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Clockwise torque results in higher reoperation rates in left-sided femur fractures

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ABSTRACT

Purpose: Effects of clockwise torque rotation onto proximal femoral fracture fixation have been subject of ongoing debate: fixated right-sided trochanteric fractures seem more rotationally stable than left-sided fractures in the biomechanical setting, but this theoretical advantage has not been demonstrated in the clinical setting to date. The purpose of this study was to identify a difference in early reoperation rate between patients undergoing surgery for left- *versus* right-sided proximal femur fractures using cephalomedullary nailing (CMN).
Materials and methods: The American College of Surgeons National Surgical Quality Improvement Program was queried from 2016-2019 to identify patients aged 50 years and older undergoing CMN for a proximal femoral fracture. The primary outcome was any unplanned reoperation within 30 days following surgery. The difference was calculated using a Chi-square test, and observed power calculated using post-hoc power analysis.
Results: In total, of 20,122 patients undergoing CMN for proximal femoral fracture management, 1.8% (n=371) had to undergo an unplanned reoperation within 30 days after surgery. Overall, 208 (2.0%) were left-sided and 163 (1.7%) right-sided fractures ($p=0.052$, risk ratio [RR] 1.22, 95% confidence interval [CI] 1.00–1.50), odds ratio [OR] 1.23 (95%CI 1.00–1.51), power 49.2% ($\alpha=0.05$).
Conclusion: This study shows a higher risk of reoperation for left-sided compared to right-sided proximal femur fractures after CMN in a large sample size. Although results may be underpowered and statistically insignificant, this finding might substantiate the hypothesis that clockwise rotation during implant insertion and (post-operative) weightbearing may lead to higher reoperation rates.
Level of evidence: Therapeutic level II.

Introduction

In proximal femoral fractures, failure rates of the bone-implant construct after fixation has been reported up to 40% [1,2]. The effect of clockwise torque rotation on femoral neck and trochanteric fracture fixation has been a frequent topic of discussion in the orthopedic biomechanical and clinical studies, as well as interesting debates in morning meetings around the world: as right turns would favor fixation on the right side. In theory, clockwise torque rotation for right-sided trochanteric fractures with displaced detachment of the lesser trochanter (AO/OTA type 31-A2) leads to replacing effects for the detachment: in other words, on the right side, turning the femoral head lag screw to the right “docks” the latero-inferior aspect of the femoral neck in into the distal fragment (Fig. 1a). For the left side, the rotational

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torque during clockwise screw insertion and (postoperative) weight-bearing leads to opposite effects resulting in upward femoral neck displacement (i.e., pull-out of the screw), leading to biomechanically more unstable constructs [3–5]. Thus, on the left side, turning the lag screw right "flexes" the latero-inferior of the femoral neck aspect upward and away from the distal femoral fragment (Fig. 1b). Indeed, this theoretical biomechanical advantage for right sided fractures has been confirmed in biomechanical- and radio stereometric (RSA) studies: migration at the fracture site occurs continuously during the first four post-operative months [3–5]. This phenomenon even led to development of anti-clockwise torque femoral lag screws to take advantage of this supposed biomechanical advantage in rotational stability (Fig. 2).

However, evaluating patients in high quality prospective international databases, failed to show that clockwise torque rotation of a sliding hip screw (SHS) results in a statistically significant increase of implant failure in left-sided femoral neck fractures compared with right-sided femoral neck fractures [6]. It may be challenging to demonstrate a significant difference because of the relatively low incidence of biomechanical failures after SHS fixation for proximal femur fractures. Even a large sample size from an Orthopaedic Trauma perspective, with high quality detailed data of 1750 patients may lack statistical power in this clinical scenario [6]. Therefore, the observed findings may be underpowered as no post-hoc analyses have been carried out to identify statistical rigor. Thus, a small difference in biomechanical effects can only be demonstrated in absolute numbers, indicating a large sample size is mandatory.

Therefore, this study was set out to evaluate short term failure rates in a large cohort of 20,122 patients with trochanteric fractures. Since CMN also use a right-turning femoral neck screw, the same effects of the clockwise torque rotation as observed with the dynamic hip screw (DHS), may be expected for the CMN (Fig. 1) [4]. Higher failure rates of left CMN insertion could therefore be hypothesized. We therefore aim to identify the difference in reoperation rate between left- and right-sided proximal femur fractures undergoing CMN in a large sample size. Our alternative hypothesis is that there is a higher reoperation rate for left sided proximal femoral fractures compared to right sided proximal femoral fractures treated with a CMN, due to the clockwise rotation during implant insertion and (postoperative) weightbearing.

Materials and methods

The data was derived from the American College of Surgeons (ACS) and the American Academy of Orthopaedic Surgeons (AAOS) Targeted Hip Fracture File of the National Surgical Quality Improvement Program (NSQIP) database. This database is de-identified, and therefore it has been exempted from Institutional Review Board (IRB) approval.

Data source

We utilized the 2016 to 2019 American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) Participant Use Files and the joint ACS and American Association of Orthopaedic Surgeons (AAOS) Hip Fracture Procedure Targeted files. NSQIP is a large clinical database built on partial sampling that collects more than 150 variables (pre-, peri-, and post-operatively) up to 30 days following surgery of more than 700 US hospitals combined. The series undergoes routine auditing, which ensures high-quality data with reported inter-reviewer rate less than 2% [7]. The Hip Fracture Procedure Targeted Files includes additional factors that are disease and procedure specific for hip fracture patients. These files were queried to identify patients older than 50 years of age who underwent intramedullary nailing for proximal femur fracture management in 2016 up to and including 2019. Excluded were patients with a pathological fracture or with an unknown side of injury.

Primary outcome

The primary outcome was reoperation (defined as any unplanned reoperation hip fracture treatment related) within 30 days following operative treatment as defined by the ACS-NSQIP files.

Explanatory variables

Preoperative variables included age (years), gender (female/male), body mass index (BMI)(kg/m2), American Society of Anesthesiologist (ASA) class (I/II/III/IV), race (American Indian or Alaska Native / Asian / Black or African American / Native Hawaiian or Pacific Islander / White / Unknown), functional status (independent / partially or totally dependent), preoperative dementia as having cognitive impairment, dementia or predefined descriptors consistent with dementia documented by a nurse or doctor stated (yes/no), preoperative delirium assessed by the chart-based method (yes/no), preoperative bone protection medication prescription (yes/no), preoperative need of mobility aid, e.g. cane, walker, wheelchair, or scooter (yes/no), preoperative pressure sore (yes/no), medical co-management (no / yes, co-management throughout stay / yes, partial co-management during

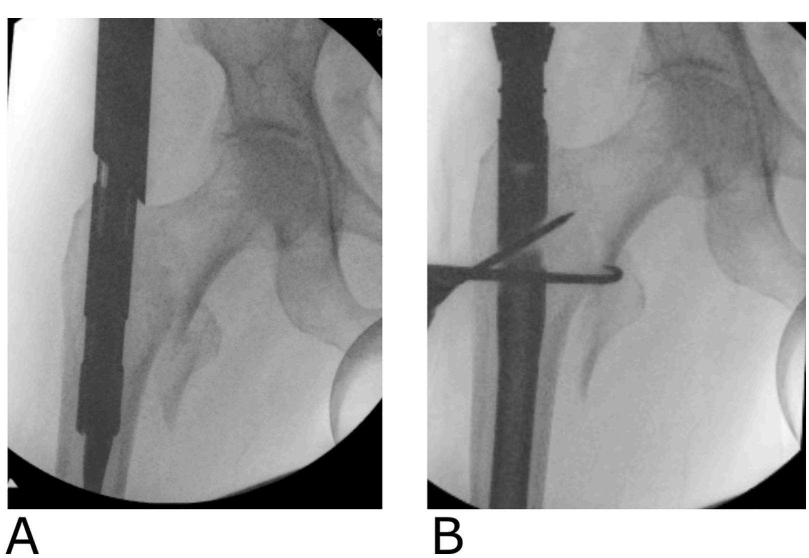

Fig. 1. AO/OTA type 31-A2 trochanteric fracture, displaced with detachment of lesser trochanter.

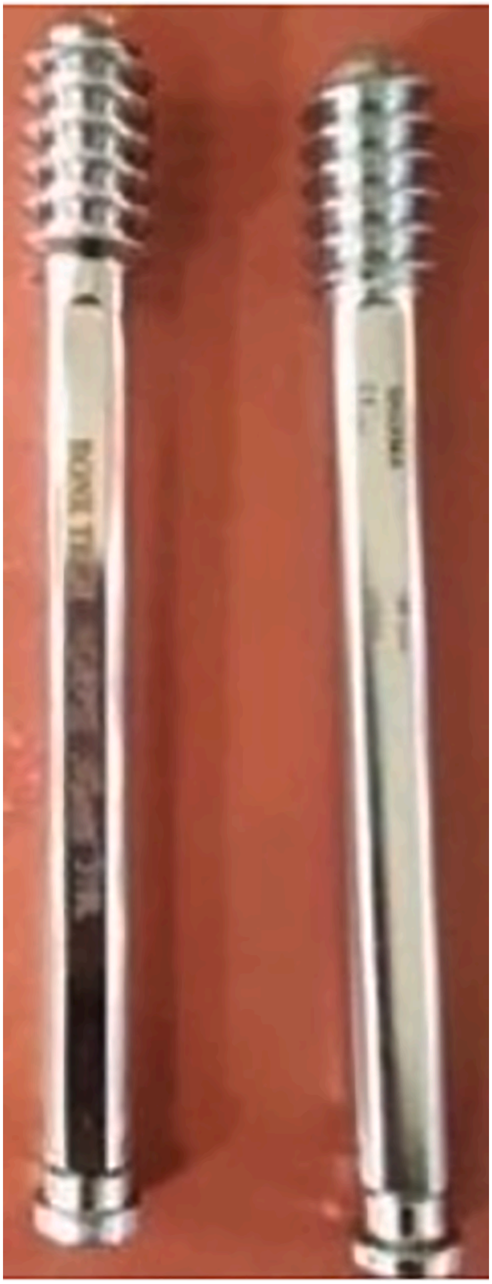

Fig. 2. Anti-clockwise and clockwise threaded screw.

stay), standardized hip fracture protocol (yes/no), diabetes (insulin dependent / non-insulin dependent / no), smoking (yes/no), dyspnea (at rest / moderate exertion / no), chronic obstructive pulmonary disorder (COPD) (yes/no), congestive heart failure (yes/no), hypertension requiring medication (yes/no), acute renal failure (yes/no), dialysis (yes/no), disseminated cancer (yes/no), wound infection (yes/no), preoperative steroid use (yes/no), weight loss >10% body weight in last 6 months (yes/no), bleeding disorder (yes/no), transfusion in 72 h prior surgery (yes/no), systemic sepsis within 48 h prior surgery (none/SIRS/sepsis/septic shock), sodium (mg/dL), creatinine (mg/dL), white blood cell ($x10^3$/uL) and hematocrit (%), platelet ($x10^3$/uL), fracture side (left / right), location of fracture (head and/or neck / intertrochanteric / subtrochanteric / shaft / unknown), displaced (yes / no / unknown) and reoperation.

Statistical analysis

Categorical variables will be described as absolute numbers with frequencies, and continuous variables as medians with interquartile ranges (IQR). The difference for the risk of reoperation for left-sided fractures versus right-sided fractures was calculated using a Chi-square test. We evaluated differences between location of fractures by performing sub analyses for only head and/or neck fractures, hand and/or neck + intertrochanteric fractures and all fractures. Associations with a p-value of <0.05 were considered significant. The relative risk (also known as Risk Ratio [RR]) and odds ratio (OR) with 95% confidence interval (CI) for risk of reoperation were calculated for left-sided fractures compared to right-sided fractures. In addition, the observed power of the findings were calculated using a post-hoc power analysis with alpha = 0.05 representing the statistical power.

Software

Data pre-processing and analysis were performed using R Version 5.3 (“R: A Language and Environment for Statistical Computing" The R Foundation, Vienna, Austria 2013) and R-studio Version 1.2.1335 (R-Studio, Boston, MA, USA).

Results

From the ACS-NSQIP 2016-2019, 966 patients with a pathological fracture were excluded for data analysis. In total, 20,122 patients had CMN for proximal femur fracture management met the inclusion criteria, of which 371 (1.8%) had to undergo an unplanned reoperation related to the earlier treatment of the hip fracture, within 30 days after surgery (Table 1).

Of the included patients, a small majority sustained a left-sided fracture (10,274 patients, 51.1%). The majority of fractures were located in the intertrochanteric region (15,858 patients, 78.8%), and of all patients the majority of fractures were classified as being displaced (15,724 patients, 78.1%). Most of the patients were 80 years or older (12,686 patients, 63%) and of all patients 70.6% were women. Patients were mainly classified as ASA class III (12,564 patients, 62.9%), followed by ASA class IV (4,220 patients, 21.0%) and ASA class II (3,091 patients, 15.4%). Regarding functional status, 77.6% of the patients were preoperatively independent, followed by 19.0% being partially dependent. In total, the majority of the patients had no need for use of mobility aid preoperatively (10,870 patients, 56.5%).

Missing data

Rates of missing data were as followed: BMI 2,211 (11.0%), ASA class 17 (0.01%), preoperative delirium 71 (0.4%), and preoperative need for mobility-aid 866 (4.3%). Of preoperative laboratory values the rates of missing data resulted: preoperative sodium 103 (0.5%), preoperative creatinine 113 (0.6%), white blood cell count 92 (0.5%), hematocrit 89 (0.4%) and platelet 133 (0.7%).

Findings

Overall, 371 patients (1.8%) had to undergo an unplanned reoperation hip fracture treatment related within 30 days, of which 208 (1.0%) were left-sided and 163 (0.8%) right-sided fractures (Table 2, $p = 0.05$). The risk of failure for a left-sided hip fracture was 23% higher compared a right-sided fracture (OR 1.23 95% CI: 1.00–1.51). A post-hoc power analysis was 49.2% ($\alpha = 0.05$). In displaced fractures a left-right difference was present, but did not reach statistical significance ($p = 0.09$) and showed a RR of 1.22 (95% CI 0.97–1.54) and an OR of 1.23 (95% CI 0.97–1.56) with observed power of 40.0%. In a sub analysis of intertrochanteric fractures with head and/or neck fractures also a difference was seen, more implant failures in left sided fractures with a neck

Table 1
Baseline characteristics of included patients, $n = 20{,}122$.

Variable	n (%) | median (IQR)
Age (years)	
50-59	779 (3.9)
60-69	2381 (11.8)
70-79	4276 (21.3)
80-89	7674(38.1)
90+	5012 (24.9)
Female sex	14199 (70.6)
Body mass index (kg/m^2)	24.36 (21.16-28.26)
ASA classification	
I	97 (0.5)
II	3091 (15.4)
III	12654 (62.9)
IV	4220 (21.0)
V	43 (0.2)
Race	
American Indian or Alaska Native	96 (0.4)
Asian	326 (1.6)
Black or African American	593 (3.0)
Native Hawaiian or Pacific Islander	13 (0.1)
White	14690 (73.0)
Unknown	4404 (21.9)
Functional status	
Independent	15618 (77.6)
Partially Dependent	3816 (19.0)
Totally Dependent	604 (3.0)
Unknown	84 (0.4)
Preoperative dementia	5782 (28.7)
Preoperative delirium	2537 (12.7)
Preoperative bone protective medication prescription	6414 (31.9)
Preoperative need for mobility aid	10870 (56.5)
Preoperative pressure sore	649 (3.2)
Medical co-management	
No	1774 (8.8)
Yes-co-management throughout stay	15455 (76.8)
Yes-partial co-management during stay	2893 (14.4)
Standardized hip fracture protocol	11123 (55.3)
Diabetes	
Insulin dependent	1675 (8.3)
Non-insulin dependent	2225 (11.1)
No	16222 (80.6)
Smoking	2449 (12.2)
Dyspnea	
At rest	198 (1.0)
Moderate exertion	1517 (7.5)
No	18407 (91.5)
Chronic obstructive pulmonary disorder	2312 (11.5)
Congestive heart failure	711 (3.5)
Hypertension requiring medication	13607 (67.6)
Acute renal failure	104 (0.5)
Dialysis	400 (2.0)
Disseminated cancer	281 (1.4)
Wound infection	752 (3.7)
Preoperative steroid use	1104 (5.5)
Weight loss >10% body weight in last 6 months	362 (1.8)
Bleeding disorder	3377 (16.8)
Transfusion	1037 (5.2)
Systemic inflammatory response syndrome (SIRS)	
None	18053 (89.7)
SIRS	1958 (9.7)
Sepsis	99 (0.5)
Septic shock	12 (0.01)
Sodium (mg/dL)	138.0 (136.0-140.0)
Creatinine (mg/dL)	0.88 (0.70-1.14)
White blood cell (x10^3/uL)	9.5 (7.6-11.9)
Hematocrit (%)	34.0 (30.1-38.0)
Platelet (x10^3/uL)	197 (157-243)
Fracture side	
Left	10274 (51.1)
Right	9848 (48.9)
Location of fracture	
Head and/or neck	1910 (9.5)
Intertrochanteric	15858 (78.8)
Subtrochanteric	1600 (8.0)
Shaft	153 (0.8)
Unknown	601 (3.0)
Displaced	
Yes	15724 (78.1)
No	1601 (8.0)
Unknown	2797 (13.9)
Reoperation	371 (1.8)

IQR = interquartile range; ASA = American Society of Anesthesiologists

fractures, (left sided 160 (2.0%) versus right sided 124 (1.6%), $p = 0.14$), RR 1.17 (95% CI 0.95–1.46). However differences between left and right were not significant in hip fractures without head and/or neck fractures ($p = 0.43$) RR 1.30 (95% CI 0.68–2.51), a post-hoc power analysis was low (31.2 and 12.1%).

Discussion

The aim of this study was to identify the difference in reoperation rates between left- and right-sided proximal femur fractures treated with a CMN in a large sample size. In a group of 20,122 patients, in total 371 (1.8%) had to undergo any unplanned reoperation within 30 days after surgery. A nearly significant (p = 0.052, with p-values ≤ 0.05 regarded as significant) higher risk of reoperation was found for left-sided proximal femur fractures.

The reoperation rate found in this study was 1.8% within the first 30 days after operation. Donavan *et* al. found slightly higher reoperation rates in the first postoperative month for internal fixation after femoral neck fractures in their retrospective cohort study (3.2%)" [16]. This difference may be explained by underrepresentation of reoperation rate because of the retrospective design of the ACS-NSQIP data registry. If reoperation rates were missed in the data registry, we assume that this would likely have occurred equally for both sides. Therefore, this would not have biased our results comparing left- and right-sided proximal femur fractures undergoing CMN. In the case of underrepresentation of reoperation rate, a higher actual rate may reveal more power to the findings, which could lean more towards statistical significant difference. At longer follow-up, higher reoperation rates of CMN were found varying between 20% and 40%, respectively after one and two years [1, 2]. Whether the latter can be attributed to pull-out of the hip screw is unlikely since a very low incidence of implant-fracture failure was found within the first days. Beyond this period also increasing stiffness across the fracture will occur due to bone healing. The latter will also diminish a potential effect of torsional torque at the fracture/implant site when walking, since the fracture is healed during the postoperative course. [15].

To the best of our knowledge this is one of the first studies evaluating the effect of torque direction on reoperation rates in left- and right sided hip fractures. Future efforts can further evaluate the biomechanical effect of anticlockwise torque. In addition, this is the first study carrying out a post-hoc power analysis to substantiate the hypothesis that clockwise torque rotation during implant insertion and (postoperative) weightbearing may lead to higher reoperation rates. The nearly significant ($p = 0.052$) difference in favor of right-sided proximal femur fractures reveals a power of 49.2% in our cohort of 20,122 patients. The RR and OR of reoperation rate in left-sided hips compared to right-sided hips was respectively 1.22 (95% CI 1.00–1.50) and 1.23 (95% CI 1.00–1.51). Left-sided fractures have a mean 22% higher risk of reoperation (ranging from none to 50%) compared to right-sided hip fractures. When the risk of reoperation is relatively rare, the OR is approximately equal to the RR (since the odds are approximately equal to the risk) and the interpretation of the OR is the same as that for the RR.

A post-hoc power analysis is carried out to estimate the retrospective power of an observed effect to detect a standardized mean difference (i.

Table 2
Risk of reoperation per location of the fracture, NSQIP 2016-2019.

	n	Reoperation, n (%) left	right	*p*-value	RR (95%CI)	OR (95%CI)	Observed power (α=0.05)
All	20,122	208 (1.0)	163 (0.8)	0.052	1.22 (1.00–1.50)	1.23 (1.00–1.51)	49.20%
Displaced	15,724	160 (1.0)	124 (0.8)	0.09	1.22 (0.97–1.54)	1.23 (0.97–1.56)	40.00%
Head and/or neck + intertrochanteric	17,768	183 (1.0)	148 (0.8)	0.14	1.17 (0.95–1.46)	1.18 (0.95–1.47)	31.20%
Head and/or neck	1,910	21 (1.1)	15 (0.8)	0.43	1.30 (0.68–2.51)	1.31 (0.67–2.56)	12.10%

n = number; % = percentage; CI = confidence interval; RR = risk ratio; OR = odds ratio

e., to detect a difference between two groups). If a study has inadequate power, it may not be able to detect a difference even though a true difference exists, which is called a type I error. As the sample size increases, the type I error will decrease. This means that the results found in this study (with a power of 49.2%) are underpowered and therefore we fail to reject or accept the null hypothesis, which could also be explained by underrepresentation of reoperation rate.

Our findings potentiate the clinical relevance of the theoretical biomechanical difference in rotational stability, with right-sided trochanteric fractures seem more rotationally stable than left-sided trochanteric fractures found in the radio stereometric analysis of Van Embden et al. [4]. Our findings are also in line with the results of Mohan et al. [3] who described that the clockwise torque during screw insertion may be responsible for potentially higher rates of unstable fixation in left-sided trochanteric fracture. This hypothesis could not be substantiated in a recently published study of Würdemann et al. [6], showing no association between fracture side and implant failure (OR of implant failure in left-sided hips compared with right-sided hips was 0.91 (95% CI 0.54–1.53, p = 0.72). However, these results are likely to be underpowered as no post-hoc analysis has been carried out. Also, multiple large randomized controlled trials investigating implant failure in femoral neck fractures did not mention fracture side as a confounding factor indicating biomechanical effects of clockwise rotation effect are not clinically relevant [9,10]. As stated earlier, the biomechanical effects of clockwise torque rotation can only be demonstrated in absolute numbers. In 20,211 patients, an almost significant higher risk of reoperation was shown for left sided fractures indicating the theoretical biomechanical advantage of right sided implants are clinically relevant. The biomechanical aspects of rotational stability in trochanteric fractures have been subject of debate for many years [11,12] and, as a result, anti-rotation screws are being studied for both sides in FNFs [13,14]. Although Mohan et al. [3] indicated that appropriate measures are indicated to reduce the torque for unstable left-sided fractures treated with a DHS, no study specifically examined the effects of anti-clockwise torque implants for left-sided hip fractures.

The results of this study should be viewed in light of several limitations. First, this was a retrospective study beholden to limitations inherent to the retrospective research design. Second, the data was derived from the NSQIP Targeted Hip Fracture database and results may not be generalized to the international population. The ACS-NSQIP database provides detailed clinical information on many patients from both academic and nonacademic hospitals, allowing analysis of broad cross-section of the American population. By nature of selection of participating ACS-NSQIP hospitals, data may be subject to selection bias. Third, data of implant failure was not documented; the exact reason for reoperation could therefore not be identified. Fourth, NSQIP collects data up to 30 days postoperatively and reoperation may occur beyond this timeframe [4,8]. In addition, it is also likely that some cases that would actually need a revision surgery are unable to receive them due to various reasons. Implant failure is more likely to occur when full weightbearing is allowed, where postoperative weightbearing is restricted. Other hip fracture registries record a longer follow-up, which may capture the reoperations occurring beyond the 30-day period, such as the Australian and New Zealand Hip Fracture Registry, Dutch Hip Fracture Audit or the Swedish Hip Fracture Register. Fifth, we were not able to capture the influence of screw characteristics related to occurrence of a reoperation. A proximal femoral nail mostly contains a helical blade which could be associated with different rates of failure compared to other hip nailing systems that contain a (lag) screw (e.g., gamma nail or intramedullary hip screw) [17,18]. Lastly, the NSQIP database is built on random partial sampling, which may fall short of providing data for complication, and could have led to underreporting of the reoperation rate. Future studies can aim to capture these by designing prospective databases with a longer follow-up and ideally more detailing in reasons for unplanned reoperations.

Conclusion

In summary, the results of this study show a higher risk of reoperation for left-sided compared to right-sided proximal femur fractures after CMN in a large sample size. This difference could be related to the clockwise screw insertion and (postoperative) weight bearing. However, considering the limitations of this study, we could not substantiate the hypothesis that clockwise rotation during implant insertion and (postoperative) weightbearing may lead to higher reoperation rates. Future research should focus on planning long-term follow-up studies identifying reoperation rates due to implant failure in left- and right-sided femur fractures in a large sample size. This may suggest that considering side-specific torque direction or implants that do not depend on insertion torque vectors can be considered in implant designs in the future.

Ethical review committee statement

The data was derived from the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) and the hospitals participating in the ACS-NSQIP herein. This database is de-identified, and therefore it has been exempted from Institutional Review Board (IRB) approval.

Declaration of Competing Interest

Each author certifies that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article. One of the authors (JO) certifies that she received, an amount less than USD 10,000 from the Marti-Keuning-Eckhardt Foundation.

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