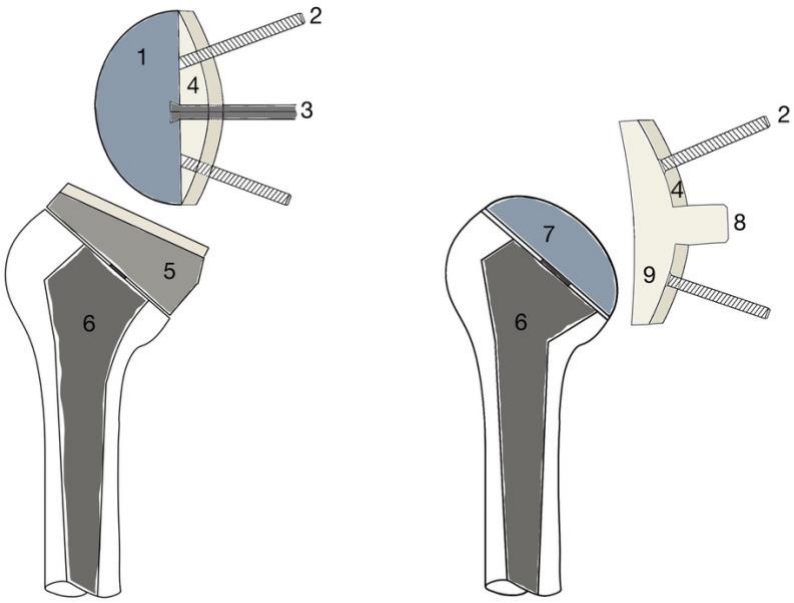
8.3. Types of shoulder prosthesis designs

For the implantation of a shoulder prosthesis, the surgical orthopedist can choose different designs, depending on the respective indication: the hemi prosthesis, anatomical total shoulder (aTSA), or reversed total shoulder arthroplasty (RSA). Current concepts of shoulder prosthetics involve a completely spherical shape, with no difference in range of motion (ROM) compared to an elliptical head [34].

In Figure 2, the components of different methods are schematically presented. The glenosphere (1) in RSA leads to lateralization and caudalization of the rotation point, depending on the selected size. In most RSA models, the glenosphere is affixed to the baseplate (4), typically attached to the glenoid with screws (2) after prior preparation. Some variants require cementing of the baseplate. The central screw (3), or a peg, functions as a point of orientation for axis alignment in all planes, identified using a Kirschner wire and temporarily set. According to the mechanical concept of RSA, the humeral component differs from that of a hemi- or anatomical TSA. The humeral stem (6) is implanted using a similar procedure, following the selection of the resection level at the anatomical column with various gauges. However, a socket/reversed metaphysis (5) is used as an attachment, connecting the stem and polyethylene (PE). In aTSA, anatomical conditions generally remain unchanged. The baseplate (4) on the bony glenoid is again secured with screws (2) after surface preparation. The central peg (8) can guide all levels. The liner, or cup (9), also made

of PE, is fitted to the baseplate. Before implanting the humeral stem (6), the head (7) is positioned on it, and the entire humeral component is carefully hammered into the humerus.

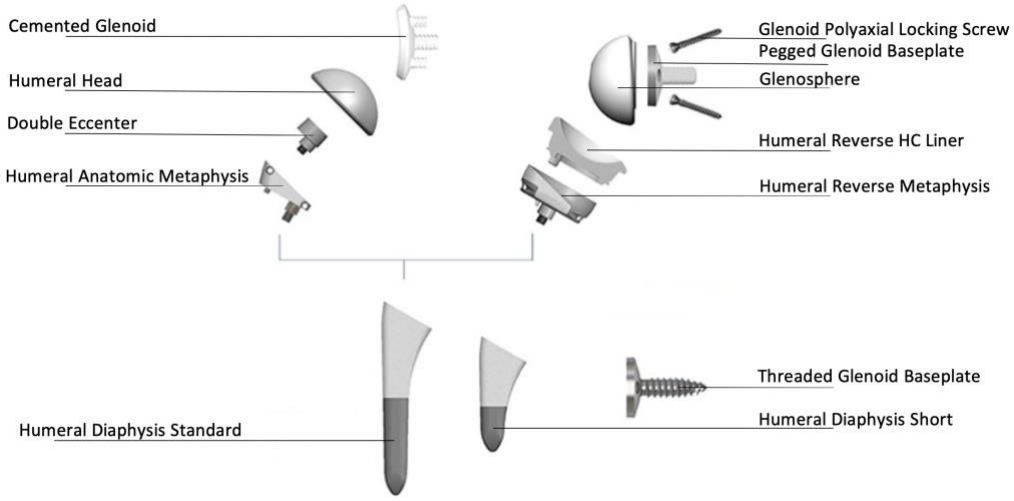
Figure 2 Illustration of the components of reversed shoulder arthroplasty (RSA) and total shoulder arthroplasty (aTSA)



Note: 1) Glenosphere, 2) Glenoid Fixation Screw, 3) Central Screw, 4) Baseplate/Glenoid, 5) Socket/Reversed Metaphysis, 6) Humeral Stem, 7) Head, 8) Central/Metal Peg, 9) Liner/Cup, painted by Martin Liebhauser with Concepts, TopHatch Inc.

Figure 3 illustrates the structure of a modern, modular shoulder prosthesis. As previously outlined by Castagna et al., transitioning from aTSA to RSA in revision is linked to a shorter operation time, fewer intraoperative complications, and a higher satisfaction level in mid-term follow-ups, attributed to the modular design [16].

Figure 3 Setup scheme of the modularity of a modern shoulder prosthesis



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The Australian National Arthroplasty Registry classifies shoulder prosthetics into partial, total, and revision categories (refer to Table 1). Partial shoulder prosthesis encompasses partial and half-surface replacements, along with anatomical humeral head replacements offered with or without a stem by manufacturing companies. Total shoulder prostheses include total surface replacements (humeral head and glenoid), total mid-head, classic anatomical shoulder prostheses, and RSA. Revision prostheses are further categorized into minor, major, and total revisions.

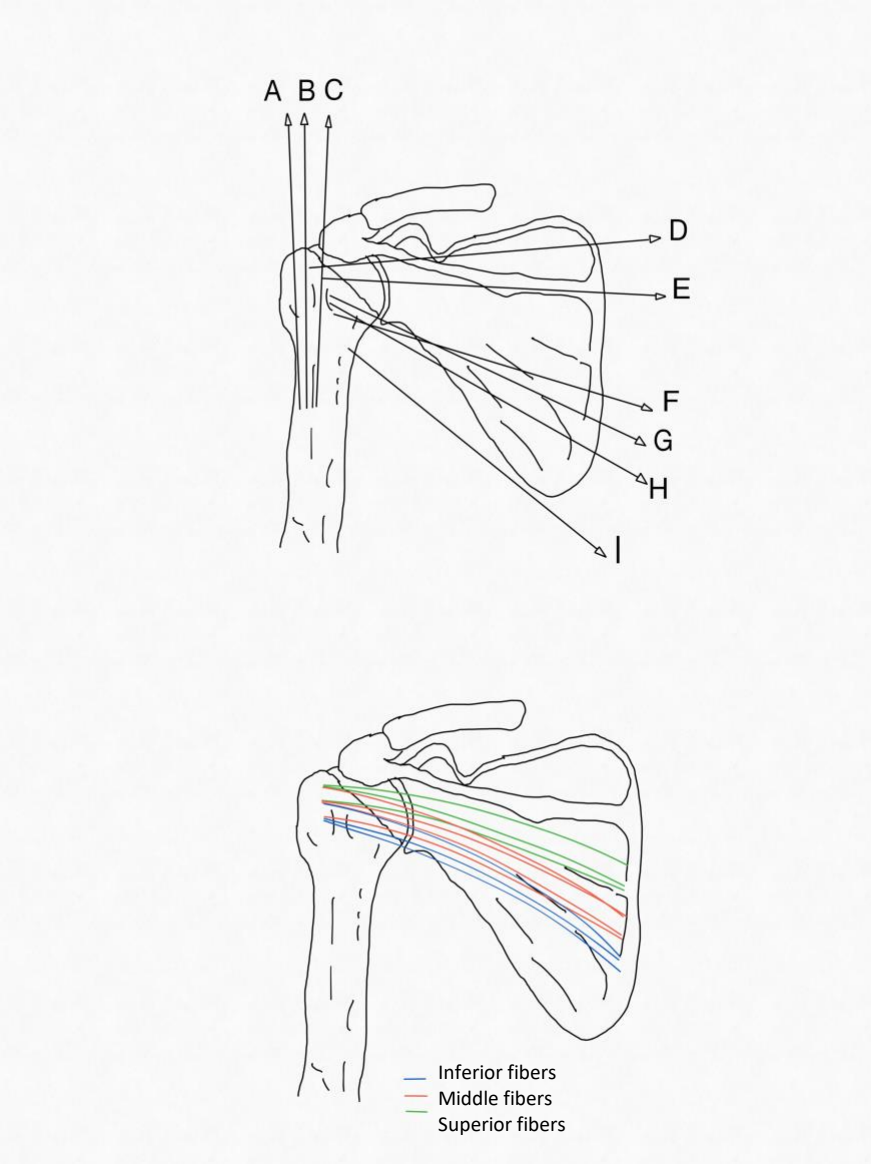
Table 1 Different types of Shoulder Arthroplasty adopted by the Australian Arthroplasty Registry [20]

PARTIAL	TOTAL	REVISION
Partial Resurfacing	Total Resurfacing	Minor
Hemi Resurfacing	Total Mid Head	Major Partial
Hemi Mid Head	Total Stemmed	Major Total
Hemi Stemmed	Total Reverse	

A study by Barragan Echenique et. al. [35] investigated the efficacy of superior capsular reconstruction and RSA by using the moment arm values in a descriptive laboratory study. They found out, that infraspinatus fiber groups (superior, middle and inferior) had different and inverse moment arms during abduction/elevation and that a reconstruction is the most effective in comparison to the intact shoulder joint. After implantation of a RSA, the infraspinatus muscle turns into an adductor. The force vectors act as a stabilizer for the shoulder joint in a neutral position. The lines as shown in Figure 4 describe the direction of the different muscles: A anterior delta muscle, B middle delta muscle, C posterior delta muscle, D supraspinatus, E pectoralis major, F subscapularis, G infraspinatus, H teres minor, I latissimus dorsi. The infraspinatus muscle is graphically shown with separation of the three different parts: the superior, middle and inferior fibers. The superior infraspinatus muscle fibers have an abduction moment that decreases with elevation until it shifted to adduction. The middle and inferior infraspinatus fibers have an adduction moment that decreases until it turs into abduction. After a SSP tear, superior fibers lost adduction potential and inferior and middle infraspinatus fibers lost any adduction potential.

Due to the natural range of motion of the shoulder joint, a pivot point can be concluded that seems variable. The movement of the humeral head on the glenoid is accomplished through 2 pivot points, both located near the center of the humeral head. The components of the RSA generate a fixed "center of rotation" (COR) to achieve greater stability. The medialization of the COR results in lengthening of the deltoid muscle and a larger torque arm [36] and thereby a steeper ascending vector direction compared to the normal anatomy of the shoulder joint [7].

Figure 4 Direction of forces of the shoulder joint



Note: A anterior delta muscle, B middle delta muscle, C posterior delta muscle, D supraspinatus, E pectoralis major, F subscapularis, G infraspinatus, H teres minor, I latissimus dorsi; *painted by Martin Liebhauser with Concepts, TopHatch Inc.*

8.3.1. Anatomical Shoulder Arthroplasty

Hemi- and total anatomic shoulder prosthesis

The partial shoulder prosthesis, or hemiarthroplasty, is designed to restore the anatomical and, therefore, pre-existing biomechanics of the glenohumeral joint. This involves resurfacing the damaged humeral articular surface with a smooth, rounded cap to achieve natural joint movement. Unlike other surgical partial approaches, hemiarthroplasty preserves the natural bone stock. Indications such as avascular necrosis (AN) yield the highest patient

satisfaction and the lowest pain levels, followed by Osteoarthritis (OA) and rheumatoid Arthritis (RA). Patients with a primary pathology of the rotator cuff (RC) tend to have poorer results [37].

As described by the Australian Registry of Arthroplasty, the primary reason for performing a hemi prosthesis on the island is the fracture of the humeral head in female patients, followed by osteoarthritis in males [20]. Proximal humeral fractures are more prevalent in women than men (114 vs. 47 per 100,000 patient years), tend to occur more frequently in the winter months, and are associated with osteoporotic bone structure [38].

In the case of an elective shoulder prosthesis, the goal is to choose the optimal time for surgery, involving planning, infection prophylaxis, clarification of any potential sources of infection, and postoperative rehabilitation with early registration, physiotherapy, and support with activities of daily living (ADL). Pre-existing conditions and the patient's compliance play crucial roles in the postoperative outcome. For fracture prostheses, the optimal timing for the operation is no longer applicable, as it typically occurs within 14 days or only after an unsuccessful attempt at conservative therapy. The shorter duration of surgery when implanting a hemiprosthesis reduces the risk of infection and, due to fewer work steps, also minimizes intraoperative complications compared to aTSA (8% vs. 12%) [39, 40]. As a result, the hemiprosthesis is commonly employed for head fractures, despite having a higher rate of revisions (for any reason) compared to total prosthesis (13% vs. 7%, $p < 0.001$) [40].

As an example, Zimmer Biomet offers the anatomical shoulder combined system for this indication, which includes three fixed neck angle adaptors with different angulations (42°, 45°, and 48°). These adaptors can be paired with Bigliani/Flatow™ humeral heads and glenoids, as well as the Trabecular Metal™ glenoid. However, in recent years, it has been observed that primary treatment with a Reverse Shoulder Arthroplasty (RSA) yields superior results in terms of postoperative pain, range of motion, and satisfaction when compared to aTSA [41].

8.3.2. Reverse total shoulder Arthroplasty (RSA)

The first reversed total shoulder prosthesis (RSA) was described by Paul Grammont in 1985 [42]. The main biomechanical advantages are (1) the large glenoid ball offers a greater arc of motion than a small one (2) the small lateral offset places the center of rotation directly in contact with the glenoid surface, the torque at the pint of fixation of the glenoid is reduced (3) the center of rotation is medialized, therefore more deltoid fibers are recruited for elevation and abduction (4) the tension of the delta muscle increases by lowering the humeral head [43].

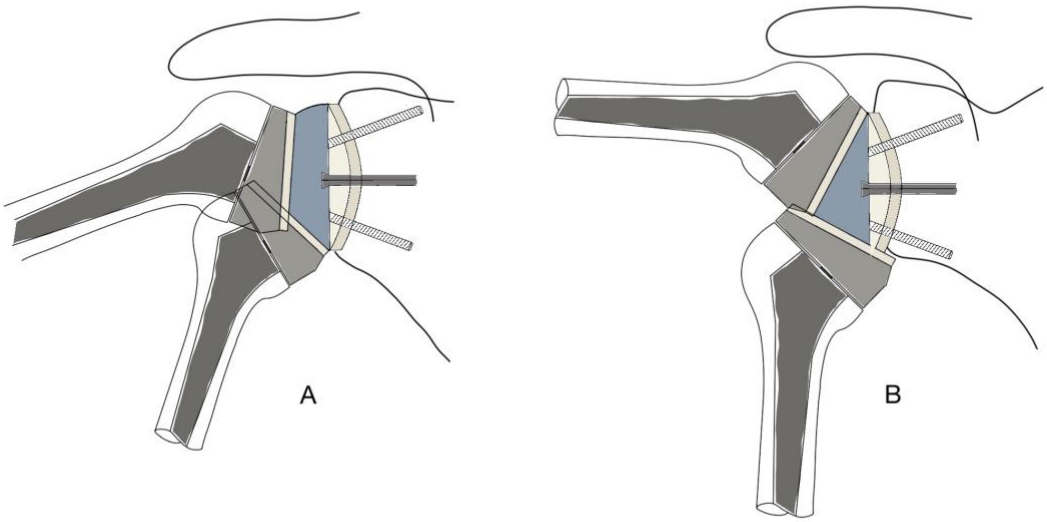
There is described an improvement of shoulder pain and function in challenging shoulder conditions like massive rotator cuff tears, cuff tear arthropathy, proximal humerus fracture and inflammatory arthropathy [44]. The aim was to medialize and lower the center of rotation to transfer the vector axis of the M. deltoideus (MD) to assume the abilities of the Supraspinatus muscle (SSP) if the tendon is damaged or the muscle is working insufficient because of long lasting injury and fatty degeneration as a result. In RSA the inferior positioning of the base plate is important to minimize the risk of notching, but Polyethylene/PE-induced osteolysis and implant-to-bone or implant-to-implant contact may still be present and result in the higher risk of screw breakage [45].

After the Food and Drug Administration (FDA) approved the RSA in 2003, its popularity is increasing worldwide. In 2014, over 45% reversed type SA were implanted in the US [46]. This was achieved because the better understanding of the biomechanics and the vector forces of the shoulder joint and the associated complications, such as scapular notching, could be significantly reduced by fine-tuning the components. In addition, the range of motion could be increased, which also increased patient satisfaction [47]. In the meantime, it has been shown that the implantation of an RSA is indicated for patients with existing massive RM damage. Thanks to modular prosthesis components, there is also an indication for bone loss/lysis of the glenoid, in revision prosthetics (from TSA to RSA) and for proximal humeral tumors [48].The force applied to the glenoid seems to be greater when abducted after RSA, as the lever arm shifts laterally. In the neutral position, the forces are balanced, and the resulting vector is steeper and larger in RSA than in aTSA. Nevertheless, anchoring to the bony

glenoid plays a crucial role in terms of primary stability and after the healing process. For example, products with glenoid lateralization and inferior offset of the center of rotation are offered for the inverse shoulder prosthesis, since the impingement between the scapula (acromion), the humerus head and the implant component is considered a limiting factor in mobility [32].

As shown graphically in Figure 5, with a centrally aligned glenosphere (A), on the one hand, abduction is limited by the acromion where there is bony contact with the greater tuberosity of the humeral head. Adduction is also limited by the terminal contact of the polyethylene cup to the inferior rim of the glenoid. With eccentric inferior positioning (B), the degrees of freedom in abduction and adduction are increased, as the study by Gerber et al. (2005) described the movement improvement through an eccentric inferior positioning of the glenosphere with an increased impingement-free zone between 11 and 39° [49]. As shown, the abduction angle is greater in the inferior eccentric position.

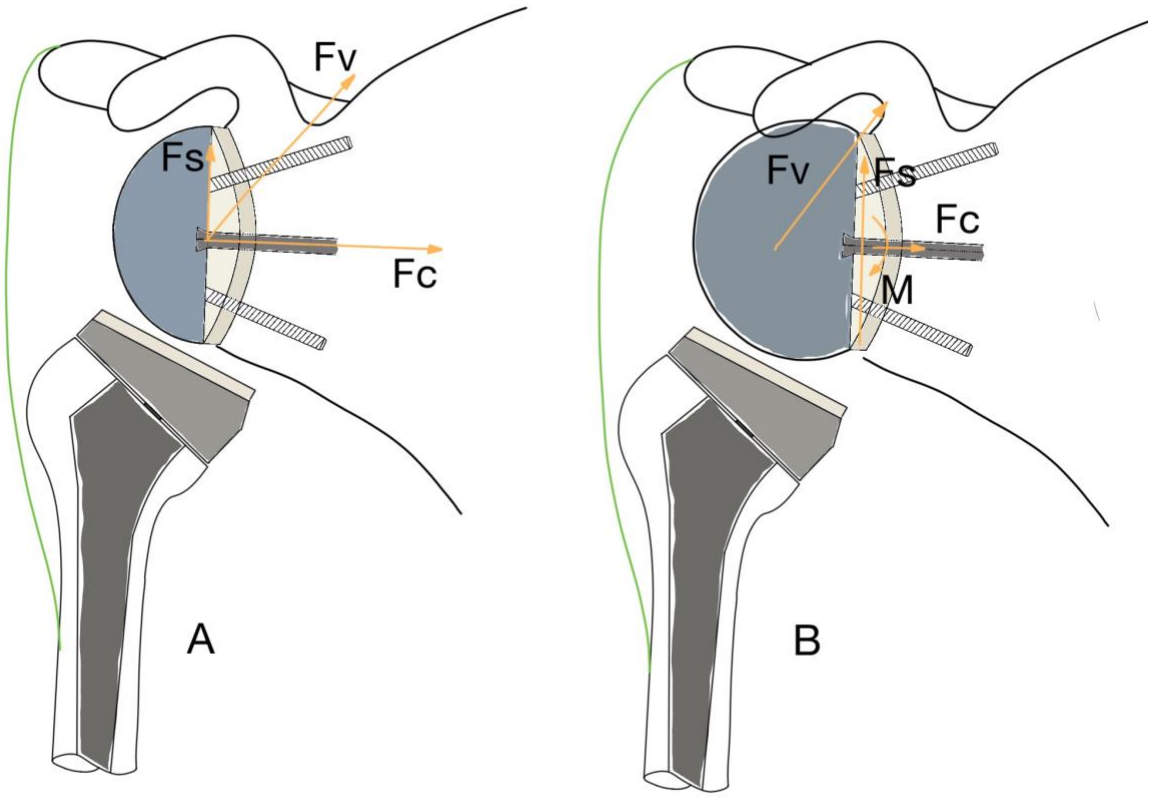
Figure 5 A) Comparison of a centered glenosphere and B) inferior eccentric placement



Note: painted by Martin Liebhauser with Concepts, TopHatch Inc.

In the case of the native shoulder joint, the maximum forces are reached at an abduction of 90°, with further elevation these in turn slowly but steadily decrease. With the RSA, the maximum force effect is reached at about 60 to 70°, with further elevation the forces remain approximately constant [50]. The initial stabilization of the baseplate with screws appears to be the most important factor for long-term bony healing, as shown by a study by Gutierrez [51]. Figure 6 shows the vectors that act on the glenosphere during medialization and lateralization of the COR.

Figure 6 A) The vector force Fv is the result of the compressive Fc and shear force Fs. Through the medialized Center of Rotation the Delta Muscle is lengthened and is able to work more actively, especially in case of subscapularis malfunction B) lateralization results in a reduced force of compression, but a new Moment M at the bone -implant interface is generated. There is a greater angle of impingement-free motion.



Note: painted by Martin Liebhauser with Concepts, TopHatch Inc.

No study could be found that examined the positioning of the glenoid in connection with implant fractures or implant failure. It can be assumed that due to the eccentric position of the glenoid, increased shearing forces and additional torque are transmitted to the COR.

In a central position, these may not occur biomechanically due to the complete bony support, but there is a permanently new impingement situation and the resulting increased micro-movements in the course of increased loosening, incorrect healing and subsequent implant failure with implant fractures.

9. Strength of Materials - Strength and allowable stress

The calculation and verification of component dimensions in the strength analysis are essential steps in evaluating the impact of external loads on the component. This process enables the optimization of geometry to ensure that the maximum stress in the vulnerable component cross-section does not exceed the permissible value for that specific point.

Permissible stress is determined by various factors, including material properties, the type of stress and load, and the geometric shape of the component. Additionally, influences such as temperature, residual stress, and material defects are considered during the calculation to ensure accurate results and reliable performance of the component under different operating conditions. The dimensioning process is customized to address potential types of failure, wherein sections of the component may lose functionality due to geometric alterations or breakage.

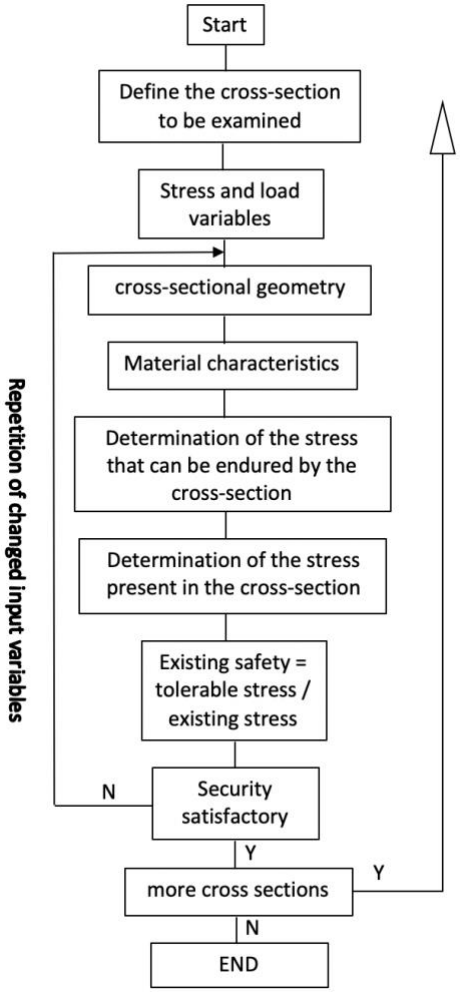
Two primary construction models for shoulder prostheses are modular and en-bloc. The power transmission in modular designs differs significantly from block designs, resulting in increased wear and a heightened risk of material fatigue. Material breakage can occur due to various factors:

1. Unacceptably large deformation
2. Time or fatigue failure
3. Detachment from the environment and subsequent instability
4. Mechanical wear and tear
5. Chemical factors

In general material theory, a specialized calculation algorithm (Figure 7) is utilized for strength verification. Prosthetic components are subjected to both intended and unintended loads during functional stress. Intended loads are those designed to fulfil the prosthesis's function, while unintended loads often stem from undesirable events such as falls, loosening, malpositioning, increased wear, unforeseen maximum loads, shearing stresses between different materials, incorrect connection after cementation, insufficient bone healing, etc..

These factors collectively contribute to the overall stress experienced by the prosthetic components, necessitating comprehensive strength verification procedures to ensure their durability and functionality in clinical settings.

Figure 7 General proof of strength (calculation algorithm)



Note: Adopted from Roloff/Matek Maschienenelemente, VIEWEG Vol. 13, p34, ISBN 3-528-74028, created by Martin Liebhauser with Concepts, TopHatch Inc.

Depending on the external forces acting on a component, internal force effects within the component cross-section are classified as follows: Normal forces (FN), shear forces (FO), bending moments (M), and torsional moments (T). These force effects lead to various types of stress on the component, including (a) Tension and compression, (b) Shear, (c) Bending, and (d) Torsion. In addition to these fundamental stress loads, other phenomena may occur. Buckling, for instance, is a specific type of compressive stress, while surface pressure arises when two bodies are pressed against each other. Understanding and addressing these

different stress types are crucial for accurately assessing the mechanical behaviour of components and ensuring their structural integrity under diverse loading conditions.
When two or more types of stress occur simultaneously, such as tension and bending or bending and torsion, a composite stress (resultant stress σ_{res} or τ_{res}, depending on the material's ductile or brittle nature) is taken into account during the calculation. The equivalent stress (σ_v) is determined based on various types of stress, with the relevant strength hypothesis serving as the foundation for this assessment. This approach allows for a comprehensive evaluation of the combined effects of different stress components on the component's mechanical behaviour, ensuring that the calculated stress values accurately reflect the actual loading conditions experienced by the component.

In endoprosthetics, press-fit connections with a cone/wedge design between the prosthesis shaft/neck and head are widely utilized. These cone/wedge shanks, typically crafted from proprietary titanium alloys, are often coated with plasma-sprayed titanium at the power-transmitting points. Described as tapered press connections, the connection between two different components ensures a precisely centric fit, resulting in high accuracy and smooth operation. Following attachment, subsequent axial displacement is typically restricted, at least in one direction. The cone inclination is determined by the cone ratio (C, Equation 1), and the cone inclination angle is represented as α/2 (Equation 2). Self-locking with taper press connections is commonly achieved when the taper ratio is C < 1:5. This design characteristic enhances stability and minimizes the risk of dislocation or loosening, contributing to the overall longevity and reliability of the implant system in endoprosthetics applications.

$$C = \frac{1}{x} = \frac{D1-D2}{l} \qquad \text{(Equation 1)}$$

$$\tan\frac{\alpha}{2} = \frac{D1-D2}{2\times l} \qquad \text{(Equation 2)}$$

D1 and *D2* represent the large and small cone diameters, respectively, while *l* denotes the cone length. In the field of endoprosthetics, there is a consensus to standardize cones as much as possible.

In the manufacturing of taper connections, adhering to standardization through DIN specifications offers several advantages. It allows the use of standardized manufacturing tools and general gauges for quality control. This approach streamlines the production process and facilitates the compatibility and interchangeability of components across different manufacturers. This standardization enables the interconnection and use of components from different companies, even if such usage is considered off-label. By conforming to established standards, manufacturers can ensure that their products meet the necessary criteria for safety, reliability, and performance, thereby enhancing patient outcomes and promoting greater confidence in the use of taper connections in endoprosthetics.

In the calculation, it is assumed that the setting angle (α/2) for both the outer and inner parts remains consistent and unaffected by manufacturing variations (tolerance T = 0). Taper connections are established by axially clamping the outer and inner parts after controlled sliding (Figure 8). The axial relative displacement of the parts induces lateral expansion, resulting in the generation of a corresponding surface pressure (pF) within the effective area. Considering the smoothing factor G (as defined in Equation 3), the minimum required delay (a_{min}) is then determined based on the torque that needs to be transmitted. This meticulous approach ensures the accuracy and reliability of the calculation, crucial for the effective functioning of taper connections in endoprosthetic applications.

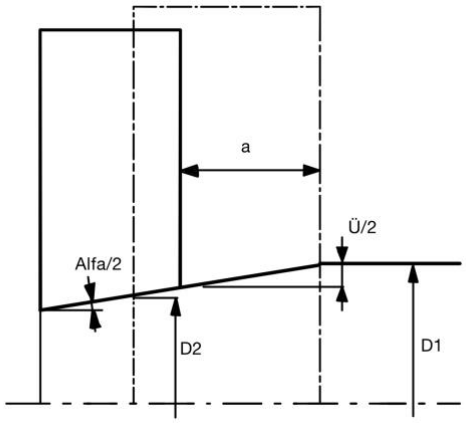
$$a_{min} = \frac{\frac{Ü_u}{2}}{\tan\left(\frac{\alpha}{2}\right)} = (Z_k + G)/(2 \times \tan\left(\frac{\alpha}{2}\right)) \qquad \text{(Equation 3)}$$

The permissible maximum delay (a_{max}) is determined by the permissible joint pressure or surface pressure of the weakest component, as described by Equation 4. This calculation ensures that the taper connection operates within safe limits, preventing excessive stress on any individual component and promoting the longevity and reliability of the endoprosthetic system.

$$a_{max} = \frac{\frac{Ü_0}{2}}{\tan\left(\frac{\alpha}{2}\right)} = (Z_g + G)/((2 \times \tan(\alpha/2)) \qquad \text{(Equation 4)}$$

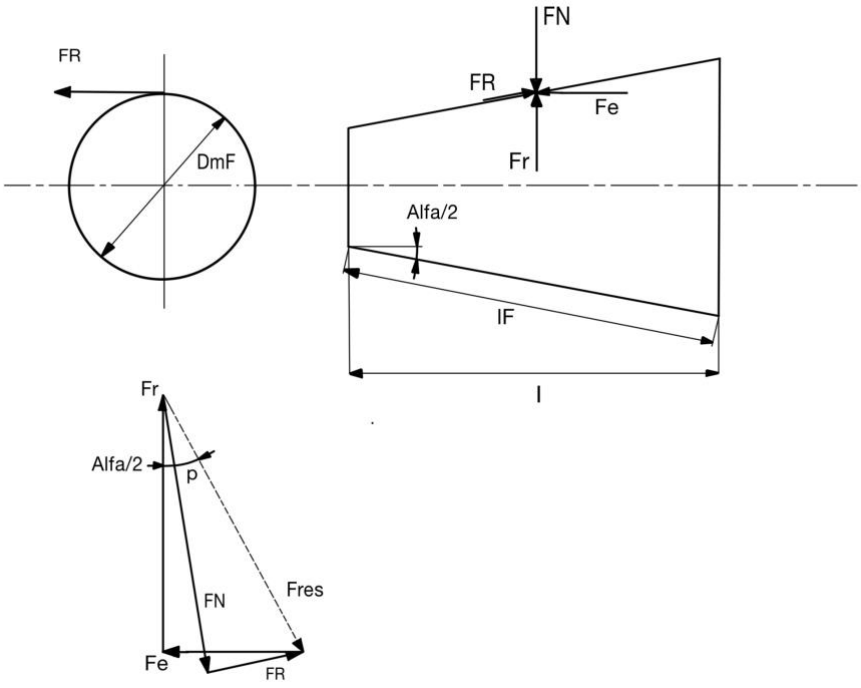
With DF = DmF = (D1 + D2)/2 (mean joint diameter), the deflection α can be determined using the equations for the cylindrical interference fit. This calculation allows for the precise evaluation of the interference fit between components, ensuring proper assembly and optimal mechanical performance in endoprosthetic applications.

Figure 8 Displacement to generate the required joint pressure (press-fit connection between prosthesis components)



Note: Created by Martin Liebhauser with Concepts, TopHatch Inc., modified from Roloff/Matek p. 335 [52]

Figure 9 Forces on the cone of a press fit junction



Note: Created by Martin Liebhauser with Concepts, TopHatch Inc., modified from Roloff/Matek p. 336 [52]

Figure 9 illustrates the forces acting on a cone connection, with these forces being concentrated at the center of the cone for the sake of simplifying the analysis. In the scenario

of frictional locking, the frictional moment (MR) is equal to or greater than the external torque (T). The circumferential frictional force associated with the mean cone circumference is described in Equation 5. This depiction aids in understanding the distribution of forces within the cone connection, crucial for evaluating its mechanical behaviour and performance in endoprosthetic systems.

$$F_{Rt} = F_R = F_N \times \mu \rightarrow M_R = F_R \times \frac{D_{mF}}{2} = F_N \times \mu \times \frac{D_{mF}}{2} \geq T \qquad \text{(Equation 5)}$$

These equations pertaining to cone-press connections are essential for calculation and product planning, yet their application necessitates a complex modification due to the non-constant wall thickness of the outer part (cone of the head), which changes due to the spherical construction. This variability in wall thickness poses a challenge in accurately assessing the mechanical behaviour and performance of the connection, requiring careful consideration and possibly advanced modeling techniques to account for the geometric complexities involved.

9.1. Material testing

The tensile test is standardized and employed to assess the material behaviour under uniaxial stress, offering crucial parameters that can be extrapolated to other stress types. This test involves slowly and dynamically applying force until failure, during which both the force (F) and length (L) are recorded. The characteristic values obtained from this test are independent of the masses of the component being tested, providing valuable insights into the material's strength and elasticity regardless of the specific application.

Tensile force F $\leftrightarrow$ Tensile stress σ_Z

$\sigma_Z = \frac{F}{S0}$ S_0 = initial cross section

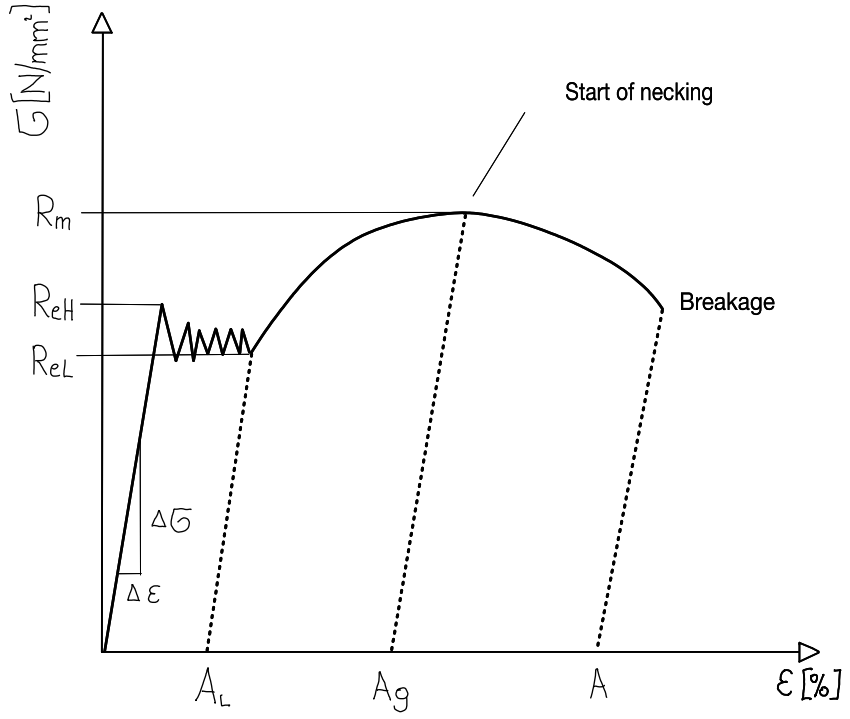
Length change ΔL $\leftrightarrow$ Strain ε

$\varepsilon = \frac{L-L0}{L}$ L_0 = Initial gauge length

The values obtained from the test procedure are documented in a stress-strain diagram (Diagram 1). In this test, the tensile machine applies linear force to elongate the tensile specimen. It is crucial for end-product applications to determine the force per unit area that a material can withstand. Therefore, the precise standardized cross-section of the tensile specimen is essential to accurately create a stress-strain diagram.

Typically, the stress-strain diagram exhibits a distinctive curve shape. Initially, the curve rises linearly, known as Hook's straight line. Subsequently, the curve transitions into a wave-like pattern, although this characteristic does not apply to all materials. This wave motion represents the flow zone, where the material experiences stress beyond its elastic limit. The tension then increases rapidly before sharply declining. Ultimately, the diagram progresses into a straight line once the specimen fractures.

Diagram 1 Stress-strain-diagram



Note: R_m = Breaking stress, R_{eH} = upper yield limit, R_{eL} = lower yield limit, E = tensile modulus, A = ultimate strain, A_g = uniform elongation, A_L = Lüders elongation

Material breakage can be categorized into deformation-free, deformation-poor, and deformation-rich, primarily dependent on the material's properties. Breakage without deformation occur in extremely brittle materials that lack plastic deformability. When the normal stress reaches the material's fracture strength, it breaks precisely perpendicular to

the axis. Low-deformation fractures occur in plastically deformable yet tough materials. In such cases, the material undergoes slight constriction before breaking again perpendicular to the axis. An angle of approximately 45° forms between the edge of the constriction and the fracture point. This behavior stems from stress deflection, which induces a multi-axial stress state in the constriction. High-deformation fractures are characteristic of ductile materials. Here, the material typically undergoes complete constriction at the center of the sample before tearing off. Regarding the fracture surface, two main types are distinguished: shear fracture and cleavage fracture. Shear fracture often arises in localized deformations under the influence of shear stress.

Cleavage fracture occurs following local separation under the influence of normal stress. The crystallographic fracture pattern can be categorized into transcrystalline fractures and intergranular fractures. In transcrystalline fractures, the crack path traverses directly through the grains, whereas in intergranular fractures, the crack path follows along the grain boundaries. Traditionally, bone screws were exclusively made of metal; however, modern advancements have led to the utilization of various materials, including titanium and titanium alloys, stainless steel, magnesium and magnesium alloys, bone, bioceramics, and polymers.

Bone screws crafted from pure titanium offer stability, corrosion resistance, and biocompatibility. Nevertheless, titanium alloys containing nickel and chromium may trigger allergic reactions. Despite their high purity, stainless steel screws are not entirely corrosion-resistant, and the release of soluble products can result in metallosis, characterized by the deposition of metal molecules causing local tissue changes.

9.1.1. Characteristic values from the stress-strain diagram

The stretch limit (Re) provides information on how much a component can be loaded before it begins to deform plastically. Up to this yield point, the stretching or deformation of the workpiece is elastic and therefore reversible. A further distinction is made between an upper stretch limit (ReH) and a lower stretch limit (ReL). The tensile strength (Rm) indicates the stress that must be applied to the material before it can be separated. Other important parameters include the elongation at break (A) and the modulus of elasticity (E).

These parameters provide insights into the material's ductility and stiffness, respectively. Elongation at break refers to the percentage increase in length of the material at the point of fracture, while the modulus of elasticity, also known as Young's modulus, represents the material's resistance to deformation under tensile or compressive loads. These parameters collectively contribute to the comprehensive characterization of the mechanical properties of a material.

9.1.2. Material technology in endoprosthetics – non-ferrous metals

Non-ferrous metals refer to all metals in the periodic table except for iron. They are widely utilized in endoprosthetics due to their high purity and biocompatibility. These metals are typically found in metal alloys where iron is not the primary element, with the proportion of pure iron not exceeding 50%. Common non-ferrous metals include copper, aluminium, zinc, bronze, brass, gold, and silver. The term is also colloquially applied, especially to zinc, bronze, and brass, which are known for their distinctive colours.

Within the category of non-ferrous metals, further distinctions are made between pure metals (such as precious, heavy, and light metals) and non-ferrous alloys (including wrought and cast alloys). The material designation of prosthesis elements often includes the chemical symbol of the base metal and the main alloying elements. For instance, Medacta company utilizes the titanium alloy Ti6Al4V (titanium with 6% aluminium and 4% vanadium) for components like the reversed metaphysis and the glenoid baseplate/glenosphere, as well as for manufactured screws (Table 2). This alloy is widely favoured not only in endoprosthetics but also in industries like automobile manufacturing and the production of valves and pumps due to its exceptional strength and corrosion resistance properties [53].

Cast alloys are metallic materials composed of at least two different alloy partners suitable for casting. Typically characterized by a predominantly heterogeneous structure formed during crystallization at the eutectic point or during post-eutectic crystallization, cast alloys differ from wrought alloys. In contrast to wrought alloys, which are typically ductile and

homogeneous, cast alloys tend to be harder and more brittle. The mechanical properties of cast alloys are primarily determined during the casting process itself.

Factors such as solidification conditions — such as wall thickness and temperature — significantly influence the crystallization process, thereby shaping the final properties of the material. This inherent heterogeneity and the influence of solidification conditions distinguish cast alloys from their wrought counterparts.

Table 2 Materials of the Medacta Shoulder System, Switzerland (www.medacta.com)

	Material			
	Shaft	**Humeral**	**Glenoid/Glenosphere**	**Screws**
Anatomic	Cementless/Cemented Ti-Plasma spray + HA	Head CoCrMo ISO 5832-12	Highly cross-linked PE	
Reverse	Cementless/Cemented Ti-Plasma spray + HA	Reversed Metaphysis Ti6Al4V ISO 5832-3	Pegged glenoid Baseplate Ti6Al4V - ISO 5832-3 with HA	Screw Ti6Al4V - ISO 5832-3 (ASTM F136)
		Reverse HC Liner Highly cross-linked PE	Glenoid baseplate Ti6Al4V - ISO 5832-3	Locking Screw CoCrMo - ISO 5832-12
			Glenosphere CoCrMo - ISO 5832-12 (ASTM F1537)	Non-locking Screw Ti6Al4V - ISO 5832-3

9.2. Materials and Companies

Shoulder joint prostheses are classified as medical devices in the highest risk class (class 3). These devices undergo rigorous development programs involving numerous clinical studies. If the risk-benefit profile is deemed appropriate, the product receives certification from a notified body and may then be used for medical purposes. Continuous evaluation of the benefit-risk profile is conducted as part of medical device vigilance, overseen by authorities such as the Federal Office for Safety in Health Care (BASG) in Austria.

The implementation of the new EU Medical Devices Regulation 2017/745 (MDR) on May 26, 2021, replaced the previous Medical Devices Directive 93/42/EEC and the Active Implantable Medical Devices Directive 90/385/EEC. The MDR introduces various enhancements and innovations compared to the previous legal framework, along with an expanded scope of application. Key features include a safety-focused approach throughout the product lifecycle based on clinical data, a system for product identification and traceability, heightened requirements for Notified Bodies, and an expanded European database for medical devices.

Today, more than 40 companies manufacture and sell shoulder prostheses for human implantation, as indicated in Table 3.

Table 3 Worldwide producing and selling companies of humeral and glenoid components for implantation of a shoulder prosthesis

System	Company
Trauma Shoulder System (Trauma-Schulter-System)	aaP Implants, Inc. (aap Implantate AG)
Polarus Modular Shoulder	Acumed LLC
Salzer-Tumor-Schulterendoprothesen-System/Concorde	Aesculap
Oxford Shoulder	Alphanorm
Arge Schultersystem/Finnenschulter/UPO	Arge Medizintechnik
ARGO-PULL/EPOCA	Argomedical
Univers Fraktur Prothese	Arthrex
Non- Modular Shoulder Prosthesis - NEER II	Baumer SA
Atlas-Prothese	Biomet Merck
Bi-Angular / Bi-Polar Shoulder System	Biomet Orthopedics, Inc.
BioPro Shoulder System	BioPro
URSA Shoulder System	Biotek
Anatomical Shoulder System	Centerpulse Orthopedics Inc (PurchasedZimmer)
Oxford Shoulder	Corin Group PLC
NGR (New Generation Replacement)-Prothese	Cremascoli Ortho GmbH
Delta-I-Reverse Shoulder Prosthesis	DePuy
Delta III/Xtend RSA/Global advantage CTA	Depuy Orthopaedics
Foundation® 4-Part Fracture System/RSA	Encore Medical
BUECHEL-PAPPAS™ Humeral Stems	Endotec, Inc.
Total Shoulder System/Modular	ESKA Implants GmbH & Co.
Equinoxe Reverse Shoulder/TSA	Exactech
MRS	Gruppo Bioimpianti S.R.L.
Agilon/MUTARS	implantcast GmbH
Lobe-Lok™ System	Implants International Limited
Integrated Shoulder System	Industrias Quirúrgicas De Levante S.L.
Physio-Shoulder System	Japan Medical Materials (JMM)
Lima SMR High Modularity Shoulder System	LIMA GROUP
Endo-Model Shoulder Prosthesis Mark II	Link Orthopaedics (Waldemar Link GmbH & Co)
Affinis Total Shoulder Endoprosthesis	Mathys (Mathys AG Bettlach)
Standard modular shoulder prosthesis	Medicalex-Francemed
OTI Shoulder System	Osteoimplant Technology Inc.
Promos Modular Shoulder System	PLUS Orthopedics USA, Inc.
MMS shoulder prosthesis	Protetim
Cofield I/II, Neer II/III/Modular	Smith & Nephew
Aequalis Shoulder Prosthesis	Southmedic
Bayley-Walker Shoulder System	Stanmore Implants Worldwide Ltd
Concost-Schulter	Stryker Howmedica GmbH
Solar Total Shoulder System	Stryker Orthopaedics (Stryker Howmedica GmbH)
Anatomical Shoulder	Sulzer Orthopedics GmbH
Aequalis	Tornier GmbH
Apoil-Schulterprothese	Trois S Ortho
Modulares-Vario-Schulter-System	Tschirrren & Co. / Muri (CH)
BME (Biomechanik Eppendorf)-Prothese	Waldemar Link GmbH & Co
OLYMPIA Total Shoulder System	Wright Medical Technology, Inc
Shoulder II Total Shoulder System	Zimmer
Bigliani/Flatow The Complete Shoulder Solution	Zimmer (Zimmer Chirurgie GmbH)
Kirschner-II-C-Schulterprothese	Zimmer Chirurgie GmbH

Note: Adopted from http://faculty.washington.edu/alexbert/Shoulder/OddShoulderProstheses.htm

Shoulder prostheses are available in monoblock variants for anatomical or reversed type prostheses (such as Neer II), as well as modular designs allowing for specific adaptation during implantation and potential conversion (e.g., from anatomical to reversed type) in case of implant failure, pain, instability, periprosthetic fracture, or increasing rotator cuff lesion. While these prostheses are designed to last 10 to 15 years, revisions are often required at a mean of 3.9 years after the primary procedure [54]. In 2018, the primary reasons for revision included glenoid erosion (24%), pain (23.5%), rotator cuff insufficiency (12.2%), and instability/dislocation (11.2%). Notably, there were no reported breakages of the PyroTITAN prosthesis in 2018. This marks a significant contrast from the previous year, 2017, during which five breakages were reported, with three of them attributed to loosening.

One of the reasons for the higher risk of breakage in shoulder prostheses could be attributed to the modular setup principle commonly utilized by manufacturers. This approach aims to restore anatomical individual situations as accurately as possible. However, the disadvantage of this modularity setup lies in the transmission of force, which must pass through the junctions of the components. This increased junctional stress is associated with a higher risk of breakage, as has been extensively documented in the context of femoral revision stems [55, 56]. Another drawback associated with the modular design is the occurrence of tribocorrosion, particularly in titanium stems, to a much greater extent than in cobalt-chromium stems. Tribocorrosion refers to the combined action of mechanical wear and chemical corrosion that occurs at the articulating surfaces of the implant components. This phenomenon can lead to material degradation, increased wear rates, and potentially adverse tissue reactions, compromising the long-term performance and durability of the prosthetic implant. Therefore, while titanium may offer advantages such as biocompatibility and reduced weight, its susceptibility to tribocorrosion poses a significant challenge in modular shoulder prostheses [54].

The Ascend Flex emerged as the most frequently used prosthesis model in 2018 for humeral head and humeral stem prostheses in *primary hemi-stemmed shoulder replacement*, with a caseload exceeding 50 per year, as reported by the Australian Registry of Arthroplasty. The Affinis System emerged as the most utilized *total mid-head shoulder prosthesis*, followed by the Simpliciti System. Notably, only caseloads exceeding 50 per year are considered in this

context. Since 2008, various models have been utilized for *total resurfacing of the shoulder joint*. However, the number of procedures decreased from 12 to 9 in 2018, with only the Global/CAP being utilized.

In 2018, the most frequently used humeral stem prostheses in *primary total stemmed shoulder replacement*, with a caseload exceeding 50 per year, included Ascend Flex, SMR, Comprehensive, Global Unit, Global AP, and Equinoxe. Additionally, the leading glenoid prostheses were Global, Perform, Comprehensive, SMR L1, and Equinoxe. Furthermore, there has been a decline in the utilization of *total stemmed shoulder replacement*, decreasing from 55.9% of all total shoulder replacements in 2008 to 14.4% in 2018. An observable trend is the increase in hybrid fixation, which combines cementless humerus with cemented glenoid components.

In *primary reversed shoulder arthroplasty* in 2018, the most widely used humeral stem prostheses included SMR, Delta Xtend, Equinox, Comprehensive, RSP, Ascend Flex, Aequalis, Affinis, Trabecular Metal, and Global Unite, each with a caseload exceeding 50 per year. Glenoid models such as Delta Xtend, SMR L1, Aequalis, Comprehensive Reverse, Equinox, RSP, Affinis, and Trabecular Metal were frequently employed in Australia in 2018, each with at least 50 cases per year.

In 53.2% of cases, only the humeral component was replaced, potentially including minor components like the humeral head or glenosphere. Stemmed humeral shoulder devices, engineered to fit within the humerus canal, commonly feature coatings to promote enhanced ingrowth. These coatings often consist of surfaces composed of porous metal, hydroxyapatite, and other materials, aimed at facilitating better integration with the surrounding bone tissue.

Biomechanical studies have demonstrated that there is no significant difference in micromotion in the axial direction between cemented and initially non-cemented humeral shafts. However, when considering rotational micromotion, the cemented stem exhibits superiority over the press-fit stem. This suggests that while both types of stems may exhibit similar levels of stability in terms of axial micromotion, the cemented stem provides better

resistance to rotational forces. This finding underscores the importance of considering various modes of micromotion when evaluating the performance and stability of shoulder prostheses, particularly in relation to different fixation methods [57].

9.2.1. Quality Management

Manufacturers of medical devices are mandated to establish, document, apply, maintain, continuously update, and enhance a comprehensive quality management system (QMS). Adhering to the relevant standard EN ISO 13485 enables manufacturers to effectively implement legal requirements and other aspects of the Quality Management System. Key requirements encompassed by the standard include the concept for regulatory compliance.

1. The identification and fulfilment of Medical Devices Regulation (MDR) requirements: Compliance with the European Union's MDR.
2. Management responsibility: Clear delineation of roles and responsibilities within the organization.
3. Resource management: Efficient allocation and oversight of internal and external resources, including external processes.
4. Risk management: Systematic identification, assessment, and mitigation of risks associated with the medical devices.
5. Clinical evaluation including PMCF (Post-Market Clinical Follow-up): Ongoing assessment of product performance and safety in real-world clinical settings.
6. Product realization: Comprehensive processes encompassing product development and production.
7. Unique product information (UDI): Implementation of Unique Device Identification for traceability purposes.
8. Post-market surveillance including vigilance communication: Monitoring of product performance in the market and communication with relevant stakeholders regarding any safety issues.
9. Corrective and preventive measures: Timely implementation of actions to address non-conformities and prevent recurrence.
10. Effectiveness monitoring and measurement of results: Evaluation of the effectiveness of both the QMS and the products manufactured.

Furthermore, since February 2022, new requirements for medical implants have included the consideration of mechanical properties of the materials used, such as fracture resistance, strength, and ductility. This emphasizes the importance of ensuring that implant materials meet specified mechanical standards to ensure safety and efficacy [21]. The risk analysis process involves identifying hazards and evaluating the corresponding risks. In the context of implants, factors such as service life should be considered. Additionally, there has been an expansion in product requirements related to the mechanical properties of the materials used.

New requirements, compared to the previous guidelines outlined in the MDR directive 90/385/EEC (Medical Devices Regulation), mechanical properties such as fracture resistance, strength, and elongation have been incorporated. This enhancement reflects a more comprehensive approach to ensuring the safety and performance of implants by considering their mechanical characteristics in greater detail. Such an update is crucial for aligning with advancements in materials science and ensuring that implants meet rigorous quality and safety standards [21]. Via Eudamed, manufacturers are required to report "every statistically significant increase in the frequency or severity of non-serious incidents or expected undesirable side effects that could have a significant impact on the risk-benefit analysis and could lead to risks for lead or could lead to the health or safety of patients, users or other persons which are unacceptable in view of the intended benefit" (Art. 88, MDR).

The German implant register is currently in the development phase and is expected to commence regular operations on January 1, 2023. Various stakeholders, including healthcare facilities, affected patients, statutory and private health insurance companies, and implant manufacturers, are mandated to participate in this initiative. This registry aims to enhance post-market surveillance and improve patient safety by systematically monitoring the performance and safety of implants, facilitating early detection of adverse events, and ensuring timely interventions when necessary [58].

10. Indication for shoulder arthroplasty

The decision regarding the appropriateness of shoulder prosthesis implantation therapy for a patient depends on several factors. Primarily, indications for this procedure encompass conditions such as osteoarthritis, rotator cuff injuries, bone fractures, rheumatoid arthritis, and other inflammatory changes, as well as osteonecrosis [59, 60], Table 4 provides a comprehensive overview of indications for both anatomical hemi- and total shoulder prostheses. These indications are evaluated in conjunction with the patient's medical history, physical condition, lifestyle, and treatment goals to determine the most suitable course of action for shoulder joint restoration. Additionally, factors such as age, activity level, and overall health status are taken into consideration during the decision-making process.

Table 4 Indications for hemi-, total anatomic-, and total reversed shoulder arthroplasty (SA)

Hemiarthroplasty	Osteonecrosis with a preserved glenoid Proximal humeral fracture Cuff tear arthropathy Inflammatory arthropathy (rheumatoid) if - Massive cuff tear - Insufficient glenoid bone stock
Total anatomic shoulder arthroplasty	Primary osteoarthritis Post-traumatic osteoarthritis Inflammatory arthropathies Osteonecrosis with an affected glenoid
Total reversed shoulder arthroplasty	Primary osteoarthritis with RM pathology Oncological diseases of the proximal Humerus Failed anatomic TSA

Note: Modified from [40, 60]

For a long time, aTSA was considered the gold standard for the treatment of high-grade arthrosis of the glenohumeral joint, since long-term analyses have described satisfaction rates of 86-95% [61, 62]. However, it could be seen in the data analysis that after aTSA, with pre-existing rotator cuff (RC) damage, the results were significantly worse and were associated with higher loosening rates of the glenoid component. As a result, such a patient is now also offered the hemi prosthesis or surface joint replacement, if medically advisable [63]. RSA offers a mechanical advantage and improved elevation in pre-existing RC lesions [64]. Modern implants now offer a survival rate of up to 90% after 10 years [16, 65].

11. Specific

11.1. The metal – bone junction

After shoulder arthroplasty, the metal bone junction plays a critical role in the implant's stability and longevity. This interface must facilitate osseointegration while minimizing stress shielding. Successful integration relies on proper implant design, surface texture, and surgical technique to promote bone ingrowth and mitigate implant loosening. Additionally, the metal bone junction must withstand biomechanical forces to ensure functional restoration and prevent complications such as implant migration or fracture.

Continuous advancements in materials and surgical methods aim to enhance the durability and performance of this interface, fostering improved outcomes and patient satisfaction post-arthroplasty. The glenoid component plays a crucial role in transferring forces from the scapula to the humeral head after SA. One of the most prevalent complications in aTSA is glenoid loosening. However, it remains unclear whether component loosening is a leading factor preceding breakage.

Both cemented and non-cemented fixation options are available for the glenoid component. In designs that do not require cement augmentation, stability and osseointegration to the bone are achieved through structures known as glenoid "pegs." These pegs are also present in glenoid components designed for cementation. Interestingly, research by Stautberg et al. suggests that two pegs offer comparable stability to three [66].

11.2. Area of Implant Breakage

Commonly used materials in SA include cobalt-chromium alloys (CoCr) and titanium alloys (Ti) for the stem, while materials like CoCr, Ti, or ceramics are utilized for the head. Several studies have investigated the incidence of tribocorrosion in shoulder arthroplasty, revealing a correlation with osteolysis and aseptic loosening, especially when mixed materials are employed (e.g., CoCr head, Ti stem) [54, 67, 68].

For illustration, the comparison of calculated breakage rate per ocy (aTSA and RSA) from register and clinical studies concerning breakage location is shown (Diagram 2). The calculated fracture rate per 100,000 ocy is presented logarithmically, breakage of the “head” component was not considered graphically, because values are too low. The amount of IB in this figure is higher in clinical studies than in registries [25]. This results from the sole consideration of aTSA and RSA (the implant fractures after resurfacing, as listed in the Australian registry, were not included).

Diagram 2 Comparison of breakage rate per 100.000 ocy, data extracted from clinical trials and Australian Registry

	Breakage rate per 100.000 ocy		
	Head	**Humeral**	**Glenoid/Insert**
Clinical trials aTSA	0	9	2328
Registry aTSA	1	1	147
Clinical trials RSA	0	42	312
Registry RSA	0,32	0,43	4

Note: Breakage rate per 100.000 observed component years is shown logarithmically. aTSA = anatomical total shoulder arthroplasty; RSA = total reversed shoulder arthroplasty; ocy = observed component years; with permission from Liebhauser, M. [25] CCBY regulations.

The included clinical trials showed implant fracture of the humeral component in 9 cases and 2328 implant fractures of the glenoid/insert in aTSA. Registry data from Australia showed one fracture of the humeral head, one fracture of the humeral component and 147 implant fractures of the glenoid/insert in aTSA over an observation period of 22 years. In comparison, 42 fractures of the humeral components and 312 fractures of the glenoid/insert were found in RSA in clinical studies. Registry data from Australia documented 4 glenoid/insert fractures over a 22-year observation period.

11.2.1. Glenoid/Baseplate

Implant breakage of the glenoid component can occur on the pegs or keels, baseplate, or screws. Keeled glenosphere baseplates are more difficult to fix to the prepared bone than pegged designs [69, 70]. Surface irregularities, fractures, rim erosions and central wear on PE within the aTSA system can be observed after 2.5 years [71]. PE abrasions stimulate an increase in the local macrophage activity. Due to the formation of a membrane, it further leads to a resorption of the trabecular bone and the bone-cement interface, resulting in loosening of the components [72, 73]. Loosening of the glenoid through snatching and the subsequent breakage of the implant can often be demonstrated in the case of brittle bones or pronounced osteoporosis [24, 74]. It can be further observed if direct contact with the bony glenoid is insufficiently prepared or the glenoid component has been poorly positioned [75] or, if there is a superior bone defect of more than 50 percent [76].

Pure tissue ingrowth glenoid components were already described in the 2000s with high revision rates of up to 12.5%. This has also been appreciated in connection with metal-poly loosening and subsequent screw breakage [71]. At the beginning of the 21st century, metal-backed glenoids (MPG) showed a higher rate of loosening than all-PE components [77, 78]. A direct association with material breakage has not been described. Nevertheless, it can be assumed, because IB with component loosening was described in several articles [24, 71, 74].

A recent review by Kim et al (2020), however, showed that newer and modern MPGs performed significantly better in terms of loosening, ROM, and clinical scores compared to the conventional older designs [79]. The review by Ravi et. al. (2021), confirms that glenoid (401 out of 3,041; 16%) and baseplate failure (83 out of 3,041; 3%) occur more frequently than pain and stiffness (62 out of 3,041; 2%) [80].

In the annual registry of Australia 2018 [20] the cumulative incidence revision diagnosis of primary total stemmed shoulder replacement shows a higher rate of implant breakage as infection for a reason to revision. In principle, the humeral head size is very variable and is primarily influenced and changed over time by arthritic changes. Due to the large range of motion of the shoulder joint, stability is an insecurity factor that is most likely to cause dislocations. The aim is the most anatomical imitation possible in order to maintain the range

of motion and the tendon tensile forces. Overstuffing leads to increased stress on the SSP tendon and is subsequently associated with a reduction in strength, restricted movement and an increased risk of tendon tearing.

The humeral head size is mostly available in three different measures: < 44mm, 44-50mm and > 50mm. The nonarthrotic humeral head has an average diameter of 46.2mm (range, 37.1 to 56.9) [81, 82]. In Diagram 3 can be seen three different diagrams, each presents the most common reason for revision in correlation to the timeline. The head size 44 – 50mm shows even a higher incidence of revision after breakage of the glenoid insert than infection. In contrast, with sizes < 44mm and > 50mm, infection is a more common reason for revision surgery. Accordingly, the head size plays a significant role in total stemmed shoulder prosthesis with regard to implant fractures.

11.2.2. Glenosphere

In a retrospective study of 479 RSA, Middernacht et al. [23] described the frequency of signs of loosening in the glenosphere after an observation period of at least 12 months (range 12–72 months). A disengagement of the glenosphere was demonstrated in 16 cases (3.2%), an additional break of the central screw in 3 cases, after 24 months (range 12–48 months). Due to the noticeably poorer clinical outcome, with an average Constant Murley Score of 46 (range 26–61), compared to 62 (range 45–81) for disengagement without IB, an absolute indication for revision surgery was described [23].

11.2.3. Cage Screw

The screw connection that is used for primary stabilization of the glenoid, breaks in the event of loosening, as can occur by notching after RSA [83-85]. In a study of 324 patients, Roche et al. presented that notching showed a significantly poorer initial stability of the baseplate, ROM and clinical scores after a minimum follow-up of 5 years [24].

11.2.4. Humeral Component

According to the Australian registry, IB in the humeral component are the least common (Table 6). Over a period of 6 years, only 13 cases were reported (2.14% of ALL described implant fractures during this period) [13]. The study group by Cil et al. (2010) concur with the results, although the survival rate of the humeral components, after an observation period of 20 years, was calculated by the Kaplan Maier curve and resulted to be 83%. Of the 1.584 examined SAs, only 0.2% showed a breakage of the humeral component, and underwent revision surgery [86]. The literature describes a clear connection between a radiologically confirmed implant loosening and an infection with Cutibacterium acnes, 2-3 years after the primary surgery [87].

According to Middernacht et al. [23], loosening of the stem is also associated with an increased risk of breakage, but no connection between periprosthetic joint infection (PJI) and IB could been seen in the literature so far. Threaded screws in orthopaedic surgery are common in use for multiple procedures. They are the main instrument to receive a stable connection between `bone and bone` or `bone and implant`. To enhance the primary stability, bone cement - Polymethylmethacrylate (PMMA) - can be used, before the second stability is available by bone ingrowth. The modern cementing technique was introduced by Sir John Charnley in the late 1950s in his laboratories who might be the founder of modern artificial joint replacement [88].

There has to be distinguished between primary and secondary stability of the glenoid.
Primary stability of the base plate can be achieved by screwing or a keeled, single/double pegged construction. Screws are in use with a locking or non-locking mechanism and offer the possibility for additionally fixation of the baseplate. There is no scientific evidence for a main difference concerning stability or fixation between these varieties. Baseplates with a central screw may have a better primary stability than pegged or keeled ones [43], if a peg is used, it should be conical and coated with hydroxyapatite for initial stability [89].

The coating is essential for *secondary stability* and osseous ingrowth of the base plate. There seems to be two locking screws sufficient for fixation [90], additional screws have no added value. If the depth of the central peg anchorage is reduced, the use of four metaglene screws,

in case of less bone stock, should be used to verify adequate stability [91]. The registry of arthroplasty shows us, that hybrid fixation with cementless Glenoid has a 10 year cumulative revision rate of over 20.6% in contrast to cemented Glenoid with only a cumulative revision rate 6.9% (6.0, 7.9). If the glenoid type is modular metal backed, the cumulative revision rate after 10 years seems to be as high as 27.7% (25.5, 30.2), all Polyethylene only 7.1% (6.2, 8.1), when the SMR L2 is excluded, the cumulative revision rates are 21.6% vs. 7.1%. There cannot be seen a significant difference in revision rate between a keeled or pegged All-Polyethylen cemented Glenoid design (6.6 vs 7.2) after 10 years.

12. Materials and Methods

PubMed, MEDLINE, EMBASE, CINHAL and the Cochrane Central Register of Controlled Trials database were utilized for this systematic review using the items "(implant fracture/complication/breakage) OR (glenoid/baseplate complication/breakage) AND (shoulder arthroplasty)" according to the PRISMA guidelines (Figure 1) [92].

A reference check of original articles and reviews was done and literature research was performed by reviewing bibliographies and screening peer-reviewed orthopedic journals for relevant articles in July 2023. Studies were included in this analysis if (1) the reason for revision was stated within a text or table, (2) the time of observation was given or calculable from the data presented, (3) any kind of IB or fracture was explicitly described. The quality assessment was performed according the Cochrane standards by using the JADAD Score (Table 8).

Table 5 Quality assessment of included studies, adopted with permission from Liebhauser et al [25]

Study	JADAD scores	Randomization	Double blinding	Drop-out or withdrawals	Allocation concealment
Montoya, F. et al (2013)	0	H	H	U	H
Somerson, JS. et al (2018)	0	H	H	U	H
Cil, A. et al (2010)	0	H	H	U	H
Fucentese, SF. et al (2010)	0	H	H	U	H
Budge, MD. et al (2013)	0	H	H	U	H
Martin, SD. et al (2005)	0	H	H	U	H
Vuillermin, CB. et al (2015)	0	H	H	U	H
Boileau, P. et al (2015)	0	H	H	U	H
Styron, JF. et al (2016)	0	H	H	U	H
Kang, JR. et al (2019)	0	H	H	U	H
Somerson, JS. et al (2018)	0	H	H	U	H
Ascione, F. et al (2018)	0	H	H	U	H
Middernacht, B. et al (2008)	0	H	H	U	H
Frankle, M. et al (2005)	0	H	H	U	H
Cappellari, A. et al (2022)	0	H	H	U	H

Note: L is low risk of bias; H is high risk of bias; U is unclear risk of bias

Experimental studies, case reports, and biomechanical studies were deliberately omitted due to the diversity in the specimens or populations examined. This decision was made to ensure consistency in the data analyzed. It's important to note that registry data and clinical

studies involve different patient populations due to varying admission criteria, leading to heterogeneity in the included population, which may contribute to different findings. Larger effects are less likely to be solely attributed to biases compared to smaller effects. Clinically significant differences typically arise when there is a discrepancy of three confidence intervals, which is not evident in the current study and has been documented in previous research.

The review considered a broad classification of shoulder arthroplasty types, including anatomical, reversed, and their subtypes. All instances of implant fractures, such as those occurring in the stem, socket, head, glenoid/baseplate, glenosphere, screws, or polyethylene (PE) inlay, were incorporated into the analysis. PE inlay breakage or damage was included, although similar investigations focusing on the knee joint often exclude PE inlay damage from wear and tear mechanisms [27].

Clinical studies were included after being reviewed by two independent surgeons (ML and AD) in coherence with the senior author. Furthermore, annual reports from worldwide arthroplasty registries were searched for data containing IB after SA. Detailed information about all listed national registries of SA are summarized in Table 1.

The implant breakage per 100,000 observed component years (ocy) was calculated by assuming a linear distribution. The employed formula was introduced by the European Arthroplasty Registry in 2011. The observed rate/100 component years was equivalent to the yearly revision rate and hence expressed as percentage. The same formula has already been used for answering similar questions regarding the knee or hip joint. Obtained rates were commonly very small and therefore expressed per 100,000 component years, rather than per component itself. The research question was answered by comparing the calculated results.

Data were retrieved from the annual reports of Australia, Italy (RIAP and Emilia Romagna), Norway and Denmark [13, 17-19, 93]. Calculations were based on the incidence of revision surgeries after IB. Annual reports from England/Wales/Northern Ireland, New Zealand, Finland, Slovakia, and Canada were evaluated but no relevant data could be found [15, 19, 94-96]. Five registries and fifteen clinical studies were included in this review as outlined in the PRISMA 2020 Flow-diagram (Table 6).

Table 6 PRISMA 2020 flow diagram for new systematic reviews which included searches databases, registries and other sources; adopted with permission from Liebhauser et al [25] CCBY regulations.

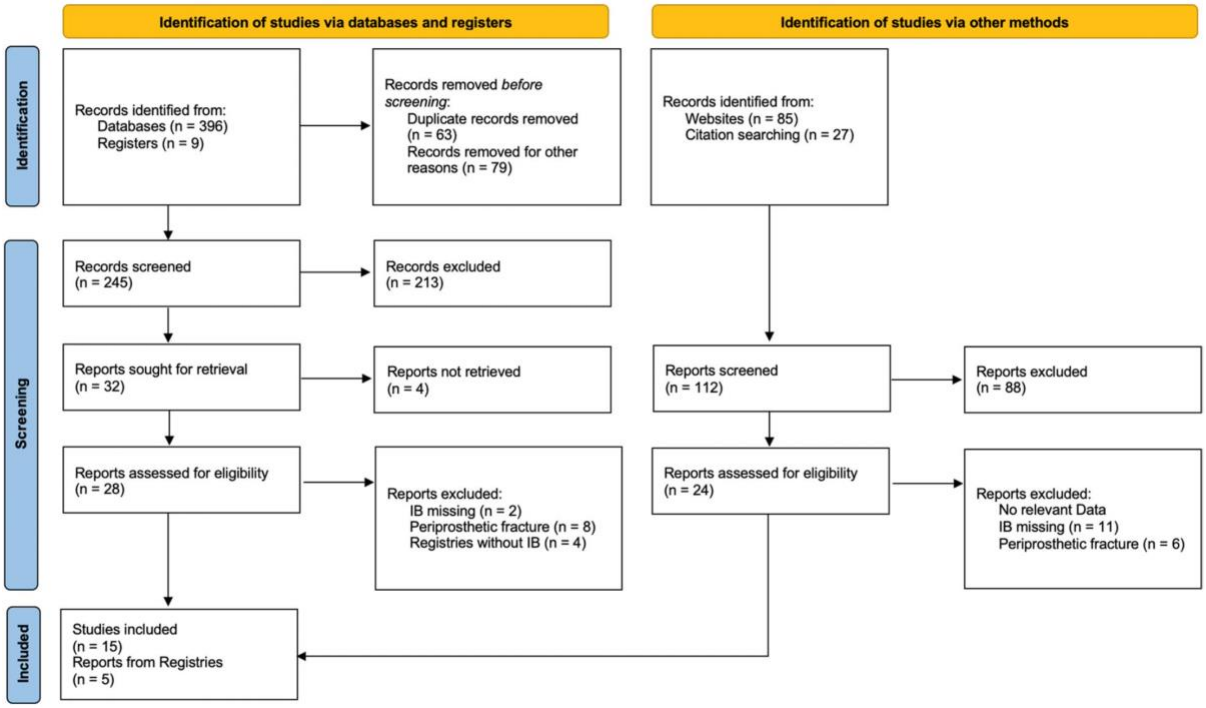


Table 7 Internet presentation of national arthroplasty registries and published articles; adopted with permission from Liebhauser et al [25] CCBY regulations.

Location	Internet site
Australia	https://aoanjrr.sahmri.com/annual-reports
Italy	https://riap.iss.it/riap/en
	http://ior.it/en/curarsi-al-rizzoli/register
UK	https://reports.njrcentre.org.uk
New Zealand	http://nzoa.org.nz
Denmark	http://dssak.ortopaedi.dk
Finland	https://thl.fi/en/web/thlfi
Norway	http://nrlweb.ihelse.net
Sweden	http://ssas.se
Netherland	https://www.lroi-report.nl
USA	http://www.aaos.org

The NZJR present the breakage rate per 100 ocy but an implant fracture in is not presented. The available data of time to revision could be very helpful, if the "implant breakage" would have been considered. In comparison, the Australian Arthroplasty register present clear and focused datasets of 'reason of revision' with sufficient numbers. The question might be asked, if the event of implant breakage in New Zealand doesn`t occur or if documentation lacks. It is evident, that more useful data would be desired concerning studies and registries that involve the timespan between surgery and revision as well as reason for

revision – if those data would be available, a meta-analysis could be performed to compare the different producing companies.

13. Calculation model

Since the registry data and studies include an observation period, but the lifespan of the implants cannot be derived from this, it was not possible to carry out a meta-analysis. Therefore, the calculation of the 'Observed Component Years per 100,000 Patient Years' was used, as in the evaluation of implant fractures in the knee and hip joint.

For the creation of a meta-analysis, the time of implantation and the time interval from primary implantation to the occurrence of implant fracture or revision surgery would be necessary for each study and for each register. In this way, it could be calculated how many implants are still fully functional after a certain observation period (e.g. 1, 2, 5, 10 years).

To calculate the fracture rate / 100,000 observed component years:
(C/(B x A x 100)) x 10.000.000

Number of years of follow up	A
Number of prosthesis implantations	B
Number of implant fractures	C

Observed Component years = patient years

A x B

14. Results

Five registries and fifteen clinical studies were included in this review as outlined in the PRISMA 2020 Flow-diagram (Figure 12). Data were retrieved from the annual reports of Australia, Italy (RIAP and Emilia Romagna), Norway and Denmark [13, 17-19, 93]. Calculations were based on the incidence of revision surgeries after IB. Annual reports from USA, England/Wales/Northern Ireland, New Zealand, Finland, Slovakia, and Canada were evaluated but no relevant data could be found [15, 19, 94-97].

14.1. Clinical Studies

Fifteen clinical studies were included and published between 2005 and 2022. Of these, nine studies involved total shoulder arthroplasty (aTSA) (Table 2) [86, 98-105] and six studies reversed shoulder arthroplasty (RSA) (Table 3) [23, 100, 106, 107]. The study design was carried out retrospectively in all cases except for one article by Budge et al. [102]. It was designed prospectively to evaluate a porous tantalum glenoid component, and performed by a single surgeon.

The overall percentage of IB after SA (TSA and RSA) in clinical studies ranged between 0.1 and 21.0 % (mean 4.1%). There is a higher incidence of IB after TSA than RSA (1.51 vs 0.3%). A total observation period of 973 months (81 years) was calculated, 682 months (56.8 years) for aTSA and 291 months (24,3 years) for RSA. Cumulative data showed a total of 730,155 ocy. Overall fracture rates per 100,000 ocy diversify between 9 and 6648 (aTSA: 9 to 6648; RSA: 17 to 3030). The mean follow-up time in aTSA was 75 months (38 to 240) and 49 months for RSA (24 to 98).

The most frequent location of IB after TSA was the glenosphere in association with screw breakage in six out of nine listed studies [98, 99, 101-103, 105]. A porus tantalum (PT) - backed glenoid showed 4 fractures out of 19 shoulders at the keel-glenoid face junction. This correlates with the highest incidence out of all studies (21%) and includes a follow-up time of 38 months (range 24-64) [108]. In RSA, the diaphyseal/epiphyseal portion of the hardware was detected in two out of four studies [106, 107]. Only one study described just a low

number of central screw breakages (0.6%) [23]. The study by Cappellari et al (2022) described zero IB out of 91 RSA within an observational period of 46 months [109].

Table 8 Overview of characteristics of included studies reporting on total shoulder arthroplasty (aTSA) with implant breakage, adopted with permission from Liebhauser et al [25]

Author (year) Reference	Type of SA	Implant Type	Follow up (months)	n (Total)	n (Breakage)	Breakage localization	Fracture rate/100.000 ocy
Montoya (2013)	aTSA	Univers cobalt-chrome metal-backed, bone-ingrowth glenoid component	64	53	5 (9,4%)	Cage screw	1769
Somerson (2018)	aTSA	na	60	1673	5 (0,3%)	na	60
Cil (2010)	aTSA	na	240	1112	2 (0,2%)	Humeral	9
Fucentese (2010)	aTSA	Sulmesh, Zimmer	50	22	3 (13,6%)	Glenoid	3273
Budge (2013)	aTSA	Porous, tantalum-backed glenoid	38	19	4 (21%)	Keel–glenoid face junction	6648
Martin (2005)	aTSA	Plasma-sprayed, screw-fixed uncemented glenoid	90	140	21 (15%)	Glenoid/ Screw	2000
Vuillermin (2015)	aTSA	Modular metal-backed glenoid component TSA (Arthrex, Naples, FL, USA)	66	51	3 (5,9%)	Metal-backed glenoid screw	1070
Boileau (2015)	aTSA	Aequalis MB glenoid prosthesis, Tornier	24	165	6 (3,6%)	Screw	1818
Styron (2016)	aTSA	Trabecular metal anchored glenoid	50	66	1 (1,5%)	na	364

Table 9 Overview of characteristics of included studies reporting on reverse shoulder arthroplasty (RSA) with implant breakage; adopted from Liebhauser et al [25]

Author (year) Reference	Type	Implant Type	Follow up (months)	n (Total)	n (Breakage)	Breakage localization	Fracture rate/100.000 ocy
Kang, JR. et al. (2019)	RSA	Comprehensive Reverse Shoulder System; Zimmer Biomet, Warsaw, IN, USA)	30	1649	9 (0,5%)	Humeral bearing fracture	218
Somerson, JS. et al. (2018)	RSA	na	60	2390	2 (0,1%)	na	17
Ascione, F. et al. (2018)	RSA	Grammont-style reverse shoulder arthroplasty	98	1035	3 (0,3%)	Diaphyseal/epiphyseal portion	35
Middernacht, B. et al. (2008)	RSA	Delta III TM (DePuy International Ltd, Leeds, UK)	24	479	3 (0,6%)	Fracture of central screw	313
Frankle, M. et al. (2005)	RSA	Lateralized centre of rotation	33	60	5 (8,3%)	Glenoid baseplate and screw breakage	3030
Cappellari, A. et al. (2022)	RSA	-	46	91	0	-	0

14.2. Arthroplasty Registries

Data from orthopedic registries that are nationally accessible and open to the public were analyzed globally to investigate the occurrence of implant breakage following shoulder arthroplasty. Specifically, implant breakage was only mentioned in registries from Australia, Italy (Emilia-Romagna and RIAP), Denmark, and Norway [13, 17, 18, 93] as shown in Table 3. According to data collected from arthroplasty registries worldwide, a total of 101,063 shoulder arthroplasties (SAs) were performed over a span of 5 to 25 years (1994 – 2021). Among these, 7,579,725 follow-up years were recorded, during which 681 cases of implant breakage (IB) were identified. Overall, IB accounted for 7.26% of all revision surgeries (0.67% of all primary SA procedures). The Emilia-Romagna Region and RIAP registry in Italy reported the lowest fracture rates among all primary SA cases (0.06% in both registries), while the highest rates were observed in Norway (0.40%) and Australia (0.88%) [25].

Table 10 Revisions due to implant breakage after shoulder arthroplasty reported by the national Arthroplasty Registry of Australia, Italy (RIAP), the Emilia-Romagna Region, Norway, and Denmark; adopted with permission from Liebhauser et al [25]

Registry	**Published**	**Data collection**	**Follow-up (years)**	**Primary total shoulder arthroplasties (*N*)**	**Primary reversed shoulder arthroplasties (N)**	**Shoulder arthroplasties TOTAL (N)**	**Revisions (*N*)**	**Implant breakage (*N*)**	**Implant breakage of all revisions (%)**	**Implant breakage of all primary SA (%)**	**Fracture rate/100.000 ocy**
Australia	2022	1999 - 2021	22	15,463	42,513	69,243	7104	608	8,56	0,88	40
Italy (RIAP)	2020	2013 - 2018	5	na	na	1793	45	1	2,22	0,06	11
Emilia-Romagna Region ITALY	2018	2008 - 2016	8	na	3683	5331	359	3	0,84	0,06	7
Norway	2020	1994 - 2019	25	na	na	9441	921	38	4,13	0,40	16
Denmark	2020	2004 - 2019	15	na	na	15,255	954	31	3,25	0,20	14
Total			75			101,063	9383	681	7,26	0,67	9

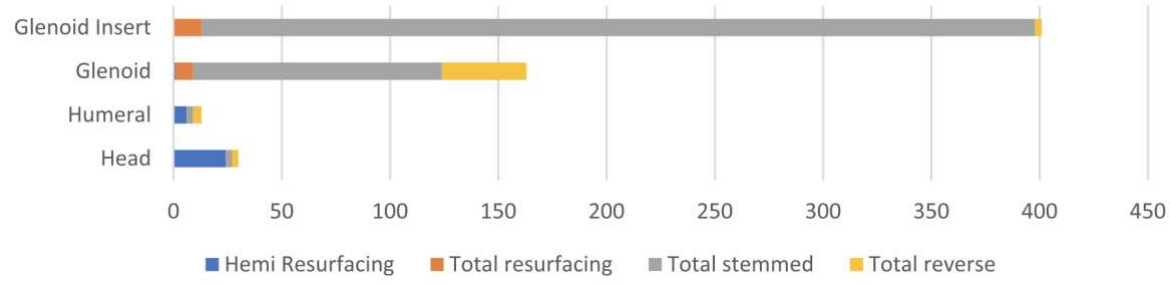
14.3. The Australian Arthroplasty Registry

The Australian registry [13] provides the most detailed information on IB. Register data could be integrated into this work from 1st of September 1999 to 31th of December 2021 (according to the 2022 annual report). A total of 608 IB of TSA, RSA and subtypes could be identified and are summarized in Table 11. Glenoid erosion and pain were the most common reasons for revision surgery (over 20% respectively), rotator cuff insufficiency, instability/dislocation and loosening exceeded 10% in each case, lysis and infection occurred in less than 5%. IB was mainly accompanied by arthrofibrosis, mispositioning, periprosthetic fracture, and incorrect sizing.

SA was divided into subtypes like hemi and total resurfacing, total stemmed, and total reversed. Subsequent delineation was made regarding the location of the IB: Head-, humeral-, glenoid- and glenoid insert component. The most frequently broken component (n=393) was the glenoid insert, followed by the glenoid component (n=146).

Table 11 Illustration of the part of the broken implant after failed shoulder arthroplasty and its frequency from 2007 until 2021 out of the Australian Arthroplasty Register (Data from Annual Report 2022), adopted with permission from Liebhauser et al [25]

	Head	Humeral	Glenoid	Glenoid Insert
Hemi Resurfacing	24	6	1	0
Total resurfacing	0	0	8	13
Total stemmed	3	3	115	385
Total reverse	3	4	39	3
	30	13	163	401



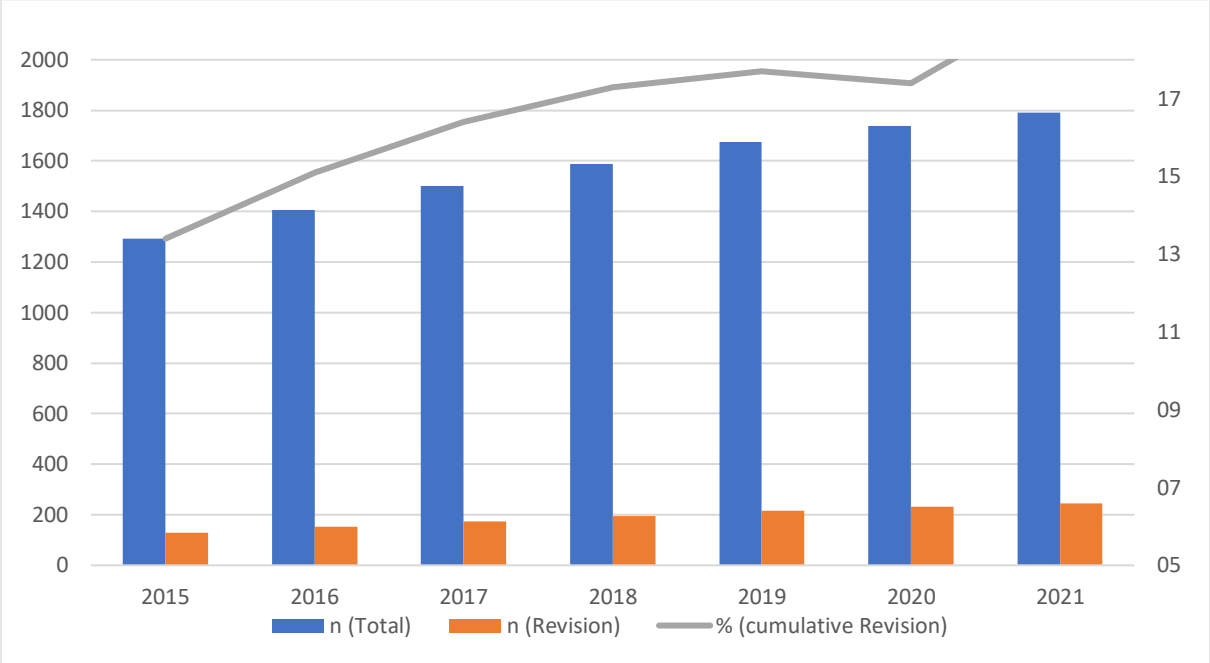
Note: Summarized listed implant breakages with an observation period from 6 years, adopted from the Australian Registry of Arthroplasty [13]

Table 12 Dataset of Implant breakage from 2015 until 2020, extracted out of the Australian Registry of Arthroplasty; adopted with permission from Liebhauser et al [25]

Year	Method	n	Delta - 1a	Revised 10a	Cumulative percent	Implant breakage			
						Head	Humeral	Glenoid	Glenoid Insert
2020	**Primary partial shoulder Replacement**	7346	**284**	754					
	Hemi resurfacing	1739	**64**	232	17.4 (15.3, 19.7)	0	0	0	0
	Primary total shoulder replacement	53815	**6896**	1942					
	Total resurfacing	235	**1**	na	na	0	0	1	3
	Total stemmed	14872	**641**	640	12.0 (10.9, 13.1)	0	0	7	5
	Total reverse	35980	**5650**	1238	6.2 (5.7, 6.8)	0	2	7	1
2019	**Primary partial shoulder Replacement**	7062	**272**	711					
	Hemi resurfacing	1675	**87**	217	17.7 (15.5, 20.2)	9	2	1	0
	Primary total shoulder replacement	46919	**6789**	2371					
	Total resurfacing	234	**4**	20	>7,2	0	0	1	3
	Total stemmed	14232	**785**	1182	10.0 (9.2, 10.8)	1	1	29	82
	Total reverse	30330	**5471**	1111	6.4 (5.8, 7.1)	1	0	8	1
2018	**Primary partial shoulder Replacement**	6790	**286**	658					
	Hemi resurfacing	1588	**88**	196	17.3 (15.0, 20.0)	5	1	1	0
	Primary total shoulder replacement	40130	**6317**	2023					
	Total resurfacing	230	**9**	19	> 6.9	0	0	1	3
	Total stemmed	13446	**911**	1055	12.4 (11.5, 13.3)	1	1	28	77
	Total reverse	24859	**4930**	906	6.6 (5.9, 7.4)	1	0	5	0
2017	**Primary partial shoulder Replacement**	6504	**313**	597					
	Hemi resurfacing	1500	**95**	174	16.4 (14.1, 19.2)	5	1	0	0
	Primary total shoulder replacement	33813	**5620**	1709					
	Total resurfacing	221	**10**	16	> 7	0	0	1	2
	Total stemmed	12535	**1067**	930	12.6 (11.5, 13.8)	1	1	25	69
	Total reverse	19929	**4148**	737	7.0 (6.1, 7.9)	1	0	5	0
2016	**Primary partial shoulder Replacement**	6191	**379**						
	Hemi resurfacing	1405	**113**	152	> 15.1	3	1	0	0
	Primary total shoulder replacement	28193	**4941**	1410					
	Total resurfacing	211	**13**	15	>6.9	0	0	1	2
	Total stemmed	11468	**1238**	802	12.6 (11.0, 14,3)	0	0	0	88
	Total reverse	15781	**3419**	582	> 7	0	0	0	0
2015	**Primary partial shoulder Replacement**	5812	**396**	450					
	Hemi resurfacing	1292	**75**	128	> 13.4	2	1	0	0
	Primary total shoulder replacement	23252	**4193**	1122					
	Total resurfacing	198	**17**	11	> 7.3	0	0	3	0
	Total stemmed	10230	**1324**	667	> 11.2	0	0	19	57
	Total reverse	12362	**2680**	439	> 6.5	0	0	4	1

Diagram 3 illustrates the development of the number of operations involving the implantation of a sole surface replacement of the humeral head in Australia from 2015 to 2021. The number of revisions carried out increases in line with the progression of the implantation. Patients who were initially treated with a resurfacing procedure can subsequently be offered the entire range of shoulder prosthetics, including transitioning to an anatomical hemi- or total prosthesis, as well as a Reverse Shoulder Arthroplasty (RSA). This decision should be made in consideration of the current shoulder pathology, as well as the patient's demands and health conditions. The decreasing cumulative percentage in the chart can be attributed to a lower percentage growth (17.4%) from 2019 to 2020 compared to previous years.

Diagram 3 Primary partial shoulder Replacement – Hemi Resurfacing 2015 – 2021

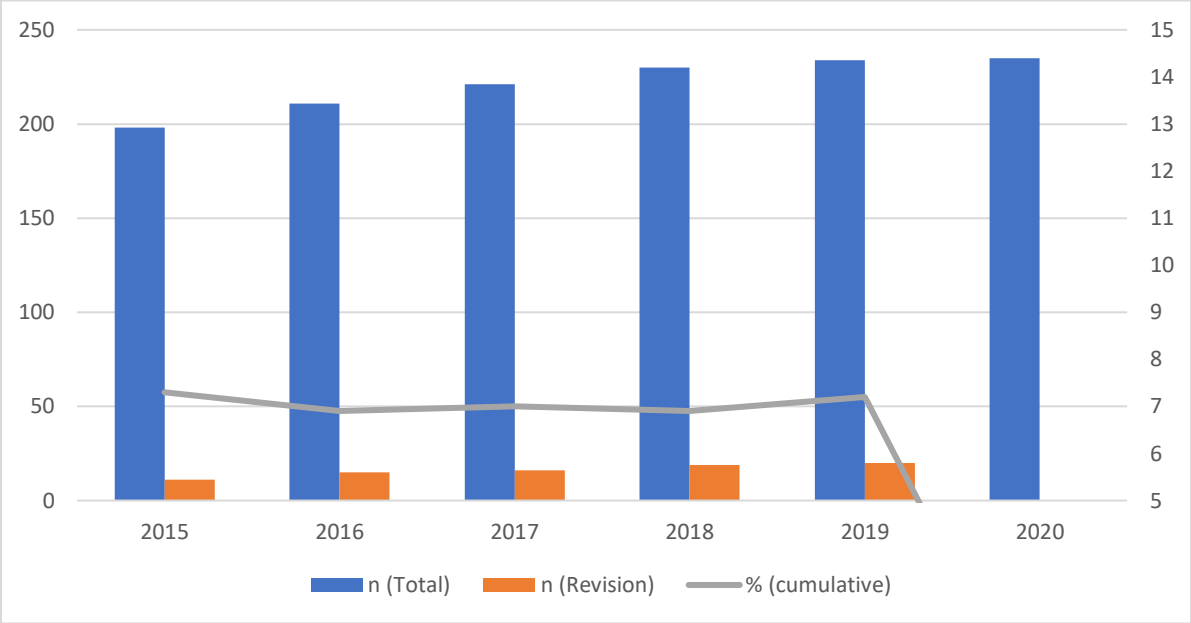


Primary Partial Shoulder Replacement - Hemi Resurfacing

	n (Total)	n (Revision)	% (cumulative Revision)
2015	1292	128	13,4
2016	1405	152	15,1
2017	1500	174	16,4
2018	1588	196	17,3
2019	1675	217	17,7
2020	1739	232	17,4
2021	1790	244	19,6

Diagram 4 show the Australian registry data associated with total shoulder resurfacing implantation from 2015 to 2020. Compared to hemi resurfacing numbers, there were significantly fewer procedures over the period. The cumulative figures show a generally negative trend, revision figures and percentage cumulative information are missing in the last annual report from 2021. In the annual report from 2022, the total resurfacing was already removed from the register and no longer examined. This is probably related to the declining number of implantations.

Diagram 4 Primary total shoulder replacement – Total resurfacing 2015 to 2020



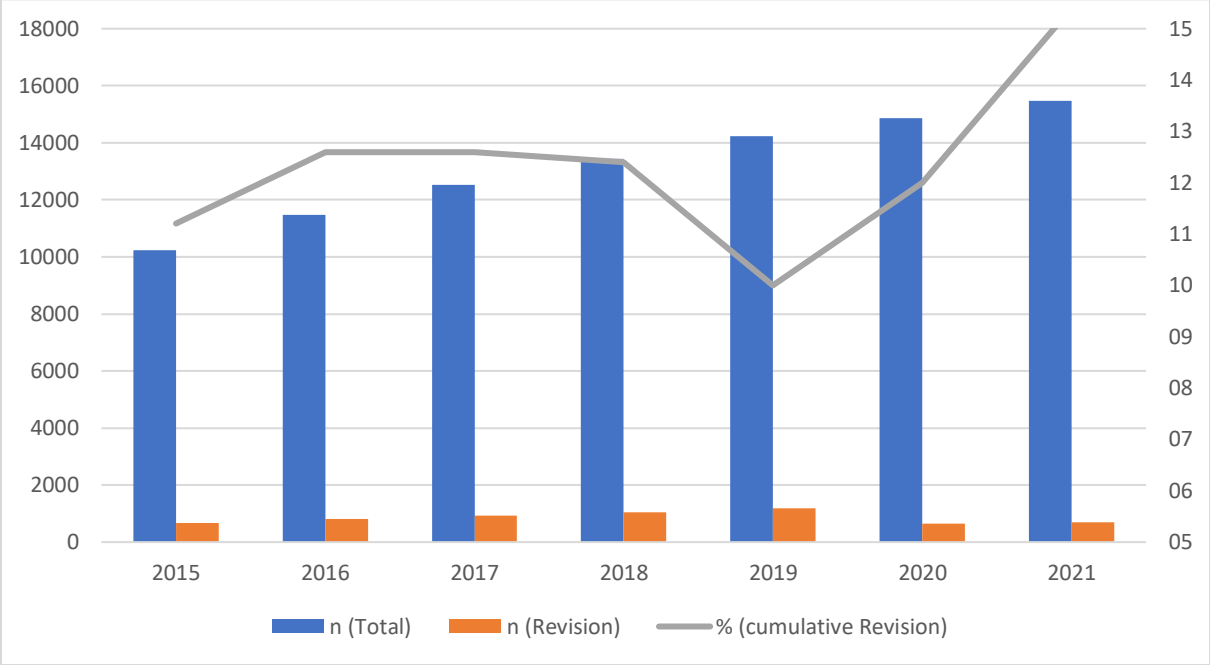
Note: Data retrieved from Australian Arthroplasty Registry 2016 – 2021

Primary Total Shoulder Replacement - Total Resurfacing

	n (Total)	n (Revision)	% (cumulative)
2015	198	11	7,3
2016	211	15	6,9
2017	221	16	7,0
2018	230	19	6,9
2019	234	20	7,2
2020	235	na	na

Significantly higher numbers of total stemmed SA implantations can be seen in Diagram 5. In comparison to resurfacing with n = 235, 15463 TSA prostheses were installed in the same period. Similar to total resurfacing or RSA, the cumulative revision numbers have been declining slightly over the years, but are increasing again from 2020 onwards.

Diagram 5 Primary total shoulder replacement – Total stemmed 2015 to 2021

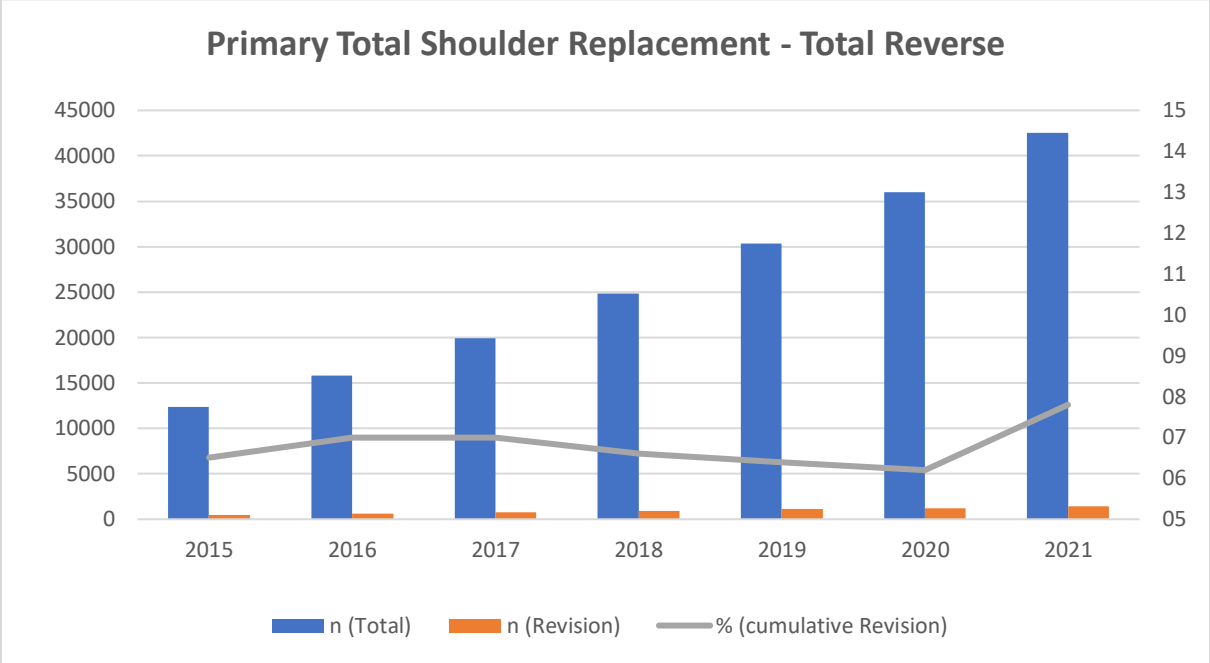


Primary Total Shoulder Replacement - Total Stemmed

	n (Total)	n (Revision)	% (cumulative Revision)
2015	10230	667	11,2
2016	11468	802	12,6
2017	12535	930	12,6
2018	13446	1055	12,4
2019	14232	1182	10,0
2020	14872	640	12,0
2021	15463	698	15,4

In shoulder prosthetics, RSA is not only showing a clear upward trend in the registry data from Australia, as can be seen in Diagram 6 from 2015 to 2021. Accordingly, the number of revisions is also increasing, but as the cumulative revision rate shows, it has fallen again over the years.

Diagram 6 Primary total shoulder replacement – Total reverse 2015 to 2021

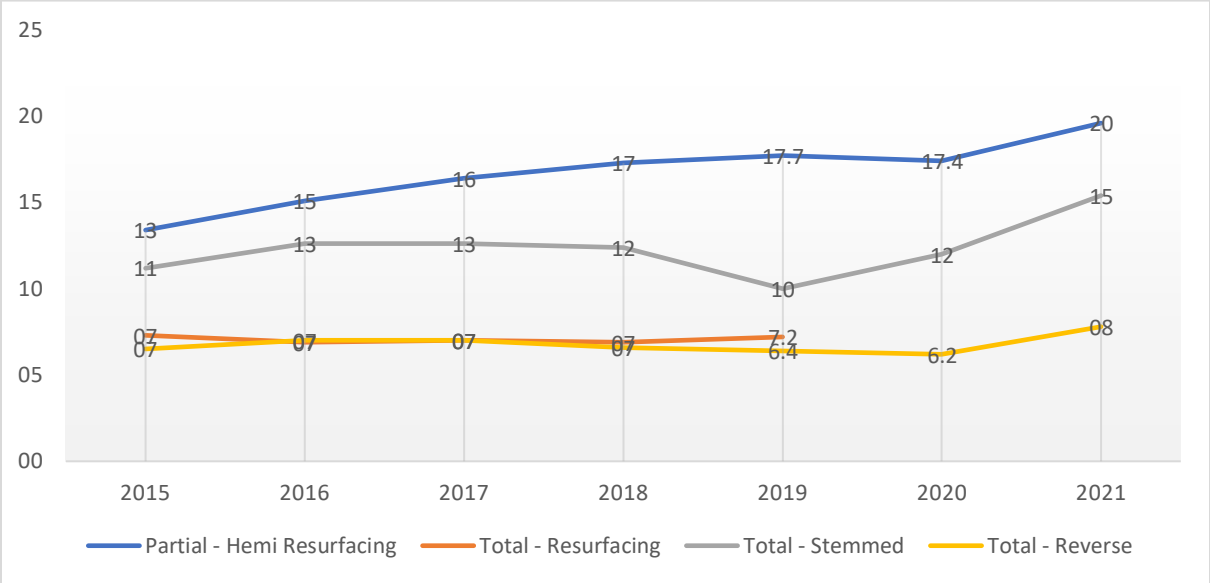


Primary Total Shoulder Replacement - Total Reverse

	n (Total)	n (Revision)	% (cumulative Revision)
2015	12362	439	6,5
2016	15781	582	7,0
2017	19929	737	7,0
2018	24859	906	6,6
2019	30330	1111	6,4
2020	35980	1238	6,2
2021	42513	1456	7,8

The cumulative percentage of implant failures and subsequent revision surgery is reported to be highest for hemi resurfacing in the Australian Prosthesis Registry. This is due to the frequency of the surgical methodology used. As of 2020, according to registry data, 1739 hemi resurfacing procedures had been performed in Australia, compared to 235 total resurfacing, 14872 total stemmed and 35980 total reversed type (Diagram 7).

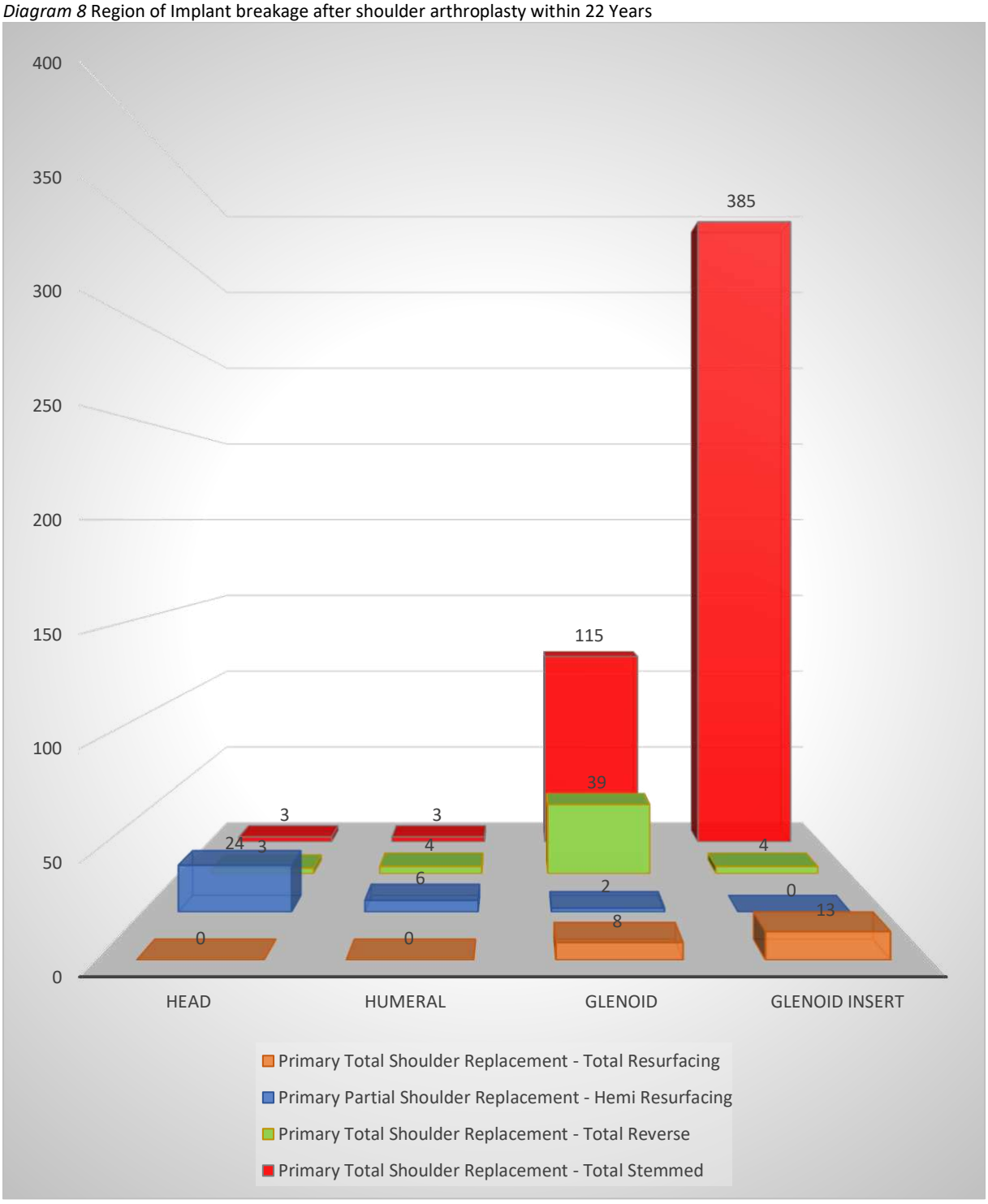
Diagram 7 Cumulative percentage of revision surgeries of all reasons minimum 10 years after primary shoulder arthroplasty until 2021



	Partial - Hemi Resurfacing	Total - Resurfacing	Total - Stemmed	Total - Reverse
2015	13,4	7,3	11,2	6,5
2016	15,1	6,9	12,6	7,0
2017	16,4	7,0	12,6	7,0
2018	17,3	6,9	12,4	6,6
2019	17,7	7,2	10	6,4
2020	17,4	na	12	6,2
2021	19,6	na	15,4	7,8

Diagram 8 shows the distribution of breakage region that can be separated into the head, the humeral, the glenoid and glenoid insert component independently of the company. The most evident component of failure is the glenoid insert with 378 breakages, followed by the glenoid with 108 documented cases within a timeframe of five years after implantation of a total stemmed shoulder prosthesis.

Diagram 8 Region of Implant breakage after shoulder arthroplasty within 22 Years



Note: Data retrieved from Australian Arthroplasty Registry 1999 – 2021

15. Comparative Analysis

The comparative analysis was already published by Liebhauser and colleagues in 2023 [25] with CCBY regulations: Registries and clinical trials include different populations as registries are not affected by the eligibility criteria issues in contrast to clinical studies. Data of clinical trials are less generalizable compared to registry data. Overall, there is population heterogeneity and differences could be solely attributed to that. In analysis of arthroplasty registers clinically relevant and substantial differences are evident, if the confidence interval was exceeded three times, which was already established in previous investigations by Sadoghi and Hauer [26, 110]. If the proposed margin of three confidence intervals was not exceeded, our conclusion does not show a difference with respect to follow up (FU) and IB. Cumulative data for IB of registries and studies are presented in Tables 5 and 6.

The total number of observed implants is eleven times higher in registries compared to clinical studies. In national registries, 681 IBs out of 101,063 SAs were observed with a breakage rate per 100,000 implants of 674. In contrast, clinical studies showed 72 IBs out of 9,005 SAs with a breakage rate per 100,000 implants of 800. The ocy in registries was 10 times higher than in clinical studies.

Table 13 Overview of the breakage incidence in clinical studies in primary total shoulder arthroplasty (TSA) and reversed shoulder arthroplasty (RSA)

	Primary TSA [86, 98-105]	**Primary RSA [23, 100, 106, 107]**	**Total**
Number of shoulder arthroplasties	3301	5704	9005
Number of breakages	50	22	72
Implant breakage (%)	1,5	0,4	0,8
Observed component years	187.607	138.332	325.939
Fracture rate/100.000 ocy	27	16	10

Note: aTSA= Total shoulder arthroplasty; RSA= Reversed shoulder arthroplasty; ocy= observed component years, adopted with permission from Liebhauser et al [25] CCBY regulations.

Table 14 Data on implant breakages after shoulder arthroplasty from National Arthroplasty registries and clinical studies in comparison; adopted with permission from Liebhauser et al [25] CCBY regulations.

Dataset	**Implants (n)**	**Revisions (n)**	**Documented implant breakage (n)**	**Fracture rate per 100,000 implants**	**Observed component years**	**Fracture rate per 100,000 observed component years**
Clinical studies aTSA	3.301	na	50	1.515	187.596	27
Clinical studies RSA	5.704	na	22	386	138.322	16
Clinical Studies TOTAL	**9.005**	**na**	**72**	**800**	**730.155**	**10**
Registries	**101.063**	**9.383**	**681**	**674**	**7.579.725**	**9**

na not available

16. Discussion

Implant breakage following shoulder prosthesis surgery is a significant concern that has been extensively studied and documented in various peer-reviewed publications. The reliability and durability of shoulder prostheses are crucial for ensuring favourable outcomes in patients undergoing these procedures. A thorough understanding of the factors contributing to implant breakage is essential for refining surgical techniques, improving implant design, and enhancing patient safety. One common theme in the literature is the identification of specific risk factors associated with implant breakage. Researchers have investigated the influence of various patient-related factors, such as age, bone quality, and pre-existing conditions like osteoporosis, on the susceptibility of implants to fractures. Additionally, the role of surgical factors, including the choice of implant material, implant design, and surgical technique, has been a key focus in numerous studies.

The main objective of this study was to evaluate the occurrence of implant breakage (IB) following shoulder arthroplasty (SA). Although implant fractures are often linked to aseptic or septic loosening, our analysis did not definitively establish such a correlation based on the data gathered from the reviewed studies and registries. Our investigation primarily aimed to compare the frequency of IB in clinical studies with data from national registry databases.

Our findings revealed a striking similarity in the incidence rates of IB between clinical studies and national registries. Specifically, the breakage rate per 100,000 observed implants was 674 in various national registries, closely paralleling the rate of 800 observed in clinical studies. Notably, the data analyzed originated from national registries of Australia, Italy, Denmark, and Norway, with a significant portion derived from the Australian registry, which played a pivotal role in shaping our calculated results. The Australian Joint Registry [13] is updated every autumn and provides cumulative data on hip, knee, and shoulder arthroplasties dating back to 1999. In this registry, 68% of all primary shoulder arthroplasties (SAs) and 88% of the included implant breakages (IBs) are documented. Notably, revision surgeries were more frequently observed in patients with a pre-obese metabolic status, accounting for 32.7% of cases (BMI: 25-29.9). This same group also presented the highest number of primary shoulder arthroplasties, constituting 35.8% of the total cases. However, Singh et al. [12], reported a contrasting perspective, stating that there is no correlation between an increased BMI (mean

30, SD 6) or other pre-existing illnesses and an elevated ASA score. In contrast, pathologies of the rotator cuff and a history of previous tumors emerge as the primary factors responsible for the need for revision surgery, with a hazard/risk over three times higher than that for rheumatoid arthritis [111].

It is important to acknowledge variations in the observation period, the number of shoulder prostheses, and the percentage of implant breakage across different studies and registers. Despite these differences, the utilization of a standardized calculation method, such as implant breakage per 100,000 observed component years, emerged as a valuable tool for comparing diverse datasets. This method facilitated a clear and comprehensible comparison, demonstrating remarkably consistent results across various datasets.

Two studies need to be discussed in detail due to differences in the investigated hardware tools. First, Cil et al. [86] presented a low rate of IB (0.2%) (rate/100,000 ocy = 9) for TSA, but only the survivorship of the humeral component was observed (implant type was not reported). Second, the prospectively designed study by Budge et al. [102] showed the highest number of fractures, 21% (rate/100,000 ocy = 6648) by using a monoblock porous tantalum glenoid. After receiving the report of the published results, the manufacturing company revised the implants due to the observed high risk of prothesis failure.

Except three clinical studies for TSA and RSA, all others stated the manufacturing company of the implanted prosthesis. The *Delta Reverse Shoulder System* with its three consecutive versions, was the most used and longest available product for SA. It can be assumed that this is the reason why literature reports the highest rate of complications for this specific prosthetic type. Later, similar complications occurred by using implants from other companies [84].

The type of primary implanted prosthesis depends on several factors, including the biomechanical function of the rotator cuff, the age of the patient, and the extent of the damage to the joint surface [84]. The main distinction in SA is partial or total surface replacement, partial or total anatomical SA or inverse SA, whereby the anatomy of the joint is changed by lateralization and caudalization of the pivot point and the vector forces. Pure bone-saving prosthesis must be separated from the stem-anchoring cap prosthesis or the

inverse shoulder prosthesis. The affected broken components, could be divided according to aTSA and RSA, but only in the Australian arthroplasty registry (Table 6).

The use of individual components, to assemble a shoulder prosthesis before implantation, has its advantages and disadvantages. The higher the number of used components, the easier the individual adjustments and, if necessary, the possibility for switching from hemi prosthesis to TSA or even to RSA is given. A monoblock prosthesis does not offer this option, but it reduces the likelihood of humeral sided complications, like dissociation and component breakage due to a reduced torque stress [112, 113].

In a study by Levy et al. [113], 137 patients who underwent RSA, were retrospectively examined. The minimum follow-up time was 2 years. The study only included patients who were treated with a 2nd generation, lateral-center-of-rotation monoblock RSA. It resulted in an improved range of motion (ROM), a better general health outcome and all PROMs (Simple Shoulder Test, ASES Total, VAS for pain, etc.) were achieved by comparing to preoperative data. Only the internal rotation could not be improved. Instability, loosening, or material fractures were not described. In addition, there was no difference between the outcome of the cemented versus the press-fit technique. A reason for that finding could be, that the two groups (press-fit and cemented) were likely underpowered (116 vs. 21 patients).

The expert opinion regarding additional cementation between the bone and glenoid component varies. On the one hand, the additional introduced cement can increase the stability and quality between the components and the bone by filling the trabecular structure; on the other, incorrect cementation with interposition between the back of the component and the bone surface is seen as a risk for implant loosening, fracture and material fatigue [114-116].

Another way to reduce the likelihood of IB or loosening is the "ream and run" technique, which has been described by several authors [117-119]: The humeral component with its artificial head part articulates directly with the glenoid, which is only reamed to achieve a stabilizing concavity to create a maximum glenohumeral contact surface. No intermediate material is implanted. Therefore, no loosening (rocking horse effect) or IB can occur. Several animal studies showed that adequate postoperative exercise leads to a regeneration of the glenoid cartilage. One of the observed procedural disadvantages is, that it is only applicable to

selected patients with osteoarthritis, capsulorrhaphy arthropathy and post-traumatic arthritis [117].

In contrast to the high rate of glenoid insert and glenoid failure after a total stemmed shoulder arthroplasty (Figure 9), the cumulative percentage is higher for the partial hemi resurfacing procedure (Figure 8). The reason can be explained by the low amount of hemi resurfacing procedures in contrast to the high number of total stemmed procedures.

To highlight the incidence of glenosphere disengagement and clinical outcome, Middernacht et al. [23] presented their results in a series of 479 RSAs (468 Delta III and 11 Aequalis) with a minimum observatory time of 12 months. Three percent of RSAs showed a disengagement of the glenosphere (16 of 479). The author described the breakage of the central screw in three cases dur to complete disengagement (Delta III). Partial disengagement was seen in 45.4% of the Aequalis and in 1.7% of the 468 Delta prosthesis. Scarlat et al. [84] identified several complications after RSA after reviewing 240 papers in the timeframe from 1996 to 2012. He described complication rates varying from 10 to 65% in long term series. A direct correlation between loosening/disengagement and the breakage of the screw fixation of the glenosphere in RSA has been reported several times in the literature [26, 27, 84, 120].

In comparison to data after knee arthroplasty, it was found, that clinical studies showed an incidence of IB at least twice as high as registry data (Fracture rate/100,000 Implants: 285 versus 129) [27]. The incidence of IB after hip arthroplasty is 304/100,000 Implants in registries. The most affected component is the cup, whereas in clinical studies it is the stem [26].

Moreover, extensive research has focused on the material properties of implants. Various materials like titanium alloys, cobalt-chromium alloys, and polyethylene components have undergone scrutiny regarding their mechanical strength, resistance to fatigue, and susceptibility to wear. Materials in Medicine has served as a prominent platform for investigating the mechanical properties of implant materials and their implications for breakage risk. Biomechanical factors influencing implant breakage have been examined through studies utilizing advanced modeling techniques. Finite element analysis has been utilized to simulate stress distribution within implants, offering insights into how different loading conditions may contribute to breakage. These modeling studies, often published in

journals like Medical Engineering & Physics, have advanced our comprehension of the intricate biomechanics governing implant stability.

Clinical registries have been instrumental in providing real-world data on incidents of implant breakage. Large-scale studies, as documented in The Journal of Bone & Joint Surgery, have leveraged registry data to identify trends, prevalence rates, and common failure modes. Such studies have significantly contributed to the evidence base informing clinical decision-making and implant selection.

Addressing implant breakage necessitates a multidisciplinary approach involving orthopedic surgeons, materials scientists, biomechanical engineers, and other healthcare professionals. Collaborative efforts among these disciplines have led to comprehensive reviews and meta-analyses, consolidating evidence from multiple studies to offer a more nuanced understanding of the factors contributing to implant breakage.

However, there are several limitations to this research. The amount of data collected from clinical studies and worldwide arthroplasty registries remains insufficient to draw definitive conclusions about specific failure mechanisms. Detailed information regarding implant breakage is often lacking in registries or clinical studies. There's a high likelihood that the incidence of implant fractures is underreported in registries and clinical studies, potentially leading to an underestimation of the actual fracture rate following shoulder arthroplasty. Therefore, the true incidence of implant fractures post-shoulder arthroplasty could be higher than indicated in this review. This is the first study to evaluate the incidence of IB after SA by evaluating national registries and clinical studies. Individual studies present with equal results concerning events of IB as national registries do, but only due to detailed results obtained from the Australian registry. The goal should be the accurate collection of data from national registries, modelled on the Australian one. The prospective study of Budge et al. [102], enhances that registry datasets could help to identify implants with a higher rate of failure. Surgeons do have the possibility to inform patients more accurately about potential complications after SA.

16.1. The future of shoulder arthroplasty

Currently, fourth-generation implants are being used in shoulder prosthetics. Due to the variability of the modular design, the prosthetic implantation is already planned to be patient-specific, and the use of innovative materials such as "ultra-highly cross-linked polyethylene" extends the durability of the prosthesis and reduces wear.

Platform humeral stems represent a significant advancement in shoulder endoprosthetics, offering enhanced stability and functionality in shoulder joint replacement surgeries. Unlike traditional stemmed implants, platform humeral stems feature a modular design that allows for greater flexibility and customization to accommodate a wide range of patient anatomies and surgical needs. One of the key benefits of platform humeral stems is their versatility in addressing various indications and surgical scenarios. Surgeons can choose from a range of stem sizes, lengths, and configurations to achieve optimal fit and fixation within the humeral canal. This modularity enables precise alignment and restoration of the patient's natural anatomy, leading to improved biomechanics and joint stability postoperatively [121].

Moreover, platform humeral stems often incorporate innovative features such as porous coatings or hydroxyapatite coatings, which promote osseointegration and enhance long-term implant durability [122]. These coatings facilitate bone ingrowth and integration, reducing the risk of implant loosening or migration over time. Another advantage of platform humeral stems is their ability to preserve bone stock and facilitate future revision surgeries if necessary. By minimizing bone removal and preserving the integrity of the humeral canal, these implants offer greater flexibility for future interventions, such as implant revision or conversion to reverse shoulder arthroplasty, without compromising the structural integrity of the bone [123].

Furthermore, platform humeral stems can accommodate various bearing surfaces, including metal-on-polyethylene, ceramic-on-polyethylene, or even metal-on-metal articulations, providing surgeons with options to tailor the implant to each patient's specific needs and preferences [124].

In summary, platform humeral stems represent a significant advancement in shoulder endoprosthetics, offering versatility, stability, and long-term durability. Their modular design, innovative coatings, and preservation of bone stock make them a valuable option for surgeons and patients seeking optimal outcomes in shoulder joint replacement surgery.

Stemless prostheses for shoulder joint replacement offer several potential advantages, including preservation of bone stock, reduced surgical trauma, and improved range of motion. However, they also come with limitations such as limited long-term data, surgical learning curve, and potential complications. Patient selection, surgeon experience, and careful consideration of individual factors are crucial in determining the suitability of stemless implants for each patient. Further research and clinical studies are needed to fully understand the comparative effectiveness and long-term outcomes of stemless shoulder prostheses.

16.1.1. Outpatient shoulder arthroplasty

Outpatient total shoulder arthroplasty (TSA), also known as ambulatory or same-day shoulder replacement surgery, is gaining popularity as advancements in surgical techniques, anaesthesia protocols, and postoperative care continue to improve. This approach allows patients to undergo shoulder replacement surgery and return home on the same day, rather than staying overnight in a hospital. There are several advantages for this organisational setting, that will be described as follows:

Outpatient SA offers patients the advantage of recovering in the comfort of their own homes, potentially leading to quicker recovery times compared to traditional inpatient surgery. Being in familiar surroundings can also contribute to a more positive psychological outlook, which may further enhance the recovery process. By avoiding an overnight hospital stay, outpatient TSA can lead to significant cost savings for both patients and healthcare systems. This is particularly beneficial for individuals with high deductible health plans or limited insurance coverage, as it reduces the financial burden associated with hospital stays.

Outpatient surgery centers often have lower rates of hospital-acquired infections compared to traditional hospitals, reducing the risk of complications post-surgery [125]. This is especially relevant in the current healthcare landscape, where preventing infections is a top priority.

Many patients prefer the convenience and flexibility of outpatient surgery, as it allows them to return home sooner and resume their normal activities more quickly. This can lead to higher levels of patient satisfaction [125] and improved overall experience with the surgical process [126].

Outpatient SA can help streamline surgical workflows and optimize resource utilization in healthcare facilities. By minimizing hospital admissions and reducing the length of stay, surgical centers can increase efficiency and accommodate more patients within the same timeframe [127].

There are also some challenges that need to be addressed. The correct patient selection for an ambulant surgery is very important because not all patients are suitable candidates for outpatient procedures [128]. Factors such as age, overall health status, comorbidities, and social support network need to be carefully evaluated to determine whether a patient can safely undergo same-day surgery or would be better served by traditional inpatient care.

Anesthesia plays a crucial role in outpatient SA, as patients need to be adequately sedated and pain-controlled during the procedure while ensuring a smooth recovery process postoperatively. Anesthesia protocols tailored for outpatient surgery should prioritize fast-acting agents with minimal side effects to facilitate early discharge [129]. Following outpatient SA, patients require close monitoring to detect and manage any complications that may arise, such as pain management issues, bleeding, or infection. Clear discharge instructions and access to follow-up care are essential to ensure a seamless transition from the surgical center to home care. Coordinating outpatient SA requires careful logistical planning to ensure all necessary resources, including surgical staff, equipment, and postoperative care facilities, are readily available [130]. Proper scheduling and communication among healthcare providers are crucial to minimize delays and optimize patient outcomes.

While outpatient shoulder surgery is generally safe for appropriately selected patients, there is a risk of unplanned hospital admissions due to unforeseen complications or inadequate pain control post-surgery [131]. Healthcare providers should be prepared to promptly address any issues that may arise and facilitate timely transfer to a hospital if needed.

Outpatient shoulder arthroplasty offers several potential benefits, including quicker recovery, cost savings, and increased patient satisfaction. However, it also presents challenges related to patient selection, anesthesia management, postoperative care, and logistical considerations. With careful planning and adherence to established protocols, outpatient SA can be a safe and effective option for eligible patients seeking shoulder joint replacement surgery. Ongoing research and clinical experience will further refine best practices and optimize outcomes in the evolving field of outpatient orthopedic surgery.

16.1.2. The subscapularis sparing approach:

The subscapularis muscle is a key component of the shoulder joint, responsible for stabilizing the joint and facilitating various movements, including internal rotation and adduction. In traditional shoulder arthroplasty procedures, such as total shoulder arthroplasty (TSA) or reverse shoulder arthroplasty (RSA), the subscapularis tendon is often detached to gain access to the glenohumeral joint, leading to potential complications such as muscle weakness, decreased range of motion, and prolonged rehabilitation [132]. To mitigate these issues, surgeons have developed the subscapularis-sparing approach for shoulder arthroplasty, which aims to preserve the integrity of the subscapularis tendon while still achieving successful joint replacement. In this text, we'll delve into the concept of the subscapularis-sparing approach, its advantages, challenges, and clinical implications.

One of the primary advantages of the subscapularis-sparing approach is the preservation of subscapularis function. By avoiding detachment or extensive manipulation of the subscapularis tendon, this technique minimizes the risk of postoperative muscle weakness and dysfunction, allowing for better preservation of shoulder strength and range of motion. Preserving the subscapularis tendon in shoulder arthroplasty can lead to faster recovery and rehabilitation compared to traditional techniques that involve tendon detachment. Patients undergoing the subscapularis-sparing approach may experience less pain, earlier return of shoulder function, and shorter rehabilitation periods, ultimately resulting in improved overall outcomes.

Detachment of the subscapularis tendon in traditional shoulder arthroplasty procedures can increase the risk of complications such as tendon tears, muscle atrophy, and joint instability [132]. By sparing the subscapularis tendon, surgeons can minimize these risks and enhance

the safety of the surgical procedure, leading to better long-term implant survival and patient satisfaction. Preserving the integrity of the subscapularis tendon helps maintain the stability of the glenohumeral joint following shoulder arthroplasty. A functional subscapularis muscle contributes to better joint kinematics, reduced risk of dislocation, and improved overall joint stability, particularly in patients undergoing RSA where stability is critical for optimal implant performance.

Studies have shown that the subscapularis-sparing approach for shoulder arthroplasty can result in excellent clinical outcomes, including pain relief, improved shoulder function, and high patient satisfaction rates [133-135]. By preserving the natural anatomy and biomechanics of the shoulder joint, this technique offers the potential for superior long-term results compared to traditional approaches.

There are also some challenges that need to be addressed: Performing shoulder arthroplasty with a subscapularis-sparing approach requires advanced surgical skills and specialized techniques. Surgeons must carefully navigate around the subscapularis tendon while ensuring proper implant placement and fixation, which can be challenging, especially in cases of severe joint deformity or pathology [136]. Preserving the subscapularis tendon may limit visualization and exposure of the glenohumeral joint during surgery, particularly in cases where extensive soft tissue release is required. Surgeons must employ meticulous surgical techniques and appropriate instrumentation to optimize exposure while avoiding damage to surrounding structures.

Not all patients are suitable candidates for the subscapularis-sparing approach [136]. Factors such as the extent of joint pathology, preexisting subscapularis dysfunction, and surgical complexity must be carefully evaluated to determine the appropriateness of this technique for each individual patient.

While preserving the subscapularis tendon can reduce the risk of postoperative muscle weakness, there is still a potential for subscapularis insufficiency or dysfunction following surgery [132]. Close postoperative monitoring and tailored rehabilitation protocols are essential to optimize subscapularis strength and function and minimize the risk of complications.

Although early clinical studies have demonstrated promising outcomes with the subscapularis-sparing approach, long-term durability and survivorship of implants using this technique remain to be fully elucidated. Continued research and longitudinal follow-up are needed to assess the longevity of implants and the incidence of complications over time.

The subscapularis-sparing approach for shoulder arthroplasty offers several potential advantages, including preservation of subscapularis function, faster recovery, reduced risk of complications, improved joint stability, and enhanced clinical outcomes. However, it also presents challenges related to surgical technique complexity, limited visualization, patient selection criteria, risk of subscapularis insufficiency, and long-term durability. With careful patient selection, meticulous surgical technique, and appropriate postoperative management, the subscapularis-sparing approach can be a valuable option for patients undergoing shoulder arthroplasty, offering the potential for improved outcomes and patient satisfaction [137]. Ongoing research and advancements in surgical technology will further refine and optimize this technique in the field of shoulder surgery.

16.1.3. The pyrocarbon shoulder hemiarthroplasty

Pyrocarbon surface technology has transformed orthopedic surgery, particularly in joint replacement procedures like shoulder hemiarthroplasty. Utilizing a biocompatible material composed of carbon atoms arranged in a crystalline lattice structure, pyrocarbon surfaces offer exceptional strength, durability, and wear resistance. These properties make them ideal for articulating surfaces in shoulder implants.

One of the standout advantages of pyrocarbon surfaces in shoulder hemiarthroplasty is their low friction and wear characteristics. The smooth surface reduces frictional forces within the joint, minimizing wear and tear on the implant over time. This translates to improved longevity and reduced risk of implant failure compared to traditional materials like metal or polyethylene [138]. Moreover, pyrocarbon's high biocompatibility ensures it is well-tolerated by the body, reducing the risk of inflammatory responses or adverse reactions. This compatibility promotes successful osseointegration, enhancing clinical outcomes and patient satisfaction following surgery.

Another key benefit lies in the ability to precisely replicate the natural anatomy of the shoulder joint. Pyrocarbon implants can be engineered to mimic the humeral head and articulating surfaces, facilitating optimal biomechanical function and joint stability. This replication supports improved range of motion, strength, and overall shoulder function postoperatively. Pyrocarbon implants also offer versatility in design, allowing surgeons to customize sizing, shape, and configuration according to each patient's unique anatomical needs. This versatility enables personalized treatment strategies, ensuring optimal implant fit and fixation for better outcomes [138]. Furthermore, the risk of subsidence, where the implant sinks into the bone over time, is reduced. The material's biomechanical properties and ability to distribute load forces evenly help minimize stress on surrounding bone, mitigating the risk of implant migration or loosening.

However, challenges accompany the use of pyrocarbon surfaces. Cost is a notable factor, as pyrocarbon implants tend to be more expensive than traditional materials. This may limit accessibility, particularly in regions with limited financial resources. Moreover, while early studies demonstrate promising outcomes, long-term data on durability, survivorship, and complication rates are still limited [139]. Continued research is essential to fully understand pyrocarbon's performance over time and identify any potential issues. Surgical expertise is crucial for implanting pyrocarbon surfaces effectively. Surgeons must be skilled in the unique properties of pyrocarbon implants and proficient in precise implantation techniques. Lack of experience may increase the risk of complications or suboptimal outcomes [140].

Pyrocarbon surfaces offer numerous advantages in shoulder hemiarthroplasty, including low wear, biocompatibility, anatomical replication, versatility, and reduced subsidence risk. While challenges exist, ongoing research and technological advancements continue to enhance the role of pyrocarbon surface technology in improving outcomes for patients undergoing shoulder joint replacement.

16.1.4. Pyrocarbon Interposition Spherical Arthroplasty

This represents an innovative approach to shoulder joint restoration, particularly in cases of advanced glenohumeral arthritis or rotator cuff deficiency where traditional surgical options may be limited. This procedure involves the placement of a pyrocarbon implant between the humeral head and the glenoid, serving as an intermediary articulating surface to facilitate smooth joint motion [141].

One of the key advantages of pyrocarbon interposition spherical arthroplasty is its ability to preserve bone stock while addressing joint pathology. Unlike traditional total shoulder arthroplasty (aTSA) or reverse shoulder arthroplasty (RSA), which involve extensive bone resection and alteration of native anatomy, pyrocarbon interposition arthroplasty retains the patient's natural bone structure. This preservation of bone stock is particularly advantageous in younger patients or those with higher functional demands, as it maintains the potential for future revision surgeries and preserves options for alternative procedures. Moreover, pyrocarbon implants offer low friction and wear characteristics, promoting smooth joint movement and reducing the risk of implant-related complications such as loosening or osteolysis.

The biocompatibility of pyrocarbon further enhances implant integration and reduces the likelihood of adverse tissue reactions. Pyrocarbon interposition spherical arthroplasty may also offer a less invasive surgical option compared to traditional arthroplasty techniques, potentially leading to shorter recovery times, reduced postoperative pain, and improved patient satisfaction. However, like any surgical procedure, it is essential to carefully select appropriate candidates and weigh the benefits against potential risks and complications. Continued research and clinical evaluation will further refine the indications, outcomes, and long-term durability of pyrocarbon interposition spherical arthroplasty in the management of shoulder joint pathology.

16.1.5. The use of Ceramic material in shoulder arthroplasty

Ceramic materials have emerged as a promising option in shoulder arthroplasty, offering unique advantages over traditional implant materials like metal or polyethylene.

Ceramic implants, typically made from materials such as alumina or zirconia, exhibit excellent biocompatibility, mechanical properties, and wear resistance, making them an attractive choice for shoulder joint replacement surgery [142].

One of the primary advantages of ceramic implants in shoulder arthroplasty is their superior wear characteristics. Compared to traditional metal or polyethylene implants, ceramic materials demonstrate significantly lower wear rates, reducing the risk of implant-related complications such as osteolysis and aseptic loosening. This enhanced wear resistance contributes to the longevity and durability of ceramic implants, potentially leading to improved long-term outcomes for patients. Moreover, ceramic implants offer excellent biocompatibility, minimizing the risk of adverse tissue reactions or inflammatory responses. The inert nature of ceramic materials reduces the likelihood of allergic reactions and promotes successful osseointegration, facilitating optimal implant stability and function postoperatively [143].

Another benefit of ceramic implants is their ability to replicate the natural anatomy of the shoulder joint. Ceramic materials can be precisely engineered to mimic the surface characteristics of native cartilage, promoting smooth articulation and preserving joint kinematics. This replication of natural joint mechanics enhances range of motion, stability, and overall shoulder function following arthroplasty surgery. Furthermore, ceramic implants may be particularly advantageous in young and active patients due to their durability and resistance to wear. With increasing demand for shoulder arthroplasty in younger populations, ceramic implants offer a viable option for addressing joint pathology while accommodating higher levels of physical activity and functional demands.

Ceramic materials play a valuable role in modern shoulder arthroplasty, offering superior wear resistance, excellent biocompatibility, and the ability to replicate natural joint mechanics. While further research is needed to evaluate long-term outcomes and complications, ceramic implants represent a promising option for patients undergoing shoulder joint replacement surgery.

16.1.6. The use of Vitamin E Polyethylene

Vitamin E polyethylene (VEPE) has emerged as a significant advancement in orthopaedic surgery, particularly in shoulder arthroplasty, where the demand for durable and wear-resistant bearing surfaces is paramount. VEPE is a specialized form of ultra-high molecular weight polyethylene (UHMWPE) that incorporates vitamin E into its molecular structure, imparting enhanced oxidative stability and mechanical properties. This innovation addresses the longstanding challenge of polyethylene wear in joint arthroplasty, offering promising solutions for improving implant longevity and reduced implant breakage and higher patient satisfaction [144].

One of the primary advantages of VEPE in shoulder arthroplasty is its superior wear resistance compared to conventional polyethylene. By incorporating vitamin E, a potent antioxidant, into the polymer matrix, VEPE mitigates oxidative degradation and reduces wear rates, thereby minimizing the risk of particle-induced osteolysis and implant loosening. This enhanced wear resistance translates to improved implant durability and longevity, potentially extending the lifespan of shoulder prostheses and reducing the need for early revision surgeries. Moreover, VEPE exhibits excellent biocompatibility, promoting tissue integration and minimizing the risk of adverse reactions or inflammatory responses. The biologically inert nature of VEPE reduces the likelihood of allergic reactions or hypersensitivity, ensuring compatibility with the body's natural tissues and facilitating optimal implant performance postoperatively [145].

Another advantage of VEPE in shoulder arthroplasty is its ability to maintain mechanical integrity and dimensional stability under physiological loading conditions. The addition of vitamin E enhances the polymer's resistance to fatigue and creep, minimizing deformation and preserving the implant's structural integrity over time. This mechanical robustness contributes to improved joint stability, range of motion, and overall functional outcomes for patients undergoing shoulder arthroplasty. Furthermore, VEPE offers versatility in surgical applications, allowing for the development of modular implants with customizable bearing surfaces to suit individual patient needs. Surgeons can choose from a range of VEPE formulations, including conventional, highly cross-linked, and vitamin E-infused polyethylene, to optimize implant performance and longevity based on patient characteristics and surgical requirements [146].

Vitamin E polyethylene represents a significant advancement in shoulder arthroplasty, offering enhanced wear resistance, biocompatibility, and mechanical properties compared to conventional polyethylene materials. By addressing the challenges of polyethylene wear and oxidative degradation, VEPE implants hold promise for improving the longevity and clinical outcomes of shoulder prostheses, ultimately benefiting patients with degenerative shoulder joint conditions.

A systematic review by Ozdag et al. [147] describes the arthroscopic removal of the PE glenoid component after aTSA for glenoid loosening and concludes that this minimally invasive technique represents a good alternative to open glenoid resection, despite only 25 cases being included in the review overall. Arthroscopic resection of the glenoid component (ARGC) after aTSA shows a reduction in VAS and an improvement in ASES score [148]. Continued research and clinical studies are warranted to further validate the efficacy and long-term performance of VEPE in shoulder arthroplasty and refine its application in orthopedic surgery.

16.1.7. Glenoid Component Fixation

Glenoid component fixation is a critical aspect of shoulder arthroplasty, as it plays a pivotal role in ensuring the stability, longevity, and functional outcomes of the prosthetic joint [149]. The glenoid component serves as the articulating surface for the humeral head implant and must withstand the forces exerted during shoulder motion while promoting osseointegration for durable fixation. Various fixation techniques and implant designs have been developed to optimize glenoid component fixation and address the challenges associated with glenoid bone loss, implant loosening, and instability [149, 150].

One of the primary considerations in glenoid component fixation is achieving adequate bone stock and implant stability. In cases of severe glenoid bone loss or deformity, bone grafting or augmentation may be necessary to restore bone morphology and provide sufficient support for the implant [151]. Additionally, surgeons may employ techniques such as reaming or bone preparation to optimize the implant-bone interface and enhance initial fixation. Several fixation methods are commonly used in shoulder arthroplasty, including cemented, press-fit, and hybrid techniques.

Cemented fixation involves securing the glenoid component with bone cement, providing immediate stability and fixation. While cemented fixation offers reliable initial fixation, concerns regarding cement mantle integrity, implant loosening, and long-term durability have prompted exploration of alternative fixation methods.

Press-fit fixation relies on mechanical interlocking between the implant and the surrounding bone without the use of cement. This technique leverages the inherent stability of the bone-implant interface and promotes osseointegration for long-term fixation. Press-fit implants may incorporate features such as porous coatings or textured surfaces to enhance bone ingrowth and implant stability. However, achieving optimal press-fit fixation requires careful preparation of the glenoid bone and precise implant positioning to minimize micromotion and ensure implant stability.

Hybrid fixation combines elements of both cemented and press-fit techniques, offering the benefits of immediate stability and long-term osseointegration. In hybrid fixation, a portion of the glenoid component is cemented into place, while the remaining portion relies on press-fit fixation for secondary stability. This hybrid approach aims to balance the advantages of cemented fixation, such as immediate stability, with the benefits of press-fit fixation, including long-term osseointegration and implant durability.

In recent years, advancements in implant design and surgical techniques have expanded the options for glenoid component fixation in shoulder arthroplasty. Modular implants, adjustable offset designs, and patient-specific instrumentation have enabled more precise implant placement and enhanced stability. Additionally, the use of advanced biomaterials, such as porous metals and vitamin E-infused polyethylene, has contributed to improved osseointegration and reduced rates of implant loosening.

Despite these advancements, challenges remain in achieving optimal glenoid component fixation, particularly in cases of severe bone loss or anatomical variability. Surgeons must carefully assess patient-specific factors, including bone quality, soft tissue integrity, and functional demands, to determine the most appropriate fixation technique and implant design. Continued research and innovation in glenoid component fixation are essential to

further improve outcomes and address the evolving needs of patients undergoing shoulder arthroplasty.

16.1.8. Computer-assisted preoperative planning

Another helpful modernization is represented by the surgical planning, which has been applied in knee or hip arthroplasty for some time now. This helps in making the right choice of endoprosthetic, such as whether a long or short stem or merely a surface replacement seems appropriate for the specific anatomical conditions. The validity and reproducibility of prosthesis planning have been confirmed multiple times [152, 153].

Currently, there is a wide selection of software companies, with almost any provider's desired prosthesis being able to be virtually represented after a computed tomography scan. This allows the surgeon to choose the optimal version, inclination, and glenoid component, aiming for optimal positioning. It becomes apparent whether a custom-made implant or a patient-specific guide should be used. It has been demonstrated that this can reduce the risk of misplacement of the glenoid component [154].

17. Conclusion

This study provides valuable insights into the frequency of implant breakage following shoulder arthroplasty, emphasizing the comparability of data obtained from clinical studies and national registry databases. The standardized calculation method employed in our analysis enhances the interpretability of results and highlights the importance of continued collaboration with national registries for ongoing research in this critical area of orthopaedics.

Implant breakage occurs more rarely than aseptic loosening or infection after shoulder arthroplasty. The incidence of implant breakage in registries and clinical studies is almost equal. During follow-up care, a slowly increasing pain must be further clarified, even without primary X-ray findings. Primary loosening might be the main reason of IB, investigations are needed to underline this hypothesis with data.

While many patients experience significant pain relief and improved shoulder function following arthroplasty, the ongoing issue of high long-term failure rates remains unacceptable. Potential areas for enhancing implant longevity include advancements in surgical techniques, like approaches that preserve the subscapularis muscle and computer-guided planning; improvements in the design and attachment methods of the humeral component, such as stemless, short-stem, and convertible implants; enhancements in the materials used for bearing surfaces, such as pyrocarbon, ceramic, and metal-on-metal options; and progress in the design and attachment methods of the glenoid component, such as augmented components, ingrowth pegs, and inlay glenoid components.

Additional work-up, associating periprosthetic joint infections with loosening of the prosthesis and subsequent material breakage, would be desirable. The authors believe that in clinical practice the result of this analysis can help to advice patients on potential complications following shoulder arthroplasty.

18. References

1. Bankes, M.J. and R.J. Emery, *Pioneers of shoulder replacement: Themistocles Gluck and Jules Emile Pean.* J Shoulder Elbow Surg, 1995. **4**(4): p. 259-62.
2. Marotte, J.H., G. Lord, and P. Bancel, *[Neer arthroplasty in complex fractures and fracture-dislocations of the shoulder. 12 cases (author's transl)].* Chirurgie, 1978. **104**(8): p. 816-21.
3. Neer, C.S., 2nd, *Articular replacement for the humeral head.* J Bone Joint Surg Am, 1955. **37-A**(2): p. 215-28.
4. Krueger, F.J., *A vitallium replica arthroplasty on the shoulder; a case report of aseptic necrosis of the proximal end of the humerus.* Surgery, 1951. **30**(6): p. 1005-11.
5. Brand, R.A. and L.U. Bigliani, *Biographical sketch: Charles S. Neer, II, MD (1917-2011).* Clin Orthop Relat Res, 2011. **469**(9): p. 2407-8.
6. Fenlin, J.M., Jr., *Total glenohumeral joint replacement.* Orthop Clin North Am, 1975. **6**(2): p. 565-83.
7. Berliner, J.L., et al., *Biomechanics of reverse total shoulder arthroplasty.* J Shoulder Elbow Surg, 2015. **24**(1): p. 150-60.
8. Mehta, N., et al., *The Biomaterials of Total Shoulder Arthroplasty: Their Features, Function, and Effect on Outcomes.* JBJS Rev, 2020. **8**(9): p. e1900212.
9. Habermeyer, P. and T. Ebert, *[Current status and perspectives of shoulder replacement].* Unfallchirurg, 1999. **102**(9): p. 668-83.
10. Erickson, B.J., et al., *The influence of humeral head inclination in reverse total shoulder arthroplasty: a systematic review.* J Shoulder Elbow Surg, 2015. **24**(6): p. 988-93.
11. Neer, C.S., 2nd, *Indications for replacement of the proximal humeral articulation.* Am J Surg, 1955. **89**(4): p. 901-7.
12. Singh, J.A., J.W. Sperling, and R.H. Cofield, *Revision surgery following total shoulder arthroplasty: analysis of 2588 shoulders over three decades (1976 to 2008).* J Bone Joint Surg Br, 2011. **93**(11): p. 1513-7.
13. Graves, S., Turner, C., *Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee & Shoulder Arthroplasty: 2021 Annual Report. Adelaide: AOA.* 2021.
14. Amundsen, A., et al., *Low revision rate despite poor functional outcome after stemmed hemiarthroplasty for acute proximal humeral fractures: 2,750 cases reported to the Danish Shoulder Arthroplasty Registry.* Acta Orthop, 2019. **90**(3): p. 196-201.
15. McKie, J., Hobbs, T., Frampton, C., Coleman, B., Pattett, A. , *The New Zealand Joint Registry*, in *Twenty-One Year Report*. 2020, The New Zealand Joint Registry 2020: www.nzoa.org.nz/nzoa-joint-registry.
16. Castagna, A., et al., *Conversion of shoulder arthroplasty to reverse implants: clinical and radiological results using a modular system.* Int Orthop, 2013. **37**(7): p. 1297-305.
17. L.J., S., *Danish Society for surgery of the shoulder and the elbow - Annual report 2020.* 2020.
18. Urakcheeva, I., Biodi, A., Torre, M., *Italian Arthroplasty Registry. Annual Report 2019 - Addendum.* 2019: http://riap.iss.it/riap/en/activities/reports/.
19. Havelin, L.I., *The Norwegian Joint Registry.* Bull Hosp Jt Dis, 1999. **58**(3): p. 139-47.
20. Graves, S., Turner, C. et al., *Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) Hip, Knee & Shoulder Arthroplasty: 20th Annual Report. Adelaide: AOA*. 2019.
21. Prinz, T., Grabow, N., , *Zulassung medizinischer Implantate nach der europäischen Medizinprodukteverordnung (MDR)*, B.f.B.u.F. Institut für ImplantatTechnologie und Biomaterialien e.V., Deutschland., Editor. 2022:

https://www.vde.com/resource/blob/2182192/ab8a8c083e21c40e4eecea6d3a86b217/positionspapier-data.pdf.
22. Edwards, T., Morris, BJ., *Shoulder Arthroplasty*. Vol. 2nd Ed. 2019: Elsevier.
23. Middernacht, B., et al., *Glenosphere disengagement: a potentially serious default in reverse shoulder surgery.* Clin Orthop Relat Res, 2008. **466**(4): p. 892-8.
24. Roche, C.P., et al., *The impact of scapular notching on reverse shoulder glenoid fixation.* J Shoulder Elbow Surg, 2013. **22**(7): p. 963-70.
25. Liebhauser, M., et al., *Implant breakage after shoulder arthroplasty: a systematic review of data from worldwide arthroplasty registries and clinical trials.* BMC Musculoskelet Disord, 2023. **24**(1): p. 804.
26. Sadoghi, P., et al., *The incidence of implant fractures after total hip arthroplasty.* Int Orthop, 2014. **38**(1): p. 39-46.
27. Gilg, M.M., et al., *The incidence of implant fractures after knee arthroplasty.* Knee Surg Sports Traumatol Arthrosc, 2016. **24**(10): p. 3272-3279.
28. Bigliani, L.U., et al., *Glenohumeral stability. Biomechanical properties of passive and active stabilizers.* Clin Orthop Relat Res, 1996(330): p. 13-30.
29. Karduna, A.R., et al., *Kinematics of the glenohumeral joint: influences of muscle forces, ligamentous constraints, and articular geometry.* J Orthop Res, 1996. **14**(6): p. 986-93.
30. Miller, M., *Review of Orthopedics*. Vol. 5. 2008: Saunders ELSEVIER.
31. Schuenke, M., Schulte, E., Schuhmacher, U., *Prometheus - Lernatlas der Anatomie*. 2005: Stuttgart: Thieme.
32. Elwell, J., G. Athwal, and R. Willing, *Maximizing range of motion of reverse total shoulder arthroplasty using design optimization techniques.* J Biomech, 2021. **125**: p. 110602.
33. Howard, M.C., N.A. Trasolini, and B.R. Waterman, *Optimizing Outcomes After Reverse Total Shoulder Arthroplasty: Rehabilitation, Expected Outcomes, and Maximizing Return to Activities.* Curr Rev Musculoskelet Med, 2023. **16**(4): p. 145-153.
34. Muench, L.N., et al., *Rotational range of motion of elliptical and spherical heads in shoulder arthroplasty: a dynamic biomechanical evaluation.* Arch Orthop Trauma Surg, 2022. **142**(1): p. 67-76.
35. Barragan Echenique, D.M., et al., *Infraspinatus Muscle Fiber Moment Arms During Abduction: A Biomechanical Comparison of Values for Intact Rotator Cuff, Supraspinatus Tear, Superior Capsular Reconstruction, and Reverse Total Shoulder Arthroplasty.* Orthop J Sports Med, 2022. **10**(5): p. 23259671221098378.
36. Kontaxis, A. and G.R. Johnson, *The biomechanics of reverse anatomy shoulder replacement--a modelling study.* Clin Biomech (Bristol, Avon), 2009. **24**(3): p. 254-60.
37. Alizadehkhaiyat, O., et al., *Outcome of Copeland shoulder resurfacing arthroplasty with a 4-year mean follow-up.* J Shoulder Elbow Surg, 2013. **22**(10): p. 1352-8.
38. Launonen, A.P., et al., *Epidemiology of proximal humerus fractures.* Arch Osteoporos, 2015. **10**: p. 209.
39. Singh, J.A., et al., *Surgery for shoulder osteoarthritis.* Cochrane Database Syst Rev, 2010(10): p. CD008089.
40. Mattei, L., et al., *Anatomic shoulder arthroplasty: an update on indications, technique, results and complication rates.* Joints, 2015. **3**(2): p. 72-7.
41. Maier, D., et al., *Proximal humeral fracture treatment in adults.* J Bone Joint Surg Am, 2014. **96**(3): p. 251-61.
42. Trouilloud, P., et al., *Anatomic basis of a superior approach to the acetabulum with osteotomy of the ala of the ilium.* Surg Radiol Anat, 1987. **9**(3): p. 185-91.
43. Middernacht, B., A. Van Tongel, and L. De Wilde, *A Critical Review on Prosthetic Features Available for Reversed Total Shoulder Arthroplasty.* Biomed Res Int, 2016. **2016**: p. 3256931.

44. Hansen, M.L. and H. Routman, *The biomechanics of current reverse shoulder replacement options.* Annals of Joint, 2019. **4**.
45. Irlenbusch, U. and G. Kohut, *Evaluation of a new baseplate in reverse total shoulder arthroplasty - comparison of biomechanical testing of stability with roentgenological follow up criteria.* Orthop Traumatol Surg Res, 2015. **101**(2): p. 185-90.
46. Palsis, J.A., et al., *Current Trends in the Use of Shoulder Arthroplasty in the United States.* Orthopedics, 2018. **41**(3): p. e416-e423.
47. Berhouet, J., P. Garaud, and L. Favard, *Evaluation of the role of glenosphere design and humeral component retroversion in avoiding scapular notching during reverse shoulder arthroplasty.* J Shoulder Elbow Surg, 2014. **23**(2): p. 151-8.
48. Rugg, C.M., M.J. Coughlan, and D.A. Lansdown, *Reverse Total Shoulder Arthroplasty: Biomechanics and Indications.* Curr Rev Musculoskelet Med, 2019. **12**(4): p. 542-553.
49. Nyffeler, R.W., C.M. Werner, and C. Gerber, *Biomechanical relevance of glenoid component positioning in the reverse Delta III total shoulder prosthesis.* J Shoulder Elbow Surg, 2005. **14**(5): p. 524-8.
50. Kwon, Y.W., et al., *Analysis of reverse total shoulder joint forces and glenoid fixation.* Bull NYU Hosp Jt Dis, 2010. **68**(4): p. 273-80.
51. Gutierrez, S., et al., *Biomechanical comparison of component position and hardware failure in the reverse shoulder prosthesis.* J Shoulder Elbow Surg, 2007. **16**(3 Suppl): p. S9-S12.
52. Roloff, H., Matek, W. , *Roloff/Matek Maschinenelemente*. Vol. 13. 1995: Friedr. Vieweg.
53. Peters, M., Leyens, C., *Titan und Titanlegierungen*. 2002: https://onlinelibrary.wiley.com/doi/book/10.1002/9783527611089.
54. Eckert, J.A., et al., *Fretting and Corrosion in Modular Shoulder Arthroplasty: A Retrieval Analysis.* Biomed Res Int, 2016. **2016**: p. 1695906.
55. Efe, T. and J. Schmitt, *Analyses of prosthesis stem failures in noncemented modular hip revision prostheses.* J Arthroplasty, 2011. **26**(4): p. 665 e7-12.
56. Lakstein, D., et al., *Revision total hip arthroplasty with a modular tapered stem.* Hip Int, 2010. **20**(2): p. 136-42.
57. Harris, W.t., G.A. Mote, and D.S. Malay, *Fixation of the proximal interphalangeal arthrodesis with the use of an intraosseous loop of stainless-steel wire suture.* J Foot Ankle Surg, 2009. **48**(3): p. 411-4.
58. Bundestag, D., *Gesetz zum Implantateregister Deutschland (Implantateregistergesetz - IRegG)*. 2020: http://www.gesetze-im-internet.de/iregg/BJNR249410019.html.
59. Neer, C.S., 2nd, *Shoulder arthroplasty today.* Orthopade, 1991. **20**(5): p. 320-1.
60. Sanchez-Sotelo, J., *Total shoulder arthroplasty.* Open Orthop J, 2011. **5**: p. 106-14.
61. Neer, C.S., 2nd, K.C. Watson, and F.J. Stanton, *Recent experience in total shoulder replacement.* J Bone Joint Surg Am, 1982. **64**(3): p. 319-37.
62. Norris, T.R. and J.P. Iannotti, *Functional outcome after shoulder arthroplasty for primary osteoarthritis: a multicenter study.* J Shoulder Elbow Surg, 2002. **11**(2): p. 130-5.
63. Franklin, J.L., et al., *Glenoid loosening in total shoulder arthroplasty. Association with rotator cuff deficiency.* J Arthroplasty, 1988. **3**(1): p. 39-46.
64. Boileau, P., et al., *Neer Award 2005: The Grammont reverse shoulder prosthesis: results in cuff tear arthritis, fracture sequelae, and revision arthroplasty.* J Shoulder Elbow Surg, 2006. **15**(5): p. 527-40.
65. Favard, L., et al., *Reverse prostheses in arthropathies with cuff tear: are survivorship and function maintained over time?* Clin Orthop Relat Res, 2011. **469**(9): p. 2469-75.
66. Stautberg, E.F., 3rd, et al., *Stability of two versus three peripheral pegs of the glenoid component in modern total shoulder arthroplasty.* Int Orthop, 2017. **41**(11): p. 2345-2351.

67. Cusick, M.C., et al., *Glenosphere dissociation after reverse shoulder arthroplasty.* J Shoulder Elbow Surg, 2015. **24**(7): p. 1061-8.
68. Teeter, M.G., et al., *Tribocorrosion in shoulder arthroplasty humeral component retrievals.* J Shoulder Elbow Surg, 2016. **25**(2): p. 311-5.
69. Anglin, C., et al., *Loosening performance of cemented glenoid prosthesis design pairs.* Clin Biomech (Bristol, Avon), 2001. **16**(2): p. 144-50.
70. Welsher, A., et al., *A comparison of pegged vs. keeled glenoid components regarding functional and radiographic outcomes in anatomic total shoulder arthroplasty: a systematic review and meta-analysis.* JSES Open Access, 2019. **3**(3): p. 136-144 e1.
71. Scarlat, M.M. and F.A. Matsen, 3rd, *Observations on retrieved polyethylene glenoid components.* J Arthroplasty, 2001. **16**(6): p. 795-801.
72. Schmalzried, T.P., et al., *The role of access of joint fluid to bone in periarticular osteolysis. A report of four cases.* J Bone Joint Surg Am, 1997. **79**(3): p. 447-52.
73. Schmalzried, T.P., F.J. Dorey, and H. McKellop, *The multifactorial nature of polyethylene wear in vivo.* J Bone Joint Surg Am, 1998. **80**(8): p. 1234-42; discussion 1242-3.
74. Rodosky, M., Bigliani, LU., *Surgical treatment of nonconstrained glenoid component failure.* Oper Tech Orthop, 1994. **4**: p. 226-36.
75. Franta, A.K., et al., *The complex characteristics of 282 unsatisfactory shoulder arthroplasties.* J Shoulder Elbow Surg, 2007. **16**(5): p. 555-62.
76. Martin, E.J., T.R. Duquin, and M.T. Ehrensberger, *Reverse total shoulder glenoid baseplate stability with superior glenoid bone loss.* J Shoulder Elbow Surg, 2017. **26**(10): p. 1748-1755.
77. Boileau, P., et al., *Cemented polyethylene versus uncemented metal-backed glenoid components in total shoulder arthroplasty: a prospective, double-blind, randomized study.* J Shoulder Elbow Surg, 2002. **11**(4): p. 351-9.
78. Papadonikolakis, A. and F.A. Matsen, 3rd, *Metal-Backed Glenoid Components Have a Higher Rate of Failure and Fail by Different Modes in Comparison with All-Polyethylene Components: A Systematic Review.* J Bone Joint Surg Am, 2014. **96**(12): p. 1041-1047.
79. Kim, D.M., et al., *Do Modern Designs of Metal-Backed Glenoid Components Show Improved Clinical Results in Total Shoulder Arthroplasty? A Systematic Review of the Literature.* Orthop J Sports Med, 2020. **8**(9): p. 2325967120950307.
80. Ravi, V., et al., *Outcome and complications following revision shoulder arthroplasty : a systematic review and meta-analysis.* Bone Jt Open, 2021. **2**(8): p. 618-630.
81. Boileau, P. and G. Walch, *The three-dimensional geometry of the proximal humerus. Implications for surgical technique and prosthetic design.* J Bone Joint Surg Br, 1997. **79**(5): p. 857-65.
82. Jun, B.J., et al., *The effects of prosthetic humeral head shape on glenohumeral joint kinematics during humeral axial rotation in total shoulder arthroplasty.* J Shoulder Elbow Surg, 2016. **25**(7): p. 1084-93.
83. Ladermann, A., et al., *Glenoid loosening and migration in reverse shoulder arthroplasty.* Bone Joint J, 2019. **101-B**(4): p. 461-469.
84. Scarlat, M.M., *Complications with reverse total shoulder arthroplasty and recent evolutions.* Int Orthop, 2013. **37**(5): p. 843-51.
85. Ramirez, M.A., Y. Lu, and A. Schaver, *Catastrophic Failure of Reverse Shoulder Arthroplasty from a Broken Screw: A Case Report.* JBJS Case Connect, 2020. **10**(3): p. e19 00504.
86. Cil, A., et al., *Survivorship of the humeral component in shoulder arthroplasty.* J Shoulder Elbow Surg, 2010. **19**(1): p. 143-50.
87. Moroder, P., Gerhardt, C., Renz, N., Trampuz, A., Scheibel, M., *Diagnostik und Management des Endoprotheseninfekts am Schultergelenk.* Obere Extremität, 2016. **11**(2): p. 78-87.

88. Charnley, J., *The reaction of bone to self-curing acrylic cement. A long-term histological study in man.* J Bone Joint Surg Br, 1970. **52**(2): p. 340-53.
89. Hopkins, A.R. and U.N. Hansen, *Primary stability in reversed-anatomy glenoid components.* Proc Inst Mech Eng H, 2009. **223**(7): p. 805-12.
90. James, J., et al., *Reverse shoulder arthroplasty glenoid fixation: is there a benefit in using four instead of two screws?* J Shoulder Elbow Surg, 2013. **22**(8): p. 1030-6.
91. Konigshausen, M., et al., *Influence of different peg length in glenoid bone loss: A biomechanical analysis regarding primary stability of the glenoid baseplate in reverse shoulder arthroplasty.* Technol Health Care, 2015. **23**(6): p. 855-69.
92. Page, M.J., et al., *The PRISMA 2020 statement: an updated guideline for reporting systematic reviews.* BMJ, 2021. **372**: p. n71.
93. Bordini, B., Stea, S., Ancarani, C. et. al., *REPORT of Regional Register of Orthopaedic Prosthetic Implantology*. 2018, Bologna: http://www.ior.it/en/curarsi-al-rizzoli/register-orthopaedic-prosthetic-implants.
94. Porter, M., Howard, P. et. at., *National Joint Registry for England, Wales, Northern Ireland and the Isle of Man - 15th Annual Report*. 2018: www.njrcentre.org.uk.
95. Hobbs, T., Frampton, C., et. al., *The New Zealand Joint Registry*. 2018: www.nzoa.org.nz/nz-joint-registry.
96. De Reus, I.M.A., Spekenbrink-Spooren, A. et. al., *Dutch Arthroplasty Register (LROI)*. 2018, Netherlands Orthopaedic Association (NOV): www.lroi-report.nl.
97. Best, M.J., et al., *Increasing incidence of primary reverse and anatomic total shoulder arthroplasty in the United States.* J Shoulder Elbow Surg, 2021. **30**(5): p. 1159-1166.
98. Fucentese, S.F., et al., *Total shoulder arthroplasty with an uncemented soft-metal-backed glenoid component.* J Shoulder Elbow Surg, 2010. **19**(4): p. 624-31.
99. Montoya, F., et al., *Midterm results of a total shoulder prosthesis fixed with a cementless glenoid component.* J Shoulder Elbow Surg, 2013. **22**(5): p. 628-35.
100. Somerson, J.S., et al., *Analysis of 4063 complications of shoulder arthroplasty reported to the US Food and Drug Administration from 2012 to 2016.* J Shoulder Elbow Surg, 2018. **27**(11): p. 1978-1986.
101. Boileau, P., et al., *Metal-backed glenoid implant with polyethylene insert is not a viable long-term therapeutic option.* J Shoulder Elbow Surg, 2015. **24**(10): p. 1534-43.
102. Budge, M.D., et al., *Results of total shoulder arthroplasty with a monoblock porous tantalum glenoid component: a prospective minimum 2-year follow-up study.* J Shoulder Elbow Surg, 2013. **22**(4): p. 535-41.
103. Martin, S.D., D. Zurakowski, and T.S. Thornhill, *Uncemented glenoid component in total shoulder arthroplasty. Survivorship and outcomes.* J Bone Joint Surg Am, 2005. **87**(6): p. 1284-92.
104. Styron, J.F., et al., *Survivorship of Trabecular Metal Anchored Glenoid Total Shoulder Arthroplasties.* Tech Hand Up Extrem Surg, 2016. **20**(3): p. 113-6.
105. Vuillermin, C.B., et al., *Catastrophic failure of a low profile metal-backed glenoid component after total shoulder arthroplasty.* Int J Shoulder Surg, 2015. **9**(4): p. 121-7.
106. Ascione, F., et al., *Long-term humeral complications after Grammont-style reverse shoulder arthroplasty.* J Shoulder Elbow Surg, 2018. **27**(6): p. 1065-1071.
107. Kang, J.R., et al., *Primary reverse shoulder arthroplasty using contemporary implants is associated with very low reoperation rates.* J Shoulder Elbow Surg, 2019. **28**(6S): p. S175-S180.
108. Budge, M.D., et al., *A biomechanical analysis of initial fixation options for porous-tantalum-backed glenoid components.* J Shoulder Elbow Surg, 2013. **22**(5): p. 709-15.
109. Cappellari, A., et al., *Reverse shoulder arthroplasty for treatment of proximal humerus complex fractures in elderly: A single institution experience.* Injury, 2022. **53 Suppl 1**: p. S2-S7.

110. Hauer, G., et al., *Survival Rate and Application Number of Total Hip Arthroplasty in Patients With Femoral Neck Fracture: An Analysis of Clinical Studies and National Arthroplasty Registers.* J Arthroplasty, 2020. **35**(4): p. 1014-1022.
111. Sperling, J.W., R.H. Cofield, and C.M. Rowland, *Neer hemiarthroplasty and Neer total shoulder arthroplasty in patients fifty years old or less. Long-term results.* J Bone Joint Surg Am, 1998. **80**(4): p. 464-73.
112. Cuff, D., et al., *Torsional stability of modular and non-modular reverse shoulder humeral components in a proximal humeral bone loss model.* J Shoulder Elbow Surg, 2011. **20**(4): p. 646-51.
113. Levy, J.C., et al., *Primary Monoblock Inset Reverse Shoulder Arthroplasty Resulted in Decreased Pain and Improved Function.* Clin Orthop Relat Res, 2019. **477**(9): p. 2097-2108.
114. Yian, E.H., et al., *Radiographic and computed tomography analysis of cemented pegged polyethylene glenoid components in total shoulder replacement.* J Bone Joint Surg Am, 2005. **87**(9): p. 1928-36.
115. Terrier, A., P. Buchler, and A. Farron, *Bone-cement interface of the glenoid component: stress analysis for varying cement thickness.* Clin Biomech (Bristol, Avon), 2005. **20**(7): p. 710-7.
116. Matsen, F.A., 3rd, et al., *Glenoid component failure in total shoulder arthroplasty.* J Bone Joint Surg Am, 2008. **90**(4): p. 885-96.
117. Matsen, F.A., 3rd, *The ream and run: not for every patient, every surgeon or every problem.* Int Orthop, 2015. **39**(2): p. 255-61.
118. Somerson, J.S., et al., *Clinical and Radiographic Outcomes of the Ream-and-Run Procedure for Primary Glenohumeral Arthritis.* J Bone Joint Surg Am, 2017. **99**(15): p. 1291-1304.
119. Chawla, S.S., et al., *Drivers of lower inpatient hospital costs and greater improvements in health-related quality of life for patients undergoing total shoulder and ream-and-run arthroplasty.* J Shoulder Elbow Surg, 2021. **30**(8): p. e503-e516.
120. Frankle, M., et al., *The Reverse Shoulder Prosthesis for glenohumeral arthritis associated with severe rotator cuff deficiency. A minimum two-year follow-up study of sixty patients.* J Bone Joint Surg Am, 2005. **87**(8): p. 1697-705.
121. Kirsch, J.M., et al., *Platform shoulder arthroplasty: a systematic review.* J Shoulder Elbow Surg, 2018. **27**(4): p. 756-763.
122. Hammond, L.C., et al., *Clinical outcomes of hemiarthroplasty and biological resurfacing in patients aged younger than 50 years.* J Shoulder Elbow Surg, 2013. **22**(10): p. 1345-51.
123. Sandow, M. and C. Schutz, *Total shoulder arthroplasty using trabecular metal augments to address glenoid retroversion: the preliminary result of 10 patients with minimum 2-year follow-up.* J Shoulder Elbow Surg, 2016. **25**(4): p. 598-607.
124. Matsumura, N., et al., *Factors related to large bone defects of bipolar lesions and a high number of instability episodes with anterior glenohumeral instability.* J Orthop Surg Res, 2021. **16**(1): p. 255.
125. Vilar-Compte, D., et al., *Surgical site infections in ambulatory surgery: a 5-year experience.* Am J Infect Control, 2001. **29**(2): p. 99-103.
126. Singer, R.W., *Real-World Evidence of the Impact of a Novel Surgical Irrigant on Surgical Site Infections in Primary Total Knee Arthroplasty Performed at an Ambulatory Surgery Center.* Surg Infect (Larchmt), 2024. **25**(3): p. 240-246.
127. Brophy, R.H., et al., *Risk Factors for Surgical Site Infections After Orthopaedic Surgery in the Ambulatory Surgical Center Setting.* J Am Acad Orthop Surg, 2019. **27**(20): p. e928-e934.
128. Michelson, J., *Improved detection of orthopaedic surgical site infections occurring in outpatients.* Clin Orthop Relat Res, 2005(433): p. 218-24.

129. Julien, R.E. and B.A. Williams, *Regional anesthesia procedures for outpatient shoulder surgery.* Int Anesthesiol Clin, 2005. **43**(3): p. 167-75.
130. Gabriel, R.A. and B.M. Ilfeld, *Use of Regional Anesthesia for Outpatient Surgery Within the United States: A Prevalence Study Using a Nationwide Database.* Anesth Analg, 2018. **126**(6): p. 2078-2084.
131. Li, J., et al., *Novel Regional Anesthesia for Outpatient Surgery.* Curr Pain Headache Rep, 2019. **23**(10): p. 69.
132. Rosenthal, Y. and Y.W. Kwon, *Total Shoulder Arthroplasty Utilizing the Subscapularis-Sparing Approach.* Orthop Clin North Am, 2020. **51**(3): p. 383-389.
133. An, K.Y., J.Y. Park, and T.R. Yoon, *Subscapularis-sparing deltopectoral approach in reverse total shoulder arthroplasty.* Int Orthop, 2022. **46**(12): p. 2845-2851.
134. Desai, S.S., et al., *Technical note: subscapularis-sparing approach to perform anatomic total shoulder arthroplasty using a multiplanar humeral osteotomy and angled glenoid instruments.* J Orthop Surg Res, 2022. **17**(1): p. 14.
135. Savoie, F.H., 3rd and M.J. O'Brien, *The Subscapularis-Sparing Approach in Humeral Head Replacement.* Bull Hosp Jt Dis (2013), 2015. **73 Suppl 1**: p. S148-53.
136. Ladermann, A., et al., *Subscapularis- and deltoid-sparing vs traditional deltopectoral approach in reverse shoulder arthroplasty: a prospective case-control study.* J Orthop Surg Res, 2017. **12**(1): p. 112.
137. Ransom, E.F., et al., *Subscapularis sparing total shoulder arthroplasty through a superolateral approach: a radiographic study.* J Shoulder Elbow Surg, 2020. **29**(4): p. 814-820.
138. Garret, J., et al., *Midterm results of pyrocarbon interposition shoulder arthroplasty: good outcomes after posttraumatic osteonecrosis without malunion of the tuberosities.* JSES Int, 2022. **6**(5): p. 787-794.
139. Hirakawa, Y., et al., *Poor results after pyrocarbon interpositional shoulder arthroplasty.* J Shoulder Elbow Surg, 2021. **30**(10): p. 2361-2369.
140. Barret, H., et al., *Pyrocarbon interposition shoulder arthroplasty in young arthritic patients: a prospective observational study.* J Shoulder Elbow Surg, 2020. **29**(1): p. e1-e10.
141. Garret, J., et al., *Pyrocarbon interposition shoulder arthroplasty: preliminary results from a prospective multicenter study at 2 years of follow-up.* J Shoulder Elbow Surg, 2017. **26**(7): p. 1143-1151.
142. Meftah, M., et al., *Long-term performance of ceramic and metal femoral heads on conventional polyethylene in young and active patients: a matched-pair analysis.* J Bone Joint Surg Am, 2013. **95**(13): p. 1193-7.
143. Bell, S.N. and J.A. Coghlan, *Short stem shoulder replacement.* Int J Shoulder Surg, 2014. **8**(3): p. 72-5.
144. Gomoll, A., T. Wanich, and A. Bellare, *J-integral fracture toughness and tearing modulus measurement of radiation cross-linked UHMWPE.* J Orthop Res, 2002. **20**(6): p. 1152-6.
145. Noyes, M.P., B. Meccia, and E.E. Spencer, Jr., *Five- to ten-year follow-up with a partially cemented all-polyethylene bone-ingrowth glenoid component.* J Shoulder Elbow Surg, 2015. **24**(9): p. 1458-62.
146. Haider, H., et al., *Does vitamin E-stabilized ultrahigh-molecular-weight polyethylene address concerns of cross-linked polyethylene in total knee arthroplasty?* J Arthroplasty, 2012. **27**(3): p. 461-9.
147. Ozdag, Y., et al., *Arthroscopic Removal of the Polyethylene Glenoid Component After Total Shoulder Arthroplasty: A Systematic Review.* J Shoulder Elb Arthroplast, 2022. **6**: p. 24715492221142967.
148. Brochin, R., et al., *Trends in Periprosthetic Knee Infection and Associated Costs: A Population-Based Study Using National Data.* J Knee Surg, 2021. **34**(10): p. 1110-1119.

149. Walch, G., et al., *Patterns of loosening of polyethylene keeled glenoid components after shoulder arthroplasty for primary osteoarthritis: results of a multicenter study with more than five years of follow-up.* J Bone Joint Surg Am, 2012. **94**(2): p. 145-50.
150. Bonnevialle, N., et al., *Aseptic glenoid loosening or failure in total shoulder arthroplasty: revision with glenoid reimplantation.* J Shoulder Elbow Surg, 2013. **22**(6): p. 745-51.
151. Stephens, S.P., E.E. Spencer, and M.A. Wirth, *Radiographic results of augmented all-polyethylene glenoids in the presence of posterior glenoid bone loss during total shoulder arthroplasty.* J Shoulder Elbow Surg, 2017. **26**(5): p. 798-803.
152. Moineau, G., et al., *Three-dimensional measurement method of arthritic glenoid cavity morphology: feasibility and reproducibility.* Orthop Traumatol Surg Res, 2012. **98**(6 Suppl): p. S139-45.
153. Walch, G., et al., *Three-dimensional assessment of the dimensions of the osteoarthritic glenoid.* Bone Joint J, 2013. **95-B**(10): p. 1377-82.
154. Walch, G., et al., *Three-dimensional planning and use of patient-specific guides improve glenoid component position: an in vitro study.* J Shoulder Elbow Surg, 2015. **24**(2): p. 302-9.