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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Amanda McBroom,

Plaintiff,

v.

Ethicon, Inc.; and Johnson & Johnson,

Defendants.

No. CV-20-02127-PHX-DGC

ORDER

This products liability action involves pelvic mesh devices made by Defendants Ethicon, Inc. and Johnson & Johnson. Plaintiff Amanda McBroom received implants of Defendants' devices and claims they are defective and caused her serious injury. Plaintiff filed suit in 2015 as part of a multidistrict litigation ("MDL") proceeding in West Virginia. Doc. 1; *see In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327 (S.D. W. Va. 2012). The case was transferred to this Court on November 4, 2020. Docs. 41, 56.

The parties have filed motions to exclude expert opinions under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Docs. 79, 80. The motions are fully briefed. Docs. 81, 82, 86, 88. The parties' requests for oral argument are denied because it will not aid the Court's decision. *See* Fed. R. Civ. P. 78(b); LRCiv 7.2(f). For reasons stated below, the Court will deny Plaintiff's motion and grant in part and deny in part Defendants' motion.[1]

[1] The Court has adopted the MDL Court's rulings on all *Daubert* issues. *See* Doc. 76 at 1. This order addresses unresolved issues the parties raised in their MDL briefing. *Id.* at 2.

I. Background.

Defendants design and manufacture polypropylene-based pelvic mesh devices (sometimes called "tape" or "slings") to treat female stress urinary incontinence and pelvic organ prolapse. In 2007, Plaintiff was implanted with two of Defendants' pelvic mesh devices – the Gynecare TVT Secur System ("TVT Secur" or "TVT-S") and the Gynecare Prolift Pelvic Floor Repair System ("Prolift"). Docs. 1 ¶¶ 8-10, 30-1 at 3.[2] Dr. Scott Crawford performed the surgical procedure at Banner Medical Center in Phoenix, Arizona. Doc. 1 ¶¶ 10-12. Plaintiff claims that she began experiencing adverse symptoms from the Prolift and TVT-S in 2011. Doc. 30-1 at 4. In July 2014, Plaintiff had surgery to remove an exposed portion of the Prolift mesh. Doc. 32-3 ¶ 39.

Plaintiff brought this action in 2015, asserting various claims under Arizona law and seeking compensatory and punitive damages. Doc. 1; *see McBroom v. Ethicon, Inc.*, No. 2:15-cv-03043 (S.D. W. Va. Mar. 13, 2015).[3] In March 2021, the Court granted in part Defendants' motion for partial summary judgment. Docs. 30, 83. The following claims remain: design defect, negligence and negligent infliction of emotional distress to the extent based on negligent design, and punitive damages. *See* Doc. 83 at 10-11.[4]

Plaintiff moves to exclude the opinions of Drs. Brian Flynn, Salil Khandwala, Steven MacLean, and Edward Stanford. Doc. 79. Defendants move to exclude the opinions of Drs. Bruce Rosenzweig, Donald Ostergard, and Scott Guelcher. Doc. 80.

II. Rule 702 and *Daubert* Standards.

Under Rule 702, an expert may offer "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the

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[2] "TVT" stands for "tension-free trans-vaginal tape." Defendants produce other pelvic mesh devices not at issue in this case, including the Gynecare TVT System ("TVT"), the TVT Obturator System ("TVT-O"), and the Prolift+M Pelvic Floor Repair System ("Prolift+M").

[3] Arizona law governs Plaintiff's claims because Arizona is where she resides, received the implants, and suffered her alleged injuries. Docs. 31 at 3-4, 35 at 2.

[4] The Court granted summary judgment on the failure to warn claim for lack of causation (*id.* at 3-8), and granted summary judgment on the negligence and negligent infliction claims to the extent they are based on an alleged failure to warn (*id.* at 9-11).

testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). The proponent of expert testimony has the burden of showing, by a preponderance of the evidence, that the proposed testimony is admissible under Rule 702. *See* Fed. R. Evid. 104(a); *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007). The trial court acts as a gatekeeper for expert testimony to assure that it "both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597; *see Davis v. McKesson Corp.*, No. CV-18-1157-PHX-DGC, 2019 WL 3532179, at *3-4 (D. Ariz. Aug. 2, 2019).

III. Plaintiff's Motion.

A. Dr. Flynn.

Dr. Flynn is a urogynecologist and a female pelvic medicine and reconstructive surgery specialist. He has prepared lengthy expert reports in which he offers various opinions on the safety and efficacy of the two devices implanted in Plaintiff – the TVT-S and Prolift. Docs. 79-3, 79-5.[5] Plaintiff discusses little from Dr. Flynn's reports, only a few of his opinions, and almost none of his qualifications and clinical experience. Relying largely on certain aspects of Dr. Flynn's deposition testimony, Plaintiff moves to exclude all of his opinions because: (1) he followed no reliable methodology in assessing the medical literature and ignored literature that is contrary to his opinions (Doc. 79 at 4-10); (2) opinions based on his personal experience are not supported by a reliable methodology (*id.* at 10-12); and (3) his analysis of laser-cut mesh is unreliable (*id.* at 12-13).[6] As explained more fully below, the Court will deny Plaintiff's motion with respect to Dr. Flynn.

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[5] Plaintiff asserts that Dr. Flynn intends to opine on three other pelvic mesh devices – the TVT, the TVT-O, and the Prolift+M (Doc. 79 at 4 & n.4) – but those opinions are not relevant in this case. *Cf.* Doc. 82 at 2-9 (Defendants' response addressing opinions specific to the Prolift and TVT-S). The Court will not consider Plaintiff's arguments concerning devices other than the TVT-S and Prolift.

[6] Citations to page numbers refer to numbers attached at the top of the pages by this Court's filing system, not page numbers of the original document or those placed by the MDL Court's filing system.

1. Medical Literature.

Plaintiff notes at the outset that the MDL Court characterized Dr. Flynn's review of the medical literature as "shaky." Doc. 79 at 4. But the MDL Court declined to exclude Dr. Flynn's safety and efficacy opinions on that basis. Doc. 50-7 at 7. What is more, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596; *see also Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010) ("Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion.") (citing *Daubert*); *United States v. Wells*, 879 F.3d 900, 933 (9th Cir. 2018) (same); *Meador v. Aramark Sports & Ent. Servs. LLC*, No. CV-19-08345-PCT-JJT, 2021 WL 1597897, at *2 (D. Ariz. Apr. 23, 2021) (same and noting that "[t]he advisory committee notes on the 2000 amendments to Rule 702 explain that Rule 702 (as amended in response to *Daubert*) 'is not intended to provide an excuse for an automatic challenge to the testimony of every expert'").

Plaintiff next asserts that Dr. Flynn's opinions should be excluded because he did not review "all of the literature" or base his opinions on the "entire body of scientific evidence." Doc. 79 at 4. Nothing in Rule 702 or *Daubert* "requires an expert to consider every single article on a topic in order to be admitted as an expert." *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2187, 2018 WL 4220616, at *5 (S.D. W. Va. Sept. 5, 2018); *see In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prod. Litig.*, No. CV 16-2738 (FLW), 2020 WL 8968851, at *56 (D.N.J. Apr. 27, 2020) ("There is [no] requirement that an expert review every single study in the relevant body of literature."); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, MDL No. 2545, 2018 WL 4030585, at *6 (N.D. Ill. Aug. 23, 2018) ("The fact that Dr. Zipes does not discuss every study AbbVie views as relevant, or that he may have overlooked a study, does not mean that he unreliably applies his methodology."); *In re Citimortgage, Inc. HAMP Litig.*, No. MDL 11-2274 DSF, 2013 WL 8844095, at *3 (C.D. Cal. Oct. 7, 2013)

(an expert's "failure to deal with the entire universe of documents is not a reason for exclusion"); *Am. Nat'l Prop. & Cas. Co. v. Stutte*, No. 3:11-CV-219, 2015 WL 1641955, at *4 (E.D. Tenn. Apr. 13, 2015) (rejecting argument that "an expert's analysis must fully incorporate every single piece of available evidence"); *Smilovits v. First Solar, Inc.*, No. CV12-00555-PHX-DGC, 2019 WL 6875492, at *5 (D. Ariz. Dec. 17, 2019) ("[C]riticism of an expert's decision to base an opinion on some facts but not others should be challenged through the traditional means at trial, not through a *Daubert* motion.") (citation omitted). Plaintiff does not dispute that there are thousands of published articles about stress urinary incontinence and pelvic organ prolapse surgery. *See* Doc. 82 at 3-4. Indeed, Plaintiff asserts that she "cannot discuss every piece of evidence" that Dr. Flynn purportedly disregarded because it would be unduly burdensome. Doc. 79 at 6; *see also* Doc. 79-1 at 31 (Dr. Flynn's testimony that "[t]here's no way you can be aware of every single article in the medical literature."). The mere fact that Dr. Flynn did not review all existing literature and scientific evidence does not render his opinions unreliable. The Court will not exclude his opinions on this ground.

Plaintiff further asserts that Dr. Flynn has admitted that he performed no "systematic review" of the literature, but Plaintiff does not explain what such a review would entail. Doc. 79 at 5 (citing Doc. 79-1 at 9). Defendants note, correctly, that Plaintiff has taken Dr. Flynn's testimony out of context – he agreed that his Prolift report itself is not a systematic review of all existing literature, but did not state that he never performed a comprehensive literature review. Doc. 82 at 2. Dr. Flynn explained that he relied in part on systematic literature reviews and meta-analyses performed by others, as well as his own clinical experience with the Prolift. Doc. 79-1 at 9. He further testified that he performed a thorough review of the medical literature using relevant keyword searches in PubMed, and these searches led to different but related articles because "it's sort of a chain reaction once you start looking at PubMed." *Id.* at 27.[7] Dr. Flynn discusses in his reports various

[7] PubMed is a free online resource for the search and retrieval of biomedical and life sciences literature. *See* National Institutes of Health, *PubMed Overview*, https://pubmed.ncbi.nlm.nih.gov/about/ (last visited on June 15, 2021). The PubMed database

articles and studies he found through PubMed and has prepared a reliance list that includes hundreds of medical literature references. *See* Doc. 79-7. Dr. Flynn routinely reads medical journals and scientific articles that affect his clinical practice, he belongs to a journal club that meets several times a year, and he is a peer-reviewer for a number of medical journals. Docs. 79-1 at 27-28, 79-3 at 3. Plaintiff does not address the literature Dr. Flynn relied on in forming his opinions, nor has she shown that Dr. Flynn's failure to perform an undefined "systematic review" of the literature renders his opinions unreliable. *See In re Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *3 (S.D. W. Va. Aug. 30, 2016) ("Ethicon does not address in its Motion any of Dr. Margolis's cited literature in his report, thus giving me no reason to exclude Dr. Margolis on reliability grounds.").

Plaintiff refers to several articles she believes are contrary to Dr. Flynn's opinions and that he purportedly does not discuss in his reports. Doc. 79 at 6-10. Specifically, Plaintiff cites a 2014 article by Nambiar from the Cochrane Collaboration, an updated 2016 Cochrane Review, a 2012 study by Stanford in the International Urogynecology Journal, a 2010 randomized control trial by Iglesia, and a 2009 study by Dr. Diwadkar in the Obstetrics and Gynecology Journal. *Id.* But Plaintiff does not include these articles as part of her briefing, nor does she discuss them in any detail. The Court cannot exclude Dr. Flynn's opinions based on mere references to articles that Plaintiff believes are contrary to the literature on which Dr. Flynn relies, which Plaintiff also fails to provide.

Plaintiff's assertion that Dr. Flynn simply ignored the referenced articles without explanation is not entirely correct. *See* Doc. 79 at 6-10. Some of the articles are included on his reliance list, and he explained why he found certain articles less relevant and reliable than the literature on which he bases his opinions. *See* Doc. 82 at 5-9. Plaintiff will be free to cross-examine Dr. Flynn on this point. *See Wilkerson v. Bos. Sci. Corp.*, No. 2:13-

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contains more than 32 million citations and abstracts of biomedical literature. *Id.* Available to the public since 1996, PubMed was developed and is maintained by the National Center for Biotechnology Information at the U.S. National Library of Medicine. *Id.* Plaintiff does not specifically address PubMed or Dr. Flynn's use of this resource in performing his literature review.

CV-04505, 2015 WL 2087048, at *10 (S.D. W. Va. May 5, 2015) ("Whether Dr. Margolis's reasons for rejecting certain studies are accurate or whether Dr. Margolis inconsistently applies these reasons to the literature are appropriate topics for cross-examination."); *Trevino v. Bos. Sci. Corp.*, No. 2:13-CV-01617, 2016 WL 2939521, at *40 (S.D. W. Va. May 19, 2016) ("If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination."); *Lampron v. Ethicon, Inc.*, No. 20-CV-317-JD, 2020 WL 3051780, at *3 (D.N.H. June 8, 2020) ("To the extent the challenged opinions are Dr. Carbone's interpretations of the medical literature, . . . those opinions may be challenged on cross examination based on the infirmities raised by the Lamprons in their motion.").

Dr. Flynn testified that literature he has not reviewed possibly could change his opinions, but he thinks it unlikely. Doc. 79-1 at 46-47. Plaintiff criticizes Dr. Flynn for both "doubt[ing] anything could change his opinions" and admitting that contrary literature "might change his opinions[.]" Docs. 79 at 6, 88 at 2. The fact that Dr. Flynn has expressed confidence in his opinions, while leaving open the possibility that the opinions could change based on literature he has not reviewed, provides no basis for exclusion. *See Daubert*, 509 U.S. at 590 ("[I]t would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science."); *Primiano*, 598 F.3d at 565 ("Lack of certainty is not, for a qualified expert, the same thing as guesswork.").

It is not the job of the Court to ensure that the evidence heard by the jury is "error-free," but to ensure that it is "sufficiently reliable to be considered by the jury." *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 495607, at *4 (D. Ariz. Jan. 22, 2018) (citation omitted); *see In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489793, at *7 (S.D. Fla. Feb. 24, 2010) ("The Court must be careful not to conflate questions of admissibility of expert testimony with the weight appropriately to be accorded to such testimony by the fact finder."). Plaintiff's arguments

may be appropriate subjects for cross-examination, rebuttal expert testimony, or jury argument, but they do not so undercut Dr. Flynn's opinions as to render them inadmissible under Rule 702. *See In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2327, 2016 WL 4556807, at *4 (S.D. W. Va. Aug. 31, 2016) ("To the extent that the plaintiffs believe that Dr. Flynn should have considered additional studies or disagree with his conclusion to discount certain studies, they are free to cross-examine Dr. Flynn on those matters."); *Heinrich v. Ethicon, Inc.*, No. 2:20-cv-00166-APG-VCF, 2021 WL 1854648, at *2 (D. Nev. May 10, 2021) ("Flynn identified the studies he relied on, explained why he concluded that those studies better reflect the TVT-S, and explained why the Single Incision Review did not change his opinions on the TVT-S's safety and efficacy. Flynn's review of the relevant literature was extensive, and his testimony based on the medical literature is admissible. Any flaws in Flynn's decision to discount the Single Incision Review can be explored through cross examination and will be a matter for the jury to resolve."); *see also In re Ethicon*, 2016 WL 4536885, at *3 ("Dr. Margolis has cited medical literature that supports his safety and efficacy opinions. To the extent Ethicon disagrees with this medical literature or wishes to explore nuances, its efforts are better saved for cross-examination."); *In re Packaged Seafood Prods. Antitrust Litig.*, No. 15-MD-2670 JLS (MDD), 2020 WL 5739316, at *4 (S.D. Cal. Sept. 24, 2020) ("There is no rule that an expert must consider and discuss all of the evidence on the record in order to proffer admissible testimony. . . . Those are grounds for cross-examination.") (citation omitted); *Porte v. Ill. Cent. R.R. Co.*, No. CV 17-5657, 2018 WL 4404063, at *3 (E.D. La. Sept. 14, 2018) ("To the extent that Dr. Saux or other experts may not take into account every study that is relevant . . . or otherwise exhibited bias in rendering their opinions, those issues go to the weight of their opinions, and not the questions of admissibility.").

2. Dr. Flynn's Experience.

Dr. Flynn's opinions are not based solely on his literature review – he also bases them on his education, training, specialized knowledge, and clinical experience. *See* Docs. 79-3 at 2, 79-5 at 2. Plaintiff contends that Dr. Flynn's opinions should be excluded

because his personal experience is based on no "reliable scientific method." Doc. 79 at 10; *see also* Doc. 88 at 10 (Dr. Flynn "has not followed a reliable methodology because he is guessing at his own experience"). Plaintiff cites no legal authority in support of this contention, nor does she discuss Dr. Flynn's vast experience treating stress urinary incontinence and pelvic organ prolapse.[8]

Although some expert testimony "rests upon scientific foundations," in other cases "the relevant reliability concerns may focus upon personal knowledge or experience." *Kumho Tire*, 526 U.S. at 150 (noting *Daubert*'s description of the Rule 702 inquiry as a "flexible one"). "The *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable to . . . testimony[] whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000)); *see* Fed. R. Evid. 702, advisory committee's note to 2000 amendment ("Some types of expert testimony will be more objectively verifiable, and subject to the expectations of falsifiability, peer review, and publication, than others. Some types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular area of expertise."). This holds true for much medical testimony. As the Ninth Circuit has noted, medicine "is not a science but a learned profession, deeply rooted in a number of sciences and charged with the obligation to apply them for man's benefit." *Primiano*, 598 F.3d at 565 (citation omitted). "Despite the importance of evidence-based medicine, much of medical decision-making relies on judgment – a process that is difficult to quantify or even to assess qualitatively." *Id.* (citation omitted). Thus, "a doctor's experience might be good reason to admit his testimony." *Id.* at 566.

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[8] The MDL Court reserved ruling on the issue until trial, noting that experience is a reliable basis for expert testimony but that it did not have enough information to evaluate the relevance and reliability of Dr. Flynn's particular experience. Doc. 50-5 at 7-8 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

As the MDL Court noted, Dr. Flynn teaches how to implant pelvic mesh devices, has performed more than 1,000 surgeries for stress urinary incontinence and pelvic organ prolapse, and performs around 50 revision surgeries each year. *In re Ethicon*, 2016 WL 4556807, at *4. Dr. Flynn spends 85% of his time in a clinical practice – more than half of which involves female pelvic medicine and reconstructive surgery – and has handled about 200 cases involving the Prolift systems. Doc. 79-5 at 3. He has used polypropylene mesh kits in more than 800 of his cases, including more than 500 cases using TVT products. Doc. 79-3 at 3.

"This clinical experience is sufficient to satisfy the threshold reliability requirements of Rule 702." *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 993675, at *2 (D. Ariz. Feb. 21, 2018) (same where the doctor had been treating patients with inferior vena cava filters for more than 25 years and had implanted and removed hundreds of such filters); *see Heinrich*, 2021 WL 1854648, at *2 (finding that "Flynn is qualified to render the opinions he offers"); *see also Triant v. Am. Med. Sys. Inc*, No. CV-12-00450-PHX-DGC, 2020 WL 4049844, at *7 (D. Ariz. July 20, 2020) (the doctor's opinions on oxidative degradation rested on a reliable foundation where he had "decades of experience treating urological conditions and [had] specific clinical and research interests in female pelvic reconstructive surgery"); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611-12 (S.D. W. Va. 2013) ("Dr. Shull's extensive experience with pelvic floor disorders and the use of mesh to treat such disorders qualifies him to render opinions on such issues[.]"); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 420-21 (S.D.N.Y. 2016) (the expert's "experience as a medical doctor specializing in OB/GYN and his familiarity and experience in placing and teaching how to place IUDs . . . are indicative of the reliability of his opinions"); *Primiano*, 598 F.3d at 567 ("Dr. Weiss's background and experience, and his explanation of his opinion, leave room for only one conclusion regarding its admissibility. It had to be admitted.").

Plaintiff claims that Dr. Flynn's recollection of his experience is "everchanging" because he could not specifically recall when he began using certain TVT devices. Doc. 79

at 10. Plaintiff also notes that Dr. Flynn had to guess how many Ethicon products he has implanted, does not keep track of the devices involved in revision surgeries, and has not reviewed patient files. *Id.* at 10.

Plaintiff's criticisms are appropriate for cross-examination, rebuttal expert testimony, and jury argument, but they provide no basis for exclusion under Rule 702. *See In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 6186496, at *2 (D. Ariz. Feb. 21, 2018) ("Plaintiffs may cross examine Dr. Grassi about the basis for his statement and the number of patients with Bard filters he has encountered, but Plaintiffs have identified no basis for excluding the statement under Rule 702."); *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 495188, at *4 (D. Ariz. Jan. 22, 2018) (finding that the expert had sufficient experience to offer his opinions where he had "implanted and removed hundreds of IVC filters, including those manufactured by Bard[,]" and noting that the defendants may "challenge the reliability of these opinions through cross examination or qualified experts of their own"); *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 12685965, at *19 (S.D. W. Va. Nov. 20, 2014) ("Numerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions. Such practice can hardly be described as a 'mystery.' If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions."); *McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1138 (D. Or. 2010) ("Plaintiffs . . . argue that Dr. Burkhead cannot rely on his own clinical experience because he performed no systematic review of his patients' records. However, Dr. Burkhead is entitled to draw inferences regarding causes of chondrolysis such as patient age and surgical error from the medical literature and his extensive experience.").[9]

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[9] Plaintiff asserts that Dr. Flynn has not produced his "case log" that purportedly identifies which products he has implanted since 2004, but presents no argument that the case log is discoverable and should have been disclosed. Doc. 79 at 11-12; *see also Heinrich*, 2021 WL 1854648, at *2 ("To the extent Heinrich contends Flynn should not be allowed to testify because he did not disclose the spreadsheet, there is no indication she moved to compel its production.").

3. Laser-Cut Mesh.

Plaintiff seeks to exclude Dr. Flynn's opinion that there is "no difference in laser-cut versus mechanically cut mesh." Doc. 79 at 12; *see* Docs. 79-3 at 30, 79-8 at 22. Plaintiff asserts that, "in an earlier deposition, Dr. Flynn admitted he was not an expert with regard to this very topic." Doc. 79 at 12.[10] But Dr. Flynn was asked whether he had "read what the internal Ethicon employees, scientists, and medical directors were saying about the issues in [that] case[.]" Doc. 79-10 at 4. He explained that he is not an Ethicon employee and his role in the case was not to discuss the biomechanical data because "other people that are experts for Ethicon . . . can probably speak to it better than [him]." *Id.* But he made clear that he is qualified "to answer questions as a physician and clinician with respect to laser-cut and mechanically-cut [mesh]." *Id.* Contrary to Plaintiff's assertion, Dr. Flynn has not admitted that he lacks expertise to opine on clinical differences between these kinds of mesh. *See In re Ethicon*, 2016 WL 4556807, at *4 (explaining that Dr. Flynn is a board-certified urologist with undergraduate training in biomedical engineering and that his "extensive clinical experience, combined with his review of scientific literature, qualifies him to opine on mesh's reaction to and effect on the human body").

Dr. Flynn will testify that there is no clinically significant difference between laser-cut and mechanical-cut mesh in his own practice. Doc. 82 at 10-11. Plaintiff contends that Dr. Flynn has applied no "reliable methodology" to his own experiences and has only a rough idea of how many TVT devices he has implanted were laser cut. Docs. 79 at 13, 88 at 11; *see* Doc. 79-2 at 36 ("Doing a calculation, rough calculation in my mind, probably close to half and half."). But Dr. Flynn makes clear in his TVT-S report that he has "used both mechanical-cut and laser-cut mesh, and clinically there is no difference between the two." Docs. 79-3 at 14. When asked why he believes laser-cut mesh and mechanical-cut mesh are both safe and effective given that no literature has made a head-to-head comparison of the two meshes, Dr. Flynn provided this explanation (Doc. 79-2 at 34):

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[10] The deposition was taken in *Perry v. Luu*, No. 1500-cv-279123 (Cal. Super. Ct. Jan. 7, 2015). *See* Doc. 79-10 at 2.

> I've implanted over 80 midurethral slings. And I've been using midurethral slings since 2004. So I've used both mechanical-cut and laser-cut mesh. That's what was taught to me as a resident and fellow and what I incorporated in my practice. So from my own clinical experience from 2004 to 2006, maybe even later, 2008, when using mechanical-cut mesh, I got excellent results. I had over 90 percent success with a complication rate of somewhere around 2 to 2 and a half percent.
>
> Later in my practice I switched over to laser-cut mesh [including] the . . . TVT-Secur. . . . [A]ll of these products performed quite similarly in terms of having efficacy and safety that was very similar to the mechanical-cut [mesh].
>
> So after doing 800 cases, I'm very comfortable commenting on both of the meshes. I found the way they resulted in my patients and the outcomes I got were quite similar.

Dr. Flynn's clinical experience with both laser-cut and mechanical-cut mesh is sufficient to satisfy the threshold reliability requirements of Rule 702. *See In re Bard*, 2018 WL 993675, at *2. The Court will not preclude him from testifying about his own clinical experience, and, based on that experience, opining that there is no clinical difference between the two meshes. *See* Docs. 79-3 at 14, 79-8 at 14; *Heinrich*, 2021 WL 1854648, at *2 ("Flynn has explained the bases of his opinion, and it is grounded in the medical literature and his own experience. The fact that he is not a materials scientist does not preclude him from opining on whether the two cuts have clinically significant differences."). Plaintiff will be free to cross-examine Dr. Flynn about the alleged lack of supporting literature on this point. *See* Doc. 79 at 12.

B. Dr. Khandwala.

Dr. Khandwala is a board-certified urogynecologist and specialist in female pelvic medicine and reconstructive surgery. He has issued expert reports on the Prolift and TVT-S. Docs. 79-11, 79-12, 82-3, 82-4. Plaintiff moves to exclude Dr. Khandwala's opinions regarding: (1) Prolift mesh contraction, porosity, and stiffness (Doc. 79 at 14-17); (2) TVT-S biomaterial issues – mesh shrinkage, degradation, particle loss, and porosity (*id.* at 20-22); (3) the TVT-S design (*id.* at 23-24); and (4) the TVT-S instructions for use ("IFU"), warnings, and patient brochures (*id.* at 17-20). The Court will deny the motion.

1. Prolift Mesh Contraction, Porosity, and Stiffness.

a. Contraction.

Plaintiff asserts that Dr. Khandwala "opines in one solitary sentence of his report that polypropylene mesh does not contract," and that the "entirety of the evidence [he] relies upon consists of an ultrasound study [that] used AMS mesh rather than the Gynemesh PS or Ultrapro mesh used in either the Prolift or Prolift +M." Doc. 79 at 15. But Plaintiff addresses the report dated March 2, 2016. *See id.*; Doc. 79-11 at 2, 17 & n.56 (citing Dietz, HP, et al., *Mesh Contraction: myth or reality?*, Am. J. Obstet. Gynecol. (2011)). In a subsequent report on the Prolift – dated November 12, 2018 – Dr. Khandwala discusses a study involving "a group of over 500 Prolift patients with three years follow up, [in which] the authors found that only 0.4% required surgical intervention for contraction." Doc. 82-3 at 19 & n.78 (citing De Landsheere, L., et al., *Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up*, Am. J. Obstet. Gynecol. (2012)). Dr. Khandwala also discusses a study exploring the impact of surgical placement on mesh size, which "noted that what seemed to be a decrease in the dimension of the mesh is actually an error [because] the mesh is improperly placed at surgery or it folds immediately after placement and this is interpreted as mesh contraction[.]" *Id.* at 19 & n.79 (citing K. Svabik, et al., *Vaginal Mesh Shrinking – Ultrasound Assessment and Quantification*, 1st Faculty of Med., Charles Univ. in Prague, Int'l Urogynecol. J. (2009)). Dr. Khandwala includes a table showing that "what looks like a 45% mesh contraction is in fact a 16% shrinkage which is typically seen once the ballooning from the prolapse is corrected and with any scar tissue formation." *Id.* Contrary to Plaintiff's assertion, Dr. Khandwala does not rely solely on the 2011 ultrasound study.

Plaintiff asserts generally that Dr. Khandwala formed his opinions based on "a very limited and flawed body of evidence" and failed to account for "the abundant scientific literature supporting the premise that polypropylene mesh contracts." Doc. 79 at 15-16. But Plaintiff fails to identify the "abundant scientific literature." *Id.* If there is literature

Dr. Khandwala failed to review in forming his opinions, Plaintiff will be free to ask him about it on cross-examination. *See Trevino*, 2016 WL 2939521, at *40.[11]

Dr. Khandwala was asked at his deposition whether he has conducted a Prolift study in which he measured the length of the vagina following surgery to look for mesh contraction. Doc. 79-13 at 91. He explained that he had performed a clinical trial with Prolift patients that "compared the vaginal length before and after [surgery], and there was no change." *Id.*; *see also id.* at 90 ("In my paper that I published, we looked at what is called a total vaginal length, and we assessed it before the procedure and after the procedure and concluded there was no difference in the length."). Plaintiff contends that the clinical trial did "not assess whether mesh shrinks but only whether the vagina has been shortened[,]" and that "it is impossible to determine whether vaginal width was impacted by mesh contraction[.]" Doc. 79 at 15 (citing Doc. 79-15, Elmér, C., et al., *Trocar-Guided Transvaginal Mesh Repair of Pelvic Organ Prolapse*, Obstet. Gynecol., Vol. 13, No. 1 at 117-26 (Jan. 2009)); *see also* Doc. 88 at 12 (asserting that "observations of mesh's effects on the vagina are not a proxy for the effects of the vagina on mesh"). Plaintiff will be free cross-examine Dr. Khandwala about this purported "methodological flaw" (Doc. 79 at 15), but her criticism of the clinical trial provides no basis for excluding Dr. Khandwala's opinions under Rule 702. *See In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prod. Litig.*, --- F.Supp.3d ----, 2020 WL 8968851, at *18 (D.N.J. Apr. 27, 2020) (noting that "the mere fact a party disagrees with an expert's methodology is not a basis for exclusion under *Daubert*") (citation omitted).[12]

When asked about the basis for his opinion that polypropylene mesh does not contract, Dr. Khandwala provided this explanation (Doc. 79-13 at 116-17):

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[11] Plaintiff's reliance on *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014), is misplaced. *See* Doc. 79 at 16. The expert in that case simply disagreed with contrary studies without explanation, and even suggested – with no factual support – that the studies involved fabricated data. *Sanchez*, 2014 WL 4851989, at *13.

[12] Plaintiff also can cross-examine Dr. Khandwala's about his belief that, because mesh shrinkage "doesn't happen, there is no way to measure it." *See* Docs. 79 at 15, 88 at 13 (citing Doc. 79-13 at 90, 92, 118).

> Well, it's my own personal experience that I have never seen a mesh contraction . . . . [An] example[] I can give you is when there is exposure which I have managed expectantly over a long period of time, so exposure I define as when the vaginal mesh is seen in the vagina, where the epithelium is separated and you can see the mesh, in all those cases, also, when we follow these patients up it does not change at all, even though the mesh is exposed to the vagina which has its own bacterial flora, it still does not change form, it remains as is.
>
> Going further, when I have removed in a few cases those exposed mesh pieces, they were strong as though I had just put in yesterday, so nothing has happened to this. Despite the fact that it has been exposed to the vaginal flora, nothing changes. So there is no contraction, nothing happens. So my clinical experience clearly shows that this does not happen, and it has been supported in literature, also.

See also id. at 118 ("I've always maintained and I've always seen that it is the vagina which conforms back to normal anatomy, and because it conforms back to normal anatomy it appears that it's shrinking, but it's actually just . . . going back to where it was placed."). Plaintiff notes that Dr. Khandwala has never microscopically evaluated explanted mesh, has done no mesh bench testing, and could point only to a single pathology report referencing explanted mesh. Doc. 79 at 16 (citing Doc. 79-13 at 95-96). These criticisms are fair game for cross-examination, but provide no basis for exclusion.

Dr. Khandwala, according to Plaintiff, has "acknowledged the difficulty a physician would have in assessing degradation or shrinkage with the naked eye." *Id.* But Dr. Khandwala was referring to the measurement of mesh pore size, not the size of mesh as a whole. Doc. 79-13 at 124 ("[T]he mesh pore size is about 2.4 millimeters. There's no way any physician goes and starts measuring these pores and sees if it's constant or not."). And contrary to Plaintiff's assertion, Dr. Khandwala's opinion that Prolift mesh does not contract is not based solely on the "gross examination" of mesh. *See id.* at 14-16; Doc. 88 at 13. He also relied on his clinical trial comparing vaginal length before and after surgery, and explained that his opinion is supported in the medical literature as well. *See* Doc. 79-13 at 117.[13]

[13] Plaintiff's citation to *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501 (S.D.

b. Porosity and Stiffness.

Plaintiff asserts that Dr. Khandwala is not qualified to testify on mesh porosity and stiffness, noting that the MDL Court reserved ruling on this issue. Doc. 79 at 16 & n.10. Plaintiff is wrong. The MDL Court specifically found that Dr. Khandwala is qualified to testify about mesh porosity and stiffness. *See In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327, 2016 WL 4599218, at *3 (S.D. W. Va. Sept. 2, 2016) ("The plaintiffs also seek to exclude Dr. Khandwala's testimony on mesh porosity and stiffness, though on what grounds is unclear. To the extent they are challenging Dr. Khandwala's qualifications, the Motion is DENIED for the reasons discussed above on biomaterials.").

Plaintiff further asserts – in conclusory fashion – that Dr. Khandwala's opinions on "the porosity, stiffness, and technical qualities of Gynemesh PS and Ultrapro mesh . . . are based upon limited and insufficient data." Doc. 79 at 17 (citing Doc. 79-11 at 11-13). The only specific opinion Plaintiff challenges, however, concerns Ultrapro mesh used in the Prolift+M. *Id.* (citing Doc. 79-11 at 12 ("[A]fter absorption of poliglecaprone-25 in the Ultrapro mesh, 'the lateral stiffness of the mesh is maintained[;] however, the longitudinal stiffness decreases allowing for the expansion of the neighboring viscera and hence potentially decreasing the potential risk of dyspareunia.'")).[14] But Plaintiff did not receive a Prolift+M implant (*see* Doc. 1 ¶ 8), and she does not explain why the challenged opinion is even relevant. Nor does she provide a basis under Rule 702 for excluding opinions on the porosity and stiffness of Gynemesh PS. *See In re Ethicon*, 2016 WL 4599218, at *3 (denying motion to exclude Dr. Khandwala's testimony where "the plaintiffs [had] not sufficiently supported their arguments or credibly called into question the reliability of this expert testimony").

W. Va. 2014), provides no basis for exclusion because the expert in that case admitted that, in his experience, it was impossible to determine whether the shape or size of mesh has changed significantly. *Tyree*, 54 F. Supp. 3d at 58-81.

[14] *See also* Doc. 79-11 at 11-12 (explaining that the Prolift is made with Gynemesh PS); *Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 902 (S.D. Iowa 2020) (noting that the Prolift+M "use[s] Ultrapro mesh rather than Gynemesh PS").

2. TVT-S Biomaterial Issues.

An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Plaintiff contends that Dr. Khandwala is not qualified to opine on the properties of polypropylene mesh used in the TVT-S – specifically, that the mesh does not shrink, degrade, or experience particle loss or pore contraction. Doc. 79 at 20-23. In his TVT-S reports, Dr. Khandwala thoroughly discusses his qualifications and his experience with polypropylene mesh. *See* Docs. 79-12 at 3-7, 82-4 at 5-8 (discussing his education, training, board-certifications, teaching experience, clinical experience, and clinical trials). Plaintiff discusses none of these qualifications and little of his clinical experience. *See* Doc. 79 at 21-22 (stating only that he has "removed polypropylene mesh on approximately 25 occasions and only seven or eight of these would relate directly to the [TVT-S]").

Plaintiff notes instead that Dr. Khandwala has conceded he is not a biomaterials expert, a pathologist, or a toxicologist. *Id.* at 20; *see* Doc. 50-8 at 6. But "[s]uch concessions are not dispositive, particularly when taken out of context." *In re Ethicon*, 2016 WL 4599218, at *3. As the MDL Court noted, Dr. Khandwala is a board-certified urogynecologist with a subspecialty in female pelvic medicine and reconstructive surgery. *Id.* He has used polypropylene mesh in more than 2,000 stress urinary incontinence surgeries, including approximately 300 TVT-S procedures. *See id.*; Doc. 79-12 at 3-7. Having carefully considered Dr. Khandwala's education, training, specialized knowledge, clinical experience, and research, the Court finds that he is qualified to offer opinions about the properties of TVT-S mesh from a clinical perspective. *See* Doc. 82 at 20-21; *In re Ethicon*, 2016 WL 4599218, at *3 (Dr. Khandwala's "extensive clinical experience qualifies [him] to opine on mesh's reaction to and effect on the human body from a clinical perspective"); *Trevino*, 2016 WL 2939521, at *44 ("[Dr. Douso] has extensive experience with BSC's products for treating SUI and POP, including use of the . . . mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the

defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice."); *Winebarger v. Bos. Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *26 (S.D. W. Va. Apr. 24, 2015) ("[A] urogynecologist's extensive experience with performing mesh implant and explant surgeries can qualify him or her to opine on how the product reacts inside the body.") (citation omitted); *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2017 WL 6554163, at *4 (D. Ariz. Dec. 22, 2017) ("The Court finds that the doctors' knowledge and experience in the field of interventional radiology and the use of IVC filters in patients form a sufficient foundation for their opinions.").

Plaintiff contends that Dr. Khandwala's opinions on the properties of TVT-S mesh are not the product of a reliable methodology because he has never microscopically evaluated explanted mesh, has done no mesh bench testing, and has not studied the issue of porosity. Docs. 79 at 21-23, 88 at 16-18. In his TVT-S reports, Dr. Khandwala describes the general basis for his opinions (Docs. 79-12 at 3, 82-4 at 5):

> My opinions in this report are based on my critical review of TVT SECUR that I have implanted in hundreds of women, my extensive clinical experience implanting of over a thousand polypropylene midurethral slings, my education, subspecialty training, analysis of my own clinical trials, reading of the peer reviewed medical literature, discussions with colleagues, my assessment of the anatomy and the function of devices in clinical surgery, and my Professional Education and experience in teaching the procedure in cadaver labs and on real surgical case proctorships.

Dr. Khandwala also provides, in detailed fashion, the specific reasons for his opinions that TVT-S mesh does not shrink, degrade, or experience particle loss or pore contraction. Docs. 79-12 at 68-74, 82-4 at 76-81. These reasons include his own experience with the mesh since the TVT-S came on the market and his review of relevant medical literature – dozens of peer-reviewed scientific articles, FDA sources, society statements, clinical trials, and meta-analyses. *See id.*; Doc. 81 at 21-22 (citations omitted). The Court finds that Dr. Khandwala's opinions on how the TVT-S reacts within the body satisfy the reliability

requirements of Rule 702. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D. W. Va. 2014) (doctor's degradation opinion was reliable where it was "draw[n] on clinical experience and a review of relevant literature").

3. TVT-S Design.

Plaintiff contends that Dr. Khandwala's deposition testimony shows he is not qualified to opine on the design of TVT devices, but Plaintiff fails to identify the specific opinions she seeks to have excluded. Doc. 79 at 23-24 (citing Doc. 79-17 at 31-34). Plaintiff essentially asks the Court to rule in a vacuum, without providing the specific content of Dr. Khandwala's design-related opinions or any necessary context. Whether particular design-related opinions offered by Dr. Khandwala are admissible must therefore be ruled on during the course of his testimony and in response to specific objections by Plaintiff. *See Bernal v. Daewoo Motor Am., Inc.*, No. CV09-1502-PHX-DGC, 2011 WL 13183093, at *1 (D. Ariz. Aug. 31, 2011) (denying *Daubert* motion where the defendants generally asked the Court to preclude an expert from offering opinions on biomechanics "but fail[ed] to identify specific opinions that are the subject of its motion"); *In re Ethicon*, 2016 WL 4599218, at *5 ("[I]n some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering testimony the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context."); *In re Bard*, 2017 WL 6554163, at *3 (denying *Daubert* motion where the defendants "identif[ied] no specific testimony that the Court should exclude" and noting that "[l]ine drawing in the context of such generalized arguments is not possible").

4. Adequacy of the TVT-S IFU, Warnings, and Patient Brochures.

Plaintiff contends that Dr. Khandwala is not qualified to opine on the adequacy of the IFU, warnings, and patient brochures for the TVT-S. Doc. 79 at 17-20. But Plaintiff again fails to identify the specific opinions she seeks to have excluded. Defendants also make clear in their response that Dr. Khandwala "will not be offered to opine on whether

the IFU or patient brochures were legally 'adequate[.]"' Doc. 82 at 18 (citing *In re Ethicon*, 2016 WL 4536885, at *2 ("While an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU.")); *see also In re Ethicon*, 2016 WL 4599218, at *4 (denying the plaintiffs' motion as moot where "Ethicon state[d] that Dr. Khandwala will not testify at trial regarding the adequacy of the relevant [IFU]").

What is more, the Court has granted summary judgment on Plaintiff's failure to warn claim (Doc. 83 at 3-8), which renders any opinions about the adequacy of IFUs and other product warnings irrelevant. *See* Doc. 86 at 2 (Defendants' reply brief explaining that warning-based opinions should be excluded as irrelevant and potentially confusing and misleading to the jury given the dismissal of the failure to warn claim); Doc. 90 at 9 (finding that Dr. Ostergard's opinions about the informed consent process are not relevant to the remaining claims, and that testimony about informed consent would serve only to waste time and confuse the issues). Plaintiff contends that in determining whether the Prolift and TVT-S are defective and unreasonably dangerous under Arizona law, "the warnings and information Defendants provided physicians, as well as information that may have been commonly known to physicians, is relevant." Doc. 92 at 2 (noting that Arizona recognizes both the consumer expectation test and the risk-benefit analysis test for product liability claims) (citations omitted).

But Plaintiff does not explain how the *adequacy* of Defendants' IFUs and product warnings are relevant to the remaining claims. *See id.*; *cf. In re Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 457544, at *6 (S.D. W. Va. Feb. 3, 2014) ("[T]he TVT's warning . . . simply informs users of the product's risks and enables them to decide whether they want to use the product at all. Complaints about the inadequacies of such a warning are quintessentially considered as a failure to warn claim. . . . Therefore, evidence of the TVT's allegedly inadequate warning is not relevant to the design defect claim."); *Williams v. Ethicon, Inc.*, No. 1:20-CV-04341-SDG, 2021 WL 857747, at *6 (N.D. Ga. Mar. 8,

2021) ("Williams cannot pursue her claims premised on a failure to warn because she cannot establish proximate cause. This disputed testimony [about the adequacy of the warnings in the TVT's IFU] relates solely to a failure to warn. Therefore, Dr. Rosenzweig's opinions are not relevant to the surviving claims in this case."). Admitting evidence of inadequate warnings also poses a substantial risk of confusing the jury and misleading it into believing that there is a failure to warn claim in the case. The probative value of this evidence is scant because Plaintiff no longer has a failure to warn claim, she cannot show that inadequate warnings caused her alleged injuries (*see* Doc. 83 at 3-8), and the warnings do not relate to using the Prolift and TVT-S in a safe manner (*see In re Ethicon*, 2014 WL 457544, at *6). The Court will exclude evidence regarding the adequacy of IFUs and product warnings. *See* Fed. Rs. Evid. 402-403; *see also In re Ethicon*, 2014 WL 457544, at *6 ("Because the plaintiffs failed to proffer evidence that inadequate warnings caused Ms. Lewis's injuries, those warnings are not relevant to the punitive damages claim.").

C. Dr. MacLean.

Dr. MacLean is a materials scientist and engineer. He has expertise in the physical and chemical behavior of polymeric materials in end-use applications. He has issued a report on polypropylene and Defendants' Prolene mesh. Doc. 79-18. The report contains rebuttal opinions to several of Plaintiff's experts, including Dr. Howard Jordi. *See id.* at 78-83.

Plaintiff moves to exclude: (1) Figure 26 of Dr. MacLean's report and his opinion that "Dr. Jordi's conclusions concerning the melt[ing] point of the Bellew explant are incorrect" (Doc. 79 at 25-26);[15] and (2) his opinion that "Prolene mesh does not undergo in vivo surface degradation" (Doc. 79 at 26-28). The Court will deny the motion on both issues.

[15] The mesh Dr. Jordi analyzed had been explanted from the plaintiff in the Bellew bellwether case. *See Bellew*, 2014 WL 12685965, at *1.

1. Dr. Jordi's Nanothermal Analysis and Figure 26.

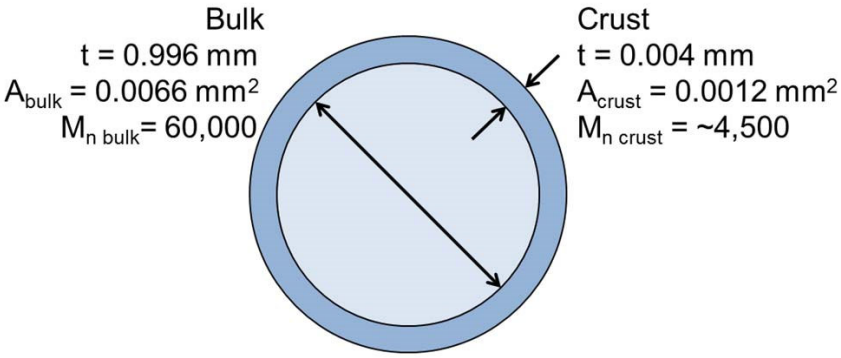
Dr. Jordi conducted nanothermal analysis on pristine and explanted Prolene mesh fibers to determine surface melting temperatures. *See* Doc. 79-18 at 79. He concluded that the more than 50 ℃ difference in the melting points of pristine mesh and the explanted mesh (176 ℃ and 124 ℃, respectively) was caused by surface oxidation, i.e., degradation. *See id.* at 80. His analysis showed that the 124 ℃ melting temperature of the explanted mesh's surface corresponded with a molecular weight value of 4,500. Docs. 79 at 25, 82 at 25.

Dr. MacLean disagrees with Dr. Jordi's conclusion that surface oxidation caused the temperature difference in the explanted mesh melting point. Doc. 79-18 at 80. Relying on data generated by Plaintiff's own experts – molecular weights derived by Dr. Jordi and crust thickness measurements reported by Dr. Iakovlev – Dr. MacLean opines that a bulk analysis of the surface material would have been able to detect changes in molecular weight due to surface degradation, and that bulk molecular measurements in Ethicon's seven-year dog study revealed no significant change in the molecular weight of explanted mesh. *Id.* Dr. MacLean provides this explanation (Doc. 79-18 at 80):

> According to Dr. Jordi, the over 50 °C decrease in observed melting temperature can be considered proof of sample oxidation. This is incorrect for two reasons. First, surface oxidation of a fiber would result in a decrease in molecular weight. An isotactic polypropylene sample with a melting temperature of 124 °C would correspond with a M_n of roughly 4,500.131. A decrease in molecular weight of this magnitude of the surface material would be apparent in bulk molecular weight measurements of the explanted samples. If one assumes that the cracked region has a depth of 4μm and is uniformly distributed over the surface of 5-0 sutures as seen in the Seven Year Dog Study (suture diameter of 0.1 mm), then the bulk PROLENE M_n should drop from 60,000 in the pristine sample to approximately 51,000 (see Figure 26). However, from the bulk molecular measurements made in the Seven Year Dog Study, it is known that the molecular weight of explanted sutures is 61,000 ± 6,000. Since the molecular weight according to Dr. Jordi is below the statistically predicted range of values, it is unlikely that oxidation is the cause of the melting temperature drop.

See also Doc. 79-19 at 71 ("We've used a rule of mixtures. We've used [Dr.] Jordi's data to characterize the degraded – the alleged degraded molecular weight. And based on our work, based on our analysis, the bulk material analysis would actually catch any shifts that are happening out in the fiber.").

Figure 26, set forth below, is a cross sectional schematic and calculated theoretical total molecular weight (M_n) of excised Prolene mesh from the dog study using Dr. Jordi's surface melting temperature to calculate the molecular weight of the crust layer (Doc. 79-18 at 81):



$$M_{n\,total} = \frac{(A_{crust} \times M_{n\,crust}) + (A_{bulk} \times M_{n\,bulk})}{A_{total}}$$

$$M_{n\,total} = \sim 51{,}000$$

Dr. MacLean's analysis is flawed, Plaintiff claims, because he "does not use the crack depth measurements from the dog study but instead 'assumes' a crack depth of 4 microns from other studies[.]" Doc. 79 at 25. Plaintiff asserts that Dr. MacLean's opinion would be erroneous if the crack depths in the dog study only measured 2 microns, and that he has "cherry-picked" data that supports his opinion in an attempt to mislead or confuse the jury. *Id.* at 26; *see also* Doc. 88 at 19 ("Dr. MacLean assumes the depths of the cracks in the Dog Study are 4 microns [because] he knows that a crack depth somewhere below 4 microns invalidates his calculations.").

Defendants respond that Dr. MacLean's 4 micron crack depth measurement is not an unsupported assumption. The same measurement had been used by Dr. Iakovlev. Doc. 82 at 24 (citing Doc. 82-9 at 10 (Iakovlev, et al., *Degradation of polypropylene in*

vivo: A microscopic analysis of meshes explanted from patients, Soc. Biomat., at 9 (July 30, 2015))); *see also* Doc. 79-19 at 71-72 (Dr. MacLean's testimony that he used the 4 micron measurement because it was "the running number that [plaintiffs'] experts keep using, including Dr. Iakovlev").

Nor does this alleged flaw in Dr. MacLean's analysis warrant exclusion. "The most appropriate place to challenge the assumptions made by an expert is at trial on cross-examination and with countervailing expert testimony." *Trinity Med. Servs., L.L.C. v. Merge Healthcare Sols., Inc.*, No. 17-CV-592-JWD-EWD, 2020 WL 1309892, at *7 (M.D. La. Mar. 19, 2020); *see Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 767 (7th Cir. 2013) ("The judge should have let the jury determine how the uncertainty about the [data] affected the weight of Graham's testimony. Ryobi was free to use cross-examination to attack the assumption and to ask Graham how altering the assumption would affect his analysis."); *Hunting Energy Servs., Inc. v. Kavadas*, No. 3:15-CV-228 JD, 2018 WL 4539818, at *23 (N.D. Ind. Sept. 20, 2018) ("[T]he defendants are free to dispute Mr. Johnson's premises, but that is not a ground to exclude his opinions."); *Charbonneau v. Mortg. Lenders of Am. L.L.C.*, No. 2:18-cv-02062-HLT (ADM), 2021 WL 84169, at *4 (D. Kan. Jan. 11, 2021) ("Dr. Krueger's assumptions are not disqualifying. . . . [C]oncerns about the underlying assumptions of the expert's opinion are better challenged through cross-examination than in determining the admissibility of expert testimony[.]") (citation and brackets omitted); *Mickelsen v. Aramark Sports & Ent. Servs.*, No. 2:18-cv-00158-DN, 2021 WL 1709522, at *5 (D. Utah Apr. 28, 2021) ("If Aramark is concerned the jury may be misled, it may clarify during its cross-examination of Mr. Finocchiaro that his opinion is based on assumptions he has made following evaluation of the available data."). Plaintiff will be free to cross-examine Dr. MacLean and present expert testimony of her own about his use of the 4 micron measurement. The same is true with respect to his purported "math-magic," his "erroneous" statement about the dog study, and internal Ethicon documents describing

smaller crack depths. *See* Docs. 79 at 25-26, 88 at 20. Plaintiff's motion will be denied in this regard.[16]

2. Prolene Surface Degradation.

Defendants designated Dr. Thomas Barbolt as their Rule 30(b)(6) corporate witness on Prolene's ability to degrade in vivo. *See* Doc. 79 at 27. When asked at his deposition whether Prolene surface degradation can occur, Dr. Barbolt answered "Yes":

> Q. [Y]ou – as the spokesperson for Ethicon, it's Ethicon's position that [Prolene] degradation, surface degradation, can occur, correct?
>
> [A.] Yes.

Doc. 79-21 at 31, Tr. 409:2-8; *see also* Tr. 385:14-20 (agreeing "that the surface of polymer fibers, including the polypropylene fibers in TVT, can crack"); Tr. 407:19-408:25 (acknowledging that an Ethicon employee had investigated degradation of Prolene sutures and concluded that surface degradation does occur). Plaintiff contends that Defendants are bound by this testimony and that Dr. MacLean should be precluded from offering a contrary opinion. Doc. 79 at 27 (citing *Rainey v. Am. Forest & Paper Ass'n. Inc.*, 26 F. Supp. 2d 82, 94 (D.D.C. 1998)).[17]

Defendants contend that the following testimony from Dr. Barbolt shows that he "referred to subjective observations of surface cracking, not objective observations of degradation":

> Q. Are you telling the ladies and gentlemen of the jury that when the outer surface of the polypropylene fibers crack and peel away from the surface, that that is not degradation?

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[16] The Court notes that Plaintiff has not challenged Dr. MacLean's second reason for disagreeing with Dr. Jordi's conclusion – that he did not consider alternative explanations for the decrease in melting temperature. *See* Doc. 79-18 at 80-81 ("The decrease in melting temperature could also be caused by tissue or small molecule plasticizers that are preferentially on or adhered to the outside diameter surface of the fiber, but these factors were never explored by Dr. Jordi.").

[17] Plaintiff identifies no specific opinions from Dr. MacLean's report on this point, although he did testify that he does not agree with Dr. Barbolt's testimony that the Prolene undergoes surface degradation. *See* Doc. 88 at 20 (citing Doc. 79-19 at 48).

> [A.] I am telling listeners that the key endpoint of adverse effects of degradation are molecular weight and tensile strength, both quantitative measures, not subjective assessments of surface changes, but quantitative measures that hold great weight and suggest that there's no degradation to the Prolene fiber in terms that are significant.

Doc. 82 at 26 (quoting Doc. 82-10 at 22). Defendants, however, do not address whether they are bound by Dr. Barbolt's testimony that Prolene surface degradation can occur. *See id.*

Although some courts have held that the deposition testimony of a Rule 30(b)(6) witness binds a corporation and cannot later be contradicted, that is not the view in the Ninth Circuit or a majority of courts. In *Snapp v. United Transportation Union*, 889 F.3d 1088 (9th Cir. 2018), the Ninth Circuit recognized that a corporation "'*generally* cannot present a theory of the facts that differs from that articulated by the designated Rule 30(b)(6) representative.'" *Id.* at 1103 (quoting 7 James Wm. Moore et al., *Moore's Federal Practice* § 30.25[3] (3d ed. 2016)) (emphasis in *Snapp*). But the Court of Appeals noted that this general proposition "should not be overstated" and provided this explanation:

> "[T]he testimony of a Rule 30(b)(6) deponent does not absolutely bind the corporation in the sense of a judicial admission, but rather is evidence that, like any other deposition testimony, can be contradicted and used for impeachment purposes. The Rule 30(b)(6) testimony also is not binding against the organization in the sense that the testimony can be corrected, explained and supplemented, and the entity is not 'irrevocably' bound to what the fairly prepared and candid designated deponent happens to remember during the testimony."

Id. at 1104 (quoting 7 *Moore's Federal Practice* § 30.25[3] (3d ed. 2016)). *Snapp* also made clear that "a Rule 30(b)(6) deponent's own interpretation of the facts or legal conclusions do not bind the entity." *Id*.

Other circuits agree. *See*, *e.g.*, *Mays v. LaRose*, 951 F.3d 775, 790 (6th Cir. 2020) ("most courts don't treat concessions by Rule 30(b)(6) designees as binding"); *Vehicle Mkt. Research, Inc. v. Mitchell Int'l, Inc.*, 839 F.3d 1251, 1260 (10th Cir. 2016) (the majority of courts to reach the issue treat the testimony of a Rule 30(b)(6) representative as merely an

evidentiary admission, and do not give the testimony conclusive effect); *Keepers, Inc. v. City of Milford*, 807 F.3d 24, 34-35 (2d Cir. 2015) ("[The plaintiff] rightly notes that an organization's deposition testimony is 'binding' in the sense that whatever its deponent says can be used against the organization. But Rule 30(b)(6) testimony is not 'binding' in the sense that it precludes the deponent from correcting, explaining, or supplementing its statements." (footnote omitted)); *A.I. Credit Corp. v. Legion Ins. Co.*, 265 F.3d 630, 637 (7th Cir. 2001) ("[T]estimony given at a Rule 30(b)(6) deposition is evidence which, like any other deposition testimony, can be contradicted and used for impeachment purposes.").

Dr. Barbolt testified that Prolene surface degradation can occur. Plaintiffs may use this testimony at trial as evidence from a designated corporate representative, including to impeach other testimony from Dr. Barbolt or Dr. MacLean. But Defendants are not precluded by Rule 30(b)(6) from correcting, explaining, or supplementing the testimony. *Snapp*, 889 F.3d at 1104. Plaintiff's motion on this issue will be denied.

D. Dr. Stanford.

Dr. Stanford is a board-certified obstetrician and gynecologist with extensive experience in female pelvic medicine and reconstructive surgery. He has authored a general expert report on TVT products. Doc. 79-22. Plaintiff moves to exclude his opinions on three issues: (1) the adequacy of Defendants' warnings and what other doctors know about the risks of pelvic mesh devices (Doc. 79 at 28-31); (2) his personal experience related to the safety and efficacy of the TVT (*id.* at 31); and (3) mesh degradation (*id.* at 31-32). The Court will deny the motion on all three issues.

1. Adequacy of Warnings and Doctors' Knowledge of Risks.

Plaintiff contends that Dr. Stanford does not possess the regulatory expertise needed to offer opinions about what an IFU should include or the adequacy of its warnings. *Id.* at 30 (citing *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015) ("Dr. Raybon has no demonstrated experience in the requirements for product labeling, and as such, he may not testify as to what the Avaulta label should or should not have included under the law. However, as an experienced urogynecologist, he

may testify about the risks he perceives that the Avaulta poses to patients[.]")). As explained above, evidence concerning the adequacy of IFUs will be excluded as irrelevant and otherwise inadmissible under Rule 403. Moreover, Defendants concede that Dr. Stanford is not a regulatory expert and will not opine on the adequacy of product warnings even if such opinions were relevant to the remaining claims. *See* Docs. 82 at 27, 86 at 2; *see also In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 495187, at *4 (D. Ariz. Jan. 22, 2018) ("Dr. Eisenberg will not be allowed to use physician expectations to establish Bard's legal obligations."). Consistent with the MDL Court's rulings, however, Dr. Stanford, as an experienced gynecologist, may testify about the specific risks of implanting pelvic mesh devices. *See In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig*., 2016 WL 4493666, at *4 (S.D. W. Va. Aug. 25, 2016) (citing *Wise*, 2015 WL 521202, at *14)). Plaintiff's motion will be denied in this regard.

Plaintiff asserts that Dr. Stanford's "guessing that all physicians know all risks all the time" is troubling because he disregards contrary scientific literature. Doc. 79 at 30. Plaintiff identifies no specific opinion in which Dr. Stanford has "guessed" about what other physicians may know. Defendants argue that Dr. Stanford, as an experienced clinician, is qualified to opine about risks that are obvious to pelvic mesh surgeons and may testify as to knowledge common within the medical community. Doc. 82 at 28.

The Court agrees with Defendants. To the extent such opinions are relevant to the remaining claims, Plaintiff's motion will be denied. *See In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-CV-02865, 2017 WL 2987173, at *2 (S.D. W. Va. July 12, 2017) ("[T]o the extent Ethicon seeks to exclude Dr. Rosenzweig's testimony about factual issues or the knowledge of the medical community in general, I disagree. Expert witnesses may properly offer opinions on these topics."); *see also Rivera v. Philip Morris, Inc.*, 395 F.3d 1142, 1154 (9th Cir. 2005) (considering expert testimony that the addictive properties of nicotine were commonly known in the tobacco industry). Any

testimony about common knowledge within the medical community, of course, must be supported by adequate foundation.[18]

2. Dr. Stanford's Experience with TVT Products.

Plaintiff seeks to preclude Dr. Stanford from testifying about his clinical experience with TVT products because his opinions are based on no reliable methodology and have not been peer-reviewed or published. Doc. 79 at 31. As explained above, the peer-review and publication requirements "simply are not applicable to . . . testimony[] whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *Hankey*, 203 F.3d at 1169. Plaintiff asserts that it is impossible to verify Dr. Stanford's statement that he "cannot recall a bladder or urethral injury in several years," noting that he does not keep a patient registry. Doc. 79 at 31 (quoting Doc. 79-22 at 13). But not all expert testimony will "rely on anything like a scientific method" and be "objectively verifiable[.]" Fed. R. Evid. 702, advisory committee's note to 2000 amendment. Plaintiff will be free to cross-examine Dr. Stanford about his clinical recollections and the lack of a patient registry. Plaintiff's motion will be denied in this regard. *See Hankey*, 203 F.3d at 1169; *Primiano*, 598 F.3d at 565-66; *see also United States v. Plunk*, 153 F.3d 1011, 1017 (9th Cir. 1998) (holding that a law enforcement officer's training, experience, and personal knowledge sufficiently supported his expert testimony regarding jargon used in the narcotics trade).[19]

3. Mesh Degradation.

Plaintiff's experts have opined that polypropylene mesh degrades, becomes brittle, and cracks in vivo. *See* Doc. 79-22 at 19. Dr. Stanford states, from a clinical perspective,

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[18] Defendants do not argue that Dr. Stanford should be permitted to opine on the state of mind of any particular physician, and any such opinion would not be admissible. *See In re Ethicon*, 2017 WL 2987173, at *2 ("Ethicon essentially argues that I should preclude Dr. Rosenzweig from testifying as to implanting surgeons' state of mind. I agree[.]").

[19] Plaintiff notes that the MDL Court has ruled that an expert cannot relate precise statistics based on their own assurances that those statistics are reliable, but Plaintiff identifies no "precise statistics" that Dr. Stanford cites in his report about his personal experiences. *See* Doc. 79 at 31 (citing *In re Ethicon*, MDL No. 2327, 2016 WL 4542054, at *4 (S.D. W. Va. 2016)); Doc. 82 at 30.

that he is aware of no publication showing that TVT mesh degrades, cracks, or loses support. *Id.* at 19-20. He acknowledges that mesh implants can fail to control continence and prolapse, but notes that there is no evidence that this occurs due to brittleness or degradation. *Id.* He cites a study showing that the microscopic view of a cracked surface is the effect of the formalin-protein fixation process and not in vivo degradation, and notes that other studies have suggested that some surface degradation may occur over time but the mesh's support matrix is clinically preserved. *Id.* (citations omitted). He also offers this analogy (*id.* at 30):

> At most, over time, if some surface degradation does occur the support matrix is clinically preserved and the support scaffold is preserved. I offer a clinical analogy. One can see that the surface of the steel beam of a bridge degrades over time however the strength of the scaffold is largely preserved and generally considered safe. It is the goal of using implant materials that they incorporate into the tissues through the normal healing response and create additional support that did not exist prior to surgery.

Plaintiff criticizes Dr. Stanford for making this "strange" analogy and for not having reviewed Ethicon's own studies concluding that polypropylene degrades in vivo. Doc. 79 at 31. Plaintiff will be free to cross-examine Dr. Stanford about Ethicon's studies and his analogy if he offers it at trial, but Plaintiff's criticisms are no basis for exclusion. *See* Doc. 82 at 30 (citing *In re Ethicon*, 2016 WL 4493666, at *4 ("Dr. Toglia . . . specifically cites several studies and explains that the studies are consistent with his own personal observations. The plaintiffs' objection addresses the weight, rather than the admissibility, of the opinion.")); *see also Carlson v. Bos. Sci. Corp.*, No. 2:13-cv-05475, 2015 WL 1931311, at *12 (S.D. W. Va. Apr. 28, 2015) ("Dr. Galloway considered and analyzed multiple scientific articles . . . and drew on his clinical experience to reach his opinion that polypropylene degrades. This is a reliable, scientific methodology. Any inconsistencies or discrepancies in his testimony go to its weight, not its admissibility, and BSC is free to capitalize on these matters during cross-examination.")). The Court will deny Plaintiff's motion with respect to Dr. Stanford's opinion that, from his own clinical experience and research, TVT mesh does not significantly degrade in vivo.

IV. Defendants' Motion.

A. Dr. Rosenzweig.

Dr. Rosenzweig is a urogynocologist and an assistant professor of obstetrics and gynecology at Rush University Medical Center in Chicago, Illinois. He has prepared an expert report on the TVT-S. Doc. 80-1. Defendants move to exclude: (1) his opinion that traditional non-synthetic mesh procedures are a safer alternative for treating stress urinary incontinence (Doc. 80 at 2-5); (2) his opinions comparing laser-cut TVT-S mesh to mechanical-cut mesh (*id.* at 5-7); and (3) opinions on complications that Plaintiff has not suffered and is not likely to experience in the future (*id.* at 7).

1. Non-Synthetic Mesh Procedures.

Dr. Rosenzweig opines that the benefits of the TVT-S are outweighed by the device's complications. Doc. 80-1 at 76-79. He states that this is "especially true given that traditional surgeries like the Burch and pubovaginal slings are not associated with the frequency or extent of [the TVT-S's] life changing complications." *Id.* at 76.

Defendants focus on one issue – the existence of a safer alternative design – and contend that any alleged comparative benefits of the traditional approaches to treating stress urinary incontinence are not relevant to Plaintiff's design defect claims. Doc. 80 at 3-4 (citing *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2327, 2017 WL 1264620, at *3 (S.D. W. Va. Mar. 29, 2017) (agreeing with Ethicon's argument that an expert's "opinions regarding *alternative procedures* are irrelevant to the question of whether a safer alternative *design* of a product exists") (emphasis in original)).

Plaintiff counters that the challenged opinion may be relevant to rebut assertions from Defendants' experts that TVT products are the "gold standard" for the treatment of stress urinary incontinence. Doc. 81 at 4-5. Plaintiff further argues that it would be inappropriate to issue the blanket exclusion sought by Defendants without examining the applicable state law. *Id.* at 6.

Defendants do not address Plaintiff's arguments in their reply brief (*see* Doc. 86 at 3-4), and neither side cites any Arizona authority on this issue. *See* Doc. 80 at 3-4 (citing

Mullins v. Johnson & Johnson, 236 F. Supp. 3d 940, 943 (S.D. W. Va. 2017) (applying Virginia law and finding that "[e]vidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT"); Doc. 81 at 5 ("Under Illinois law, as in many states, one consideration in determining whether a product is unreasonably dangerous – applying the risk-utility test – is 'the usefulness and desirability of the product – its utility to the user and to the public as a whole.'") (citation omitted); *see also Triant v. Am. Med. Sys. Inc.*, No. CV-12-00450-PHX-DGC, 2020 WL 4333645, at *3 (D. Ariz. July 28, 2020) ("Whether [Dr. Rosenzweig's] alternative design testimony is relevant will depend on the claims asserted by Plaintiffs under Arizona law – a topic to which the parties give scant attention. The Court is inclined to agree with [the MDL Court in *Mullins*] that an alternative surgical procedure cannot be used to show a defective design of a product. But Plaintiffs have also asserted strict liability claims, and it is possible that alternative procedures may be admitted to show that a product is unreasonably dangerous. The parties do not address this distinction or its treatment under Arizona law.") (citations omitted); *Shostrom v. Ethicon, Inc.*, No. 20-CV-1933-WJM-STV, 2021 WL 1080993, at *1 (D. Colo. Feb. 26, 2021) ("Ethicon identifies the alternatives suggested by Dr. Rosenzweig and argues that the alternatives are 'procedures' and not 'designs' or 'medical devices,' rendering them irrelevant and inadmissible. Ethicon cites numerous cases, none of which appear to apply Colorado law, for support.").[20]

[20] *Cf. Gomez v. Am. Med. Sys. Inc.*, No. CV-20-00393-PHX-ROS, 2021 WL 1163087, at *7 (D. Ariz. Mar. 26, 2021) ("The parties each cite cases from other jurisdictions in support of their positions. Again, AMS argues only available products, not procedures or unavailable products, are relevant to products liability. Gomez argues an effective substitute, including surgical procedures, is relevant. Presently, the Court is persuaded [that the] benefit of a product directly relates to its value compared to alternative options, including alternative procedures."); *Ellerbee v. Ethicon, Inc.*, No. 8:20-CV-1514-TPB-AEP, 2021 WL 2010640, at *2 (M.D. Fla. May 20, 2021) (citing Florida law and finding that "Dr. Rosenzweig's opinions that alternate medical procedures were safe and effective are relevant to demonstrating the product's inherent risks and assist the jury in appreciating the risk-utility analysis."); *Heinrich v. Ethicon, Inc.*, No. 2:20-cv-00166-APG-VCF, 2021 WL 2290996, at *2 (D. Nev. June 4, 2021) (evaluating the relevance of Dr. Rosenzweig's opinions about alternative procedures under Nevada law, which applied to the plaintiffs' claims); *Williams*, 2021 WL 857747, at *6 (same under Georgia law); *Bell v. Ethicon, Inc.*, No. 4:20-CV-3678, 2021 WL 1111071, at *7 (S.D. Tex. Mar. 23, 2021) ("Because Texas also applies a risk-utility analysis, the testimony on alternative surgical procedures is relevant and helpful to the jury as it informs whether the utility of the products

The relevance of opinions on alternative procedures for treating stress urinary incontinence must be determined at trial based on applicable Arizona law and contentions Defendants make may about the safety and efficacy of the TVT-S as a treatment option. *See id.*; *Heinrich*, 2021 WL 2290996, at *3 ("Heinrich notes that the defendants and their experts often tout TVT-S as the 'gold standard' for treating SUI while it was on the market. Evidence that other available procedures were just as efficacious without the attendant alleged complications is relevant to rebut that testimony."). Defendants' motion will be denied in this regard.

2. Laser-Cut Mesh.

Dr. Rosenzweig opines that laser-cut mesh is stiffer than mechanical-cut mesh and the increased stiffness can cause a higher incidence of erosion and sexual dysfunction. Doc. 80-1 at 14-15. Defendants note that Dr. Rosenzweig opined in his TVT and TVT-O reports that laser cutting was a viable solution to correct the fraying, roping, and curling issues associated with mechanical-cut mesh. Doc. 80 at 5-6 (citing Doc. 80-2 at 45-57). Defendants claim that Dr. Rosenzweig's opinions about laser-cut mesh and mechanical-cut mesh are "unreliably inconsistent." *Id.* at 6.

Plaintiff notes, correctly, that Dr. Rosenzweig has different criticisms of laser-cut mesh and mechanical-cut mesh. Doc. 81 at 6. He provided this explanation in the *Perry* case:

> Q. In your opinion, which is better, laser-cut mesh or mechanical-cut mesh?
>
> A. Well, both have problems. We know that mechanical-cut mesh frays, has particle loss, ropes and curls. Laser-cut mesh is stiffer . . . .
>
> Q. So, you believe that both mechanical-cut mesh and laser-cut mesh are defective?
>
> A. Mechanical-cut mesh ropes, curls, frays. Once you stretch it to a greater than 10 to 15% elongation, it can undergo permanent elongation. You can lose pore size. Laser-cut mesh is stiff and therefore you get the properties of stress shielding which increases erosion, incontinence and pain.

Id.; Doc. 81-1 at 3; *see also* Doc. 81-5 at 52.

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at issue were outweighed by the risks in light of alternative treatments.").

Defendants have not shown that Dr. Rosenzweig's opinions on laser-cut mesh and mechanical-cut mesh are fatally inconsistent. "Any inconsistencies in Dr. Rosenzweig's opinions about whether laser versus mechanically cut mesh are safer alternative designs to each other are matters for cross examination, not exclusion." *Heinrich*, 2021 WL 2290996, at *3; *see also Ellerbee*, 2021 WL 2010640, at *3 ("To the extent that Defendants believe Dr. Rosenzweig's opinions on the cut of the mesh differ from his opinions in other cases, such issue is ripe for cross-examination. His opinions are sufficiently supported and appear relevant to this case."); *In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2327, 2016 WL 8788207, at *7 (S.D. W. Va. Aug. 26, 2016) ("The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment[.]"); *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, No. 17-CV-5096 (WMW/BRT), 2020 WL 5512507, at *8 (D. Minn. Sept. 14, 2020) ("At best, St. Jude has identified inconsistent or contradictory positions between Dr. Burke's expert reports and Dr. Burke's deposition testimony. Such inconsistences are matters for cross-examination, not grounds for exclusion."); *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 2007-MD-1871, 2011 WL 13576, at *9 (E.D. Pa. Jan. 4, 2011) ("Any inconsistency in Dr. Brinton's opinions over time, and any flaws in his conclusions, go to weight, not admissibility.").

Defendants further contend that, from a clinical perspective, Dr. Rosenzweig's opinions on laser-cut mesh are unreliable because he does not recall ever implanting laser-cut mesh. Doc. 80 at 6. But Dr. Rosenzweig has performed more than 300 removal surgeries (Docs. 81 at 8, 81-4 at 2-3), and a significant percentage of those involved laser-cut mesh that, according to Dr. Rosenzweig, caused complications due to stiffness (Doc. 81-4 at 2-3). This clinical experience is sufficient to satisfy the threshold reliability requirements of Rule 702. *See Triant*, 2020 WL 4333645, at *2 ("AMS does not meaningfully address [Dr. Rosenzweig's] experience, but appears to argue that because Dr. Rosenzweig has never implanted any AMS device, he is unqualified to provide opinions on its devices. But [the MDL Court] made clear . . . that a physician's 'experience

removing polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him to testify on product design.'") (quoting *Heatherly v. Bos. Sci. Corp.*, No. 2:13-CV-00702, 2018 WL 3797507, at *4 (S.D. W. Va. Aug. 9, 2018) (emphasis in original; brackets omitted)); *Gomez*, No. 2021 WL 1163087, at *6 (same).

The Court will deny Defendants' motion with respect to Dr. Rosenzweig's opinions on laser-cut mesh. *See* Docs. 80 at 5-7, 80-1 at 14-15.

3. Other Complications.

Consistent with the MDL Court's rulings, Defendants seek to preclude Dr. Rosenzweig from discussing complications that Plaintiff has not suffered and that no competent physician has testified she likely will experience in the future. Doc. 80 at 7 (citing Doc. 80-1 at 71-76 (Dr. Rosenzweig's report discussing "the possibility that polypropylene can cause tumors or cancer"); *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2327, 2016 WL 4500767, at *5 (S.D. W. Va. Aug. 26, 2016) (excluding Dr. Blaivas's testimony regarding cancer and death complications because "[e]vidence of complications that a plaintiff did not experience is irrelevant and lacking in probative value")). Plaintiff does not contend that opinions regarding cancer and death complications are relevant and otherwise admissible. Plaintiff instead asserts that "a regular complication associated with the mesh, such as dyspareunia, would be relevant to a design defect inquiry in a state where the jury is asked to balance the risks and the utility of a particular device – even if that particular plaintiff did not suffer from the common problem." Doc. 81 at 9. But the MDL Court rejected the argument that it should reserve ruling on this issue because variances in state law could impact the relevance of other complications. *See id.*

The Court will follow the MDL Court's approach and preclude Dr. Rosenzweig from opining about complications Plaintiff has not suffered and is not likely to suffer in the future. *See In re Ethicon*, 2016 WL 4500767, at *5; *Bellew*, 2014 WL 12685965, at *10 ("Evidence of complications that the plaintiff did not experience is irrelevant and

lacking in probative value."); *see also* Doc. 90 at 5-8 (same with respect to Dr. Ostergard). Defendants' motion will be granted on this issue.[21]

B. Dr. Donald Ostergard.

Dr. Ostergard has been a board-certified obstetrician and gynecologist since 1970. From 1979 to 2011, he served as a clinical professor of obstetrics, gynecology, and women's health at the University of Louisville School of Medicine. He presently serves as a professor-in-residence at the UCLA School of Medicine and Harbor-UCLA Medical Center in Torrance, California.

Dr. Ostergard has prepared a general expert report on the Prolift and polypropylene mesh. Doc. 80-4 at 2.[22] Defendants move to exclude: (1) Dr. Ostergard's opinions about FDA regulatory requirements and product warnings (Doc. 80 at 9-12); and (2) his safer alternative opinions (*id.* at 12-17). The Court will deny the motion as moot.

1. FDA Regulatory Requirements and Product Warnings.

Defendants argue in their motion that Dr. Ostergard is not qualified to offer opinions about FDA regulatory requirements or the adequacy of product warnings. *Id.* at 9. In their reply, which was filed after dismissal of the failure to warn claim, Defendants argue that such opinions are not relevant to the remaining claims and should be excluded under Rule 403. Doc. 86 at 2. The Court agrees for reasons set forth above. The Court will exclude Dr. Ostergard's opinions about FDA regulatory requirements for IFUs and the adequacy of product warnings under Rules 402 and 403, and will deny Defendants' challenge under Rule 702 as moot. *See* Doc. 90 at 9 (same with respect to Dr. Ostergard's opinions on informed consent); *see also In re Ethicon*, 2014 WL 457544, at *6.[23]

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[21] The Court may reconsider this ruling if Plaintiff can show at trial that other complications are relevant to the remaining claims under Arizona law. *See Ellerbee*, 2021 WL 2010640, at *3 ("[E]vidence concerning risks and complications not experienced by Plaintiffs appear to be both relevant and admissible as part of the risk-utility analysis."). If Plaintiff chooses to raise this issue at trial, she shall do so outside the hearing of the jury.

[22] The Court addressed case-specific opinions of Dr. Ostergard in an earlier order. *See* Doc. 90.

[23] The Court generally does not consider arguments raised for the first time in a reply brief. *See United States v. Bunnell*, No. CR-14-00119-PHX-DGC, 2021 WL 212338,

2. Safer Alternatives.

Defendants seek to exclude as unreliable Dr. Ostergard's opinions that four types of mesh – Polyform, Popmesh, Pelvitex, and Timesh – are safer alternatives to Gynemesh PS, the type used in the Prolift. Doc. 80 at 12-17. Specifically, Dr. Ostergard states that the lighter-weight Popmesh and Polyform are "preferred" to Gynemesh PS and that the stiffness of Gynemesh PS is a "detrimental quality" in comparison to Polyform, Pelvitex, and Timesh. Doc. 80-4 at 4-5. Plaintiff avows that Dr. Ostergard "has never contended and will not testify that ANY of these four devices are a safer alternative device to the Gynemesh PS." Doc. 81 at 14-15 (citing Doc. 81-8 at 121). The Court will hold Plaintiff to her word, and Defendants may object if Dr. Ostergard crosses the line in this regard. The Court will deny Defendant's motion on this issue as moot. *See In re Ethicon*, 2016 WL 4599218, at *4.[24]

C. Dr. Guelcher.

Dr. Guelcher is a chemical and biomolecular engineer with more than 20 years of experience in his field. Doc. 80-13 at 1. He has written extensively on biomaterials, including more than 80 peer-reviewed and published articles. *Id.* at 2. Two of those articles address oxidation and degradation of polypropylene mesh. *Id.* He also has presented abstracts at scientific meetings regarding oxidation of polypropylene in biomedical devices. *Id.*

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at *2 (D. Ariz. Jan. 21, 2021). But dismissal of the failure to warn claim clearly renders opinions about FDA regulatory requirements for IFUs and product warnings irrelevant. Plaintiff also has had an opportunity to address this issue. *See* Doc. 92 (the parties' joint report identifying arguments that are moot in light of the summary judgment order).

[24] Plaintiff claims that Defendants ignore other statements in Dr. Ostergard's report that purportedly "support his conclusions that mesh designs with lower weight, greater porosity, lower density, and lower stiffness that are not degradable are able to reduce the risks from that of the Gynemesh and only in this combination make a safer alternative design." Doc. 81 at 16; *see* Docs. 80-4 at 14-15, 81-10 at 14-15. If Plaintiff intends to elicit opinions about safer alternatives from Dr. Ostergard at trial, Plaintiff first shall raise the issue with the Court outside the presence of the jury. *See In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2327, 2016 WL 4536456, at *3 (S.D. W. Va. Aug. 30, 2016) (granting Defendants' motion to exclude Dr. Ostergard's opinions about safer alternatives); Doc. 80 at 8 (citing Doc. 72-1 at 2 (MDL Court's finding that additional arguments concerning Dr. Ostergard's opinions on safer alternatives are best resolved "at trial without the need for further briefing or an evidentiary hearing")).

Dr. Guelcher has prepared a general report on polypropylene mesh. *Id.* at 2-31. Defendants move to exclude: (1) his degradation opinions to the extent they are based on testing performed for the Talley study he co-authored (Doc. 80 at 18-33);[25] and (2) his opinions regarding "alternative designs" (Doc. 80 at 33-35). The Court will deny Defendants' motion with respect to Dr. Guelcher.

1. Degradation Opinions.

Dr. Guelcher offers the following degradation-related opinions (Doc. 80-13 at 4):

- Polypropylene reacts with molecular oxygen by autoxidation outside the body at elevated temperatures, resulting in chain scission and deterioration in its mechanical properties;

- After implantation in the body, polypropylene reacts with reactive oxygen species secreted by inflammatory cells, resulting in oxidation, chain scission and mesh embrittlement;

- The dynamic environment where the polypropylene mesh is implanted coupled with the foreign body reaction leads to oxidation, chain scission, reduction in molecular weight, embrittlement, degradation, flaking, pitting, and cracking;

- The human body does not stop responding to an implanted mesh, or any frayed particles of mesh released during implantation, unless the product is removed in its entirety; and

- The mesh devices examined for this report are intended to last for the lifetime of the patient, but the presence of antioxidants does not permanently protect the [polypropylene] against degradation, and thus it is not possible to guarantee that it will perform its intended function after implantation.

Defendants contend that the oxidation testing Dr. Guelcher performed for the Talley study is "riddled with methodological flaws" and his "degradation opinions are unreliable to the extent they are based on [that] testing." Doc. 80 at 18. Defendants identify the purported flaws in the testing (*see id.* at 21-33), but do not describe the extent to which Dr.

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[25] *See* Doc. 80-8 (Talley, et al., *Oxidation and degradation of polypropylene transvaginal mesh*, J. Biomater. Sci., Polymer Ed. (2017)).

Guelcher's various degradation opinions are based on the testing.[26] Nor do Defendants explain why Dr. Guelcher's limited reliance on the Talley study renders his general opinions on mesh degradation unreliable. *See Wood v. Am. Med. Sys. Inc.*, No. 1:20-cv-00441-DDD-KLM, 2021 WL 1178547, at *4 (D. Colo. Mar. 26, 2021) ("American Medical argues that the Talley Study is unreliable . . . . The trouble with American Medical's argument is it fails to explain why any of the[] features of the Talley Study render the [Dr. Guelcher's] opinions unreliable.").

Plaintiff states, contrary to Defendants' assertion, that the Talley article is not central to Dr. Guelcher's degradation opinions. Doc. 81 at 18-19. Plaintiff explains that Dr. Guelcher's opinions about the mesh used in Defendants' devices have not changed, that the opinions are well-supported and scientifically reliable, and that the Talley study is simply another peer-reviewed study that supports Dr. Guelcher's opinions. *Id.* at 18-20.

"[S]ubmission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected." *Daubert*, 509 U.S. at 593. The Talley study was peer reviewed and approved for publication in a credible scientific journal. *See* Doc. 80-8. Defendants likely have identified flaws in the Talley study, but those flaws "are fodder for cross-examination[.]" *Wood*, 2021 WL 1178547, at *4 ("[Defendants] fail[] to explain why scraping or an artificial lab environment render the Talley Study unreliable. Nor do they explain why a failure to rule out alternative explanations for the oxidative degradation found by the Talley Study means its reasoning or methodology is fundamentally flawed. The court cannot, therefore, rule out its use."); *Gomez*, 2021 WL 1163087, at *13 ("Drs. Guelcher and Mays seek to use [the Talley] study to support their opinion that polypropylene mesh, generally, degrades in vivo. The details of the study go to weight, not admissibility of the opinions."); *see also In re Ethicon Inc. Pelvic Repair Sys. Prods.*

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[26] The sole reference to the testing that Defendants identify is Dr. Guelcher's statement that polypropylene mesh oxidizes and degrades in vitro and explanted polypropylene mesh had oxidized in the human body. *See id.* at 20-21 (citing Doc. 80-8 at 12-13); *see also* Doc. 80-10 at 33 (123:25-124:8).

Liab. Litig., No. 2327, 2016 WL 4547055, at *3 (S.D. W. Va. Aug. 31, 2016) ("Ethicon challenges the conclusions of [studies relied on by Dr. Guelcher] by suggesting that degradation should be measured by methods different than those used in the studies. Such concerns are better suited for cross-examination."); *In re Toy Asbestos*, No. 19-CV-00325-HSG, 2021 WL 1201231, at *4 (N.D. Cal. Mar. 30, 2021) ("Defendant's criticism of Dr. Brody's animal studies . . . goes to weight and not admissibility. The Ninth Circuit has cautioned that the Court's gatekeeping function 'is supposed to screen the jury from unreliable nonsense opinions, but not exclude opinions merely because they are impeachable.'") (quoting *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013)). Defendants' motion will be denied in this regard.

2. Alternatives to Defendants' Polypropylene Mesh.

Dr. Guelcher offers this opinion on alternatives to Defendants' polypropylene mesh products (Doc. 80-13 at 4, 26-29):

> Using autologous fascia lata, allograft, sutures (including polypropylene sutures), or polyvinylidene fluoride (PVDF) mesh does not present with the same chronic complications associated with the material properties of Ethicon's [polypropylene] mesh. All of these alternative materials, including using a less dense version of its [polypropylene] mesh, were available when Ethicon's [stress urinary incontinence] and [pelvic organ prolapse] meshes were first commercialized.

Defendants move to exclude this opinion because (1) it addresses alternative treatment options and not alternative designs, and (2) it otherwise is unreliable. Doc. 80 at 33-35.

a. Relevance.

Defendants contend that the issue of alternative designs with respect to pelvic mesh products must be examined in the context of products, not procedures. *Id.* at 33 (citing *Mullins*, 236 F. Supp. 3d at 942). As explained above, the relevance of opinions on alternative procedures for treating stress urinary incontinence and pelvic organ prolapse must be determined at trial based on applicable Arizona law, which neither side addresses. *See also* Doc. 81 at 23 ("the law regarding alternative designs varies from state-to-state" and Defendants' arguments "should not be decided on a general motion"). Defendants'

reliance on *Mullins* is misplaced because that case applied Virginia law. *See Mullins*, 236 F. Supp. 3d at 942-43 ("I am convinced that an alternative, feasible design must be examined in the context of products – not surgeries or procedures. The Fourth Circuit, in applying Virginia law, has addressed this issue squarely.") (citing *Talley v. Danek Med., Inc.*, 179 F.3d 154 (4th Cir. 1999)); *see also Talley*, 179 F.3d at 157 ("Talley filed this action in the district court against Danek, relying on diversity jurisdiction and alleging negligence, breach of warranty, and fraud under Virginia law."). Defendants' motion will be denied on this point.

b. Reliability.

Defendants note that Dr. Guelcher has not tested the alternative procedures and materials he proposes, but cite no authority holding that testing is a requirement for the admissibility of alternative design opinions. Defendants further contend that none of the literature Dr. Guelcher cites establishes that his proposed alternatives are safer and as effective as Defendants' mesh products, that Dr. Guelcher has failed to acknowledge medical literature showing that Defendants' mesh devices are as safe as his proposed alternatives, and that it is widely reported in the medical literature that exposure and wound complications are not complications unique to mesh. Doc. 80 at 34-35. These criticisms are proper subjects for cross-examination, rebuttal expert testimony, and jury argument, but they do not warrant exclusion. *See Salinero v. Johnson & Johnson*, No. 1:18-CV-23643-UU, 2019 WL 7753453, at *17 (S.D. Fla. Sept. 5, 2019) ("The Court concludes that Dr. Guelcher's opinions about PVDF meshes and their relative likelihood to degrade are the kind of 'shaky but admissible' evidence that is not barred by *Daubert* and is the proper subject of cross-examination."); *see also* Doc. 82 at 6 (explaining that if there is literature that Plaintiff claims an expert has failed to review in preparing his expert report, Plaintiff is free to ask the expert about that literature on cross-examination). Defendants' motion will be denied in this regard.[27]

[27] Defendants' citation to *Nease v. Ford Motor Co.*, 848 F.3d 219, 234 (4th Cir. 2017), is not helpful because the expert had "simply proclaimed without any support that the alternative designs he identified were safer[.]"

D. Rulings on Defendants' Motion.

Defendants' motion will be denied with respect to Dr. Rosenzweig's opinions on safer alternative mesh and laser-cut mesh (Doc. 80 at 2-7), and will be granted on his opinions about complications Plaintiff has not suffered and is not likely to experience in the future (*id.* at 7). The motion will be denied as moot with respect to Dr. Ostergard (*id.* at 7-17), and denied as to Dr. Guelcher (*id.* at 17-35).

IT IS ORDERED:

1. Plaintiff's motion to exclude expert opinions (Doc. 79) is **denied**.

2. Defendants' motion to exclude expert opinions (Doc. 80) is **granted in part and denied in part** as set forth above.

Dated this 1st day of July, 2021.

David G. Campbell
Senior United States District Judge