UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

MARK FITZSIMMONS,

Plaintiff,

v. Case No: 2:19-cv-182-FtM-29NPM

BIOMET ORTHOPEDICS, INC., BIOMET, INC., and BIOMET MANUFACTURING CORP.,

Defendants.

OPINION AND ORDER

This matter comes before the Court on defendants' Motions to Exclude expert testimony (Doc. #124; Doc. #125), filed on October 2, 2020. Plaintiff filed Memorandums in Opposition (Doc. #132; Doc. #134) on October 16, 2020, to which defendants filed Replies (Doc. #144; Doc. #145) on November 10, 2020. For the reasons set forth below, the motions are granted in part and denied in part.

I.

In December 2008, plaintiff Mark Fitzsimmons underwent a surgical procedure to implant a M2a Magnum Hip System in his left hip. (Doc. #1, ¶ 20.) The M2a Magnum implant was designed, manufactured, marketed, promoted, and sold by defendants (collectively "Biomet"). (Id. ¶¶ 3-5.) Plaintiff's implant subsequently failed, causing significant metallosis and requiring a revision surgery in April 2017. (Id. ¶ 21.) Plaintiff filed

suit against defendants in May 2017, alleging (1) strict products liability, (2) negligence, (3) breach of implied warranties, (4) breach of express warranty, and (5) failure to warn. (Id. pp. 7-14.)

Plaintiff's case, one of thousands filed against defendants, was consolidated for pretrial proceedings into a Multi-District Litigation (MDL) action in the United States District Court for the Northern District of Indiana. In re: Biomet M2A Magnum Hip Implants Prods. Liab. Litig., 896 F. Supp. 2d 1339 (J.P.M.L. 2012). After considerable pretrial proceedings in the MDL court, including rulings on motions to exclude common-issue expert opinions, this case was transferred back to this district in February 2019. (Doc. #56; Doc. #57.) The parties then engaged in case-specific discovery until September 2020, and the matter is set for trial for March 2021. (Doc. #108.) Now at the summary judgment stage, the parties have filed various motions to exclude case-specific expert opinions, including defendants' two motions currently before the Court seeking to preclude opinions from Mari Truman (Doc. #124) and George Kantor (Doc. #125).

II.

The admission of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which provides that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Rule 702 contemplates that the district court serve as gatekeeper for the admission of scientific testimony in order to ensure that any and all expert testimony is both relevant and reliable. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993); Tampa Bay Water v. HDR Eng'g, Inc., 731 F.3d 1171, 1183 (11th Cir. 2013). "The Supreme Court did not intend, however, that the gatekeeper role supplant the adversary system or the role of the jury: vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." McDowell v. Brown, 392 F.3d 1283, 1299 (11th Cir. 2004) (marks and citations omitted).

In determining the admissibility of expert testimony under Rule 702, the Court applies a "rigorous" three-part inquiry. United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc). Expert testimony is admissible if (1) the expert is

qualified to testify on the topic at issue, (2) the methodology used by the expert is sufficiently reliable, and (3) the testimony will assist the trier of fact. Arthrex, Inc., v. Parcus Med., LLC, 2014 WL 3747598, *1 (M.D. Fla. July 29, 2014) (citing Tampa Bay Water, 731 F.3d at 1183). The burden of laying the proper foundation for the admission of expert testimony "is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1335 (11th Cir. 2010) (quoting McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1256 (11th Cir. 2002)). The admission of expert testimony is a matter within the discretion of the district court, which is accorded considerable leeway in making its determination. Frazier, 387 F.3d at 1258.

III.

A. Mari Truman

Mari Truman is a biomedical engineer with a B.S.E. in biomedical engineering and a master's degree in mechanical engineering. In re Biomet M2a Magnum Hip Implant Prods. Liab. Litig., 2017 WL 10845178, *10 (N.D. Ind. Dec. 21, 2017). The MDL court previously denied defendants' motion to exclude Truman from offering the following general opinions: (1) all metal-on-metal devices are defectively designed; (2) metal-on-polyethylene devices are a reasonably safe alternative to metal-on-metal devices; (3) defendants should have conducted additional testing

of its metal-on-metal devices; (4) defendants should have provided additional and more aggressive warnings to surgeons about the risks associated with its metal-on-metal devices; (5) defendants downplayed the risks of its metal-on-metal devices; and (6) excessive metal ions cause certain clinical effects in patients with metal-on-metal devices. Id. at *11-15.

In a case-specific report, Truman now offers additional opinions regarding plaintiff's particular implant. (Doc. #124-1, pp. 19-226.) In its motion, defendants seek to preclude Truman from offering several of these opinions, including (1) four biomechanical opinions, (2) five new common-issue opinions, and (3) any medical-causation opinions. (Doc. #124, pp. 7-17.) The Court will address each of these in turn.

(1) Biomechanical Opinions

a. Amount and Rate of Wear

In her report, Truman examined the rate of wear in plaintiff's implant by creating a 3D model of the device's head and cup. (Doc. #124-1, p. 64.) Truman estimated the implant had a total wear volume of 719 mm^3, or approximately 89.9 mm^3 per year it was implanted. (Id.) Using wear volume measurements provided by defendants, Truman determined plaintiff's "M2a Magnum bearings surface experienced greater than advertised wear and therefore greater than expected wear." (Id.) At her deposition, Truman testified that in physically examining plaintiff's device, "it was

pretty obvious in looking at the cup that there was uneven wear on that cup." (Doc. #124-2, p. 309.) Because the wear was "so obvious" and "excessive," Truman did not feel it was necessary to have physical measurements. (Id. pp. 274, 309.) Instead, Truman "estimate[d] a ballpark quantity based on some rough dimensions," as described in her report. (Id. pp. 274-75.) Defendants seek to exclude Truman's opinion because she "performed no physical measurements," and her opinion "is based largely on a speculative 'visual' assessment of the device at issue." (Doc. #124, p. 7.)

The Court disagrees that Truman's assessment is speculative, since it is based on physical examination of plaintiff's device. See Hardison v. Biomet, Inc., 2020 WL 4334108, *12 (M.D. Ga. July 27, 2020) (noting that Truman's opinion was "based on more than mere speculation after visually inspecting the device"). The Court finds defendants' argument goes to the weight of Truman's opinion, and not its admissibility. See Bayes v. Biomet, Inc., 2020 WL 5594059, *5 (E.D. Mo. Sept. 18, 2020) ("That Truman did not . . . confirm these opinions with testing of the implant goes to the weight, rather than the admissibility, of her opinions.") The Court's conclusion is bolstered by the evidence presented by defendants' own expert, who calculated a substantially similar wear rate. (Doc. #132-2, p. 47) (calculating a loss rate of 88.5 mm^3 per year). Accordingly, defendants' request to exclude Truman's opinion as to the amount and rate of wear is denied.

b. Separation, Migration, and Third-Body Wear

In her report, Truman offered various opinions on the condition of plaintiff's implant, noting "evidence of cup damage and third body wear of the bearings."[1] (Doc. #124-1, p. 49 n.6.) Truman also opined that due to the cup's position, there was "edge loading" in plaintiff, and likely "head separation."[2] (Id.) The report also cited evidence from one of plaintiff's doctors that the device had migrated after it was implanted. (Id. p. 47.) Defendants seek to exclude Truman's opinions on head separation, migration, and third-body wear. (Doc. #124, pp. 8-10.)

Defendants argue that Truman's opinion that head separation occurred is speculative. (Id.) The Court disagrees. Truman's report indicated the device likely had head separation due to plaintiff's reported hearing of a clicking noise after the implant was in place for eight years. (Doc. #124-1, p. 49 n.6.) At her deposition, Truman conceded she "didn't see significant evidence" of head separation, but testified that the clicking noise was consistent with it. (Doc. #124-2, p. 322-23.) Her report also

[1] "'Third-body wear' occurs when foreign particles are deposited on the articulating (moving) surfaces of the hip implant. These particles can cause scratching and increased friction between the articulating surfaces." Bayes, 2020 WL 5594059, *5.

[2] "Head separation occurs when the femoral head component of a hip implant is not properly seated in the cup. This can result in increased friction and wear at the rim of the acetabular cup, known as 'edge-loading.'" Bayes, 2020 WL 5594059, *5.

stated that the lack of a "head stripe wear pattern" was consistent with "very small head separation." (Doc. #124-1, p. 60.) The Court finds this sufficient to support the admission of the testimony. See Bayes, 2020 WL 5594059, *5 (permitting Truman to testify regarding the presence of head separation because the opinion was based on, *inter alia*, the observed clicking noise). That Truman did not rule out other potential causes of the clicking sound, or was not able to say the head separation was "a clinically significant event" (Doc. #124-2, p. 344), are matters which go to the weight of the testimony, not its admissibility.[3]

Defendants next seek to prevent Truman from offering any opinions on whether and when migration occurred. (Doc. #124, pp. 9-10.) Defendants argue such an opinion would be "undoubtedly unreliable and misleading" because Truman did not perform any formal or scientific measurements, and because it contradicts the opinion of plaintiff's own orthopedic expert. (Id. p. 10.) When asked at deposition if there was evidence of migration, Truman testified, "It did appear to me that the cup had changed angle from the time it was implanted to the time it was retrieved, yes."

[3] Defendants also argue Truman should not be permitted to opine that head separation caused edge loading. (Doc. #124, p. 10.) While conceding edge loading did occur, defendants argue that Truman speculates that head separation occurred, and therefore she cannot testify that head separation caused edge loading. (Id.) As the Court has determined Truman's opinion regarding head separation is not speculative, defendants' argument regarding edge loading is also rejected.

(Doc. #124-2, p. 282.) Based on x-rays, Truman estimated the migration occurred within the first two to three weeks after the surgery. (Id. pp. 282-83.) Nonetheless, Truman testified that she would "defer to the orthopedic people to have opinions on the x-rays." (Id. p. 433.) Because Truman has stated she will defer to the medical experts on migration, defendants' request to exclude Truman's opinion as to when migration occurred is rendered moot.[4] The motion is otherwise denied as to the existence of migration.

Finally, defendants seek to exclude Truman's opinion regarding third-body wear. Defendants generally state that all of Truman's opinions on the above issue are speculative, and state all the opinions should be excluded. (Doc. #124, pp. 8-10.) To the extent defendants suggest the opinion is speculative or irrelevant, the Court disagrees. Truman's report cited the presence of third-body wear on the device's bearings (Doc. #124-1, p. 49 n.6), and Truman testified that "a lot" of the damage to the device was "due to third body wear" (Doc. #124-2, pp. 324-25). The Court finds this evidence admissible and will deny defendants' request.

[4] The Court agrees with plaintiff (Doc. #132, p. 6) that Truman is allowed to rely on the opinions of the medical experts on this issue. See In re Biomet, 2017 WL 10845178, *15 (noting that while Truman cannot testify as an expert on a medical issue, she can permissibly rely on other experts' opinions regarding the same).

c. Taper Mismatch

In her report, Truman determined that both modular taper interfaces in the M2a Magnum femoral head of plaintiff's implant were "defective because the production prints allowed a taper fit mismatch > 4'30"." (Doc. #124-1, pp. 141-42.) At her deposition, Truman acknowledged that because it is impossible to manufacture devices perfectly every time, there is an allowance for how much a device "can deviate from perfect." (Doc. #124-2, p. 301.) The "prescribed allowance for deviation from perfect shape that's provided on the print" is called the "tolerance band." (Id. pp. 301-02.) In determining the taper interfaces of plaintiff's implant were outside the tolerance range and therefore defective, Truman acknowledged that she did not have the prints for the devices that were used in plaintiff's implant, and was not able to determine the actual dimensions of the tapers used. (Id. p. 300.) Without the actual print or manufacturing records for plaintiff's implant, or the ability to examine the devices' tapers, Truman was not able to tell where those devices fell within the tolerance range. (Id. p. 303.) Accordingly, Truman agreed that "we don't know what the actual taper mismatch would have been for [plaintiff's] devices in their manufactured condition." (Id. pp. 303-04.)

Defendants argue Truman's opinion should be excluded as "entirely speculative" because "she performed no measurements on

[plaintiff's] device to determine if a mismatch even existed here." (Doc. #124, pp. 11-12.) The Court agrees. Because Truman used the production prints for the implant rather than the actual measurements of plaintiff's device, Truman's opinion that plaintiff's device contained a taper mismatch outside of the acceptable range is speculative. See Hardison, 2020 WL 4334108, *13 (excluding Truman's taper mismatch opinion as "overly speculative" because it related to the device generally and not the plaintiff's specific device). Accordingly, the Court will grant defendants' request to exclude this testimony.

d. Corrosion

In her report, Truman stated that plaintiff's "Magnum head could not be removed due to CCW [clinical cold welding] and corrosion product is visually evident at the base of the tapers."[5] (Doc. #124-1, p. 68.) She also cited scientific literature discussing corrosion and its effects. (Id. pp. 68-69.) At her deposition, Truman reiterated that there was corrosion, but admitted she could not say how much there was or whether "it was severe or just a little bit." (Doc. #124-2, p. 327.)

Defendants argue Truman's opinion regarding corrosion should be inadmissible "because she did not perform any testing," but

[5] "The term 'clinical cold welding' describes taper corrosion so severe that the taper insert and femoral head components of a hip implant become permanently fused together." Bayes, 2020 WL 5594059, *4.

rather "simply bases her statements on her visual inspection of the device and a review of photographs." (Doc. #124, p. 12.) The Court disagrees. See Hardison, 2020 WL 4334108, *12-13 ("As to the corrosion in the device, Biomet argues that Ms. Truman's failure to test—when Ms. Truman had the opportunity to do so—Mr. Hardison's device for corrosion renders her corrosion opinions inadmissible speculation. . . . Here, Ms. Truman's opinion is based on more than mere speculation after visually inspecting the device, and she cites to scientific literature to support her conclusion. . . . Thus, the Court will not exclude Ms. Truman's corrosion opinion. The Court remains confident that a thorough and sifting cross examination will sufficiently allow Biomet to point out any criticism it may have regarding her lack of testing.").

(2) Common-Issue Opinions

Next, defendants seek to prevent Truman from offering various opinions on the grounds that they are common-issue opinions not previously disclosed. (Doc. #124, p. 13.) In transferring this case, the MDL court noted that "[t]he admissibility under Rule 702 of opinions and testimony for all generic (meaning not case-specific) experts to be used at trial have been heard and ruled upon in the MDL." (Doc. #40, p. 9.) Accordingly, any opinions Truman now seeks to offer on common issues would be precluded. Plaintiff responds that Truman's opinions are not "new" common-issue opinions, but rather case-specific opinions that apply

directly to plaintiff. (Doc. #132, pp. 9-11.) Accordingly, the Court will examine each opinion at issue.

a. Appropriate Installation Position

The MDL court previously determined Truman was qualified to offer opinions on the adequacy of defendants' warnings. In re Biomet, 2017 WL 10845178, *13. In an MDL common-issue report, Truman offered opinions applicable to the family of devices known as M2a devices, as well as the specific M2a Magnum device which plaintiff received. (Doc. #124-2, p. 248.) In her case-specific report, Truman opined that defendants "did not have sufficient warnings to alert surgeons concerning the appropriate installation position" of the M2a Magnum device to minimize various risks. (Doc. #124-1, p. 138.) Defendants argue that because Truman did not offer this opinion in her common-issue report, she cannot offer it now. (Doc. #124, pp. 13-14.) The Court agrees.

In her common-issue report, Truman's opinion regarding the appropriate installation position and defendants' failure to warn was specific to the M2a-38 device, not the M2a Magnum device. (Doc. #124-2, pp. 372-74.) Truman acknowledged as much at her deposition, agreeing that her case-specific opinion was "slightly different" than her MDL opinion, as she had "been working on some other M2a-38 reports and . . . had specifically used that one." (Id. p. 374.) Plaintiff argues that because Truman's MDL opinions related to the family of M2a devices, her more specific opinion

regarding the M2a Magnum falls within the MDL general opinions. (Doc. #132, pp. 9-10.) The Court disagrees. Truman's MDL opinion was specific to a device within the M2a family, and that device was not the M2a Magnum. Accordingly, to the extent Truman now applies that opinion to the M2a Magnum, it is a new common-issue opinion and inadmissible. See Bayes, 2020 WL 5594059, *4 ("[To] the extent Biomet seeks to exclude common-issue opinions included in Truman's MDL report, the Court denies the motion. Conversely, to the extent Truman's rebuttal report includes new or different common-issue opinions *not* included in her MDL report, the Court grants Biomet's motion to exclude those opinions.").

b. Cold Welding

In her case-specific report, Truman opined that the M2a Magnum had "several warning defects," and specifically that defendants "did not warn of cold welding in the M2a Magnum." (Doc. #124-1, p. 142.) The Court agrees with defendants that this is a common-issue opinion that should have been provided in Truman's MDL report. (Doc. #124, p. 14.) At her deposition, Truman acknowledged that while her MDL report discussed warnings "at some length," "[t]he cold welding issue wasn't brought up in the MDL." (Doc. #124-2, p. 392.) While Truman testified that the opinion was specific to plaintiff "because he had clinical cold welding in his devices," she agreed that "[t]his is a general opinion that relates to what [she] see[s] as warning failures, not only warning

failures that only occurred in [plaintiff's] case." (Id. p. 393.) Because Truman's opinion is a novel common-issue opinion, the Court will exclude it.[6]

c. Assembly Instructions and Tools

Truman opined that defendants failed to provide assembly instructions or specialized tools, and that this constituted system design and warning defects in the Magnum system. (Doc. #124-1, p. 142.) Because plaintiff concedes this opinion is not relevant to this case (Doc. #132, p. 10), the Court will grant defendants' request to exclude it (Doc. #124, p. 14).

d. Positional Tradeoffs

In her case-specific report, Truman opined that "[p]ositioning of total hip bearings involves tradeoffs," and that

> surgeons are justified in attempting to restore the normal biomechanics of the patient's hip joint using standard techniques unless they are clearly informed in advance of surgery by a THA [total hip arthroplasty] prothesis manufacturer that use of a specific implant design may fail and cause patient harm when used outside a specific and more restricted envelope.

(Doc. #124-1, pp. 143-44.) Truman further opined that defendants "should have told surgeons about the risk of edge loading,

[6] To the extent plaintiff argues Truman's opinion is case specific because she examined plaintiff's explanted device and it displayed cold welding (Doc. #132, p. 10), the Court disagrees. The opinion at issue is not that plaintiff's device displayed cold welding, which would be a case-specific opinion, but rather that defendants failed to warn of cold welding in the M2a Magnum, which is a common-issue opinion.

excessive wear and excessive metal ions when the M2a Magnum cup is inserted at inclination angles > 45˚ (50˚ max with measurement error)." (Id. p. 144.) Defendants suggest this is a new common-issue opinion, and therefore should be excluded. (Doc. #124, p. 14.) The Court agrees in part.

Truman's opinion on this issue is actually two separate opinions. First, Truman opines that a surgeon is justified in attempting to restore normal biomechanics of a hip joint unless warned otherwise by a prothesis manufacturer. Plaintiff argues this is a case-specific opinion because defendants "contend[] that the excessive wear of metal ions in Plaintiff was caused by malpositioning of the Magnum device at implant."[7] (Doc. #132, p. 10.) The Court disagrees. Truman's opinion is not specific to the surgeon who implanted the device in plaintiff, but rather applies to all surgeons conducting hip implants. Accordingly, the opinion is a common-issue opinion. Furthermore, because it seems undisputed that Truman did not offer this opinion in her prior MDL report, the Court will grant defendants' request to exclude it.

Truman has also opined that defendants should have warned surgeons regarding potential dangers if the implant was inserted

[7] Defendants have offered evidence that the cause of plaintiff's elevated ion levels was the improper or malpositioned angle of the implant. (Doc. #124-6, p. 573.)

at certain angles. Truman testified at her deposition that she "offer[ed] opinions about angles" in her MDL report (Doc. #124-2, p. 440), and a review of the MDL report confirms this assertion.[8] The Court finds these opinions substantially the same as the opinion offered in Truman's case-specific report, and therefore the latter cannot be considered "new." Accordingly, the Court declines to exclude this portion of the opinion.

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[8] In her MDL report, Truman offered the following opinions:

> Since Biomet chose to sell the M2a products and they chose not to test the performance at high inclination angles or under head micro separation conditions which were known to cause excessive wear in all THA devices, they should have communicated this to the surgeons, and they should have included AGRESSIVE WARNINGS concerning the high risk of excessive metal wear debris, and excessive high Co and Cr ions, and they should have pointed out the potential harms associated with excessive wear and elevated metal ions. These warnings should have been present when the device was introduced into commerce.
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> . . .
>
> Biomet also should have had the knowledge concerning appropriate inclination and anteversion angles for MoM [metal-on-metal] articulations and should have shared information concerning the risks and should have taught against, warned about or contraindicated installation in angles > ~ 50° and combined anteversion > 25° but did not do so. These instructions should have been in their surgical techniques and other training materials.

In re Biomet M2a Magnum Hip Implant Prods. Liab. Litig., MDL-2391 (Doc. #3387-2, pp. 126, 139.)

e. Cup Orientation and Stability

In her case-specific report, Truman opined that "[w]hen the cup is oriented to improve not only stability, but also wear . . ., there was little or no added stability achieved by the use of femoral heads larger than 36mm." (Doc. #124-1, p. 144.) At her deposition, Truman agreed this was "a general statement, a common opinion" that did not specifically apply to plaintiff, but also noted she "did discuss this in [her] MDL [report] also." (Doc. #124-2, pp. 439-40.) Plaintiff concedes that Truman's opinion is not relevant to her specific findings in this case, but nonetheless argues it "is allowable as a general opinion because the MDL Judge struck none of Ms. Truman's general opinions." (Doc. #132, p. 11.) To the extent Truman offered this opinion in her MDL report[9], the Court will decline defendants' request to exclude it as a new common-issue opinion.

(3) Medical-Causation Opinions

Finally, defendants seek to preclude Truman from offering medical-causation opinions due to her lack of appropriate qualifications. (Doc. #124, pp. 15-17.) Because plaintiff

[9] Truman's MDL report discussed dislocations and range of motion, as well as whether "the risk of dislocation would reduce as the head diameter increases." In re Biomet M2a Magnum Hip Implant Prods. Liab. Litig., MDL-2391 (Doc. #3387-2, pp. 130.) Truman concluded the "data show that there is no beneficial effect in reducing dislocations in head sizes above 36 mm." Id. p. 131.

concedes Truman "will not issue medical causation opinions in this case" (Doc. #132, p. 11), this issue has been rendered moot.

B. George Kantor

George Kantor is a board-certified orthopedic surgeon, specializing in hip, knee, and shoulder replacement, and has performed roughly 5,000 total hip arthroplasty procedures over the course of his career. In re Biomet, 2017 WL 10845178, *15. The MDL court previously denied defendants' motion to exclude Kantor from offering the following general opinions: (1) metal-on-metal devices generally are defectively designed and their risks outweigh their benefits; (2) defendants' instructions for use were inadequate; and (3) elevated metal ions might cause cancer. Id. at *15-18.

Kantor has now prepared a case-specific report which offers a variety of opinions and concludes that plaintiff "has sustained permanent and irreversible damage" because of the implant. (Doc. #125-4, p. 168.) Defendants seek to exclude several of Kantor's opinions, including the following: (1) plaintiff's implant caused plaintiff's injuries; (2) edge loading or impingement did not cause plaintiff's elevated cobalt-chromium levels; (3) a component of plaintiff's device caused his elevated cobalt-chromium levels; (4) plaintiff experienced cobalt and chromium toxicity; and (5) plaintiff will need future medical treatments and surgeries.

(Doc. #125, pp. 6-23.) The Court will address each of these in turn.

(1) Specific Causation

As noted, Kantor opines that plaintiff has sustained permanent damage caused by defendants' implant. (Doc. #125-2, p. 168.) Defendants seek to exclude this opinion on the grounds that it is "derived from an unreliable methodology." (Doc. #125, p. 6.) Specifically, defendants argue Kantor "failed to give due consideration to obvious alternative causes," such as malposition of the device. (Id. pp. 7-14.) Having reviewed the arguments of the parties, as well as Kantor's case-specific report and deposition testimony, the Court disagrees.

The issue essentially boils down to whether Kantor conducted a sufficient differential diagnosis in determining the cause of plaintiff's injuries. (Id. p. 7.) A "[d]ifferential diagnosis is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." Guinn v. AstraZeneca Pharm. LP, 602 F.3d 1245, 1253 (11th Cir. 2010) (marks and citation omitted)). "When properly conducted, a differential diagnosis can be a reliable methodology under Daubert." Id. However, "an expert does not establish the reliability of his techniques or the validity of his conclusions

simply by claiming that he performed a differential diagnosis on a patient." Id. (citation omitted). Furthermore, while "a reliable differential diagnosis need not rule out all possible alternative causes, it must at least consider other factors that could have been the sole cause of the plaintiff's injury." Id.; see also Redd v. DePuy Orthopaedics, Inc., 700 Fed. App'x 551, 554 (8th Cir. 2017) ("Although . . . an expert need not rule out all possible causes of an injury, an expert nonetheless should 'adequately account[] for obvious alternative explanations.'" (quoting Fed. R. Evid. 702 advisory committee notes to 2000 amendment)).

Defendants argue that Kantor's differential diagnosis is unreliable because he "improperly rules out malposition as an alternative cause" of plaintiff's injuries.[10] (Doc. #125, p. 9.) The Court must first determine whether Kantor was required to consider malposition at all prior to determining whether Kantor erred in ruling out malposition as an alternative cause.

As noted, a causation expert need only account for "obvious alternative explanations." Redd, 700 Fed. App'x at 554. Accordingly, if the improper positioning of the device does not

[10] Defendants also suggest Kantor failed to eliminate edge loading or impingement as possible causes of plaintiff's injuries because Kantor failed to physically examine the implant. (Doc. #125, pp. 12-13.) This argument will be addressed later in the Opinion and Order.

constitute an obvious alternative explanation, Kantor could not have erred by failing to consider it. See Bayes v. Biomet, Inc., 2020 WL 5095346, *9 (E.D. Mo. Aug. 28, 2020) (finding Kantor adequately accounted for alternative opinions despite not considering defendant's alternative suggestion that metallosis was caused by unrelated spinal surgery where defendant offered no evidence attributing metallosis to the spinal surgery, and therefore such an alternative explanation was not an "obvious" one).

In support of its argument that Kantor failed to consider an obvious alternative cause, defendants offer the testimony of the orthopedic surgeon who performed the revision surgery on plaintiff. (Doc. #125, pp. 3, 9-11.) In a deposition, the surgeon testified that during the surgery, he found that the angle of the acetabular cup component of plaintiff's implant was unacceptable.[11] (Doc. #125-3, pp. 85-86.) The surgeon testified that because he has never seen elevated cobalt and chromium ion levels like plaintiff experienced unless the device was in a malposition, it was his opinion that plaintiff's elevated ion

[11] Plaintiff disputes this, as the surgeon later testified, after reviewing plaintiff's radiographic findings, that it did not appear the device was in a malposition when implanted. (Doc. #134, pp. 9-10; Doc. #125-3, pp. 106-07). Because the Court ultimately finds Kantor adequately considered the positioning of the device as a cause of plaintiff's injuries, this dispute is moot.

levels were caused by the malposition of the implant. (Id. p. 86.) Kantor himself testified that malposition of the implant's components would cause significant damage to the prothesis, and could cause edge loading and increased wear of the articulating surfaces. (Doc. #125-5, pp. 362, 367-68.) The Court finds this evidence sufficient to demonstrate the improper positioning of the implant could be a possible cause of plaintiff's injuries.

Having reviewed Kantor's report and deposition, the Court is satisfied that Kantor gave appropriate consideration to whether plaintiff's implant was positioned improperly. Kantor's report noted that the THA surgery occurred in December 2008, and there were no complications with either the surgery or in the immediate post-operative course. (Doc. #125-4, p. 161.) Kantor then made the following observations:

> Intra operative x-rays confirmed appropriate component positioning and excellent placement of both femoral and acetabular components. There is no evidence of component malposition and intra operative trial x-rays and multiple post operative follow up interval x-rays confirm well seated well positioned components that are stable and go onto complete osteointegration by May and June of 2009. The acetabular abduction (acetabular component) angle measures consistently at 46 degrees with proper version and the femoral component exhibits excellent canal fill and placement. At 6-month post index THA implantation there is no evidence of radiolucencies, osteolysis or bone destruction from toxic metal ion wear debris.

(Id. pp. 161-62.) At his deposition, Kantor testified that his opinion that there was no evidence of malposition was based on his

measurements and his review of x-rays taken during the surgery, as well as x-rays taken one week, two weeks, six months, and eighteen months after the surgery. (Doc. #125-5, pp. 329-30.) Kantor testified that his opinion was also informed by his experience "looking at thousands and thousands and thousands of hips." (Id. p. 339.)

Based on this evidence, the Court finds Kantor adequately considered whether plaintiff's implant was in a malposition, and therefore defendants' argument to exclude his specific causation opinion fails. See Bayes, 2020 WL 5095346, *8 (rejecting argument that Kantor did not "adequately account for the position of the left acetabular cup" because Kantor "denies that the left cup was out of position at all," and defendant's criticisms in how Kantor came to that conclusion "go to the weight, rather than the admissibility, of Kantor's causation opinion").[12]

[12] Defendants also argue that Kantor erred by ignoring the evidence of the revision surgeon. (Doc. #125, pp. 9-11.) During his deposition, Kantor was asked if he would defer to the surgeon as to the position of the component at the time of revision, and Kantor replied that he "absolutely would not." (Doc. #125-5, p. 351.) Kantor explained why he would not defer to the surgeon's opinion (id. pp. 351-53), and the Court does not find this to be improper. See Bayes, 2020 WL 5095346, *8-9 (rejecting argument that Kantor's opinion was inadmissible for failing to account for contradictory evidence and noting defendant would have the opportunity to cross-examine Kantor regarding such evidence); see also Synergetics, Inc. v. Hurst, 477 F.3d 949, 956 (8th Cir. 2007) (noting "mere disagreement with the assumptions and methodology used does not warrant exclusion of expert testimony").

(2) Edge Loading and Impingement

At his deposition, Kantor testified that he did not see any evidence of edge loading in plaintiff's case. (Doc. #125-5, pp. 378-79, 417, 419.) He also testified that plaintiff's metal ion levels would not be consistent with either edge loading or impingement of the device. (Id. pp. 416, 419.) Defendants seek to exclude these opinions on the grounds that Kantor never analyzed plaintiff's device, and therefore the opinions "are based on nothing more than assumptions." (Doc. #125, p. 15.) The Court disagrees.

Defendants' argument is premised on its assertion that "Kantor concedes that an analysis of [plaintiff's] device is necessary to determine whether impingement or edge loading contributed to [plaintiff's] cobalt-chromium levels." (Id.) However, the evidence does not support this assertion. During his deposition, Kantor conceded that he had not examined plaintiff's device or spoke with Truman about her opinions. (Doc. #125-5, p. 316.) He also noted that he would like to examine the device in the future, which may provide additional information regarding the generation of metal ions and the device's wear patterns. (Id. pp. 319-20.) He stated he "would be curious to see if there is equatorial edge loading" due to the design of the implant, and that an analysis of the device "has some relevance." (Id. pp. 321, 322.) Nonetheless, he specifically testified that his case-

specific opinions did not require visual inspection of plaintiff's implant, and that he was able to stand by those opinions with a reasonable degree of medical certainty without performing a visual inspection. (Id. p. 486.) Kantor clarified that his desire to examine the device was "more for intellectual curiosity as opposed to anything substantive or anything that [he] would change in [his] report." (Id. pp. 486-87.)

Thus, Kantor did not testify that a physical examination of the device was necessary to determine whether edge loading or impingement caused plaintiff's metal-ion levels, and he stated such an examination was unnecessary for any of his opinions. The Court therefore denies defendants' motion to exclude on this issue. To the extent it is relevant, defendants may raise Kantor's failure to examine the device on cross-examination. See Bayes, 2020 WL 5594059, *5 (expert's inability to examine device to confirm her opinions "goes to the weight, rather than the admissibility, of her opinions").

(3) Cause of Elevated Cobalt-Chromium Levels

During his deposition, Kantor testified plaintiff's metal-ion levels were "frighteningly high," and offered four potential sources of the ions. (Doc. #125-5, p. 417.) One such source was corrosion of the device's "mixed-metal coupling." (Id. pp. 417-18.) Defendants seek to exclude this opinion as "entirely unsupported by scientific or factual evidence." (Doc. #125, p.

16.) Specifically, defendants argue that the components of the coupling at issue cannot be the source of cobalt-chromium ions because they are made of a titanium alloy, not mixed metals. (Id. pp. 16-17.)

The Court agrees. The Court will exclude Kantor's opinion that the titanium alloy components of the device caused plaintiff's elevated cobalt-chromium levels. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) ("[N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."); McDowell v. Brown, 392 F.3d 1283, 1299 (11th Cir. 2004) (noting there must be a "fit" with respect to the offered opinion and the facts of the case, and "there is no fit where a large analytical leap must be made between the facts and the opinion").[13]

[13] In his response, plaintiff does not challenge defendants' assertion that the components at issue are made of a titanium alloy. Rather, plaintiff argues there is sufficient evidence to support the opinion that plaintiff's injuries were caused by elevated cobalt-chromium levels, and that such levels were caused by the device. (Doc. #134, pp. 13-14.) However, whether the device caused plaintiff's elevated cobalt-chromium levels is separate from whether Kantor can opine that the levels were caused by the specific components at issue.

(4) Cobalt and Chromium Toxicity

In his report, Kantor noted that plaintiff's "preoperative cobalt and chromium levels were 184 and 112 respectively," and that "[i]t is now a well documented and established fact that blood or serum metal ion levels above 1 are abnormal." (Doc. #125-4, p. 163.) At his deposition, Kantor testified that "any level above 1, of either cobalt or chromium, but especially cobalt, will result in tissue damage," and that "1 is the upper limits of normal[,] above which there is damage." (Doc. #125-5, p. 388.) Defendants seek to preclude Kantor from opining that a cobalt or chromium level above one is "abnormal," asserting that such an opinion "is completely without scientific basis." (Doc. #125, p. 21.)

Defendants' argument is based on its claim that the scientific literature Kantor relied upon to opine that metal ion levels above one are abnormal does not actually support that assertion. (Id. pp. 19-20; Doc. #145, p. 5.) At his deposition, Kantor was asked what threshold he used for cobalt and chromium to identify plaintiff's levels as dangerously high, and he responded as follows:

> Well, I use the – it's not what I use. It's what we use. We have now established what the appropriate chromium levels are. And I would refer you to Plummer and Jacobs, JBJS, 1964, and every subsequent neurology evaluation since then. There's probably 100, but that's the sentinel definitive -- the definitive study -- that anything above 1 is abnormal. Anything above 1 can cause

> ARMD, adverse reaction to metal debris. So anything above 1 is abnormal.

(Doc. #125-5, p. 387.) Defendants argue Kantor misrelies on the Plummer and Jacobs article because it "merely provides a guideline cobalt level to assist in the diagnosis of corrosion in a metal-on-polyethylene device," and "it certainly does not establish a baseline for abnormal levels of cobalt-chromium." (Doc. #125, p. 20.)

In the article, which defendants attached as an exhibit to their motion, the authors reviewed twenty-seven patients who underwent revision for an adverse local tissue reaction secondary to corrosion of a metal-on-polyethylene device. (Doc. #125-9, p. 783.) The authors examined the patients' preoperative cobalt and chromium levels, which were elevated in each patient, and concluded that "serum metal levels are a good initial screening test" for a corrosion diagnosis. (Id. pp. 785, 786.) In doing so, the authors stated that in evaluating serum metal levels, "anything greater than 1 [part per billion] is considered abnormal." (Id. p. 786.) The Court finds this sufficient support for Kantor's opinion that "serum metal ion levels above 1 are abnormal," and therefore denies defendants' request to exclude the testimony.

Defendants also seek to preclude Kantor from testifying about the systemic effects of cobalt and chromium toxicity. (Doc. #125, pp. 18-19.) During his deposition, Kantor testified that

plaintiff's cobalt and chromium levels were "catastrophically" and "frighteningly high." (Doc. #125-5, p. 387.) When asked what systemic effects occur as a result of cobalt toxicity, Kantor identified cardiovascular issues, central nervous system effects, and thyroid problems. (Id. pp. 390-91.) Defendants argue that because it is undisputed plaintiff has not suffered from any of these, Kantor should be precluded from testifying about the systemic effects of cobalt and chromium toxicity. (Doc. #125, pp. 18-19); see also Bayes, 2020 WL 5594059, *4 (finding expert's opinion regarding clinical cold welding was irrelevant and would not assist the jury if the patient did not experience clinical cold welding). The Court disagrees.

In addition to the above, Kantor also identified "excessive fatigue" and musculoskeletal problems as symptoms of cobalt toxicity, both of which plaintiff has experienced. (Doc. #125-5, pp. 391-93.) Kantor also testified that while plaintiff has "been very fortunate" in the symptoms he's experienced, "the jury is not out in terms of the development of systemic effects." (Id. pp. 391, 392.) Because Kantor has linked plaintiff's symptoms with the systemic effects of ion toxicity, the Court will deny defendants' request to exclude the opinion at issue. Defendants may use plaintiff's limited symptoms to challenge the opinion that plaintiff is suffering from the systemic effects of cobalt or chromium toxicity.

(5) Future Medical Care

Finally, defendants seek to preclude Kantor from opining on plaintiff's future medical care. (Doc. #125, pp. 21-23.) The parties agree that an award for future medical damages requires such damages be reasonably certain. (Id.; Doc. #134, p. 18); see also Montesinos v. Zapata, 43 So. 3d 97, 99 (Fla. 3d DCA 2010) ("[A]n award of future economic damages is appropriate 'when such damages are established with reasonable certainty.'" (quoting Auto-Owners Ins. Co. v. Tompkins, 651 So.2d 89, 91 (Fla. 1995)). It is plaintiff's burden to establish that future medical expenses "will more probably than not be incurred," and that burden "will only be met with competent substantial evidence." Montesinos, 43 So. 3d at 99 (citations omitted).

In his report, Kantor discussed the potential problems that may arise due to a failed metal-on-metal implant, noting the following:

> When MoM implant failure occurs in this manner, necrosis of the bone, tendons and tissue can be a direct result of the premature failure of the device. This outcome can result in permanent damage to the bone and soft tissues adjacent to the patient's implant, which is irreversible.
>
> Complications resulting from the premature failure of the MoM implants, such as the Biomet MoM hip implants, include the likelihood of a patient needing multiple future revision surgeries with increasing complexities of those revision procedures to be expected, especially in light of the bone and tissue damage that often accompany the failure of a MoM hip implant. In comparison to MoP [metal-on-polyethylene] or CoP [ceramic-on-

> polyethylene] alternatives, there is a significantly increased risk of dislocations, infections, and peri-prosthetic pathologic fractures published in multiple joint registries in countries following the sub set of MoM prosthetic implant systems.

(Doc. #125-4, p. 159.) With regards to plaintiff specifically, Kantor made the following conclusion:

> Because of the extensive bone necrosis/destruction [plaintiff] is at risk for periprosthetic fracture to both the pelvic and femoral bones that serve as the foundation for his THA. These complications are well documented in the literature and are common in my practice and all hip surgeons undertaking complex removal and revision of MoM THA systems. Due to his relatively young age at index surgery (55 years) he will unfortunately have to deal with these issues in the future. He will in all likelihood require even more difficult reconstructive revision procedures that are associated with increased risk and well documented complications. Future revision and reconstructive procedures to his right hip will require addressing the ongoing osteolysis (bone loss) that is progressive and compromising the acetabular and femoral bone foundation of his total hip arthroplasty construct. The osteolysis and bone destruction that the patient has and is currently experiencing must be evaluated on a regular basis even if his symptoms are currently minimal. The risk of peri-prosthetic fracture in these cases is well documented and unfortunately difficult technically for the revision surgeon to correct. Radiographic studies including plain films, CAT Scans and special MRIs are of paramount importance for assessment of progressive metal ion disease and its future destruction to the bone and soft tissues of the right THA of [plaintiff].

(Id. pp. 168-69.)

Defendants argue that Kantor should be prevented from offering any opinions on plaintiff's future medical care because such opinions are speculative. (Doc. #125, pp. 21-23.) This argument is based on defendants' assertion that Kantor's

deposition testimony demonstrates he was either unable to offer an estimate on the possibility of future revision surgeries, or offered an estimate below fifty percent. (Id. p. 22.) The Court finds defendants have misinterpreted the testimony.

At the deposition, Kantor testified that if the estimates of plaintiff's life expectancy based on actuarial charts were accurate, "there is no question that he will have additional surgery." (Doc. #125-5, p. 474.) Kantor further explained that he believed "the primary problem" was going to be a periprosthetic fracture, and estimated there was a twenty to forty percent chance of a revision surgery due to such a fracture. (Id. pp. 474-76.) He also stated he was unable to answer whether revision surgery would be needed due to a dislocation, and that there was a ten to twenty percent chance plaintiff would need the surgery due to an infection. (Id. pp. 478-79.)

The Court agrees with plaintiff that taken together, Kantor's testimony establishes that plaintiff will require a future revision surgery, the cause of which currently cannot be stated with certainty. (Doc. #134, p. 18.) To the extent Kantor qualified his opinion about the need for a future surgery, such a qualification goes to the opinion's weight and not admissibility. See White v. Westlund, 624 So. 2d 1148, 1151 (Fla. 4th DCA 1993) ("[W]hatever qualification is placed on the opinion by the expert (i.e., surgery is possible or likely) goes to the *weight* of the

opinion, and not its *admissibility*. Therefore, we agree that a medical expert may testify that future medical procedures are 'possible' or 'likely,' and need not phrase an opinion in terms of such surgery or treatment being 'reasonably necessary.'"). Based on Kantor's report describing the likely complications metal-on-metal hip implant patients experience and the likelihood plaintiff will require a future revision surgery, as well as Kantor's testimony that "there is no question" such a surgery will be required, the Court finds Kantor's opinions are reasonably certain. Accordingly, the Court denies defendants request to exclude Kantor's future medical care opinions.[14]

Accordingly, it is hereby

ORDERED:

Defendants' Motion to Exclude the Opinions and Testimony of Mari Truman and Memorandum in Support (Doc. #124) and Motion to Exclude the Opinions and Testimony of George S. Kantor, M.D. and Memorandum in Support (Doc. #125) are **GRANTED in part and DENIED in part** as set forth above.

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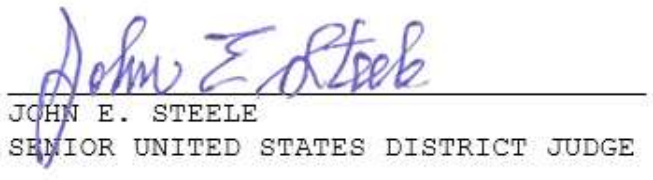
[14] Defendants also seek to exclude evidence of any medical treatments required by a future revision surgery, such as physical therapy, x-rays, ultrasounds, and rehabilitation. (Doc. #125, pp. 22-23.) Plaintiff has offered evidence of such treatments via a medical care projection created by plaintiff's "life care planning" expert. (Doc. #125-11, pp. 792-811.) As defendants have filed a separate motion to exclude this expert's opinions and testimony (Doc. #122), the Court finds it unnecessary to address this issue at this time.

DONE and ORDERED at Fort Myers, Florida, this 18th day of November, 2020.



JOHN E. STEELE
SENIOR UNITED STATES DISTRICT JUDGE

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