Value Proposition
An estimated 15.7% of all critically ill patients have or will develop pressure ulcers during in intensive care units (ICU). Hospitals are not reimbursed by insurance for hospital acquired severe pressure ulcers. We have developed support surface technology that uses targeted cooling of the skin to prevent pressure ulcers from developing or advancing. We will use this targeted cooling technology (PRO-TECT™) in a mattress overlay product for hospital critical care units where pressure ulcers are common and costly. Despite strong evidence from animal and human studies that indicates temperature control is an effective method for preventing pressure ulcers and inhibiting their progression from superficial to serious, no current products employ a cooling feature for this purpose.

Market Opportunity
A device that reduces the risk of developing a pressure ulcer or mitigates later stage progression will significantly reduce costs for the 6,000 US hospitals’ ICUs for critically ill patients. Combined, there are approximately 67,000 ICU beds in the US that are occupied by 55,000 patients daily, totaling 5 million patients annually. The cost to treat Stage 3 or 4 pressure ulcers is estimated to be $45k per incident and is borne entirely by the healthcare site. The progression of superficial pressure ulcers (Stage 1 or 2) to full thickness (Stage 3 or 4) is approximately 20% despite current pressure ulcer treatment guidelines, resulting in annual treatment costs of $8 billion.

Competitive Landscape
A handful of manufacturers dominate the US market for support surfaces for pressure ulcer prevention and treatment, including Hill-Rom, Stryker, Arjo-Huntleigh, RecoverCare, Tempur-Sealy, and ROHO. None of these companies offer support surface product with targeted cooling.

Technology
PRO-TECT includes the key feature of cooling only the areas of the body at highest risk without causing uncomfortable cooling to the entire body—a challenge others have apparently failed to overcome. Selective cooling of those areas of the body that immerse deeply into the mattress is achieved with actively cooled gel pads embedded at the bottom of air cells in targeted area.

Stage of Development
We have been evaluating the effects of temperature control on tissue integrity since 2007. We were the first to show the protective effects of cooling the skin in humans and have developed a prototype device. The First in Human study (128 patients) for this technology is to begin in Jun. ’15.

IP Landscape
A patent application (US20140228918A1) broadly claims “a segmented fluid cushion comprising a plurality of cells interconnected to allow fluid to flow from each cell to at least one of the other plurality of cells; and wherein one or more of the plurality of cells contains a heat exchange material.”

Funding
Pitt has been supported through grants totaling $900K from the National Institute on Disability and Rehabilitation Research and the Paralyzed Veterans of America.
Dr. Brienza is Professor in the School of Health and Rehabilitation Sciences with additional professorial appointment in the Dept. of Bioengineering and the McGowan Institute for Regenerative Medicine. Although trained as an engineer, Dr. Brienza has considerable additional experience conducting clinical and preclinical research. Over the past 23 years, his research has been continuously funded through grants from NIH (PI on 3 R01s); NIDRR (PD on 4 Center grants and PI on 2 Field Initiated grants), and other private foundations, industry and VA sources. The majority of this work has been focused on pressure ulcer prevention. Dr. Brienza has been an active member of the pressure ulcer community. He was first elected to the Board of the National Pressure Ulcer Advisory Panel Board (NPUAP) in 2001 and has since served for 4 terms on the Board of Directors. He is a Fellow of the American Congress of Rehabilitation Medicine (AIMBE) and the Rehabilitation Engineering and Assistive Technology Association of North America (RESNA). Dr. Brienza serves on the Editorial Board of Advances in Skin and Wound care and is on the standing committee to review publication for the Cochran Wound Group.

Education
University of Notre Dame BS Electrical Engineering
University of Virginia Ph.D. Electrical Engineering

Publications

