Assessing Tissue Perfusion in Diabetic Foot Ulcers and Non-Healing Wounds: LUNA Fluorescence Angiography System

Treating diabetic foot ulcers (DFUs) and non-healing wounds is a challenge to many clinicians due to the need for updated diagnostic imaging technology and patient adherence. In recent years, studies have shown a growing epidemic of peripheral arterial disease (PAD) and critical limb ischemia (CLI) due to a growing aging population and increased diabetes prevalence. Given these issues, various clinicians presented on emerging solutions October 18–20, 2013 at the LUNA Summit in Las Vegas, Nevada.

Diabetes currently affects 194 million people worldwide. Two to six percent of those people will develop a DFU.1 If the trend continues at the current rate, over 50 percent of the population aged 65+ will have diabetes by 2040, a startling number considering the corresponding risk of complications such as DFUs, PAD, CLI, and amputation.2–6 While amputations have declined over the last 15 to 20 years, there are still 65,000–70,000 amputations performed annually7–10 and in 54 to 73 percent of these cases, there is no angiogram performed despite the fact that angiograms can reduce the odds of amputation by 90 percent.7–9,11,12 In 60 to 71 percent of lower extremity amputations, revascularization is not attempted prior to amputation and amputation is frequently used as the first and only treatment for CLI.11,12 If clinicians utilize diagnostic imaging technology efficiently, it may help them choose more effective treatment to enhance wound healing in these patients and help prevent amputations.

Medial calcinosis, scarring, wounds, prior amputations, and infection often limit current methods of evaluating tissue perfusion and there is no current method to quantify perfusion.13 For example, transcutaneous oximetry monitoring provides useful objective data, but obtaining that data can be a challenge due to environmental variables such as room temperature and patient variables such as edema or inflammation, caffeine, or nicotine use.14 With this modality, only the periwound is measured and it is not possible to place a probe into the wound itself. In extremely thin patients, bony prominences limit scanning ability as well and interpreting that data is quite challenging.14

The Solution: Introducing the LUNA Fluorescence Angiography System

One potential solution for screening and treating challenging wounds is the new LUNA Fluorescence Angiography system manufactured by Novadaq.

The LUNA Fluorescence Angiography System is an emerging modality in assessing tissue perfusion in DFUs and chronic non-healing wounds using SPY Technology. SPY Technology utilizes fast, real-time imaging that allows clinicians to capture and review high-quality image sequences of blood flow in vessels and microvessels, tissue and organ perfusion.

Using the LUNA system, clinicians treating chronic wounds in patients with peripheral vascular disease can distinguish between perfused and non-perfused tissue during the monitoring and treatment of serious wounds, including DFUs and pressure sores. The ability to distinguish between perfused, healthy tissue and non-perfused, non-viable tissue may contribute to more effective treatment strategies and wound healing outcomes.

The LUNA system utilizes an injectable dye, indocyanine green (ICG), which absorbs and reflects light, resulting in fluorescence images that are visible on a computer monitor showing blood flow in vessels and perfusion in the area of the wound. The injectable dye, ICG, has 50 years of safe clinical use and is metabolized by the liver.15 It was first used as a fluorescence imaging agent for ophthalmic angiography and it tightly binds with plasma protein in blood.15 When injected, ICG stays within the vasculature and does not leak into the extravascular space and therefore allows for multiple images in the same patient setting.15 ICG is contraindicated in patients allergic to iodine.15

When using the LUNA system, the operator has full control of the imaging head and determines where imaging is necessary in the patient’s limb. Clinicians can then conclude if there is enough flow to promote healing in the wound. Images are immediately visible and the procedure takes approximately five to 10 minutes.

With real-time tissue perfusion visualization, clinicians can give patients instant feedback about the diagnosis and treatment of a wound, determine whether there is adequate blood flow, and make informed decisions about the best treatment in each individual case for the best healing outcome. Fluorescence imaging is commonly used in other medical procedures such as; mastectomy and breast reconstruction, colorectal resections, head and neck reconstruction, abdominal wall reconstruction, amputations (including replantations), lower extremity reconstruction, determining the need for hyperbaric oxygen therapy (HBOT), and wound care.

Hyperbaric Oxygen Therapy

The LUNA Fluorescence Angiography system may help identify patients who would benefit from HBOT. HBOT elevates the tissue oxygen tension in wounds and is indicated for use in wounds caused by arterial insufficiency, delayed radiation injury (soft tissue and bony necrosis), and compromised grafts and flaps.

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Some non-healing surgical wounds could be avoided by using fluorescence angiography to detect microvascular disease. This enables clinicians to delay surgery until optimal angiogenesis is achieved with HBOT. Detecting microvascular disease early and utilizing HBOT can decrease the risk of major amputation from 9 percent (1 in 10) to 31 percent (1 in 3).

Dr. Andrew Salzberg presented one example of successful collaboration with fluorescence angiography and HBOT as shown in figures 2A to 2C. Figure 2A shows a standard fluorescence vascular angiogram of a patient’s foot at the beginning of his HBOT. At the first 30-second interval during HBOT, you can see where the wound is a bit more vascularized (Figure 2B). At the next 30-second interval during HBOT, one can see the improved vascularization (Figure 2C). The intervals are relative to the imaging sequence to make valid comparisons before and after therapy. Fluorescence angiography imaging before and after HBOT allowed the physician to determine the need for further HBOT post-revascularization.

Another example shows an ulcer on the side of the foot. The ulcer has somewhat decreased adequate blood flow (Figures 3A–3D). With the LUNA fluorescence angiography system, the clinician gets a detailed procedure report of how much dye was injected, how many images were taken, and the outcomes before and after HBOT in ischemic patients. Patients tend to be more adherent when they can visualize their blood flow as dramatically increased or decreased during treatment.
Case Reports

Case Report 1

A 43-year-old male patient presented to the wound care center with a one-month history of a painful ulceration on the fourth metatarsal (Figures 4A and 4B). SPY technology indicated the inability to restore perfusion of the fourth metatarsal and the surgeon was able to determine the need for digit amputation as well as the level of amputation needed (Figures 5A and 5B). The patient’s wound subsequently healed without further incident.16

Case Report 2

A 61-year-old male patient presented with a 15-month non-healing wound on his heel and a history of prior amputation. He was examined previously in several different wound centers and had a palpable dorsalis pedis pulse. He was treated with a total contact cast and the ulcer did not heal. Upon examination, Joseph Mills, MD, knew that the heel was ischemic. An arteriogram showed multiple stenoses in the tibioperoneal trunk and an occluded posterior tibial artery. Dr. Mills tried to put in a wire and was successful to the ankle but there was no plantar branch to re-enter. After treating the tibioperoneal trunk and peroneal artery, he used the ICG angiography, which showed marked improvement in regional perfusion and the wound healed within six weeks (Figure 6). ICG angiography allowed Dr. Mills to predict healing outcomes post-intervention.13

Case Report 3

A 62-year-old patient with type I insulin-dependent diabetes presented with a history of cigarette smoking for 30 years, myocardial infarction in his 50s, and percutaneous coronary intervention of his right coronary artery. He developed a diabetic foot ulcer that required seven surgeries over five years. He had more than a year of IV antibiotics through a PICC line and five years of relative immobility and home confinement. A right below-the-knee amputation was performed but he developed a deep vein thrombosis and pulmonary embolism postoperatively. Fluorescence angiography was not used in this case. The patient’s diagnosis and treatment might have proceeded differently if fluorescence angiography imaging diagnostics were utilized.

Amputation: What Are The Costs?

Amputation is less cost-effective than bypass or endovascular intervention. The patient cost for amputation includes lost wages, co-payments and deductibles, and modifications for disabled living, which doesn’t include other negative patient outcomes such as poor ambulation (60%–80% are unable to walk),17 depression (35%),11,18 high 2-year mortality rates (30%–50%),20–22 contralateral amputation (36%–50%),11,18,20 hospital readmissions (22% at 30 days),19 lengthy healing process,25–26 reduced quality of life,23–26 and chronic pain (95%).23–26 Economic burdens of DFUs and amputation according to a Medicare analysis in 2008 was $54,100 for amputations and $35,100 for DFUs (Figure 7).7,27

Figure 6. The patient in case report 2 presented with a 15-month non-healing wound and fluorescence angiography showed the blood flow to the wound to determine accurate treatment (A). After treating the TP trunk and peroneal artery, angiography showed marked improvement in regional perfusion (B)

Figure 7. The economic burden of DFUs and amputation is shown.
Reimbursement for New Technology

Reimbursement for fluorescence angiography procedures is reasonable when properly documented. For fiscal year 2013, the Centers for Medicare and Medicaid Services assigned code C9733 to describe LUNA fluorescence angiography. The clinician should verify the claim with the insurance company to ensure he or she is using the correct coding. Precise documentation noting all procedures performed and the medical necessity for each will aid clinicians in getting reimbursed.

As of the LUNA Summit on October 19, 2013, the average national Medicare payment was approximately $350 per medically necessary LUNA procedure. The key to reimbursement is proper documentation, including the medical history, procedures performed, and medical necessity of each.

Conclusion

With LUNA fluorescence angiography imaging technology, clinicians can properly assess a wound’s ability to heal, enabling them to possibly consider other treatment options that may preserve the patient’s limb. The LUNA fluorescence angiography system offers a simple procedure utilizing laser light and yielding fast, real-time angiographic results in a matter of minutes. As shown in the case reports, this technology can assist clinicians in determining wound healing outcomes. While further studies are currently underway and are a necessary part of learning more about this emerging technology, the current data is both intriguing and promising. For further information about ongoing research, please visit http://novadac.com.

References