UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MARY BAYES and PHILIP BAYES,	)	
	)	
Plaintiff(s),	)	
	)	
vs.	)	Case No. 4:13-cv-00800-SRC
	)	
BIOMET, INC., et al.,	)	
	)	
Defendant(s).	)	

Memorandum and Order

In 2008, Plaintiff Mary Bayes had both her hips replaced with artificial hip implants designed by Defendant Biomet Orthopedics, LLC. After her hip replacements, she encountered severe complications requiring numerous additional hip surgeries. Mary and her husband Philip[1] filed suit against Biomet, and the Court determined that they have presented enough evidence that Biomet defectively designed the hip implant to merit a jury trial. The numerous motions the parties filed include eight different motions to exclude expert testimony. Having ruled on Biomet's motions to exclude Plaintiffs' experts, the Court now takes up Plaintiffs' motions to exclude Biomet's experts [105] [113] [116].

I. Background

The Court has thoroughly recounted the facts of this case in its Order on Biomet's Motion for Summary Judgment. *See* Doc. 225. In the same Order, the Court explains some of the medical terminology at issue in this case and likewise does not repeat those explanations here.

[1] The Court refers to Plaintiffs Mary and Philip Bayes by their first names to distinguish them, and not to imply any familiarity.

II. Legal Standard

To be admissible, Federal Rule of Evidence 702 requires the expert testimony (1) help the trier of fact determine facts at issue; (2) be based on sufficient facts or data; and (3) be the product of reliable principles and methods. In addition, the expert must have reliably applied those principles and methods to facts of the case. This Court must act as a "gatekeeper" in determining the admissibility of expert testimony and must "make a preliminary assessment of whether the proffered expert's methodology is both scientifically valid and applicable to the case." *Bland v. Verizon Wireless, (VAW) LLC*, 538 F.3d 893, 896 (8th Cir. 2007); *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993).

Federal Rule of Evidence 403 permits the trial court to exclude relevant evidence if its probative value is "substantially outweighed" by a danger of "unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403.

III. Biomet's expert Dr. Thomas Bauer

Biomet's expert Dr. Thomas Bauer, M.D., is an orthopedic pathologist. He is the head of the Department of Pathology and Laboratory Medicine at the Hospital for Special Surgery in New York City. Bauer has M.D. and Ph.D. degrees from the University of Nebraska and completed his residency in Anatomic and Clinical Pathology at Johns Hopkins. He is board certified in Anatomic and Clinical Pathology and has more than thirty years of experience as a pathologist. Bauer is a member of the American Academy of Orthopaedic Surgeons, the Orthopaedic Research Society, and the College of American Pathologists.

A. Bauer's opinions

Biomet retained Bauer to provide a pathology opinion on Mary Bayes's case. Bauer reviewed Mary's medical records, deposition transcripts of Plaintiffs and of other retained experts, and microscope slides containing tissue excised from Mary's left hip during her first revision surgery. Based on his review of the records and examination of the tissue slides, Bauer prepared a report opining that Mary's left-hip tissue at the time of revision showed features consistent with an immune reaction. Doc. 140-1 at 26. After the parties discovered tissue samples taken during Mary's right-hip revision surgery, Bauer issued a supplemental report opining that Mary's right-hip tissue did not show features of an immune reaction. Doc. 140-2 at 3.

B. Plaintiffs' motion to exclude

Plaintiffs do not move to exclude Bauer's case-specific pathology opinions regarding Mary's right or left hip. Instead, Plaintiffs only move to preclude Bauer from testifying regarding certain background opinions included in his expert report. First, Plaintiffs ask the Court to preclude Bauer from opining on alternative causes of hip-implant failure. Second, Plaintiffs seek to exclude Bauer's opinion that immune reaction caused by polyethylene wear debris was, for many years, the leading cause of hip-implant failure. Third, Plaintiffs seek to exclude Bauer's opinion regarding purported misuse of the terms "metallosis," "pseudotumor," and "adverse local tissue reaction." Finally, Plaintiffs seek to exclude certain photographs included in Bauer's expert report for lack of foundation.

1. Bauer's opinions regarding alternative causes of hip-implant failure

Plaintiffs first seek to preclude Bauer from testifying regarding the following portion of his expert report:

> **B. Total Hip Arthroplasty**. During a hip replacement operation, the femoral head is excised and the femoral component of the implant is placed into the

> proximal femur. At about the same time, another implant, the acetabular component, is placed into the pelvis. The position and alignment of these implants is important for them to function as intended. The femoral and acetabular components can be composed of various types of materials, including metal alloys, polyethylene, or ceramic. No synthetic articulation is perfect, so hip motion always leads to the production of small particles of debris from the implants. There are many factors that influence the number of particles and the size of the debris particles. Those factors include, among other things: 1) surgical variables, such as implant position or device impingement, 2) patient factors, such as weight and activity, and 3) implant factors such as material composition, implant size, implant shape and surface finish. For example, if the acetabular component is oriented too vertically, then the head or neck of the femoral component might come in contact with the edge of the implant instead of the center of the articular surface. This can lead to excessive wear of both the acetabular component and the femoral head (Figs 8, 9). Repeated dislocation or impingement of the neck of the femoral component on the acetabular implant can also cause unexpected wear. For any given patient, surgeons have to balance the advantages and disadvantages of each implant system and each surgical procedure.

Doc. 106-1 at 7. Plaintiffs argue that Bauer is not qualified, as a pathologist, to opine on this subject matter. The Court disagrees. Although not an orthopedic surgeon, Bauer is a member of the American Academy of Orthopedic Surgeons (AAOS) and a former member of the Practice Guidelines Committee of the AAOS. Bauer has published extensively regarding the evaluation of orthopedic implants. Further, Bauer testified that his opinions set forth in the passage above are "fundamental principles of arthroplasty that sort of everybody in medical school learns." Doc. 106-3 at 100:5-7. Plaintiffs may cross-examine Bauer on his qualifications. But at this gatekeeping stage, the Court finds Bauer qualified to opine on this subject matter.

Plaintiffs also argue that Bauer's testimony on alternative causes of hip-implant failure would be unnecessarily duplicative, since other experts are qualified to opine on the same subject matter. Plaintiffs do not point to any specific opinions or testimony from another expert witness that duplicates Bauer's opinions set forth above. The Court will not permit needlessly repetitive or cumulative testimony at trial, but on the present record finds no cause to exclude Bauer's testimony as duplicative.

2. Bauer's opinion that polyethylene wear debris was the most frequent cause of hip-implant failure

Plaintiffs also ask the Court to preclude Bauer from offering the following opinion included in his report: "[T]he most frequent cause of hip implant failure between about 1985 and 2015 was aseptic implant loosening caused by the macrophage reaction to particles of debris, usually polyethylene." Doc. 106-1 at 9. Plaintiffs argue this opinion is irrelevant and unfairly prejudicial, since the failure rate of polyethylene implants does nothing to show that metal-on-metal implants are reasonably safe. Biomet responds that the opinion is relevant "because it provides important context on the development of metal-on-metal implants in total hip arthroplasty" since "polyethylene wear was the driving force behind the development of the second generation of metal-on-metal implants at issue in this case." Doc. 140 at 4.

The Court will allow Bauer to offer this opinion. To prevail on their design-defect claim, Plaintiffs must show that Biomet's design of the M2a Magnum was unreasonably dangerous. *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 792 (Mo. Ct. App. 2008). The failure rate of polyethylene devices provides at least some context for the design challenges Biomet faced in designing the metal-on-metal M2a Magnum. *See Moore v. Ford Motor Co.*, 332 S.W.3d 749, 768 (Mo. 2011) (permitting evidence "of the relative safety of other designs" on claims of strict-liability design defect and negligent design). Accordingly, the Court does not find that the probative value of Bauer's opinion is substantially outweighed by the danger of unfair prejudice. Fed. R. Evid. 403.

3. Bauer's opinions regarding misuse of terms

Plaintiffs next seek to exclude Bauer's opinions regarding the misuse of certain medical terms associated with hip-implant failure. In his report, Bauer opines that medical professionals

sometimes misuse the terms "metallosis," "pseudotumor," and "adverse local tissue reaction (ALTR)." Regarding metallosis, Bauer opines:

> Sometimes surgeons use the term "metallosis" to describe gray or black discoloration around an implant. However the term is non-specific, and many factors, such as blood clot or old organizing hemorrhage can make tissue appear black.

Doc. 106-1 at 17. Bauer further opines that pathologists sometimes use the term "metallosis" to refer generally to opaque particles in macrophages, but "this can also be misleading" because the particles observed in macrophages can also come from non-metallic sources. *Id.*

Regarding "pseudotumor," Bauer opines that the term is used "inconsistently by surgeons, radiologists, and pathologists" to describe various phenomena, some of which are not associated with metal-on-metal implants. According to Bauer, this inconsistent usage has "rendered the term nearly meaningless." *Id.* Finally, with respect to "adverse local tissue reaction," Bauer opines that the term is "completely non-specific" because it can refer to tissue showing a number of different reactions, including infection, reaction to particle debris, or immune response. *Id.* Bauer is similarly critical of the term "adverse reaction to metal debris." *Id.*

Plaintiffs contend that Bauer lacks qualifications or a "reliable methodology" to offer these opinions, and argue that the proffered testimony is "really an attempt to offer expert testimony concerning the credibility of other witnesses." Doc. 106 at 8. The Court disagrees. First, the Court finds Bauer qualified to offer opinions regarding the proper use of these medical terms based on his 30-plus years of experience as a pathologist. To the extent Plaintiffs challenge the factual basis of Bauer's opinion, such criticism goes to weight, rather than admissibility. *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001) ("As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the

admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination.").

Finally, the Court rejects Plaintiffs contention that Bauer's opinions constitute impermissible comment on other witnesses' credibility. Plaintiffs are correct that experts "should not offer an opinion about the truthfulness of witness testimony." *Nichols v. Am. Nat. Ins. Co.*, 154 F.3d 875, 883 (8th Cir. 1998). But that is simply not what Bauer has done. Unlike in *Nichols*, where the Eighth Circuit held expert testimony inadmissible because the expert commented directly on the psychological credibility of the plaintiff, Bauer does not mention another witness. Bauer only opines that these terms are sometimes used in inaccurate or misleading ways. If Bauer's opinion is correct, then his testimony will help the jury to understand and evaluate testimony that employs these terms. And if Plaintiffs contend that Bauer's opinion is *not* correct—i.e., that these terms are not prone to misuse as Bauer claims—then Plaintiffs' appropriate solution is "vigorous cross-examination" or the presentation of contrary evidence. *Daubert*, 509 U.S. at 596.

4. Photographs in Bauer's expert report

Finally, Plaintiffs seek to preclude Bauer from using certain photographs in his expert report as exhibits at trial. Plaintiffs contend that Bauer's report includes 12 photographs for which Bauer cannot establish necessary foundation, so the photographs "fail the reliability prong under Rule 702." Doc. 106 at 9. Bauer testified that the photographs depict tissue slides from his own medical practice, but he could not recall specifics regarding the patients from whose tissue the slides were made or when the photos were taken. Doc. 106-3 at 109:1-16. Biomet argues that the photographs are demonstratives only, and may be used at trial for that purpose.

In Bauer's report, each of the photographs at issue is accompanied by a caption, written by Bauer, describing a biological process depicted in the image. For example, the following caption accompanies the photograph labeled Figure 17:

> Tissue around an infected implant contains neutrophils. These are the cells of acute inflammation and are not a feature of an adaptive immune response or particle-induced bone resorption.

Doc. 106-1 at 14. The Court finds the captions contain Bauer's substantive opinions. Conversely, demonstrative exhibits are not substantive evidence. *See Bradshaw v. FFE Transp. Servs., Inc.*, 715 F.3d 1104, 1109 (8th Cir. 2013). Thus, the photographs are merely illustrative of the opinions in Bauer's report, and do not themselves constitute opinion evidence. As such, the Court finds Plaintiffs' Rule 702 motion an inappropriate mechanism to challenge the use of these photographs at trial. "The use of charts, diagrams, and other visual aids to summarize other evidence is generally permissible in the sound discretion of the trial court." *Asarco LLC v. Nl Indus., Inc.*, 106 F. Supp. 3d 1015, 1024 (E.D. Mo. 2015) (citing *United States v. Caswell*, 825 F.2d 1228, 1235 (8th Cir. 1987)). The Court will permit Biomet to use these photographs at trial as demonstratives only.

IV. Biomet's expert Dr. Thomas Fleeter

Biomet's expert Dr. Thomas Fleeter, M.D. is a board certified orthopedic surgeon. He graduated from the Howard University School of Medicine in 1979 and then completed his residency in orthopedic surgery at George Washington University. From 1984 to 2006, he was a clinical instructor of orthopedic surgery at George Washington University. Fleeter has been a member of the American Academy of Orthopedic Surgeons since 1986.

A. Fleeter's opinions

Fleeter provided a non-case-specific expert report in the MDL. Plaintiffs did not move to exclude Fleeter's non-case-specific opinions before the deadline and the MDL judge held that

any subsequent motion to exclude those opinions would be untimely. Doc. 18 at 8-9. In the present case, Biomet retained Fleeter to "provide the orthopedic surgeon perspective" on topics including Mary's course of treatment and experience with the M2a Magnum. Doc. 141 at 1. Fleeter issued a case-specific report opining that the M2a Magnum was not the cause of Mary's left-hip-implant failure. Doc. 141-1 at 6.

B. Plaintiffs' motion to exclude

Plaintiffs do not move to exclude Fleeter's conclusion that the M2a Magnum was not the cause of Mary's left-hip-implant failure. Instead, Plaintiffs ask the Court to exclude certain subsidiary opinions in Fleeter's case-specific report. First, Plaintiffs argue that Fleeter is not qualified to opine on the adequacy of the M2a Magnum's Instructions for Use. Second, Plaintiffs seek to preclude Fleeter from opining that the design of the M2a Magnum was not defective. Third, Plaintiffs argue that Fleeter's opinions regarding the use of "constrained liners" in Mary's later revision surgeries are irrelevant and unfairly prejudicial. Finally, Plaintiffs ask the Court to exclude Fleeter's opinion that the left-hip cup was positioned at 60 degrees of abduction at the time of implantation and did not migrate thereafter.

1. Fleeter's opinions regarding adequacy of instructions

Plaintiffs argue that Fleeter is not qualified as an orthopedic surgeon to offer opinions on the adequacy of Biomet's M2a Magnum Instructions for Use. The motion is untimely. Fleeter opined in his MDL report that the Instructions for Use "were routinely updated and were consistent with the state of knowledge in the orthopedic community when issued." Doc. 141-3 at 10-11. As noted above, the MDL judge determined that any motion to exclude these opinions would be untimely. Doc. 18 at 8-9. Accordingly, the Court denies Plaintiff's Rule 702 motion

to exclude Fleeter's opinions on the adequacy of the Instructions for Use, at least insofar as those opinions are included in his MDL report.

However, since Plaintiffs filed their motion to exclude these opinions, the Court issued its order granting Biomet's motion for summary judgment on Plaintiffs' failure-to-warn claims. *See* Doc. 225. Thus, the Court will not permit any testimony—from Fleeter or any other witness—regarding the adequacy of Biomet's Instructions for Use absent a showing of relevance to some claim or defense still at issue. *See* Fed. R. Evid. 401.

2. Opinions regarding design defect

Fleeter opines that "the M2a cup was not the reason for the failure of the left hip." Doc 114-1 at 5. Plaintiffs do not ask the Court to exclude this opinion. Rather, Plaintiffs "anticipate" that, in conjunction with this testimony, Fleeter will also seek to opine that the design of the M2a Magnum hip system was not defective. Doc. 114 at 11. In response, Biomet represents that Fleeter "has not offered, and does not intend to offer, the opinion Plaintiffs seek to exclude regarding design defect." Doc. 141 at 8. The Court will not permit Fleeter to offer any opinion not included in his MDL or case-specific reports. *See* Fed. R. Civ. Proc. 37(c)(1). Because Fleeter does not intend to offer the opinion at issue, Plaintiffs' "anticipatory" Rule 702 motion is moot.

3. Fleeter's opinions regarding constrained liners

Mary has undergone a total of six revision surgeries on her left hip. Doc. 225 at 7. Unlike the metal-on-metal M2a Magnum device, metal-on-polyethylene or ceramic-on-polyethylene hip implants incorporate a plastic (polyethylene) liner between the head and cup components. Mary's third and sixth revision surgeries used a liner variant known as

"constrained liners." In his report, Fleeter explains the characteristics of constrained liners, and opines that they are prone to failure:

> While the standard acetabular component is a hemisphere, constrained liners lock the femoral head within the acetabular component. This constrained design, while preventing dislocation, have [sic] a significantly higher failure rate.

Doc. 114-1 at 5.

Plaintiffs argue the Court should exclude Fleeter's opinion as irrelevant and unfairly prejudicial. The Court disagrees. "Evidence is relevant if it has any tendency to make a fact more or less probable than it would be without the evidence; and the fact is of consequence in determining the action." Fed. R. Evid. 401. Fleeter's testimony regarding the failure rate of constrained liners has at least some tendency to show the constrained liner caused (or contributed to cause) the failure of Mary's third revision, necessitating her fourth revision. And the cause of this revision surgery matters in this action because Mary seeks damages for injuries associated with her revision surgeries. Plaintiffs argue that the constrained liners lack relevance to Mary's later dislocations and revisions because, by that time, the M2a Magnum had already irreversibly damaged her hip tissues. But Plaintiffs merely state their theory of the case, which depends on disputed questions of fact. In sum, the Court denies Plaintiff's motion to exclude Fleeter's opinion as irrelevant.

The Court also denies Plaintiffs' motion to exclude Fleeter's opinion as unfairly prejudicial. "Rule 403 'does not offer protection against evidence that is merely prejudicial in the sense of being detrimental to a party's case. The rule protects against evidence that is unfairly prejudicial, that is, if it tends to suggest decision on an improper basis.'" *United States v. Myers*, 503 F.3d 676, 682 (8th Cir. 2007) (quoting *Wade v. Haynes*, 663 F.2d 778, 783 (8th Cir. 1981)). Fleeter's opinion prejudices Plaintiffs only in the sense that it suggests another cause for Mary's injuries. This is not an improper basis for decision.

4. Fleeter's opinions regarding position of left-hip cup

Finally, Plaintiffs seek to exclude Fleeter's opinions that Dr. Martin implanted the left hip acetabular cup at roughly 60 degrees of abduction and the cup did not later migrate. In his report, Fleeter opines: "review of the x-rays confirms that the left acetabular component is positioned at approximately 60° of abduction." Doc. 114-1 at 5. During his deposition, Fleeter clarified his opinion that the abduction angle was approximately 60 degrees even in the x-rays taken at the time of implantation:

> Q. Did you review the 2008 X-rays taken post surgery of Mary Bayes after her original implantation of the Biomet M2a Magnum?
>
> A. Yes.

Doc. 141-2 at 101:20-102:1.

> Q. Your testimony as you sit here today is that 2008 X-rays show a hip abduction angle of 60 degrees?
>
> A. Roughly, yes.

Id. at 192:2-5. Plaintiffs contend that the Court should exclude Fleeter's opinion as unreliable and irrelevant. Plaintiffs do not clearly articulate why this opinion is irrelevant to this case, and the Court finds that it is plainly relevant. *See* Fed. R. Evid. 401. Fleeter's opinion directly relates to Biomet's contention that Mary's left-hip cup abduction angle—rather than a design defect in the M2a Magnum—caused her metallosis and resultant injuries.

Plaintiffs argue Fleeter's opinion that the 2008 x-rays show a 60 degree abduction angle is unreliable because Plaintiff's expert, Dr. Lux, calculated the abduction angle to be at 49 degrees. Doc. 114 at 18. But this is simply disagreement between experts on the correct interpretation of the evidence, and Plaintiffs' position lacks merit. Fleeter testified specifically as to why he believes Lux miscalculated the abduction angle:

> I had two issues with [Lux's] measurement. One, I don't think his abduction line, if we're going to call it the angle of abduction, was drawn in the right place. . . . And second of all, I think it's just about impossible to measure an angle of abduction from a single [front-to-back x-ray] of a hip. You need to have a view of both hips so you can tell whether the pelvis is tilted one way or another.

Doc. 141-2 at 109:2-19. In effect, Plaintiffs ask the Court to hold, as a matter of law, that Lux's interpretation of the 2008 x-rays is the correct one. While the Court acts as a "gatekeeper," admitting expert testimony only if it is relevant and reliable, "[t]he gatekeeper role should not . . . invade the province of the jury, whose job it is to decide issues of credibility and to determine the weight that should be accorded evidence." *United States v. Vesey*, 338 F.3d 913, 917 (8th Cir. 2003); *see also Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 562 (8th Cir. 2014) ("district courts are admonished not to weigh or assess the correctness of competing expert opinions"). In this case, as in most cases, the parties present conflicting expert opinions. The Court will not invade the province of the jury by pre-judging witness credibility.

Plaintiffs also seek to exclude Fleeter's opinions that the cup did not migrate after implantation and his "corollary opinion" that the position of the left-hip cup caused Mary's metallosis and left-hip-implant failure. Doc. 114 at 19-20. But Plaintiffs' sole argument for exclusion of these opinions is that they depend on Fleeter's "assumption" the left-hip cup was 60 degrees abducted at the time of implantation. As noted above, the Court will permit Fleeter to opine that the left-hip cup was abducted 60 degrees at the time of implantation. Thus, Plaintiff's motion to exclude to Fleeter's remaining opinions lacks merit.

In sum, the Court denies Plaintiffs' motion to exclude Fleeter's opinions and testimony.

V. Biomet's expert Dr. Steven Kurtz

Biomet's expert Dr. Steven Kurtz is the Director of Biomechanical Engineering at Exponent, Inc. He concurrently serves as a Research Professor and Director of the Implant Research Center (IRC) at Drexel University's School of Biomedical Engineering, Science, and

Health Systems. Kurtz received his Ph.D. in mechanical engineering from Cornell University in 1995. He has published extensively regarding biomechanical engineering topics related to hip replacement, including co-authoring and editing a textbook focused on the biomaterials used in total hip arthroplasty. Kurtz is a Fellow in the American Institute for Medical and Biomechanical Engineering and a member of the Orthopedic Research Society and the American Academy of Orthopedic Surgeons.

A. Kurtz's opinions

Biomet retained Exponent and Kurtz to provide a causation opinion regarding "the biomechanical and biomaterials factors related to Ms. Bayes's hip replacement surgeries." Doc. 117-2 at vii. Kurtz prepared a case-specific report opining that: (1) Mary's right hip implant exhibited an expected rate of wear and "device factors" were not a cause of her right-hip revision; (2) the position of Mary's left-hip cup contributed to the failure of her left hip implant and "device factors" were not a cause of her left-hip revisions; (3) the metal-on-metal design of the M2a Magnum reduced Mary's risk of certain causes of failure compared to alternative designs; and (4) there is insufficient evidence that an alternative design would have averted Mary's need for revision surgery. *Id.* at vii.

B. Plaintiffs' motion to exclude

Plaintiffs move to exclude all of Kurtz's opinions under Rules 702 and 403. As a preliminary matter, the Court finds that Plaintiffs' have waived their Rule 403 motion to exclude. In their introduction, Plaintiffs assert generally that Kurtz's opinions "would be substantially more prejudicial than probative, confuse the issues, and mislead the jury." Doc. 117 at 1. But apart from this single conclusory statement, Plaintiffs offer no argument or explanation for how or why the challenged opinions violate Rule 403. Accordingly, the Court denies Plaintiff's 403

motion to exclude Kurtz's opinions. *See Structural Polymer Grp., Ltd. v. Zoltek Corp.*, No. 4:05-CV-321 (CEJ), 2007 WL 1083758, at *1 (E.D. Mo. Apr. 11, 2007), *aff'd*, 543 F.3d 987 (8th Cir. 2008) ("The Court deems abandoned any claims for relief not supported by argument or citation to legal authority."); *see also Collier v. Hanger Orthopedic Grp., Inc.*, No. 12-6087-CV-SJ-SOW, 2013 WL 12201281, at *5 (W.D. Mo. Feb. 15, 2013) ("It is well established that conclusory, undeveloped arguments are not sufficient to raise an issue.").

Plaintiffs argue that Kurtz's opinions regarding Mary's right hip should be excluded under Rule 702 because his methodology is unreliable and because the opinions are not relevant. Plaintiffs ask the Court to exclude Kurtz's opinions regarding Mary's left hip because Kurtz relied on a flawed and unreliable methodology. Plaintiffs also seek to exclude Kurtz's opinions regarding alternative designs, arguing that such testimony is not relevant to any fact at issue. Finally, Plaintiffs argue that Kurtz is unqualified as a biomechanical engineer to opine on two topics addressed in his report: Biomet's M2a Magnum warnings and pathology.

1. Kurtz's opinions regarding right hip

In his report, Kurtz summarizes his opinions regarding Mary's right hip:

> The material loss from Ms. Bayes' right M2a Magnum components was 1.6 mm^3/yr. This value is within the range of expected wear rates for metal-on-metal bearings, and is consistent with a biomechanically well-functioning hip. Accordingly, I have ruled out device factors as a cause of her right hip revision.

Doc. 117-2 at vii. Plaintiffs argue the Court should exclude these opinions on two grounds. First, Plaintiffs argue Kurtz's methodology is unreliable because he did not properly measure all possible sources of wear. The M2a Magnum hip implant has three components: a ball-shaped femoral head (which is attached to the end of the femur, the elongated bone extending from the hip to the knee), a taper insert (used to attach the head of the implant to the femur), and an acetabular cup (which is seated in the hip). After removal from Mary's body, Kurtz used a

laboratory testing process to measure the volume of wear from the head and cup. He determined that the wear rate was within the expected range. Plaintiffs do not challenge the testing process Kurtz used on the cup and head. However, Kurtz could not apply the same testing process to the taper because parts of the taper were coated in dried blood, and the parties stipulated that any testing could not disturb the blood. Kurtz testified: "[T]here was too much blood and dry biological deposits on the tapers to be able to do a measurement without disturbing those." Doc. 143-2 at 177:6-9. Because of these constraints, Kurtz could only perform a visual inspection of the taper. Based on his visual inspection, Kurtz concluded that there "wasn't [a] significant amount of material loss" from the taper. *Id.* at 211:22-213:5.

Plaintiffs argue the Court should exclude Kurtz's opinion that Mary's right hip M2a Magnum exhibited an expected rate of wear because Kurtz did not include taper-wear in his measurements. The Court disagrees. Kurtz measured the cup and head. He could not measure the taper but was able to visually inspect it, and observed insignificant material loss. Thus, Kurtz's opinion that that the implant exhibited an expected rate of wear is based on the available evidence (keeping in mind that the parties' stipulation regarding the taper constrains the availability of evidence) and reasonable inference from that evidence. Plaintiffs may cross-examine Kurtz on the fact he did not measure the taper. But the Court denies Plaintiffs' motion to exclude his opinion on that basis.

Plaintiffs also move to exclude Kurtz's opinion that the right hip implant exhibited expected wear on the grounds that the opinion is "not relevant" because "it assumes that the expected wear rate is a safe wear rate." Doc. 117 at 7. Biomet responds that "Kurtz is neither a physician nor a toxicologist, and he does not purport to opine on the relative safety of the observed wear." Doc. 143 at 8. The Court finds Kurtz's opinion relevant. The fact the right hip

implant exhibited an expected rate of wear has some tendency to show the implant was mechanically well-functioning at the time it was removed. *See* Fed. R. Evid. 401. This fact is of consequence in this case because it supports Biomet's contention that other factors caused the failure of the right hip implant. *Id.* Accordingly, the Court denies Plaintiffs' motion to exclude Kurtz's opinions regarding the right hip.

2. Kurtz's opinions regarding left hip

Plaintiffs next argue the Court should exclude Kurtz's opinions regarding Mary's left hip implant as the product of unreliable methodology. Kurtz summarized his left hip opinions as follows:

> [T]he radiographic analysis indicates that Ms. Bayes' left acetabular cup was sub-optimally positioned. Vertical and highly anteverted cups, such as Ms. Bayes' left cup, are at risk for higher than expected wear. The clinical evidence indicates that she had a metal reaction in her left hip. Therefore, I hold the opinion, to a reasonable degree of scientific certainty, that the positioning of Ms. Bayes' left cup is a factor that most likely impacted the performance of her artificial hip and her need for revision surgery. I ruled out that device factors contributed to her need for left revision surgery.

Doc. 117-2 at vii. Plaintiffs argue Kurtz used unreliable methodology to reach these opinions in two respects. First, Plaintiffs argue Kurtz improperly ignored contrary evidence. Second, Plaintiffs contend Kurtz impermissibly relied on the analysis of an Exponent colleague in reaching his opinions.

As noted above, Kurtz opines that "radiographic analysis indicates [Mary's] left acetabular cup was sub-optimally positioned." Doc. 117-2 at vii. In forming this opinion, Kurtz relied on a computer program called EBRA that analyzes hip implant x-rays to calculate abduction and anteversion angles. Doc. 143-2 at 118:9-16. Kurtz testified that the EBRA software is "specialized and validated" for the purpose of measuring abduction and anteversion angles from x-rays, *id.* at 130:1-5, and Plaintiffs do not challenge the validity of the software

itself. Rather, Plaintiffs argue Kurtz improperly relied on EBRA in this case because he ignored contrary evidence.

Based on x-rays taken at the time of her left hip implant, Mary's treating physicians stated that the implant was in the "expected radiographic position" and "normal alignment." Doc. 117-4; 117-5. However, these notations in Mary's medical records do not define "expected" or "normal alignment," and do not include anteversion or abduction angles. *Id.* Kurtz's EBRA analysis did not use the x-rays taken at the time of Mary's left hip implant surgery. Kurtz testified these x-rays were of "inferior quality . . . so EBRA would not allow them to be used in the analysis." Doc. 143-2 at 141:15-21. Instead, Kurtz's EBRA analysis used x-rays taken ten months after Mary's left hip implantation. Plaintiffs argue Kurtz's reliance on the EBRA analysis is unreliable because it ignored contrary evidence including the statements from Mary's treaters and the earliest available x-rays. The Court disagrees. Plaintiffs' criticisms go the weight, rather than the admissibility of the EBRA analysis. *See Sphere Drake Ins. PLC v. Trisko*, 226 F.3d 951, 955 (8th Cir. 2000) ("Attacks on the foundation for an expert's opinion . . . go to the weight rather than the admissibility of the expert's testimony."). Plaintiffs may cross-examine Kurtz regarding evidence not included in the EBRA analysis.

Plaintiffs also argue that Kurtz impermissibly relied on an Exponent colleague to perform the EBRA analysis. At his deposition, Kurtz testified that Dr. Derek Holyoak, one of his associates at Exponent, used the EBRA software to calculate the left hip abduction and anteversion angles. Doc. 143-2 at 142:1-20. Kurtz reviewed Holyoak's work and then incorporated it into his report and opinions. *Id*. Like Kurtz, Holyoak is a biomechanical engineer with a Ph.D. in biomechanical engineering from Cornell University. Doc. 143 at 11 n.5. Kurtz testified that Holyoak is qualified to use the EBRA software without his supervision.

Doc. 143-2 at 130:24-131:2. The Court finds Kurtz reasonably relied on Holyoak's analysis. Accordingly, Kurtz's opinions—relying on Holyoak's work—are admissible. Fed. R. Evid. 703. In sum, the Court denies Plaintiffs' motion to exclude Kurtz's opinions regarding Mary's left hip.

3. Kurtz's opinions regarding alternative designs

Kurtz offers several opinions regarding the relative safety of alternative hip implant designs. He opines that the M2a Magnum's large femoral head reduced Mary's risk of dislocations compared to the smaller head sizes available in ceramic or polyethylene implants. Doc. 117-2 at vii. He opines that the Magnum's use of metal-on-metal articulation reduced Mary's risk of component breakage. *Id.* Finally, Kurtz opines there is "insufficient evidence that use of an alternative [design] in either of her hips would have averted her need for revision surgery." *Id.*

Plaintiffs argue these opinions will provide no assistance to the jury "because the risks and benefits of another device has no bearing on whether Biomet's M2a Magnum was defective." Doc. 117 at 12. The Court disagrees. Under established Missouri law, a defendant in a design-defect case "[is] entitled to present evidence . . . of the relative safety of alternative designs." *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 768 (Mo. 2011). Though Biomet cites *Moore* in its response brief, Plaintiffs fail to distinguish it—or even address it—in reply. The Court finds Kurtz's opinions regarding alternative designs relevant to Plaintiff's design-defect claims, and thus denies Plaintiffs' motion to exclude.

4. Kurtz's opinions regarding warnings and pathology

Finally, Plaintiffs argue that Kurtz is not qualified to opine on two topics addressed in his report. First, Plaintiffs argue Kurtz lacks qualifications to opine on the adequacy of Biomet's

M2a Magnum warnings. Second, Plaintiffs contend that Kurtz's opinions regarding "adverse local tissue reaction" (ALTR) intrude into the expertise of clinical pathology.

Regarding warnings, Kurtz opines:

> The information and warnings contained in Biomet's surgical technique guide and instructions for use were consistent with the state of knowledge and typical for [total hip replacement] around the time of Ms. Bayes' surgeries.

Doc. 117-2 at 21. As discussed above, the Court granted Biomet's motion for summary judgment on Plaintiffs' failure-to-warn claims. *See* Doc. 225. Thus, the Court will not permit any testimony regarding the adequacy of Biomet's instructions for use or surgical technique absent a showing of relevance to some claim or defense still at issue. *See* Fed. R. Evid. 401.

Regarding pathology, Kurtz's report includes a lengthy "background" discussion of the meaning of "adverse local tissue reaction." Doc. 117-2 at 13-16. It appears largely duplicative of Bauer's opinions on the same subject matter. Though Kurtz does not opine extensively regarding ALTR in his case-specific analysis, he does assert that Mary's left-hip revision findings "are consistent with an ALTR." *Id.* at 43; 49; 51.

Biomet concedes that Kurtz is not a physician or pathologist and represents that his role in this case "is to evaluate patient, surgeon, and device factors to assess what happened from a biomedical engineering perspective." Doc. 143 at 15. Kurtz's opinion that Mary's hip exhibited findings "consistent with an ALTR" intrudes impermissibly into the pathologist's domain. The Court has previously precluded Plaintiff's biomechanical engineer from opining on medical causation. Doc. 251. Likewise, Kurtz may not offer pathology opinions. Further, to the extent Kurtz opines on pathology, his opinions are unnecessarily duplicative of Bauer's testimony, and the Court excludes the testimony on that basis as well.

VI. Conclusion

Accordingly:

The Court denies [105] Plaintiffs' Motion to Exclude Testimony and Opinions of Biomet's Expert Dr. Thomas Bauer, M.D.

The Court denies [113] Plaintiffs' Motion to Exclude Testimony and Opinions of Biomet's Expert Dr. Thomas Fleeter, M.D.

The Court grants, in part, and denies, in part, [116] Plaintiffs' Motion to Exclude Testimony and Opinions of Biomet's Expert Dr. Steven Kurtz, Ph.D., as set forth in detail above.

So Ordered this 18th day of September, 2020.

SLR. CR

STEPHEN R. CLARK
UNITED STATES DISTRICT JUDGE