UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PAMELA M. BALLARD,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 11 C 6786**
	)	
ZIMMER, INC.,	)	**Judge Rebecca R. Pallmeyer**
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Pamela Ballard brings this products liability action against Defendant Zimmer, Inc., alleging that her hip replacement had a manufacturing defect, which caused severe injuries to her femur and surrounding muscles. She presented the opinions and testimony of Dana J. Medlin, Ph.D. in an initial report, which Dr. Medlin later supplemented with several additional affidavits. Zimmer moved to exclude Dr. Medlin's testimony [44], arguing that his methodology is unreliable. Zimmer also moves for summary judgment [40], urging that, without admissible expert testimony, Ms. Ballard cannot establish the existence of a defect or proximate cause.

The court had questions regarding the reliability of one of Dr. Medlin's supplemental affidavits, *see Ballard v. Zimmer, Inc.*, No. 11-CV-6786, 2015 WL 110146, at *1 (N.D. Ill. Jan. 7, 2015), and conducted a *Daubert* hearing to determine whether it was admissible. In her post-hearing memorandum, however, Plaintiff withdrew the troublesome affidavit. The court concludes that Dr. Medlin's remaining opinions rest on a reliable methodology and his opinions create genuine disputes of material fact precluding summary judgment. Zimmer's motions to exclude and for summary judgment are denied.

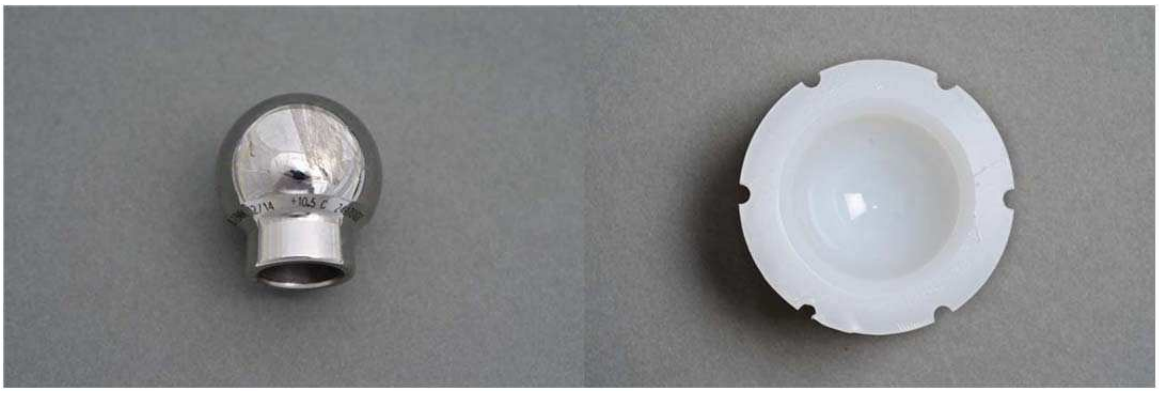
BACKGROUND

I. Plaintiff's medical history

Pamela Ballard suffered from degenerative arthritis of the right hip. In March 2003, her doctor, Wayne Paprosky, recommended a total hip replacement. (Pl.'s Resp. to Def.'s Local R.

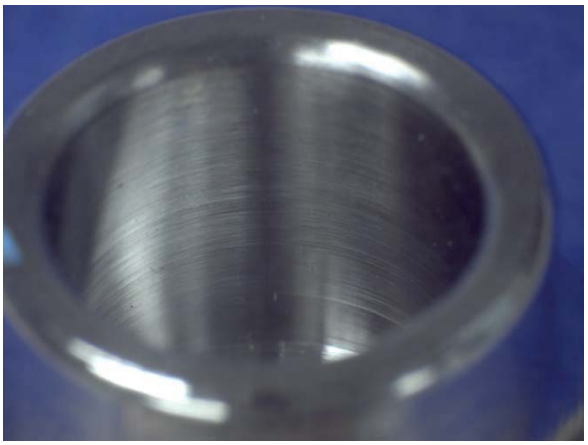
56.1 Statement [53], hereinafter "Pl.'s Resp. to Def.'s SOF," ¶ 1.) Dr. Paprosky performed the hip replacement surgery on June 24, 2003, implanting a VerSys Hip System Femoral Head ("Head") and a VerSys Hip System Beaded Fullcoat Femoral Stem ("Stem"), which were manufactured by Zimmer. (Pl.'s Resp. to Def.'s SOF ¶ 2.)

The Head and Stem work together to replace the top of the femur. The outside of the Head is spherical and replaces the rounded head of the patient's femur, which fits into the hip socket. The socket is fitted with a polyethylene liner that contains the Head:



(Steven M. Kurtz Expert Report, Ex. F to Zimmer Inc.'s Statement of Undisputed Facts in Supp. of its Mot. for Summ. J. [43-6], hereinafter "Kurtz Rep.," 9) (femoral head (left) and plastic liner (right).) The bottom of the Stem extends down into the patient's femur. (Dep. of Dana Medlin, Ex. A to Pl.'s Resp. to Mot. to Exclude [55-1], hereinafter "Medlin Dep.," 15:25–16:8, 100:17–19.)

(Kurtz Rep. at 6) (showing sample femoral Head and Stem.) The Head and the Stem fit together to form a junction. (Zimmer Mem. in Supp. of its Mot. for Summ. J. [41], hereinafter "Zimmer MSJ Mem.," 2.) The interior of the Head is a hollow cone that allows the top of the Stem to fit inside it:



(Kurtz Rep. at 9) (Sample Head.) Zimmer's Head and Stem are considered state-of-the-art and have a long and successful clinical history. (Pl.'s Resp. to Def.'s SOF ¶¶ 15–17.)

After her first surgery, Plaintiff recovered well and successfully completed physical therapy. (Pl.'s Resp. to Def.'s SOF ¶ 5.) With the new hip, Plaintiff was able to travel and hike extensively between 2004 and 2007, in locations including Alaska, the Smokey Mountains, the Outer Banks, Russia, five national parks in Utah, and Mexico. (Pl.'s Resp. to Def.'s SOF ¶ 6.) Plaintiff was also able to take water aerobics and Pilates classes, ride bikes, and use an elliptical machine. (Pl.'s Resp. to Def.'s SOF ¶ 7.)

By the end of 2009, however, Plaintiff began experiencing problems with her hip. In October 2009, Plaintiff's hip dislocated and she was taken by ambulance to the emergency room where she was sedated and her hip relocated. (Pl.'s Resp. to Def.'s SOF ¶ 8.) She then wore a custom leg brace for five to six weeks (Dep. of Pamela Ballard, Ex. D to Zimmer SOF [43-4], hereinafter "Ballard Dep.," 113:7–9, 118:2–4; Dep. of Wayne Paprosky, Ex. B to Pl.'s SOF [53-3], hereinafter "Paprosky Dep.," 107:18–22; Operative Report, Ex. B. to Zimmer SOF [43-2], hereinafter "Operative Rep.," 2), but just two or three days after she stopped wearing the brace, her hip dislocated again and she was again taken to the emergency room. (Pl.'s Resp. to Def.'s SOF ¶ 9; Ballard Dep. at 118:2–11.)

On December 8, 2009, Dr. Paprosky performed a revision surgery. (Zimmer's Stmt. of Undisputed Facts in Supp. of its Mot. for Summ. J. [43], hereinafter "Zimmer SOF," ¶ 11; Pl.'s Resp. to Def.'s SOF ¶ 11.) The initial purpose for this surgery was to implant a "constrained liner"[1] to prevent further dislocations. (Zimmer SOF ¶ 11; Pl.'s Resp. to Def.'s SOF ¶ 11;

[1] The parties have not explained what a "constrained liner" is, but the court understands the liner to be a polyethylene component that fits into the hip socket and contains the Head of the hip implant. A constrained liner is designed to limit the movement of the Head to minimize dislocation. *See* ZIMMER, *Trilogy Longevity Constrained Liner: Surgical Technique*, 2 (2007) http://www.zgreatlakes.com/Literature/Hips/97-6334-002-00%20Trilogy_Longevity_Contrained_Liner_Surgical_Technique.pdf ("Constrained inserts are designed to reduce the incidence of dislocation.").

Operative Rep. at 2.) Once the surgery began, however, Dr. Paprosky found a "Coca-Cola colored fluid" in Ms. Ballard's hip joint which was "consistent with metal-on-metal corrosion," that he had seen in previous cases. (Paprosky Dep. at 55:10–13; Pl. Resp. to Def.'s SOF ¶ 87.) As Dr. Paprosky continued dissecting,

> it became immediately evident that there was severe necrotic damage to the abductor [muscles]. The trochanteric insertion[2] was completely bare. The anterior one-third of medius [muscle] was still intact. The posterior two-thirds had completely dissolved and bone looked necrotic. There was a large cavity with direct visualization down to the components and it appeared that all of the muscle and capsular insertions had dissolved.

(Operative Rep. at 2; Pl. Resp. to Def.'s SOF ¶ 87.) Though the damage was severe, Dr. Paprosky "did not encounter any purulent material to suggest infection at any time during the case." (Operative Rep. at 2.) Based on the damage, Dr. Paprosky decided to replace the Head with a new Zimmer VerSys Hip System Femoral Head and a Trilogy Longevity Constrained Liner. (Operative Rep. at 3; Zimmer SOF ¶¶ 11, 14; Pl.'s Resp. to Def.'s SOF ¶¶ 11, 14.) Dr. Paprosky chose not to remove the Stem because that procedure risked extensive damage to Ms. Ballard's femur, including bone death. (Pl.'s Resp. to Def.'s SOF ¶ 12; Paprosky Dep. at 63:2–16.)

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[2] The parties have not defined "trochanteric insertion," but the court understands that the "trochanter" is "one of the bony prominences toward the near end of the . . . femur." *Definition of Trochanter*, MEDICINENET, http://www.medicinenet.com/script/main/art.asp?articlekey=10448 (Mar. 19, 2012). A "trochanteric insertion" might refer either to the location on the trochanter where a component is inserted, or to a particular component inserted at that spot on the femur. *Compare*, Liu, et al., *Partial Greater Trochanter Osteotomy for Hip Reduction in Total Hip Arthroplasty for High Dislocated Hip: A Preliminary Report*, 15 BMC MUSCULOSKELETAL DISORDERS 293 (2014), available at http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC4174664/ (last accessed Aug. 28, 2015) (muscles "were divided at their insertion site on the trochanter . . . after insertion of the final hip prosthesis component," muscles were repaired."); with Ricci et al., *Trochanteric Nail Insertion for the Treatmetn of Femoral Shaft Fractures*, 19 J. ORTHOP. TRAUMA. 511, 511 (2005) (study designed to evaluate the use "of a new femoral nail, specifically designed to be inserted through the greater trochanter.").

In this lawsuit, Ms. Ballard alleges that her hip implant suffered from a manufacturing defect that caused the Stem to rock within the Head, releasing metal ions and resulting in corrosion and necrosis of her muscles and bone.

II. Plaintiff's expert Dr. Dana Medlin

In support of her claims, Plaintiff presents the opinions and testimony of Dr. Dana Medlin, a biomechanical engineer with a Ph.D. in materials science engineering from the University of Nebraska-Lincoln. Dr. Medlin has more than 20 years of experience in metallurgical, materials, and biomedical engineering—including five years at Zimmer in its Materials Research Group as the Global Metallurgy Leader and Principal Engineer. (Dr. Medlin Curriculum Vitae [53-2], 2.) While at Zimmer, Dr. Medlin focused on metals research, developing new materials to be used in Zimmer's various implants, and worked on a hip implant and some knee projects. (Medlin Dep. at 29:12–15, 31:10–15.) Most of Dr. Medlin's experience is with hips and knees, but he has knowledge of the materials that are used to develop implants for other parts of the body, as well. (*Id.* at 31:25–32:6.)

Dr. Medlin concluded, based on his examination of the explanted Head, that there was physical evidence showing that the Stem rocked back and forth inside the Head at a microscopic level ("micro-motion"), which caused metal from the inside of the Head to wear off (a phenomenon called "fretting"), and resulted in corrosion damage to the interior of the Head. (Report of Dr. Dana Medlin, Ex. I to Zimmer SOF [43-9], hereinafter "Medlin Rep.," 3, 8.)

To reach his conclusion, Dr. Medlin conducted a visual examination of the Head, using various levels of magnification. (*Id.* at 3–7.) First, during the basic visual examination, he noted that the interior of the Head (where the Stem fits in) had "two large thumbnail-shaped scars on diametrically opposed sides of the internal taper," indicating, to him, that micro-motion had worn scars into the interior of the Head. (*Id.* at 3.) He also observed that the scars were located closer to the opening at the bottom of the Head; from that observation, he determined that "the

proximal [deeper] region of the bore [Head] had better fixation on the trunnion [Stem] than the distal region [towards the opening]." (*Id.* at 4.)

(Medlin Rep. at 4) (pictures showing thumbnail-shaped scars on opposite sides of the interior of the Head.) This discrepancy in fixation "caused micro-motion (rocking) and fretting at the opening of the bore." (*Id.*) Dr. Medlin next inspected the interior of the Head using a scanning electron microscope at various levels of magnification to examine the damage to the Head. (*Id.* at 5.) This examination showed evidence of corrosion, which Dr. Medlin opined was due to metal ions released into Plaintiff's body from the metal that had worn off the interior of the Head. (*Id.* at 7.) Based on the type of damage and its location within the Head, Dr. Medlin determined that micro-motion had caused fretting and corrosion. (*Id*.)

After identifying micro-motion as the source of the damage to the Head, Dr. Medlin concluded that the cause of the micro-motion itself was a "mismatch in the taper angle and/or diameter between the" Head and Stem. (Medlin Rep. at 8.) That is, the two components were not close enough in their respective dimensions, allowing the Stem to rock inside the Head, causing metal ions to wear off the inside of the Head. (*Id*.) Dr. Medlin proposed two possible explanations for the cause of the mismatch between the dimensions of the Head and Stem: One possibility is that the Head and Stem's diameters were both within Zimmer's design specifications, but at the extreme ends of Zimmer's permissible ranges for the dimensions: for

example, he explained, "matching a [Stem] at the smallest diameter tolerance to a [Head] with the largest diameter tolerance may develop in a micro-motion condition that can result in fretting wear and corrosion." (*Id.* at 7.) The other possibility is that, because "[o]nly 14 of the 100 heads in this lot were inspected" for the diameter dimensions and taper angle, there was the potential for manufacturing error which "may leave some of these components outside the required tolerance range," that is, outside of Zimmer's specifications. (*Id.* at 8.) Thus, even if the Stem was within specifications, the Head may have been outside of the required specifications, creating a mismatch between the Stem and Head. At his deposition, on May 8, 2013, Dr. Medlin acknowledged that he did not take any measurements of the inside of the Head as he did not have the correct equipment. (Medlin Dep. at 50:19.) He also opined, however, that given the significant amount of damage to the interior of the Head, any measurements taken of the explanted Head would not reliably gauge the pre-implantation measurements. (Medlin Dep. at 56:15–19.)

After his deposition, in response to Zimmer's motions to exclude and for summary judgment, Plaintiff submitted two additional affidavits from Dr. Medlin. The affidavit attached to the motion to exclude ("Articles Affidavit") includes eight short paragraphs which elaborate on the methodology Dr. Medlin used in his initial report. (Medlin Aff., Ex. B to Pl.'s Resp. to Mot. to Exclude [55-3], hereinafter "Articles Aff.") Attached to the affidavit are several peer-reviewed articles from scientific journals, which utilize visual examinations, microscopy, stereomicroscopy, and scanning electron microscopy to assess the extent and nature of damage to explanted orthopedic components. (Reference List, Ex. 1 to Articles Aff.) According to Dr. Medlin, these articles confirm that there is no single accepted methodology for determining pre-implantation dimensions from measurements of explanted components. (Articles Aff. at ¶ 5.) In the Articles Affidavit, he also reiterated his opinion that any attempt to determine pre-implantation dimensions would be unreliable, given the amount of damage to Mrs. Ballard's component. (*Id.* at ¶¶ 6–8.)

The second affidavit Dr. Medlin submitted, the "Calculations Affidavit," prompted the court to hold a hearing to assess its reliability. *Ballard v. Zimmer, Inc.*, No. 11-CV-6786, 2015 WL 110146, at *8–9 (N.D. Ill. Jan. 7, 2015). In the Calculations Affidavit, Dr. Medlin purported to use data collected by Zimmer's expert Dr. Kurtz, to demonstrate that the femoral Head had been manufactured outside of Zimmer's specifications. After the hearing, however, Plaintiff submitted a memorandum withdrawing that affidavit and asserting that "Plaintiff will not attempt to elicit such testimony from Dr. Medlin at trial." (Pl's. Post-Hearing Mem. [82], 1.)

III. Defendant's experts

Zimmer designated two expert witnesses, Dr. Steven Kurtz and Dr. Joyce Tsuji, whose testimony, Zimmer urges, undermines Dr. Medlin's conclusions and supports summary judgment in Zimmer's favor. Plaintiffs have not challenged the admissibility of Zimmer's experts, and the court discusses each expert's report only briefly.

A. Dr. Kurtz

Dr. Kurtz has a Ph.D. in mechanical engineering from Cornell University and is the Director of the Biomedical Engineering practice at Exponent, Inc. an engineering and scientific consulting firm. (Zimmer's SOF ¶ 41.) He is also the Director of the Implant Research Center at Drexel University's School of Biomedical Engineering, Science, and Health Systems. (*Id.*) Dr. Kurtz performed a visual examination similar to the one performed by Dr. Medlin, including basic visual observation and microscopy, but also used a tool called a Talyrond 585 to measure the radius of the inside of the explanted Head. (Kurtz Rep. at 11.) Using the Talyrond, Dr. Kurtz measured the radius of the explanted Head at six different locations along its vertical axis, at 1.9 millimeter intervals. (*Id.*) When measuring the radius, Dr. Kurtz excluded the sections of the Head that were most damaged. (*Id.*) The Talyrond fitted a circle to the remaining sections of the Head and measured the radius of the best-fit circle. (*Id.*) According to Dr. Kurtz, this is a reliable method for measuring the pre-implantation dimensions of the Head. (Kurtz Dep., Ex. A to Pl.'s Resp. to Def.'s Mot. to Strike [74-1], hereinafter "Kurtz Dep.," 139:5–18, 156:3–21.) He

took his six radii measurements and plotted them according to their vertical height to recreate the cone shape of the interior of the Head and then plotted a best-fit line through the points. (Kurtz Rep. at 11.) "The taper angle was then estimated from the gradient of the . . . line," and Dr. Kurtz determined that the angle of the inside of the Head was within Zimmer's specifications. (*Id.* at 12.) He did not reach a conclusion about the diameter, because his radii measurements were relative, not absolute. (Zimmer's Post-Hearing Mem. [83], 5.)

B. Dr. Tsuji

Zimmer's second retained expert, Dr. Joyce Tsuji, is a toxicologist with a Ph.D. in physiology and ecology from the University of Washington. (Expert Rep. of Joyce Tsuji, Ex. K to Zimmer SOF [43-11], hereinafter "Tsuji Rep.," 4.) She conducted postdoctoral research focused on quantitative genetics in the Department of Zoology at the University of Washington. (*Id.*) She has been continuously certified in toxicology by the American Board of Toxicological Sciences since 1992. (*Id.*) She opined that "individuals can vary greatly in their reaction to metallic hip implants, in terms of their metal ion levels, reaction and symptoms at various metal ion levels, and likelihood of adverse outcome." (*Id.* at 2.) Although various risk factors have been investigated, Dr. Tsuji asserts that there is no way to predict which patients will have adverse outcomes. (*Id*.) Dr. Tsuji identifies the FDA's published risk factors for increased device wear and adverse local tissue reactions, noting that "Mrs. Ballard had at least two of these risk factors: female and high levels of physical activity." (Tsuji Rep. at 12–13.) But Dr. Tsuji did not definitively opine that those factors had caused the corrosion and fretting Ms. Ballard experienced, as "these risk factors are not absolute predictors." (*Id.* at 13.)

DISCUSSION

Two motions are pending before the court: Zimmer's motion to exclude the testimony of Dr. Medlin and its motion for summary judgment. The court addresses each in turn.

I. Motion to exclude testimony of Dr. Dana Medlin

Defendant Zimmer moves to exclude the opinions and testimony of Plaintiff's expert Dr. Dana Medlin as not sufficiently reliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). (Zimmer's Mem. in Supp. of its Mot. to Exclude Testimony of Dana Medlin [45], hereinafter "Zimmer's Daubert Mem.," 2.) Because Plaintiff has stipulated that she will not elicit testimony based on Dr. Medlin's Calculations Affidavit, the court considers only Dr. Medlin's initial report and Literature Affidavit.[3]

In *Daubert*, the Supreme Court explained that district courts serve as gatekeepers with respect to expert testimony. 509 U.S. at 592–93. To determine the admissibility of expert testimony, courts engage in a three-part analysis: (1) a witness must demonstrate his or her expertise "by knowledge, skill, experience, training or education," FED. R. EVID. 702; (2) the reasoning or methodology employed by the expert must be reliable, *Daubert,* 509 U.S. at 592; and (3) the testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue." FED. R. EVID. 702. In other words, the witness must be qualified and the testimony must be reliable and relevant. The parties do not dispute that Dr. Medlin is qualified, so the court need only evaluate the reliability and relevance of his testimony.

Defendant's primary objection to Dr. Medlin's testimony is that he did not take any measurements of the internal portions of the Head or any measurements of the Stem. (Zimmer Daubert Mem. at 1–2.) Without these measurements, Defendant argues, Dr. Medlin's report is unreliable and speculative because he has no basis for concluding that there was a "mismatch"

[3] The court agrees with Zimmer that the calculations Dr. Medlin performed based on Dr. Kurtz's data are not sufficiently reliable. Those calculations mistake the relative radius and height measurements for absolute measurements. While relative measurements can be used to reliably calculate an angle or slope of a line—because the slope is based on the *relationship* between the height and radius, regardless of their absolute values—those relative measurements are not reliable indicators of the actual width of Ms. Ballard's explanted femoral Head. Moreover, as the court noted in its original opinion, *Ballard v. Zimmer, Inc.*, No. 11-CV-6786, 2015 WL 110146, at *5, *9 (N.D. Ill. Jan. 7, 2015), there remains confusion between the radius and diameter increases that Dr. Medlin calculated which was not resolved by the subsequent affidavits.

between the components. (Zimmer Daubert Mem. at 8–9.) His testimony is also irrelevant, Zimmer continues, because Dr. Medlin did not address the ultimate question of whether the components were manufactured within Zimmer's specifications. (Zimmer Reply Mem. in Supp. of Mot. to Exclude [67], hereinafter "Zimmer Daubert Reply," 13–14.) Plaintiff counters that Dr. Medlin's approach was reliable because visual examination is a standard methodology for examining explanted components, and although Dr. Medlin's report does not provide direct evidence of the measurements, his opinions are nonetheless relevant because they are circumstantial evidence of a defect. As explained below, the court agrees with Plaintiff.

A. Dr. Medlin's methodology is reliable

Daubert teaches that the reliability of an expert's methodology may be assessed by considering factors such as "(1) whether the scientific theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether a particular technique has a known potential rate of error; and (4) whether the theory or technique is generally accepted in the relevant scientific community." *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013) (citing *Daubert*, 509 U.S. at 593–94). *Accord, C.W. ex rel. Wood v. Textron*, No. 14-3448, ___F.3d ___, 2015 WL 5023926, *5 (7th Cir. Aug. 28, 2015). The test for reliability is a flexible one, however, and the trial judge may, but need not, consider the specific factors identified in *Daubert*. *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 810 (7th Cir. 2012). Moreover, "Rule 702's requirement that the district judge determine that the expert used reliable methods does not ordinarily extend to the reliability of the conclusions those methods produce—that is, whether the conclusions are unimpeachable." *Stollings v. Ryobi Technologies Inc.*, 725 F.3d 753, 765–66 (7th Cir. 2013) (citing *Daubert*, 509 U.S. at 595). An expert may provide expert testimony based on valid and properly applied methodologies and still present a "conclusion that is subject to doubt. It is the role of the jury to weigh these sources of doubt." *Id*. "[T]he accuracy of the actual evidence is to be tested before the jury with the familiar tools of 'vigorous cross-examination, presentation of

contrary evidence, and careful instruction on the burden of proof.'" *Lapsley*, 689 F.3d at 805 (quoting *Daubert*, 509 U.S. at 596).

The court begins by noting that Dr. Medlin's methodology of examining explanted components with visual inspection, optical microscopy, stereomicroscopy, and scanning electron microscopy has been documented in the peer-reviewed literature and appears to be generally accepted in the relevant scientific community. (*See generally* Articles List, Ex. 1 to Articles Aff [55-3, 55-4].) Zimmer presents no basis for concluding that this methodology has been rejected or supplanted by newer techniques. Nor has Zimmer identified any ways in which Dr. Medlin's analysis deviated from the methods employed by the authors of the various studies he cites. In fact, Defendant's expert, Dr. Kurtz, also performed a basic visual examination and inspected the Head with optical microscopy and similarly concluded, based on his observation, that the Head "showed evidence of fretting and corrosion . . . consistent with pivoting and microscopic rocking of the male taper within the bore." (Kurtz Rep. at 10.)

Zimmer urges that, even if Dr. Medlin's methods were correct, he improperly jumped from a finding of corrosion and fretting to a conclusion that micro-motion was the cause of that corrosion and fretting. In the court's view, however, Dr. Medlin's conclusion is adequately supported. First, an inference from corrosion to micro-motion has been documented in the relevant literature. (*See* Collier et. al, *The Tradeoffs Associated with Modular Hip Prostheses*, 311 CLINICAL ORTHOPAEDICS AND RELATED RESEARCH 91, 100 (1995); Jacobs, Gilbert, and Urban, *Corrosion on Metal Orthopaedic Implants*, 80A J. BONE AND JOINT SURGERY 268, 270–71 (1998) ("It has been postulated that this corrosion process is the result of a combination of stress and motion at the taper connection and the crevice geometry of the taper.").) Second, Dr. Medlin identified micro-motion as the most likely cause based on the location of the corrosion on opposite sides of the Head, suggesting a rocking motion. The court identifies no gap in this reasoning, and though Dr. Medlin's conclusion may be "subject to doubt," it "is the role of the jury to weigh these sources of doubt." *Stollings*, 725 F.3d at 765–66.

Zimmer continues that even accepting Dr. Medlin's methodology for identifying micro-motion as the cause of the corrosion and fretting, he has no reliable basis for concluding that the micro-motion was caused by a defect in the components, rather than other potential causes, such as the Plaintiff's activity level, infection, or the placement of the Head on the Stem. Again, the court begins by noting that the literature cited by Dr. Medlin supports his theory that a mismatch between the dimensions of the components is a possible cause of the corrosion and fretting observed in Ms. Ballard's implant. One study explained that

> [a] key factor that may contribute to relative motion (fretting) at modular connections and ultimately to abrasive loss of the passivating oxide layer[4] is angular mismatch between the taper on the male aspect of the connection and the bore on the female aspect. Such a mismatch may result if the tolerances are relatively large, leading to poor mechanical stability of the connection. In this situation, the loads produced during the normal gait cycle may dislodge the interference fit of the modular connection, leading to disruption of the metal surfaces and initiation of the cascade just described.

(Jacobs, Gilbert, and Urban, *Corrosion on Metal Orthopaedic Implants*, 80A J. BONE AND JOINT SURGERY at 272.) As Dr. Medlin explained in his deposition, he did consider other possible causes of the micro-motion, but did not believe they were the likely culprits. He did not believe Plaintiff's activity level was the source of the problem because the polyethylene liner—which he testified is ordinarily the weak link in these components—showed minimal damage. (Medlin Dep. at 103:16–104:8.) Dr. Medlin testified that had Plaintiff's activity level been excessive or abnormal, he would expect to see damage to the liner. (*Id.*) The fact that Dr. Kurtz reached a different conclusion regarding Plaintiff's activity level does not require excluding Dr. Medlin's testimony. *Walker v. Soo Line R. Co.*, 208 F.3d 581, 589 (7th Cir. 2000) ("That two different experts reach opposing conclusions from the same information does not render their opinions inadmissible.") Moreover, Dr. Kurtz appears to have relied on similar methods: based on a visual examination, he also concluded that the plastic liner did not show significant signs of

[4] Dr. Medlin explained that the metals are covered with "passive surface films that protect these metals from corroding," but that they can be abraded away by micro-motion, "expos[ing] the underlying cobalt metal," leading to corrosion. (Medlin Dep. at 11:6–116:1.)

wear. (Kurtz Rep. at 10, 12.) Dr. Kurtz did not explain how this finding related to his conclusion that Plaintiff's activity level was the cause of the micro-motion. Thus, there is room for disagreement regarding whether Plaintiff's activity level caused her injuries.

Next, Dr. Medlin concluded that the placement of the Head on the Stem was not the likely cause of the micro-motion because the locations of the damage suggested that the Stem was sufficiently placed inside the Head. (Medlin Dep. at 74:16–18, 75:9–15.) He noted that he was unable to rule out debris as a cause of the damage because the component was cleaned after being explanted, "so the debris issue is difficult to evaluate, if not impossible." (*Id.* at 75:3–8.)

Zimmer argues that because Dr. Medlin could not conclusively rule out these alternative causes, his methodology is unreliable and his conclusions speculative. Those criticisms go to the weight of the evidence, not its admissibility. Process of elimination is a valid methodology, which Dr. Medlin adequately performed based on the evidence available to him. Defendants emphasize that he could not conclusively rule out the presence of debris, but this is not a failure of methodology. Dr. Medlin did consider this alternative cause and recognized that he could not rule it out completely because any evidence of debris was removed when the component was cleaned. As the Seventh Circuit has observed, "an expert's lack of absolute certainty goes to the weight of his testimony, not to its admissibility." *Stutzman v. CRST, Inc.*, 997 F.2d 291, 296 (7th Cir. 1993) (internal quote omitted). Zimmer will have ample opportunity to cross-examine Dr. Medlin about the data and evidence underlying his opinions, and possible alternative causes that he was unable to rule out. But the absence of evidence available to Dr. Medlin, and his inability to express an opinion with 100% certainty, does not imply that his methodology was flawed.

Here, even without specific measurements of the inside of the Head, or the ability to rule out every potential cause of micro-motion, the court sees no analytical gap between the physical evidence Dr. Medlin relied upon and the opinions he proffered. "Determination on admissibility

should not supplant the adversarial process," and even "shaky expert testimony may be admissible, assailable by its opponents through cross-examination." *Gayton v. McCoy,* 593 F.3d 610, 616 (7th Cir. 2010) (internal quotation marks omitted). Zimmer's criticisms of the quality of Dr. Medlin's testimony or the gaps in his underlying data do not go to admissibility, but to the appropriate weight that should be accorded to the evidence.

B. Dr. Medlin's testimony is relevant

In its reply brief, Zimmer contends that Dr. Medlin's testimony does not "fit" with Plaintiff's argument and should be excluded because it is irrelevant. (Zimmer Reply at 14.) Zimmer begins by highlighting the fact that Dr. Medlin testified that a mismatch between the components could occur even if they were manufactured within Zimmer's design tolerances. Yet the only direct evidence of the dimensions of the Head, Zimmer notes, comes from Dr. Kurtz, who determined that the taper of the Head was within Zimmer's specifications. Without any countervailing measurements of the dimensions of the Head, Zimmer concludes, Dr. Medlin's testimony cannot assist the jury in answering the final question in this case: whether Ms. Ballard's hip implant was manufactured according to Zimmer's design specifications. (Zimmer Reply at 15.)

The court disagrees with Zimmer's analysis. An expert's testimony is relevant under Rule 702 if "it assists the jury in determining any fact at issue in the case," not only the final question. *Stuhlmacher v. Home Depot U.S.A., Inc.*, 774 F.3d 405, 409 (7th Cir. 2014). "Whether an issue is relevant in a case is a question of substantive state law." *Stollings,* 725 F.3d at 767. Testimony may be relevant even where it involves only "hypothetical explanation[s] of the possible or probable causes of an event." *Stuhlmacher*, 774 F.3d at 409 (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718–19 (7th Cir. 2000)). Ultimately, whether an explanation is credible in light of the facts of the case is left to the trier of fact. *Id*.

Dr. Medlin's testimony is relevant. As explained below, Illinois law does not require direct evidence of a particular defect. The fact that Dr. Medlin did not take measurements of the

Head, therefore, does not require the court to exclude his testimony. Dr. Medlin's "testimony could assist the trier of fact even if he cannot say with complete certainty that" a mismatch between the Head and Stem caused Ms. Ballard's injury. *Walker v. Soo Line R. Co.*, 208 F.3d 581, 587 (7th Cir. 2000). Finally, the fact that Dr. Medlin acknowledged the possibility that these injuries could occur when the components were within specifications may undermine the value of his testimony to Plaintiff's case, but not its relevance to the jury. Zimmer's motion to exclude Dr. Medlin's testimony is denied.

II. Zimmer's motion for summary judgment

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A genuine dispute as to any material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In determining summary judgment motions, "facts must be viewed in the light most favorable to the nonmoving party." *Scott v. Harris*, 550 U.S. 372, 380 (2007). The party seeking summary judgment has the burden of establishing that there is no genuine dispute as to any material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). After "a properly supported motion for summary judgment is made, the adverse party 'must set forth specific facts showing that there is a genuine issue for trial.'" *Anderson*, 477 U.S. at 255 (quotation omitted).

In Illinois, a party who "sells any product in a defective condition unreasonably dangerous to the user or consumer" is subject to strict liability. *Henry v. Panasonic Factory Automation Co.*, 396 Ill. App. 3d 321, 326, 917 N.E.2d 1086, 1091 (Ill. App. Ct. 4th Dist. 2009). In Illinois, to establish strict liability based on a defect in the product, a plaintiff must show:

> (1) a condition of the product as a result of manufacturing or design, (2) that made the product unreasonably dangerous, (3) and that existed at the time the product left the defendant's control, and (4) an injury to the plaintiff, (5) that was proximately caused by the condition. The plaintiff has the burden of proof on each element.

Mikolajczyk v. Ford Motor Co., 231 Ill. 2d 516, 543, 901 N.E.2d 329, 345 (Ill. 2008).

Zimmer argues that Plaintiff has failed to identify any admissible evidence that the VerSys Hip System implanted in Ms. Ballard contained a specific defect and lacks the required expert testimony to establish proximate cause. (Zimmer Mem. in Supp. of Summ. J. [41], hereinafter "Zimmer MSJ Mem.," at 5.) Though Zimmer acknowledges that the Head and Stem showed evidence of micro-motion, wear, and corrosion after they were removed (Zimmer MSJ Mem. at 6), it contends that no jury could infer that a defect caused Plaintiff's injury. First, Zimmer asserts, Plaintiff is required to identify a specific defect, but Ms. Ballard presents no evidence demonstrating how her components deviated from Zimmer's manufacturing specifications. Second, Zimmer contends that Plaintiff has failed to present expert testimony showing that the product failed to perform in the manner reasonably expected or that the product's failure was the proximate cause of Plaintiff's injury. As explained below, neither of Zimmer's arguments support summary judgment. Illinois law permits a finding of liability without identifying a specific defect or malfunction, and a reasonable jury could conclude based on Dr. Medlin's initial report that the hip was unreasonably dangerous and caused Plaintiff's injuries.

A. Evidence of specific defect

Zimmer contends that in order to meet her burden of establishing a defect, Plaintiff must identify how her components deviated from Zimmer's intended design specifications. Specifically, Zimmer contends that she must present measurements of the Head showing how Ms. Ballard's implant deviated from Zimmer's design specifications. (Zimmer MSJ Mem. at 8–9.) Plaintiff has now withdrawn Dr. Medlin's calculations affidavit and therefore has no direct evidence showing any particular defect. Without such measurements, Zimmer continues, a jury will have to accept Dr. Kurtz's measurements of the Head, which show that Ms. Batty's component was within Zimmer's specifications. Finally, Zimmer asserts that it would be unreasonable for a jury to infer the presence of a defect from Dr. Medlin's testimony about

micro-motion and corrosion because that testimony is evidence only that an injury occurred. (Zimmer MSJ Mem. at 6–7; Zimmer Post-Hearing Mem. at 8.)

Defendants are correct that "[t]he fact that an injury has occurred, in and of itself, is insufficient to show the existence of a product defect." *Schultz v. Hennessy Indus., Inc.,* 222 Ill. App. 3d 532, 541, 584 N.E.2d 235, 241 (Ill. App. Ct. 1st Dist. 1991). Zimmer overstates the law, however, when it asserts that Dr. Medlin must testify that either "the Head or Stem was manufactured outside of Zimmer's design specifications." (Zimmer MSJ Mem. at 8–9.) As Zimmer acknowledges in its reply brief, Illinois courts "have generally held that a plaintiff need not pinpoint the specific defect in a product in order to recover under strict liability." *DiCosolo v. Janssen Pharm. Inc.*, 351 Ill. Dec. 574, 581, 951 N.E.2d 1238, 1244 (Ill. App. Ct. 1st Dist. 2011). Rather, a plaintiff may prove that a product was defective through circumstantial evidence. *DiCosolo v. Janssen Pharm. Inc.*, 351 Ill. Dec. 574, 580–81, 951 N.E.2d 1238, 1244–45 (Ill. App. Ct. 1st Dist. 2011); *Weedon v. Pfizer, Inc.,* 332 Ill. App. 3d 17, 21–22, 773 N.E.2d 720, 724 (Ill. App. Ct. 1st Dist. 2002).

Nor does Ms. Ballard have to identify the precise malfunction her hip component suffered. Under Illinois law a plaintiff "need not show a malfunction such as an exploding coffee pot, collapsed ladder, or brake pedal that goes all the way to the floor in order to prove a products liability claim involving a nonspecific defect." *DiCosolo*, 351 Ill. Dec. at 582, 951 N.E.2d at 1246 (internal quotation omitted). This is especially true in cases such as this one, where the product's "operation or performance is not observable." *DiCosolo*, 351 Ill. Dec. at 582, 951 N.E.2d at 1246 (internal quotations omitted); *see also id.* 351 Ill. Dec. at 583, 951 N.E.2d at 1247 ("evidence of an obvious malfunction is one type, but not the only type, of evidence that a plaintiff may use to prove that a product failed to perform in the manner reasonably to be expected in the light of its nature and intended function."). Thus, Zimmer's assertion that "Plaintiff has no admissible direct evidence of a manufacturing defect" (Zimmer MSJ Reply at 1) does not require summary judgment in favor of Zimmer.

B. Expert testimony of defect and causation

While Plaintiff need not identify a specific defect or malfunction, she must present expert testimony to establish that the hip implant was unreasonably dangerous. Where a plaintiff claims a manufacturing defect, Illinois courts apply the consumer-expectation test to determine whether the product is unreasonably dangerous. *Blue v. Environmental Eng. Inc.*, 215 Ill. 2d 78, 90–91, 828 N.E.2d 1128, 1138 (Ill. 2005); *Salerno v. Innovative Surveillance Tech., Inc*., 402 Ill. App. 3d 490, 498, 932 N.E.2d 101, 109 (Ill. App. Ct. 1st Dist. 2010). "This test provides that a product is 'unreasonably dangerous' when it is 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" *Calles v. Scripto-Tokai Corp.*, 224 Ill. 2d 247, 254, 864 N.E.2d 249, 254–55 (Ill. 2007) (quoting Restatement (Second) of Torts § 402A, cmt. i). Thus, to proceed "[u]nder the consumer-expectation test, a plaintiff must establish what an ordinary consumer purchasing the product would expect about the product and its safety." *Calles*, 224 Ill. 2d at 254, 864 N.E.2d 249 at 255. "This is an objective standard based on the average, normal, or ordinary expectations of the reasonable person." *Calles,* 224 Ill. 2d at 254, 864 N.E.2d 249 at 255. Even in cases involving complex medical devices, the consumer's expectation is evaluated from the standpoint of the patient in whom the device was implanted and who would be harmed if the device failed, not from the perspective of the treating physician. *Hansen v. Baxter Healthcare Corp.*, 198 Ill. 2d 420, 435, 764 N.E.2d 35, 45 (Ill. 2002).

A plaintiff may present direct evidence that a product is unreasonably dangerous under the consumer expectations test, or she may rely on circumstantial evidence showing (1) there was no abnormal use of the product, (2) there are no reasonable secondary causes of the malfunction, and (3) the product "failed to perform in the manner reasonably to be expected in light of its nature and intended function." *DiCosolo*, 351 Ill. Dec. at 579–80, 951 N.E.2d at 1243–44. (quoting *Tweedy v. Wright Ford Sales, Inc.*, 64 Ill. 2d 570, 574, 357 N.E.2d 449, 452 (Ill. 1976)). This approach "has been analogized to the *res ipsa loquitur* doctrine in negligence

cases." *DiCosolo*, 351 Ill. Dec. at 580, 951 N.E.2d at 1244. In a complex medical device case, such as this one, the answers to these questions often require expert testimony. *Cappellano*, 838 F. Supp. 2d at 830; *Show v. Ford Motor Co.*, 697 F. Supp. 2d 975, 982 (N.D. Ill. 2010) ("when specialized knowledge or expertise of a product defect is 'outside the layman's knowledge,' an expert is needed to assist the jury's understanding of whether a product is unreasonably dangerous.") (quoting *Baltus v. Weaver Division of Kidde & Co.*, 199 Ill. App. 3d 821, 834, 557 N.E.2d 580, 588–89 (Ill. App. Ct. 1st Dist. 1990)); *Henry v. Panasonic Factory Automation Co.*, 396 Ill. App. 3d 321, 326, 917 N.E.2d 1086, 1091 (Ill. App. Ct. 4th Dist. 2009). For example, a layperson would not know what activities are appropriate for a hip replacement patient, nor would a layperson understand the possible alternative causes of Ms. Ballard's injuries. Zimmer contends that Dr. Medlin's testimony is insufficient to establish any of the three elements under the circumstantial evidence approach. The court addresses each in turn.

1. Evidence showing no abnormal use

As described earlier, Dr. Medlin testified that Plaintiff's activity level did not cause her implant failure: According to Dr. Medlin, when an implant fails because of strenuous use, the polyethylene liner is typically damaged as a result of that excessive use. Had Plaintiff's activity level been excessive or abnormal, Dr. Medlin would expect the liner to be damaged and to show evidence of that strenuous activity. (Medlin Dep. at 103:16–104:8.) But Dr. Medlin did not observe such damage to the liner. Thus, Dr. Medlin concluded that Plaintiff's activity level was not a likely cause of the damage. Zimmer urges that this testimony is insufficient because Dr. Medlin did not know that Ms. Ballard went hiking and traveled extensively, and therefore could not have considered how the implant was used. (Zimmer Reply in Supp. of its Mot. for Summ. J. [66], hereinafter "Zimmer MSJ Reply," 9.) Moreover, Zimmer's expert, Dr. Kurtz, testified that Ms. Ballard's activity level "explains the magnitude of – or is consistent with the fretting that we see in the component." (Zimmer MSJ Reply at 9) (quoting Kurtz Dep. at 267:18–23.) Zimmer's arguments do not support summary judgment, as they reflect a genuine dispute among the

experts over whether Ms. Ballard's activity level caused her injury. Though a jury may ultimately agree with Zimmer, a reasonable fact finder might also credit Dr. Medlin's analysis over Dr. Kurtz's and conclude that the physical evidence demonstrates that Ms. Ballard's activity level, even if greater than that of the average patient, was not the cause of the damage to her implant.

2. Evidence ruling out secondary causes

Zimmer next contends that Ms. Ballard has failed to meet her burden of providing competent evidence ruling out secondary causes. (Zimmer MSJ Reply at 12.) Dr. Medlin failed to consider or rule out several potential causes of micro-motion, Zimmer asserts, including the presence of debris, Plaintiff's activity level, and the placement of the Head on the Stem during surgery. (*Id.*) The record, however, suggests that Dr. Medlin did consider these alternative causes. First, as the court discussed above, Dr. Medlin considered whether there was evidence that an abnormal activity level caused Ms. Batty's injury. Next, he ruled out the possibility that the Head was improperly seated on the Stem: the location of the stains inside the Head suggested that the components were properly placed during surgery. (Medlin Dep. at 74:16–18, 75:9–15; Medlin Rep. at 4.) Finally, based on his review of the medical records, Dr. Medlin determined that infection was not a likely cause of corrosion or Plaintiff's injuries. Zimmer is correct that Dr. Medlin did not conclusively rule out debris. Dr. Medlin noted that he was unable to reach a conclusion because the component was cleaned after being explanted, "so the debris issue is difficult to evaluate, if not impossible." (*Id.* at 75:3–8.) Based on this evidence, Dr. Medlin concluded that a mismatch was the most likely cause of the micro-motion.

Dr. Medlin suggested two possible explanations for that mismatch. The first explanation is that one of the components was manufactured outside of the design tolerances. Alternatively, the Head and Stem, while manufactured within specifications, might have been on opposite ends of the tolerances. Zimmer urges that Dr. Medlin's ambivalent testimony cannot create the "inference of probability" that a manufacturing defect caused Plaintiff's injuries. But the fact that Dr. Medlin's opinion is not definitive does not require summary judgment. Under Illinois law, "a

genuine issue of material fact may be found to exist in a case of product liability even if the plaintiff fails to disprove all other possible causes of his injury." *Davis v. Material Handling Associates Inc.*, 401 Ill. App. 3d 1085, 1090, 929 N.E.2d 1229, 1234 (Ill. App. Ct. 3rd Dist. 2010). Moreover, Dr. Medlin did note that only 14 of 100 components were measured for the diameter dimensions and taper angle, from which a jury might infer a strong potential for manufacturing error. (Medlin Rep. at 8.) In short, the precise cause of Plaintiff's injury is a question for the jury to decide. *See Davis*, 401 Ill. App. 3d at 1091, 929 N.E.2d at 1235 ("The requirement that the plaintiff establish the precise cause of his injury may, at times, be excused in an action grounded on strict liability in tort provided the plaintiff establishes some credible basis for the reasonable inference that a condition of the product proximately caused the injury.").

3. Evidence that hip implant did not perform as expected

Zimmer also maintains that Plaintiff cannot establish that the hip failed to perform as expected. The warnings in the package insert explain that loosening, corrosion, and wear are potential risks and, because Ms. Ballard was apprised of these risks, Zimmer continues, the fact she suffered an adverse outcome could not be inconsistent with her reasonable expectations. (Zimmer Reply at 13–14.) Zimmer highlights the language of the package insert, which warned that "[c]orrosion of metal components has been reported but the significance and long-term implications (including the possibility of metallic ion release) are uncertain and await further clinical evaluation." (Package Insert, Ex. B to Zimmer Reply [66-2], 4.) Moreover, the insert instructs physicians to discuss with all patients the increased risk of "complications and/or failure of total hip prostheses," in "patients with unrealistic functional expectations, heavy patients, [and] physically active patients. . . . Physical activity can result in loosening, wear, and/or fracture of the hip implant." (*Id.* at 1.) Zimmer, however, only introduced the package insert as an exhibit to its reply brief. As the moving party, Zimmer bears the initial burden of establishing the absence of a disputed fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Local

Rule 56.1(a)(3) specifies the form in which a moving party must make that showing: the moving party must provide "a statement of material facts as to which the moving party contends there is no genuine issue." *Cracco v. Vitran Exp., Inc.*, 559 F.3d 625, 632 (7th Cir. 2009). The warnings are not mentioned in Zimmer's statement of facts, and Plaintiff has not had an opportunity to respond to this evidence. The court declines to grant summary judgment based on this belated argument.

Even considering the language in the package insert, the court believes that Ms. Ballard is entitled to present her claim to a jury. Under Illinois law, the consumer-expectation test examines the expectations of the patient, not those of the treating physician. *See Hansen v. Baxter Healthcare Corp.*, 198 Ill. 2d 420, 435, 764 N.E.2d 35, 44-45 (Ill. 2002) (noting with approval that the Illinois Supreme Court in *Haudrich v. Howmedica, Inc.*, 169 Ill. 2d 525, 662 N.E.2d 1248 (Ill. 1996) "clearly used the 'ordinary person' standard in applying the consumer expectation test" when plaintiff sought recovery on a strict liability theory against manufacturer of a knee prosthesis that failed prematurely). Zimmer has not met its initial burden of showing that Ms. Ballard was actually apprised of the risks described in the package insert. Again introducing an argument, and evidence, in its reply brief, Zimmer asserts that Dr. Paprosky testified that he discussed the risks with Ms. Ballard, noting the "absence of any guarantee," and the possibilities of "dislocation, fracture, failure to relieve pain, limp, or poor gait, nerve damage, [and the] need for further corrective or revision surgery." (Zimmer Reply at 13 (citing "Paprosky Dep. [Doc. # 43-1] 21:1-12; 25:9-20.") Not only are these facts about the warnings missing from Zimmer's Rule 56.1 statement, Zimmer also failed to attach the quoted portions of Dr. Paprosky's deposition, even to its reply brief. Zimmer similarly failed to include the portions of Ms. Ballard's deposition, in which she purportedly "acknowledged understanding . . . the risk

of hip replacement surgery." (Zimmer Reply at 13) (citing Ballard Dep. at 94:9-17.)[5] Without providing the evidence to support its assertions, Zimmer is not entitled to summary judgment.

Finally, the court pauses to note that Ms. Ballard's understanding of potential risks might not defeat her claim. Zimmer is correct that Illinois courts consider warnings to be an important component of a consumer's expectations. *See, e.g.*, *Haddix v. Playtex Family Products Corp.*, 138 F.3d 681, 686 (7th Cir. 1998) (FDA mandated warnings on tampons precluded finding of defect under the consumer expectations test because otherwise "a consumer is entitled to expect a product to perform more safely than its government-mandated warnings indicate") (quoting *Papike v. Tambrands, Inc.*, 107 F.3d 737, 743 (9th Cir. 1997)); *Hoffman v. Hercules Chemical Co. Inc.*, No. 03 C 5222, 2004 WL 2496501, *8 (N.D. Ill. Nov. 4, 2004) ("Much of the consumer expectation test is a function of the expectations created by warnings, and since the warnings on Clobber adequately apprised consumers of the inherent danger of using Clobber, the product does not defy the expectations of a reasonable consumer."); *see also Cappellano*, 838 F.Supp.2d at 830 (patient's informed consent about risks of hip replacement defeated claim based on consumer-expectations test).

Haddix, *Hoffman*, and *Cappellano* each address a design defect—where the plaintiff suffered a negative outcome, even though the product performed as intended. In those circumstances, the warnings described possible outcomes of a properly manufactured device and plaintiffs were, therefore, deemed apprised of these risks. As the court understands Ms. Ballard's argument, however, she alleges that the device did not conform to Zimmer's intended design and did not perform as Zimmer, or Ms. Ballard, anticipated. That is, Ms. Ballard alleges that the injury she suffered exceeds even the risks described in Zimmer's warnings.

[5] Though other excerpts of Dr. Paprosky's and Ms. Ballard's deposition are attached to Zimmer's statement of facts, (*See* Paprosky Dep. [43-1]; Ballard Dep. [43-4]), the relevant pages cited in Zimmer's reply brief are not included.

Dr. Medlin's testimony provides some support for Ms. Ballard's theory. He testified that while some corrosion and fretting is inevitable, as described in the warnings, what Ms. Ballard experienced was excessive. (Medlin Dep. at 133:14–20.) Similarly, he testified that the amount of damage to Ms. Ballard's soft tissues was "very extensive" and "not something that a patient would expect to happen." (*Id.* at 119:17–120:12; *see also id.* at 124:18–125:4 ("it's been documented in the literature [that] you're going to see sometimes various amounts [of abrasion and fretting] dependent upon patient weight, activity level, machining issues, et cetera. . . . But in this particular case, this is, in my opinion, an excessive amount of fretting corrosion.").) Moreover, the quoted portions of the package insert do not discuss the possibility of soft tissue damage, necrosis, or bone death. While Zimmer may argue to the jury that Ms. Ballard's injury is within the realm of expected outcomes described in the warnings, and maintain that Ms. Ballard was aware of those risks, Plaintiff has presented evidence from which a jury could reasonably conclude that the performance of Ms. Ballard's hip component was well outside the limits of the harm that the warnings might lead her to anticipate.

C. Proximate cause

Zimmer's final argument is that, even if Dr. Medlin can establish that the product had a defect which caused micro-motion and corrosion, Ms. Ballard has failed to identify any expert evidence that the corrosion caused her injuries. (Zimmer Reply at 10–11.) Zimmer emphasizes Dr. Tsuji's opinion that it is impossible to predict a patient's reaction to metal alloys, and urges that this defeats Plaintiff's claim. Dr. Medlin testified, however, that the debris caused by micro-motion and fretting corrosion caused an adverse reaction in Ms. Ballard's soft and hard tissues, called "metallosis." (Medlin Dep. at 118:16–21.) When exposed to the metal ions released due to the corrosion, the soft and hard tissues break down and deteriorate. (*Id.* at 119:1–5.) Dr. Medlin further explained that he believed this is what caused Ms. Ballard's injuries because the two abductor muscles, surrounding her hip socket sustained "severe damage . . . where essentially most of the muscle tissues, if not all, were destroyed due to metallosis." (Medlin

Dep. at 118:5–21.) This evidence, although disputed by Zimmer, is enough to create a fact issue which precludes summary judgment.

CONCLUSION

Dr. Medlin's opinions rest on a reliable methodology and his opinions create genuine disputes of material fact regarding the existence of a defect and proximate cause, precluding summary judgment. Zimmer's motions to exclude [44] and for summary judgment [40] are denied.

ENTER:

Dated: August 31, 2015

REBECCA R. PALLMEYER
United States District Judge