[Cite as *Armstrong v. Univ. of Toledo Med. Ctr.*, 2011-Ohio-3182.]

Court of Claims of Ohio

The Ohio Judicial Center
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MILDRED ARMSTRONG, et al.

Plaintiffs

v.

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Defendant
Case No. 2009-02146

Judge Joseph T. Clark

DECISION

{¶ 1} Plaintiffs brought this action alleging medical negligence and loss of consortium. The issues of liability and damages were bifurcated and the case proceeded to trial on the issue of liability.[1]

{¶ 2} In early 2005, plaintiff, Mildred Armstrong, complained to her family practitioner of moderate to severe right shoulder pain that had persisted for three or four months.[2] Following a relatively unsuccessful course of physical therapy, plaintiff was referred for treatment to Krishna Mallik, M.D., an orthopedic surgeon employed by defendant, The University of Toledo Medical Center (UT). Plaintiff was 78 years old when she first presented to Dr. Mallik on January 28, 2005.

{¶ 3} Following a physical examination, an x-ray, and a follow-up MRI, Dr. Mallik determined that plaintiff was a candidate for a right shoulder arthroplasty. On February 8, 2006, plaintiff underwent a surgical procedure known as a Copeland

[1]Plaintiffs' March 16, 2011 motion for an extension of time to file a reply brief is GRANTED instanter.

hemiarthroplasty. According to Dr. Mallik, one of the reasons the Copeland procedure was chosen was her belief that plaintiff was the primary caregiver for her ailing husband and that she needed her shoulder to be functional as soon as possible. An alternative would have been a total right shoulder arthroplasty. Plaintiff insists that it was Dr. Mallik who chose the Copeland procedure.[3]

{¶ 4} Plaintiff testified that she spent two days in the hospital to recover from the surgery and that she continued to have pain in her shoulder post-operatively. According to plaintiff, Dr. Mallik told her that the pain was a normal part of the recovery process. Plaintiff stated that she tolerated the pain at first but that in September 2007 the pain became much worse and that in January 2008 she noticed a "bump" in the back of her right shoulder.

{¶ 5} Plaintiff complained of the pain to her family physician, Dr. Federer, who referred her to Dr. Levine for treatment. Plaintiff saw Dr. Levine on two occasions and he ordered x-rays of her right shoulder. After reviewing plaintiff's x-rays, Dr. Levine allegedly told plaintiff that a repair was "too big a job for him," and he referred her to Dr. Ionatti for treatment. Dr. Ionatti subsequently performed a total right shoulder arthroplasty in July 2008.

{¶ 6} Plaintiffs first contend that Dr. Mallik failed to inform plaintiff that one of the recognized risks associated with the Copeland hemiarthroplasty was that a second surgery may be needed in the future. A medical claim premised upon the lack of informed consent requires proof that:

{¶ 7} "(a) The physician fails to disclose to the patient and discuss the material risks and dangers inherently and potentially involved with respect to the proposed therapy, if any;

{¶ 8} "(b) the unrevealed risks and dangers which should have been disclosed by the physician actually materialize and are the proximate cause of the injury to the patient; and

"(c) a reasonable person in the position of the patient would have decided against the therapy had the material risks and dangers inherent and incidental to

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[2]The singular "plaintiff" shall be used in reference to Mildred Armstrong.

[3]Plaintiff's husband had recently been admitted to UT for treatment of a heart condition and plaintiff had requested that she be allowed to share a room with him following her surgery.

treatment been disclosed to him or her prior to the therapy." *Nickell v. Gonzalez* (1985), 17 Ohio St.3d 136, syllabus.

{¶ 9} The medical experts who testified in this case agree that a physician seeking consent from a patient to perform a surgical procedure such as the Copeland hemiarthroplasty performed upon plaintiff must disclose all of the material risks associated with such procedure including infection, bleeding, blood clots, complications from anesthesia, loss of range of motion, pain, and the need for further surgery.

{¶ 10} Plaintiff executed three separate consent forms relative to the 2006 surgery, the first on December 7, 2005, when the surgery was first scheduled to occur, a second on February 3, 2006, five days prior to the re-scheduled surgery, and the last on February 8, 2006, the date when the surgery was performed. (Plaintiffs' Exhibit 12.) Dr. Mallik testified that it is her practice to obtain consent from each of her patients in a face-to-face interview. Although she had no specific recollection of the process of obtaining plaintiff's consent and she did not recognize the handwriting on the consent forms at issue, Dr. Mallik did not find any evidence in plaintiff's records to suggest a deviation from her normal practice.

{¶ 11} The court notes that Plaintiffs' Exhibit 12 lists "further surgery" as one of the "reasonably known risks" of "any surgery." Plaintiff recalled that Dr. Mallik specifically informed her of each of the risks noted in the consent form with the single exception of the risk of further surgery. Plaintiff insists that she was not informed of such a risk on any of the occasions when she gave consent. Plaintiff testified that had she been so informed, she would not have elected to undergo the procedure.

{¶ 12} Based upon the totality of the evidence, the court finds that it is unlikely that Dr. Mallik would have neglected to inform plaintiff of the risk of further surgery on the occasions on which she obtained plaintiff's consent. Although the court does not believe that plaintiff was intentionally disingenuous, given the totality of the evidence, the court finds that plaintiff was informed of all of the known risks of the Copeland procedure, including the need for further surgery. Accordingly, plaintiffs have failed to prove a claim of medical negligence based upon the lack of informed consent.

{¶ 13} With respect to Dr. Mallik's performance of the procedure, plaintiffs must show that the medical treatment rendered by defendant fell below the recognized

standard of care, and that such negligence proximately caused injury to plaintiff. *Bruni v. Tatsumi* (1976), 46 Ohio St.2d 127, 131-132. Ordinarily, plaintiffs must show the standard of care, any deviation therefrom, and causation "through medical expert testimony in terms of probability to establish that the injury was, more likely than not, caused by the defendant's negligence." *Ramadan v. Metrohealth Med. Ctr.*, Cuyahoga App. No. 93981, 2011-Ohio-67, ¶40, quoting *Roberts v. Ohio Permanente Med. Group, Inc.* (1996), 76 Ohio St.3d 483, 485.

{¶ 14} According to the medical experts who gave testimony in this case, the two main bones of the shoulder are the humerus and the scapula (shoulder blade). The scapula extends up and around the shoulder joint at the rear to form a roof called the acromion. The end of the scapula, called the glenoid, meets the head of the humerus to form a flexible ball-and-socket joint. Movement of the joint cavity is cushioned by articular cartilage which covers both the surface of the humeral head and the face of the glenoid. Four short muscles originate on the scapula and pass around the shoulder where their tendons fuse together to form the rotator cuff. The joint is stabilized by a ring of fibrous cartilage surrounding the glenoid called the labrum.

{¶ 15} A total shoulder arthroplasty requires the replacement of both the arthritic humeral head and the glenoid. In a total shoulder arthroplasty, an artificial humeral head is seeded by drilling into the humeral shaft, inserting a 3" or 4" stem and then cementing the stem into the humerus.

{¶ 16} A Copeland hemiarthroplasty is a resurfacing arthroplasty whereby the articular surface of the existing humeral head is covered and only the arthritic portion of the humeral shaft is replaced. The device is seeded to the humerus by a short stem; cementing is not required. The primary advantage of the Copeland procedure is a much shorter recovery time. A secondary advantage is that the implant is much easier to replace when the time comes.

{¶ 17} The experts agree that the existence of a significant rotator cuff tear or a significant glenoid deficiency are contraindications for the use of the Copeland device. Although there is some suggestion in the medical records that plaintiff may have had either a tear of her rotator cuff or a glenoid deficiency, there is insufficient evidence to establish the existence of either of these conditions prior to the 2006 surgery. Similarly,

while plaintiffs' medical expert criticized Dr. Mallik's placement of the Copeland device, all of the experts who gave testimony in this matter agreed that the Copeland arthroplasty was a reasonable choice in plaintiff's case. Thus, the crux of plaintiffs' case is that Dr. Mallik violated the standard of care in performing the Copeland hemiarthroplasty surgery.

{¶ 18} Dr. Mallik testified that she was board-certified in orthopedic surgery in 2005 and that her employment at UT included instruction of residents. She had no specific recollection of plaintiff's surgery and, consequently, her testimony was based primarily upon her review of plaintiff's medical records, her surgical notes, and her standard practices.

{¶ 19} Dr. Mallik's surgical notes indicate that she removed some bone spurs and marked the articular surface of plaintiff's humeral head in preparation for the placement of the arthroplasty, that she selected a No. 3 Copeland device because it covered plaintiff's articulate surface and left no gaps, and that she found plaintiff's humeral bone to be of sufficient quality for the proper seeding of the Copeland device. Dr. Mallik testified that the absence of any notation in the surgical record of either a rotator cuff tear, a glenoid deficiency or other contraindication for the Copeland arthroplasty meant that none were observed.

{¶ 20} According to Dr. Mallik, the goal of the Copeland procedure is to cover the articular surface of the humerus, which is that portion of the humeral head surfaced with cartilage. Dr. Mallik's review of plaintiff's inter-operative and post-operative x-rays satisfied her that she had properly positioned the Copeland device.

{¶ 21} Dr. Mallik saw plaintiff post-operatively on three occasions. According to Dr. Mallik's records, plaintiff's first post-operative appointment was on February 21, 2006. At that time, plaintiff reported that, with the exception of the surgical scar, her right shoulder was pain free. On her next visit, March 14, 2006, plaintiff reportedly told Dr. Mallik that she was "completely pain free." Plaintiff denies that she was pain free in March 2006, but she does not remember what she may have told Dr. Mallik. On her last post-operative visit on May 4, 2006, Dr. Mallik noted that plaintiff was "very pleased with her range of motion and how far she has come," and that plaintiff asked Dr. Mallik about the possibility of performing surgery on her left shoulder. (Plaintiffs' Exhibit 8.)

Plaintiff denies making any such statements or inquiries. According to plaintiff, Dr. Mallik told her that she should expect no further improvement in her shoulder.

{¶ 22} Plaintiff also received post-operative physical therapy and in her last such session on May 30, 2006, she reportedly told her therapist that she had "no complaints," and that she was able to perform all of her household tasks. Plaintiff estimated her improvement at 90 percent on that occasion. At trial, plaintiff testified that she was not able to perform her household tasks in May 2006 and that she does not agree with the notation in her records.

{¶ 23} Although plaintiff insists that she complained of right shoulder pain when she saw her family physician in March, June, and December 2007, she acknowledged on cross-examination that her medical records do not reflect any such complaints. Plaintiff did not recall telling Dr. Levine that she hurt her right shoulder lifting grocery bags and she could not explain why such a notation appeared in his records of plaintiff's February 2008 visit. Plaintiff's husband testified that plaintiff's right shoulder pain had become "very bad" in late 2007; but he did not believe that she had injured her shoulder lifting grocery bags.

{¶ 24} In addition to Dr. Mallik's testimony, defendant presented the expert testimony of Kenneth Westerheide, M.D., by way of deposition. Dr. Westerheide is an orthopedic surgeon who performed his residency at the Southern California Orthopedic Institute for Shoulder and Orthopedic Surgery, where he was employed from 2002 to 2007. Although he does not perform the Copeland arthroplasty in his practice due to "longevity issues," he agrees that the procedure has its advantages for certain "low demand patients" and that the Copeland procedure was a reasonable choice in plaintiff's case. He disagrees with the assertion that there is a specific neck/shaft angle that must be achieved in seeding the Copeland device. A total shoulder arthroplasty and a Copeland hemiarthroplasty are "completely different techniques," according to Dr. Westerheide.

{¶ 25} Dr. Westerheide explained that in the Copeland procedure, the patient's individual anatomy dictates proper placement inasmuch as the humeral head remains in place and the stem of the device is much shorter. In a total shoulder arthroplasty, the entire humeral head is replaced and the device is cemented into the humerus using a

much longer stem. In such a case, the proper neck/shaft angle is essential in order to preserve normal range of motion.

{¶ 26} According to Dr. Westerheide, the standard of care requires the surgeon to choose the correct Copeland device from among the eight available sizes. Inasmuch as the coverage of the humeral head is the specific goal of the Copeland procedure, the surgeon must find a Copeland device that closely approximates the patient's anatomy. Otherwise, the standard of care requires the surgeon to abandon the Copeland procedure in favor of a total shoulder arthroplasty.

{¶ 27} Dr. Westerheide opined that the effective life of the Copeland procedure has not been established by empiric data and that there are many possible causes for the relatively short life of plaintiff's procedure, most of which have nothing to do with the care with which the device was implanted. The one criticism of Dr. Mallik expressed by Dr. Westerheide during cross-examination was that the Copeland device did not fully cover the articulate surface of plaintiff's humeral head as is desired for optimal success. He believed that many surgeons would have elected to reshape plaintiff's glenoid during the procedure but he could not say that the standard of care required such reshaping.

{¶ 28} Indeed, following his review of plaintiff's medical records, including those generated by Dr. Ionatti when he performed the total shoulder arthroplasty in 2008, and based upon his knowledge, skill, education, and training as an orthopedic surgeon, Dr. Westerheide testified that Dr. Mallik met the standard of care when she performed plaintiff's Copeland hemiarthroplasty in 2006.

{¶ 29} Plaintiffs presented the expert testimony of board-certified orthopedic surgeon, Mark Goodman, M.D., in support of their claims. Dr. Goodman opined that Dr. Mallik violated the standard of care when she seeded the Copeland device at the improper neck/shaft angle relative to the anatomy of a typical shoulder joint, which is 135 degrees. Dr. Goodman's measurement of the angle of plaintiff's Copeland device was 105 degrees to 110 degrees and he opined that it was negligent to seed the Copeland device at that angle. He further opined that such negligence was the cause of the premature failure of the procedure.

{¶ 30} For the following reasons, the court does not afford a great deal of weight to Dr. Goodman's opinions. For instance, the court is persuaded by Drs. Mallik and

Westerheide that the neck/shaft angle of the arthroplasty, although critical in a total shoulder arthroplasty, is not a substantial factor in determining the standard of care with regard to the Copeland hemiarthroplasty. The court is convinced that the surgical techniques are materially different.

{¶ 31} Additionally, with regard to Dr. Goodman's suggestion that Dr. Mallik's failure to cover the entire humeral head was a failure of due care, the court is persuaded by the testimony of Drs. Mallik and Westerheide that coverage of the entire humeral head is not the standard for the Copeland procedure. Rather, the standard of care requires that the surgeon position the device so that it covers the articulate surface of the humeral head.

{¶ 32} Finally, to the extent that Dr. Goodman opined that the expected life of a Copeland procedure is five to ten years, the court notes that he based this opinion upon literature produced by the makers of the Copeland device and upon a single article written by Dr. Ionatti and published in the Journal of Bone and Joint Surgery. The court is persuaded, however, by the testimony of Drs. Mallik and Westerheide that there is insufficient empiric data upon which the expected life of the Copeland procedure can be determined with a reasonable degree of medical certainty.

{¶ 33} Based upon the totality of the evidence, the court believes that, with the benefit of 20/20 hindsight, Dr. Mallik would have chosen to perform a total right shoulder arthroplasty in 2006 rather than the Copeland procedure. However, the evidence establishes that her choice was reasonable under the circumstances that existed at that time. Additionally, the fact that plaintiff did not realize the lasting benefit that either she or Dr. Mallik expected from the procedure does not, standing alone, prove negligence. Indeed, even Dr. Goodman had to acknowledge, upon cross-examination, that the proper surgical placement of the Copeland device does not guarantee success for the patient. Moreover, the weight of the evidence establishes that plaintiff did, in fact, realize a benefit from the surgery, however short-lived it may have been.

{¶ 34} For the foregoing reasons, the court concludes that plaintiffs have failed to prove their claims by the preponderance of the evidence and that judgment shall be entered for defendant.

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Judge Joseph T. Clark

JUDGMENT ENTRY

This case was tried to the court on the issue of liability. The court has considered the evidence and, for the reasons set forth in the decision filed concurrently herewith, judgment is rendered in favor of defendant. Court costs are assessed against plaintiffs. The clerk shall serve upon all parties notice of this judgment and its date of entry upon the journal.

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JOSEPH T. CLARK
Judge

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