

DISSERTATION

Special and standard acetabular liners in primary total hip arthroplasty. A mid-term observational study and survey with data of the German Arthroplasty Registry (EPRD).

Spezial- und Standard-Inlays in primärer Hüfttotalendoprothetik. Eine mittelfristige Beobachtungsstudie und Umfrage mit Daten des Endoprothesenregister Deutschland (EPRD).

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List of Abbreviations

n = number

p = *p*-value

KI = Konfidenzintervall

HR = Hazard Ratio

CI = confidence interval

SD = standard deviation

SHR = subhazard ratio

Abstract

Purpose. Surgeons use specially shaped acetabular liners in total hip arthroplasties to reduce mechanical complications, particularly dislocations. The performance of special liners in comparison to standard liners has not yet been evaluated with data from Germany. The aim was to investigate revision for mechanical complications comparing special and standard liners in primary total hip arthroplasty with data of the German Arthroplasty Registry (EPRD). The study was followed by a survey, which further explored the use of lipped liners in primary total hip arthroplasty – the most common special liner design in Germany.

Methods. EPRD data from November 2012 until November 2020 was analysed. Cumulative incidences and risks of revision for mechanical complications, comparing standard, lipped, offset, angulated-offset and angulated liners in primary elective cementless total hip arthroplasty, were calculated from a survival analysis and a multivariate Cox proportional-hazards model that was adjusted for patient- and prostheses-specific variables. The survey included 11 questions on the usage of lipped liners in primary total hip arthroplasty in Germany. Orthopaedic surgeons from all 789 clinics participating in the EPRD were eligible to complete the survey anonymously between 2 August 2022 and 15 October 2022.

Results. In total, 151,096 cases were included in the statistical analysis. Over the observed time span of eight years, 1.6% (n = 2,419) hips were revised for mechanical complications. Seven-year cumulative incidences of revision for mechanical complications were, compared with standard liners (0.022; 95% KI = 0.020, 0.025), higher for lipped (0.027; 95% CI = 0.023, 0.033; p = 0.004) and angulated-offset (0.051; 95% CI = 0.035, 0.071; p < 0.001) liners. The risk of revision for mechanical complications was not significantly different among standard, lipped, and angulated liners. Offset liners reduced (HR = 0.68; 95% CI = 0.50, 0.92); angulated-offset liners increased the risk (HR = 1.81; 95% CI = 1.38, 2.36). In total, 237 surveys were completed. The survey indicates that 12.2% (n = 29) of the surgeons regularly use lipped liners in primary total hip arthroplasty. Most surgeons position the lip of the liner in the posterior-superior quadrant.

Conclusion. Only offset liners were associated with a reduced risk of revision for mechanical complications. Angulated-offset liners increased the risk almost two-fold. Lipped liners were regularly used in some hospitals without reducing the risk of

mechanical complications in comparison to standard liners. A reason might be that surgeons mainly choose to position lipped liners in the biomechanical less optimal posterior-superior quadrant. The implantation of lipped liners with the elevated rim in the posterior-inferior quadrant is more effective to prevent posterior dislocation.

Zusammenfassung

Zielsetzung. Speziell geformte Pfanneninlays sollen mechanische Komplikationen von Hüfttotalendoprothesen, vor allem Dislokationen, reduzieren. Jedoch gibt es bisher noch keine Studie mit Daten aus Deutschland die Spezial- und Standard-Inlays miteinander vergleicht. Das Ziel war es, mit Daten des Endoprothesenregister Deutschland (EPRD), mechanische Komplikationen bei primären Hüfttotalendoprothesen mit Standard- und Spezial-Inlays zu untersuchen. In einer darauffolgenden Umfrage wurde das Nutzungsverhalten des in Deutschland am häufigsten verwendeten Spezial-Inlays, dem Lipped-Inlay, exploriert.

Methodik. Es wurden Daten des EPRD von November 2012 bis November 2020 analysiert. Primäre, elektive, zementfreie Hüfttotalendoprothesen mit Standard-, Lipped-, Offset-, Angulated- und Angulated-Offset-Inlays wurden hinsichtlich ihrer kumulativen Inzidenzen und ihres Risikos für eine Revision aufgrund von mechanischen Komplikationen miteinander verglichen. Dazu wurden eine Überlebenszeitanalyse und eine multivariate Cox-Regression durchgeführt; letztere unter Einbezug von patienten- und prothesenbezogener Variablen. Die Umfrage umfasste 11 Fragen zum Nutzungsverhalten von Lipped-Inlays in Deutschland. Orthopäden und Orthopädinnen aus allen 789 am EPRD teilnehmenden Kliniken konnten anonym zwischen dem 2. August 2022 und 15. Oktober 2022 an der Online-Umfrage teilnehmen.

Ergebnisse. 151.096 primäre, elektive, zementfreie Hüfttotalendoprothesen wurden in die statistische Auswertung eingeschlossen. Innerhalb des Beobachtungszeitraumes von acht Jahren wurden 1,6% (n = 2.419) der Hüftprothesen aufgrund von mechanischen Komplikationen revidiert. Die kumulative Inzidenz von Revisionen aufgrund von mechanischen Komplikationen war nach sieben Jahren im Vergleich zu Standard-Inlays (0,022; 95 % KI = 0,020-0,025) höher für Lipped- (0,027; 95 % KI = 0,023-0,033; p = 0,004) und Angulated-Offset-Inlays (0,051; 95 % KI = 0,035-0,071; p < 0,001). Das Risiko für eine Revision aufgrund von mechanischen Komplikationen unterschied sich nicht

signifikant für Standard-, Lipped- und Angulated-Inlays. Das Risiko war bei Verwendung von Offset-Inlays (HR = 0,68; 95 % KI = 0,50-0,92) reduziert, jedoch erhöht bei Angulated-Offset-Inlays (HR = 1,81; 95 % KI = 1,38-2,36). Insgesamt wurden 237 Fragebögen abgeschlossen. Es gaben 12,2 % (n = 29) der Befragten an Lipped-Inlays regelmäßig zu verwenden. Am häufigsten werden Lipped-Inlays in der posterior-superioren Position eingesetzt.

Schlussfolgerung. Nur Offset-Inlays waren mit einem reduzierten Risiko für eine Revision aufgrund von mechanischen Komplikationen assoziiert. Angulated-Offset-Inlays erhöhten das Risiko um fast das Doppelte. Lipped-Inlays werden in einzelnen Krankenhäusern regelhaft verwendet, ohne das Risiko für mechanische Komplikationen gegenüber Standard-Inlays zu reduzieren. Ursache ist möglicherweise die überwiegend gewählte, aber biomechanisch ungünstigere posterior-superiore Position der Überhöhung. Eine posterior-inferiore Position von Lipped-Inlays ist geeigneter, um einer posterioren Dislokation vorzubeugen.

1. Introduction

1.1 A Cure for the Painful Hip Joint

Osteoarthritis of the hip is as old as mankind itself (1). The first relief of this painful condition came with the inventions in the beginning of the 18th century. Early treatment approaches developed from joint excision and limb amputation to the interposition of animal tissue. Later, the ball and socket joint (Glück) and the mould arthroplasty (Smith-Petersen) were invented (2). In the mid-20th century, Sir John Charnley led the way towards modern hip replacement surgery. He introduced the “low friction arthroplasty” using a polytetrafluorethylene lining material and a small metal femoral head (3). Mendelsohn and Becker concluded in 1955: “[...] it is our strong clinical impression that this operation should be regarded as a procedure of last resort for carefully selected patients in the older-age group.” (4). Nowadays, hip arthroplasty is not only reserved as a last resort for older patients – it is also considered a safe and effective way to improve the quality of life of younger, and more active patients (5). Consequently, the longevity and excellent function of the artificial joint becomes increasingly important (6).

In 2014, complications of orthopaedic endoprotheses, implants and transplants accounted for 0.87% of all days spent in German hospitals (7). The most frequent reasons for revision hip arthroplasty are aseptic loosening (55.2%), followed by dislocation (11.8%), septic loosening (7.5%), and periprosthetic fractures (6%) (8). Moreover, instability is found to be the major reason for second revision arthroplasty (9).

To treat the unstable hip arthroplasty, Charnley introduced in 1972 a polyethylene cup with a long posterior wall (10). The idea was simple. The long posterior wall was supposed to be an additional barrier against dislocation of the femoral head. Nowadays, not only lipped liners, but several other specially shaped liner designs are available to enhance the stability of a hip arthroplasty. Today, on average, about 58% of the hip replacements last 25 years (11).

1.2 Biomechanics of the Hip Joint

Achieving optimal biomechanics of the hip joint is essential for a durable hip replacement. Body weight and hip abductor moment arms both act on the centre of rotation of the hip joint, resulting in a joint reaction force that keeps the pelvis at level. Displacement of the hip centre of rotation due to suboptimal position of the acetabular component is

associated with impaired range of motion, pain, impingement as well as increased occurrence of wear, loosening and dislocation (12). Insufficient tension of the soft tissues around the hip joint also leads to instability of the hip arthroplasty. Three dimensions need to be considered: the mediolateral (depth), the superior-inferior (height), and the angular position (inclination and anteversion) (13).

In theory, special liner designs can be used to modify the spatial orientation of the acetabular component. The offset liner modifies the mediolateral position as it lateralises the hip joint centre of rotation. The angulated liner changes the angular placement. If the angulated liner is oriented in the superior-inferior axis the abduction is changed. If the angulated liner is oriented in the anterior-posterior axis the version is changed. The angulated-offset liner modifies both the mediolateral depth and the angular placement. The lipped liner does not change the angular placement but adds an additional barrier to prevent dislocation of the prosthesis' head.

1.3 The Value of Arthroplasty Registries

With more and more implant designs available, institutions that oversee and evaluate the developments in hip replacement surgery became necessary. In 1979, the Swedish Hip Arthroplasty Registry – the first national hip arthroplasty registry – started to operate (14). Joint replacement registries enable the scientific and medical community to record large numbers of arthroplasties over an extended period of time to retrospectively study the performance of implants. Results may then guide surgeons and patients in finding the best implant options for their needs. The German Arthroplasty Registry (EPRD) was the first implant registry nationwide and was founded in 2010 as an initiative of the German Society of Orthopaedics and Orthopaedic Surgery (DGOOC). The EPRD operates a highly granular implant database which makes it possible to investigate detailed research questions.

1.4 Aims of Liner Study and Survey

Our aim was to analyse EPRD data from the start of the registry in November 2012 until November 2020 to investigate revision for mechanical complications and revision for any reason of primary elective cementless total hip arthroplasties with standard liners and four different special acetabular liner designs – lipped, offset, angulated and angulated-offset liners. We hypothesized, that there are differences in the cumulative incidence and in the risk of revision for mechanical complications and for any reason among the five

liner designs. In a second step, we planned to study the influence of patient- and prosthesis-related factors on the risk of revision for mechanical complications. In a third step, we intended to survey orthopaedic surgeons from clinics participating in the EPRD on the application of lipped liners, the most common special liner design in primary total hip arthroplasty.

2. Methods

2.1 Liner Study

EPRD data from November 2012 until November 2020 were analysed in a secondary data analysis. The EPRD holds a general vote of the ethics committee of the university of Kiel (D 473/11).

2.1.1 Methodology of the German Arthroplasty Registry (EPRD)

All hospitals participate voluntarily in the ERPD. Written informed consent is obtained from all patients. The EPRD incorporates three different data sources: (i) the two largest German public health funds *AOK-Bundesverband GbR* and *Verband der Ersatzkassen e.V.*, (ii) an implant library that is maintained by the *Bundesverband Medizintechnologie e.V.*, and (iii) the hospitals participating in the EPRD (Figure 1). A trust agency pseudonymises all data before entering the registry, using a unique lifelong patient identifier in accordance with the European General Data Protection Regulation. Currently, around 10% of patients in Germany are privately insured. Their data is not included in the registry as longitudinal follow-up of privately insured patients does not conform with the European privacy laws. Public health funds inform the EPRD about the revision of a registered implant even if the revision takes place in a clinic that does not participate in the EPRD, which leads to an almost 100% follow-up of all registered implants within the EPRD. Hospitals provide information on implants by on-side barcode scanning that automatically links the implant to the implant library. Currently, the library identifies more than 70,000 individual components. The specifics of the scanned implants are assessed for plausibility and hospitals are warned if, for example, the implant components do not match in size or are incomplete. In addition, the EPRD receives specific data about every patient and every procedure from clinics via electronic case reports. Hospital-acquired data and routine billing data of public health funds are also cross-referenced for validation

(15,16). After the exclusion of inconsistent or incomplete data, 40% of all data reported to the EPRD qualifies for statistical analysis.

In 2019, the EPRD covered 70% of all hip and knee surgeries reported by the Institute for Quality Assurance and Transparency in Healthcare (IQTiG). About 90% of the participating clinics are large volume clinics conducting over 500 hip and knee arthroplasties per year. Due to the Covid-19 pandemic, numbers of documented surgeries decreased in 2019 and 2020. Roughly 5% less surgeries were documented in the northern and eastern parts of Germany (17).

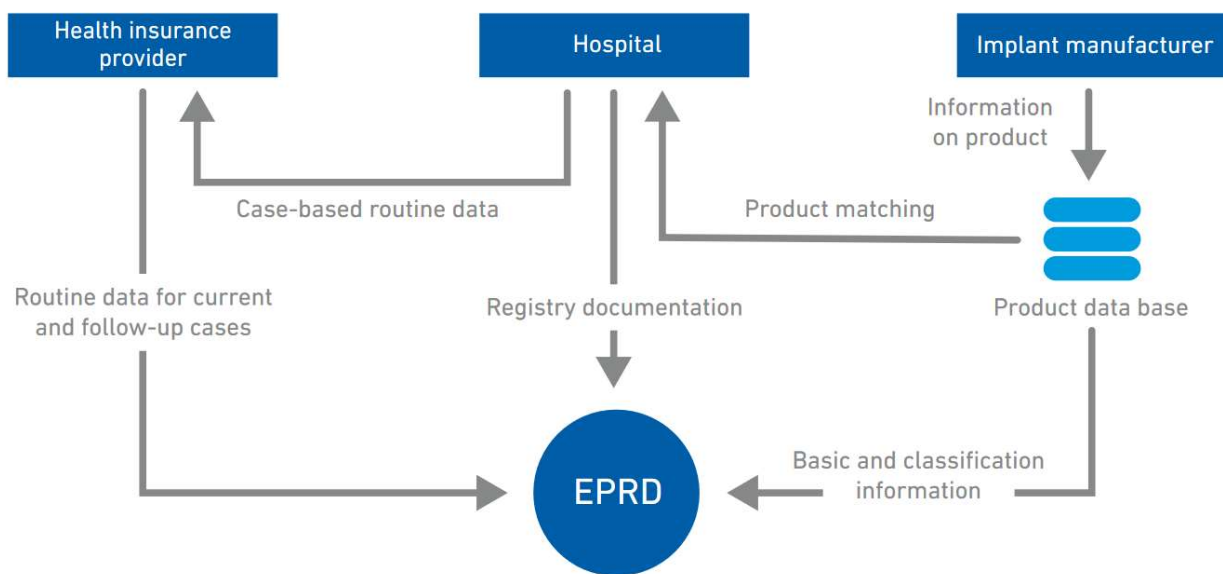


Figure 1. The data flow from hospitals, health insurers and implant manufacturers to the German Arthroplasty Registry (EPRD). From: EPRD annual report 2022; Fig. 3, p. 21 (18).

2.1.2 Data Selection

Inclusion and exclusion criteria were defined to minimize confounders and reduce conditions associated with a higher risk of mechanical complications. In 2020, the EPRD reported cementless fixation in 78.4%, modular head and stem system in 87.5%, modular acetabular cup in 87.7%, ceramic/polyethylene bearing combination in 80.1%, and no previous surgery in 96.5% of the total hip arthroplasties (19). Osteoarthritis of the hip is the indication in about 80% of the patients in Germany receiving a hip replacement (20). This led to the following inclusion criteria: (i) elective primary cementless total hip arthroplasty, non-elective total hip arthroplasties are mostly necessary due to fractures and are associated with a higher risk of failure (21); (ii) modular head and stem system (most common); (iii) ceramic head with polyethylene liner articulation (most common); (iv)

one of five liner designs: standard, lipped, offset, angulated, angulated-offset; (v) patients with diagnosed osteoarthritis of the hip. Exclusion criteria were: (i) relevant previous operation, considered as relevant were operations of the pelvis, hip joint and femur (22); (ii) comorbidities associated with a higher complication risk: Marfan's syndrome (23), Ehlers-Danlos syndrome (24), Sickle Cell Disease (25); (iii) age at admission under 18 years; (iv) femoral head sizes of 22.25 mm and 30 mm, as those were only three cases.

At the start of the selection process, the dataset included 232,301 cases fulfilling the following criteria: data from November 2012 until November 2020; primary elective total hip arthroplasties; primary diagnosis was osteoarthritis of the hip joint; polyethylene liner and ceramic femoral head articulation. At first, cemented arthroplasties, as well as non-modular systems and arthroplasties with a reconstruction shell were excluded. That left 156,870 cases. Furthermore, cases with unknown liner type (n = 922), constrained liner (n = 23), dual mobility (n = 6), lipped-increased offset liner (n = 3), and liner that were registered under "other description" (n = 75) were excluded. Then, patients under 18 years of age (n = 16), patients with previous relevant operations (n = 4,687), patients with Marfan's syndrome (n = 1), Ehlers-Danlos syndrome (n = 1) and Sickle Cell Disease (n = 37), as well as arthroplasties with femoral head sizes of 22.5 mm (n = 1) and 30 mm (n = 2) were excluded. That left 151,096 hip arthroplasties to be included in the final analysis, thereof 125,070 with standard liners, 18,697 with lipped liners, 3,728 with offset liners, 2,045 with angulated-offset liners and 1,556 with angulated liners.

Morphological characteristics of the liner designs are as follows (Figure 2, (26)). Standard liners are shaped as a completely symmetric hemisphere. Offset liners are also symmetric but have a 4-10 mm additional thickness in the dome area of the liner. Lipped and angulated liners are asymmetric. Lipped liners have an a few millimetres elevated rim covering half of the hemisphere. Angulated liners tilt the articular surface by 10° or more from the neutral position. Angulated-offset liners combine the features of angulated and offset liners. Liner designs may differ slightly between different implant producers, for example how much offset an offset liner has, the amount of tilt for angulated liners or the height of the elevated rim for lipped liners. Today, most liners are made of highly cross-linked polyethylene. However, the data includes also standard and special liners made from conventional polyethylene, medium cross-linked polyethylene, and highly cross-linked polyethylene with antioxidant (vitamin infused or with "chemical" antioxidant).



Figure 2a-d. Examples for the liner designs (LINK, Germany). **a** standard liner. **b** lipped (5 mm height). **c** offset (+4 mm). **d** angulated-offset (20°, +8 mm). Adapted from: Krull et al., 2022; Fig. 2, p. 802 (26).

2.1.3 Medical Codes

Variables and endpoints were defined with the 10th version of the International Classification of Diseases (ICD-10) (27) and the German procedure classification version 2020 (OPS) (28), since hospitals (electronic case report form (eCRF)) and public health funds (routine billing information) provided most of the information encoded in ICD-10 and OPS codes. Medical codes were selected according to the recommendations of the German Society for Medical Controlling (DGfM).

The first endpoint of interest was revision due to mechanical complications. The second endpoint of interest was revision due to any reason. Revision was defined as the removal and replacement of parts or the whole prosthesis because of failure of the prosthesis. Revision for mechanical complications excluded periprosthetic fractures.

In addition to ICD-10 and OPS codes, institutions could voluntarily report more specific reasons for revision due to mechanical complications by stating in the eCRF: implant malposition, implant wear, loosening of both components, loosening of cup, loosening of stem, dislocation, osteolysis with fixed stem, and failure of implant component. As stating specific reasons was not mandatory, specific reasons were only stated for 1.8% (n = 2,731) of the included cases. This information was used in addition to ICD-10 codes to define the primary endpoint revision for mechanical complications. Table I provides an overview of the relevant ICD-10 and OPS codes.

Comorbidities were assessed with the Elixhauser comorbidity index (29). The Elixhauser comorbidity index reflects patient morbidity and in-hospital mortality summarizing 30 disease groups defined by ICD-10 codes into one numeric score. The Elixhauser comorbidity method was shown to effectively estimate adverse events and patient mortality after orthopaedic surgery (30). The variable liner share reflects the percent

proportion of the implanted liner design in the respective hospital (26). Annual hospital volume represents the amount of hip arthroplasties performed per year in the respective hospital at the time of surgery.

Table I. ICD-10 and OPS codes for data selection. Own illustration: Paula Krull.

Variable	Code	Description
Osteoarthritis	M16.-	M16.- Osteoarthritis of the hip joint
Total hip arthroplasty	5-820.00	5-820.00 total hip arthroplasty: cementless
Mechanical complications	T84.0	T84.0 Mechanical complications of internal joint prosthesis
	T84.04	T84.04 hip joint

2.1.4 Statistical Analysis

Patient and implant characteristics for standard, lipped, offset, angulated and angulated-offset liners were calculated in mean and standard deviation for continuous variables, and frequency and percent proportion for categorical variables. Means of continuous variables were compared with the one-way analysis of variance; frequencies of categorical variables with the Pearson's Chi-squared test. Significance level was set to $p \leq 0.05$.

Cumulative incidences of revision for mechanical complications and revision for any reason were calculated with a competing risk survival analysis. For revision of mechanical complications competing risks were revision for other reasons than mechanical complications and the death of the patient. For revision of any reason the competing risk was death of the patient. Pairwise log-rank test, corrected for multiple testing with the Bonferroni method, was used to assess differences in cumulative incidences between the liner groups. The clinical relevance of the differences in cumulative incidences was evaluated with the number needed to treat. The number needed to treat was calculated from the cumulative incidences at seven years comparing special with standard liners.

A multivariate Cox proportional-hazard model was fitted to estimate the risk of revision for mechanical complications, treating competing risks as censoring events. The model was adjusted for sex of the patient, age at admission, Elixhauser comorbidity index, type of polyethylene, type of liner, femoral head size, liner share and annual hospital volume. The EPRD started to record the Body-Mass-Index (BMI) in 2017, which resulted in unavailable values from 2012 till 2017 (about one-third of the values). It was decided to exclude the variable BMI from the Cox proportional-hazards model, as opposed to exclude the cases with missing BMI values. The Elixhauser comorbidity index was grouped to "0" as reference and "1-4" and "≥ 5" as comparison groups (standard grouping

of index in the EPRD). Annual hospital volume was grouped to “> 500” as reference and “250-500” and “< 250” as comparison groups (31). Cases with missing values for annual hospital volume were excluded from the Cox proportional-hazards model (0.9%; n = 1,330). Also, the standard liner, male sex, femoral head size of 32 mm and conventional polyethylene were set as reference.

The Cox proportional-hazards model was started as a full model. Variables that were not statistically significant were step-by-step excluded from the model. Sex of the patient, femoral head size and annual hospital volume showed no statistical significance and were excluded from the model. Medium cross-linked polyethylene, highly cross-linked polyethylene and highly cross-linked polyethylene with antioxidant showed no statistically significant difference in risk and were grouped together as cross-linked polyethylene.

The reduced model was tested for non-proportional hazards with the *cox.zph* function from the R *survival* package. Age at admission, Elixhauser comorbidity index and type of polyethylene presented non-proportional hazards. Therefore, the model was adjusted with a time-split function to allow two different hazards for the time period of ≤ 360 days and > 360 days (32). The cut point was approximated by visual observation of a graph, plotting Schoenfeld residuals against the transformed time. Deviation from the horizontal line indicated non-proportional hazards. Visually identified cut points were then tried in the time-split function until the proportional-hazards assumption was satisfied. It was decided to exclude the Cox proportional-hazards model for the secondary endpoint revision for any reason from the study, as non-proportional hazards still existed after including multiple time-splits. All statistics were executed with R version 4.1.2 (R Core Team).

2.2 Survey

The online tool *UmfrageOnline* (© 2007 - 2023 enuvo GmbH) was used to design, distribute, and manage the survey. The survey was accessible from 2 August 2022 until 15 October 2022. It was decided to close the survey mid-October, due to a strong decrease of incoming replies.

The explorative survey was comprised of 11 questions about the usage of lipped liners in primary total hip arthroplasty and was sent to the contact people of all 789 clinics that were registered at the beginning of August 2022 in the EPRD database. Orthopaedic surgeons from all experience levels conducting hip replacement surgery were eligible to

anonymously complete the survey. Except the questions 2 and 3b, all questions had predefined answers. Questions 3, 4, 5b, 7, 8 and 10 had an additional free-text option. In questions 5b, 7, and 8, the option to select more than one answer was available. Question 5b could only be answered if question 5a was answered with “never”. Risk factors for dislocation of the hip in question 7 were adapted from Kunze et al. (33).

From the completed surveys, free-text answers were pooled to facilitate the statistical analysis and presentation in figures. For example, answers to question 2: “How many hip arthroplasties have you done within the last year?” were grouped to “ ≤ 50 ”, “50-100”, “101-200”, “201-300”, “301-500” and “ > 500 ”. The Fisher’s exact test was applied to evaluate if there is an association between (i) the frequency of use of lipped liners or (ii) the frequency of closure of the hip joint capsule and the surgical approach (questions 3a, 5a and 11). We hypothesized, that lipped liners are more frequently implanted if the operation was performed through the posterior approach. We further assumed, that there might be an association between the surgical approach and the frequency of closure of the hip joint capsule. Statistics were executed with R version 4.1.2 (R Core Team).

3. Results

3.1 Liner Study

3.1.1 Demographics

Table II displays the full demographic data. The mean follow-up was 927 days (SD = 611 days) with a maximum of 7.9 years in the observed time span of eight years. Overall, 82.8% (n = 125,070) of the patients received standard liners, 12.4% (n = 18,697) lipped liners, 2.5% (n = 3,728) offset liners, 1.4% (n = 2,045) angulated-offset liners and 1.0% (n = 1,556) angulated liners.

The dataset included more women (60.7%; n = 91,764) than men with the highest percentage of women (68.9%; n = 2,568) in the offset liner group. Mean age at admission was 67.6 years (SD = 9.8 years) and ranged from 18 to 96 years. One third of BMI values were not available (39.1%; n = 59,146). From the available values, most patients were overweight (mean = 28.7; SD = 5.3) but ranged from underweight to obesity class III (15.1-54.9 kg/m²). Three quarters of the patients (74.3%; n = 112,301) had an Elixhauser comorbidity index of 1-4 and 3.2% (n = 4,908) of ≥ 5 . The most frequent comorbidities

were uncomplicated hypertension (58.2%; n = 87,880), obesity (18.7%; n = 28,186), hypothyroidism (17.3%; n = 26,137) and uncomplicated diabetes (12.1%; n = 18,210).

Table II. Patient and implant characteristics. Adapted from: Krull et al., 2022; Table I, p. 803 (26).

	Standard (125,070)	Lipped (18,697)	Offset (3,728)	Angulated- offset (2,045)	Angulated (1,556)	Overall (151,096)	p-value*
Women, n (%)	75,338 (60.2)	11,663 (62.4)	2,568 (68.9)	1,189 (58.1)	1,006 (64.7)	91,764 (60.7)	< 0.001
Age, mean (SD)	67.7 (9.8)	66.7 (9.9)	69.9 (9.5)	67.5 (10.2)	65.6 (9.4)	67.6 (9.8)	< 0.001
BMI, mean (SD)	28.6 (5.2)	29.2 (5.6)	28.6 (5.5)	29.0 (5.6)	29.6 (5.8)	28.7 (5.3)	< 0.001
Missing, n (%)	47,458 (37.9)	7,976 (42.7)	2,325 (62.4)	547 (26.7)	840 (54.0)	59,146 (39.1)	
Elixhauser comorbidity index, n (%)							< 0.001
0	27,945 (22.3)	4,167 (22.3)	933 (25.0)	453 (22.2)	389 (25.0)	33,887 (22.4)	
1-4	93,051 (74.4)	13,962 (74.7)	2,650 (71.1)	1,532 (74.9)	1,106 (71.1)	112,301 (74.3)	
≥ 5	4,074 (3.3)	568 (3.0)	145 (3.9)	60 (2.9)	61 (3.9)	4,908 (3.2)	
Polyethylene, n (%)							< 0.001
PE	7,246 (5.8)	2,061 (11.0)	5 (0.1)	1 (0.0)	197 (12.7)	9,510 (6.3)	
XLPE	117,824 (94.2)	16,636 (89.0)	3,723 (99.9)	2,044 (100.0)	1,359 (87.3)	141,586 (93.7)	
Femoral head size, n (%)							< 0.001
28 mm	4,788 (3.8)	2,305 (12.3)	3 (0.1)	74 (3.6)	91 (5.8)	7,261 (4.8)	
32 mm	69,522 (55.6)	15,021 (80.3)	1,998 (53.6)	1,299 (63.5)	1,199 (77.1)	89,039 (58.9)	
36 mm	50,704 (40.5)	1,371 (7.3)	1,727 (46.3)	672 (32.9)	266 (17.1)	54,740 (36.2)	
40 mm	56 (0.0)	0 (0)	0 (0)	0 (0)	0 (0)	56 (0.0)	
Hospital volume/year†, n (%)							< 0.001
≤ 250	39,002 (31.2)	4,150 (22.2)	1,127 (30.2)	666 (32.6)	511 (32.8)	45,456 (30.1)	
251-500	37,334 (29.9)	6,221 (33.3)	856 (23.0)	801 (39.2)	654 (42.0)	45,866 (30.4)	
> 500	47,451 (37.9)	8,279 (44.3)	1,745 (46.8)	578 (28.3)	391 (25.1)	58,444 (38.7)	
Missing	1,283 (1.0)	47 (0.3)	0 (0)	0 (0)	0 (0)	1,330 (0.9)	
Liner share (%)							< 0.001
mean (SD)	87.2 (17.2)	62.1 (30.3)	53.0 (28.4)	29.8 (25.2)	34.7 (31.6)	81.9 (23.5)	
median	94.7	69.4	45.4	23.5	28.4	93.9	
[min, max]	[0.100, 100]	[0, 100]	[0.100, 92.6]	[0, 100]	[0.100, 95.2]	[0, 100]	
Death, n (%)	3,750 (3.0)	651 (3.5)	130 (3.5)	64 (3.1)	50 (3.2)	4,645 (3.1)	0.005
Revision mechanical complication, n (%)	1,908 (1.5)	365 (2.0)	46 (1.2)	66 (3.2)	34 (2.2)	2,419 (1.6)	< 0.001
Time to revision (d), mean (SD)	235 (361)	300 (422)	227 (365)	234 (389)	203 (325)	244 (372)	0.042
Revision any reason, n (%)	3,820 (3.1)	612 (3.3)	98 (2.6)	88 (4.3)	75 (4.8)	4,693 (3.1)	< 0.001
Time to revision (d), mean (SD)	183 (327)	245 (397)	265 (457)	253 (429)	199 (391)	194 (344)	< 0.001
Follow-up (d)							< 0.001
mean (SD)	911 (602)	1,040 (652)	956 (622)	730 (553)	1,080 (651)	927 (611)	
median	847	999	897	600	1,050	868	
[min, max]	[0, 2,880]	[0, 2,860]	[0, 2,880]	[0, 2,640]	[0, 2,760]	[0, 2,880]	

*Chi-squared test for categorical variables; one-way analysis of variance for continuous variables. Comparison of five liner groups. n = number, SD = standard deviation, BMI = Body-Mass-Index, PE = conventional polyethylene, XLPE = cross-linked polyethylene, d = days.

† Annual hospital volume in total hip arthroplasties per year.

Over 90% of the liners were made from cross-linked polyethylene (93.7%; n = 141,586). The most common femoral head size was 32 mm (58.9%; n = 89,039). In 56 cases the standard liner was paired with a 40 mm femoral head, thereof 51 were implanted in men and five in women. The most frequent bearing combinations were a standard cross-linked polyethylene liner articulating with a 32 mm femoral head (43.0%; n = 64,981), a standard cross-linked polyethylene liner with a 36 mm femoral head (32.3%; n = 48,785) and a lipped cross-linked polyethylene liner with a 32 mm femoral head (9.0%; n = 13,627).

Over one third of the total hip arthroplasties were implanted in high volume hospitals conducting more than 500 total hip arthroplasties per year (38.7%; n = 58,444). A major part of the total hip arthroplasties in the offset (46.8%; 1,745) and lipped (44.3%; n = 8,279) liner group were implanted in high volume hospitals. Thirty-five hospitals used special liner designs in over 80% of their total hip arthroplasties (liner share > 80%). Twenty-six of these used lipped liners, five offset liners, three angulated liners and one hospital used angulated-offset liners in over 80% of their total hip arthroplasties.

In total, 1.6% (n = 2,419) of the arthroplasties had to be revised for mechanical complications and 3.1% (n = 4,693) for any reason. Mean time to revision for mechanical complications was 244 days (SD = 372 days), but shorter for any reason 194 days (SD = 344). The lowest percentage of revision for mechanical complications was found for offset liners (1.2%; n = 46) and the highest percentage for angulated-offset liners (3.2%; n = 66). The lowest percentage of revision for any reason was found for offset liners (2.6%; n = 98) and the highest percentage for angulated liners (4.8%; n = 75). Overall, 3.1% (n = 4,645) of the patients died during the observed time span.

3.1.2 Survival Analysis

Most revisions for mechanical complications took place within the first year after the index operation (81.2%; n = 1,964). The cumulative incidence of revision for mechanical complications was significantly different between the five liner groups ($p < 0.001$). At seven years, the cumulative incidence was, compared with standard liners (0.022; 95% CI = 0.020, 0.025), higher for lipped liners (0.027; 95% CI = 0.023, 0.033; $p = 0.004$) and higher for angulated-offset liners (0.051; 95% CI = 0.035, 0.071; $p < 0.001$) (Figure 3, Table III).

The cumulative incidence of revision for any reason was significantly different between the liner groups ($p < 0.001$). At seven years, the cumulative incidence was, compared with standard liners (0.041; 95% CI = 0.038, 0.045), higher for angulated liners (0.063; 95% CI = 0.044, 0.088; $p = 0.003$) and higher for angulated-offset liners (0.078; 95% CI = 0.053, 0.111; $p = 0.002$) (Figure 4, Table IV). At seven years, for every 35 patients receiving angulated-offset liners instead of standard liners, one additional revision for mechanical complications was necessary — or in case of revision for any reason — one additional revision for every 27 patients.

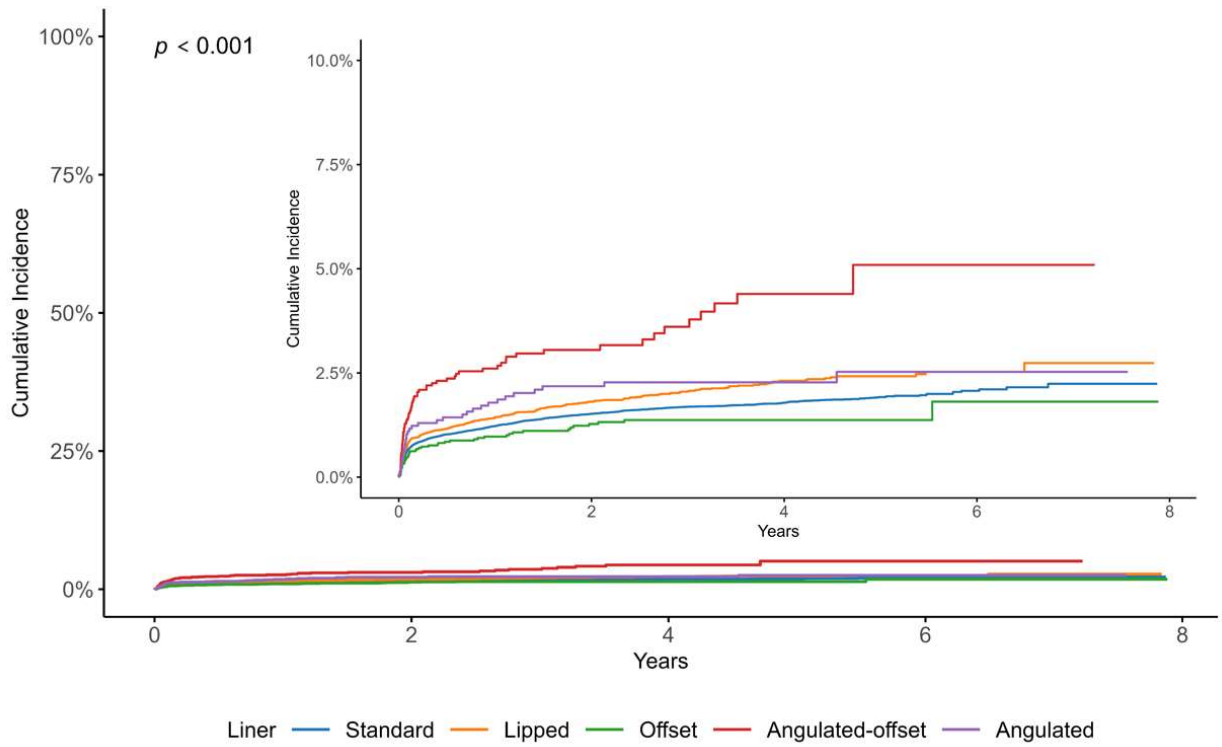


Figure 3. Revision for mechanical complications per type of liner. 100% y-scale and 10% scale for better comparability. Adapted from: Krull et al., 2022; Fig. 4, p. 806 (26).

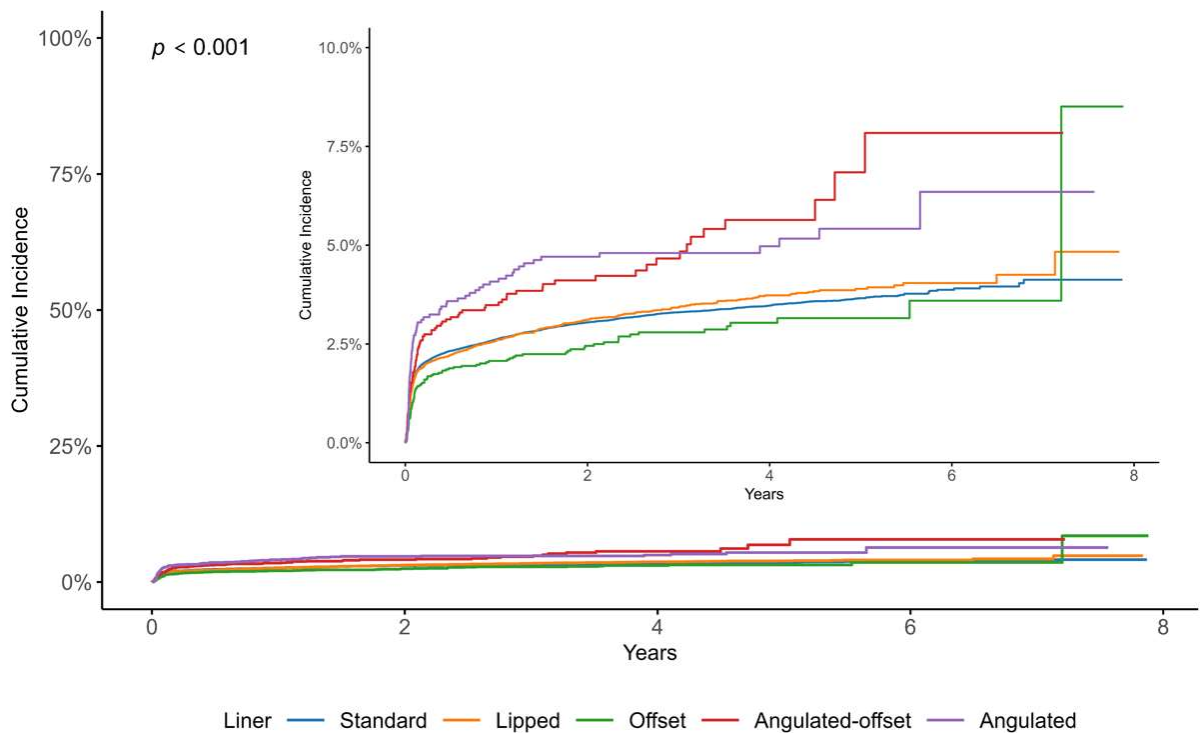


Figure 4. Revision for any reason per type of liner. 100% y-scale and 10% scale for better comparability. Adapted from: Krull et al., 2022; Fig. 5, p. 807 (26).

Table III. Cumulative incidences and confidence intervals of revision for mechanical complications for the five liners and overall. Own illustration: Paula Krull.

	1 year	2 years	3 years	5 years	7 years	p-value*	NNT ₇
Standard	0.012 (0.012, 0.013)	0.015 (0.014, 0.016)	0.017 (0.016, 0.018)	0.019 (0.018, 0.020)	0.022 (0.020, 0.025)	-	-
Lipped	0.014 (0.013, 0.016)	0.018 (0.016, 0.020)	0.021 (0.018, 0.023)	0.024 (0.022, 0.027)	0.027 (0.023, 0.033)	0.004	200
Offset	0.010 (0.007, 0.013)	0.013 (0.009, 0.017)	0.014 (0.010, 0.018)	0.014 (0.010, 0.018)	0.018 (0.010, 0.030)	1.000	250
Angulated- offset	0.026 (0.020, 0.034)	0.031 (0.023, 0.039)	0.036 (0.027, 0.047)	0.051 (0.035, 0.071)	0.051 (0.035, 0.071)	< 0.001	35
Angulated	0.018 (0.012, 0.026)	0.022 (0.015, 0.030)	0.023 (0.016, 0.031)	0.025 (0.017, 0.036)	0.025 (0.017, 0.036)	0.746	334
Overall	0.013 (0.012, 0.013)	0.016 (0.015, 0.016)	0.018 (0.017, 0.018)	0.020 (0.019, 0.021)	0.023 (0.021, 0.026)	< 0.001	-

*Log-rank test adjusted with Bonferroni correction for multiple testing. NNT₇ = Number Needed to Treat at 7 years.

Table IV. Cumulative incidences and confidence intervals of revision for any reason for the five liners and overall. Own illustration: Paula Krull.

	1 year	2 years	3 years	5 years	7 years	p-value*	NNT ₇
Standard	0.026 (0.025, 0.027)	0.030 (0.029, 0.031)	0.033 (0.032, 0.034)	0.037 (0.035, 0.038)	0.041 (0.038, 0.045)	-	-
Lipped	0.026 (0.024, 0.028)	0.031 (0.029, 0.034)	0.034 (0.032, 0.037)	0.039 (0.036, 0.042)	0.043 (0.037, 0.048)	1.000	500
Offset	0.021 (0.016, 0.026)	0.025 (0.020, 0.030)	0.028 (0.023, 0.034)	0.032 (0.025, 0.039)	0.036 (0.026, 0.048)	1.000	200
Angulated- offset	0.035 (0.027, 0.044)	0.041 (0.033, 0.051)	0.047 (0.037, 0.058)	0.068 (0.049, 0.092)	0.078 (0.053, 0.111)	0.002	27
Angulated	0.041 (0.032, 0.052)	0.047 (0.037, 0.059)	0.048 (0.038, 0.060)	0.054 (0.042, 0.068)	0.063 (0.044, 0.088)	0.003	46
Overall	0.026 (0.025, 0.027)	0.031 (0.030, 0.032)	0.033 (0.032, 0.034)	0.037 (0.036, 0.039)	0.042 (0.039, 0.045)	< 0.001	-

*Log-rank test adjusted with Bonferroni correction for multiple testing. NNT₇ = Number Needed to Treat.

3.1.3 Cox Proportional-Hazards Model

In comparison to standard liners, lipped (HR = 1.06; 95% CI = 0.94, 1.20; p = 0.352) and angulated liners (HR = 1.03; 95% CI = 0.72, 1.46; p = 0.876) showed no significant difference in risk of revision for mechanical complications. Offset liners reduced the risk by 32% (HR = 0.68; 95% CI = 0.50, 0.92; p = 0.013); angulated-offset liners increased the risk by 81% (HR = 1.81; 95% CI = 1.38, 2.36; p < 0.001).

Up to 360 days after the index operation, age at admission increased the risk of revision for mechanical complications (HR = 1.02; 95% CI = 1.01, 1.02; p < 0.001). After 360 days, age at admission decreased the risk (HR = 0.98; 95% CI = 0.97, 0.99; p < 0.001). Compared with patients with an Elixhauser comorbidity index of 0, patients with an index of 1-4 were associated with an increased risk up to 360 days after surgery (HR = 1.34; 95% CI = 1.18, 1.52; p < 0.001), which was less pronounced past 360 days (HR = 1.30; 95% CI = 1.06, 1.59; p = 0.013). A patient with an index of ≥ 5 had an almost three times

higher risk in the 360 days after surgery (HR = 2.98; 95% CI = 2.42, 3.67; $p < 0.001$), but no significantly increased risk afterwards (HR = 1.27; 95% CI = 0.75, 2.15; $p = 0.369$).

Hip arthroplasties with cross-linked polyethylene had, compared with conventional polyethylene, a significantly reduced risk of revision for mechanical complications. The reduction in risk was even more pronounced 360 days after surgery (≤ 360 days: HR = 0.74; 95% CI = 0.63, 0.87; $p < 0.001$ / > 360 days: HR = 0.45; 95% CI = 0.36, 0.57; $p < 0.001$). Higher liner share was associated with a reduced risk of revision for mechanical complications (HR = 0.995; 95% CI = 0.993, 0.997; $p < 0.001$).

3.2 Survey

In total, 420 people viewed the survey, 237 completed and 41 only partially completed the survey. Over 80% of the surveys ($n = 200$) were completed within the first two weeks after the invitation to the survey was sent to the clinics. Almost all surgeons who participated in the survey had already completed their residency (97.9%; $n = 232$) (Table V).

The most common surgical approach was the anterolateral (54.4%; $n = 129$), followed by the lateral (19.8%; $n = 47$) and the anterior (13.9%; $n = 33$) approach. Nearly 90% of the participants answered that they seldom (53.2%; $n = 126$) or never (34.6%; $n = 82$) use lipped liners in primary total hip arthroplasty. Twenty-nine participants (12.2%) replied that they regularly use lipped liners. Surgeons who primarily operate through the posterior approach use lipped liners significantly more often than those who operate through an anterior ($p < 0.001$), anterolateral ($p < 0.001$) or lateral approach ($p < 0.001$). Surgeons who responded to never use lipped liners generally do not see an advantage over standard liners (56.0%; $n = 56$) or think that lipped liners offer more drawbacks than advantages (19.0%; $n = 19$).

More than half of the surgeons decide intraoperatively to use a lipped liner (56.1%; $n = 133$), for example when instability or spontaneous luxation occur during the trial reduction of the artificial hip joint (36.4%; $n = 110$). Similarly, 30.1% ($n = 91$) use lipped liners when the acetabular cup is not optimally positioned. Preoperative reasons to use a lipped liner are patients with dysplasia of the hip (16.8%; $n = 69$) or neurocognitive disease, for example dementia or Parkinson's disease (12.2%; $n = 50$), as well as patients with lumbosacral pathology (8.5%; $n = 35$).

Table V. Questions and answers of the survey. Own illustration: Paula Krull.

Questions	Answers
Q1: Are you still an orthopaedic surgeon in training? (n = 237)	yes: 5 (2.1%); no: 232 (97.9%)
Q2: How many hip arthroplasties have you done within the last year? (n = 237)	≤ 50: 40 (16.9%); 50-100: 77 (32.5%); 101-200: 85 (35.9%); 201-300: 20 (8.4%); 301-500: 10 (4.2%); > 500: 5 (2.1%)
Q3a: Which surgical approach do you currently use most frequently for primary total hip arthroplasties? (n = 237)	anterior: 33 (13.9%); anterolateral: 129 (54.4%); lateral: 47 (19.8%); posterior: 15 (6.3%); posterolateral: 11 (4.6%); Superpath: 2 (0.8%)
Q3b: What percentage do you use the selected surgical approach? (n = 237)	50-59%: 3 (1.3%); 60-69%: 7 (3.0%); 70-79%: 8 (3.4%); 80-89%: 19 (8.0%); 90-95%: 58 (24.5%); 96-99.9%: 24 (10.1%); 100%: 111 (46.8%); NA: 7 (3.0%)
Q4: Do you increase the anteversion of the acetabular cup when you operate through the posterior approach? (n = 237)	yes: 62 (26.2%); no: 68 (28.7%); posterior approach is not used: 34 (14.3%); other: 17 (7.2%); NA: 56 (23.6%)
Q5a: How often do you use lipped liners in primary total hip arthroplasty? (n = 237)	(almost) always: 16 (6.8%); mostly: 8 (3.4%); as often as standard liners: 5 (2.1%); seldom: 126 (53.2%); never: 82 (34.6%)
Q5b: What are the reasons why you do not use lipped liners in primary total hip arthroplasty? (n = 100)	I do not see an advantage over standard liners.: 56 (56%); Lipped liners have more drawbacks than benefits.: 19 (19%); I have never used those liners.: 11 (11%); other: 14 (14%)
Q6: Do you decide to use a lipped liner pre- or intraoperatively? (n = 237)	mostly preoperatively: 21 (8.9%); mostly intraoperatively: 133 (56.1%); about the same: 8 (3.4%); NA: 75 (31.6%)
Q7: Which preoperative findings of a patient do you consider relevant to use a lipped liner in primary total hip arthroplasty? (n = 411)	BMI > 30 kg/m ² : 27 (6.6%); ASA Score ≥ 2: 7 (1.7%); > 75 years of age: 16 (3.9%); female patient: 12 (2.9%); chronic lung disease: 3 (0.7%); neurocognitive disease (e.g. dementia, Parkinson's): 50 (12.2%); depression/anxiety disorder: 8 (1.9%); alcohol abuse: 27 (6.6%); lumbosacral pathology: 35 (8.5%); abductor muscle insufficiency: 29 (7.1%); increased risk of osseus impingement (e.g. large AIIS and greater trochanter): 21 (5.1%); hip dysplasia: 69 (16.8%); arthritic hip joint: 7 (1.7%); fracture of acetabulum/defect of posterior wall: 24 (5.8%); avascular necrosis of the femoral head: 8 (1.9%); previous operation of the hip (not including hip replacement): 20 (4.9%); wish of the patient: 3 (0.7%); other: 45 (10.9%)
Q8: What are intraoperative reasons for you to use a lipped liner in primary total hip arthroplasty? (n = 302)	posterior surgical approach: 26 (8.6%); not optimal positioned acetabular cup: 91 (30.1%); poor condition of the soft tissues: 50 (16.6%); instability in trial reduction/intraoperative dislocation: 110 (36.4%); always for primary total hip arthroplasty: 14 (4.6%); other: 11 (3.6%)
Q9: In which position do you most often orient the "lip" of a lipped liner in primary total hip arthroplasty? (n = 237)	anterior-superior: 44 (18.6%); anterior-inferior: 3 (1.3%); posterior-superior: 78 (32.9%); posterior-inferior: 30 (12.7%); NA = 82 (34.6%)
Q10: How do you determine the correct position of the acetabular cup and liner for primary total hip arthroplasties? (n = 237)	intraoperative X-ray: 137 (57.8%); manual alignment guides: 47 (19.8%); computer navigation: 4 (1.7%); robotic assisted: 1 (0.4%); no navigation: 32 (13.5%); other (e.g., anatomical landmarks): 16 (6.8%)
Q11: Do you close the capsule of the hip joint for primary total hip arthroplasties? (n = 237)	mostly not: 199 (84.0%); mostly yes: 38 (16.0%)

It was possible to select more than one answer in questions 5b, 7 and 8. Question 5b could only be answered if question 5a was answered with "never". NA = not answered, BMI = Body-Mass-Index, ASA = American Society of Anaesthesiologists, AIIS = anterior inferior iliac spine.

About one third of the participants (32.9%; n = 78) answered to orient lipped liners with the lip in the posterior-superior quadrant of the acetabular cup. More than half of the survey respondents (57.8%; n = 137) replied to determine the correct position of the cup and liner with intraoperative X-ray. Further 19.8% (n = 47) use manual instrumentation and 6.8% (n = 16) employ other methods, for example anatomical landmarks.

Most surgeons (84.0%; n = 199) do not close the hip joint capsule. Surgeons who mainly operate through the posterior approach significantly more often close the hip joint capsule

compared with those who operate through the anterior ($p = 0.012$), anterolateral ($p < 0.001$) and lateral approach ($p < 0.001$).

4. Discussion

4.1 Short Summary of Results

Our primary aim was to investigate differences in cumulative incidence and risk of revision for mechanical complications among standard, lipped, offset, angulated-offset and angulated liners with EPRD data from November 2012 until November 2020. Lipped and angulated-offset liners had significantly higher cumulative incidences of revision for mechanical complications than standard liners. The offset liner was the only liner reducing the risk of revision for mechanical complications, whereas the angulated-offset liner increased the risk. Standard, lipped and angulated liners revealed no difference in the risk. Age at admission, Elixhauser comorbidity index, type of polyethylene and liner share were identified as confounders. The survey indicated that 12.2% of the surgeons use lipped liners regularly, especially if they operate through the posterior approach. Further reasons to use lipped liners were instability of the arthroplasty during trial reduction or malposition of the acetabular cup, as well as patients with a dysplastic hip, lumbosacral pathology, or neurocognitive impairment. Most lipped liners are positioned in the posterior-superior quadrant.

4.2 Interpretation and Integrated Discussion of Results

4.2.1 Asymmetric Liners

Originally, asymmetric liners were introduced to reduce posterior dislocation of the femoral head (10). In theory, lipped liners provide additional jump distance to dislocation by increasing head coverage and resistance moment to dislocation. This is supported by studies showing reduced rates of dislocation with lipped liners (34–44).

In our study, lipped liners were the most common special liner design. According to our survey, 12.2% of the participants use lipped liners regularly in primary total hip arthroplasty. However, participants that never use lipped liners stated that lipped liners would not provide any advantage over standard liners and might even have more drawbacks. This is reflected in our data analysis. We found higher cumulative incidences and no difference in risk of revision for mechanical complications for lipped liners in

comparison to standard liners. However, the difference in cumulative incidence is quite small with a number needed to treat of 200.

In practice, lipped liners are often associated with impingement between the femoral neck and the elevated rim (45–48). Torsional forces acting on the rim may cause loss of fixation between the elevated rim and the acetabular shell (49). Recurrent impingement is shown to lead to increased rates of wear, osteolysis, aseptic loosening, rim cracking, dislocation, and failure of the hip arthroplasty (50–60). Ordaz et al. reported a case of a 57-year old man with recurrent instability and dislocation (61). After multiple attempts of closed reduction failed, open revision surgery was necessary. They discovered intraoperatively that the lip of the liner was invaginated. While certainly not being a very common complication, this case illustrates that the lip of the liner might also act as an additional barrier against closed reduction.

Krushell et al. studied the effect of two types of asymmetric liners in a laboratory simulator for range of motion and stability in a well-positioned, as well as in a malpositioned acetabular cup. They found that asymmetric liners did not increase the range of motion or stability in a well-positioned acetabular cup – they rather reoriented the range of motion before dislocation (49). Especially angulated liners may be used to alter the abduction angle or version without having to change the position of the acetabular cup (62). Krushell et al. concluded that an asymmetric liner may only improve stability in a malaligned acetabular cup. In this case, the type one liner (angulated liner) may be more effective in improving stability than the type two liner (lipped liner). They suggest that if the acetabular cup is positioned properly, an asymmetric liner would not provide any additional benefit (49).

In our survey, more than half of the participants replied that they decide to use a lipped liner intraoperatively. Reasons were an unstable hip arthroplasty, spontaneous luxation of the artificial joint during trial reduction, and a less-than-ideal positioned acetabular cup. Wera et al. reported that one of the most frequent reasons for instability is malposition of the acetabular component (63). Their advice is to first try to revise the position of the cup if the reason for instability is a malpositioned acetabular component. If the choice is made to use a lipped liner, stability can only be improved with the elevated rim in the correct position. Huff et al. analysed in an experimental musculoskeletal model the optimal position of a lipped liner (64). They concluded that the elevated rim of a lipped liner was

best placed at the egress site of the acetabular shell, opposite the femoral neck/shell impingement site. If incorrectly positioned, impingement might be reinforced on the malpositioned rim, resulting in a higher risk for anterior dislocation.

The survey suggests that surgeons use lipped liners more frequently when they operate through the posterior approach. Most of them position lipped liners in the posterior-superior quadrant – which may not be optimal. Posterior dislocation of the femoral head is often provoked by high flexion and internal rotation of the hip joint, as the resultant joint force directs in the posterior-inferior quadrant. Similarly, an intraoperative in-vivo study by Hau et al. found that if a posterior approach is used, the posterior-inferior quadrant is the most frequent liner position providing the greatest stability to posterior luxation (65). Interestingly, a study of Divecha et al. with data of the National Joint Registry (NJR) found that lipped liners were only able to reduce the risk of instability for the posterior approach (SHR = 0.59; 95% CI = 0.39-0.88; $p = 0.002$), but not for the lateral approach (SHR = 0.82; 95% CI = 0.44-1.53; $p > 0.999$) (43). Unfortunately, the EPRD does not yet record the surgical approach. Our survey, as well as a survey by Stratos et al., suggests that in Germany the anterior, anterolateral, and lateral approaches are more common than the posterior approach (66). This fact could partly explain why we did not find a difference in risk of mechanical complications between lipped and standard liners. Despite the fear of dislocation with a posterior approach, meta-analyses could not confirm a higher dislocation rate for the posterior approach in comparison to the direct lateral (67) or to the direct anterior approach (68).

Considering individual patient factors, lumbosacral pathology was mentioned in our survey as a reason to use a lipped liner. The orientation of the acetabulum changes slightly from standing to sitting (69). In patients with sufficient lumbosacral mobility, the lordosis of the lumbar spine decreases and the pelvis tilts posteriorly. Accordingly, the anteversion and inclination of the acetabulum increases to make room for the flexed femur (70). In patients with reduced lumbosacral mobility, the posterior tilt of the pelvis is limited (“stuck standing”). Thus, the hip joint needs to compensate for the limited mobility of the lumbar spine with greater flexion of the femur, which can lead to anterior impingement and posterior dislocation of the femoral head (71). Lipped liners may be reasonable to use in patients with limited lumbosacral mobility to reduce posterior dislocation (33). However, it is also suggested to just position the acetabular cup in 5° more anteversion and inclination to accommodate the greater flexion of the femur (72).

We found, that angulated-offset liners increased the risk of revision for mechanical complications nearly two-fold. There was one additional revision for mechanical complications for every 35 hip arthroplasties with angulated-offset liners instead of standard liners. Gray et al. discussed impingement and spontaneous dissociation of a +4 mm offset/10° face-changing liner from its shell in four women (73). All four had to undergo revision arthroplasty within 3 to 36 months after the index operation. They concluded that osseous and component impingement should be checked intraoperatively. Also, if the acetabular component had been positioned correctly, a special liner would not have been necessary. Divecha et al. found that offset reorienting liners, although more frequently used with larger head sizes, were associated with an increased risk of instability (SHR = 1.61; 95% CI = 1.12, 2.32; p = 0.010) (43).

The use of asymmetric liners in primary total hip arthroplasty is still controversial and should be carefully evaluated. The most important preventive measure for instability is the correct position of the acetabular component. In cases where the posterior approach is used, lipped liners may improve stability if positioned with the elevated rim in the posterior-inferior quadrant.

4.2.2 Offset Liners

Offset liners were the only liners reducing the risk of mechanical complications. Offset liners modify the hip offset, which is the sum of femoral and acetabular offset. Femoral offset has been defined as the perpendicular distance between the hip centre of rotation of the femoral head and the long axis of the femur and acetabular offset as the distance between the true floor/quadrilateral plane of the acetabulum and the hip centre of rotation (74). Hip offset determines the hip abductor moment arm and soft tissue tension around the hip joint, regulating the strength of the hip abductors, the hip range of motion and consequently the hip joint stability (75). It is recommended to reconstruct the hip offset within 5 mm of the native geometry (76).

Multiple factors need to be considered in offset reconstruction. Native acetabular and femoral offsets are highly variable and average around 30.8 mm ± 3 (22-37 mm) for acetabular (74) and 43 mm ± 6.8 (23.6-61.0 mm) for femoral offsets (77). Total hip offset can not be regained with a high offset stem in all patients (77,78). Also, an increased offset femoral stem may cause more strain on the proximal medial femur (75). The loss of cartilage in an osteoarthritic hip is accompanied by loss of acetabular offset (79). As a

result of the reaming technique, the hip centre of rotation is often displaced medially (78). In these instances, offset liners could be used to reconstruct the acetabular offset.

There are two approaches in offset reconstruction. The first technique is to medialise the hip centre of rotation by reaming to the true floor of the acetabulum. Medialisation of the acetabular component reduces the body weight lever arm and consequently the joint reaction force, leading to less friction and less implant wear. In most of the cases it also ensures proper cup coverage. The second technique is to preserve acetabular bone stock and reconstruct the hip centre of rotation more anatomically. Anatomic reconstruction can decrease osseous impingement and increase the hip range of motion. Preserving acetabular bone stock is also an advantage if revision of the acetabular component becomes necessary (74,80,81).

Optimal depth, height, and version can be reliably determined by the transverse acetabular ligament. If the acetabular cup is placed too deep in orientation to the transverse acetabular ligament, an offset liner may be used to restore the acetabular offset (82). Lateralisation of the hip centre of rotation should be avoided as it can result in larger torsional forces at the liner-shell interface and bone-implant interface, which may lead to increased wear and fixation failure (83–85). Like the elevated rim of the lipped liner, the protruding rim of the offset liner, which is unsupported by the acetabular shell, may be vulnerable to stress from impingement. The minimum rim thickness can be much lower than the stated nominal thickness due to indentations that are part of the locking mechanism of offset liners (86,87).

Wear and loosening might be less of a concern with offset liners made from cross-linked polyethylene. Chapmen et al. examined wear rates of neutral and +4 mm cross-linked polyethylene liners in a 5-year prospective radiographic study (88). Wear rates of both liner types did not reach the osteolysis threshold of 0.1 mm/year for linear and 150 mm³/year for volumetric wear (89,90). In none of the two cohorts were signs of osteolysis found or revisions for osteolysis necessary. They also suggest that women with smaller pelvises might benefit from offset liners as they allow the acetabulum to accommodate larger femoral heads (88). Interestingly, in our study we observed the highest percentage of women in the offset liner group. A recent study by Patel et al. concluded that offset liners appear to be safe to use for offset restoration. They found no differences in the rates of postoperative complications, aseptic loosening, or revision surgery comparing

standard and offset liners in a three year follow-up (91). However, it is unknown how offset liners perform over longer periods of time.

Hip offset reconstruction is an important concept in hip replacement surgery and offset liners can help to restore the native hip biomechanics. In our study, offset liners were associated with a reduced risk of mechanical complications over a mid-term follow-up. However, it remains unclear in which specific way offset liners were able to reduce the risk. It is possible, that acetabular offsets in the standard liner group were insufficiently restored. Also, with offset liners made from cross-linked polyethylene, less bony impingement, and a greater hip range of motion, could have outweighed the disadvantage of slightly increased rates of wear.

4.2.3 Confounders

Older patients appeared to be especially vulnerable for mechanical complications in the first year after surgery. After the first year, older patients had a reduced risk of revision for mechanical complications. Similarly, a study by Johnsen et al. with data of the Danish Hip Arthroplasty Registry found that patients aged 80 years or older were at increased risk of failure within 30 days after surgery (92). Six months to 8.6 years after surgery, patients under 60 years were at an increased risk of implant failure. The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) reported that patients aged 75 years and older had lower rates of revision than patients aged under 55 years three months after surgery, and lower rates than patients aged 55-64 years six months after surgery (93). Bottle et al. concluded that patients under 60 years are at increased risk for early revision (94). It is known that aging is associated with loss of bone and muscles mass as well as with a reduced sensory perception (95). Older patients are more vulnerable to postoperative cognitive impairment, such as postoperative delirium (96), which can lead to non-compliance and increases the risk of falls. All of this contributes to an overall higher rate of perioperative mortality and postoperative complications (97,98). Greater physical activity in younger patients could explain why, in our analysis, younger age was associated with an increased risk of mechanical complications after one year postoperatively (99–102). Especially wear and loosening are closely related to late dislocations (103,104).

The most common comorbidity in our investigation, affecting more than half of the patients, was uncomplicated hypertension. We found that patients with multiple

comorbidities were at increased risk of revision for mechanical complications. Likewise, the Australian (AOANJRR) and the Swedish arthroplasty registry (SAR) reported that patients with a mild systemic disease, for example controlled hypertension or diabetes mellitus, are already at increased risk of reoperation (14,93).

Over 90% of the liners in our analysis were made from cross-linked polyethylene. Our findings indicate that cross-linked polyethylene, in comparison to conventional polyethylene, reduced the risk of mechanical complications. In a medium-term follow up period of 5 to 12 years, Shen et al. reported that cross-linked polyethylene reduced radiological wear, but was not able to reduce osteolysis or the rate of wear-related revisions (105). An analysis of data from the National Joint Registry by Davis et al. found a reduced risk of aseptic loosening with crosslinked polyethylene at 14 years follow up (106).

Experience plays a key role in joint replacement surgery. Ravi et al. reported that hip arthroplasties are at increased risk for revision if they are performed by surgeons conducting less than 36 procedures per year (HR = 1.44; 95% CI = 1.15-1.80; $p = 0.001$) (107). Steinbrück et al. found that hospitals with more than 500 total hip arthroplasties per year have the lowest rate of revision. Similarly, a change of the implant manufacturer increased the risk of revision from 3.2% to 3.7% after three years ($p < 0.001$) (31). We found a slightly decreased risk of revision for mechanical complications if the liner design had a high share in the respective hospital. Special liner designs were used for over 80% of the hip arthroplasties in 35 hospitals, which most likely reflects a routine use of special liners in these hospitals.

Older patients, particularly those with multiple comorbidities, are at increased risk of revision for mechanical complications within the first year after total hip arthroplasty. Modern liners are mainly made from cross-linked polyethylene, which reduces the risk of mechanical complications – even more pronounced in the longer term. Being proficient with one liner design may further reduce the risk of revision for mechanical complications.

4.3 Limitations

One of the main limitations of the liner study is confounding by indication for the different liner designs. Possible confounders that could not be included in the statistical analysis are the BMI of the patient, the surgical approach, the position of the acetabular components, and the method used for determining the correct position of the acetabular

and femoral component (for example, X-ray versus manual alignment guides). The findings may not be applicable to patients with primary diagnoses other than osteoarthritis, as well as to patients with previous operations of the hip joint. Not every implant manufacturer produces all types of special liners, for example offset liners, and liner designs may slightly differ between producers. Hospitals could have incorrectly used ICD-10 and OPS codes in their surgery reports which might have reduced the data quality. However, the ERPD runs plausibility tests between data sources to minimize false inputs. Although most mechanical complications occurred early, the maximum follow-up of the liner study is 7.9 years, which does not cover late mechanical failure.

Results of the survey reflect the preferences of some, but certainly not all, orthopaedic surgeons in Germany. The ERPD had the information on one contact person per hospital. The contact person had to further distribute the survey, which implies that possibly not all surgeons eligible to participate received the survey. In general, surveys are subjective, and we do not know how truthful or precise all answers are. In addition, survey participants could have incorrectly interpreted questions.

4.4 Conclusion

Although routinely implanted in some of the studied hospitals, preventive measures like asymmetric liners might not work. We found no difference in the risk of revision for mechanical complications for lipped and angulated liners in comparison to standard liners. Moreover, angulated-offset liners were associated with an almost two-fold increased risk of revision for mechanical complications. The offset liner was the only liner reducing the risk – however, the performance of offset liners over a longer period of time needs to be investigated. If a lipped liner is used, the posterior-inferior position might be more effective to reduce posterior dislocation. Older patients, especially patients with a high comorbidity burden, are at an increased risk of mechanical complications during the first year following surgery. To reduce mechanical complications, we suggest using a cross-linked polyethylene liner as well as having sufficient experience with the chosen liner design.

4.5 Implications for Practice and Future Research

There is still no gold-standard for the choice of acetabular liner design in total hip arthroplasty. With the liner study and survey, we aimed to shed light on the performance and the utilization of special acetabular liners in Germany to guide surgeons in their liner

selection. We found that in Germany, most special liners did not perform better than standard liners in primary total hip arthroplasty. Future research is warranted to investigate indications for special liners in (primary) total hip arthroplasty as well as to discern which patient benefits from which specific liner design. We recommend documenting the surgical approach and the position of an asymmetrical liner for future studies. It would be reasonable to repeat this analysis with additional registry data from the next 5 to 10 years to study the long-term performance of special liners – most importantly for offset liners.

The German government plans to use the EPRD as a blueprint for a National Implant Registry (Implantateregister Deutschland, IRD). The IRD is expected to start to fully operate for hip and knee implants in 2025. Currently, the NJR and the EPRD are working together to harmonize implant classification systems and product libraries with the aim to cooperate with other registries in the future. A global cooperation of implant registries benefits all with the possibility of nationwide analyses, involving even larger numbers of patients, as well as a better transferability of results between registries. Cooperation – with the aim to improve the longevity and the functionality of hip arthroplasties as well as the overall patient satisfaction.

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Statutory Declaration

“I, Paula Krull, by personally signing this document in lieu of an oath, hereby affirm that I prepared the submitted dissertation on the topic: “Special and standard acetabular liners in primary total hip arthroplasty. A mid-term observational study and survey with data of the German Arthroplasty Registry (EPRD). (Spezial- und Standard-Inlays in primärer Hüfttotalendoprothetik. Eine mittelfristige Beobachtungsstudie und Umfrage mit Daten des Endoprothesenregister Deutschland (EPRD))“, independently and without the support of third parties, and that I used no other sources and aids than those stated.

All parts which are based on the publications or presentations of other authors, either in letter or in spirit, are specified as such in accordance with the citing guidelines. The sections on methodology (in particular regarding practical work, laboratory regulations, statistical processing) and results (in particular regarding figures, charts and tables) are exclusively my responsibility.

Furthermore, I declare that I have correctly marked all of the data, the analyses, and the conclusions generated from data obtained in collaboration with other persons, and that I have correctly marked my own contribution and the contributions of other persons (cf. declaration of contribution). I have correctly marked all texts or parts of texts that were generated in collaboration with other persons.

My contributions to any publications to this dissertation correspond to those stated in the below joint declaration made together with the supervisor. All publications created within the scope of the dissertation comply with the guidelines of the ICMJE (International Committee of Medical Journal Editors; www.icmje.org) on authorship. In addition, I declare that I shall comply with the regulations of Charité – Universitätsmedizin Berlin on ensuring good scientific practice.

I declare that I have not yet submitted this dissertation in identical or similar form to another Faculty.

The significance of this statutory declaration and the consequences of a false statutory declaration under criminal law (Sections 156, 161 of the German Criminal Code) are known to me.”

Date

Signature of doctoral candidate

Declaration of Contributor Roles for the Publications

Paula Krull contributed the following to the below listed publications:

Publication 1: Krull P, Steinbrück A, Grimberg AW, Melsheimer O, Morlock M, Perka C. Modified acetabular component liner designs are not superior to standard liners at reducing the risk of revision : an analysis of 151,096 cementless total hip arthroplasties from the German Arthroplasty Registry. *Bone Jt J.* 2022 Jul;104-B(7):801–10.

Declaration of own contribution for publication 1:

All figures and tables, except figure 2, were created by first author Paula Krull as agreed upon by all authors (Paula Krull, Arnd Steinbrück, Alexander W. Grimberg, Oliver Melsheimer, Michael M. Morlock, Carsten Perka). Figure 2 was acquired by co-author Michael M. Morlock and provided by courtesy of LINK GmbH, Germany. The preliminary draft was written by first author Paula Krull as agreed upon by all authors. The text was reviewed and edited by all authors.

Contributor roles outlined in accordance with the Contributor Roles Taxonomy (CRediT):

Conceptualization	AS, AWG, MMM, CP
Data curation	OM
Formal Analysis	PK
Funding acquisition	AS, AWG, MMM, CP
Investigation	AS, AWG, OM
Methodology	PK, OM
Project administration	MMM, CP
Resources	AS, AWG, MMM, CP
Software	PK
Supervision	MMM, CP
Validation	OM
Visualization	PK, MMM
Writing – original draft	PK, AS, AWG, OM, MMM, CP
Writing – review & editing	PK, AS, AWG, OM, MMM, CP

Paula Krull (PK), Arnd Steinbrück (AS), Alexander W. Grimberg (AWG), Oliver Melsheimer (OM), Michael M. Morlock (MMM), Carsten Perka (CP).

Publication 2: Krull P, Steinbrück A, Grimberg AW, Melsheimer O, Morlock MM, Perka C. Standard- und Spezialinlays in primärer Hüftendoprothetik : Aktuelle Studien- und Umfrageergebnisse aus dem Endoprothesenregister Deutschland (EPRD) [Standard and special liner in primary hip arthroplasty : Current study and survey results from the German Arthroplasty Registry (EPRD)]. *Orthopädie (Heidelb).* 2023 Mar;52(3):222-232.

Declaration of own contribution for publication 2:

All figures and tables, except figure 1, were created by first author Paula Krull as agreed upon by all authors (Paula Krull, Arnd Steinbrück, Alexander W. Grimberg, Oliver Melsheimer, Michael M. Morlock, Carsten Perka). The upper part of figure 1, depicting pictures of the liner designs, was acquired by co-author Michael M. Morlock and provided by courtesy of LINK GmbH, Germany. The lower part of figure 1, depicting schematic drawings of the liner designs, was created by first author Paula Krull as agreed upon by all authors. The preliminary draft was written by first author Paula Krull as agreed upon by all authors. The text was reviewed and edited by all authors.

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Conceptualization	PK, AS, AWG, OM, MMM, CP
Data curation	PK, OM
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Validation	AS, AWG, OM, MMM, CP
Visualization	PK
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Signature of doctoral candidate

Excerpt from Journal Summary List

Journal Data Filtered By: **Selected JCR Year: 2021** Selected Editions: SCIE,SSCI
 Selected Categories: **"ORTHOPEDICS"** Selected Category Scheme: WoS
Gesamtanzahl: 86 Journale

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfaktor
1	Journal of Physiotherapy	2,608	10.714	0.00316
2	OSTEOARTHRITIS AND CARTILAGE	22,876	7.507	0.01717
3	AMERICAN JOURNAL OF SPORTS MEDICINE	47,641	7.010	0.03636
4	JOURNAL OF BONE AND JOINT SURGERY-AMERICAN VOLUME	55,669	6.558	0.03243
5	JOURNAL OF ORTHOPAEDIC & SPORTS PHYSICAL THERAPY	10,856	6.276	0.00706
6	ARTHROSCOPY-THE JOURNAL OF ARTHROSCOPIC AND RELATED SURGERY	22,695	5.973	0.01958
7	Bone & Joint Journal	11,210	5.385	0.01936
8	Journal of Orthopaedic Translation	1,965	4.889	0.00243
9	EFORT Open Reviews	2,037	4.775	0.00498
10	Brazilian Journal of Physical Therapy	2,714	4.762	0.00287
11	CLINICAL ORTHOPAEDICS AND RELATED RESEARCH	47,131	4.755	0.01884
12	JOURNAL OF ARTHROPLASTY	31,049	4.435	0.03783
13	Bone & Joint Research	2,339	4.410	0.00372
14	EUROPEAN CELLS & MATERIALS	3,770	4.325	0.00158
15	Spine Journal	13,705	4.297	0.01567
16	Journal of Orthopaedics and Traumatology	1,439	4.239	0.00172
17	KNEE SURGERY SPORTS TRAUMATOLOGY ARTHROSCOPY	23,806	4.114	0.02695
18	JOURNAL OF THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS	9,794	4.000	0.01165

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfaktor
62	Clinical Spine Surgery	2,060	1.723	0.00587
63	PROSTHETICS AND ORTHOTICS INTERNATIONAL	2,242	1.672	0.00162
64	Journal of Hip Preservation Surgery	851	1.604	0.00173
65	Acta Orthopaedica et Traumatologica Turcica	1,684	1.557	0.00189
66	Joint Diseases and Related Surgery	526	1.549	0.00041
67	HAND CLINICS	2,575	1.536	0.00166
68	Journal of Orthopaedic Surgery	2,593	1.482	0.00358
69	JOURNAL OF PEDIATRIC ORTHOPAEDICS-PART B	2,263	1.473	0.00168
70	JOURNAL OF BACK AND MUSCULOSKELETAL REHABILITATION	2,079	1.456	0.00227
71	Hand Surgery & Rehabilitation	557	1.419	0.00122
72	ORTHOPEDE	6,444	1.345	0.00496
73	Journal of Foot & Ankle Surgery	4,823	1.345	0.00471
74	Journal of Plastic Surgery and Hand Surgery	1,186	1.295	0.00129
75	Operative Orthopadie und Traumatologie	690	1.286	0.00051
76	Zeitschrift fur Orthopadie und Unfallchirurgie	690	1.108	0.00062
77	SPORTVERLETZUNG-SPORTSCHADEN	319	1.073	0.00023
78	Indian Journal of Orthopaedics	2,053	1.033	0.00192
79	ORTHOPEDE	1,627	1.004	0.00131
80	Orthopaedic Nursing	732	0.988	0.00060
81	Clinics in Podiatric Medicine and Surgery	822	0.769	0.00059
82	ISOKINETICS AND EXERCISE SCIENCE	701	0.729	0.00026

Printing Copies of the Publications

Publication 1: Krull P, Steinbrück A, Grimberg AW, Melsheimer O, Morlock M, Perka C. Modified acetabular component liner designs are not superior to standard liners at reducing the risk of revision : an analysis of 151,096 cementless total hip arthroplasties from the German Arthroplasty Registry. *Bone Jt J.* 2022 Jul;104-B(7):801–10.

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Publication 2: Krull P, Steinbrück A, Grimberg AW, Melsheimer O, Morlock MM, Perka C. Standard- und Spezialinlays in primärer Hüftendoprothetik : Aktuelle Studien- und Umfrageergebnisse aus dem Endoprothesenregister Deutschland (EPRD) [Standard and special liner in primary hip arthroplasty : Current study and survey results from the German Arthroplasty Registry (EPRD)]. Orthopädie (Heidelb). 2023 Mar;52(3):222-232.

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Curriculum Vitae

My curriculum vitae does not appear in the electronic version of my paper for reasons of data protection.

Publication List

Krull P, Steinbrück A, Grimberg AW, Melsheimer O, Morlock M, Perka C. Modified acetabular component liner designs are not superior to standard liners at reducing the risk of revision : an analysis of 151,096 cementless total hip arthroplasties from the German Arthroplasty Registry. *Bone Jt J.* 2022 Jul;104-B(7):801–10. Journal Impact Factor: 5.385.

Krull P, Steinbrück A, Grimberg AW, Melsheimer O, Morlock MM, Perka C. [Standard and special liner in primary hip arthroplasty : Current study and survey results from the German Arthroplasty Registry (EPRD)]. *Orthopädie (Heidelb).* 2023 Mar;52(3):222–32. Journal Impact Factor: 1.004.

Szymiski D, Walter N, Krull P, Melsheimer O, Grimberg A, Alt V, Steinbrück A, Rupp M. Aseptic revisions and pulmonary embolism after surgical treatment of femoral neck fractures with cemented and cementless hemiarthroplasty in Germany: an analysis from the German Arthroplasty Registry (EPRD). *Journal of Orthopaedics and Traumatology.* 2023 Feb 22;24(1):9. Journal Impact Factor: 4.239.

Szymiski D, Walter N, Krull P, Melsheimer O, Lang S, Grimberg A, Alt V, Steinbrück A, Rupp M. The Prophylactic Effect of Single vs. Dual Antibiotic-Loaded Bone Cement against Periprosthetic Joint Infection Following Hip Arthroplasty for Femoral Neck Fracture: An Analysis of the German Arthroplasty Registry. *Antibiotics.* 2023 Apr;12(4):732. Journal Impact Factor: 3.424.

Szymiski D, Walter N, Krull P, Melsheimer O, Grimberg A, Alt V, Steinbrueck A, Rupp M. Infection after intracapsular femoral neck fracture – does antibiotic-loaded bone cement reduce infection risk after hemiarthroplasty and total hip arthroplasty?: data from the German Arthroplasty Registry. *Bone Joint Res.* 2023 May 16;12(5):331–8. Journal Impact Factor: 4.410.

Szymiski D, Walter N, Krull P, Melsheimer O, Schindler M, Grimberg A, Alt V, Steinbrueck A, Rupp M. Comparison of mortality rate and septic and aseptic revisions in total hip arthroplasties for osteoarthritis and femoral neck fracture: an analysis of the German Arthroplasty Registry. *J Orthop Traumatol.* 2023 Jun 17;24(1):29. Journal Impact Factor: 4.239.

List of Congress Presentations

Paula Krull. Überhöhte Inlays, offset-Inlays - was reduziert die Revisionsrate? Endoprothetik-Kongress Berlin (EKB); 2022 Feb 11; Berlin, Germany.

Paula Krull. HTEP in Registern: Wann ist welches Inlay das Beste? Deutscher Kongress für Orthopädie und Unfallchirurgie (DKOU); 2022 Oct 25; Berlin, Germany.

Paula Krull. Mechanical failure of standard and modified liner designs in primary cementless total hip arthroplasty. An analysis based on the German Arthroplasty Registry. 11th Annual International Congress of Arthroplasty Registries (ISAR); 2022 Sep 3; Dublin, Ireland.

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