

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KAREN J. GREGG and : CIVIL ACTION
MICHAEL W. GREGG, :
Plaintiffs, : NO. 95-4630
 :
v. :
 :
 :
 :
DANIEL M. KANE, M.D., STEPHEN :
L. TROKEL, M.D., VISX, INC. :
and WILLS EYE HOSPITAL, :
Defendants. :

M E M O R A N D U M

BUCKWALTER, J.

June 10, 1998

By Order dated September 5, 1997, I denied Defendants' motions for summary judgment in this tort action for injuries to Plaintiff Karen Gregg's eye, and the case proceeded to trial. At the close of Plaintiffs' case, the remaining defendants moved for judgment as a matter of law pursuant to Federal Rule of Civil Procedure 50 (a)(1).¹ After argument, I entered judgment for Defendants Wills Eye Hospital (Wills) and VISX. (NT 11/11/97 at 68-105), but I denied Dr. Daniel Kane's motion, as I found that there remained jury issues as to his negligence. I later summarized my holding as follows:

[E]ven if VISX and Wills were somewhat careless in what they did, . . . there wasn't enough evidence to

¹ Plaintiffs do not challenge my dismissal of defendant Stephen Trokel on the first day of trial.

convince me that it would be anything but a guesswork for the jury to find that their carelessness was a substantial factor in what happened here. But I found that if there's any substantial factor at all in this case, it's the doctor.

(NT 11/11/97 at 218).

The jury returned a verdict for Dr. Kane, finding that he had not negligently performed the operation, and that Mrs.

Gregg had given her informed consent to the operation.

Plaintiff now moves for a new trial against Dr. Kane, Wills and

VISX. I will deny these motions. Plaintiff has failed to

satisfy her heavy burden of demonstrating that the jury's verdict must be reversed,² and, on review of the pleadings and the trial

² A jury verdict may not be overturned as against the clear weight of the evidence where the court would have reached a different conclusion than the jury, but only where "the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks our conscience." Williamson v. Consolidated Rail Corp., 926 F.2d 1344, 1353 (3d Cir. 1991). The issues of negligence and informed consent were well-presented and straightforward, and I cannot say that the jury's resolution of them was against the clear weight of the evidence. See id. at 1352 ("Where the subject matter of the litigation is simple and within a layman's understanding, the district court is given less freedom to scrutinize the jury's verdict than in a case that deals with complex factual determinations . . ."). Further, I am confident that the jury's instructions on the Trokel consent form stated the correct legal standard, Robinson v. City of Pittsburgh, 120 F.3d 1286, 1293 (3d Cir. 1997), and that it was not capable of confusing or misleading the jury. Link v. Mercedes-Benz of North America, Inc., 788 F.2d 918, 922 (3d Cir. 1986). The same is true of my negligence instruction. Plaintiffs offered evidence as to Mrs. Gregg's enrollment in the protocol; their counsel in closing argued that the enrollment demonstrated negligence; and my instruction, while not specifically including the enrollment process, did not exclude it as a factor for the jury to consider, nor did it limit them to considering only the actual operation itself, rather than the entire course of dealing between Mrs. Gregg and Dr. Kane. I instructed them to consider "careless or unskilled performance by a physician of the duties imposed on him by his professional relationship with his patient," (NT 11/13 at 97) and whether Kane "failed to exercise the degree of skill and care expected in the field of laser surgery in his treatment of the plaintiff." I accordingly do not find that my reference to "surgery" limited the jury to consider only the operation itself when evaluating Kane's alleged negligence.

transcript, I am satisfied that entry of judgment for Wills and VISX was correct.

I. BACKGROUND

Plaintiffs Karen and Michael Gregg's Second Amended Complaint stated causes of action in negligence; reckless indifference, intentional misconduct and informed consent against Defendants. They alleged that Mrs. Gregg suffered injury from the second of two Phototherapeutic Keratectomy (PTK) procedures performed at Wills by Dr. Kane using a 20/20 Excimer laser manufactured by Defendant VISX.

Excimer laser technology was studied pursuant to Investigational Device Exemptions issued by the Food and Drug Administration (FDA). Wills Eye purchased an excimer laser from VISX in 1991. Dr. Kane, who is not an employee of Wills, was an investigator for the VISX laser study at Wills. Because the laser was an experimental device, patients received laser treatment at no cost.

Mrs. Gregg had high myopia in both eyes: -19.75 diopters in her left eye, and -21 diopters in her right eye. Aside from the myopia, the vision in her right eye was good, but a previous retinal hemorrhage left her without central vision in her left eye. Her best corrected visual acuity in her right eye was 20/40 with glasses in 1992. Both of her corneas were healthy, and she did not have prior corneal surgery. Mrs.

Gregg's level of refractive abnormality was such that she was considered to suffer from pathological or malignant myopia, and her goal in seeking medical help was to reduce her myopia. Her ophthalmologist referred her to Dr. Kane for possible excimer laser treatment.

Wills conducted excimer laser studies under two protocols: the PTK protocol, and a Photorefractive Keratectomy (PRK) protocol for moderate myopia. In PRK surgery, the laser vaporizes part of the corneal tissue to round off the cornea; the greater a patient's myopia, the greater the amount of tissue which must be removed. The PRK trials were divided into three groups: low, moderate and high myopia. Low myopia trials were for patients with -1 to -6 diopter myopia; moderate trials for patients with -6 to -8 diopter myopia; and, and high trials for patients with -8 to -20 diopter myopia. Wills did not participate in VISX's high myopia PRK protocol, and Mrs. Gregg would not have qualified for that protocol.

VISX divided the PTK trials into two groups, the second of which is relevant here: Group II for patients with "refractive abnormalities, either pathologic or surgically induced." Unlike the PRK protocol, the PTK protocol did not include diopter limits.

When Mrs. Gregg first consulted Dr. Kane in the fall of 1992, he recommended excimer laser surgery to correct her myopia

by removing corneal tissue. Dr. Kane explained to Mrs. Gregg the investigational nature of the laser surgery, and he submitted a registration/eligibility form to VISX. Kane registered Mrs. Gregg for the PTK Group II based on her refractive abnormality, i.e., her pathological myopia. VISX approved the registration in November 1992. Although Mrs. Gregg testified that Dr. Kane provided her with a consent form utilized by Dr. Stephen Trokel for a PRK low myopia trial in New York, it is uncontested that Mrs. Gregg signed the appropriate form for the PTK Group II protocol, and the jury found that she had given her informed consent to the PTK procedure.

Kane operated on Mrs. Gregg's left eye on December 17, 1992, and her vision in that eye improved from 20/400 to 20/100. Mrs. Gregg then sought laser treatment for her right eye. Kane advised her to wait six months, after which she again requested the treatment. Kane submitted another PTK Group II registration/enrollment form to VISX, which again approved the surgery. Mrs. Gregg again signed the required PTK Group II consent form. After her second operation on July 23, 1993, Mrs. Gregg's right eye vision improved, but she then developed glare and haze problems, and in December 1993 her vision decreased. Her vision in her right eye has gone from 20/40 with glasses to 20/200 with glasses. While this astigmatism has been somewhat

ameliorated with a contact lens, she is nonetheless unable to work or drive.

II. DISCUSSION

The decision whether to grant a new trial rests in the trial judge's discretion. Allied Chemical Corp. v. Daiflon, Inc., 449 U.S. 33, 36 (1980). Fed. R. Civ. P. 59 permits the grant of a new trial where there has been a manifest error of law or fact, or newly discovered evidence, but Fed. R. Civ. P. 61 bars the granting of a new trial where any error is harmless. Entry of judgment as a matter of law for Wills and VISX was appropriate "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there [was] not sufficient evidence from which a jury could reasonably find liability." McDaniels v. Flick, 59 F.3d 446, 453 (3d Cir. 1995). Plaintiffs attack my entry of judgment for Wills and VISX on procedural and substantive grounds.

First, I am confident that Plaintiffs' motion for judgment as a matter of law was properly raised, and that Plaintiff cannot now attack it on procedural grounds when they made no contemporaneous objection on those grounds and indeed addressed the merits of the motions. Williams v. Runyon, 130 F.3d 568, 572 (3d Cir. 1997). Nor do I agree that it was improper to address whether Plaintiffs adduced sufficient

evidence to demonstrate causation when defendants' motion attacked Plaintiffs' case on negligence grounds.³ The transcript demonstrates that all parties were well-prepared to debate the elements of Plaintiffs' negligence claims.

Secondly, Plaintiffs do not demonstrate an error of fact or law, but merely reargue evidence which I have already found did not support negligence on Wills or VISX's behalf. The evidence demonstrated that the PTK protocol did not contain a diopter limitation; that it did not prohibit fellow-eye treatment; and that refractive surgery under the PTK protocol was appropriate for Mrs. Gregg. Plaintiffs' presentation of Dr. Kane's testimony is selective, and it ignores Kane's subsequent opinion that Plaintiffs' counsel had misrepresented the import of a scholarly article in presenting its alleged conclusions to him. The article which Plaintiffs represented as attacking the excimer laser trials was not only inconclusive, it was not published until after both of the operations in question, and Plaintiff did not indicate which parts of the article may have been publicly discussed prior to the second surgery.

It was because these factors appeared to create a jury issue as to negligence that I denied VISX and Wills' motions for

³ The elements of a negligence claim under Pennsylvania law are: 1) a duty or obligation, recognized by law, requiring the defendant to conform to a certain standard of conduct; 2) a failure to conform to the standard of conduct; 3) a causal connection between the conduct and the resulting injury; and 4) actual loss or damage resulting to the interests of another. Galullo v. Federal Express Corp., 937 F. Supp. 392, 394 (E.D. Pa. 1996).

summary judgment in September 1997. The evidence as presented, however, was not only insufficient to support these issues, it actually undercut them and thus, even viewing it in the light most favorable to Plaintiffs, it would not support a reasonable jury finding that either VISX or Will's negligence was a substantial factor in causing injury to Mrs. Gregg.

Moreover, having determined that the jury's verdict for Dr. Kane was not against the clear weight of the evidence, I am unable to find that the evidence was sufficient to demonstrate that the alleged negligence of either VISX or Wills could have constituted a substantial factor in the injuries to Mrs. Gregg. The jury rejected the bases of negligence which Plaintiffs argued, and which they again advance: that Mrs. Gregg was improperly enrolled in the PTK protocol; that laser surgery was not indicated for a patient like Mrs. Gregg with high myopia and one healthy eye, and that the performance of the surgery was below the standard of care.⁴

I therefore disagree with Plaintiffs' argument that even if I deny Dr. Kane's motion for a new trial, I may still grant VISX's motion, as a jury could reasonably find that the surgery should never have happened, but that it was VISX's fault rather than Dr. Kane's. Plaintiffs do not support this

⁴As I decline to overturn the jury's verdict for Dr. Kane, it is not necessary to reach Plaintiff's agency arguments against Wills or VISX.

contention, and I find no way to leapfrog the jury's determinations for Dr. Kane on negligence and informed consent, and find that other parties further removed from any injuries to Mrs. Gregg were at greater fault. I will accordingly enter an Order denying each of Plaintiffs' motions.

