IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JORI A. GREYBILL, as Independent Executor of the Estate of MARY JO OTT, Deceased,	)	
Plaintiff,	)	
v.	)	No. 10 C 4546
ZIMMER, INC., ZIMMER HOLDINGS, INC.,	)	
Defendant.	)	

OPINION AND ORDER

This action was filed by Mary Jo Ott against defendants Zimmer, Inc. and Zimmer Holdings, Inc. ("Zimmer") to recover for pain, disability, expense, and lost income from an allegedly defective medical device implanted in her right hip. The prosthesis, a Trilogy Acetabular System Constrained Liner ("TCL") was designed and manufactured by Zimmer. On October 31, 2010, Mary Jo Ott died from unrelated causes. Pursuant to the Illinois Survival Act, the executor of her estate, plaintiff Jori Greybill, continues this action on behalf of the estate.

At the time this action was filed, Ott was a citizen of Lake County, Illinois. The defendants are Delaware corporations with their principal places of business in Indiana. The amount in controversy exceeds $75,000. The court has jurisdiction. 28 U.S.C. § 1332(a).

The Second Amended Complaint alleges claims based on strict liability and negligence. It is alleged that the TCL was defective and unreasonably dangerous for one or more of the following reasons: Under normal use, the TCL reduces the range of motion which leads to premature failure of the device, including excessive neck/cup contact, failure of the polyethylene liner, and failure of the reinforcing ring. The femoral component impinges upon the liner and the retaining ring disengages, resulting in painful and debilitating dislocation of the hip. It is also alleged that the TCL was distributed without proper warnings or limitations concerning its propensity for dislocations.

The case is now before the court on defendants' motion for summary judgment. Defendants essentially contend that plaintiff's case fails because of failure to provide expert testimony supporting the alleged defects or, alternatively, because of failure to comply with the expert report and notice requirements of Rule 26 of the Federal Rules of Civil Procedure.

On a motion for summary judgment, the entire record is considered with all reasonable inferences drawn in favor of the nonmovant and all factual disputes resolved in favor of the nonmovant. ***Crawford v. Metro. Gov't of Nashville & Davidson Cnty., Tenn.***, 555 U.S. 271, 274 n.1 (2009); ***Malen v. MTD Prods., Inc.***, 628 F.3d 296, 303 (7th Cir. 2010); ***Stokes v. Bd. of Educ. of City of Chicago***, 599 F.3d 617, 619 (7th Cir. 2010). The burden of establishing a lack of any genuine issue of material fact rests on the movant. ***Ponsetti v. GE Pension Plan***, 614 F.3d 684, 691 (7th Cir. 2010); ***Outlaw v. Newkirk***, 259 F.3d 833, 837 (7th Cir. 2001). The nonmovant, however, must make a showing sufficient to establish any essential element for which she will bear the burden of proof at trial. ***Celotex Corp. v. Catrett***, 477 U.S. 317, 322 (1986); ***Montgomery v. Am. Airlines, Inc.***, 626 F.3d 382, 389 (7th Cir. 2010). The movant need not provide affidavits or deposition testimony showing the nonexistence of such essential elements. ***Celotex***, 477 U.S. at 324; ***Freundt v. Allied Tube & Conduit Corp.***, 2007 WL 4219417 *2 (N.D. Ill. Nov. 29, 2007); ***O'Brien v. Encotech Constr.***, 2004 WL 609798 *1 (N.D. Ill. March 23, 2004). Also, it is not sufficient to show evidence of purportedly disputed facts if those facts are not plausible in light of the entire record. *See* ***Lorillard Tobacco Co. v. A & E Oil, Inc.***, 503 F.3d 588, 594-95 (7th Cir. 2007); ***Yasak v. Ret. Bd. of Policemen's Annuity & Benefit Fund of***

Chicago, 357 F.3d 677, 679 (7th Cir. 2004); ***Lampley v. Mitcheff***, 2010 WL 4362826 *6 (N.D. Ind. Oct. 27, 2010). As the Seventh Circuit has summarized:

> The party moving for summary judgment carries the initial burden of production to identify "those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." ***Logan v. Commercial Union Ins. Co.***, 96 F.3d 971, 978 (7th Cir. 1996) (citing ***Celotex Corp. v. Catrett***, 477 U.S. 317, 323, 106 S. Ct. 2548 (1986) (citation and internal quotation omitted)). The moving party may discharge this burden by "'showing'--that is, pointing out to the district court--that there is an absence of evidence to support the nonmoving party's case." ***Celotex***, 477 U.S. at 325, 106 S. Ct. 2548. Once the moving party satisfies this burden, the nonmovant must "set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). "The nonmovant must do more, however, than demonstrate some factual disagreement between the parties; the issue must be 'material.'" ***Logan***, 96 F.3d at 978. "Irrelevant or unnecessary facts do not preclude summary judgment even when they are in dispute." ***Id.*** (citation omitted). In determining whether the nonmovant has identified a "material" issue of fact for trial, we are guided by the applicable substantive law; "[o]nly disputes that could affect the outcome of the suit under governing law will properly preclude the entry of summary judgment." ***McGinn v. Burlington Northern R.R. Co.***, 102 F.3d 295, 298 (7th Cir. 1996) (citation omitted). Furthermore, a factual dispute is "genuine" for summary judgment purposes only when there is "sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." ***Anderson v. Liberty Lobby, Inc.***, 477 U.S. 242, 249, 106 S. Ct. 2505 (1986). Hence, a "metaphysical doubt" regarding the existence of a genuine fact issue is not enough to stave off summary judgment, and "the nonmovant fails to demonstrate a

> genuine issue for trial 'where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party . . . .'" ***Logan***, 96 F.3d at 978 (quoting ***Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.***, 475 U.S. 574, 587, 106 S. Ct. 1348 (1986)).

Outlaw, 259 F.3d at 837.

The skeletal structure of the hip involved in this case is the acetabulum, which is the cup-shaped socket of the hip joint. The upper end of the femur (thighbone) fits into the acetabulum and articulates with it, forming a ball and socket joint. When this structure fails as a result of trauma or degenerative hip disease, a replacement medical device or prosthetic hip system is surgically implanted. Hip joint replacement (hip arthroplasty) has become the world-wide standard of care for this disease.

The medical device in dispute, the TCL, consists of a liner and reinforcing ring. The liner fits into a metal shell and articulates with metal femoral heads. The articular surface opening of the TCL is reduced slightly to allow for mechanical capture of the femoral head. The reinforcing ring fits into a groove on the outer surface of the liner to reinforce the capture of the femoral head within the liner.

The package literature and the instructions to the surgeon state in part as follows:

IMPORTANT NOTE
The surgeon should be aware and the patient informed of the following information:

The patient must be instructed about all postoperative restrictions (particularly those related to occupational and sports activities), and about the possibility that the prosthetic hip (or its components) may wear out or fail and need to be replaced.

Complications and or failure of total hip prostheses are more likely to occur in:

-- Patients with unrealistic function expectations
-- Heavy patients, especially those over 225 pounds (102 kg)
-- Small-boned patients
-- Physically-active patients

* * *

INDICATIONS
The *Trilogy* Acetabular System Constrained Liner is indicated for either cemented or noncemented use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability and for whom all other options to constrained acetabular components have been considered.

* * *

CONTRAINDICATIONS
Bone necrosis induced by radiation can occur as the result of therapeutic exposure to >35Gy for the treatment of cancer. Osteoradionecrosis of the acetabulum is a relative contraindication to total hip joint replacement because of the likelihood of failure of the acetabular implant due to poor

> bone stock. In cases where hip arthroplasty is necessary when pelvic radiotherapy has previously occurred, use of protrusion rings, bone graft harvested from outside the zones of irradiation, and bone cement may be required to minimize the risk of subsequent failure of the acetabular implant.
>
> The *Trilogy* Constrained Liner should not be used with skirted femoral heads. The skirt will reduce the range of motion, increasing the possibility of impingement and subsequent dislocation of the device.
>
> * * *
>
> **PATIENT COUNSELING INFORMATION**
> The prosthesis will not restore function to the level expected with a normal healthy joint, and the patient should be instructed as to the limitations of the device. The range of motion achievable with a constrained liner is less than the range of motion of a normal joint, and less than with a semiconstrained prosthesis. The patient should be told that, although the constrained hip liner provides resistance to dislocation, it can dislocate if subjected to excessive loading. Once dislocated, additional surgery will be required to reduce the joint.
>
> Patients should be instructed that significant reduction in the range of motion is inherent in the design characteristics of a constrained acetabular liner, and activities that may force the joint to exceed those range of motion limits should be avoided.

Def. Exh. 5.

The medical records show that Ott had an extensive history of right hip problems. In 1999, Dr. Mitchell Sheinkop performed a total right hip replacement. On January 13, 2004, he performed right hip revision surgery. On June 1, 2004,

Dr. Sheinkop performed a second revision of Ott's right hip replacement during which he implanted the TCL. He noted that the abductor muscles were "somewhat intact but certainly diminished from a normal state. It was therefore felt that likely constrained liner would be the appropriate liner exchange." On August 17, 2008, Ott suffered a dislocation of her right hip which required a closed reduction.

On September 5, 2008, Ott underwent a third revision of her right hip prosthesis performed by Dr. Michael O'Rourke. Dr. O'Rourke increased the diameter of the femoral head and replaced the TCL with a nonconstrained device. On November 10, 2008, November 23, 2008, August 9, 2009, and August 17, 2009, Ott suffered dislocations of her right hip. Each required closed reductions. On August 21, 2009, Ott underwent a fourth revision procedure of her hip prosthesis during which Dr. O'Rourke implanted a new head and a Zimmer Longevity Constrained Liner.

Ott also had serious left hip problems necessitating a total left hip replacement in October 2007, followed by dislocations of that hip in July 2008 and October 2008.

Ott died on October 31, 2010 at age 66. At the time of her death, it was reported in her medical records that she suffered from rheumatoid arthritis, abdominal wound healing from a perforated diverticulum, atrial fibrillation,

ventricular tachycardia, a pacemaker, chronic obstructive pulmonary disease, acute renal failure, sepsis, congestive heart failure, tricuspid regurgitation, morbid obesity, an acute abdomen, and respiratory arrest.

Ott was approximately 5 foot 5 inches in height and her weight was reported in medical records to be between 250 and 275 pounds, which corresponds to a body mass index between 42 and 46 kg/m2.

Ott's traumatic right hip dislocations are said to have occurred because the prosthetic femoral component chronically impinged upon the prosthetic socket and the prosthetic retaining ring, causing a fatigue failure of those components. Impingement occurs when the femoral component repeatedly collides into the liner and reinforcing ring.

Dr. Sheinkop is a board-certified orthopedic surgeon who has been specializing in hip and knee replacement since 1972. He has replaced thousands of hips in his career and has been invited to teach other physicians how to perform hip replacements. He has been retained by Zimmer as an expert witness in other cases. Dr. Sheinkop's credentials were provided to the defendants and are not disputed.

In Dr. Sheinkop's opinion, the TCL should have functioned without complications for up to 15 years. Ott was not paralytic or limited to a low activity

level. She lived independently, drove a car, worked a full-time job, cared for herself, performed all the activities of daily life, and was a compliant patient.

In Dr. Sheinkop's opinion, the severely reduced range of motion of the TCL caused Ott's femoral component to impinge upon her liner and ring and caused those components to fail, resulting in traumatic dislocation. He further testified that the cutouts incorporated into the designs of other Zimmer devices, the Durasul and the TLCL, would have prevented impingement, fatigue failure, and traumatic dislocation. Dr. Sheinkop opined that the restricted range of motion in the TCL is a design flaw and an inherent shortcoming.

Dr. Sheinkop bases his opinions on his training and experience with the TCL, the experience of other patients' failures due to impingement, and also upon his analysis of the cutouts in the design of other Zimmer prosthetic devices including the Epsilon Durasul Constrained Line, later incorporated in the Trilogy line as the Trilogy Longevity Constrained Liner. This liner increased the range of motion and decreased the likelihood of impingement and dislocation according to Dr. Sheinkop.

Dr. O'Rourke is a board-certified orthopedic surgeon who specializes in hip and knee replacements. His credentials are not disputed. Dr. O'Rourke removed Ott's TCL on September 5, 2008. He increased the diameter of the

femoral head and replaced the TCL with a non-constrained device. He removed a damaged liner and damaged ring. Dr. O'Rourke found significant metallic debris in Ott's surrounding tissue. He stated that the metallic debris resulted from abnormal repetitive impingement between the neck of the femoral component and the liner and the ring of the TCL. The chronic problem prostheticly led to the ring cracking and the hip dislocating. In Dr. O'Rourke's opinion, Ott's medical history and other medical condition did not cause the TCL to impinge and fail.

Plaintiff contends that deposition testimony of Zimmer representatives shows that additional cyclical testing of the TCL would have revealed defects or limitations resulting in additional warnings.

Zimmer has disclosed and submitted reports from two experts, John Cherf, M.D., an experienced orthopedic surgeon, and Steven Kurtz, Ph.D., a biomechanical engineer with expertise in the medical device industry.

Dr. Cherf opined that Ott had several risk factors for instability in her right hip, including abnormal anatomy, multiple surgical procedures, obesity, and inflammatory arthritis. He concluded that she was predisposed to dislocation after total hip replacement, and that it is unlikely that anything would have prevented the recurrent dislocations. He stated that the surgical choices were appropriate and that there was no defect in the design of the TCL.

Dr. Kurtz opined that the TCL did not fail due to a defect in design, or due to a deficiency in the instructions for use. He based his opinion on a review of the manufacturing records and the state of the art in the orthopedic medical device industry at the time.

Dr. Kurtz examined the applicable ASTM[1] testing standards for impingement testing of acetabular prostheses published in 2008. He stated that they were not standardized at the time of the commercialization of the TCL and stated that he was not aware of any scientifically valid evidence to suggest that additional preclinical testing would have averted Ott's need for revision surgery.

The TCL was approved for sale in the United States by the Food and Drug Administration on December 20, 2002. The device was accompanied by a package insert and a description of the surgical technique.

Defendants contend that the failure of plaintiff, both in form and substance, to submit independent expert reports and data in compliance with Rule 26 of the Federal Rules of Civil Procedure requires that summary judgment be granted in their favor.

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[1] American Society for Testing Materials (ASTM F2582-08) Standard Test Method for Impingement of Acetabular Prostheses.

Defendants state first that plaintiff submitted no expert identification notice or expert reports. Plaintiff responds that treating physicians can be deposed without any requirement for a written report, citing Fed. R. Civ. P. 26(a)(2) cmt. (1993). However, it has also been held that this exception does not apply if the treating physicians are also called to give independent expert opinions that go "beyond the scope of treatment, observation, and diagnosis." ***Krischel v. Hennessy***, 533 F. Supp. 2d 790, 794-95 (N.D. Ill. 2008); ***Griffith v. Ne. Ill. Reg'l Commuter R.R. Corp.***, 233 F.R.D. 513, 518 (N.D. Ill. 2006); ***Sowell v. Burlington N. & Santa Fe Ry. Co.***, 2004 WL 2812090 *3-6 (N.D. Ill. 2004). *But compare* ***Termini v. Bd. of Lake Cty. Comm'rs***, 2010 WL 2674507 *4 (N.D. Ind. June 29, 2010). Even assuming the failure to disclose expert reports violated Rule 26(a)(2), the testimony of those witnesses is not barred if defendants were not prejudiced by the failure to provide reports. Fed. R. Civ. P. 37(c)(1); ***Tribble v. Evangelides***, 670 F.3d 753, 758-61 (7th Cir. 2012); ***Stuhlmacher v. Home Depot USA, Inc.***, 2012 WL 5866297 *2 (N.D. Ind. Nov. 19, 2012); ***Owens v. Powell***, 2009 WL 347001 *6 (N.D. Ill. Feb. 5, 2009); ***U.S. Gypsum Co. v. LaFarge N. Am., Inc.***, 508 F. Supp. 2d 601, 615 n.3 (N.D. Ill. 2007).

Defendants' contention that they were unable to prepare for the depositions is not borne out by the record. All of Ott's extensive medical records

were produced and available at the depositions of the attending physicians. The physicians' credentials were also provided. Defendants' attorney participated in the depositions. After the depositions, defendants' experts were able to prepare reports. Rule 26(d)(2)(a) states that the methods of discovery may be used in any sequence. It does not appear that defendants have been prejudiced by the failure of plaintiff to provide expert reports. Moreover, the opinions have now been fully disclosed well in advance of any trial. *See* ***U.S. Gypsum***, 508 F. Supp. 2d at 615 n.3.

Zimmer argues that Illinois law requires independent expert testimony to prove any design defect, citing, among other cases, ***Show v. Ford Motor Co.***, 697 F. Supp. 2d 975, 983, 987 (N.D. Ill. 2010), *aff'd*, 659 F.3d 584 (7th Cir. 2011) (vehicle rollover); ***Baltus v. Weaver Div. of Kiddie & Co.***, 199 Ill. App. 3d 821, 557 N.E.2d 580, 588 (1st Dist. 1990) (transmission jack); ***Fulton v. Theradyne Corp.***, 2007 WL 772953 *5 (N.D. Ill. March 12, 2007) (walker); ***Muller v. Synthes Corp.***, 2002 WL 460827 *8 (N.D. Ill. March 26, 2002) (spine locking plate); ***Klootwyk v. DaimlerChrysler Corp.***, 2003 WL 21038417 *3-4 (N.D. Ill. May 7, 2003) (automobile air-bag); ***Niehaus v. United Seating & Mobility, Inc.***, 2011 WL 5325652 *3 (S.D. Ill. Nov. 3, 2011) (wheelchair); ***Jaske v. Zimmer, Inc.***, 2010 WL 345897 *5 (N.D. Ill. Jan. 26, 2010) (artificial knee implant).

Plaintiff contends that not every strict product liability claim requires expert testimony focused on the design of a failed device, citing cases in which independent expert testimony was not required: ***Tweedy v. Wright Ford Sales, Inc.***, 64 Ill. 2d 570, 357 N.E.2d 449, 452 (1976) (brake failure); ***Hill v. Int'l Harvester Co.,*** 798 F.2d 256, 259 (7th Cir. 1986) (locked steering wheel), ***Millette v. Radosta***, 84 Ill App. 3d 5, 404 N.E.2d 823, 835-36 (1st Dist. 1980) (steering wheel defect); ***Weedon v. Pfizer, Inc.***, 332 Ill. App. 3d 17, 773 N.E.2d 720, 731 (1st Dist. 2002) (medical device).

The Illinois cases cited by the parties show that there is no absolute rule that independent expert testimony is required in every strict liability case. The need for such testimony will depend upon the facts, and in some cases, the knowledge and qualifications of the witnesses to provide circumstantial evidence. As the court stated in ***Millette***, expert testimony is itself a form of circumstantial evidence. 404 N.E.2d at 835. *Accord* ***DiCosolo v. Janssen Pharm., Inc.***, 2011 IL App (1st) 93,562, 951 N.E.2d 1238, 1247 (2011); ***Roman v. Gen. Motors Corp.***, 727 F. Supp. 1153, 1155 (N.D. Ill. 1989).

An Illinois case close on the facts to this case is ***Weedon***, *supra*. There, the plaintiff sued in strict liability for injuries sustained when a venous access device implanted in his chest to provide chemotherapy leaked and caused serious

tissue damage. The plaintiff did not produce any expert testimony relating to the design of the access device. The attending physicians testified, however, that there were no surgical errors and, in their opinion, the device leaked. The Illinois Appellate court reversed summary judgment for the defendant, finding an issue of fact that precluded summary judgment based on the attending physicians' testimony.

Here, as in ***Weedon,*** there is testimony by the attending physicians explaining the nature of the failure and disintegration of the TCL, a disclaimer by the physicians of fault on the part of the patient, and a statement of what was defective in the prosthesis. This evidence, although disputed by defendants' experts, is enough to create a fact issue which precludes summary judgment for the defendants.

The dispute as to what, if any, additional package information should have been supplied with the TCL is an issue that cannot be resolved apart from a resolution of the facts relating to the existence of a defective medical device.

Zimmer also states in passing that plaintiff has failed to comply with the expert witness standards set forth in Rule 702 of the Federal Rules of Evidence and as stated in ***Daubert v. Merrell Dow Pharm., Inc.***, 509 U.S. 579 (1993). This issue has not been briefed and remains open for consideration.

IT IS THEREFORE ORDERED that defendants' motion for summary judgment [59] is denied. This case is set for a hearing on status on March 14, 2013 at 2:00 p.m.

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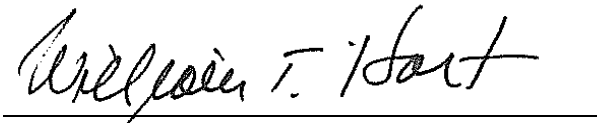

UNITED STATES DISTRICT JUDGE

DATED: FEBRUARY 14, 2013