Richard Carreon, managing director and CEO, ImpediMed discusses how BIS technologies can address lymphedema and other complications arising from breast cancer. The technology aims to boost survival rates.

Studies show that over 40 percent of breast cancer survivors suffer from lymphedema within three years of initial diagnosis. The distressing and sometimes debilitating condition cannot be cured and must be managed for the rest of a survivor’s life. Until now, providers had few options to monitor the onset of the condition.

A new solution to this issue is ImpediMed’s L-Dex technology for lymphedema measurement, a medical device employing bioimpedance spectroscopy (BIS) technology. To understand more about this medtech development, Richard Carreon, managing director and CEO, explains the application to Digital Journal.

**Digital Journal: What is the approximate survival rate for breast cancer?**
Richard Carreon: More women are diagnosed with breast cancer than any other cancer, excluding skin cancer. This year, an estimated 266,120 women in the United States will be diagnosed with invasive breast cancer, and 63,960 women will be diagnosed with in situ breast cancer. An estimated 2,550 men in the United States will be diagnosed with breast cancer. The five-year survival rate tells you what percent of people live at least five years after the cancer is found. The average five-year survival rate for people with breast cancer is 90 percent. The average 10-year survival rate is 83 percent.

If the cancer is located only in the breast, the five-year relative survival rate of people with breast cancer is 99 percent. Sixty-two percent (62 percent) of cases are diagnosed at this stage. If the cancer has spread to the regional lymph nodes, the five-year survival rate is 85 percent. If the cancer has spread to a distant part of the body, the five-year survival rate is 27 percent. Currently, there are more than three million women living with breast cancer in the United States with breast cancer.

DJ: What is lymphedema and what are the implications?

Carreon: Lymphedema refers to swelling that generally occurs in one of your arms or legs. Sometimes both arms or both legs swell. Lymphedema is most commonly caused by the removal of or damage to your lymph nodes as a part of cancer treatment. It results from a blockage in your lymphatic system, which is part of your immune system. The blockage prevents lymph fluid from draining well, and the fluid buildup leads to swelling.

While there is presently no cure for lymphedema, it can be managed with early diagnosis and diligent care of your affected limb.

Lymphedema signs and symptoms, which occur in your affected arm or leg, include:
Swelling of part or all of your arm or leg, including fingers or toes
A feeling of heaviness or tightness
Restricted range of motion
Aching or discomfort
Recurring infections
Hardening and thickening of the skin (fibrosis)
The swelling caused by lymphedema ranges from mild, hardly noticeable changes in the size of your arm or leg to extreme changes that make the limb hard to use. Lymphedema caused by cancer treatment may not occur until months or years after treatment.

DJ: How can lymphedema be managed?

Carreon: There is no cure for lymphedema today. Treatment focuses on reducing the swelling and controlling the pain. This highlights the importance of early detection and early intervention to prevent the progression of the disease to clinical lymphedema.

Lymphedema treatments include compression garments. Long sleeves or stockings made to compress your arm or leg encourage the flow of the lymph fluid out of your affected limb. Other treatments include light exercises in which you move your affected limb may encourage lymph fluid drainage and help prepare you for everyday tasks, such as carrying groceries.
Bandaging your entire limb encourages lymph fluid to flow back toward the trunk of your body. A special massage technique called manual lymph drainage may encourage the flow of lymph fluid out of your arm or leg. Also, with pneumatic compression, a sleeve worn over your affected arm or leg connects to a pump that intermittently inflates the sleeve, putting pressure on your limb and moving lymph fluid away from your fingers or toes.

There is also Complete decongestive therapy. This approach involves combining therapies with lifestyle changes. Generally, CDT isn't recommended for people who have high blood pressure, diabetes, paralysis, heart failure, blood clots or acute infections.

In cases of severe lymphedema, a doctor may consider surgery to remove excess tissue in the arm or leg to reduce swelling. There are also newer techniques for surgery that might be appropriate, such as lymphatic to venous anastomosis or lymph node transplants.

DJ: What proportion of breast cancer survivors suffer from lymphedema? Does this vary by regions?

Carreon: A recent meta-analysis reports the incidence of breast cancer–related lymphedema to range from 0 to 3 percent after lumpectomy alone to as high as 65 percent to 70 percent after modified radical mastectomy (removal of breast and axillary lymph nodes) with regional nodal radiation. Overall, 80 percent to 90 percent of women who will develop lymphedema do so within three years of treatment, but the risk persists years later as the remaining 10 percent to 20 percent will develop lymphedema at a rate of one percent per year. Data suggest that lymphedema is probably more common than generally reported, and clearly the length of follow-up in a given study influences the reported incidence. Risk factors include number of nodes removed and location of those nodes, radiation, and obesity. These are more relevant to the development of lymphedema than regional location.

DJ: What is ImpediMed’s L-Dex technology for lymphedema measurement?

Carreon: ImpediMed’s digital health platform utilizing the L-Dex technology is based on the use of bioimpedance spectroscopy, or BIS, which is the most accurate and most sensitive type of bioimpedance. BIS provides the most accurate measure of extracellular fluid (ECF) available in a rapid and non-invasive manner. It is able to determine small fluid shifts, as small as ~36mL, in the human body which are medically meaningful.

For lymphedema, this means L-Dex can detect excess accumulation of ECF long before any visible or measurable swelling occurs. This earlier detection enables earlier intervention which has been shown to drastically reduce the incidence of clinical, chronic lymphedema in study after study.

DJ: How does bioimpedance spectroscopy work?

Carreon: Bioimpedance spectroscopy uses 256 unique frequencies that are sent through the body and the impedance is measured at each one. It provides an accurate determination of solely the ECF compartment which includes lymph fluid, as well as the impedance of intracellular fluid and total body water. A simple 30-second measurement made with ImpediMed’s SOZO device can provide accurate estimates of fluid levels and their distribution, L-Dex scores for unilateral...
or bilateral lymphedema of the arm or leg in men or women, as well as general fluid and tissue analysis for the general health and nutritional status of patients.

**DJ: What is the collected data used for?**

**Carreon:** In the clinic or hospital, the data provided by SOZO can be instrumental in detecting the onset of lymphedema at the earliest possible point, which has been shown to drastically reduce the incidence of clinical lymphedema and greatly improve outcomes for patients. The wealth of additional data provided by SOZO can be used to monitor and manage the overall health of cancer survivors or to monitor patients living with heart failure.

The deidentified data collected by ImpediMed in the cloud allows us to analyze large datasets of population health information and create new or improved algorithms for current outputs, as well as create new predictive algorithms in the future for even earlier identification of potential health issues to both lower the cost of care and improve the patient outcomes.

**DJ: How was the technology assessed?**

**Carreon:** ImpediMed's bioimpedance spectroscopy technology has been verified and validated in a variety of studies and trials, both clinical and not, since the early 1990s. There are over 400 peer-reviewed and published papers using ImpediMed's BIS technology. ImpediMed's technology has been compared many times to DXA for tissue analysis and dilution techniques for fluid determination and correlation results are excellent.

The L-Dex technology has also been the subject of countless published studies and is now the recommended technology for the early assessment of lymphedema by organizations, such as the NLN (National Lymphedema Network), NAPBC (National Accreditation Program for Breast Centers), the APTA (American Physical Therapy Association), and many clinics and hospitals across the United States.

More about lymphedema, breast cancer, medical technology, medtech