REVERSE and RENDER; and Opinion Filed November 5, 2015.

In The
Court of Appeals
Fifth District of Texas at Dallas

No. 05-14-00864-CV

JOHNSON & JOHNSON AND ETHICON, INC., Appellants
V.
LINDA BATISTE, Appellee

On Appeal from the 95th Judicial District Court
Dallas County, Texas
Trial Court Cause No. DC-12-14350

MEMORANDUM OPINION

Before Justices Lang, Fillmore, and Whitehill
Opinion by Justice Fillmore

This product liability case involves the TVT-Obturator (TVT-O), a medical device manufactured and sold by appellants, Johnson & Johnson and Ethicon, Inc., to treat stress urinary incontinence (SUI).[1] SUI is the involuntary loss of urine when the bladder is put under stress such as from sneezing, coughing, laughing, or exercising. The TVT-O contains a tape made of polypropylene mesh. Using a helical trocar, or curved needle, a surgeon pulls the tape through incisions in the anterior wall of a woman's vagina, through the obturator foramen,[2] and out through incisions in the woman's inner thighs. The tape remaining in the body forms a hammock underneath the urethra to help prevent the leakage of urine.

[1] The jury was instructed to treat Johnson & Johnson and Ethicon, Inc. as if they are a single entity. We shall do the same in this opinion.

[2] The obturator foramen is an opening situated between the ischium and pubis of the hip bone. http://www.merriam-webster.com/medlineplus (accessed through https://nlm.nih.gov) (last visited on Nov. 3, 2015). The obturator foramen is closed by the obturator membrane, except for a small opening for the passage of the obturator vessels and nerve. *Id.*

Dr. John McNabb implanted a TVT-O into Linda Batiste to treat her SUI. Batiste subsequently sued appellants, alleging she was injured by the polypropylene mesh. Ten members of the jury found a design defect in the TVT-O caused Batiste's injuries and awarded her $1.2 million in damages. The trial court rendered judgment based on the jury's verdict.

Appellants first request that we reverse the trial court's judgment and render judgment that Batiste take nothing because she failed to present legally sufficient evidence the TVT-O is unreasonably dangerous, there is a safer alternative design, or that a specific defect in the TVT-O was a producing cause of her injuries and because there are no facts of record to rebut the statutory presumptions that appellants are not liable for any alleged defect in the TVT-O. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 82.008(a), (c) (West 2011).[3] In the alternative, appellants request we reverse the trial court's judgment and remand the case for a new trial because the trial court erred by: (1) excluding all evidence referencing the Food and Drug Administration (FDA), including FDA approval or clearance of any medical device, and of position statements issued by independent associations and societies of medical professionals concerning the safety and efficacy of synthetic mesh slings, and (2) admitting evidence of other lawsuits complaining about

[3] Section 82.008 provides, in relevant part:

> (a) In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product's formula, labeling, or design complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm.
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> (c) In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant allegedly caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval, and that after full consideration of the product's risks and benefits the product was approved or licensed for sale by the government or agency. The claimant may rebut this presumption by establishing that:
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> (1) the standards or procedures used in the particular pre-market approval or licensing process were inadequate to protect the public from unreasonable risks of injury or damage; or
>
> (2) the manufacturer, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the government or agency information that was material and relevant to the performance of the product and was causally related to the claimant's injury.
>
> TEX. CIV. PRAC. & REM. CODE ANN. § 82.008(a), (c).

the TVT-O and other medical devices manufactured by appellants and of "issue reports" involving other patients. Because Batiste failed to offer legally sufficient evidence that any alleged defect in the TVT-O was the producing cause of her injuries, we reverse the trial court's judgment and render judgment that Batiste take nothing. Based on this conclusion, we need not address appellants' remaining complaints. *See* TEX. R. APP. P. 47.1.

Background[4]

Batiste has a complex medical history. She has had nine abdominal surgeries, including two "C-sections," two open abdominal procedures, and five laparoscopic procedures, which have left significant scarring. In 2003, she had a stroke that left her disabled. She had a second stroke in 2007. She has weakness on her left side as well as some loss of memory as a result of the two strokes. Due to spinal disease, she has undergone four surgeries in her lower back and one surgery in her neck. Following a heart attack, a stent was placed through her femoral artery to address a ninety-five percent blockage in her right coronary artery.

Batiste has been diagnosed with chronic obstructive pulmonary disease, a result of smoking. She suffers from poorly controlled diabetes, which is the probable cause of her diabetic neuropathy, or damage to her nerves that results in pain in her extremities, and of her peripheral vascular disease. Batiste is periodically afflicted with gout and shingles, and she suffers from arthritis. She has also had a clitoral cyst and a groin cyst. For a number of years, Batiste has complained to medical providers about her abdominal, back, hip, and leg pain and has been prescribed pain medication in an attempt to alleviate her pain.

Batiste began suffering from incontinence in 1993. Initially, her incontinence was just "dribbles," but the condition worsened over time and became "life-altering." In 2005, Batiste

[4] Because our opinion addresses only whether Batiste presented legally sufficient evidence that a defect in the TVT-O caused her injuries, we recite only those facts necessary to address this issue. Further, the applicable standard of review requires us to review the evidence in the light most favorable to the jury's verdict. Therefore, we have not recounted much of the evidence presented at trial that does not support the jury's verdict.

discussed with a physician the possibility of "tacking her bladder" to address her incontinence, but decided not to have the procedure. Ultimately, Batiste needed to use up to seven pads during the day and "pull-ups" at night due to urine leakage. On occasion, she would become incontinent during sexual intercourse, impeding her desire to engage in sexual activities. In 2010, she sought medical help for her incontinence from McNabb. McNabb treated the SUI by implanting a TVT-O into Batiste in January 2011. McNabb also performed an anterior colporrhaphy, a surgical procedure to repair a cystocele, or prolapse of Batiste's bladder.[5] To repair the cystocele, McNabb made an incision in Batiste's vagina and used sutures to raise her bladder and hold it in place. In August 2011, Batiste had her last back surgery and, in October 2011, suffered the heart attack that led to the implantation of the stent in her right coronary artery. Although Batiste's medical records do not indicate she complained to her health care providers about groin or pelvic pain between February 2011 and October 2011, she complained about groin pain following the implantation of the stent in her coronary artery. At trial, Batiste testified she has suffered from groin, pelvic, vaginal, and urethral pain since shortly after the TVT-O was implanted.

In June 2012, Batiste saw Dr. Kathryn Brown, a gynecologist, who took over the majority of McNabb's patients. Batiste complained of bladder, pelvic, back, knee, and right flank pain. Batiste indicated that when she urinated or had a bowel movement, and when she had sexual intercourse, the pain was "off the charts." When Brown examined Batiste, she found a "very small" mesh erosion on the left sidewall of Batiste's vagina. Brown described the size of the erosion as "barely the tip probably of your little finger." Without using an anesthetic, Brown

[5] A prolapse occurs when an organ falls or slips from its usual position. http://www.merriam-webster.com/medlineplus. In this case, Batiste's bladder was bulging into her vagina.

grasped the "end of the tip" of the mesh that was visible with a hemostat and cut it off. After the piece of mesh was removed, Brown could not feel any additional mesh in Batiste's vagina.

In May 2013, Batiste saw Dr. Gary Lemack, a urologist with specialty training in female pelvic medicine and pelvic reconstructive surgery, and complained of incontinence, dyspareunia or painful intercourse, and vaginal, groin, and pelvic pain. During his examination of Batiste, Lemack determined she had tenderness "overlying the areas of the sling." Lemack removed a portion of the polypropylene mesh from under Batiste's urethra in September 2013, but was unable to remove the ends of the tape that descended into her thighs. Lemack has removed "a lot of meshes," and the removal of Batiste's mesh "wasn't one of the more difficult ones." Lemack did not see any evidence of infection, inflammatory cells, "giant cells," or nerve entrapment when he removed the mesh. He saw "normal" fibrous tissue and smooth muscle and did not find any evidence of scarring other than what he would expect from the implantation of the TVT-O.

Batiste asserted claims of negligence against McNabb and appellants. Batiste also asserted strict liability claims of design, manufacturing, and marketing defects against appellants. Because McNabb had been diagnosed with early-onset Alzheimer's disease, he was not deposed. In response to requests for admission, appellants denied they were blaming McNabb for "complications" or contending either that McNabb was at fault in choosing to implant the TVT-O into Batiste or caused or contributed to cause the injuries claimed by Batiste. The trial court granted McNabb's no evidence motion for summary judgment and dismissed Batiste's claims against him. The jury was instructed McNabb was disabled and unable to testify.

After a trial lasting four weeks, Batiste nonsuited her manufacturing defect and negligence claims against appellants, leaving her strict liability claims of design and marketing defects as her operative causes of action. As relevant to this appeal, Batiste argued to the jury that the TVT-O was defectively designed because: (1) the mesh was heavyweight and contained

small pores; (2) the mesh was mechanically cut, rather than being cut by a laser, which caused it to curl, fray, and rope; and (3) the mesh oxidized, or degraded, and lost particles after it was implanted. The jury found against Batiste on her marketing defect claim. Ten members of the jury found there was a design defect in the TVT-O that was a producing cause of Batiste's injuries and awarded Batiste $1.2 million in damages.

Analysis

In their first issue, appellants argue they are entitled to a take-nothing judgment because Batiste failed to present legally sufficient evidence the TVT-O is unreasonably dangerous, there is a safer alternative design to the TVT-O, or that a specific defect in the TVT-O was a producing cause of her injuries and because there are no facts of record to rebut the statutory presumptions that appellants are not liable for any alleged defect in the TVT-O. We first consider appellants' complaint that there is legally insufficient evidence a defect in the TVT-O was a producing cause of Batiste's injuries. Appellants specifically argue Batiste only offered evidence that the TVT-O itself, rather than a defect in the device, was a producing cause of her injuries and failed to exclude other possible causes of her injuries.

In her opening brief, Batiste argued she was not required to prove a specific defect caused her injuries and that, under the common law, her "burden was to show that the TVT device was defective, and that it injured her."[6] Batiste contended she carried that burden because the evidence established the implantation of a TVT-O could potentially cause a number of complications, including dyspareunia, pelvic, groin, and leg pain, and erosion of the mesh, and that she suffered from those complications. Following oral argument, Batiste filed a post-

[6] The jury charge asked whether there was a "design defect in the TVT-O at the time it left the possession" of appellants that "was a producing cause of injury" to Batiste. Batiste did not object to this charge, and we question whether she preserved this argument for appeal. Regardless, Batiste's assertion she was required to establish only that the TVT-O, and not some defect in it, caused her injuries fails because, as explained *infra*, Texas law requires a plaintiff in a strict liability design defect case to show both the defective condition of a product and a causal connection between that defect and the plaintiff's injuries.

submission brief on the issue of specific causation. Batiste asserted the evidence shows: (1) defects in the TVT-O are known to cause particular conditions and injuries, (2) she suffers from those same conditions and injuries, and (3) qualified experts opined, based on their review of her medical history, that defects in the TVT-O caused her injuries.

Standard of Review

When an appellant challenges the legal sufficiency of the evidence on an issue on which it did not have the burden of proof at trial, it must demonstrate on appeal that there is no evidence to support the adverse finding. *Exxon Corp. v. Emerald Oil & Gas Co., L.C.*, 348 S.W.3d 194, 215 (Tex. 2011). The ultimate test for legal sufficiency is whether the evidence "would enable reasonable and fair-minded people to reach the verdict under review." *Exxon Corp.*, 348 S.W.3d at 215 (quoting *City of Keller v. Wilson*, 168 S.W.3d 802, 827 (Tex. 2005)). A legal sufficiency challenge fails if there is more than a scintilla of evidence to support the judgment. *BMC Software Belg., N.V. v. Marchand*, 83 S.W.3d 789, 795 (Tex. 2002); *see also Kia Motors Corp. v. Ruiz*, 432 S.W.3d 865, 875 (Tex. 2014). Evidence that is so weak as to do no more than create a mere surmise or suspicion that the fact exists is less than a scintilla. *Kia Motors Corp.*, 432 S.W.3d at 875. In conducting our review, we view the evidence in the light most favorable to the verdict and indulge every reasonable inference that supports it. *City of Keller*, 168 S.W.3d at 822. We "credit favorable evidence if reasonable jurors could, and disregard contrary evidence unless reasonable jurors could not." *Exxon Corp.*, 348 S.W.3d at 215 (quoting *City of Keller*, 168 S.W.3d at 827). We are mindful in our review that jurors are the sole judges of the credibility of the witnesses and the weight to be given their testimony. *City of Keller*, 168 S.W.3d at 819.

Applicable Law

To recover on a product liability claim based on an alleged design defect, "a plaintiff must prove that (1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *Genie Indus., Inc. v. Matak*, 462 S.W.3d 1, 6 (Tex. 2015) (quoting *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009)). "Producing cause" is a substantial factor in bringing about the injury and without which the injury would not have occurred. *BIC Pen Corp. v. Carter*, 346 S.W.3d 533, 541 & n.3 (Tex. 2011) (citing *Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 46 (Tex. 2007)). A producing cause must be a cause-in-fact. *Id.* at 541; *Union Pump Co. v. Allbritton*, 898 S.W.2d 773, 775 (Tex. 1995). A finding of cause-in-fact may be based on either direct or circumstantial evidence, but cannot be supported by mere conjecture, guess, or speculation. *Marathon Corp. v. Pitzner*, 106 S.W.3d 724, 727 (Tex. 2003).

Generally, proving the existence of a design defect requires competent expert testimony and objective proof that the defect the plaintiff has identified caused the injury. *Nissan Motor Co. Ltd. v. Armstrong*, 145 S.W.3d 131, 137 (Tex. 2004); *In re Zimmer*, 451 S.W.3d 893, 906 (Tex. App.—Dallas 2014, orig. proceeding). Proof other than expert testimony will constitute some evidence of causation only when "a layperson's general experience and common understanding would enable the layperson to determine from the evidence, with reasonable probability, the causal relationship between the event and the condition." *Mack Trucks Inc. v. Tamez*, 206 S.W.3d 572, 583 (Tex. 2006). The parties do not dispute that expert testimony was necessary in this case to establish causation. *See Lewis v. Johnson & Johnson*, 601 Fed. App'x 205, 211 (4th Cir. 2015) (per curiam).

An expert is required to explain the basis of his statements to link his conclusions to the facts. *Earle v. Ratliff,* 998 S.W.2d 882, 890 (Tex. 1999); *Damian v. Bell Helicopter Textron, Inc.*, 352 S.W.3d 124, 148 (Tex. App.—Fort Worth 2011, pet. denied). There cannot be too great an "analytical gap" between the expert's opinion and the facts upon which he relies, *Ledesma*, 242 S.W.3d at 39, and "a claim will not stand or fall on the mere *ipse dixit* of a credentialed witness." *Burrow v. Arce*, 997 S.W.2d 229, 235 (Tex. 1999). An expert who is attempting to determine causation must also carefully consider alternative causes. *E.I. DuPont Nemours & Co., Inc. v. Robinson*, 923 S.W.2d 549, 558–59 (Tex. 1995); *see also Kia Motors Corp.*, 432 S.W.3d at 878 (expert should exclude "'other plausible causes' presented by the evidence" (quoting *Transcontinental Ins. Co. v. Crump*, 330 S.W.3d 211, 218 (Tex. 2010)). Although a medical causation expert need not disprove or discredit every possible cause other than the one espoused by him, "if evidence presents 'other plausible causes of the injury or condition that *could* be negated, the [proponent of the testimony] *must* offer evidence excluding those causes with reasonable certainty.'" *Crump*, 330 S.W.3d at 218. The expert's failure to rule out other causes of the damage renders the opinion little more than speculation. *Robinson*, 923 S.W.2d at 559; *see also TXI Transp. Co. v, Hughes*, 306 S.W.3d 230, 237 (Tex. 2010) ("An expert's failure to rule out alternative causes of an incident may render his opinion unreliable."). Even if it is not objected to, expert testimony that is conclusory, speculative, or based on assumed facts contrary to the evidence is legally insufficient to support a verdict. *City of San Antonio v. Pollock*, 284 S.W.3d 809. 816 (Tex. 2009); *Ford Motor Co. v. Wiles*, 353 S.W.3d 198, 202 (Tex. App.—Dallas 2011, pet. denied).

Alleged Defects

At trial, Batiste identified three alleged defects in the TVT-O: (1) the use of heavyweight, small-pore mesh; (2) the use of mesh that was cut by a machine, rather than a laser; and (3) the use of mesh that could degrade and lose particles.

Mechanically Cut Mesh

When appellants began manufacturing the TVT-O, the polypropylene mesh used in the device was cut mechanically with, essentially, a large blade. Appellants received reports and complaints from physicians about the rough edges of the mesh. Testing by appellants confirmed that, when put under sufficient tension, the edges of the mechanically cut mesh could curl, fray, and rope.[7] Appellants thereafter began manufacturing a TVT-O in which the mesh was cut with a laser. The laser sealed the edges of the mesh, preventing it from curling, fraying, or roping.

Appellants continued to sell a TVT-O product containing the mechanically cut mesh. Batiste presented evidence from which the jury could infer that appellants continued to sell a TVT-O product containing mechanically cut mesh so that, in marketing the TVT-O, they could rely on clinical data that had accumulated over a number of years relating to the TVT-O and a predecessor product, the TVT, that also used the mechanically cut mesh. Appellants offered evidence they continued to sell a TVT-O product with mechanically cut mesh because some physicians preferred the product. There was no evidence of any study that found fewer complications arose in patients from the laser cut mesh than from the mechanically cut mesh.

Heavyweight, Small-Pore Mesh

The polypropylene mesh in the TVT-O contains a number of pores. Tissue grows through the pores to incorporate the mesh into the body. There will necessarily be a certain amount of scar tissue associated with this process. There could be a greater foreign body

[7] In the test, the mesh was elongated by fifty percent of its original length.

reaction to a heavyweight, small-pore mesh than to a lightweight, large-pore mesh, leading to more scar tissue, shrinkage and contraction of the mesh, and inflammation. Appellants manufacture meshes that are lighter weight and have larger pores than the polypropylene mesh used in the TVT-O. These meshes, however, are used for other purposes, such as hernia repairs, and there was no evidence that any mid-urethral synthetic sling sold in the United States has a lighter weight, larger-pore mesh than the TVT-O. Prior to Batiste's surgery, appellants began producing a mid-urethral sling that used a smaller amount of the polypropylene mesh than used in the TVT-O.

Degradation and Particle Loss

Dr. Howard Jordi, a polymer chemist, testified polypropylene sutures, which are made of the same material used to make the TVT-O mesh, have been the "suture of choice" for many surgeons since the 1960s and are probably in millions of people. Jordi and Dr. Shelby Thames, who is also a polymer chemist, testified polypropylene can degrade through oxidation. Jordi and Thames discussed a study performed by appellants in which the polypropylene sutures manufactured by appellants, as well as sutures made by other manufacturers and of different materials, were implanted into dogs. Although Thames disagreed with the findings, the study concluded the polypropylene sutures manufactured by appellants showed signs of degradation after five years. Appellants removed additional sutures from the dogs after seven years and confirmed there were signs of degradation. Jordi also testified about other studies that showed polypropylene mesh or fibers could degrade in the human body.

The mesh that was removed from Batiste was placed into formalin, a formaldehyde solution, and preserved. Jordi testified the formalin hardens the tissue on the mesh to assist a pathologist in making slides of the tissue. A reaction between the formalin and the tissue forms a new cross-linked polymer that can coat the mesh. Jordi described the new cross-linked polymer

as "hard." Jordi testified he observed surface cracking on the sample of the mesh removed from Batiste and concluded the polypropylene had degraded. There was evidence that degradation of the polypropylene could enhance the opportunity for infection and increase inflammation. Jordi admitted, however, there could be degradation from the polypropylene that would have no clinical significance in a patient, and there was no evidence as to how much the polypropylene would have to degrade before it caused injury to a patient.

As to particle loss, appellants were aware, prior to manufacturing the TVT-O, that when the mesh was put under sufficient tension, small particles of polypropylene could break off the mesh. Some physicians noted the small particles could migrate in a woman's vagina and cause pain during intercourse. Jordi sent the sample of the mesh removed from Batiste to a lab where it was rolled onto a substrate. The particles that fell from the sample were collected. According to Jordi, an analysis showed the vast majority of the particles were polypropylene.

Causation Evidence

The jury heard evidence the TVT-O was a safe and effective treatment for SUI and was considered by many physicians to be the gold standard of surgical care for the treatment of SUI. However, although the frequency and severity of the complications in patients was disputed at trial, the evidence also established the implantation of a TVT-O to treat SUI can cause, among other complications, groin, leg, and pelvic pain and that there could be an erosion of the mesh into the vagina. Appellants assert Batiste's causation evidence established only that the TVT-O, rather than a defect in the device, was a potential cause of her injuries and failed to exclude other potential causes of the injuries. Batiste contends the evidence established that she suffered from complications caused by the TVT-O and there is more than a scintilla of evidence the use of mechanically cut mesh caused the erosion she suffered in 2012 as well as her urethral pain,

particle loss caused her pelvic pain, and heavyweight, small-pore mesh caused her pelvic and groin pain.[8]

Erosion and Urethral Pain

Batiste first points to evidence that she suffered a painful erosion of the mesh into her vagina in 2012. Batiste argues the mesh erosion could occur only after the implantation of the TVT-O device, there was evidence erosions are caused by the curling, fraying, and roping of mechanically cut mesh, the TVT-O implanted in her contained mechanically cut mesh, and the mesh removed from her body reflected curling, fraying, and roping.

Brown did not testify as to whether she observed any curling, fraying, or roping of the mesh when she removed the portion of the mesh that had eroded into Batiste's vagina in June 2012 and described what she removed as the "end of the tip" of the mesh. After she removed the visible mesh, Brown could not feel any other mesh in Batiste's vagina. When asked her opinion about the possible cause of the erosion, Brown identified Batiste's status as a smoker, noting smokers do not heal as well as non-smokers. She also testified Batiste had vaginal atrophy, or a thinning of the vaginal tissue due to a loss of estrogen that is common in post-menopausal women.

Lemack testified mesh exposes or extrudes because it is infected, the closing of the vagina "didn't hold up over time," or the mesh was too close to, or not in the right layer of, the vaginal mucosa. Although he had implanted a number of mid-urethral synthetic slings, Lemack had never seen fraying "with this mesh" and had not "medically" seen fraying with any mesh.

[8] Although there was evidence that Batiste also suffers from dyspareunia, she has not specifically asserted on appeal that the evidence was legally sufficient to support a finding this injury was caused by a defect in the TVT-O. We note that, although there was evidence the erosion of the mesh potentially contributed to Batiste's dyspareunia, there was also evidence Batiste's smoking and vaginal atrophy, as well as the placement of the sling, were potential causes. Batiste's expert failed to rule out these other potential causes of her dyspareunia. *See Robinson*, 923 S.W.2d at 559; *see also Kia Motors Corp.*, 432 S.W.3d at 878.

Dr. Thomas Margolis, an obstetrician/gynecologist with a sub-specialty in pelvic reconstructive surgery, testified he implants organic slings in women to treat SUI. These slings are made from animal or cadaver tissue or tissue from the patient's abdomen or leg. He has never implanted a synthetic, polypropylene sling to treat SUI. He has, however, removed a number of polypropylene slings from patients who were having complications from the sling. Margolis has seen fraying and roping of the mesh that he has removed from other women.

According to Margolis, the defects in the TVT-O include:

> defects that are specific to the material itself, the sling itself, this here, are roping, curling, fraying, particle loss, degradation, and then in and of itself the passage of the helical trocar through the obturator foramen, the risks of injury to the obturator neurovascular bundle and the muscles and the urogenital diaphragm and the obturator diaphragm, all of the structures, the me– the body parts, if you will, that this thing goes through that can damage them.

"Complications from the mesh" that Margolis sees on a regular basis are "erosions, infections, obstructions, contraction, damage to adjacent organs, inflammation, scarring, loss of function, pain, loss of leg function, dyspareunia."

Based on photographs taken by Jordi, Margolis testified he saw curling, fraying, and roping of the sample of the mesh removed from Batiste's body. Jordi, however, did not receive this sample until sometime after Lemack removed the mesh in September 2013. Photographs of the mesh taken at least fifteen months after the erosion was removed are no evidence that any curling, fraying, and roping observed by Margolis were present in June 2012 when Brown removed the portion of the mesh that had eroded into Batiste's vagina. Further, as previously discussed, after the mesh was removed from Batiste, it was placed into formalin and a new cross-linked polymer was formed on the mesh. Accordingly, when Jordi photographed the mesh, it was not in the same condition as when it was in Batiste's body.

Although there was evidence curling, fraying, and roping of the polypropylene mesh in the TVT-O could cause an erosion, there was no evidence the mesh inside Batiste had curled,

frayed, or roped at the time the erosion was removed in 2012. *See Wal-Mart Stores, Inc. v. Merrell*, 313 S.W.3d 837, 840 (Tex. 2010) (per curiam) (evidence that allegedly defective halogen lamps could cause fires generally does not establish the lamp in question caused a particular fire). Further, there were a number of other potential causes of the erosion suffered by Batiste, including poor healing due to her status as a smoker, vaginal atrophy, the closing of the vagina over the mesh failing to "hold up," infection, or the placement of the mesh too close to the vaginal mucosa. Batiste failed to offer expert testimony excluding any of these possible causes for the erosion. *See id*. at 839–40. Accordingly, the evidence is legally insufficient to support a finding the erosion of the mesh suffered by Batiste in June 2012 was due to curling, roping, or fraying of mechanically cut mesh of the TVT-O.

Relying on Margolis's testimony, Batiste next asserts there is more than a scintilla of evidence that curling, fraying, or roping of the mechanically cut mesh caused her urethral pain. Lemack testified Batiste exhibited tenderness overlying the areas of the sling prior to the removal of the mesh. However, when Lemack removed a portion of the mesh from Batiste, he found no evidence of any erosion or extrusion of the mesh into the bladder or the urethra, no inflammation, and no scarring beyond what was expected from the implantation of a foreign device. Further, as set out above, Lemack has never seen any fraying of the TVT-O mesh, implying he did not see any fraying of the mesh he removed from Batiste. Lemack testified he was unable to determine whether Batiste's urethral pain was more likely caused by the TVT-O mesh or some other condition.

Margolis examined Batiste during trial and found that her urethra was scarred and tender. Although Margolis did not testify specifically about the cause of Batiste's urethral pain, he opined that, to a reasonable degree of medical certainty:

> [t]he pain and symptoms that I elicited and identified on examination and the signs and the findings were all from the sling and its complications, including scarring, erosion, and contracture with particle loss, they were all from the sling.

Margolis's opinion that the "sling" caused Batiste's "pain and symptoms" does not link the urethral pain to any curling, fraying, or roping of the mesh in the TVT-O and will not support the verdict. *See Ledesma*, 242 S.W.3d at 39–40; *Burrow*, 997 S.W.2d at 235 (*ipse dixit* of credentialed expert will not support judgment). Further, Margolis testified the passage of the helical trocar through the body could damage the area that it went through; however, he failed to exclude this possible damage as a cause of Batiste's urethral pain. *See Kia Motors Corp.*, 432 S.W.3d at 878; *Merrell*, 313 S.W.3d at 840 ("An expert's failure to explain or adequately disprove alternative theories of causation makes his or her own theory speculative and conclusory."). We conclude there is no evidence any curling, fraying, or roping of the mesh was a cause-in-fact of Batiste's urethral pain.

Pain from Degradation and Particle Loss

Relying on Jordi's and Margolis's testimony, Batiste next asserts there is more than a scintilla of evidence that her pelvic pain was caused by degradation of, and particle loss from, the mesh. As to degradation of the mesh, Jordi, based on his observations, and Margolis, based on photographs taken by Jordi, testified the mesh removed from Batiste showed signs of surface degradation. However, as discussed above, there is no evidence as to the amount of degradation that must occur before it has any clinical significance in a patient, and there is no evidence the mesh that was placed inside of Batiste had degraded to the extent that it caused her injury.

As to particle loss from the mesh, there was evidence the mesh could lose particles. Further, some physicians who observed particle loss from the mesh concluded the particles could migrate, causing pelvic pain and dyspareunia. Jordi testified that, although he saw some "covering" of the sample of the mesh removed from Batiste with the cross-linked polymer that

formed when the mesh was placed into formalin, there were some areas of the sample that were not covered by the new polymer. Jordi observed degradation on the surface of the polypropylene fibers and there were "large cracks [which] would appear to be regions where there may have been some flaking off." Jordi testified that if polypropylene flakes off the fibers, "it goes into the tissue of the person that it's implanted in" and can cause inflammation. Margolis, based on photographs taken by Jordi, testified he saw particle loss from the mesh removed from Batiste.

A lab that Jordi sent the sample to rolled the sample on a piece of paper and analyzed the flakes of material that fell from the sample. According to Jordi, the vast majority of the particles were polypropylene. Jordi testified his colleague cleaned the sample by holding it between forceps and, using tweezers, removing as much of the tissue remaining on the mesh as possible. According to Jordi, his colleague also may have held the sample down using a tool similar to a spatula and, to some degree, there was a "bending" of the fibers in the mesh during the cleaning process. Accordingly, the sample from which the particles were obtained was not in the same condition as when it was removed from Batiste's body due to the presence of the cross-linked polymer that had formed on the sample after it had been removed from Batiste's body and the fact the sample had been subjected to extensive handling.

Lemack testified he has never seen any particle loss from mesh slings, including mesh manufactured and sold by appellants, leading to the conclusion that he did not see particle loss when he removed a portion of the mesh from Batiste. Further, when Lemack removed the mesh from Batiste, he saw no evidence of inflammation.

Lemack was unable to determine the cause of Batiste's pelvic pain but, based on Batiste's report of the timing of the manifestation of the pain, believed it was a "result of the sling." He also "suspected" that Batiste's groin pain led to pelvic floor muscle tightness which led to some degree of pelvic pain. Margolis globally testified Batiste's pelvic pain was caused by scarring,

erosion, contracture, inflammation, particle loss, roping, fraying, degradation, damage to adjacent structures, and damage to the nerve and soft tissue of Batiste's pelvis and that all of her pain was from "the sling" and its complications.

It is clearly established in the record that pelvic pain is a known possible complication from the implantation of a TVT-O. As noted, there was no evidence that surface degradation of the polypropylene fibers alone causes pelvic pain or of the amount of degradation that would have to occur before there would be any injury to a patient. Although there was evidence that particle loss from the mesh could cause pelvic pain, there was no evidence of any particle loss from the mesh while it was inside Batiste's body. Without evidence of particle loss inside of Batiste, Margolis's opinion that particle loss, among a host of other possible factors, was a cause of Batiste's pelvic pain is not linked to any case-specific facts and is conclusory. *See Pollock*, 284 S.W.3d at 816 (opinions of qualified expert that have no basis are conclusory and cannot support judgment); *City of Keller*, 168 S.W.3d at 813 ("In claims or defenses supported only by meager circumstantial evidence, the evidence does not rise above a scintilla . . . if jurors would have to guess whether a vital fact exists."). We conclude there is no evidence any degradation of, or particle loss from, the mesh in the TVT-O was a producing cause of Batiste's pelvic pain.

Pain due to Heavyweight, Small-Pore Mesh

Batiste finally asserts the evidence established the use of a heavyweight, small-pore mesh caused her pelvic pain and the arms of the sling consisting of the same mesh caused her groin pain. Lemack believed the mesh used in the TVT-O was a large-pore mesh and did not express an opinion as to whether the weight of the mesh caused Batiste's groin or pelvic pain. When Lemack removed the mesh, he did not find any evidence of scarring "over and above" what he would have expected from the implantation of a foreign device. He saw "fibrous tissue," which

is "a normal reaction to the pelvic mesh" and smooth muscle. He saw no evidence of inflammation or nerve entrapment.

Based on the history given by Batiste,[9] Lemack believed her groin pain "was caused by the implantation of the TVT-O sling."[10] However, Lemack was not aware that Batiste had an anterior colporrhaphy at the same time the TVT-O was implanted. In Lemack's opinion, if Batiste continued to have pain after he removed the mesh, it was impossible to "absolutely know" which procedure was causing the continued pain. It was also difficult for Lemack to determine the source of Batiste's pelvic pain but, based on Batiste's report of the timing of the manifestation of the pain, believed it was a caused by the implantation of the sling. He "suspected" that Batiste's groin pain led to pelvic floor muscle tightness which led to some degree of pelvic pain.

Based on photographs taken by Jordi of the sample of mesh removed from Batiste's body, Margolis testified he could see "fibrotic bridging" on the sample.[11] Margolis testified fibrotic bridging means:

> the scar that is supposed to sort of seal this in place has not just sealed it in place, but encased it in a big cake of scarring, really contracts it down and does more than just scar it in place. It scars over it, covers it with scar, and that's problematic because we don't want to see fibrotic bridging in this stuff.

According to Margolis, fibrotic bridging "increases the amount of scar, which increases the potential for damage to adjacent organs, increases the potential for obstruction, increases the potential for pain, and for erosion, and for all of the complications that we've talked about." Margolis testified Batiste's pelvic pain was caused by "scarring, erosion, contracture,

[9] Lemack did not have access to Batiste's prior medical records and relied only on the information she provided to him.

[10] Lemack noted that, if Batiste complained of groin pain prior to the surgery to implant the TVT-O or did not complain of groin pain until after her back surgery and heart procedure in 2011, "that would change things." He stated, "if the history is that she only – that she had no pain after her surgery but, in fact, had pain only after those procedures, the I would say it would change things. That's not what I was told."

[11] We again note that the sample of the mesh received by Jordi had been placed in formalin and a new cross-linked polymer had formed between the tissue on the sample and the formalin.

inflammation, particle loss, roping, fraying, degradation, damage to adjacent structures, damage to the nerves and the soft tissues of the female – of her pelvis."

Although Margolis testified a heavyweight, small-pore mesh could contract more than a lightweight, large-pore mesh, there was no evidence regarding the extent, if any, to which the mesh contracted inside of Batiste's body.[12] Further, Margolis's testimony about fibrotic bridging established only that the scarring increased the potential for pain and other possible complications and did not establish fibrotic bridging caused any of Batiste's pelvic pain. His remaining testimony about the cause of Batiste's pelvic pain essentially states the pain results from the sling. This testimony does not tie Batiste's pelvic pain to the weight or pore size of the mesh and is insufficient to support a finding that the use of a heavyweight, small-pore mesh in the TVT-O was a producing cause of Batiste's pelvic pain. *See Ledesma*, 242 S.W.3d at 39 (expert testimony is unreliable if "there is simply too great an analytical gap between the data and the opinion proffered"); *Pollock*, 284 S.W.3d at 816.

As to Batiste's groin pain, Lemack believed the pain was probably from the implantation of the sling, but did not link the pain to the weight or pore-size of the mesh. In Margolis's opinion, the sling arm in Batiste's obturator foramen was:

> scarring and pulling and contracting. And it may not be right on the nerve, but it's close enough to the nerve that it's kinking and pulling and gnawing on that thing, and it's going to cause pain as long as it's there.

Margolis's opinion on the cause of Batiste's groin pain is premised, not on the weight or pore size of the mesh, but on the placement of the arms of the slings near the obturator nerve. There is no evidence the placement of the sling was due to the weight of mesh used in the TVT-O, and

[12] There was evidence that any mid-urethral sling, including slings made from organic materials, would contract to some extent after implantation.

Margolis did not link Batiste's groin pain to the mesh being either heavyweight or small-pore.[13] Further, Margolis identified the damage caused by passage of the helical trocar through the obturator foramen when the TVT-O was implanted as one possible cause of complications experienced after the implantation of a TVT-O, and failed to exclude this as a cause of Batiste's groin pain. *See Robinson*, 923 S.W.2d at 559; *see also Kia Motors Corp.*, 432 S.W.3d at 878. We conclude there is legally insufficient evidence that Batiste's pelvic or groin pain was due to the use of a heavyweight, small-pore mesh in the TVT-O.

Conclusion

It is undisputed the implantation of a TVT-O for the treatment of SUI can cause a number of complications, including erosion of the mesh into the vagina and urethral, pelvic, and groin pain. It is also undisputed that Batiste suffered from these complications. However, "[t]he law of products liability does not guarantee that a product will be risk free." *Matak*, 462 S.W.3d at 6 (quoting *Caterpillar Inc. v. Shears*, 911 S.W.2d 379, 381 (Tex. 1995)). Rather, to recover on her product liability claim based on an alleged design defect in the TVT-O, Batiste was required to prove a specific defect in the TVT-O, and not simply the device itself, was the producing cause of her injuries. *See id.*

While proving causation may be difficult, that does not excuse the plaintiff from introducing some evidence of causation. *Schaefer v. Tex. Emp'r Ins. Ass'n*, 612 S.W.2d 199,

[13] As noted, Batiste suffered from a number of medical conditions that could have potentially caused her symptoms. Margolis testified he performed a differential diagnosis to "rule out what's not happening and rule in what is happening" for each of Batiste's symptoms. In doing so, he considered the temporal relationship between the symptom and the surgery to implant the TVT-O. He first ruled out the anterior colporrhaphy as a source of Batiste's pelvic pain or dypareunia, stating that, unless you excise too much vaginal wall, the patient will not suffer pelvic pain from the procedure. He then considered Batiste's back injuries and concluded any pain from those injuries would manifest in her buttocks or the back of her legs and would not present as groin, vaginal, urethral, or pelvic pain or as dyspareunia. Margolis also excluded surgeries to repair two abdominal hernias as being a "surgical mile" and a "surgical galaxy" away from the vagina. He finally concluded the cardiac catheterization during which a stent was implanted in Batiste did not cause her symptoms. However, Margolis failed to address a number of potential causes of Batiste's symptoms, such as her diabetic neuropathy, which could be a source of her pelvic pain, and the possibility she suffers from interstitial cystitis, which could explain her pelvic and groin pain. Finally, Lemack testified that he believed the placement of the sling could be causing some of Batiste's problems and Margolis acknowledged the passage of the sling through the obturator foramen could cause a number of Batiste's symptoms. Margolis failed to rule out the passage or the placement of the sling, as opposed to any defect in the sling, as being the cause of Batiste's groin or pelvic pain. *See Robinson*, 923 S.W.2d at 559; *see also Kia Motors Corp*, 432 S.W.3d at 878

205 (Tex. 1980). Although Batiste alleged the TVT-O was defective based on its use of mechanically cut, heavyweight, small-pore mesh that was subject to degradation and particle loss, she failed to produce more than a scintilla of evidence that any of these alleged defects caused her injuries. Accordingly, the evidence is legally insufficient to support the jury's verdict.

We resolve that portion of appellants' first issue in which they argue Batiste failed to present legally sufficient evidence that a defect in the TVT-O caused her injuries in their favor.[14] We reverse the trial court's judgment and render judgment that Batiste take nothing on her product liability claim against appellants based on a design defect in the TVT-O.

/Robert M. Fillmore/
ROBERT M. FILLMORE
JUSTICE

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[14] Based on our resolution of appellants' argument that Batiste failed to present legally sufficient evidence of causation, we need not address appellants' remaining arguments in their first issue or their second issue. *See* TEX. R. APP. P. 47.1.

Court of Appeals
Fifth District of Texas at Dallas

JUDGMENT

JOHNSON & JOHNSON AND ETHICON, INC., Appellant

No. 05-14-00864-CV V.

LINDA BATISTE, Appellee

On Appeal from the 95th Judicial District Court, Dallas County, Texas,
Trial Court Cause No. DC-12-14350.
Opinion delivered by Justice Fillmore, Justices Lang and Whitehill participating.

In accordance with this Court's opinion of this date, the judgment of the trial court is **REVERSED** and judgment is **RENDERED** that appellee Linda Batiste take nothing on her claims against appellants Johnson & Johnson and Ethicon, Inc.

It is **ORDERED** that appellants Johnson & Johnson and Ethicon, Inc. recover their costs of this appeal from appellee Linda Batiste.

Judgment entered this 5th day of November, 2015.