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Malseating of modular dual mobility liners

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Aims

Prior studies have identified that malseating of a modular dual mobility liner can occur, with previous reported incidences between 5.8% and 16.4%. The aim of this study was to determine the incidence of malseating in dual mobility implants at our institution, assess for risk factors for liner malseating, and investigate whether liner malseating has any impact on clinical outcomes after surgery.

Methods

We retrospectively reviewed the radiographs of 239 primary and revision total hip arthroplasties with a modular dual mobility liner. Two independent reviewers assessed radiographs for each patient twice for evidence of malseating, with a third observer acting as a tiebreaker. Univariate analysis was conducted to determine risk factors for malseating with Youden's index used to identify cut-off points. Cohen's kappa test was used to measure interobserver and intraobserver reliability.

Results

In all, 12 liners (5.0%), including eight Stryker (6.8%) and four Zimmer Biomet (3.3%), had radiological evidence of malseating. Interobserver reliability was found to be 0.453 (95% confidence interval (CI) 0.26 to 0.64), suggesting weak inter-rater agreement, with strong agreement being greater than 0.8. We found component size of 50 mm or less to be associated with liner malseating on univariate analysis (p = 0.031). Patients with malseated liners appeared to have no associated clinical consequences, and none required revision surgery at a mean of 14 months (1.4 to 99.2) postoperatively.

Conclusion

The incidence of liner malseating was 5.0%, which is similar to other reports. Component size of 50 mm or smaller was identified as a risk factor for malseating. Surgeons should be aware that malseating can occur and implant design changes or changes in instrumentation should be considered to lower the risk of malseating. Although further follow-up is needed, it remains to be seen if malseating is associated with any clinical consequences.

Cite this article: *Bone Jt Open* **2021;2-10:858–864.**

Keywords: malseating, dual mobility, MDM

Introduction

Instability remains one of the most common reasons for revision following total hip arthroplasty (THA), with a reported incidence of up to 7% after primary and 25% after revision THA.[1] Dual mobility bearings have been shown to mitigate the risk of postoperative instability, including high-risk groups, such as those undergoing revision THA.[2-4]

While most early dual mobility designs used a monoblock acetabular component, modular dual mobility prostheses in which a cobalt-chromium liner is impacted into a titanium acetabular component have become more popular recently, as they provide the familiarity of use of a standard titanium acetabular component and the option for supplementary screw fixation. However, malseating of the modular acetabular liner has been identified as a potential issue with modular dual mobility designs.[5-7] Potential concerns with a malseated dual mobility modular acetabular liner include corrosion at the liner-shell interface, increased prosthetic impingement, and even complete dissociation of the liner itself.[8-10]

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doi: 10.1302/2633-1462.210.BJO-2021-0124.R1

Bone Jt Open 2021;2-10:858–864.

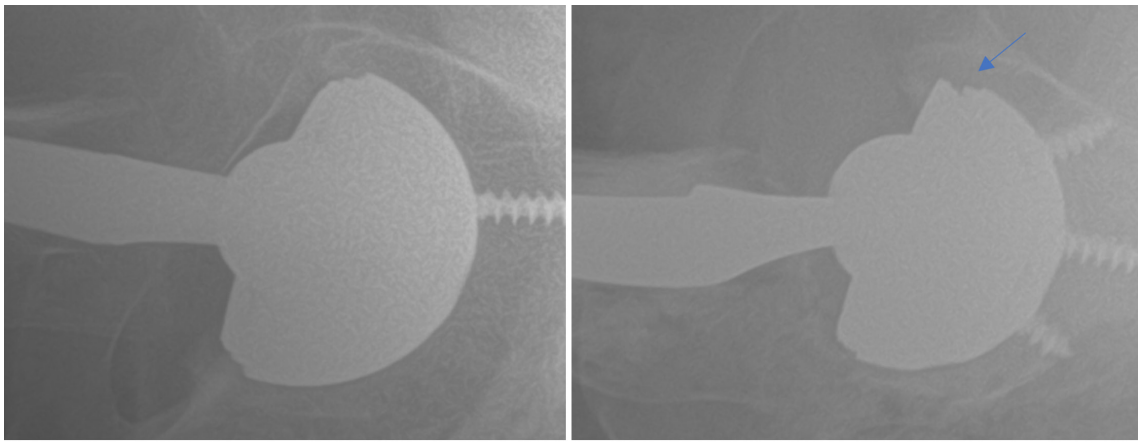

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Fig. 1

A well-malseated versus a malseated Stryker Trident implant. a) A non-malseated Stryker Trident implant demonstrating no gaps between the liner and the rim of the acetabular shell. A well-malseated versus a malseated Stryker Trident implant. b) A malseated Stryker Trident implant with a clear gap between the metal back of the liner and the rim of the acetabular shell.

The purpose of this study was to assess the incidence of malseating in patients who received dual mobility implants undergoing primary and revision THA at Rush University Medical Center, USA. We also assessed whether there were any risk factors for liner malseating, reviewed patient-reported outcome measures (PROMs) of our cohort, and looked for any complications or revisions in patients found to have a malseated liner.

Methods

This was a retrospective review performed at Rush University Medical Center, USA, of primary and revision THAs performed with a modular dual mobility bearing between April 2011 and July 2020. A total of 259 consecutive modular dual mobility implants implanted by two surgeons (CDV, DN) were identified. In all, 20 hips were excluded as they did not have both anteroposterior (AP) and cross table lateral radiographs at their postoperative visits, leaving 239 hip implants in 219 patients. Acetabular implants used included 98 Trident I (41.0%), three Trident II (1.3%), two Trident II Tritanium (0.8%), one primary Tritanium (0.4%), 14 revision Tritanium (5.9%) components (all Stryker, USA), and 121 Biomet G7 (50.6%) acetabular components (Zimmer Biomet, USA). The mean age at surgery was 65.8 years (standard deviation (SD) 12.4; 32 to 94), with our cohort consisting of 130 females (59.4%) and 89 males (40.6%), and a mean BMI of 30.0 kg/m^2 (SD 6.5; 18 to 57.4). Mean acetabular component size was 52.5 mm (SD 4.2; 46 to 66), with 54 22 mm (inner femoral head) and 185 28 mm (inner femoral head) dual mobility bearings used.

Previous methodology outlined in prior work was used to determine if a liner was malseated.[5-7,11] A Stryker modular liner was considered malseated if there was either a visible gap between the back of the liner and the rim of the acetabular shell, or if there was any angulation between the liner and the shell (Figure 1). Unlike the Stryker modular dual mobility liner, the Biomet G7 modular liner is intended to sit flush with the rim of the acetabular shell. A Biomet G7 liner was considered malseated if there were any distinct gaps seen on the otherwise flush implant surface on AP or cross table lateral radiographs (Figure 2). Two initial reviewers (JG, DP) independently reviewed all radiographs twice for evidence of malseating approximately two weeks apart. Interobserver and intraobserver reliability was calculated for the two initial reviewers, and the senior author (DN) acted as a third reviewer who confirmed liner malseating and was used as a tiebreaker on any cases where the two initial reviewers did not agree.

Demographic variables, revision rate, and patient-reported outcome measures (PROMs) of patients with malseated implants versus non-malseated implants were analyzed. PROM scores at the six-week, six-month, one-year, and two-year follow-up time points were compared to preoperative PROM scores.

Statistical analysis. Statistical analysis was performed using the SAS software (SAS, USA). Independent-samples *t*-tests or Mann-Whitney U tests were used to analyze continuous variables, while chi-squared test and Fisher's exact test were used to analyze categorical variables. Cohen's kappa test was used to measure interobserver and intraobserver reliability. Youden index was used to measure the cut-off point for component sizes that could be a risk factor for malseating.

Results

Of 239 dual mobility implants analyzed, 12 (5.0%) were found to be malseated. We found evidence of malseating on 8/98 (8.2%) Trident I, and 4/121 (3.3%) Biomet G7 implant designs. The initial two reviewers reviewed all radiographs twice, with an interobserver reliability of

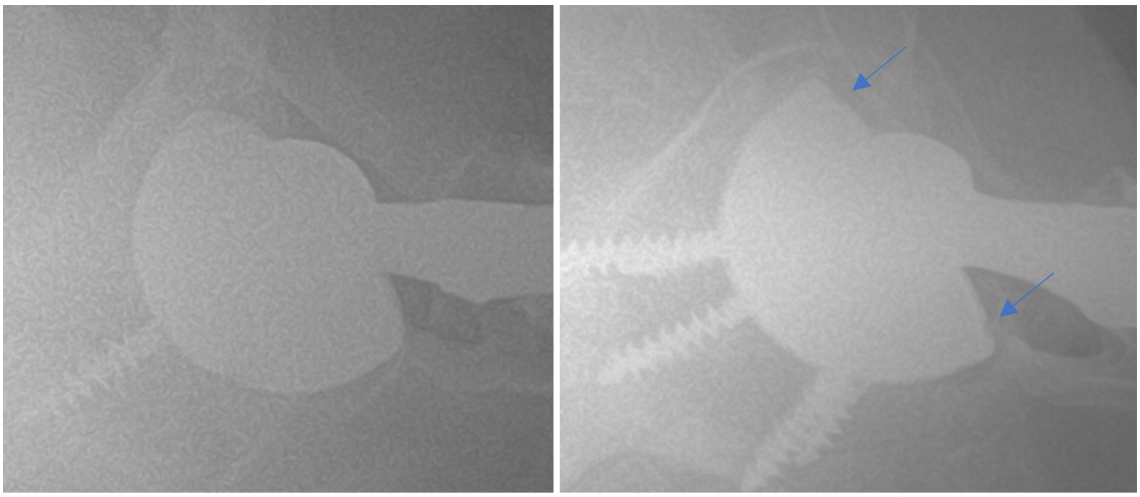

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Fig. 2

A well-malseated Zimmer Biomet G7 implant versus a malseated Zimmer Biomet G7 implant. a) A non-malseated Biomet G7 implant. A well-malseated Zimmer Biomet G7 implant versus a malseated Zimmer Biomet G7 implants. b) Malseated Zimmer Biomet G7 implants with gaps seen along the implant surface.

Table I. Comparison of sex, implant, revision rate, and component size of non-malseated versus malseated liners.

Variable	Total (n = 239), n (%)	Non-malseated outcome (n= 227), n (%)	Malseated outcome (n = 12), n (%)	p-value*
Sex				0.3796
Female	147 (65.1)	138 (93.88)	9 (6.12)	
Male	92 (38.49)	89 (96.74)	3 (3.26)	
Implant				0.4634
Trident I	98 (41.0)	90 (91.84)	8 (8.16)	
Trident II	3 (2.60)	3 (100.00)	0 (0.00)	
Trident II Tritanium	2 (0.84)	2 (100.00)	0(0.00)	
Stryker primary Tritanium	1 (0.42)	1 (100.00)	0(0.00)	
Stryker revision Tritanium	14 (5.86)	14(100.00)	0(0.00)	
Zimmer Biomet G7	121 (50.63)	117 96.69)	4 (3.31)	
Revision				1.000
Yes	5 (2.09)	5(100.00)	0(0.00)	
No	234 (97.91)	222 (94.87)	12 (5.13)	
Component size, mm				0.0308
≥ 50.01	140 (58.58)	137 (97.86)	3 (2.14)	
< 50.01	99 (41.420	90 (90.91)	9 (9.09)	

*Fisher's exact test.

0.453 (95% confidence interval (CI) 0.26 to 0.64), which suggests weak inter-rater agreement in the clinical setting where agreement below 0.8 is considered suboptimal.[12] Intraobserver reliability between both readings of the radiographs was 0.74 (95% CI 0.54 to 0.94) for reviewer one, and 0.65 (95% CI 0.39 to 0.91) for reviewer two, which suggests moderate, but still suboptimal, intra-rater agreement in the clinical setting.[12] The incidence of malseating for each surgeon was 7.1% (DN) and 2.7% (CDV), with each surgeon having used 127 and 112 dual mobility implants, respectively.

We found there to be no difference in malseated versus non-malseated implants in regard to sex, implant type, or revision rate after surgery (Table I). Malseated liners were more prevalent with smaller component size (p = 0.021, Mann-Whitney U test; Table II). Specifically, component sizes below 50.01 mm were found to be associated with malseated liners (p = 0.031, Fisher's exact test; Table I).

In all, nine of the 219 patients in our cohort experienced a postoperative complication. These included five dislocations, two small bowel obstructions, one case of pyelonephritis, and one pulmonary embolism, which occurred 11 days after surgery in a patient who was found to have a malseated implant during our review (Table III). Of the five dislocations, three subsequently require revision surgery and two were treated successfully with closed reduction. Further details of the five dislocations in our cohort are detailed in Table IV.

Table II. Univariate analysis of age, BMI, and component size of non-malseated versus malseated liners.

	Total				Non-malseated				Malseated				
Variable	**n**	**Mean**	**Median**	**SD**	**n**	**Mean**	**Median**	**SD**	**n**	**Mean**	**Median**	**SD**	**p-value***
Age at surgery, yrs	239	65.83	66.93	12.38	227	65.82	66	12.28	12	65.94	67.53	14.7	0.9749
BMI, kg/m²	239	30.01	29	6.52	227	29.95	29	6.5	12	31	29	6.98	0.5892
Component size	239	52.47	52	4.16	227	52.61	52	4.19	12	49.83	50	2.33	0.0206

*Independent-samples *t*-test or Mann-Whitney U test.
SD, standard deviation.

Table III. Breakdown of complications in non-malseated versus malseated patient cohort.

Complication	**Total (n = 9), n (%)**	**Non-malseated, n**	**Malseated, n**
Dislocation	5 (55.56)	5	0
Small bowel obstruction	2 (22.22)	2	0
Pyelonephritis	1 (11.11)	1	0
Pulmonary embolism	1 (11.11)	0	1

Table IV. Details of patients with postoperative dislocations.

Age at surgery, yrs	**Sex**	**Comorbidities/history**	**Preoperative diagnosis**	**Procedure**	**Component**	**Outcome**
75	F	History of multiple previous revision surgeries of right hip for periprosthetic joint infection	Status post removal of infected right total hip arthroplasty and placement of static antibiotic loaded spacer	Revision total hip arthroplasty	Stryker revision Tritanium 54 mm component	Initially treated with closed reduction and eventually required revision to a constrained liner
47	F	Down's Syndrome	Failed left total hip arthroplasty secondary to acetabular component loosening	Revision of left total hip arthroplasty, acetabular component	Stryker revision Tritanium 54 mm component	Complicated by periprosthetic joint infection treated with two-stage exchange
63	F	Lumbar fusion	Right hip displaced femoral neck fracture	Right total hip arthroplasty	Zimmer Biomet G7 48 mm component	Treated with closed reduction with no further complications
58	M	History of failed hip resurfacing complicated by pseudotumor. Patient revised to THA and had subsequent dislocations	Status post left total hip arthroplasty dislocation with bearing surface intraprosthetic dislocation	Left total hip arthroplasty revision	Stryker Trident I 56 mm component	Initially treated with closed reduction and later required revision surgery to an anterior lip liner
79	F	History of multiple previous revision surgeries of right hip for periprosthetic joint infection	Status post-removal of infected right total hip arthroplasty and placement of static antibiotic loaded spacer	Revision total hip arthroplasty	Stryker revision Tritanium 66 mm component	Treated with closed reduction with no further complications

None of the patients who were found to have malseated implants appeared to have clinical consequences associated with their implant including liner dissociation or required revision surgery during the study period with mean follow-up of 14 months (1.4 to 99.2) postoperatively. We found no differences in Harris Hip Score, Hip disability and Osteoarthritis Outcome Score (HOOS) Jr Score, and Veterans RAND 12-tem (VR-12) iphysical component score in malseated versus non-malseated patients at the various follow-up time points included in our analysis (Table V).

Of note, we happened to have the metal ion levels at the preoperative, one-year, and two-year time points of one of the patients that was found to have a malseated Biomet G7 liner as they were in another study evaluating metal ion levels at our institution. This patient's chromium and cobalt concentrations in serum at the two-year time point was < 0.1 mcg/l and 0.29 mcg/l, respectively (Table VI), which are within the expected range for a patient with a well functioning metal on polyethylene bearing.[13]

Discussion

Dual mobility articulations have received increased interest as several studies have noted their ability to reduce instability in high-risk patient populations and patients undergoing revision THA.[1-4,14] Dual mobility constructs increase stability by increasing the effective femoral head size, increasing jump distance, and adding a second articulation, which effectively increases the range of motion free of impingement.[15] However, there has been increased concern with modular dual mobility liners for the risk of malseating, potential corrosion at the liner-shell interface, and even liner dissociation.[7-9]

We found there to be a 5.0% incidence of malseated implants in 239 dual mobility implants analyzed at our institution, which is in line with preceding studies reporting between a 5.8% and 16.4% incidence of

Table V. Comparison of preoperative versus postoperative PROMs of non-malseated versus malseated patients.

	Total		Non-Malseated		Malseated		
PROM variable	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**p-value***
Change in Harris Hip Score, time point							
Six weeks	111	19.41 (21.60)	107	19.49 (21.87)	4	17.25 (14.13)	0.840
Six months	64	30.59 (21.43)	61	30.34 (21.55)	3	35.67 (22.28)	0.7871
One year	70	34.9 (20.92)	65	35.09 (21.20	5	32.4 (18.65)	0.7581
Two years	20	41.74 (19.49)	16	42.88 (20.61)	4	37.2 (15.72)	0.6158
Change in HOOS Jr. Score, time point							
Six weeks	152	18.94 (18.91)	144	18.72 (18.88)	8	22.75 (20.32)	0.5552
Six months	80	26.67 (21.92)	77	26.27 (22.19)	3	37.02 (9.69)	0.4081
One year	82	32.87 (19.6)	75	33.43 (19.54)	7	26.92 (20.77)	0.4041
Two years	21	38.11 (22.41)	17	39.57	4	31.91 (10.28)	0.5525
Change in VR-12 physical score, time point							
Six weeks	165	1.89 (9.86)	157	1.97 (9.60)	8	0.47 (14.87)	0.9572
Six months	94	12.15 (10.69)	90	12.3 (10.84)	4	8.84 (6.39)	0.5296
One year	89	12.49 (11.51)	82	12.58 (11.88)	7	11.47 (6.25)	0.578
Two years	25	17.57 (9.02)	23	17.42 (9.30)	2	19.37 (6.70)	0.7758

*Independent-samples *t*-test or Mann-Whitney U test.
HOOS, Hip disability and Osteoarthritis Outcome Score; PROM, patient-reported outcome measure; SD, standard deviation; VR-12, Veterans RAND 12-item.

Table VI. Metal ion levels of patient found to have malseated liner in our cohort.

Time point	Titanium in serum, mcg/l	Chromium in serum, mcg/l	Cobalt in serum, mcg/ml	Cobalt-chromium ratio
Preoperative	< 0.3	0.1447	0.1657	1.1451
One year	5.8816	< 0.1	0.2864	2.864
Two years	4.6395	< 0.1	0.2936	2.936

malseating.[5-7] We found that smaller component sizes were associated with malseated implants on univariate analysis, and also found that component sizes below 50.01 mm were associated with malseating. These findings suggest that smaller component sizes, specifically below 50 mm, could be a risk factor for the development of a malseated liner. This finding is similar to a previous study by Romero et al[7] that also found smaller component size to be associated with malseated implants in their univariate analysis, but did not examine a cut-off point for component size. While the incidence of malseating for each surgeon was 7.1% and 2.7%, respectively, we believe these incidences are due to the fact that the first surgeon primarily using Stryker implants, while the second primarily used Zimmer Biomet implants, and the differences between these designs.

Although the phenomenon of malseating has been well documented, the exact cause of a malseated liner remains unknown. Some possible hypotheses include a prominent acetabular screw, and soft-tissue or bone interposition at the rim of the implant.[5-7,16,17] In addition, the Stryker modular dual mobility liner does not sit flush with the face of the acetabular shell, making it difficult to assess if the liner is completely seated circumferentially. Another proposed explanation is that the acetabular shell can deform upon impaction into hard bone, thus slightly altering its hemispherical shape. This could inhibit seating of the hard, cobalt alloy modular liner. Techniques to reduce the risk of malseating should include thorough removal of all soft tissue and osteophytes around the periphery of the component that may impede seating of the liner and confirmation that any acetabular screws are well seated. Recently, Chalmers et al[17] found a 1.3% incidence of malseated implants in their patient cohort, and advocated using a four-quadrant test to mechanically verify proper implant engagement, particularly in the inferior segment which can be challenging to visualize intraoperatively. The four-quadrant test involves tapping the modular liner in all four quadrants using a liner impactor and assessing whether there is any movement or disengagement of the liner.

The clinical consequence of modular liner malseating remains unknown. We found there to be no differences between malseated and non-malseated patients in regard to revision rate, Harris Hip Score, HOOS Jr Score, and VR-12 physical component PROM scores at any postoperative follow-up time point, further suggesting that to date there are no meaningful patient-reported clinical consequences associated with liner malseating. Previous studies have proposed that malseated liners have an increased propensity for fretting corrosion, and thus potentially increased risk of adverse local tissue reaction.[8,9] Romero et al[7] conducted a simulated corrosion chamber analysis of the modular dual mobility liner shell microenvironment, and demonstrated earlier fretting current onset at lower peak loads in malseated liners compared to well seated liners. However, the authors noted that this finding does not suggest that all malseated implants will develop this issue. This study also only tested one angle

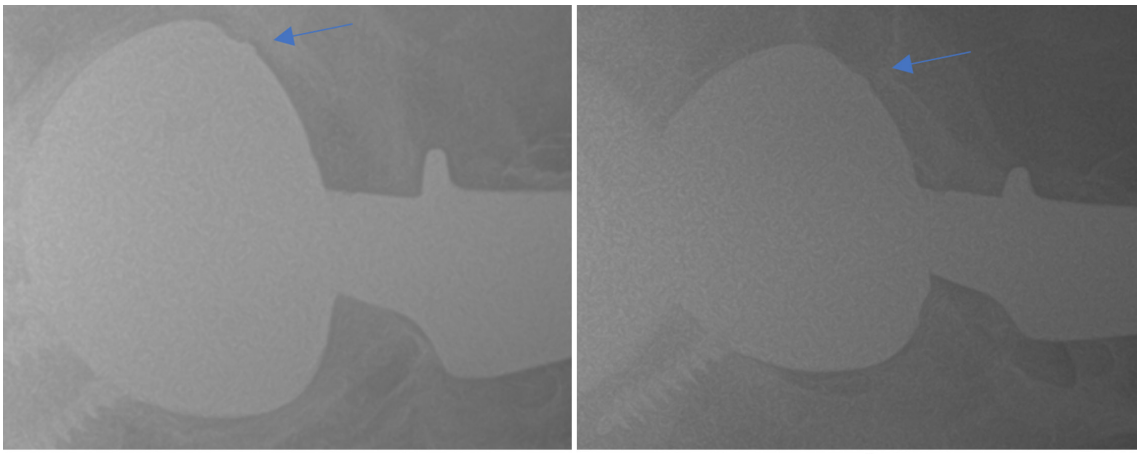

Fig. 3

Two radiographs taken on the same day of a Stryker Trident implant demonstrating how the same implant can look different on two separate radiographs taken on the same day; a) A Stryker Trident II implant demonstrating possible concern for malseating. b) The same Stryker Trident II implant from a radiograph taken on the same day demonstrating lower concern for malseating.

of malalignment and their results only reflect that of the highest malseated alignment they observed clinically. They did not test the extent of increased fretting and risk of corrosion in cases with lower angles of malseating.[7]

A major limitation of this study was the variability in interobserver and intraobserver reliability for identifying malseating on plain radiographs. The interobserver reliability agreement of 0.453 (95% CI 0.26 to 0.64) in particular highlights the degree of difficulty encountered when trying assess whether a liner was malseated on plain radiographs. Agreement of greater than 0.80 has been suggested as the minimum acceptable level of agreement in the clinical setting.[12] We also found it to be particularly difficult to determine whether Zimmer Biomet G7 implants were, in fact, malseated due to the flush nature of the Biomet G7 implant and the extremely subtle differences between malseated and non-malseated implants for this design (Figure 2). With both the Stryker and Zimmer Biomet designs, we also found instances where an implant could appear malseated on one postoperative image, but not on a subsequent image taken at a later visit. We found one particular instance where two radiographs taken on the same day for a patient with a Stryker Trident II implant appeared to look different, with one radiograph demonstrating possible concern for malseating and the second demonstrating a lower concern for malseating (Figure 3). This case highlights both the difficulty in accurately assessing liner malseating and also how even a subtle change in the technique of radiograph acquisition could change how the liner appears. The presence of locking tabs in the periphery of the Stryker components, along with projections through screw holes of both components, can alter the appearance of the modular liner.

A further limitation of this study is that it is a retrospective review of a relatively limited sample size. Furthermore, we only had serum metal ion levels for one malseated patient in our cohort. Future studies could examine whether there are any differences between the serum metal ion levels of patients found to have malseated vs non-malseated implants. This would help elucidate whether there are any clinically relevant differences in serum metal ion levels between these patient groups, and determine if malseated implants in patients are truly susceptible to fretting and corrosion that produce a clinically relevant increase in serum metal ion levels. Finally, our clinical follow-up is short, and careful follow-up over an extended period of time will be needed to ensure that no clinical consequences of malseating are realized.

In conclusion, we identified approximately 5% of modular dual mobility liners were malseated at our institution with component sizes of 50 mm or less at greatest risk. However, we did not find any differences in clinical outcomes between patients with or without a malseated liner at short-term follow-up. Design and/or instrument changes should be considered to facilitate concentric seating of modular dual mobility liners to decrease the risk of malseating.

Take home message

- Malseating of dual mobility constructs can occur with this study reporting a 5.0% incidence of malseating in our cohort.
- Smaller cup component sizes was identified as a risk factor for malseating, specicially cup component sizes below 50 mm.
- While no clinical consequence of malseating were reported in this study, surgeons should be aware of this phenomena and ensure proper concentric seating of dual mobility liners to decrease the risk of malseating.

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Funding statement:
- The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. In addition, benefits have been or will be directed to a research fund, foundation, educational institution, or other non- profit organization with which one or more of the authors are associated.

ICMJE COI statement:
- C. Della Valle reports consultancy from DePuy, Smith & Nephew, and Zimmer Biomet, royalties from Zimmer Biomet, Smith & Nephew, SLACK, and Wolter Kluwer, stock/stock options from Parvizi Surgical Innovations and Orthophor, and research support as a principal investigator from Smith & Nephew, Stryker, Zimmer Biomet, and CD Diagnostics, all of which is outside of this submitted work. D. Nam declares consultancy from Kinetic Concepts and Stryker, and research support as a principal investigator from Kinetic Concepts and Zimmer Biomet, which is also unrelated.

Acknowledgements:
- We thank Yanyu Zhang (Statistician at Rush University Medical Center, Chicago, Illinois, USA) for providing support for statistical analysis related to this study.

Open access funding
- This study was self-funded by the orthopedic department at Rush University Medical Center, Chicago, USA.