BIS Backgrounder

BREAST CANCER-RELATED LYMPHEDEMA NOW HIGHLY PREVENTABLE, STUDIES SHOW

SOZO: A New Comprehensive and Dynamic Physiologic Measurement from ImpediMed

Over 250,000 women each year develop breast cancer[1], and as many as 2-65 percent of these patients may develop incurable breast cancer-related lymphedema (BCRL)[2], a secondary disease caused by cancer or its treatment. BCRL can be treated, and in many cases halted, when caught early. Technology from ImpediMed makes early detection, simple intervention and prevention possible.

Two Key Studies Using Bioimpedance Spectroscopy Recently Released

Pat Whitworth, M.D., of the Nashville Breast Center, followed breast cancer patients at risk for the development of lymphedema from April 2010 to November 2016.[6] ImpediMed's bioimpedance spectroscopy technology was utilized in a prospective surveillance model to identify patients with early/subclinical indications for the development of BCRL. The six-year study of nearly 600 breast cancer survivors showed a demonstrable reduction in patients with BCRL for those who received a pre-surgical baseline bioimpedance spectroscopy test with ImpediMed's L-Dex® U400, a precursor to its new SOZO™ system, and subsequent monitoring throughout their treatment. Positively, only 18 of the 596 patients (3 percent) developed BCRL – as compared to the 2-65 percent of patients who could have developed lymphedema, as prior published studies have suggested.

David I. Kaufman, M.D., F.A.C.S, Chief of Breast Surgery St. Joseph Hospital, Bethpage, NY, Assistant Professor of Surgery, Hofstra Northwell School of Medicine, Hempstead, NY, conducted a retrospective analysis beginning in 2010 of 264 patients prospectively surveilled for the development of BCRL using ImpediMed's bioimpedance spectroscopy technology.[7] All patients had a baseline assessment and a minimum of two post-operative follow-up assessments, at which time 28 patients (10.6%) had elevated L-Dex scores and underwent a 4-week compression sleeve treatment. After treatment, only 4 patients had persistently elevated L-Dex scores, yet remained asymptomatic.

Detecting Lymphedema through Bioimpedance Spectroscopy (BIS)

Bioimpedance refers to the process of sending a painless electrical current, typically at one or more frequencies, through the body. Measuring the body's resistance and reactance in response to this electrical current provides easy access to detailed information regarding fluid and tissue status without the need for an invasive procedure.

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ImpediMed and its subsidiaries pioneered the use of BIS, producing the first commercially available BIS devices in 1990. Studies have shown that with ImpediMed's patented BIS technology, healthcare providers are able to clinically assess a patient and detect lymphedema as much as 4-10 months earlier than other methods.[3] ImpediMed's patented BIS technology is clinically proven and measures impedance at 256 different points over a full spectrum of frequencies from 3 kHz to 1000 kHz, allowing precise analysis of extracellular fluid, intracellular fluid and total body water.

Although other bioimpedance systems do exist, these methods are often a single frequency approach. Such approaches rely on population-specific data to create an estimated reading of the patient's fluid levels in comparison to a true individual assessment derived through BIS. BIS does not depend on population-specific algorithms, making it a more precise measurement of fluid. Additionally, BIS can replace more traditional means of testing for lymphedema (e.g., circumference measurement [tape measure], water displacement and perometer methods, etc.) as a quantitative measurement that can detect the disease subclinically.

A New Comprehensive and Dynamic Physiologic Measurement from ImpediMed

Just cleared by the FDA for use in the United States, SOZO by ImpediMed aids in the clinical assessment and management of lymphedema. Only SOZO uses ImpediMed's patented BIS and L-Dex technologies to gather and retain thousands of unique data points. Then, it applies indication-specific algorithms to produce accurate, detailed and actionable results in less than 30 seconds, identifying opportunities for early interventions. Studies point to the fact that L-Dex values are a non-invasive and sensitive method to aid in the assessment and early detection of lymphedema of the limb.[3,4,5]

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References

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7. Kaufman, D.I., et al., *Utilization of bioimpedance spectroscopy in the prevention of chronic breast cancer-related lymphedema.* Breast Cancer Res Treat, 2017

About ImpediMed

Founded and headquartered in Brisbane, Australia with U.S. offices in Carlsbad, Calif. and Bloomington, Minn., and a European office in Thessaloniki, Greece, ImpediMed is the world leader in the design and manufacture of medical devices employing bioimpedance spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of tissue and fluid status.

ImpediMed was the first company to receive FDA clearance in the U.S. to aid healthcare professionals to clinically assess unilateral lymphedema of the arm and leg in women and the leg in men, for its L-Dex® device. In addition, ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO, sold in select markets globally. For additional information, visit www.impedimed.com.