

Defining Optimal Prosthetic Socket Pressure Profiles to Protect Limb Health

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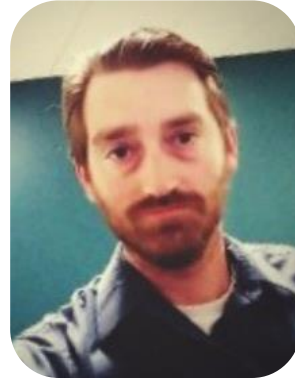
Collaborators and Disclaimers



Mallory Hook



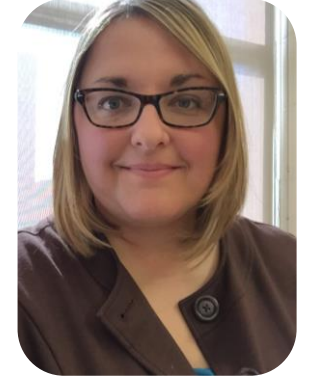
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Disclaimer

- Dr. Wernke, Mrs. Hook, and Dr. Handford are full time employees of WillowWood
- The study was funded by the Department of Defense (W81XWH2210469)

Fitting and Delivering a Prosthesis

The subtle margin of good and bad pressure application impacts all aspects of prosthesis use

Past and Present Prostheses

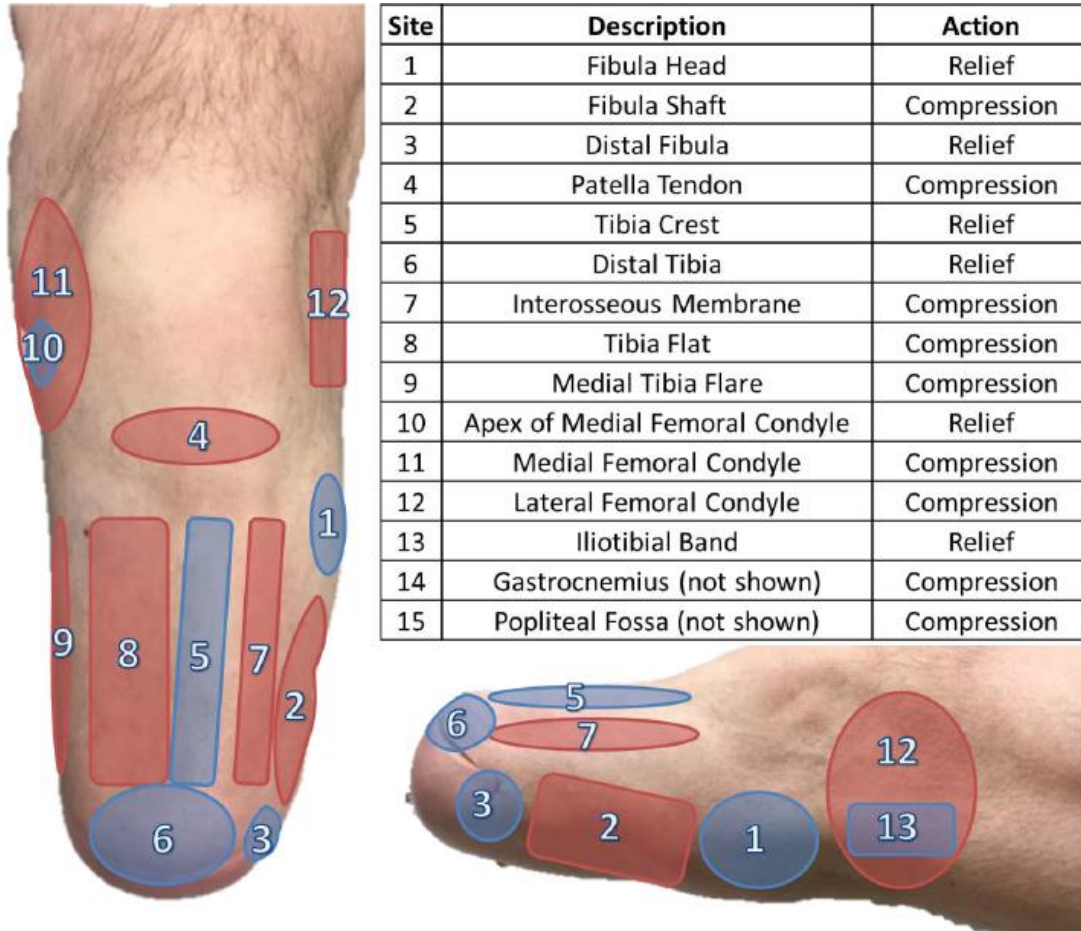


Fitting Process



Common Socket Designs

Socket fit philosophies vary among clinicians



Total Surface Bearing Socket



Patella Tendon Bearing Socket



HiFi Socket

Persistent Challenges

Patients report high discomfort within the socket and high prevalence of wounds

Types of skin tissue injury

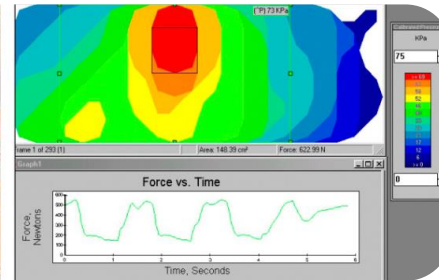
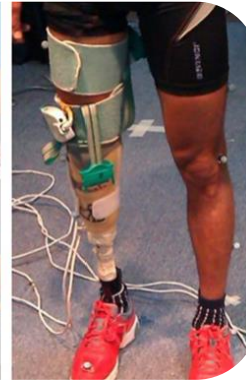


- 98% report socket fit as primary concern and high reported discomfort
 - Adds unpaid follow-up visits
- 50% amputees experience wounds within the socket
 - Costly treatment – Pressure ulcer \$20,900 - \$151,700

Quantifying the Interface

Previous attempts and data failed to translate to the clinic

Optical, Acoustic, Resistive, and Radiological Attempts

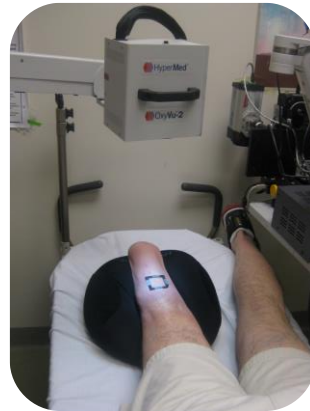


- Clinical translation limited because...
 - too costly
 - too cumbersome
 - too restrictive
 - too fragile
 - lacked meaning

Limb Health Measurements May Provide Insight

The key to provide meaning to interface measurements

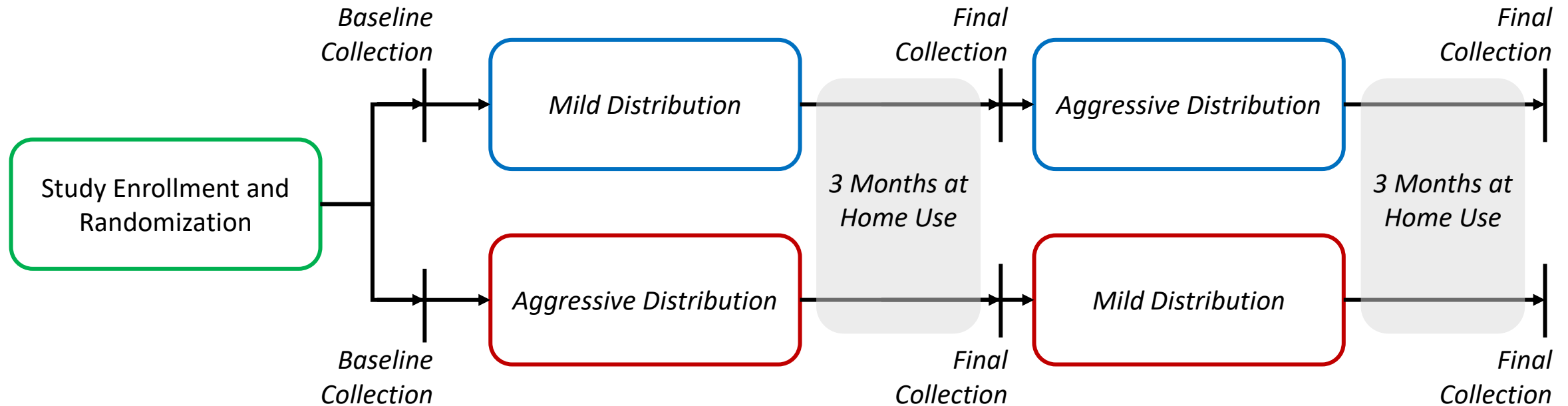
Out of Socket and In-socket Limb Health Measurements



- \$7.1M of prior funding developing techniques and knowledge base
- Health outcomes of interest predict wound formation
- Initial work focused on the impact of suspension on tissue health
- We then found a key relationship between movement of the limb and tissue health

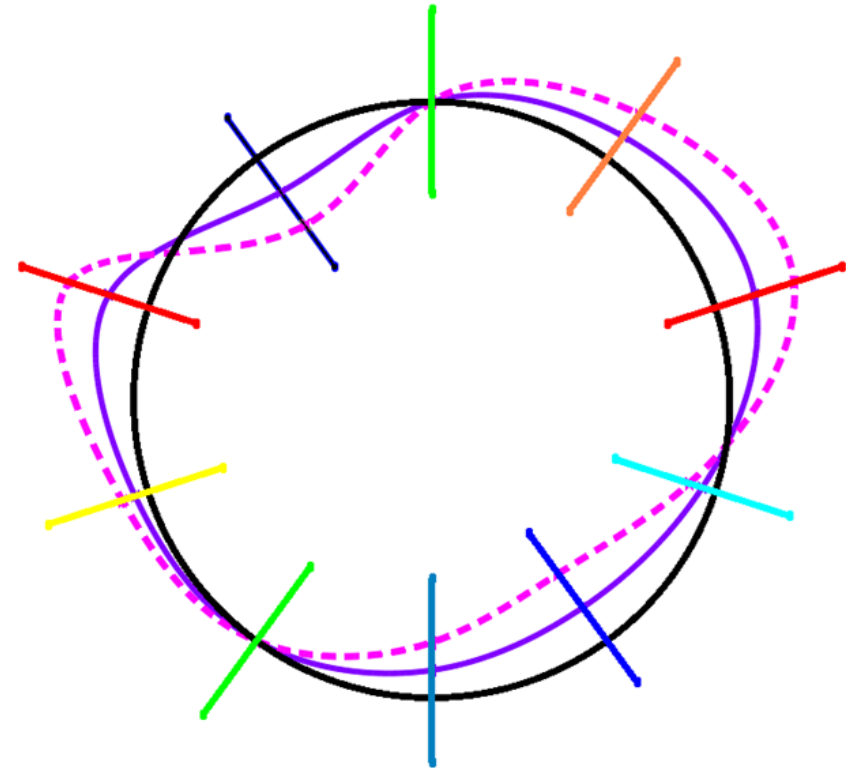
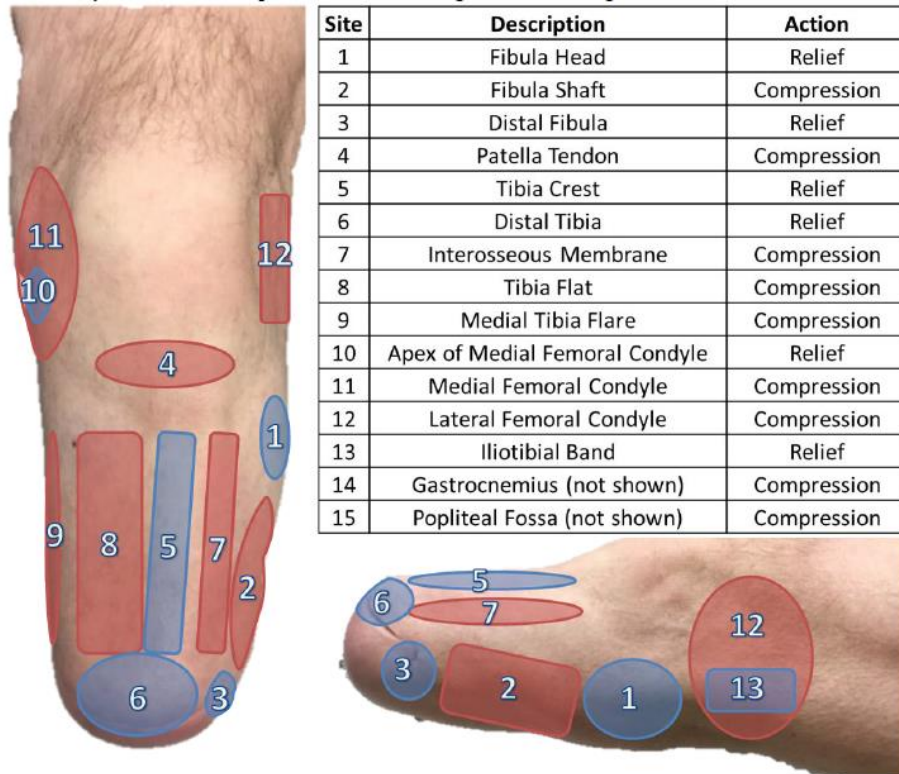
Study Procedures

- *Purpose:* Measure limb health in response to socket design
 - Design 1: Mild pressure distribution
 - Design 2: Aggressive pressure distribution

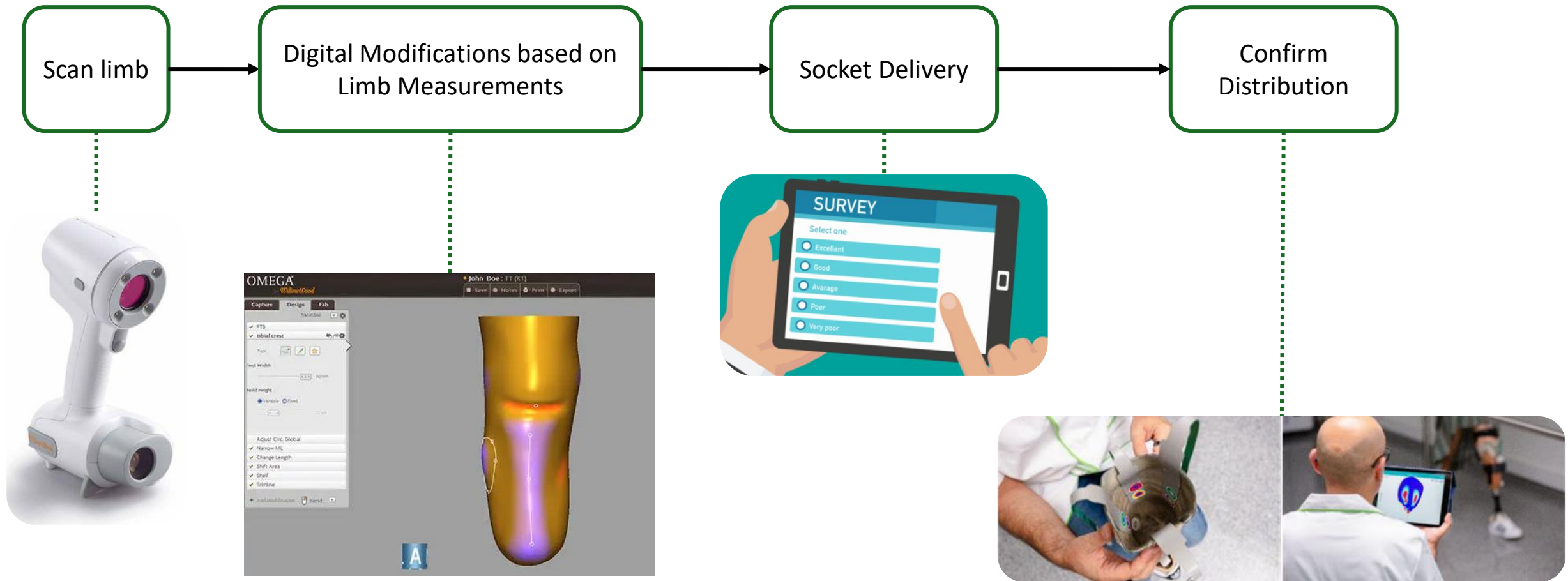


Study Socket Fitting Procedures

- Traditional education identifies these 15 sites
- Prosthetist considers these sites and other factors in a systematic decision framework
- CAD controls the modifications between conditions



Study Socket Fitting Procedures



Study Outcomes

- CLASS survey
 - 4 domains: Stability, Suspension, Comfort, Appearance
- PEQ survey
 - 9 Subscales: Utility, Appearance, Sounds, Residual Limb Health, Perceived Response Frustration, Social Burden, Ambulation, Well Being
- Socket Comfort Score
- Limb health measurements

Limb Health Measurements

- Transepidermal Water Loss
 - Skin barrier function measurement that relates to health issue before and after activity
- Surface Electrical Capacitance
 - Measures skin moisture before and after activity
- Cutometer
 - Measures skin properties before activity
- Ultrasound
 - Measures skin properties before activity

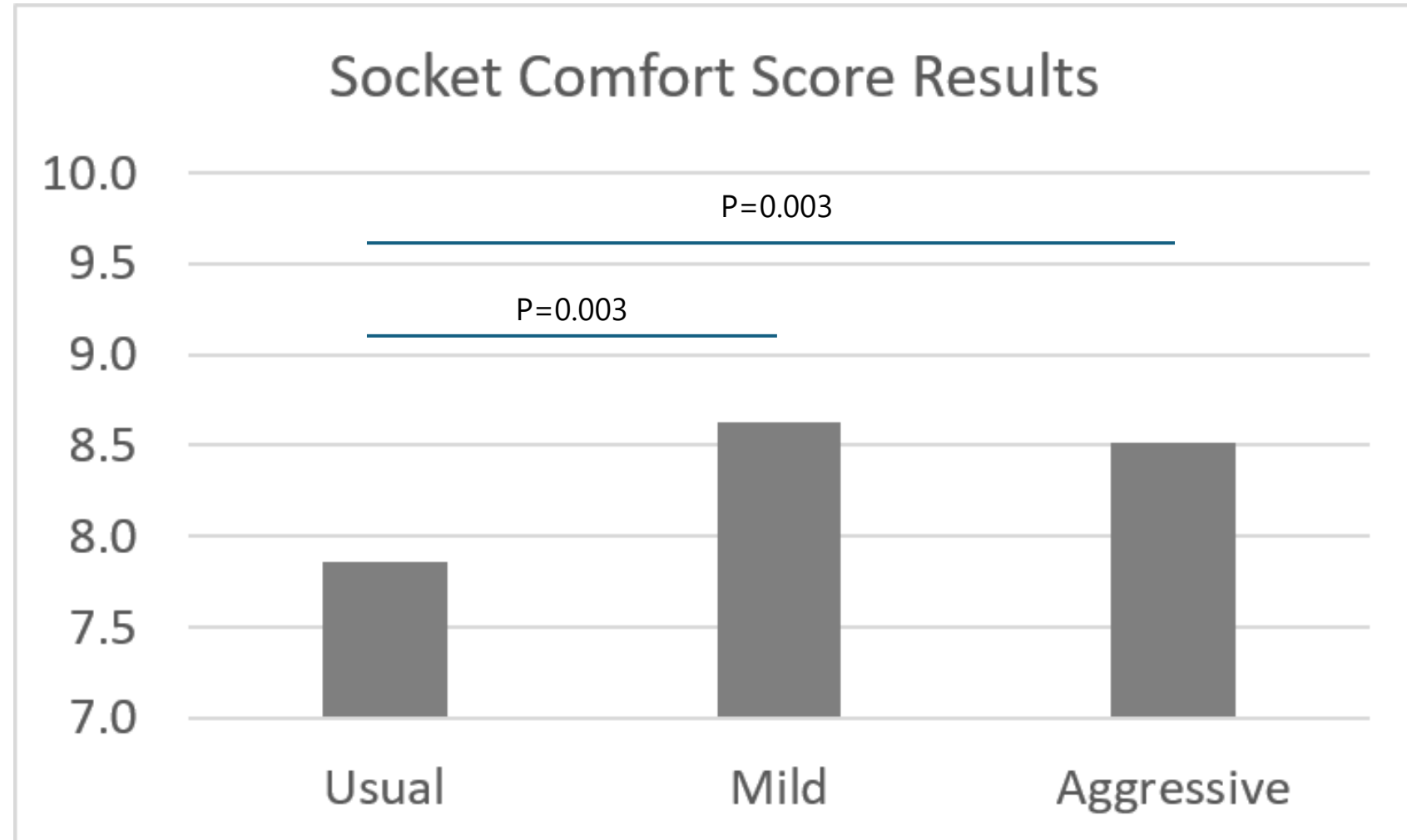


Study Participants

- 42 subjects enrolled
 - Inclusion Criteria
 - All participants have unilateral transtibial amputation or limb difference
 - At least 8 months post amputation
 - No wounds on limb at time of enrollment
 - Demographics
 - Average Age: 53.9 [20-87]
 - Average Time Since Initial Amputation: 20.9 [1.6-72]
 - Trauma-34, Dysvascular-4, Cancer-3, Congenital-1
 - K4-7, K3-32, K2-3
 - Pinlocking-21, Suction-14, Vacuum-7

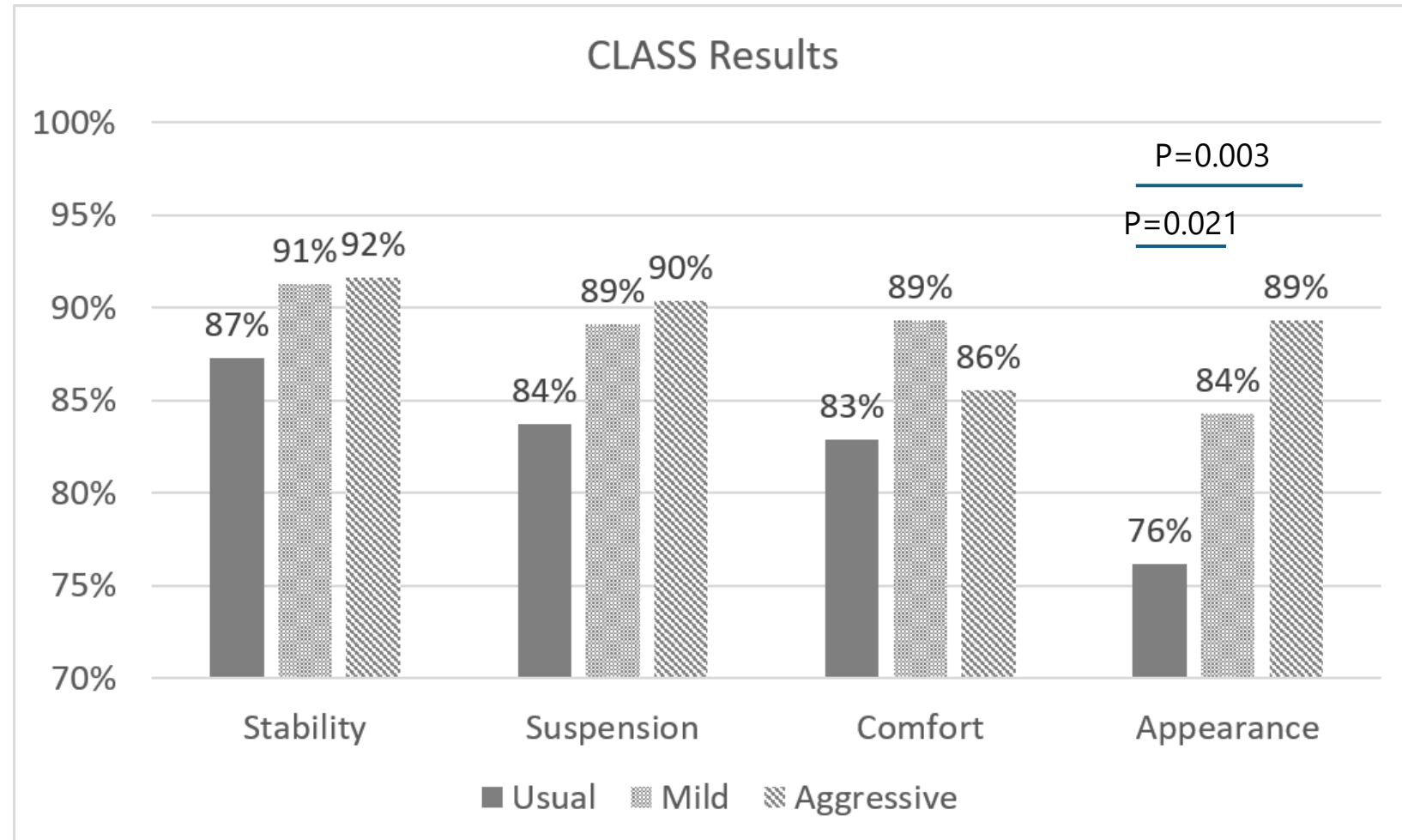
Socket Comfort Score Results

- Both test sockets were significantly more comfortable than the usual socket but not different from one another



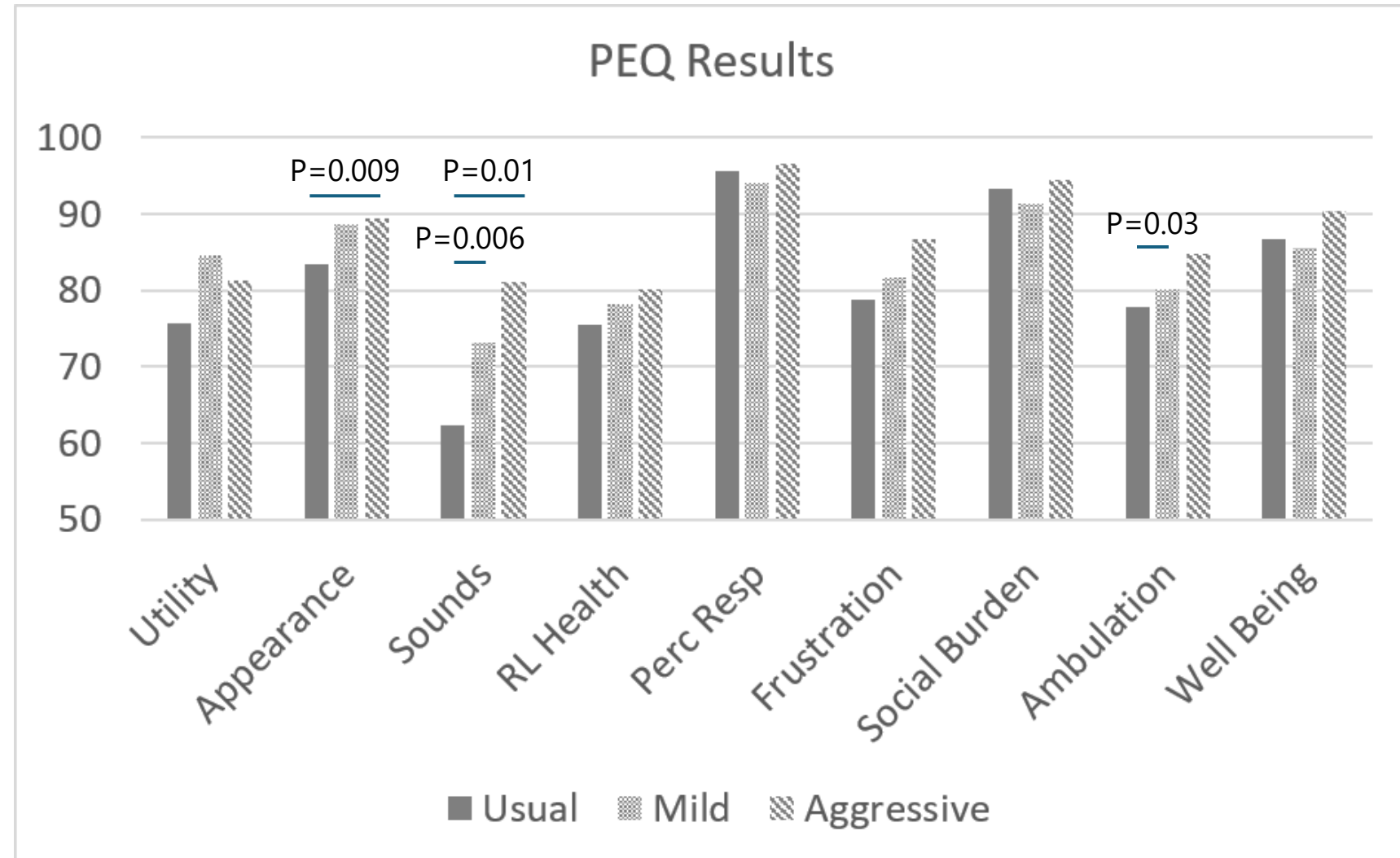
CLASS Survey Results

- No significant differences for the stability, suspension, and comfort subscales
- Significant differences in appearance between the usual socket and either test socket

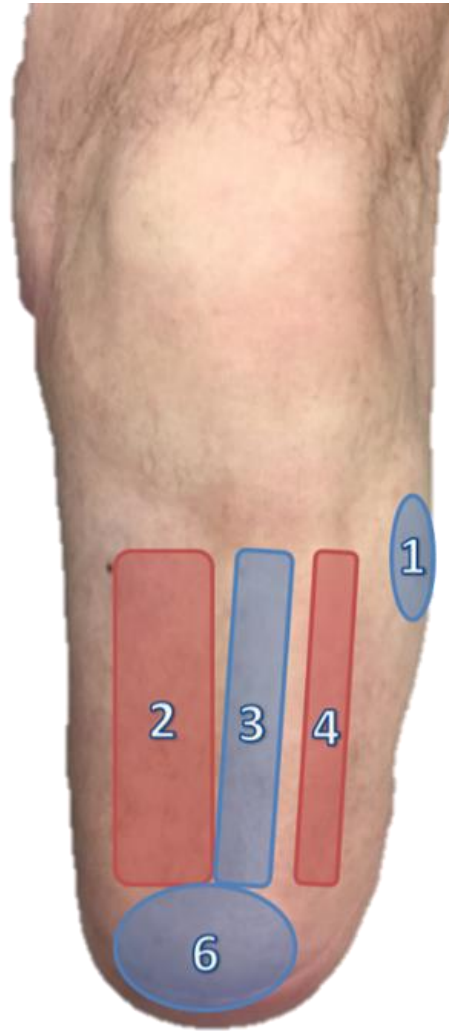


PEQ Results

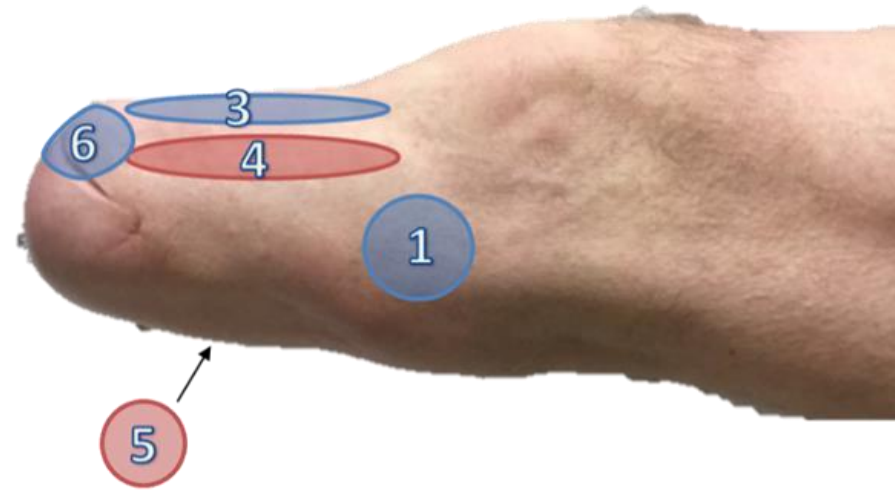
- A few significant differences between the usual socket and one or both of the test sockets



Limb Health Measurements

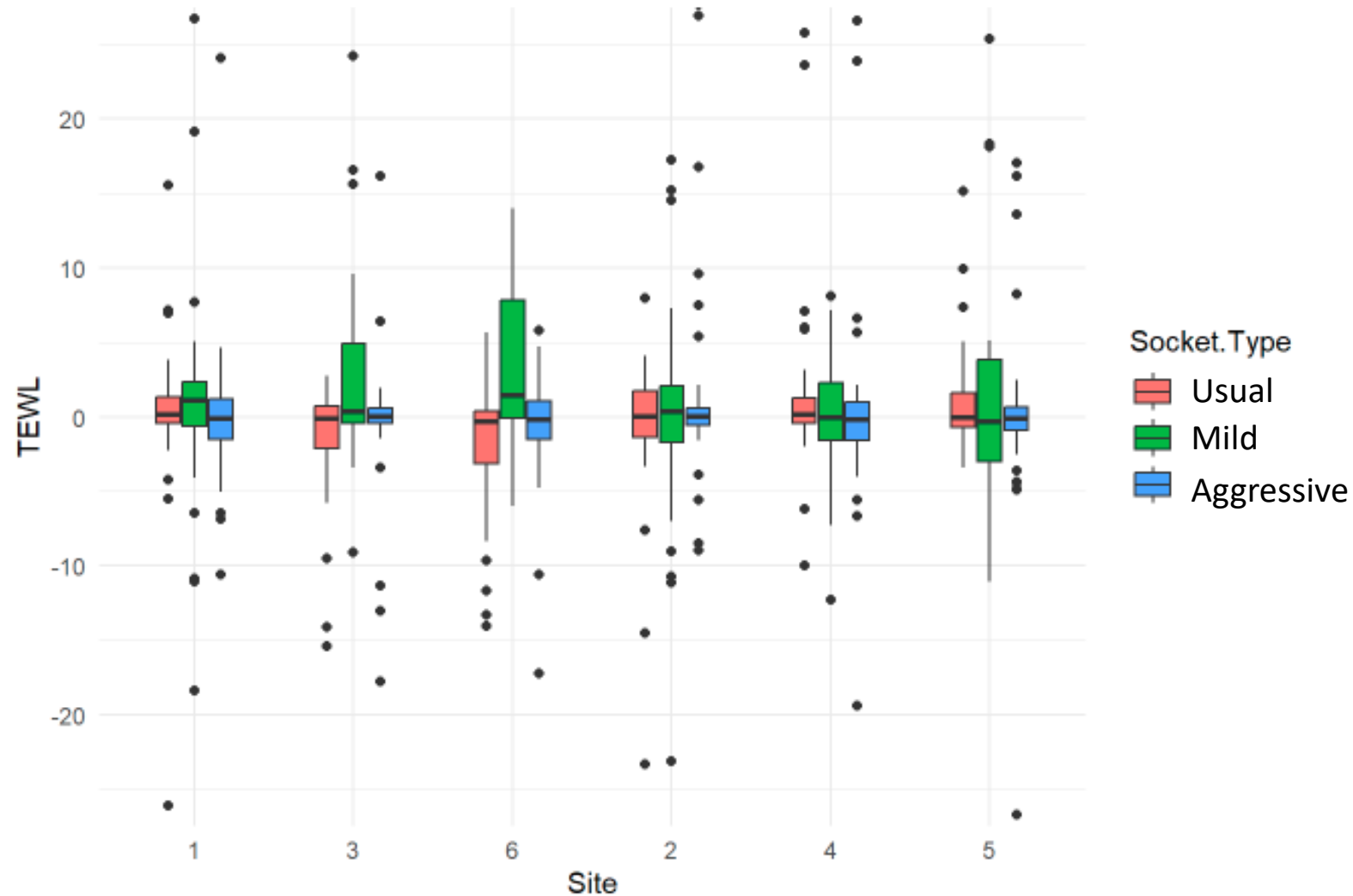


Site	Description	Action
1	Fibula Head	Relief
2	Tibia Flat	Compression
3	Tibia Crest	Relief
4	Interosseous Membrane	Compression
5	Gastrocnemius	Compression
6	Distal Tibia	Relief



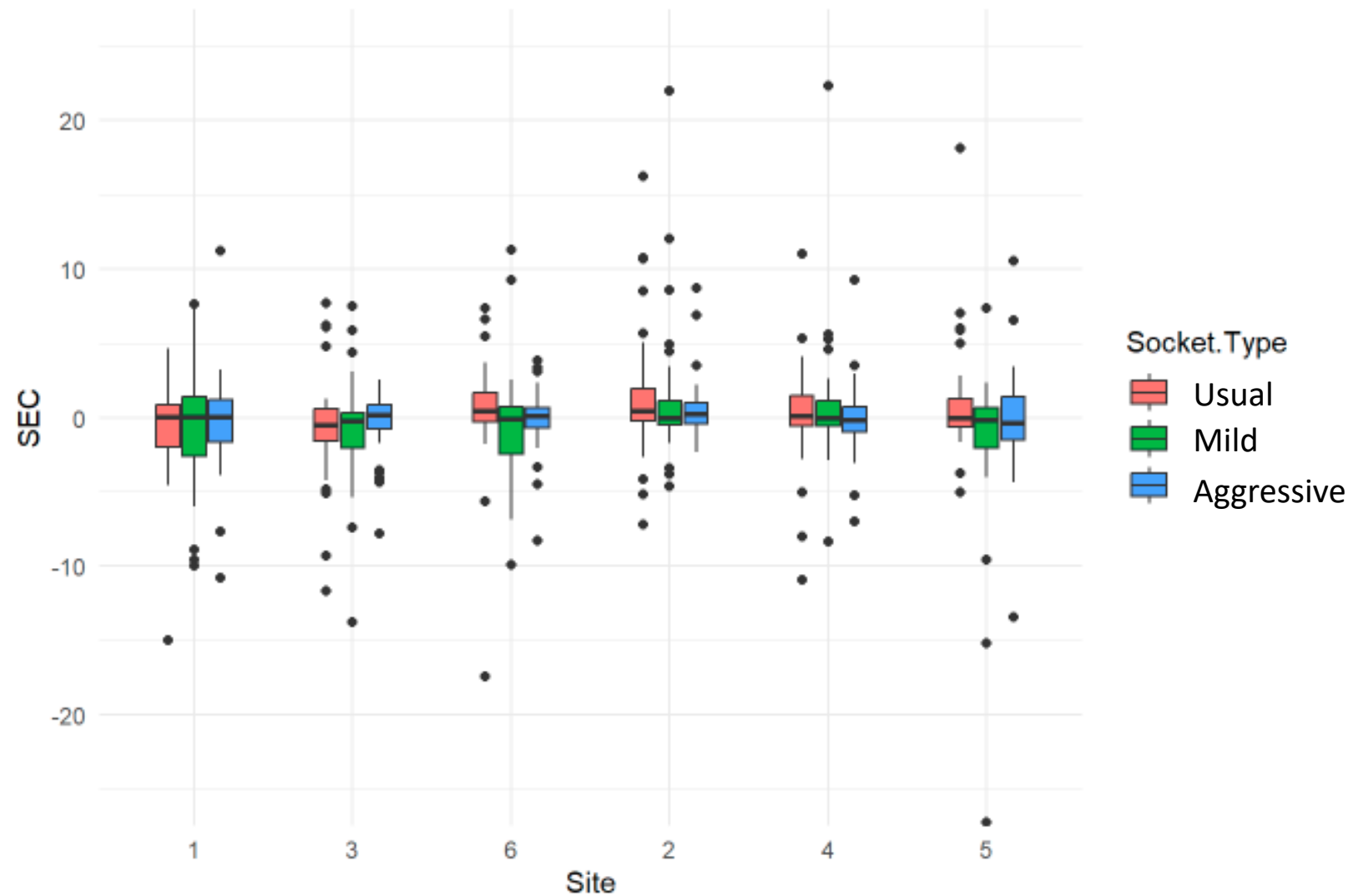
TEWL Results

- Sites 3 and 6 were significantly higher compared to usual socket ($p=0.004$ and $p=0.0002$ respectively)
- Site 6 alone and across all sites of relief (1, 3, 6) was significantly lower for aggressive compared to mild socket ($p=0.03$ and $p=0.01$ respectively)



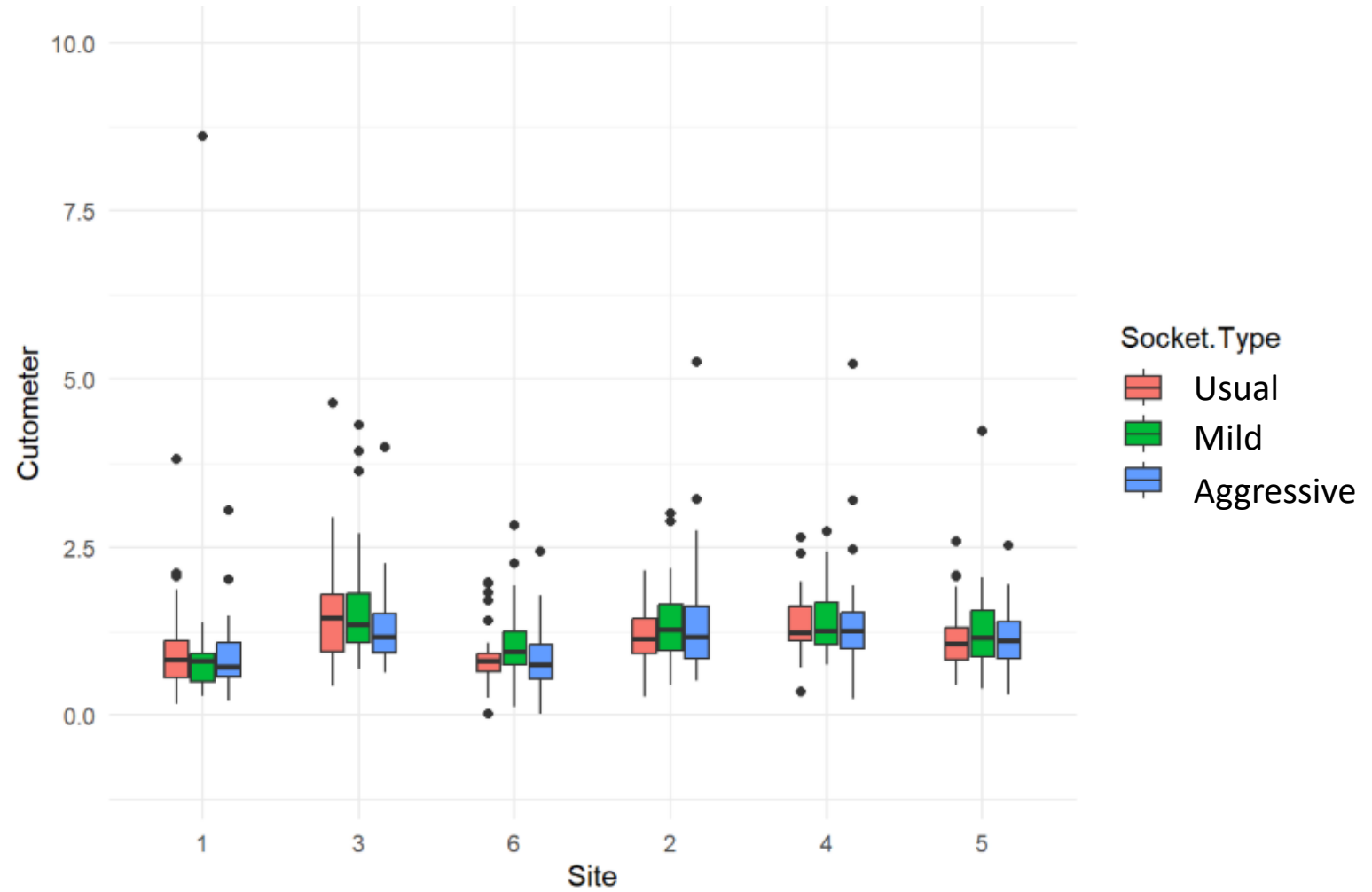
SEC Results

- No significant differences between any of the socket conditions



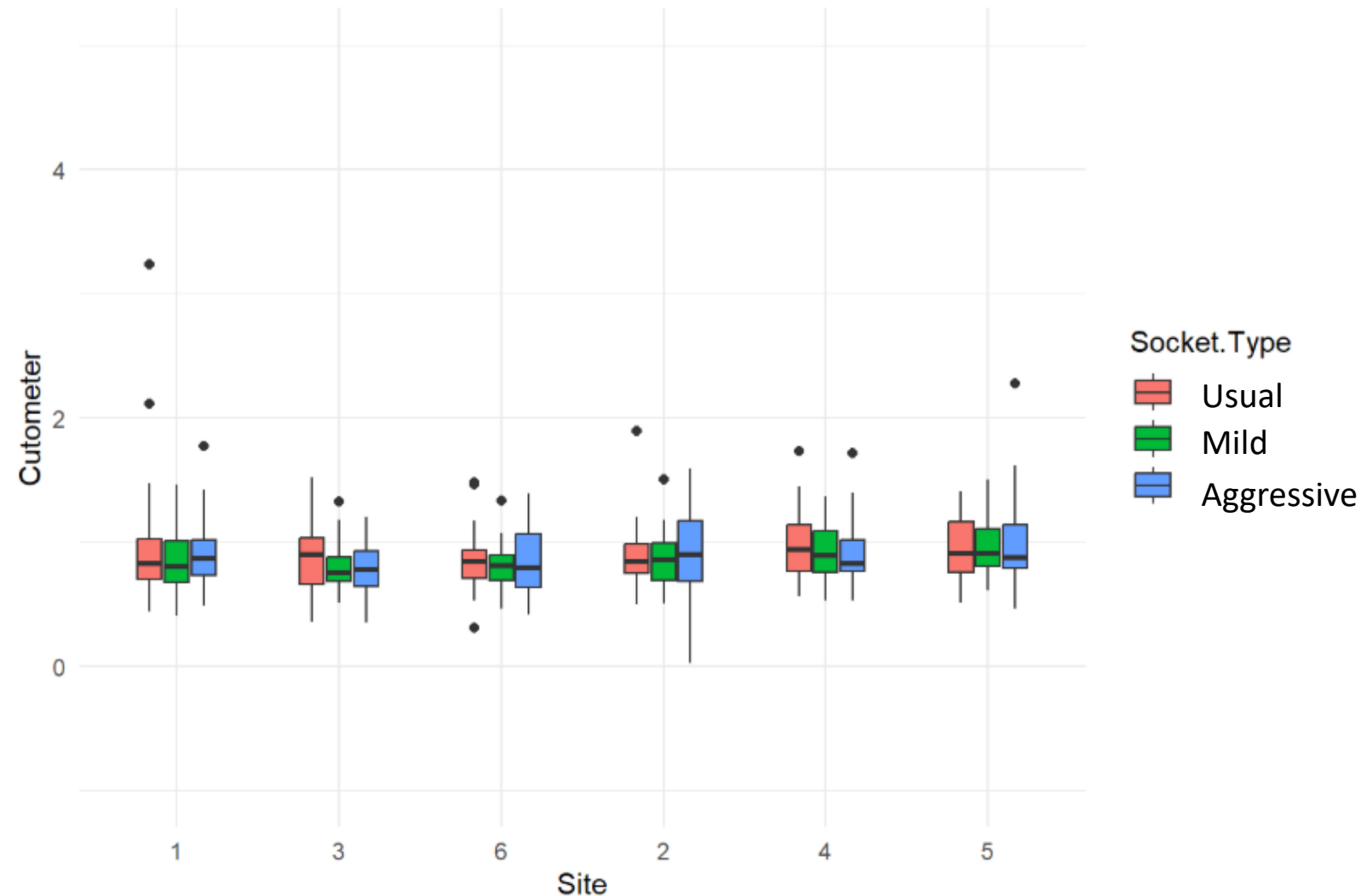
Cutometer Results – Total Deformation

- No significant differences between any of the socket conditions



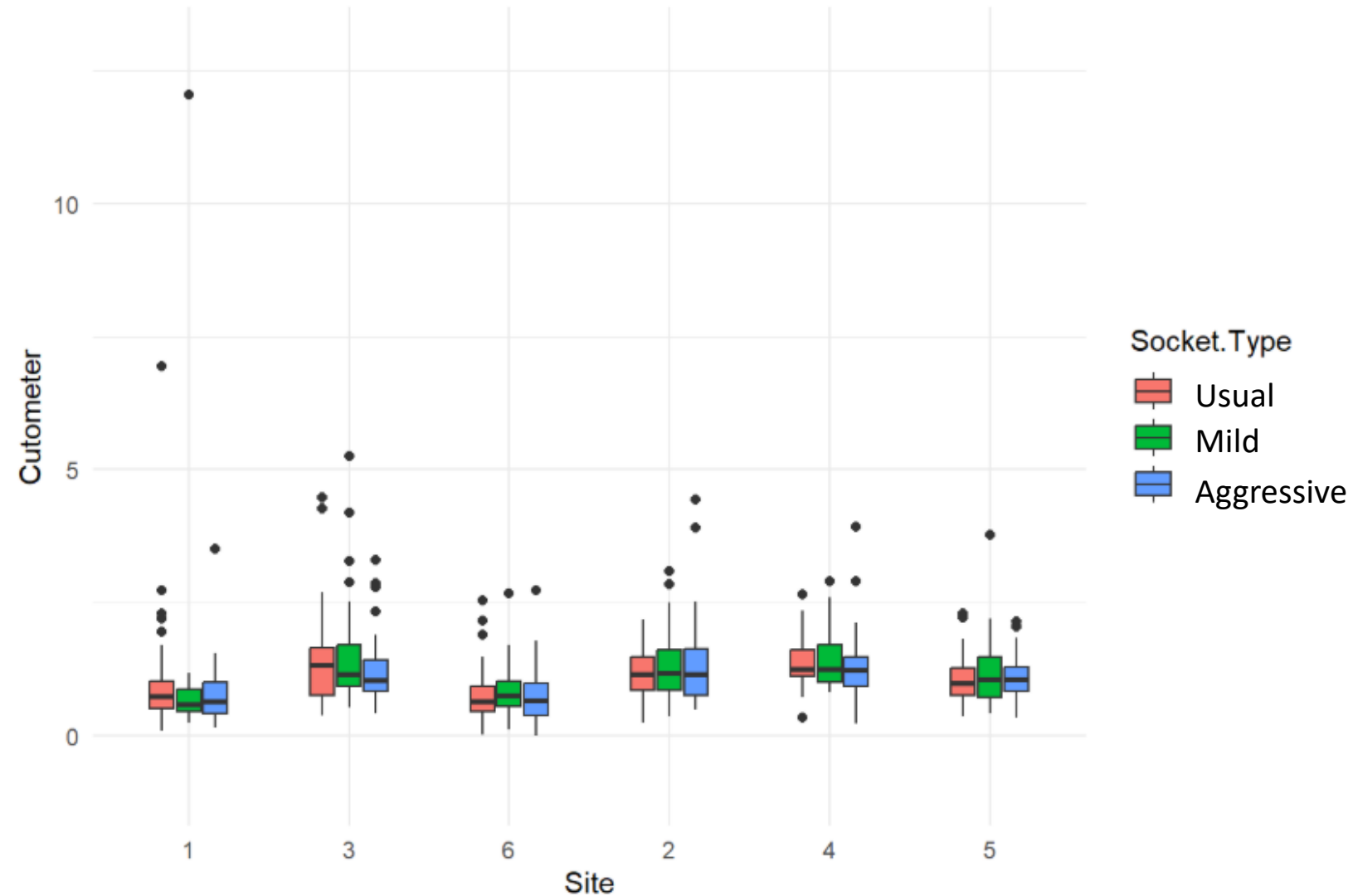
Cutometer Results – Net Elasticity

- Net elasticity for Site 3 was significantly lower for aggressive compared to usual socket ($p=0.04$)



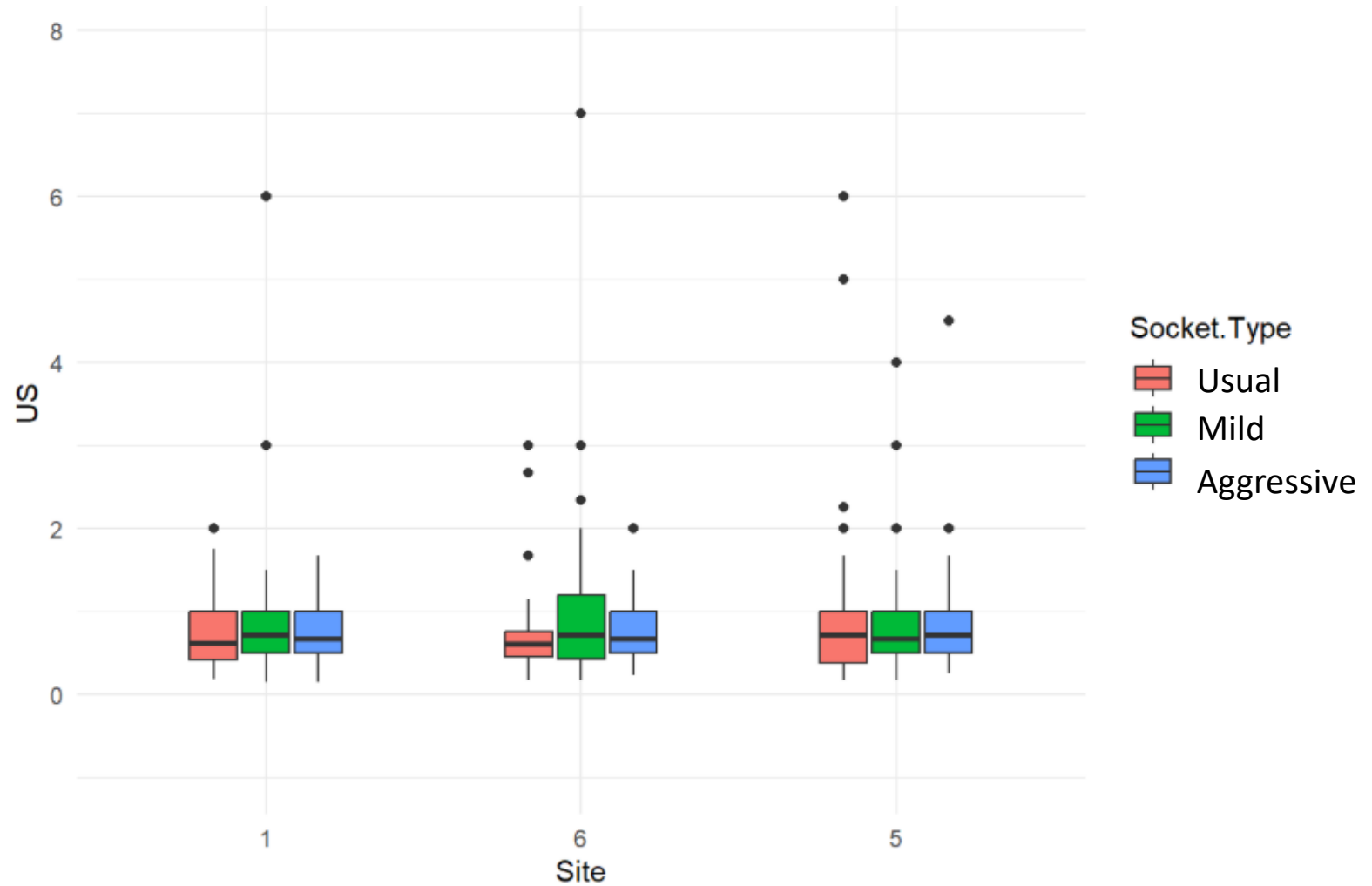
Cutometer Results – Total Recovery

- No significant differences between any of the socket conditions



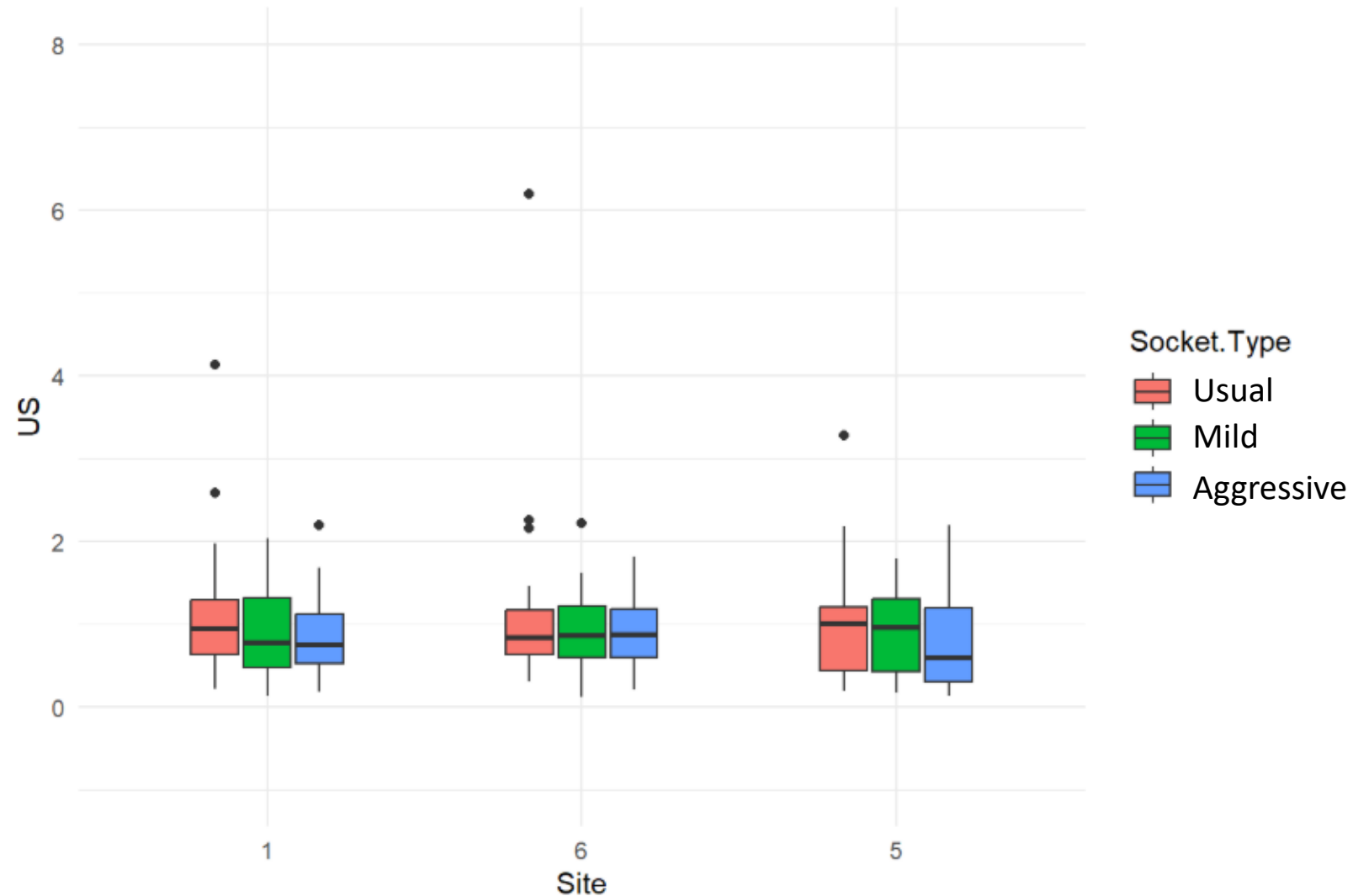
Ultrasound Results – Dermal Density

- No significant differences between any of the socket conditions



Ultrasound (Dermal Thickness) Results

- No significant differences between any of the socket conditions



Discussion

- Opinions about the various sockets captured by the CLASS, PEQ and SCS indicate no differences among the study sockets
- TEWL measurements indicate there is an impact of socket design on tissue health. Specifically, you can compress areas of soft tissue to various degrees without a significant impact of the skin tissue health. However, bony prominences should be off-loaded sufficiently to promote skin health, since the aggressive socket contouring yielded better TEWL
- The other limb health measures did not indicate changes based on socket design. Two factors may contribute:
 - 3-month treatment windows may have been too short for these changes to skin mechanics
 - Changes that were occurring might need high sensor resolution than the equipment used in this study

Clinical Impact

- The study developed a systematic approach to socket design so that it can be studied in a controlled way
 - This could be a useful tool/process clinically. Nearly all of the sockets fit in this study did not require changes post fabrication.
- By providing data toward what is a good socket fit, we can prevent skin irritation or injury and improve prosthesis use. Further, this information can provide definition to what is a good socket fit, and in time through technology advancement, provide a metric that can be tracked and maintained

Thank you for your attention

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