HARMONIC® Ultrasonic Technology: Advances in Surgery for Peripheral Vascular Disease

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Introduction

Many surgeons, seeking the ability to cut, coagulate, and seal vessels near sensitive structures with minimal lateral thermal spread, have chosen ultrasonic devices such as the family of HARMONIC® surgical instruments to perform these tasks. Other options for cutting, coagulation, and sealing during surgery include mono- and bipolar electrosurgery devices; however, the application of high heat in electrosurgery can cause surrounding tissue damage. This effect has led to interest in device modalities that can effectively cut, coagulate, and seal with a lower risk for heat-related damage.

Providing minimal lateral thermal spread for dissection near vital structures, the ultrasonic HARMONIC FOCUS® Curved Shears (Figure 1) is the newest device in the HARMONIC® family that includes the HARMONIC WAVE® Open Shears and HARMONIC ACE® Curved Shears. The FOCUS® and other HARMONIC® devices operate by denaturing proteins via heat produced by ultrasonic vibrations at a frequency of 55.5 kHz. The FOCUS® Curved Shears also allow for sealing vessels up to 5 mm as well as lymphatics (Figure 2). These devices are designed to minimize the hazards of electrosurgery by not conveying electricity to or through the patient.

According to Apostolos K. Tassiopoulos, MD, FACS, associate professor of surgery and chief of the Division of Vascular Surgery at Stony Brook University Medical Center in Stony Brook, NY, the multifunctional design of the FOCUS® minimizes the need for frequent instrument changes and shortens time for dissections in a variety of operations, which may result in an overall reduced operating time. Although data from randomized clinical trials are necessary to provide confirmation.

The success of HARMONIC® technology in fields such as gastrointestinal and thyroid surgery has led to its exploration for use in lower limb vascular surgery, which often presents with unique challenges related to arterial and venous exposure in lymphatic-rich areas and the potential for nerve damage.

Peripheral Vascular Disease: A Surgical Approach to Treatment

Peripheral vascular disease (PVD) often is referred to as peripheral arterial disease (PAD). The disease most commonly results from atherosclerosis of the large arteries, usually affecting the lower extremity or leg. The prevalence of PAD increases with age; patients with PAD can be in their 50s, but are generally older. Patients with PAD often have poor nutritional status, and present with concomitant coronary artery disease, hypertension, and diabetes. Diabetes is an independent risk factor for poor wound healing, and its related effects, such as neuropathy, can exacerbate factors associated with inadequate healing.

Severe PAD may require bypass surgery, which can be a difficult process for patients, as many are elderly and sicker. "Any prolonged hospitalization, any setback experienced by these patients may put them at higher risk for heart attack or stroke as compared with younger, healthier patients," said Patrick E. Muck, MD, FACS, chair of the Section of Vascular Surgery, and program director of Vascular Surgery Residency at the Good Samaritan Hospital in Cincinnati, Ohio. "Anything that can be done to minimize their wound complications will contribute to the success of the procedure and to patient recovery."

PVD or PAD may refer to arterial inflow disorders (ie, arterial insufficiency), or venous outflow disorders (ie, venous insufficiency). Three procedures are designed to correct aortoiliac or inflow disease: aorta bifemoral bypass grafting, in which a bypass graft is inserted to carry blood flow from the aorta to the femoral arteries; axillo–femoral grafting, in which a graft placed at the axillary artery and extended to the femoral arteries; and femoro–femoral bypass grafting, in which a graft originates in a normal femoral artery in one leg and transports blood to the femoral artery in the opposite leg. For infrainguinal or outflow disease, femoro–popliteal and femoral–tibial grafting, in which a graft from the femoral artery in the groin is attached to the popliteal artery or to one of the tibial arteries, respectively, are

Figure 1. HARMONIC FOCUS® Curved Shears.
Image courtesy of Ethicon Endo-Surgery.

Figure 2. HARMONIC FOCUS® used in femoro-popliteal bypass surgery.
Image courtesy of Ethicon Endo-Surgery.

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1 Data on file at Ethicon Endo-Surgery, Inc. Based on preclinical testing of lymphatic vessels up to and including 1 mm in diameter.

2 Use of the HARMONIC® technology in pancreatectomy® saved over 30 minutes compared with cut, clamp, and tie.
used to treat PAD and restore normal blood flow. In some situations, a synthetic graft (made of artificial material) may be used for the bypass graft, rather than a vein graft.3

Neither physician currently uses electrocautery in femoro-femoral or femoral-popliteal procedures. Instead, both stated that they use a scalpel to cut through the dermis and then use the HARMONIC FOCUS® to cut through the layers of subcutaneous tissue to reach the target vessel (Figure 3). “The biggest issue that we had with electrocautery was the potential for damage to the surrounding tissue,” Dr. Muck said. “With the FOCUS®, however, that is less of a concern.

“The FOCUS® moves through the tissue quickly,” Dr. Muck added. “It can grasp, coagulate, and cut tissue; and you can also use it to dissect. It’s like having multiple devices in one. Typically, you cut with the Bovie® [device] and then get a right angle, or put the Bovie® down and ask for a different instrument in order to help dissect out the artery. But with the HARMONIC® [device], you can do it all with one instrument.”

According to Dr. Tassiopoulos, the FOCUS® accomplishes 2 major objectives in dissecting soft tissue (Figure 4). “First, the FOCUS® seals small vessels in the subcutaneous tissue that can bleed slowly throughout and after the procedure. This is particularly important because all of these patients are fully anticoagulated during the operation;” Dr. Tassiopoulos said. “Second, the FOCUS® also seals the subcutaneous and peri-arterial lymphatic vessels, which helps establish a dry surgical wound at the end of the procedure.”

“If you don’t seal the lymphatic tissue, or if you cut or desiccate that fat tissue—always a risk with electrocautery—you invite poor wound healing;” Dr. Muck added. “The incision can open and infection can then set in.”

Complications of Peripheral Vascular Surgery

Less serious complications from peripheral vascular surgery may include swelling or inflammation at the incision site. Other complications, such as blockage of the bypass, bleeding from the incision, or infection, are potentially more serious, according to the physicians. The area potentially at the highest risk for infections or wound complications following surgery is the groin incision4; reported rates of wound complications vary widely. Swinnen and colleagues evaluated 116 dissections (88 patients) and reported that 11% (13 patients) were diagnosed with wound infections by day 28.5 Other researchers have found higher infection rates in vascular graft procedures.6

Both physicians are encouraged by the potential for reduction in wound complications they have personally observed using the FOCUS® and consider this one of the device’s most important advantages. “If we can minimize infection rates, we can improve the procedure in ways that directly impact patient outcomes,” Dr. Tassiopoulos said. “We will see decreased operative-related morbidity, fewer office visits, fewer rehospitalizations, a reduction in the need for at-home wound care, and a reduced need for antibiotics.” Ideally, Dr. Tassiopoulos noted, data confirming these observations will be forthcoming, as data in other indications have developed over time.

Learning Curve

“The HARMONIC [FOCUS®] is very efficient because you are using it as a cutter, dissector, and a [sealing] instrument—[thereby] minimizing instrument exchange,” Dr. Muck said. He noted that learning how to effectively use the FOCUS® for multiple tasks took practice. “The first couple of cases took longer because the device felt a bit unfamiliar. My colleagues in general surgery, who were using it for breast and thyroid surgery, encouraged me to continue using it. Once I got past the learning curve and got more comfortable using the device, its merits and advantages became overwhelmingly apparent,” Dr. Muck said. “So far there have been no clinical trials conducted in this area. However, they may be in the works. I have no doubt that as the data is accrued, the HARMONIC FOCUS® will prove itself and, at that time, more physicians will begin using it.”

References

2. Data on file, Ethicon Endo-Surgery, Inc. * In a retrospective analysis of data from 623 US hospitals, use of the HARMONIC® Technology in pancreaticectomy procedures performed in 2008 resulted in a statistically significant mean time savings as compared to cut, clamp, and tie [6.9 hours vs 7.4 hours (P=0.022)].