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

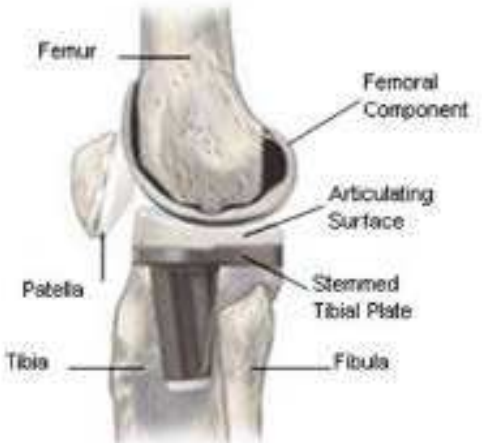
IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2272**
	)	**Master Docket No. 11 C 5468**
KATHY L. BATTY,	)	
Plaintiff,	)	
v.	)	**No. 12 C 6279**
ZIMMER, INC., ZIMMER HOLDINGS, INC., and ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC.,	)	**Judge Rebecca R. Pallmeyer**
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Kathy Batty is one of hundreds of Plaintiffs who have sued Defendants, Zimmer, Inc. and its affiliates (collectively, "Defendant" or "Zimmer"), manufacturers of the Zimmer NexGen Flex Knee system. Plaintiffs, who have had the NexGen Flex system implanted, allege that the femoral and tibial components of the system are prone to premature loosening, resulting in pain, loss of movement, and in some cases requiring revision surgery. Ms. Batty's case has been chosen for a "bellwether" trial. Both parties have identified several expert witnesses. In earlier rulings [1536], [1539], and [1557], the court considered challenges to Ms. Batty's experts Dr. Brown, Dr. Fetto, and Dr. Klein, as well as Plaintiff's challenges to Zimmer's experts, Dr. Darryl D'Lima and Michael Vitale. In this opinion, the court addresses Plaintiff's objections to expert testimony from two more of Zimmer's proposed experts, Dr. Stuart Goodman [1333] and Dr. Timothy Wright [1405]. For the reasons set forth below, Plaintiff's objections to Dr. Goodman are sustained, and her objections to Dr. Wright are sustained in part and overruled in part.

BACKGROUND[1]

Plaintiff Kathy Batty suffers from degenerative joint disease in both knees. In April 2009, her treating physician, Dr. Alan Klein, performed total knee replacements on both of Ms. Batty's knees, implanting a NexGen LPS-Flex Gender Solutions femoral component (the “NexGen Flex” or "Flex") and a NexGen Stemmed Tibial Component Option in each of Ms. Batty’s knees. These components, the model at issue in these lawsuits, are designed to enhance the patient’s flexion capacity to 155 degrees, significantly more than earlier implants, including Zimmer’s own knee implant model (the “NexGen Standard”). The knee implant replaces the top part of the shin bone (the tibia) and the bottom part of the thigh bone (the femur). The tibial component of a knee implant consists of a metal tray that sits on top of the tibia and a stem that extends downward into the tibia. Seated on top of the flat metal tray of the tibial component is a polyethylene surface that serves as the point of contact for the femoral component, also referred to as the "poly," "articulating surface," or the "articular surface." The femoral component attaches to the bottom of the femur:



[1] The court has described the facts of the case in detail in its earlier opinions, *see In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468, 2015 WL 3669933 (N.D. Ill. June 12, 2015); *In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468, 2015 WL 3799534 (N.D. Ill. June 17, 2015); *In re Zimmer NexGen Knee Implant Products Liab. Litig.,* No. 11-CV-5468, 2015 WL 4880953 (N.D. Ill. Aug. 13, 2015), and provides only a brief overview here.

(Expert Report of Dr. Stuart Goodman, Ex. O to Pl.'s Goodman Mem. [1335-15], hereinafter "Goodman Rep.," 3.)

Just over a year after her surgeries, in July 2010, Ms. Batty began to experience pain in both knees. She had her implants replaced in April and May of 2011. In this litigation, Ms. Batty alleges that the Flex design caused her implants to prematurely loosen from her bones by increasing the forces and strain on the implant. One of Ms. Batty's specific theories of defect is that the design puts excessive strain on the back ("posterior") edge of the tibial component, a phenomenon called "posterior edge loading." Plaintiff's expert Dr. Brown opined that the Flex design decreases the contact area between the femoral and tibial component at certain angles of flexion. (Expert Report of Thomas Brown, Ex. B to Zimmer's Mot. to Exclude Testimony of Dr. Brown [1302-2], hereinafter "Brown Rep.," 45–46.) A more limited contact area concentrates the forces passing through the knee in a smaller spot on the tibial component, increasing the pressure experienced by the component at that location. (*Id.*) Dr. Brown contends that with the Flex design, those concentrated forces are also located toward the posterior edge of the tibial tray, rather than in the center, resulting in posterior edge loading. Posterior edge loading, Dr. Brown continues, causes a corresponding upward force on the front ("anterior") of the tibial component. (*Id.* at 47–48.) That upwards anterior force, according to Plaintiff, causes the tibial component to pull away from the bone at microscopic levels. (*Id.* at 48.) Repeated posterior edge loading can, therefore, cause the tibial component to rock or toggle, and eventually loosen from the tibial bone. (*Id.*)

Zimmer retained Dr. Timothy Wright, a biomechanical engineer, and Dr. Stuart Goodman, an orthopedic surgeon and Ph.D. in medical science, to opine on the biomechanical principles underlying the design of the NexGen Flex, to respond to Plaintiff's theories of defect, and to opine on the specific reasons that Ms. Batty's implants failed.

Dr. Wright opines that the NexGen Flex design was not defective, but rather was an "evolutionary change to the clinically successful" NexGen Standard design. The NexGen Flex

enabled flexion beyond 130 degrees and "actually mitigated the risks" of aseptic loosening compared to the Standard, he asserts, because the Flex design increases the contact area between the femoral and tibial components, distributing the forces more evenly. (Expert Report of Timothy Wright, Ex. A to Pl.'s Wright Mem. [1407-1], hereinafter "Wright Rep.," 3.) According to Dr. Wright, Plaintiff's theories of defect "lack a credible scientific basis." He specifically rebuts Plaintiff's theory of posterior edge loading, concluding that such loading is "rare" and is unlikely to contribute to implant failure.[2] (*Id.* at 3, 22, 25.) Finally, he offers an alternative cause for Ms. Batty's implant failure, asserting that it was not the result of the design of the Flex implant, but was due to the misalignment of her tibial component in relation to her tibia, uneven cementing of the tibial components, Ms. Batty's active lifestyle, and a possible low grade infection. (*Id.* at B.3–B.5.)

Dr. Goodman similarly analyzes the design rationale for the NexGen Flex and concludes that it is supported by relevant scientific principles. He opines that the success of the Flex design has been borne out in the clinical evidence. (Goodman Rep. at 6–11, 24.) He also reviewed Ms. Batty's medical records and, like Dr. Wright, believes that Ms. Batty's implant failure was caused by poor cementing technique, the misalignment of the components, Ms. Batty's activity level, and a possible low-grade infection. (Goodman Rep. at 19–20.) Finally, in Dr. Goodman's view, the written disclosures and instructions for surgeons adequately warn about the risks of aspetic loosening and revision. (Goodman Rep. at 11–12.)

DISCUSSION

Plaintiff urges the court to exclude portions of Dr. Goodman's and Dr. Wright's testimony as unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.,* 509

[2] Dr. Wright rebuts several of Plaintiff's other theories of defect, including: (1) the additional two millimeter bone cut required with the Flex; (2) the limited axial rotation available in the Flex; (3) the increased likelihood of condylar lift-off; and (4) the increased risk of radiolucencies behind the flanges of the femoral component. (Wright Rep. at 21.) Plaintiff does not challenge Dr. Wright's opinions on these topics, and the court, therefore, has not summarized those sections of Dr. Wright's report.

U.S. 579 (1993).[3] Though Drs. Wright and Goodman cover a wide range of topics in their reports, Plaintiff's challenges to their testimony are narrow. Plaintiff urges the court to exclude two of Dr. Wright's conclusions as based on unreliable methodologies: (1) his opinion that the NexGen Flex has had "excellent clinical success," as demonstrated by the relevant clinical data, and (2) that posterior edge loading is "rare" with the NexGen Flex design. With respect to Dr. Goodman, Plaintiff challenges only his opinions regarding the alignment of Ms. Batty's implant. The court addresses each challenge in turn.

I. Dr. Wright

Dr. Timothy Wright is a biomechanical engineer who has 35 years of experience designing, testing, and analyzing orthopedic implants. (Wright Rep. at 1.) He received his Bachelor of Science degree from Lehigh University in 1971. (*Id.*) Between 1972 and 1976, he completed a Masters degree and Ph.D. in Materials Science at Stanford University. (*Id.* at 1, A.3.1.) During his graduate education, he worked in the Biomechanics Laboratory, Department of Applied Mechanics at Stanford, focusing his research on orthopedic biomechanics. (*Id.* at 1.) After completing his Ph.D., he joined the Hospital for Special Surgery ("HSS") in New York as a Research Fellow in the Department of Biomechanics, and has been working at HSS continuously since then, rising to the position of Director of the Department of Biomechanics, which he has held since 1992. (*Id.* at 1.)

A. Clinical Evidence

Dr. Wright opines that the NexGen Flex "design does not have a greater propensity for aseptic femoral or tibial component loosening than the NexGen standard design, and both designs have repeatedly demonstrated excellent clinical performance . . . as evidenced by dozens of clinical studies and the outcomes reported by national joint registries." (Wright Rep.

[3] The court assumes familiarity with the *Daubert* standards set forth in its earlier opinion, *see In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11–CV–5468, 2015 WL 3669933, at *6–7 (N.D. Ill. June 12, 2015), and declines to repeat them here.

at 3.) Dr. Wright acknowledged that two studies cited by Plaintiff's expert Dr. Brown— H.S Han et al., *High Incidence of Loosening of the Femoral Component in Legacy Posterior Stabilized-Flex Total Knee Replacement*, 89-B J. BONE JOINT SURG. 1457, 1461 (2007) and Cho et al., *Three- to Six-Year Follow-up Results After High-Flexion Total Knee Arthroplasty: Can We Allow Passive Deep Knee Bending?*, 19 KNEE SURG. SPORTS TRAUMATOLOGY ARTHROSCOPY 899, 903 (2011)—suggest that the Flex designs have an increased risk of aseptic loosening. Dr. Wright dismissed those studies, however, because they "are overwhelmed by the far larger group of studies showing excellent results, including a lack of aseptic loosening, with the Flex design." (Wright Rep. at 20.) Dr. Wright reviews six studies and data from the Australian Orthopaedic Association's National Joint Registry,[4] and opines that, if the design were defective, consistent failure of the device would manifest in the clinical evidence. But according to Dr. Wright, the data from the studies and the Australian Registry shows that "the NexGen Flex design has achieved excellent clinical results that reinforce my opinions that the components are well-designed from a biomechanical and engineering standpoint." (Wright Rep. at 21.)

Plaintiff contends that Dr. Wright's analysis of the clinical literature is unreliable because he did not perform a comprehensive literature review and instead "cherry picked" relevant studies to support his conclusion. (Pl.'s Mem. in Supp. of Mot. to Exclude Testimony of Timothy Wright [1406], hereinafter "Pl.'s Wright Mem.," 2, 23.) Dr. Wright does not claim to have performed a comprehensive literature review, however, and the fact that he did not follow the standard methodology for such a review is not fatal to his testimony. Plaintiff has not argued that Dr. Wright misinterpreted the studies he did cite, and the court believes that the data Dr. Wright reviewed will provide important context for the jury in deciding whether the design is

[4] The Australian Orthopaedic Association's National Joint Registry is a patient registry that collects uniform data on all joint replacement surgeries from every hospital in Australia performing such surgeries. The data is used to evaluate patient outcomes based on "patient characteristics, prosthesis type and features, method of prosthesis fixation and surgical technique." *See About*, AUSTRALIAN ORTHOPAEDIC ASSOCIATION NATIONAL JOINT REPLACEMENT REGISTRY, https://aoanjrr.dmac.adelaide.edu.au/en/background (last visited Aug. 20, 2015).

defective. Each party has offered expert testimony to explain and interpret the various studies and data applicable to this litigation. If Dr. Wright failed to consider relevant data, Plaintiff may highlight that failure at trial. In short, Plaintiff has identified no reason that her criticisms of Dr. Wright's analysis cannot be raised through vigorous cross-examination or with competing expert evidence and his testimony is sufficiently reliable to survive *Daubert* scrutiny.

The court cautions, however, that though adequately reliable, Dr. Wright's testimony pertaining to the clinical evidence and registry data runs the risk of "needlessly presenting cumulative evidence." FED. R. OF EVID. 403. Zimmer has now proposed three different experts to testify about the relevant clinical literature and evidence: Dr. Wright, Dr. Goodman, and Dr. Vitale. Each one of those experts discusses a similar set of studies as well as the data contained in the Australian registry. The court sees no additional probative value from presenting this evidence through three different expert witnesses and will exclude redundant and cumulative evidence at trial.

B. Posterior Edge Loading

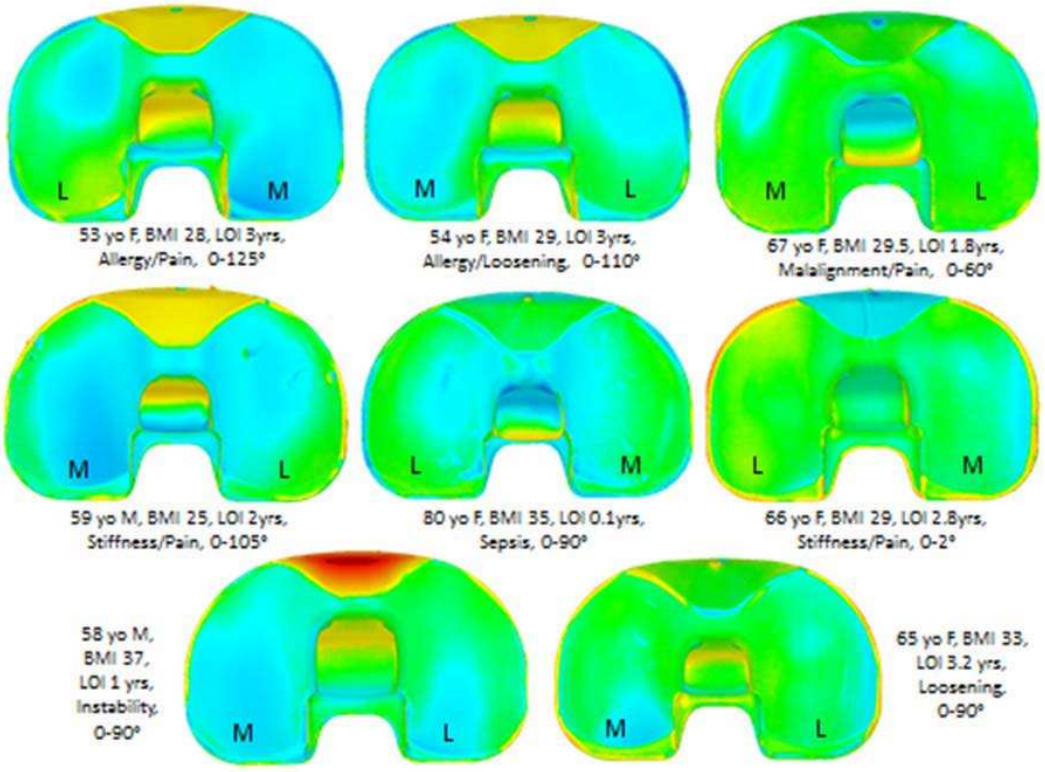
Dr. Wright also responds to Dr. Brown's theory of defect based on posterior edge loading. According to Dr. Wright, Zimmer's design actually mitigates the risk of posterior edge loading by providing larger contact areas between the femoral and tibial components, distributing forces more evenly across the tibial component. (Wright Rep. at 23.) Dr. Wright cites three pieces of evidence in support of his conclusion: (1) Zimmer's contact area measurements taken during the design of the Flex system, (2) a computer model simulation conducted by Dr. D'Lima, and (3) a "retrieval analysis of NexGen articular surfaces used with the Flex femoral components." (Wright Rep. at 23–24.)

In this motion, Plaintiffs challenge the reliability of Dr. Wright's retrieval study.[5] Dr. Wright described his methodology as follows:

[5] Plaintiff separately challenged Dr. D'Lima's computer model, an objection the court has overruled, *In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468,

> As part of an ongoing examination of high flex designs, retrieved tibial inserts used with Zimmer Flex femoral components have been gathered from revision surgeries as part of our ongoing Implant Retrieval Program at Hospital for Special Surgery. We have used laser scanning of the components along with scans from the pristine, never implanted Zimmer components of the same design and size. By aligning the scans, we compared how deformed the retrieved components were in relation to the pristine components. In eight retrieved specimens, we found little deformation on the bearing surfaces, consistent with reasonable levels of contact stress, even at the posterior edges, the location where the Plaintiffs contend high contact stresses would be consistent with extreme deformation and wear of the polyethylene.

(Wright Rep. at 24.) Immediately following this explanation, Dr. Wright included eight "colormetric maps of deformation" in the polyethylene surface:



(*Id.* at 25.) The caption states that "[t]he colors denote deformational differences with pristine, never implanted components." (*Id.*) But Dr. Wright included no scale to define what the various colors mean (which color is neutral, which is raised, and which is depressed?) or how much

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2015 WL 4880953, at *7 (N.D. Ill. Aug. 13, 2015), and assert that they will challenge Zimmer's contact area measurements "on the facts." (Pl.'s Wright Mem. at 6–7.)

deviation from the un-implanted scans each color represents (what fraction of a millimeter?). Dr. Wright's report continues, stating only that "these findings suggest that posterior edge loading is a rare event and that the loads experienced by Zimmer Flex components are insufficient in magnitude to cause significant polyethylene damage to contribute to implant failure," without further explanation. (Wright Rep. at 25.) Dr. Wright has not sufficiently presented his underlying data or explained how he reasoned from that data to his conclusions. The court, acting as a gatekeeper, must exclude "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997).

After his initial report, Dr. Wright supplemented his retrieval study with twelve additional scans, conducted after he had submitted his report but before his deposition. (Retrieval Study Supplement, Ex. C to Pl.'s Wright Mem. [1470-3], hereinafter "Retrieval Supp.") This time, the scans included color scales defining the amount of deviation from a never-implanted component. Even in this supplemental report, however, Dr. Wright did not provide the color scales for the first eight scans. Moreover, one of the supplemental twelve scans is presented with a different scale than the remaining eleven: While the scales accompanying the first eleven scans range from -1.5 millimeters to 1.5 millimeters, the scan labeled "Study 19"[6] ranges from -2.9289 millimeters to 2.9289 millimeters. Dr. Wright has not acknowledged or explained his use of a different color scale for this particular scan. In light of Dr. Wright's apparent use of different scales without explanation in the supplemental scans, the court has concerns that the initial eight scans may also rely on different scales and are, thus, not directly comparable to one another. Without more clarity regarding the color scales, Dr. Wright has simply not provided any basis from which the court can conclude he employed a reliable methodology.

[6] Dr. Wright has provided no explanation for the labels assigned to the various scans. The scans submitted in the supplemental report are labeled with numbers 1–7, 9, 13, 15, 18, and 19. (*See* Retrieval Supp. at 5–16.)

Even if the confusion surrounding the color scale were resolved, there are additional gaps in Dr. Wright's reasoning that support the court's decision to exclude testimony about his retrieval study. Dr. Wright has not explained the basis for his conclusion that "the loads experienced by Zimmer Flex components are insufficient in magnitude to cause significant polyethylene damage to contribute to implant failure." (Wright Rep. at 25.) Dr. Wright did not define the threshold he used to distinguish between "significant polyethylene damage" that contributes to implant failure, and insignificant polyethylene damage that does not. Nor did he cite any studies that quantify the amount of deformation considered safe. Finally, he did not compare the deformation observed on NexGen Flex implants to deformation observed on Zimmer Standard implants.

Nor does the court follow how Dr. Wright determined that "posterior edge loading is a rare event." (Wright Rep. at 25.) First, Dr. Wright examined only 20 scans, many of which were used only at low flexion angles (0–90 degrees) or at flexion angles that were not reported at all. One of the implants in the original report was only implanted for "0.1" years, and one in the supplemental report was implanted for only "0.36" years, suggesting very little time for wear or damage to the polyethylene to occur. (Wright Rep. at 25; Retrieval Supp. at 1.) Moreover, several of the implants scanned were revised for reasons other than aseptic loosening, undermining any comparison with Ms. Batty and the other plaintiffs in this litigation. (Wright Rep. at 25 (reasons for revision included "sepsis," "stiffness," "instability," and "malalignment/pain"); Retrieval Supp. at 1 (reasons for revision included "instability," "stiffness," "infection," and "arthrofibrosis").) Federal Rule of Evidence 702 requires the court to ensure that an expert's opinions are based on "sufficient facts or data." FED. R. EVID. 702; *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 810 (7th Cir. 2012). The court is not satisfied that these 20 scans are sufficient to support a conclusion that posterior edge loading is "rare" in all NexGen Flex patients. Second, Dr. Wright has not explained why he believes that the absence of polyethylene deformity necessarily implies the absence of posterior edge loading on the

underlying tibial tray. He cites no study to support that assertion and provides no data or testing of his own. He has not addressed the possibility that the polyethylene could simply transfer stresses to the tibial tray, without wearing down, resulting in posterior edge loading without any deformation of the polyethylene surface. The court concludes that "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. Dr. Wright's testimony relating to his retrieval study is, therefore, excluded.

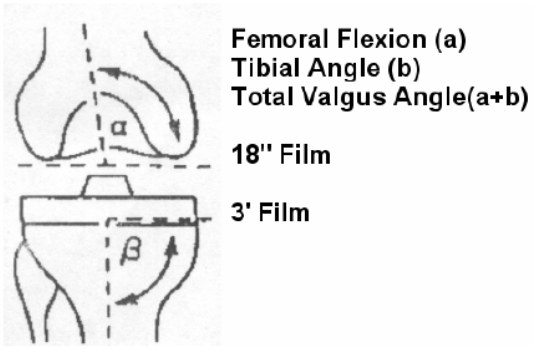
II. Dr. Goodman

Dr. Stuart Goodman is an orthopedic surgeon and a Professor of Orthopedic Surgery and of Bio-engineering at Stanford University. (Goodman Rep. at 39.) He received his Bachelor of Science, Masters of Science, and medical degrees from the University of Toronto. (Goodman Rep. at 2.) He continued on at University of Toronto for his orthopedic residency, which he completed in 1984. (*Id.*) In 1985, he completed fellowships in adult reconstruction and orthopedic trauma at the Wellesley Hospital and Sunnybrook Medical Center in Toronto. (*Id.*) He has been board certified in orthopedic surgery by the American Board of Orthopedic Surgery since 1987. (*Id.*) In 1994, he obtained a Ph.D. in Medical Science from Lund University in Sweden. (*Id.*)

Like Dr. Wright, Dr. Goodman's report is broad in scope. He begins by explaining how a total knee replacement can be used to treat arthritis and then describes the various complications that can arise after a total knee replacement. He notes that surgeons may improperly align the implant or may use an inadequate or uneven layer of cement to fasten the implant to the bone. (Goodman Rep. at 3–4.) He also describes the rationale behind the NexGen Flex femoral component design, concluding, as Dr. Wright did, that the design allows for greater contact area between the femoral and tibial components, thus reducing the risk of posterior edge loading. (Goodman Rep. at 6.) Dr. Goodman asserts that "the overwhelming majority of reported studies have demonstrated the safety and efficacy of the Zimmer NexGen [Flex] worldwide. This is consistent with the 2013 Australian Arthroplasty Registry data, an

important source for determination of clinical outcome for surgeons." (Goodman Rep. at 11.) Finally, Dr. Goodman analyzes Ms. Batty's medical records (Goodman Rep. at 12–19), and opines that the loosening she experienced was caused by her implanting surgeon's poor cementing technique, the misalignment of the components, Ms. Batty's activity level, and a possible low-grade infection. (Goodman Rep. at 19–20.)

Plaintiff challenges only one aspect of Dr. Goodman's report: his assertion that Ms. Batty's knee was misaligned. There are two angles that determine whether a knee implant is properly aligned: one is the overall alignment of the knee, that is, the relationship between the femur and the tibia. The overall alignment can be in "varus," that is a bow-legged misalignment, or in "valgus," which is a knock-kneed misalignment.



(Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System, Ex. C to Pl.'s Goodman Mem. [1335-3], 7.)[7] The overall angle of the knee is the sum of the α and β angles. If the sum is less than 180 degrees, the knee is in varus alignment. If the sum is greater or equal to 180 degrees, the knee is in valgus. Dr. Wright testified that the target for the overall knee alignment is two to five degrees valgus, or a sum of 182 to 185. (Dep. of Timothy Wright, Ex. B. to Pl.'s Goodman Mem. [1335-2], hereinafter "Wright Dep.," 69:9–11.)

[7] The diagram reflects a knee viewed "anterior-posterior," that is, from front to back or from back to front. When a right knee is viewed from front to back, the lateral side appears on the left; for a left knee viewed from front to back, the lateral side appears on the right. Though the diagram does not specifically include such medial or lateral labels, the court understands that, in this diagram, medial (towards the midline of the body), is on the right side of the diagram and lateral (the outside of the knee) is on the left. In other words, the diagram depicts a right knee viewed from front to back, or a left knee, viewed from back to front.

The second angle that is relevant to the long-term success of the knee is the alignment of the tibial component in relation to the tibial bone, which is measured by the β angle. If β is less than 90 degrees, the tibial component is in varus alignment. If it is greater than or equal to 90 degrees, the tibial component is in valgus.

Though Dr. Goodman's report explains why varus alignment of the overall knee or of the tibial component can lead to implant failure, he does not adequately explain how he determined that Ms. Batty's components were in fact in varus alignment. There are only three sentences in Dr. Goodman's report that describe the alignment of Ms. Batty's implant. Dr. Goodman reviewed Ms. Batty's x-rays taken prior to her surgery and observed "a patient with progressive degenerative arthritis of both knees with varus alignment." (Goodman Rep. at 17.) After the surgery, Dr. Goodman states, "[t]he tibial components were placed in varus alignment, as seen on the postoperative radiographs." (*Id.*) By March of 2011, he noted, "the right tibial component was in varus and loose." (*Id.*) Based on this review of the x-rays, Dr. Goodman concludes that "[t]he alignment of the knees remained in 4-5 degrees of varus postoperatively." (*Id.* at 18, 20.) There is no explanation in Dr. Goodman's report for how he measured the alignment of Ms. Batty's knees. During his deposition, however, he explained that he "relied on the specific measurements, the numbers that are outlined in this report via the measurements from the Hospital for Special Surgery," referring to the measurements Dr. Wright made in preparing his expert report on Ms. Batty. (Dep. of Stuart Goodman, Ex. L to Pl.'s Goodman Mem. [1335-12], hereinafter "Goodman Dep.," 132:14–17.)

There is, of course, nothing improper about Dr. Goodman's reliance on Dr. Wright's measurements, but on this record, it is not clear to what extent he did so. Dr. Wright and Dr. Goodman agreed that the tibial component was in varus in relation to the tibial bone, but they state different opinions about the overall alignment of the knee. Dr. Wright concluded that the overall angle of the knee was two degrees valgus, which is within what he believes is target range of knee alignment. (Wright Dep. at 64:11–20, 69:12–17.) Dr. Goodman testified, as he

stated in his report, however, that the overall angle of the knee was "varus." (Goodman Dep. at 136:6–9; 181:4–7.)

Zimmer attempts to massage this disagreement by arguing that when Dr. Goodman said that the overall knee alignment was "varus" he really meant that it was "less valgus than what a surgeon wants to achieve." (Goodman Dep. Errata Sheet at 131:12–13; *see* Zimmer Resp. to Pl.'s Mot. To Exclude Testimony of Stuart Goodman, [1450], hereinafter "Zimmer Goodman Resp.," 4; Aff. of Stuart Goodman, Ex. E to Zimmer Goodman Resp. [1450-5], hereinafter "Goodman Aff." ¶ 6.) Dr. Goodman testified at his deposition that the ideal overall alignment of the knee is three to ten degrees of valgus. (Goodman Dep. 179:25–180:13.) So, Ms. Batty's knee, which is two degrees valgus, is less valgus than ideal. (Zimmer Goodman Resp. at 4.) Zimmer cites an article that provides some support for this interpretation of Dr. Goodman's testimony: In a study of overall knee alignment after total knee replacements, the authors present their findings in a bar graph, which characterizes "Varus" as "alignment below 2.4 degrees of valgus," "Neutral" is defined as alignment between 2.4 and 7.2 degrees of valgus, and "Valgus" is defined as alignment above 7.2 degrees of valgus. (*See* David Fang, Merrill Ritter, and Kenneth Davis, *Coronal Alignment in Total Knee Arthroplasty: Just How Important Is It?*, 24 J. OF ARTHROPLASTY 39, 41 (2009), Ex. J to Zimmer Goodman Resp. [1450-10], hereinafter "Fang.") But even this explanation does not eliminate the confusion: Accepting Zimmer's explanation, Ms. Batty's alignment of two degrees valgus would be one to nine degrees away from ideal as defined by Goodman, not the "4–5" degrees Dr. Goodman presents in his report. Dr. Goodman's affidavit attached to Zimmer's Response brief makes a further attempt to resolve the matter by suggesting that "the ideal overall anatomic alignment is 6–7 degrees valgus, with a margin of error rate of 2–3 degrees," and thus Ms. Batty's alignment is four to five degrees away from the "6–7 degrees valgus" ideal. (Zimmer Goodman Resp. at 4) (citing Goodman Aff. ¶ 6.)

Zimmer's complicated explanation is theoretically plausible, but the court remains concerned that Dr. Goodman's opinions regarding alignment may have been based on a simple error in measuring the angles. More importantly, Dr. Goodman's testimony on this issue has a strong probability of confusing and misleading the jury. To the extent it has probative value, that proof appears to be cumulative of Dr. Wright's testimony regarding the alignment of Ms. Batty's implants. *See* FED. R. EVID. 403. Dr. Goodman is, therefore, precluded from testifying about the alignment of Ms. Batty's components.

CONCLUSION

Plaintiff's motion to exclude testimony by Dr. Stuart Goodman [1333] regarding the alignment of Ms. Batty's implant is granted. Plaintiff's motion to exclude the testimony of Dr. Timothy Wright [1405] is granted with respect to his "retrieval study" and denied with respect to his analysis of the clinical literature documenting patient outcomes with the NexGen Flex.

ENTER:

Dated: August 27, 2015

REBECCA R. PALLMEYER
United States District Judge