

A Novel Method for Proning Patients with Acute Respiratory Distress Syndrome

Kieran Leong DO, Yasheen Brijlal MSc, Amy Hoelscher DNP, Ronald Reilkoff MD
University of Minnesota, Medical Devices Center

Introduction

Acute respiratory distress syndrome (ARDS) is a lethal disease effecting around a quarter of a million patients a year¹ in the U.S. and costs the U.S. healthcare system \$9-16 billion/year². Severe cases have a greater than 50% mortality³.

Proning therapy (face down ventilation) has been shown to decrease mortality by half, improve oxygenation, decrease the number of days on the ventilator⁴, and has been strongly recommended by all major critical care societies. Despite this, only 10-33% of candidates receive this life saving therapy with the current barriers being awareness, safety concerns, and expense of the current solutions (**Image 1**).

Here we present a novel, patent pending medical device (**Image 2**) designed to address safety and cost concerns to ensure patients with severe ARDS receive appropriate therapy.



Image 1: Current Solutions are Problematic

Left: Manual proning comes with safety concerns; **Right:** Rotoprone therapeutic bed is too expensive at ~\$150,000 or \$1,300/day

Material and Methods

Testing was performed on an existing intensive care bed at the Earl E. Bakken Medical Devices Center. Two flat, deflated layers were placed underneath a person and the upper layer was wrapped around the patient and inflated. The base was then inflated providing a cradle for the inner cylinder. Directional fabric was present on both the exterior of the inflatable shell and base reducing force required to prone the subject (**Image 3**).

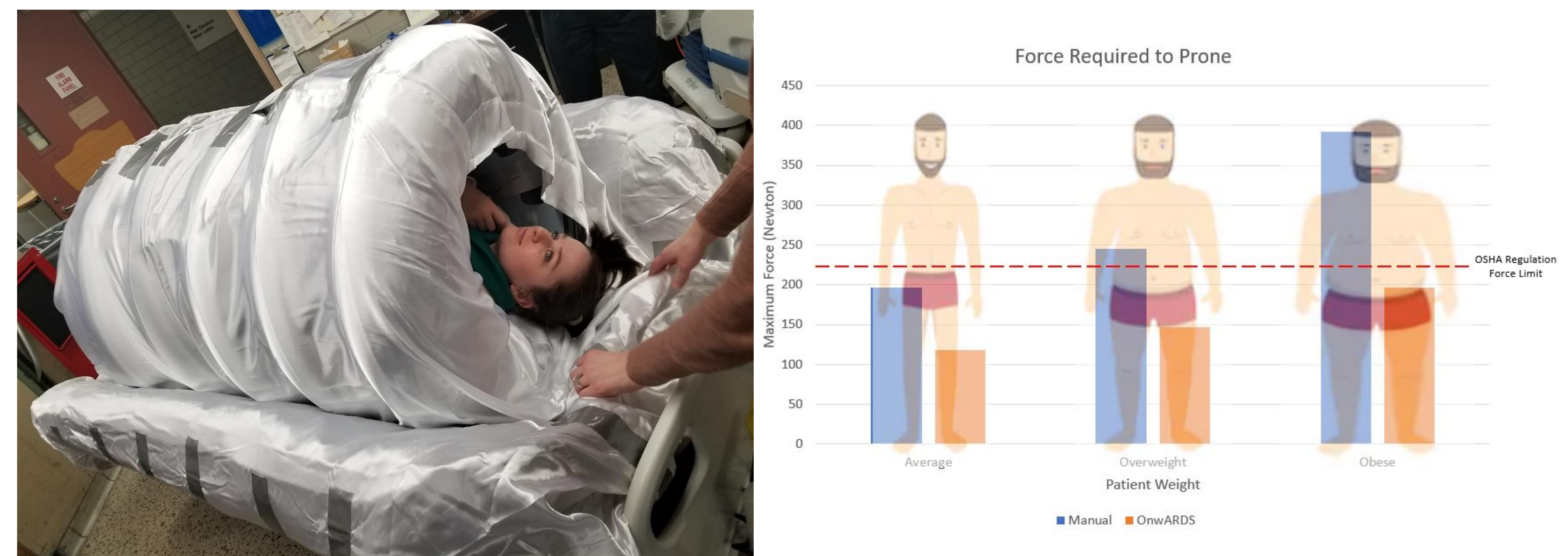


Image 3: Left: In human testing; Right: Peak force reduction compared to manual proning

Discussion

Our novel device is single-use, disposable solution that is compatible with existing beds and has been showing to reduce the effort required to prone patients. It has a low regulatory risk as a class I FDA device. It is safe, easy, and cost-effective solution designed to increase adoption of a proving, live saving therapy.

References:

1. Definition and epidemiology of acute respiratory distress syndrome. *Ann Transl Med.* 017;5(14):282.
2. Cost and Healthcare Utilization in ARDS. *Semin Respir Crit Care Med.* 2013;834(40).
3. Acute respiratory distress syndrome: estimated incidence and mortality rate. *Crit Care.* 1998;2(1):29-34.
4. Prone positioning in severe acute respiratory distress syndrome. *N Engl J Med.* 2013;368(23):2159-2168.

Image 2: Our solution

Patient is enclosed in an inflatable shell and supported within an inflatable base lined with a low friction surface