**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

WAYNE V. JASKE,

Plaintiff,

v.

ZIMMER, INC.,

Defendant.

No. 03 C 2939
Judge James B. Zagel

**MEMORANDUM OPINION AND ORDER**

## I. INTRODUCTION

Plaintiff in this case brings strict liability and negligence claims against Defendant knee implant manufacturer. Defendant now moves to exclude the testimony of one of Plaintiff's experts, claiming it to be unreliable and irrelevant. Defendant also moves for summary judgment, arguing that without expert testimony to establish that the alleged product defect caused Plaintiff's injuries, Plaintiff lacks evidence to support his claim. For the following reasons, Defendant's motions are granted.

## II. STATEMENT OF FACTS

On November 6, 1995, Plaintiff Wayne Jaske ("Jaske") had knee replacement surgery, during which the Miller Galante II ("MGII") knee system was installed. The MGII consists of three parts: (1) the metal stemmed tibial plate, which attaches to the tibia; (2) the metal femoral component which attaches to the femur; and (3) a polyethylene tibial articulating surface ("TAS"), which sits between the two metal pieces and is designed to be affixed to the tibial plate.

At the time of the surgery, Jaske was 41 years old and weighed 201 pounds.

In January 2002,[1] Jaske complained to Dr. Scott Seymour of activity-related knee pain. After x-rays and a bone scan, Dr. Seymour determined that the tibial components of the MGII were "[p]robably loose." On June 6, 2002, during a revision surgery, it was discovered that the MGII's tibial base plate was loose and had fractured, and that the TAS had delaminated. At the time of the revision surgery, Jaske was 48 years old and weighed 260 pounds.

Both parties agree that the tibial plate fractured as a result of fatigue, but disagree as to the cause of this fatigue. Plaintiff maintains that the delaminated surface of the TAS was uneven, and that the metal femoral component was "riding" on this uneven surface. The repeated stress applied to the tibial plate caused the fatigue fracture. According to Plaintiff, the delamination of the TAS was the result of oxidation of the polyethylene caused by a gamma irradiation process used by Defendant to sterilize the MGII subsequent to its manufacture. It is this defect that Plaintiff blames for the fatigue fracture of the tibial plate.

Defendant puts forth a different reason for the fatigue and subsequent fracture. According to Defendant, Plaintiff's tibial plateau, which supports the tibial base plate, underwent bone loss, also known as resorption. As a result of resorption, portions of the base plate were unsupported, causing cyclic stress in the base plate, and resulting in the fatigue fracture. Moreover, Defendant maintains that the loosening and subsequent fracture of the base plate are known risks associated with knee implants, and that activity level, physical stature, and surgical technique are factors that may affect the life of the implant and whether parts of it will loosen and/or fracture.

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[1] Plaintiffs do not name a specific time frame for this event, but they do not appear to dispute Defendant's assertion of when this occurred.

## III. MOTION TO EXCLUDE

Defendant now moves to exclude the testimony of Plaintiff's expert witness, Lyle R. Jacobs ("Jacobs"). Jacobs is a metallurgical engineer retained to examine the tibial base plate removed from Plaintiff's knee. In his initial expert report, submitted on September 18, 2002, Jacobs concluded that "the subject knee prosthesis fractured by fatigue with the fatigue emanating from the smooth surface on which the logo was present[,]" or the top of the plate, affixed to the TAS. At his subsequent deposition in August 2005, Jacobs testified to this conclusion, and explained that the fatigue failure was caused by "repetitive tensile or bending forces[.]" He declined to offer an opinion "as to why those bending tensile forces were acting on that base plate[.]"

Two years later, in September 2007, in response to Defendant's motion to exclude Plaintiff's other three expert witnesses,[2] Plaintiff filed an affidavit from Jacobs in which he opined that:

> the fracture was not the result of forces applied from beneath the device such as bone resorption, but as the result of repetitive forces/stresses applied to the top of the device such as those forces (fatigue) resulting from the uneven surface of the [TAS].

Defendant moved to strike this affidavit, arguing that it was inconsistent with his deposition testimony, untimely, unreliable due to the five-year gap between Jacobs' opinions, and

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[2] Judge Moran, who presided over the matter, found that two of Plaintiff's experts, Drs. Duvall and Gobran, should be permitted to provide expert testimony as to "the existence, characteristics, and potential causes of oxidation in the TAS." Dr. Duvall is an engineer specializing in polymer materials, and Dr. Gobran is a materials scientist and engineer.

This case was reassigned to me on April 24, 2009.

prejudicial based on its late disclosure. In response, on September 4, 2008, Plaintiff submitted a second affidavit from Jacobs, explaining the late disclosure, and including the following opinion:

> Because the TAS became oxidized as a result of gamma irradiation in the sterilization process and thereby degraded and delaminated (as explained by [Plaintiff's experts] Drs. Duvall and Gobran), it provided an uneven surface which caused stress to be placed on the metal tibial plate. Over time. [sic] this stress resulted in the fracture.

Judge Moran, who presided over the matter, denied Defendant's motion to strike, but made no finding as to whether Jacobs' opinions satisfied the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).[3] Defendant now asserts that the opinions Jacobs puts forth in his affidavits do not satisfy the *Daubert* standard, and should therefore be excluded.

**A. Daubert Standard**

Federal Rule of Evidence 702, allows for qualified expert witness testimony to assist the trier of fact in understanding evidence or determining a fact at issue where "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Essentially, the expert testimony must be both relevant and reliable. "To gauge reliability, the district judge must determine whether the expert is qualified in the relevant field and whether the methodology underlying the expert's conclusions is reliable." *Masters v. Hesston Corp*., 291 F.3d 985, 991 (7th Cir. 2002). In determining whether an expert's methodology is scientifically valid under Rule 702, courts should consider, among other factors, whether the scientific theory

[3] Judge Moran did find the timing of the affidavit to be "suspect," in that it came more then 20 months after Duvall issued his final report, which explained the position of the TAS in relation to the tibial base plate - information of which Jacobs was unaware at the time of his initial evaluation and deposition.

or technique (1) has been tested; (2) has been subject to peer review and publication; (3) has associated with it a known rate of error and controlling standards; and (4) has been "generally accepted." *Daubert*, 509 U.S. at 593-94 (1993).

**B. Discussion**

Both parties agree that the fracture at issue was caused by fatigue, and that the fracture initiated on the smooth, top surface. But Defendant challenges Jacobs' opinion that the delaminated TAS was the cause of that fracture. The Seventh Circuit has interpreted *Daubert* as imposing a two-step inquiry to determine an expert's fitness to testify. First the district court must "determine whether the expert's testimony pertains to scientific knowledge." *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090, 1106 (7th Cir. 1994). "This task requires that the district court consider whether the testimony has been subjected to the scientific method; it must rule out subjective belief or unsupported speculation." *Id.* (citation and quotations omitted). Second, the district court must "determine whether the evidence or testimony assists the trier of fact in understanding the evidence or in determining a fact in issue. That is, the suggested scientific testimony must 'fit' the issue to which the expert is testifying." *Id.* (citation omitted).

Defendant contends that Jacobs is not qualified to offer expert testimony on the cause of the stress and subsequent fracture of the tibial base plate. In support of this argument, Defendant points to the fact that Jacobs' proffered expertise lies in metallurgy, and not medical devices, polyethylene, or biomechanics. As recently as 2009, Jacobs was able to identify neither the tibia nor the base plate, nor was he able to correctly explain the layout of the implant components within the knee. Moreover, Jacobs admits that he is unfamiliar with loads placed on the knee joint and on the base plate, and that such information is not within his area of expertise.

Plaintiff points out that as a metallurgist, Jacobs has over 50 years of industrial experience. He has also worked for Zimmer in the past, testing metal components for defects and ensuring that they performed to specification. Jacobs has done similar work for other manufacturers of orthopedic medical devices. In order to assess the forces that the metal components of a product could withstand, Jacobs would examine their microcleanliness, microstructure, hardness, and strength properties and compare them to existing specifications.

"Whether a witness is qualified as an expert can only be determined by comparing the area in which the witness has superior knowledge, skill, experience, or education with the subject matter of the witness's testimony." *Jones v. Lincoln Elec. Co.*, 188 F.3d 709, 723 (7th Cir. 1999) (citation omitted). Jacobs' experience qualifies him to testify with regard to the properties of the metal, where the fracture started, and that the fatigue fracture was "the result of repetitive forces/stresses applied to the top of the device[.]" Jacobs is not, however, qualified to opine that the fracture was the result of the uneven surface of the TAS. As a metallurgist, Jacobs has examined the properties of metal components, determined whether those components could withstand certain forces, and looked for defects within the metal itself. And he is certainly qualified to testify to the causes of the tibial plate failure had the cause of the failure been a metallurgical defect or was somehow caused by properties of the metal itself. But here, Jacobs is offering to testify as to the failure of the metal and causes, basically forces outside of the metal component. Without an expert understanding of the stresses placed on the knee, it is difficult to see how Jacobs could testify as to the cause of the fracture where the cause put forth is one that emanated from outside of the metal component.

In support of its position, Plaintiff relies on *Stilwell v. Smith & Nephew, Inc*., 482 F.3d 1187 (9th Cir. 2007). In that case, the plaintiff filed suit against the manufacturer of the two metal construction nails used to stabilize her fractured femur, alleging strict liability and negligence. According to the plaintiff, the nails failed during the healing process due to their defective design and/or manufacture. *Id.* at 1188. A metallurgist retained by the plaintiff was prepared to testify that (1) the nails fractured due to fatigue, "of a low stress, high cycle type," (2) as a result of the nails' shape, the stress was concentrated in a certain area of the nails enabling cracking; and (3) the shape was a defect which shortened the life span of the nails. *Id*. at 1189. The defendant manufacturer moved to bar the expert testimony on the basis that he was unqualified to testify as to "whether a medical device made of metal failed due to a design or manufacturing defect" where he lacked an understanding of how the bone healing process affected the stress placed on the device. *Id.* at 1191. The district court excluded the testimony, reasoning that the expert lacked an understanding of the biomechanical purpose for which the nails were designed. *Id.* The issue, the court opined, "was not whether the [ ] nail would suffer fatigue failure but rather whether the device was designed to fail only after it succeeded in supporting a union of the fractured bone[.]" *Id.* The district court then granted the defendant's motion for summary judgment. *Id.*

In its review of the district court's decision, the Ninth Circuit reversed the exclusion of the expert testimony, reasoning that the district court's analysis "focused on the helpfulness, rather than reliability" of the expert testimony at issue. *Id.* at 1192. Whether testimony is "helpful" depends on whether "there is a link between the expert's testimony and the matter to be proved." *Id.* The Court found that such a link existed, and that the testimony was admissible.

However because the plaintiff was unable to establish a genuine issue of fact as to whether the nails were the cause of her injuries, the Court affirmed the grant of the defendant's motion for summary judgment. *Id.* at 1194-95.

Plaintiff in this case claims that *Stillwell* is instructive here, but I disagree. The district court in *Stillwell* focused on the helpfulness analysis and excluded the expert testimony on the basis that it failed to establish the requisite causation. *Id.* at 1192-93. The district court noted that the expert could testify as to the fatigue and fracture of the nails, but was unqualified to opine as to "both the intended fatigue life" and "the biological factors that impact the effectiveness" of the nails. *Id.* at 1192. The Ninth Circuit did not address the reliability issue raised by the district court, but reversed solely on the ground that the testimony that the expert was qualified to give was related to the ultimate issue in that case. *Id.* at 1193. In this case, I find not that the causation testimony is unhelpful, but rather that Jacobs is not qualified to give it. For this reason, *Stillwell* is not on point.

Plaintiff next relies on *Reed v. Smith & Nephew*, 527 F. Supp. 2d 1336 (W.D. Okla. 2007), in which the court permitted the expert testimony of a metallurgist that the hip implant at issue (1) "failed as a result of fatigue fracture under repeated load cycling[;]" (2) contained inherent flaws and microcracks which provided multiple site for fatigue cracking; and (3) was defective. *Id.* at 1343. The court noted that the expert did "not attempt to delve into the fields of biomaterials or biomechanics, except to note in his opinion that the fracture was not caused solely by stresses from the patient's body or medical reasons, which simply hastened a failure caused by 'the defects in the material and the defects in the device.'" *Id.* The expert in that case was testifying as to defects in the metal, which, in his opinion, were a primary cause of the

fractures. He opined that repeated load cycling played a role, but did not opine as to the specific causes of the load cycling. The court found the expert to be qualified to testify "that the device failed due to internal structural flaws[.]" *Id.* at 1344.

Here, Jacobs proposes to testify that (1) the metal base plate fractured as a result of fatigue; (2) the fatigue was the result of repetitive forces/stresses applied to the top of the plate; and (3) the fatigue was the result of the uneven surface of the TAS. There is little question that Jacobs is qualified to give the first and second opinions, and notably, both are consistent with Zimmer's view that fracture initiated on top. The problem here is the specific external cause to which Jacobs testifies. It is true that a metallurgist is qualified to opine as to the characteristics of metal and the way it behaves under certain circumstances. But here, Jacobs lacks any expertise in the biomechanics of the knee, or, the specific circumstances to which the metal was exposed. Without such an understanding it is difficult to see how he could posit that the cause of the fracture was the plastic portion of the implant - the portion that Plaintiff claims was defective. Unlike in *Coleman*, where the expert was testifying as to internal defects of the metal and whether they contributed to the failure of the implant, Jacobs is attempting to testify that the metal piece fractured as a result of external stress caused by the allegedly defective TAS. While this testimony relates to the matter to be proved, Jacobs is not qualified to give it.[4]

[4] Even if Jacobs proposed to testify that the delaminated TAS is one possible cause of the fatigue fracture, this testimony would be unreliable. Included in the guideposts set forth in Rule 702 are whether the testimony relates to "matters growing naturally and directly out of research they have conducted independent of the litigation," or developed "expressly for purposes of testifying"; "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion"; and "[w]hether the expert has adequately accounted for obvious alternative explanations". *Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 534-35 (7th Cir. 2005), *opinion vacated in part on rehearing by* 448 F.3d 936 (7th Cir. 2006). It appears from the submitted materials that such testimony does not stem from any independent research.

## IV. MOTION FOR SUMMARY JUDGMENT

### A. Standard of Review

Summary judgment should be granted when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c)). A genuine issue of triable fact exists only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Pugh v. City of Attica, Ind.,* 259 F.3d 619, 625 (7th Cir. 2001) (quoting *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986)).

Once the moving party has set forth the basis for summary judgment, the burden then shifts to the nonmoving party who must go beyond mere allegations and offer specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *see Celotex Corp. v. Catrett,* 477 U.S. 317, 323-24 (1986). The nonmoving party must offer more than "[c]onclusory allegations, unsupported by specific facts" in order to establish a genuine issue of material fact. *Payne v. Pauley*, 337 F.3d 767, 773 (7th Cir. 2003) (citing *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990)). A party will be successful in opposing summary judgment only if it presents "definite, competent evidence to rebut the motion." *EEOC v. Sears, Roebuck & Co*., 233 F.3d 432, 437 (7th Cir. 2000). I consider the record in the light most favorable to the nonmoving party, and draw all reasonable inferences in the nonmovant's favor. *Lesch v. Crown Cork & Seal*

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Moreover, such testimony is based on the notion that the stress causing the fatigue came from the top of the tibial base plate, a notion which is not in dispute. Jacobs testified that Defendant's theory fails to account for this, but he does little to explain how or why it fails to do so, and says instead bone resorption could be the cause of the fracture "[o]nly if it were to cause that top surface . . . to bend[.]"

*Co.,* 282 F.3d 467, 471 (7th Cir. 2002). I will accept the nonmoving party's version of any disputed fact only if it is supported by relevant, admissible evidence. *Bombard v. Fort Wayne Newspapers*, *Inc.,* 92 F.3d 560, 562 (7th Cir. 1996).

**B. Strict Liability and Negligence**

Under Illinois law, to succeed under theories of strict liability and negligence, a plaintiff must establish "the existence of a defective condition in the product at the time it left the manufacturer's control," *Carrizales v. Rheem Mfg. Co.*, 589 N.E.2d 569, 580 (1991), and "a causal link between the alleged design defect ... and [the plaintiffs] injury," *Baltus v. Weaver Division of Kidde & Co.*, 557 N.E.2d 580, 586 (1990). *Fuesting*, 421 F.3d at 532. Having excluded Jacobs' opinion that the tibial plate fracture was caused by the defective TAS, I must now determine whether Plaintiff can survive Defendant's motion for summary judgment.

There are no disputed material facts between the parties relevant to this motion. The parties are largely in agreement as to what happened, but disagree as to why it happened, and that is an area which, under Illinois law, requires an expert opinion. *See, e.g., Sorce v. Naperville Jeep Eagle, Inc.*, 722 N.E.2d 227, 327-28 (1999) ("When circumstantial evidence [of strict liability] is presented, it should, at a minimum, include either proof that tends to exclude other extrinsic causes or an expert opinion that the product contained an unreasonably dangerous defect at the time it left the manufacturer's control."); *Sanchez v. Firestone Tire & Rubber Co.*, 604 N.E.2d 948, 950 (1992) (In order to establish at the summary judgment stage some credible basis "for the reasonable inference that a condition of the product caused the injury[,]" plaintiff must establish "more than a mere possibility" either by " proof that tends to exclude other

extrinsic causes or expert testimony" that the alleged defect caused the injury.).[5] Without Jacobs' causation testimony, Plaintiff is unable to support a reasonable inference of causation. As noted *supra*, the testimony of Drs. Gobran and Duvall is limited to "the existence, characteristics, and potential causes of oxidation in the TAS." Another of Plaintiff's experts, Dr. Weis, an orthopedic surgeon, testified that he has not ruled out any reasons for the tibial plate loosening or the TAS delamination.[6] Several possible causes exist for the wear of the TAS, the fracture of the tibial plate, and the need for revision surgery, and none of the admissible expert testimony rules out any other causes. Without any evidence to support the probability that the delaminated TAS caused the tibial plate to loosen and fracture, Plaintiff's claims cannot survive Defendant's motion for summary judgment.

**V. CONCLUSION**

For the foregoing reasons, Defendant's motion to exclude the testimony of Lyle R. Jacobs is granted in part, and Defendant's motion for summary judgment is granted.

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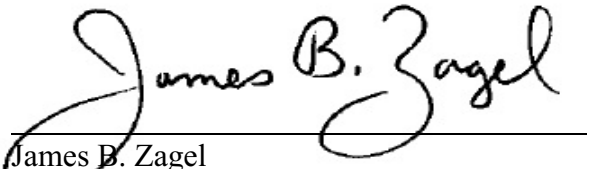

James B. Zagel
United States District Judge

DATE: January 26, 2010

[5] There may well be an expert somewhere who could honestly support Plaintiff's contention that the defective TAS caused the fatigue and fracture of the tibial base plate. In this case Plaintiff was permitted by Judge Moran to introduce new expert opinion to deal with a newly discovered fact, however, I have found the expert who gave this opinion to be unqualified to do so under *Daubert*. Having been given this additional chance to support his case, it would not be appropriate to give Plaintiff another.

[6] In his March 19, 2008, Memorandum Opinion and Order, Judge Moran noted that Plaintiff did not intend Dr. Weis to testify as to the cause of the tibial plate fracture.