Treatment reality of tension band wiring and locked plate fixation of the olecranon – analysis of complications, risk profiles and trends

Short Study Protocol

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1. Background of the Study

The incidence of the olecranon fracture (OF) in adults is around 12 per 100,000 inhabitants per year.[1] The anatomical shape of the proximal ulna is largely responsible for the stabilization of the humeroulnar joint and reconstruction is therefore obligatory, but often challenging. Surgical treatment of the olecranon fracture is performed using tension band wiring (TBW) or locking plate fixation (LPF) osteosynthesis. It is not yet clear, which procedure is superior for a specific patient. In future, an individualized and objectified assessment of expected general and fracture-specific complications should enable the treatment to be individually adapted to the patient's risk profile. This shall prevent complications, unnecessary treatments, and treatment costs. In the project presented here, the reality of care for surgically treated patients with olecranon fractures will be analyzed using routine data collected by the BARMER health insurance fund.

The aim of the study is to analyze differences in the outcome of patients with an olecranon fracture treated with TBW compared to LPF and to identify independent risk factors for unfavorable course.

2. Population

The German reimbursement system governs the remuneration of health care services subject to encoded diagnoses (International Statistical Classification of Diseases, German Modification; ICD-10 GM) and procedures (German procedure classification – *Operationen- und Prozedurenschluessel*; OPS) by means of the 'German Diagnosis Related Groups' taxonomy (GDRG). This obligatory documentation and accounting system is specified and further regulated in detail by mandatory coding instructions.

The database consists of retrospective health claims data of the German BARMER health insurance company. This includes anonymized data from following sectors:

- Inpatient data (§301 SGB V): In addition to information on costs, duration of hospitalization and information about treating hospital, standardized information on diagnoses (coded according to ICD-10 GM) and procedures (coded according to OPS) are available.
- Outpatient data (§295 SGB V): In addition to information on costs, diagnoses (ICD-10 GM) and procedures (OPS).
- Pharmaceutical therapies (§300 SGB V): Information on medication (coded via ATC classification), as well as costs and DDD (Defined Daily Dose).

All adult patients with an age of 18 years and older with an inpatient treated OF (ICD S52.01) treated with LPF or TBW between 01/2011 and 09/2023 will be included to the evaluations. Patients were grouped by age (i.e. 18-44 years, 45 – 69 years, ≥ 70 years). Younger patients (<70 years) and older patients (≥ 70 years) will be analyzed in separate studies.

2.1. Treatment Groups

The patient population will be divided into four treatment groups based on the first treatment received.

Group 1: *Locking Plate fixation for simple fractured OFs (sLPF)*
Patients allocated to this treatment group received a locking plate fixation after the first coded diagnosis of simple fractured OF.

Group 2: *Locking Plate fixation for multi-fragmented OFs (LPF)*
Patients allocated to this treatment group received a locking plate fixation after the first coded diagnosis of multi-fragmented OF.

Group 3: *Tension band wiring for simple fractured OFs (sTBW)*
Patients allocated to this treatment group received a tension band wiring fixation after the first coded diagnosis of simple fractured OF.

Group 4: *Tension band wiring for multi-fragmented OFs (TBW)*
Patients allocated to this treatment group received a tension band wiring fixation after the first coded diagnosis of multi-fragmented OF.

If TBW and LPF were coded at the same day and side, patients will be allocated to the LPF groups.

2.2. Inclusion and Exclusion Criteria

Within an index period from 01/2011 to 09/2023 all patients will be included, who met all inclusion criteria and no exclusion criterion (see table 1).

Inclusion Criteria
Inpatient coded diagnosis of olecranon fracture (ICD S52.01)
Exclusion Criteria
Incomplete basic information
Incomplete insurance status within two years before index
Previous treatment of olecranon fracture
Unclear treatment of olecranon fracture (other as variable and code from table 2)
Age < 18 years
Coded polytrauma
Bone tumors/ bone metastasis
Both sides injured or missing information of surgery side

Table 1: Inclusion and exclusion criteria.

The first hospitalization within the index period with coded diagnosis for OF (S52.01 main and secondary diagnosis) and at least one coded surgical treatment using TBW (OPS 5-793.27, 5-794.17) or LPF (OPS 5-793.k7, 5-794.k7) will be defined as the index case. In addition, all overlapping cases without time delay (admission date new case = discharge cases with surgery) will be defined as one case-series and will be included in the index case.

3. Endpoints and Variables

3.1. Variables

The following table lists all variables relevant to the analysis along with their ICD, OPS or ATC codes. For each patient, possible comorbidities will be recorded at baseline by including all outpatient and inpatient information coded within two years prior to the index hospitalization and during first hospitalization (exceptions are marked accordingly).

The "minor outpatient complications" defined below (see the last row of the following table) will be based exclusively on outpatient information coded after discharge of the first hospitalization.

All other variables concerning complications during follow-up will be collected exclusively from inpatient information during hospitalization and after discharge.

Variable	Classification	Code
Olecranon fracture	ICD	**S52.01**
Simple fracture TBW	OPS	**5-793.27**
Multi-fragmented TBW	OPS	**5-794.17**
Simple fracture LPF	OPS	**5-793.k7**
Multi-fragmented LPF	OPS	**5-794.k7**
Comorbidities at Baseline		
Alcohol abuses	ICD	**E**24.4, **F**10, **G**31.2, G62.1, G72.1, **I**42.6, **K**29.2, K70, K85.2, K86.0, **T**51.0, T51.9
Arthrosis	ICD	**M**15-**M**19 (only before index admission)
Atherosclerosis	ICD	**I**70
Atrial fibrillation and flutter	ICD	**I**48
Asthma		**J**45
Bone tumor/metastasis	ICD	**C**40.0, C79.5, C79.86, C79.9
Cancer	ICD	**C**
Chronic kidney disease	ICD	**N**18, N19
Chronic polyarthritis	ICD	**M**05, M06
Congestive heart failure	ICD	**I**50
Coronary heart disease	ICD	**I**25
Dementia	ICD	**F**00, F01, F02, F05.1, **G**30, G31.1
Depressive episode	ICD	**F**32, F33
Diabetes mellitus	ICD	**E**10-E14
Dorsalgia	ICD	**M**54
Hypertension	ICD	**I**10-I15
Infection	ICD	**M**86.02, M86.12, M86.22, M86.32, M86.42, M86.52, M86.62, M86.82, M86.92, **T**84.5, T84.6, T84.7 (only before index admission)
Neurotic, stress-related and somatoform disorders	ICD	**F**41, F43, F45
Nicotine abuses	ICD	**F**17
Obesity	ICD	**E**66
Osteoporosis	ICD	**M**80-M85
Parkinson	ICD	**G**20
Polytrauma	ICD, OPS, DRG	ICD: **T**07, OPS: **5-982**, or coded DRG started with “W” (only during index hospitalization)
Elbow arthrosis	ICD	**M**25.52 (only before index admission)
Previous stroke	ICD	**I**60-I69 (only before index admission)
Prior level of care (LoC)		Level of care in the database (from 2017)
Problems related to care-provider dependency	ICD	**Z**74

Pharmaceutical therapy		
Any anticoagulant	ATC	B01AA, B01AB, B01AC, B01AE, B01AF, B01AX
Vitamin D or calcium	ATC	A11CC
Bisphosphonates	ATC	M05BA, M05BB
Any osteoporosis pharmacotherapy	ATC	Vitamin D/Calcium or Bisphosphonates
Contraceptives for topical use	ATC	G02B (only for matching)
Hormonal contraceptives for systemic use	ATC	G03A (only for matching)
General Complications		
Acute liver failure	ICD	**K**72.0, K72.7, K72.9
Acute myocardial infarction	ICD	**I**21, I22
Acute renal failure	ICD	**N**17
Acute respiratory distress syndrome	ICD	**J**80
Cardiac arrest	ICD	**I**46
Deep vein thrombosis	ICD	**I**80.1, I80.2, I82.2, I82.3
Delirium	ICD	**F**05
Pulmonary embolism	ICD	**I**26
Sepsis	ICD	**A**41, A40, **B**37.7, **R**65.0, R65.1, R65.9, R57.2
Stroke	ICD	**I**60-I64
Ischemic stroke	ICD	**I**63-I64
Resuscitation	OPS	8-77 (also defined as complication, if it happens on the same day as surgery)
Intensive care	OPS	8-980, 8-98f (only during hospital stay)
Blood transfusion	OPS	8-800.0, 8-800.1, 8-800.c (only during hospital stay)
Surgical complications (at least one day after surgery)		
Conversion to TBW	OPS	**5-793**.27, **5-794**.17
Conversion to LPF	OPS	**5-794**.k7, **5-793**.k7
Endoprosthetic joint and bone replacement	OPS	**5-824**.40, 5-824.41, 5-824.50, 5-824.51, 5-824.52
Conversion to other fracture fixation	OPS	**5-790.**07**,** 5-790.17, 5-790.27, 5-790.37, 5-790.47, 5-790.57, 5-790.67, 5-790.97, 5-790.d7, 5-790.k7, 5-790.m7, 5-790.n7, 5-790.p7, 5-790.x7, **5-793.**17, 5-793.37, 5-793.67, 5-793.77, 5-793.87, 5-793.97, 5-793.a7, 5-793.b7, 5-793.c7, 5-793.g7, 5-793.h7, 5-793.m7, 5-793.n7, 5-793.x7, **5-794.**07, 5-794.27, 5-794.57, 5-794.67, 5-794.77, 5-794.87, 5-794.a7, 5-794.b7, 5-794.c7, 5-794.g7, 5-794.m7, 5-794.n7, 5-794.x7
Conversion, any	OPS	Any conversion as defined above
Upper limb amputation, ipsilateral (exarticulation elbow or forearm)	OPS	**5-862**.2, 5-862.3, 5-862.4
Bursitis	ICD	**M**70.2, M70.3 (only during hospital stay)
Compartment syndrome	ICD	**S**51.86 (only during hospital stay)

Consequences of injury of the upper extremity	ICD	**T**92.1 (only during hospital stay)
Haematoma after surgery	ICD	**T**81.0 (only during hospital stay)
Implant dislocation	ICD	**T**84.11 (only during hospital stay)
Mechanical malfunction or material failure/loosening	ICD	**T**85.88, T85.9 (only during hospital stay)
Peri-prosthetic or peri-implant fracture	ICD	**M**96.6, T84.11 (only during hospital stay)
Surgical incidents	ICD	**Y**69, Y82.8, Y84.9 (only during hospital stay)
Delayed union (if coded within six months)	OPS	**5-781**.a7, **5-782**.17, 5-782.27, 5-782.37, 5-782.47, 5-782.57, 5-782.a7, 5-782.b7, 5-782.x7, **5-784**.07, 5-784.17, 5-784.27, 5-784.37, 5-784.47, 5-784.77, 5-784.87, 5-784.b7, 5-784.c7, 5-784.d7, 5-784.e7, 5-784.f7, 5-784.x7
Infection	ICD	**T**84.5, T84.6, T84.7, **M**86.02, M86.12, M86.22, M86.32, M86.42, M86.52, M86.62, M86.82, M86.92 (only during hospital stay)
	OPS	**5-780**.47, 5-780.57, 5-780.67, 5-780.77, 5-780.87, 5-780.97, **5-785**.17, 5-785.57, 5-785.77, **5-800**.24, 5-800.25, 5-800.34, 5-800.35, 5-800.a4, 5-800.a5, 5-800.b4, 5-800.b5, **5-810**.14, 5-810.15, 5-810.74, 5-810.75, 5-810.84, 5-810.85, **5-850**.h2, 5-850.j2, **5-892**.37, 5-892.47, **5-896**.27, **8-989**, 8-989.0, 8-989.1, 8-989.2, 8-989.3, 8-989.4, 8-989.5, 8-989.6
Infection, resistant	ICD	**U**80-83 (only during hospital stay)
	OPS	**8-987**
Joint damage / cartilage damage	OPS	**5-780**.37, **5-784**.57, 5-784.67, **5-800**.84, 5-800.85, **5-810**.44, 5-810.45, **5-812**.04, 5-812.05, 5-812.34, 5-812.35, 5-812.94, 5-812.95, 5-812.a4, 5-812.a5, 5-812.e4, 5-812.e5, 5-812.f4, 5-812.f5, 5-812.g4, 5-812.g5, 5-812.h4, 5-812.h5, 5-812.k4, 5-812.k5, 5-812.m4, 5-812.m5
Luxation	OPS	**8-201**.4, 8-201.5 (also including outpatient sector after discharge)
Malunion	OPS	**5-781**.07, 5-781.17, 5-781.27, 5-781.37, 5-781.47, 5-781.57, 5-781.67, 5-781.77, 5-781.87, 5-781.97
Nerve injury	OPS	**5-040**.1, 5-040.2, 5-040.3, **5-041**.1, 5-041.2, 5-041.3, **5-044**.1, 5-044.2, 5-044.3, **5-045**.1, 5-045.2, 5-045.3, **5-046**.1, 5-046.2, 5-046.3, **5-047**.1, 5-047.2, 5-047.3, **5-048**.1, 5-048.2, 5-048.3, **5-049**.1, 5-049.2, 5-049.3, **5-04b**.1, 5-04b.2, 5-04b.3, **5-050**.1, 5-050.2, 5-050.3, **5-051**.1, 5-051.2, 5-051.3, **5-052**.1, 5-052.2, 5-052.3, **5-053**.1, 5-053.2, 5-053.3, **5-054**.1, 5-054.2, 5-054.3, **5-055**.1, 5-055.2, 5-055.3, **5-056**.1, 5-056.2, 5-056.3, **5-057**.1, 5-057.2, 5-057.3 (only during hospital stay)
Non-union / Pseudoarthrosis (if coded after six months)	OPS	**5-781**.a7, **5-782**.17, 5-782.27, 5-782.37, 5-782.47, 5-782.57, 5-782.a7, 5-782.b7, **5-784**.07, 5-784.17, 5-784.27, 5-784.37, 5-784.47, 5-784.77, 5-784.87, 5-784.b7
Osteonecrosis	ICD	**M**87.22, M87.32, M87.82, M87.92
Postoperative stiffness, Adhesive capsulitis, Frozen elbow	OPS	**5-800**.64, 5-800.65, 5-800.c4, 5-800.c5, **5-810**.24, 5-810.25, 5-810.94, 5-810.95

Vascular injury	OPS	**5-388**.12, **5-395**.12, **5-397**.12 (only during hospital stay)
Secondary surgery, open (LPF and TBW)	OPS	**5-780**.07, 5-780.17, 5-780.27, 5-780.37, 5-780.67, 5-780.x7, **5-782**.17, 5-782.27, 5-782.37, 5-782.47, 5-782.57, 5-782.a7, **5-784**.07, 5-784.17, 5-784.27, 5-784.37, 5-784.47, 5-784.57, 5-784.67, 5-784.77, 5-784.87, 5-784.a7, 5-784.b7, **5-785**.07, 5-785.17, 5-785.27, 5-785.37, 5-785.47, 5-785.57, 5-785.67, 5-785.77, **5-789**.b7, 5-789.c7, **5-794**.07, 5-794.27, 5-794.57, 5-794.67, 5-794.77, 5-794.87, **5-800**.14, 5-800.15, 5-800.34, 5-800.35, 5-800.44, 5-800.45, 5-800.54, 5-800.55, 5-800.74, 5-800.75, 5-800.84, 5-800.85, 5-800.94, 5-800.95, 5-800.x4, 5-800.x5, **5-801**.04, 5-801.05, 5-801.34, 5-801.35, 5-801.44, 5-801.45, 5-801.b4, 5-801.b5, 5-801.c4, 5-801.c5, 5-801.g4, 5-801.g5, 5-801.h4, 5-801.h5, 5-801.k4, 5-801.k5, 5-801.m4, 5-801.m5, 5-801.n4, 5-801.n5, 5-801.p4, 5-801.p5, **5-850**.02, 5-850.12, 5-850.22, 5-850.32, 5-850.42, 5-850.52, 5-850.62, 5-850.72, 5-850.82, 5-850.92, 5-850.a2, 5-850.b2, 5-850.c2, 5-850.d2, 5-850.e2, 5-850.f2, 5-850.g2, 5-850.h2, 5-850.j2, **5-851**.12, 5-851.22, 5-851.32, 5-851.42, 5-851.52, 5-851.62, 5-851.72, 5-851.82, 5-851.92, 5-851.a2, 5-851.b2, 5-851.c2, 5-851.d2, **5-852**.02, 5-852.12, 5-852.22, 5-852.32, 5-852.42, 5-852.52, 5-852.62, 5-852.72, 5-852.82, 5-852.92, 5-852.a2, 5-852.b2, 5-852.c2, 5-852.d2, 5-852.h2, 5-852.j2, **5-853**.02, 5-853.12, 5-853.22, 5-853.32, 5-853.42, 5-853.52, 5-853.62, 5-853.72, 5-853.82, 5-853.92, 5-853.x2, **5-855**.02, 5-855.12, 5-855.22, 5-855.32, 5-855.42, 5-855.52, 5-855.62, 5-855.72, 5-855.82, 5-855.92, 5-855.a2, 5-855.b2, **5-859**.02, 5-859.12, **5-862**.2, 5-862.3, 5-862.4, **5-892**.07, 5-892.17, 5-892.27, 5-892.37, 5-892.47, **5-896**.07, 5-896.17, 5-896.27
Secondary arthroscopy (LPF and TBW)	OPS	**5-782**.b7, **5-784**.c7, 5-784.d7, 5-784.e7, 5-784.f7, **5-810**.04, 5-810.05, 5-810.14, 5-810.15, 5-810.24, 5-810.25, 5-810.44, 5-810.45, 5-810.54, 5-810.55, 5-810.64, 5-810.65, 5-810.74, 5-810.75, 5-810.84, 5-810.85, 5-810.94, 5-810.95, 5-810.x4, 5-810.x5, **5-811**.24, 5-811.25, 5-811.34, 5-811.35, 5-811.44, 5-811.45, 5-811.x4, 5-811.x5, **5-812**.04, 5-812.05, 5-812.34, 5-812.35, 5-812.94, 5-812.95, 5-812.a4, 5-812.a5, 5-812.e4, 5-812.e5, 5-812.f4, 5-812.f5, 5-812.g4, 5-812.g5, 5-812.h4, 5-812.h5, 5-812.k4, 5-812.k5, 5-812.m4, 5-812.m5, 5-812.x4, 5-812.x5, **5-819**.04, 5-819.05, 5-819.14, 5-819.15, 5-819.x4, 5-819.x5
Implant removal (LPF)	OPS	**5-787**.07, 5-787.17, 5-787.37, 5-787.67, 5-787.77, 5-787.g7, 5-787.k7, **5-810**.34, 5-810.35
Implant removal (TBW)	OPS	**5-787**.07, 5-787.17, 5-787.27, 5-787.67, 5-787.77, 5-787.g7, **5-810**.34, 5-810.35
Revision of the osteosynthesis (LPF and TBW)	OPS	**5-785**.07, 5-785.17, 5-785.27, 5-785.37, 5-785.47, 5-785.57, 5-785.67, 5-785.77, **5-789**.37, **5-78a**.07, 5-78a.17, 5-78a.27, 5-78a.57, 5-78a.67, 5-78a.77, 5-78a.87, 5-78a.97, 5-78a.c7, 5-78a.g7, 5-78a.k7, 5-78a.m7, 5-78a.n7, 5-78a.x7, **5-793**.07, 5-793.17, 5-793.27, 5-793.37, 5-793.67, 5-793.77, 5-793.87, 5-793.97, 5-793.a7, 5-793.b7, 5-793.c7, 5-793.g7, 5-793.h7,

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Resection arthroplasty (for spacer placement)	OPS	**5-829**.4
Secondary arthroplasty	OPS	**5-824**.4, 5-824.5
Arthrolysis	OPS	**5-800**.64, 5-800.65, **5-810**.24, 5-810.25, 5-810.94, 5-810.95
Classification of complications and long-term endpoints/events		
Major adverse event		resuscitation, cardiac arrest, myocardial infarction, stroke, acute renal failure, acute liver failure, acute respiratory distress syndrome, sepsis or death from any case
Thromboembolic event		Deep vein thrombosis, pulmonary embolism, ischemic stroke or death from any case
Surgical complications		Adhesive capsulitis, arthrolysis, debridement, frozen elbow, implant removal within first 3 months, infection, infection with antibiotic-resistant germs, joint damage/cartilage damage, luxation, delayed union, non-union/ pseudoarthrosis, malunion, nerve injury, vascular injury, osteonecrosis, postoperative stiffness, secondary arthroplasty, secondary arthroscopy, secondary surgery (open) including revision surgery, upper limb amputation
Implant-associated complications (IAC)		Impingement, bursitis, mechanical malfunction or material failure/loosening, periprosthetic or periimplant fracture
Non-implant associated complications (non-IAC)		Infection, infection with antibiotic-resistant germs, hematoma after surgery
Minor outpatient complications (LPF and TBW) [1]	ICD	**G**56.1, G56.2, G56.3, **I**80.80, I80.81, **M**00.02, M00.12, M00.22, M00.82, M00.92, M13.12, M13.82, M13.92, M19.12, M19.22, M19.82, M19.92, M24.02, M24.12, M24.22, M24.32, M24.42, M24.52, M24.62, M24.82, M24.92, M25.12, M25.22, M25.32, M25.42, M25.52, M25.62, M25.72, M25.82, M25.92, M61.02, M61.12, M61.22, M61.42, M61.52, M61.92, M62.02, M62.12, M62.22, M62.32, M62.42, M62.52, M62.62, M62.82, M62.92, M65.02, M65.12, M65.22, M65.82, M65.92, M84.02, M84.22, M84.32, M84.82, M84.92, M86.12, M86.22, M86.32, M86.42, M86.62, M86.82, M86.92, M87.22, M87.32, M87.82, M87.92, M89.52, M96.6, **T**79.60, T81.4, T84.01, T84.11, T84.5, T84.6, T84.7
	OPS	All outpatient codes OPS for LPF or TBW coded collected above

Table 2: Definition of all variables

[1] Data collection exclusively based on outpatient information coded after discharge.

3.2. Endpoints

The following two sub-chapters list the primary and secondary endpoints to be analyzed together with their definition. For more information, as well as underlying ICP, OPS and ATC codes, see Chapter 3.1.

3.2.1. Primary Endpoints

Variable	Definition
Revision	- Time from surgery to revision defined above.
Implant removal (only)	- Time from surgery to implant removal - Within first 3 months after surgery, an implant removal will also considered as a surgical complication - No SC is allowed to occur within 3 months and on the same day
Surgical complications (SC)	- Time from surgery of OF to surgical complications, with death being considered as a competing risk event.
In-hospital SC rate (IH-SC)	- SC after surgery during index hospitalization (yes/no)
In-hospital implant–associated complications (IH-IAC)	- IAC after surgery during index hospitalization
In-hospital non-implant associated complications (IH-non-IAC)	- Non-IAC after surgery during index hospitalization

Table 3: Primary endpoints

3.2.2. Secondary Endpoints

Overall survival (OS)	- Time from surgery to death of any cause. - Death will be determined using the coded death as the reason for withdrawal in the BARMER database. In addition, all inpatient cases will be reviewed during follow-up, to determine whether death was reported as the reason for discharge.
30-day mortality	- Death from any cause within first day after surgery (yes/no) - All patients with shorter follow-up time are excluded
Major adverse events (MAE)	- Time from surgery to resuscitation, cardiac arrest, myocardial infarction, stroke, acute renal failure, acute liver failure, acute respiratory distress syndrome, sepsis or death from any case.
In-hospital MAE rate (IH-MAE)	- MAE during index hospitalization (yes/no)

Thromboembolic events or death (TE)	- Time from surgery to a thromboembolic event or death of any cause.
In-hospital TE rate (IH-TE)	- TE during index hospitalization (yes/no)
In-hospital death	- Death during index hospitalization (yes/no) - Counted, when death was reported as the reason for discharge.
Minor outpatient complications (MOC)	- Time from discharge to minor outpatient complications, with death being considered as a competing risk event.
Length of hospital stay (LOS) during index	- Days of hospitalization (from admission to last discharge with index case series).
Charges during index	- Sum of charges of all cases of the index case series
Treatment trends during study period	- Distribution of treatment variants per year

Table 4: Secondary Endpoints

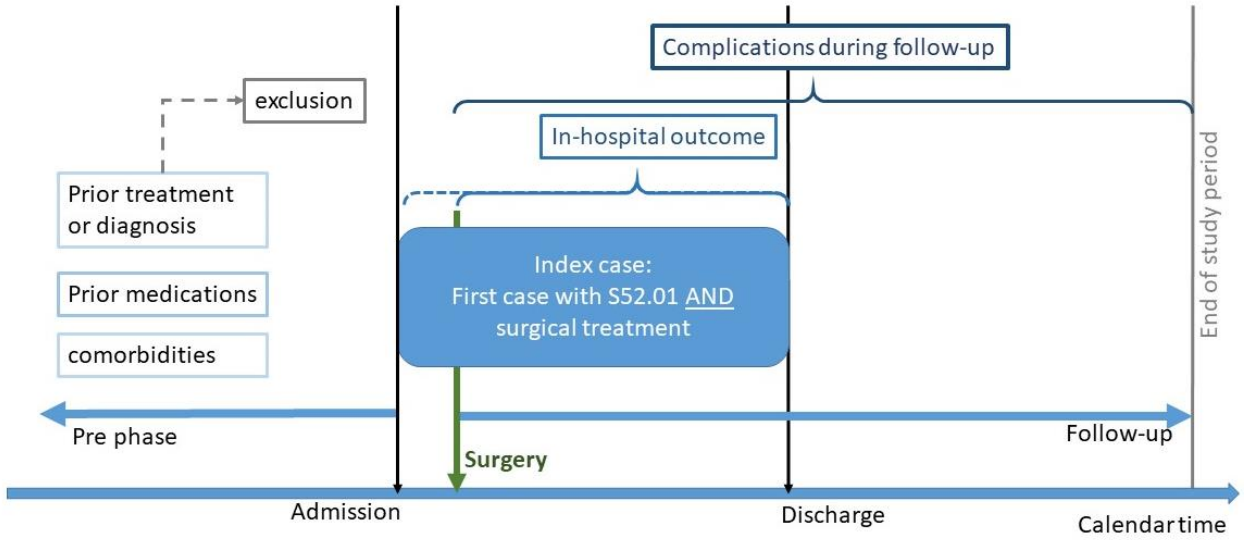

Figure 1: chronological scheme of the study including time ranges for complications

3.3. Possible sources of bias due to variable definition

In-hospital complications will be defined by the above reported codes that are coded in the same inpatient case as the surgery of OF (i.e. the index case series). For all OPS codes, the date has to be later in course of hospitalization than the surgery of OF (datum surgery with LPF/TBW < datum OPS code). ICD codes are all coded at the date of discharge and no chronological order within one case will be available. However, the defined complications are of such a serious nature that they always represent an unfavorable scenario from the patient's point of view, irrespective of the chronological course during hospitalization. It can also be assumed that, preoperatively, they did not represent a contraindication for surgery, if they were present before. Thus, it can be firstly assumed that complications predominantly occurred after surgery and, secondly, that any bias from (a few) events happens before surgery should be very low. In summary, all ICD codes for the above-mentioned complications that will be coded during the index case will be considered as in-hospital complications.

For all SC, only OPS ipsilateral coded procedures will be considered as complications. For ICD codes, no laterality will be available and thus, SC during follow-up will be mostly defined on OPS codes. For

osteonecrosis, however, it is therefore possible to wrongly count contralateral events as a complication which might add some bias, but both groups will be effected in the same manner.

4. Statistical Methods

4.1. Descriptive Statistics of Baseline Variables and Treatment trends

For descriptive analysis of treatment trends over time and baseline characteristics, the entire cohort will be used. For nominal and ordinal variables, the absolute and relative numbers will be calculated. All baseline parameter (see table 2 in chapter 3.1) will be reported for the entire cohort and grouped by treatment groups.

Time trends in the treatment of olecranon fractures using TBW vs LPF over study time will be presented as absolute and relative frequencies per year and possible trend will be tested via two-sided Cochran-Armitage trend test. Subgroup analyses, i.e. female/male patients or grouped by age, will be performed, if the data will be sufficiently large. All calculated p-values for time trends will be only calculated to illustrate the results and are in no way of a confirmatory nature. Therefore, the p-values in this part should be interpreted with caution.

4.2. Analysis of Primary and Secondary Endpoints

To analyze differences in the treatment groups (TBW versus LPF), a 1:1 propensity score (PS) matching will be performed to guarantee sufficient balance between them. Each patient treated with TBW will be matched with a patients treated with LPF, based on age, sex, fracture complexity, year of treatment, all clinical relevant comorbidities and pharmaceutical therapy at index hospitalization (listed in table 2 “Comorbidities at Baseline” and “Pharmaceutical therapy”). Analysis set will defined by all patients included in the matching.

The balance will be evaluated using risk differences, z-differences and sum of squared z-differences (SSQZ) and will be reported for all variables before and after matching. The hyper-parameter (i.e. caliper with, distance for continuous variables, factors with exact matching) of the PS matching will be chosen in such way that the sum of squared z-differences (SSQZ) will be minimized around the number of variables included in the matching procedure (k), i.e.

$$k/2 \leq SSQZ \approx k.$$

Overlap between matching groups will be presented by the histogram of *logit(p_s)*. The dependency of the Matching partners and thus a stratified evaluation will not be considered.

In-hospital complications and 30-days mortality

All in-hospital endpoints as well as 30-day mortality are given by binary variables. Absolute and relative frequencies for both treatment group will be reported and differences between them will be tested via two-sided χ^2-independence test. Moreover, a multivariable logistic regression model will be performed to adjust for patient’s risk profile. Odds ratio (OR) comparing TBW and LPF for all in-hospital complications and 30-day mortality will be illustrated using forest plots.

30-day mortality will be defined as primary endpoint instead of in-hospital death to avoid bias due to differences in the LOS of both treatment groups. Absolute and relative frequencies for in-hospital death will be reported for the sake of completeness; however, p-values for possible differences will not be interpreted in a confirmatory manner.

Complications during follow-up

The start of observation will be defined by the day of surgery. Median follow-up time will be determined for the entire analysis set using Kaplan Meier estimate (death as censored event).

For **OS, MAE and TE**, the Kaplan-Meier estimator will be determined for both groups and plotted for the survival functions along with unadjusted 95% confidence intervals (95%CI). Furthermore, at different time points (1 month, 3 months, 1-5 years), the event rates (1- survival function) will be reported with 95%CI and the total number of observed events per group. For the comparison of groups, the Log rank test will be conducted. Multivariable Cox regression models will analyze the impact of baseline variables on the endpoints. The resulting hazard ratios (HRs) will be presented along with its unadjusted 95% confidence intervals and illustrated in forest plots.

For **SC and minor outpatient complications**, death will be considered as a competing risk event. Hence, cumulative incidence function (CIF) determined by Aalen-Johansen estimate and sub-distributional hazards using Fine & Gray Cox models[2] will be calculated. Groups will be compared with Gray's test. All results were presented in an analog way explain above (plot of CIFs, reporting of CIF at different time points, forest plot for the HRs).

Multiple comparison problem

As mentioned above, patients were grouped by age (i.e. 18-44 years, 45 – 69 years, ≥ 70 years), where younger (<70 years) and older patients (≥ 70 years) will be analyzed (and published) in separate studies. To account for the multiple test problem in each study separately (<70 years and ≥ 70 years), all p-values comparing treatment-effects determined from multivariable analysis of all primary endpoint will be jointly adjusted using Bonferroni-Holm method[3] to control the family-wise error rate with respect to the multiple comparison problem. Adjusted p-values will be compared with the overall significance level of 5%.

Time-dependent analysis

Should the evaluation reveal an overlap of the survival curves approximated with Kaplan-Meier, we will further investigate these with a time-dependent survival analysis or landmark analysis with suitably chosen cut-off values. In addition, the time-dependent hazard ratio will be plotted in the form of a step function. All time-dependent analyses will be of an exploratory nature only.

4.3. Sensitivity analysis

As a sensitivity analysis, Cox regression analysis for OS, MAE, TE and SC as well as logistic regression analysis for 30-day mortality, IH-MAE, IH-TE and IH-SC will be also performed using the entire OF cohort with different weights:

Approach	Definition of weights	
	Control (LPF)	Treatment (TBW)
Entire cohort with original data*	1	1
Inverse Probability of Treatment Weighting (IPTW)[4]	$\frac{1}{1-p_s}$	$\frac{1}{p_s}$
Balanced (or overlap) weighting[5]	p_s	$1-p_s$

PS weighting[6]	$\frac{\min(p_s, 1-p_s)}{1-p_s}$	$\frac{\min(p_s, 1-p_s)}{p_s}$

*Table 5: Weighting approaches for sensitivity analysis. *As a first analysis, regression analyses will be performed using the entire cohort without weights. [4,5,6] refer to the references. p_s propensity score determined using logistic regression.*

5. Treatment of Missing Values

Missing values or inconsistent data in sex, day of birth, exit date of database lead to exclusion from study. For all other variables, no missing data will occur in the study, since all variables will be defined by existing ICD/OPS or ATC codes. If no related code will be found, the according variable will be set to zero. Since the considered comorbidities are highly relevant for any imbursement, it is very unlikely that they are not coded in the database. However, there could be a bias by setting all the variables as known variables.

6. Software

All statistical analyses will be performed using SAS (SAS Enterprise Guide Version 8.3, SAS Institute Inc., Cary, NC, USA) and R version 4.2.1, R foundation, Vienna, Austria.

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