

[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS  
FOR THE ELEVENTH CIRCUIT

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No. 20-11311  
Non-Argument Calendar

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D.C. Docket No. 0:18-cv-60095-RAR

ELMITHA PIERRE,  
MAXO JEAN JACQUES,

Plaintiffs-Appellants,

versus

INTUITIVE SURGICAL, INC.,

Defendant-Appellee,

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Appeal from the United States District Court  
for the Southern District of Florida

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(April 2, 2021)

Before ROSENBAUM, JILL PRYOR, and LUCK, Circuit Judges.

PER CURIAM:

In this products-liability case, Elmitha Pierre and Maxo Jean Jacques allege that Pierre was injured by the Endowrist HotShears Monopolar Curved Scissors

(“Scissors”), an electrosurgical medical device manufactured and sold by Intuitive Surgical, Inc. They contend that Intuitive was both negligent and strictly liable for the Scissors’ defective design, and both negligent and strictly liable for failing to warn them of the resultant danger from the Scissors. The district court granted summary judgment to Intuitive, concluding that Pierre failed to present sufficient evidence that her injury was caused by the Scissors to prove her design-defect claims, and that, for her failure-to-warn claims, she did not show that the warnings were inadequate or that the alleged failure to warn was the proximate cause of her injuries. On appeal, Pierre argues that she presented sufficient evidence of causation to get to a jury on her design-defect claims. After careful review, we affirm the judgment in favor of Intuitive.

## I.

Pierre suffered a thermal injury (a burn) to her bowel during a robotically assisted hysterectomy performed on January 24, 2014. Pierre’s surgeon, Dr. Yat-Min Chen, performed the surgery using the da Vinci Surgical System, a robotic surgical device manufactured and sold by Intuitive that allows a surgeon to conduct minimally invasive surgery using a variety of instruments, including electrosurgical instruments.

Intuitive manufactures electrosurgical laparoscopic instruments for use with the da Vinci system, including the Scissors, which use monopolar electric energy to

cut and coagulate tissue, and the Fenestrated Bipolar Forceps (“Forceps”), which use bipolar electric energy.<sup>1</sup> Both instruments were used in Pierre’s surgery. So too was a metal suction tube not manufactured by Intuitive and not docked to the da Vinci system.

Near the end of the surgery, Dr. Chen noticed that Pierre had suffered damage to her bowel. After realizing the damage to Pierre’s bowel, Dr. Chen requested a consultation from the general surgeon on call. The surgeon looked at Pierre’s tissue for approximately five minutes, determined there was not much damage, and recommended keeping her in the hospital for observation. As a result, no repairs were made to her bowel during the surgery. Six days later, however, Pierre began experiencing devastating physical side effects due to the damage to her bowel.

Pierre claims that the injury to her bowel was caused by electrical arcing from the Scissors due to an insulation defect in its shaft. She reached that conclusion in part because, less than a year before the surgery, Intuitive had voluntarily recalled older versions of the Scissors (versions 9 and 10) due to a potential for these instruments “to develop very small cracks (‘micro-cracks’) near the distal (scissor) end.” According to the recall notice, these micro-cracks, which “may not be visible

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<sup>1</sup> Monopolar energy is a type of energy characterized by the passage of a current from a single electrode at the tip of an electrosurgical instrument to tissue and through the patient to a return pad to complete the electric current circuit. Bipolar energy is a type of energy characterized by the confinement of electrical current to the tissue between the two electrodes of the instrument.

to the user,” “may create a pathway for electrosurgical energy to leak to tissue and potentially cause thermal injury.” While a newer version of the Scissors (version 12) was used in Pierre’s surgery, and it has not been subject to a recall, Pierre maintains that the same type of insulation defect in the older versions was also present in the version used in her surgery.

Several months after the surgery, in October 2014, Dr. Chen attended an advanced training course offered by Intuitive and, seeking to understand how Pierre’s injury had occurred, asked Dr. Pitter, the now-deceased instructor, to review Pierre’s videotaped hysterectomy procedure. After reviewing the video, according to Dr. Chen, Dr. Pitter concluded that the damage to Pierre’s bowel was most likely due to “arcing.” But Dr. Pitter did not state whether the arcing was from the Scissors or the Forceps, nor did he tell Dr. Chen that the Scissors used in Pierre’s surgery were defective.

Dr. Chen did not witness any arcing from any of the devices used during the surgery. He also testified that arcing, alone, does not necessarily indicate an insulation failure because arcing may come from either the tip of the instrument or the shaft of the instrument. And because arcing occurs quickly, it is difficult to determine from which end arcing comes.

Dr. Chen testified that he believed Pierre’s injury was caused by the metal suction tube conducting energy from one of the electrosurgical instruments to the

bowel. And in his view, the source of the energy was “the bipolar, because [he] didn’t fire the monopolar” at the time he believes the injury occurred. In other words, Dr. Chen believed that it was “more likely” that energy from the Forceps—not the Scissors—transferred to the metal suction tube, which was near Pierre’s bowel, and inadvertently conducted energy to the bowel.

## II.

Pierre sued Intuitive in federal district court under diversity jurisdiction, *see* 28 U.S.C. § 1332, alleging Florida state-law claims of design defect and failure to warn under strict products-liability and negligence theories.<sup>2</sup> Intuitive filed a motion for summary judgment, which the district court granted in full. Only the design defect claims are at issue in this appeal.

In granting summary judgment on the design-defect claims, the district court explained that two elements of Pierre’s claims were disputed: (1) whether the Scissors were defective or unreasonably dangerous, or both; and (2) if so, whether such defect proximately caused Pierre’s injuries. As to the first issue, the court found that Pierre presented sufficient evidence to create a genuine issue of material fact as to whether the Scissors used in her surgery were defectively designed under Florida law. This evidence included “numerous adverse event reports” and returned

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<sup>2</sup> Jacques, Pierre’s husband, joined as a plaintiff alleging a derivative claim of loss of consortium.

instruments with microcracks associated with version 12 of the Scissors—the same version used in her surgery—and expert testimony that version 12 was not reasonably safe without incorporating Active Electrode Monitoring (“AEM”) technology or other coaxial shielding and monitoring of the shaft of the device.

But the district court found that Pierre’s claims failed for lack of proof of causation. The court stated that expert testimony was required to establish causation in this products-liability case, and that Dr. Chen was Pierre’s only expert on that issue.<sup>3</sup> But Dr. Chen’s testimony, in the court’s view, was insufficient for several reasons.

First, according to the district court, because Dr. Chen intended to offer opinions based on information outside of his personal observations, his testimony was inadmissible without a written expert report as required by Rule 26(a)(2)(B), Fed. R. Civ. P. Second, in the court’s view, Dr. Chen’s causation testimony was based on Dr. Pitter’s hearsay statements, which did not qualify as nonhearsay statements of a party-opponent under Rule 801(d)(2), Fed. R. Evid., or fall within any hearsay exception. And third, the court reasoned, even assuming Dr. Chen’s testimony was admissible without an expert report, Pierre sought to establish causation through differential diagnosis, which “alone[] is simply insufficient to

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<sup>3</sup> The district court previously excluded the causation testimony of Pierre’s other expert, Roger Odell, and Pierre does not challenge that ruling on appeal.

create a genuine issue of material fact.” Accordingly, the court concluded that Pierre had not produced sufficient admissible evidence to create a genuine issue of material fact as to causation—a necessary element of her design defect claims.

Pierre now appeals the district court’s grant of summary judgment on her design-defect claims. She contends that the district court abused its discretion by excluding Dr. Chen’s causation testimony and Dr. Pitter’s statements. She further asserts that the court erred in concluding that she presented insufficient causation evidence.

### III.

We assume (without deciding) that the district court abused its discretion in excluding Dr. Chen’s causation testimony and Dr. Pitter’s statement that Pierre’s injury was caused by “arc-ing.” Even assuming Dr. Chen’s causation testimony and Dr. Pitter’s “arc-ing” statement were admissible, summary judgment was still proper for the reasons we explain below. *See Feliciano v. City of Miami Beach*, 707 F.3d 1244, 1251–52 (11th Cir. 2013) (stating that we may affirm on any ground supported by the record).

### IV.

We review a district court’s grant of summary judgment *de novo*, viewing the evidence and drawing all reasonable inferences in favor of the non-moving party. *Crane v. Lifemark Hosps., Inc.*, 898 F.3d 1130, 1133–34 (11th Cir. 2018). Summary

judgment is appropriate if “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a).

To prove causation under a strict products-liability theory or a negligent-design theory, a plaintiff must demonstrate that the defective or unreasonably dangerous product “proximately caused his injury.” *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1295 (11th Cir. 2005). “Florida has adopted a preponderance standard for causation in both negligence and strict liability actions; a mere possibility of causation is not enough.” *Hessen for Use & Benefit of Allstate Ins. Co. v. Jaguar Cars, Inc.*, 915 F.2d 641, 647 (11th Cir. 1990). Therefore, if the matter is “one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant.” *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1256 (11th Cir. 2010) (quoting another source).

In cases where a jury is asked to assess complex medical or scientific issues outside the scope of a layperson’s knowledge, an expert’s testimony is required to establish causation. *See id.*; *see also Shepard v. Barnard*, 949 So. 2d 232, 233 (Fla. Dist. Ct. App. 2007) (approving trial court’s grant of summary judgment against plaintiff after excluding plaintiff’s medical experts’ testimony, because the doctors were needed “to provide opinions regarding any causal link between the alleged

injury and the medical treatment”). Without expert testimony in such complex cases, the plaintiff’s claim fails as a matter of law. *See Guinn*, 602 F.3d at 1256; *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1316 (11th Cir. 2014) (affirming the district court’s summary judgment under Florida law because the plaintiff failed to produce “*Daubert*-qualified, general and specific-causation-expert testimony that would be admissible at trial to avoid summary judgment.”).

Pierre maintains that she presented sufficient proof of causation through Dr. Chen’s testimony, which “effectively ruled out” all the possible causes of a thermal injury like Pierre’s “with the exception of an insulation failure.” Pierre further notes that Dr. Chen identified the injury as caused by “arcing,” which she characterizes as evidence of an insulation defect. Although she recognizes that “differential diagnosis evidence by itself does not suffice for proof of causation,” *Rink*, 400 F.3d at 1295, she maintains that Dr. Chen’s differential diagnosis<sup>4</sup> is sufficient when combined with her causation evidence showing that, in general, defective Scissors “can cause thermal injury to an adjacent organ such as the bowel.”

The central flaw in Pierre’s argument is that no reasonable construction of Dr. Chen’s testimony supports her claim that Dr. Chen identified an insulation defect as

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<sup>4</sup> “Differential diagnosis includes three steps: (1) the patient’s condition is diagnosed, (2) all potential causes of the ailment are considered, and (3) differential etiology is determined by systematically eliminating the possible causes.” *Chapman v. Procter & Gamble Dist., LLC*, 766 F.3d 1296, 1308 (11th Cir. 2014).

the most likely cause of her injury. As we recounted above, Dr. Chen testified that he believed Pierre's injury was caused by the metal suction tube conducting energy from one of the electrosurgical instruments to the bowel. While that opinion is not inconsistent with an insulation defect in the Scissors, Dr. Chen's testimony otherwise fails to support Pierre's theory. First, Dr. Chen identified the likely source of the energy as "the bipolar" Forceps, not the monopolar Scissors, "because [he] didn't fire the monopolar" at the time he believes the injury occurred. And second, Dr. Chen explained that "arcing" alone does not necessarily indicate an insulation failure because arcing may come from either the tip of the instrument or the shaft of the instrument, and that, because arcing occurs quickly, it is difficult to determine whether arcing comes from the tip or the shaft. Thus, in Dr. Chen's view, it was "more likely" that the injury was caused because thermal energy from the Forceps—not the Scissors—transferred to the metal suction tube, which was near Pierre's bowel, and inadvertently conducted energy to the bowel.

Pierre responds that "the video evidence simply disproves any concern that thermal energy transferred to the suction tube," suggesting that a lay jury could make that determination based on the video alone. But the interpretation of the hysterectomy video presented complex medical and scientific issues outside the scope of a layperson's knowledge, so expert testimony was required. *See Guinn*, 602 F.3d at 1256. And Pierre's own expert, after reviewing that same video,

contradicted Pierre's current assertion, testifying that he believed that thermal energy inadvertently transferred to the suction tube and caused her injury.

At best, Pierre's evidence presents a "mere possibility" that an insulation defect in the Scissors caused her thermal injury. But "a mere possibility of causation is not enough." *Hessen*, 915 F.2d at 647. Because a verdict in Pierre's favor would require the jury to engage in impermissible "speculation or conjecture," "it bec[ame] the duty of the court to [enter judgment] for the defendant." *See Guinn*, 602 F.3d at 1256.

For these reasons, the district court properly granted summary judgment in favor of Intuitive.

**AFFIRMED.**