

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

PAUL WOODSON,

Plaintiff,

-vs-

Case No. 6:07-cv-275-Orl-22GJK

UNITED STATES OF AMERICA,

Defendant.

MEMORANDUM OPINION AND ORDER

This is a medical negligence action arising under the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671-2680. Plaintiff Paul Woodson seeks damages from the United States of America for injuries he says he sustained while he was under the care of health care providers at the Veterans Administration Clinic in Orlando, Florida. Particularly, Woodson contends that Clinic staff failed to timely diagnose complications stemming from a cardiac catheterization procedure performed at Winter Park Memorial Hospital on August 22, 2005, causing him to suffer, among other injuries, permanent vascular and neurological damage to his right leg and foot. After a two-day bench trial held on October 7-8, 2009, the Court now renders a decision on the merits.

I. BACKGROUND

The following facts presented at trial are undisputed. On August 19, 2005, Paul Woodson, a United States Army veteran, walked into the Orlando VA Clinic with complaints of chest discomfort. Unable to treat him emergently at the Clinic, VA health care providers arranged for Woodson to be transported by ambulance to Winter Park Memorial Hospital (WPMH), where he was admitted for further evaluation. After an exercise stress test revealed a possible reversible ischemia,

Woodson was scheduled for a cardiac catheterization procedure on his right leg at WPMH on August 22, 2005. The procedure showed no critical arterial disease, and no procedural complications were noted at the time. Woodson was discharged from the hospital that evening with orders to follow up at the Orlando VA Clinic in one week.

The day after he was released from the hospital, however, Woodson began experiencing pain in his right leg. He called WPMH, but was told he must schedule an appointment with the Orlando VA Clinic instead. Over the next two weeks, Woodson called the Clinic on a daily basis to try to schedule an appointment for an assessment of his leg pain. Finally, on September 8, 2005, he walked into the Clinic and requested an appointment. He was examined that day by Michael Cooksey, a VA physician's assistant, who noted his leg pain and prior catheterization procedure, prescribed additional pain medication, and recommended that he follow up at the Clinic if his symptoms persisted or worsened. Approximately two weeks later, on September 21, Woodson returned to the VA Clinic complaining of continued right leg pain and weakness. He was examined again by Michael Cooksey on that visit, who noted good pulses in his right leg but wrote that an arterial doppler test should be scheduled to confirm. Woodson was told to follow up at the Clinic as needed.

Approximately six weeks later, on October 31, Woodson returned to the VA Clinic complaining of continued right leg discomfort. This time, Michael Cooksey recommended that he discontinue his current pain medication and keep his appointment for the arterial doppler test. Woodson complied, and an arterial doppler was performed on November 17, 2005.¹ The test showed

¹ Neither the medical records nor the trial testimony explained why it took almost two months for Cooksey's doppler orders to be carried out.

an ankle brachial index (ABI) of 0.65 in his right leg, indicating some narrowing of his femoral artery, and he was referred to the vascular surgery department for further evaluation. Accordingly, Woodson was examined by Ann Lopez, a nurse practitioner in the vascular surgery department, on December 12, 2005. Lopez noted likely femoral artery disease in Woodson's right leg and instructed him to undergo an angiogram to confirm this diagnosis. The angiogram was originally scheduled for December 30, 2005, but, due to scheduling conflicts that later developed at the Orlando VA Clinic, Woodson was ultimately asked to report to the Tampa VA Hospital on January 11, 2006 instead.

Woodson appeared at the Tampa VA Hospital as scheduled, and the angiogram conducted that day indicated a complete blockage of Woodson's right external iliac artery along with a portion of his right common femoral artery. Based on this result, and after discussing treatment options with Dr. Armstrong, a vascular surgeon, Woodson elected to undergo surgical intervention the following day. On the morning of January 12, 2006, Dr. Armstrong began exploratory surgery on Woodson's right groin. Once inside, Dr. Armstrong found that the blockage in Woodson's external iliac artery could not be cleared and, thus, the artery was rendered "unusable." Jt. Ex. 1 at 538. Consequently, Dr. Armstrong opted to perform a left-to-right femoral-femoral bypass procedure in order to restore blood flow to Woodson's right leg. This procedure involved threading a graft across the inside of Woodson's abdomen from the right groin area to the left groin area and attaching it to the common femoral arteries in each of Woodson's legs such that some of the blood flow from his left leg could be diverted to his right leg. Dr. Armstrong did not report any complications with the surgery, and Woodson convalesced in the hospital for several days thereafter. On January 21, 2006, he was discharged from the hospital with orders to follow up with the vascular surgery clinic in two weeks

and to undergo another doppler test in one month. Woodson complied, and on both visits Woodson's condition was deemed normal.

According to the medical records introduced at trial, Woodson had no notable visits to the Clinic regarding complications from his bypass surgery until December 2008, when he reported groin swelling to a staff nurse via telephone. He was scheduled for an appointment at the Clinic on December 18, 2008. On that day, he was seen by Dr. Ana Goncalves, who noted a possible bypass occlusion and referred him for a vascular consult. On December 29, 2008, he met with Dr. Brad Johnson, a vascular surgeon at Tampa VA Hospital, who referred him for further vascular testing. These tests revealed that Woodson's bypass graft was occluded. After being advised of his treatment options, Woodson opted for an additional surgery to remove the occlusion from his bypass graft. Dr. Johnson performed the surgery on January 9, 2009, and did not note any complications at that time. Woodson was discharged from the hospital on January 14, 2009, but returned the following day after developing a lymphocele, i.e., a collection of lymphatic fluid, in his right groin. He was treated overnight, but left the hospital the next day against the advice of his physicians. He returned on January 20, 2009 for surgery to drain and clean the site of the lymphocele. He was discharged five days later with instructions to return in one week for possible drain removal. Woodson complied with Dr. Johnson's follow up orders.

Woodson's bypass graft was found to be occluded again on May 27, 2009. His prior vascular surgeon, Dr. Armstrong, did not recommend any further surgery at that time because tests showed that, despite the blockage, Woodson had adequate blood flow to his right leg and foot. To date, Woodson has not undergone additional surgery to remove the occlusion.

Presently, Woodson says he suffers from continued right thigh pain and weakness such that

he is generally unable to walk even short distances without stopping to rest. In addition, he says he continues to experience neuropathy in his right foot, which he describes as a constant severe burning sensation. He also claims that he suffers intermittent swelling in his right leg due to the lymphatic damage that occurred in January 2009. Finally, Woodson says he has experienced persistent erectile dysfunction since his January 2006 bypass surgery, which has not been relieved by medication.

II. LEGAL STANDARD

In a negligence action under the Federal Tort Claims Act, the law of the place where the alleged act or omission occurred controls. 28 U.S.C. §§ 1346(b), 2674. The alleged negligence in this suit occurred at the VA Clinic in Orlando, Florida; therefore, Florida law governs.

Florida's medical negligence provisions dictate that "the claimant shall have the burden of proving by the greater weight of evidence that the alleged actions of the health care provider represented a breach of the prevailing professional standard of care for that health care provider." F.S. § 766.102(1). Further, except in cases where a surgical instrument or supply has been left inside a patient's body after surgery, there is no presumption of negligence; rather, "the claimant must maintain the burden of proving that an injury was proximately caused by a breach of the prevailing professional standard of care by the health care provider." F.S. § 766.102(3). To establish proximate cause in Florida, a plaintiff must prove that the defendant's negligence more likely than not caused the plaintiff's injury. *Gooding v. Univ. Hosp. Bldg., Inc.*, 445 So. 2d 1015, 1018 (Fla. 1984).

III. ANALYSIS

The issues in this case are straightforward. First, the Court must determine the standard of care applicable in this case. Then, the Court must decide whether Orlando VA Clinic health care

providers breached the standard of care during the time Woodson was a patient. Finally, if a breach occurred, the Court must then decide whether that breach proximately caused Woodson's injuries. Woodson bears the burden of establishing all three of these elements by a preponderance of the evidence. *Gooding*, 445 So. 2d at 1020.

To assist the Court in making the required determinations, each party presented the testimony of one or more expert witnesses at trial. Woodson's first expert was Dr. John E. Markis, a medical doctor with over 35 years of experience practicing cardiology in Boston, Massachusetts. Woodson additionally offered the expert testimony of Dr. Paul E. Collier, a board-certified general and vascular surgeon currently practicing in Pennsylvania. In rebuttal, the United States offered the testimony of Dr. David V. Cossman, a board-certified vascular surgeon currently in private practice in Los Angeles, California.

A. The Standard of Care

While the experts ultimately diverged in their opinions regarding the specifics of Woodson's case, they generally agreed on the standard of care for detection of a femoral artery occlusion arising from a cardiac catheterization procedure. All three experts opined that health care providers, including nurses, should, at minimum, check the leg pulses of a patient who complains of persistent leg pain following a catheterization procedure. The experts further agreed that, upon finding a weakened or absent leg pulse, health care providers should subject the patient to further vascular testing, i.e., doppler study, angiogram or arteriogram, to locate and investigate the cause of decreased blood flow to the leg. Finally, the experts agreed that, should further testing reveal an occlusion of the external iliac or common femoral artery, or both, the patient may elect to undergo

surgical intervention to restore normal blood flow to the affected leg.²

Based on the agreement of the parties' experts as to the standard of care, the Court finds that health care providers at the Orlando VA Clinic met the standard of care if they checked Woodson's right leg pulses when he appeared on September 8, 2005 with complaints of persistent right leg pain since his cardiac catheterization procedure approximately two weeks before. Further, the Court finds that if the VA Clinic staff discovered that Woodson's leg pulses were weak or absent on that day, they upheld the standard of care if they referred Woodson for additional vascular testing, such as a doppler study. Finally, if VA Clinic staff promptly discovered Woodson's arterial occlusion following additional testing, the Court finds that they upheld the standard of care if they discussed surgical intervention options with Woodson and, upon Woodson's consent, performed surgery to restore blood flow to the leg.

B. Breach

Having defined the standards of care applicable in this case, the Court now proceeds to consider whether the Orlando VA Clinic staff fell below those standards. The evidence at trial showed that Woodson's right leg pulses were not evaluated on his first post-catheterization visit to the VA Clinic on September 8, 2005. In this regard, the medical records reflect that on this day Woodson complained of increasing right leg pain and weakness "due to cath insertion 15 days ago." Jt. Ex. 1 at 236. Nonetheless, neither the nursing note, nor the ambulatory care note indicated that

² All three experts acknowledged that surgery would not necessarily be *required* at this point unless the patient complained of severe leg pain at rest, indicating acute limb ischemia, a condition that can lead to gangrene and amputation of the affected limb without timely surgical intervention. The experts agreed that surgical intervention in cases like Woodson's, where no evidence of acute limb ischemia is found, is not generally considered urgent and may even be put off indefinitely depending on the patient's age, overall health, and the occlusion's impact on daily activities.

Woodson's leg pulses were checked. *See* Jt. Ex. 1 at 236-39. Woodson's experts, Drs. Collier and Markis, testified that VA Clinic staff fell below the standard of care when they failed to at least check Woodson's leg pulses at his first post-catheterization visit. Defense expert Dr. Cossman wholeheartedly agreed. In fact, all three experts testified that VA Clinic staff continued to fall below the standard of care until Woodson's condition was conclusively diagnosed in early January 2006. In the experts' view, Woodson's condition should have been fully investigated upon his first presentation at the Clinic on September 8, instead of drawn out for approximately four months afterward. The Court therefore finds that the health care providers at the Orlando VA Clinic breached the standard of care by failing to promptly diagnose Woodson's condition when he first presented to the clinic with complaints of post-catheterization leg pain.³

C. Proximate Cause

Having found that the standard of care was breached, the Court now considers whether this breach was the proximate cause of Woodson's injuries. Though their ultimate opinions regarding causation differed, the three experts retained in this case generally agreed on the method by which a cardiac catheterization procedure is performed in the leg. The access point for the catheter is the common femoral artery, located in the groin area. From there, access to the coronary arteries is

³ Although the parties did not belabor this point at trial, the Court here notes that the VA Clinic may even have fallen below the standard of care prior to September 8, 2005. In this regard, Woodson himself provided unrebutted trial testimony that on the day after his catheterization procedure, he called the VA Clinic complaining of leg pain. He further testified that he was told he must schedule an appointment and that the first available appointment was in three weeks. Woodson then recounted that he called the Clinic almost every day after that to try to get an earlier appointment, sometimes waiting as long as two hours on the phone to speak to a representative. Though these facts do not alter the outcome of this case, the Court hopes that Woodson's inability to obtain a critical follow-up appointment within the VA health care system is the exception and not the rule.

achieved by proceeding proximally underneath the inguinal ligament and through the external iliac artery toward the abdominal aorta. After the procedure is complete and any arteriograms or angiograms obtained, the puncture site is resealed, either by applying pressure to the site for several minutes or by using a closure device, e.g., an Angio-Seal. The experts agreed that arterial occlusion is a known complication of the cardiac catheterization procedure.

Turning to Woodson's case, all three experts opined that Woodson's occluded artery was a complication from the cardiac catheterization procedure performed at WPMH on August 22, 2005. They further agreed that the blockage stretched from at or near the puncture site in the common femoral artery all the way up through the external iliac artery. Finally, the physicians believed that this blockage formed within a day or two of the catheterization procedure.

The experts were less agreeable as to whether Woodson would have suffered the same complications had the Orlando VA Clinic upheld the standard of care upon Woodson's first visit following the catheterization procedure. In this regard, each physician had his own theory as to how Woodson's artery was injured during the catheterization procedure and whether he would have needed a femoral-femoral bypass to restore blood flow to his leg even if the occlusion had been detected some four months earlier.

Dr. Markis, Woodson's expert cardiologist, believed that the occlusion was caused by misplacement of the Angio-Seal device at the conclusion of the catheterization procedure. As Dr. Markis described it, there are multiple ways that misplacement of the device could cause an arterial occlusion. For example, collagen meant for the outside of the artery could escape into the interior of the artery, interrupting blood flow in the leg. Or, some or all of the device, if not properly anchored to the wall of the artery, could impede blood flow, eventually causing the artery to fully

occlude. Though Dr. Markis was unsure of the precise method by which Woodson's Angio-Seal device was misplaced, he believed that such misplacement was more likely than not the cause of the occlusion in Woodson's common femoral and external iliac arteries. His belief in this regard was based on the angiogram performed at the time of Woodson's catheterization procedure, which, in his view, showed no signs of direct damage to the arteries in Woodson's right leg.

Despite the passage of over two weeks between Woodson's catheterization procedure and the time he first presented to the VA Clinic on September 8, 2005, Dr. Markis believes that Woodson's occluded artery could have been remedied without the need for a bypass procedure had it been discovered at that time. In this regard, Dr. Markis indicated that the occlusion was likely still fresh enough to allow a surgeon to simply insert a Fogarty catheter into the occluded artery, inflate a balloon and pull the clot out. He further indicated that this procedure would likely have been successful, and preferable, in Woodson's case.

Woodson's expert vascular surgeon, Dr. Collier, had a somewhat different theory as to what caused Woodson's artery to occlude. Dr. Collier believed that more likely than not, upon removal of the catheter from Woodson's common femoral artery, the innermost layer of the artery wall flipped down into the artery, causing blood to dissect, or push down between the layers of the vessel.⁴ In Dr. Collier's view, this dissection substantially narrowed the artery, which slowed the blood flow enough to cause it to clot up to the next major branch, i.e., to the top of the external iliac artery.

⁴ Dr. Collier later indicated that the occlusion could also have been caused by the misplacement of the Angio-Seal device but discarded that possibility in favor of the dissection theory because he saw no evidence of either collagen or the device in the pathology report stemming from Woodson's bypass surgery.

In the end, however, Dr. Collier agreed with Dr. Markis' assessment of the probable course of treatment for Woodson had his condition been discovered in September 2005. Like Dr. Markis, Dr. Collier believed that based on Woodson's age, physical condition, and lack of major vascular disease, a localized procedure in the groin would have been extremely successful. In this regard, Dr. Collier explained that a surgeon likely could have reopened Woodson's common femoral artery, removed the clot via Fogarty catheter, repaired the inside of the artery via endarterectomy, and patched the artery with a piece of neighboring vein. In fact, based on his surgical experience, Dr. Collier believed that this procedure would have been a viable option even two to two and a half months after Woodson's artery occluded.⁵

Defendant's vascular surgery expert, Dr. Cossman, offered a third alternative explanation for the cause of Woodson's occlusion. Dr. Cossman prefaced his opinion, however, by indicating that he did not know for sure what the mechanism of arterial injury was in this case and he also did not know for sure where exactly the injury occurred. He was willing to offer, however, that in his experience, when the injury is isolated in the common femoral artery, the external iliac artery usually stays open. He explained that this was likely due to the existence of smaller arteries, i.e., the circumflex arteries, which allow the blood to continue to run off from the external iliac artery even when the common femoral artery is occluded. In Woodson's case, Dr. Cossman believed that because the external iliac artery was fully occluded, it must have sustained injury. If indeed this was the case, Dr. Cossman opined, the artery would likely have rethrombosed once the original clot was removed, rendering it useless for permanently reestablishing blood flow.

⁵ Dr. Collier further testified that he had personally been able to remove clots using this method up to a couple of *years* after the clot first formed.

Based on his surgical experience, and the fact that Dr. Armstrong's post-operative report indicated that the occlusion in the external iliac artery was "rock hard," Dr. Cossman believes that even if surgery had been performed four months earlier, a localized clot removal would not have successfully re-established blood flow to Woodson's leg. In other words, Dr. Cossman believes that Woodson would likely have required a femoral-femoral bypass even if he had undergone surgery in September 2005.

At the end of the day, all three experts appeared knowledgeable, credible and highly qualified to render opinions in this case, and each provided a plausible explanation for how and why Woodson's artery occluded. However, the Court need not decide which of the experts' explanations is the most likely or the most persuasive; Woodson ultimately failed to demonstrate that, more likely than not, he would not have suffered the same injuries had even a localized thrombectomy been successfully performed four months earlier.

At trial, Woodson identified a number of surgical complications which, in his view, were caused by the delay in diagnosing his occluded artery in late 2005 and early 2006. First, Woodson complained of continued right thigh neuropathy beginning around the time of his January 2006 bypass surgery. However, all three experts agreed that thigh neuropathy is a risk of *any* surgery in the groin area. Thus, they opined, Woodson's risk of experiencing thigh neuropathy would likely have been the same even if a localized operation had been conducted four months earlier.⁶

Woodson next claims that he should be compensated for the lymphatic damage he

⁶ Though Dr. Markis initially testified that Woodson's thigh neuropathy was less likely to occur with a direct repair surgery, he conceded on cross-examination that either surgery would have entailed the same risk of thigh neuropathy.

experienced following the January 2009 surgery to remove the bypass graft occlusion. As with Woodson's thigh neuropathy, however, Drs. Collier and Cossman opined that a risk of lymphatic damage is inherent in *every* operation in the groin area.⁷ Thus, had Woodson undergone surgery in September 2005, his risk of developing a lymphocele would have been no less than it was in January 2009.⁸

Woodson's allegation that the VA Clinic is responsible for his erectile dysfunction is equally untenable. All three experts agreed that none of the surgeries Woodson has undergone thus far are known to have any direct impact on sexual performance. Dr. Collier suggested that there may be some psychological connection between Woodson's ability to feel the graft inside his abdomen and his erectile dysfunction. Dr. Cossman suggested that perhaps Woodson's medication could be the culprit. Neither of these explanations satisfies the Court that Woodson's erectile dysfunction was more likely than not caused by the VA Clinic's delay in diagnosing his arterial occlusion.

Finally, Woodson charges that the VA Clinic should compensate him for the neuropathy in his right foot. At trial, the experts agreed that this complication is a nerve injury caused by prolonged lack of blood flow to the foot. However, Woodson testified that he first noticed burning

⁷ Dr. Markis' opinion that Woodson would have been less likely to develop lymphatic complications if a localized repair was conducted in September is entitled to less weight; Dr. Markis testified that he is not an expert in vascular surgery.

⁸ Dr. Collier opined that Woodson would not have developed a lymphocele if he'd had localized surgery in September 2008 because the localized procedure would not have necessitated the January 2009 surgery that ultimately resulted in the lymphocele. Unfortunately, this observation fails to acknowledge that Woodson's actual failure to develop lymphatic complications during his first surgery in January 2006 does not necessarily mean that the outcome would have been the same four months earlier. As Dr. Collier testified, the risk of developing lymphatic complications is the same for *every* groin surgery.

in his foot in November or December 2008, almost three years after his bypass surgery. Though both Dr. Collier and Dr. Markis believed that this complication nonetheless arose due to the VA Clinic's four month delay in reestablishing blood flow to Woodson's right leg, neither expert explained why the complication took approximately three years to manifest itself. Indeed, Dr. Markis testified that he did not know in general how long it might take for foot neuropathy to develop as a result of decreased blood flow. Therefore, the Court finds that Woodson has presented insufficient evidence to establish a causal connection between his foot neuropathy and the VA Clinic's failure to uphold the standard of care three years earlier.

As an aside, to the extent Woodson believes that the Orlando VA Clinic's failure to promptly diagnose his occlusion caused him to be subjected to additional surgeries that he otherwise would not have needed, the Court is unconvinced. Both Dr. Cossman and Dr. Collier agreed that Woodson's bypass graft failed because he developed intimal hyperplasia, a condition that causes arteries to compensate for injuries by generating excess scar tissue. According to both surgeons, this scar tissue can substantially narrow the artery, causing blood flow to slow and ultimately clot, resulting in an occlusion. The experts opined that intimal hyperplasia can result from either a femoral-femoral bypass procedure or a localized endarterectomy and patch. Dr. Cossman further explained that the likelihood of developing an occlusion due to intimal hyperplasia is comparable for both procedures. Dr. Collier did not offer any testimony discounting Dr. Cossman's assessment in this regard.⁹ Therefore, it appears that Woodson was just as likely to develop intimal hyperplasia,

⁹ Dr. Collier did opine that the primary patency rate of a localized clot removal, endarterectomy and patch is 90% in five years as opposed to 70% in five years for a femoral-femoral bypass graft; however, it appeared from the remainder of Dr. Collier's testimony that these figures reflected only the likelihood of total occlusion, and did not take into account the likelihood that

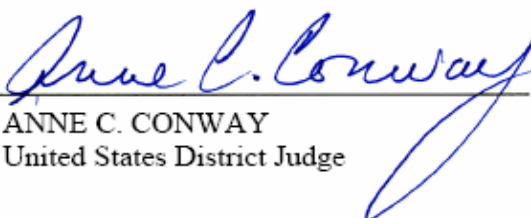
and therefore subsequent occlusions, had he undergone even a direct repair in September 2005.

IV. CONCLUSION

In sum, although the precise mechanism by which Woodson's femoral artery was injured, and, thus, the repair options that were available to him in September 2005, remain unclear, Woodson must still establish that his claimed injuries were more likely than not the result of the Orlando VA Clinic's failure to promptly diagnose his arterial occlusion. He was unable to do so at trial. Therefore, the Court concludes that Woodson has failed to uphold his burden of demonstrating that the Clinic's breach of the standard of care during the four months following his cardiac catheterization procedure was the proximate cause of his injuries.

Accordingly, the Court finds in favor of the Defendant, United States of America. The Clerk is directed to enter judgment for Defendant and close this case.

DONE and ORDERED in Chambers, in Orlando, Florida on December 2, 2009.


ANNE C. CONWAY
United States District Judge

Copies furnished to:

Counsel of Record

further groin surgery might be needed to remedy symptoms associated with a substantial narrowing of the artery due to intimal hyperplasia.