

# Functionality to measure outcomes for safety, effectiveness and cost implications

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 POLISH WOUND  
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# EWMA 2018

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## New Frontiers in Wound Management

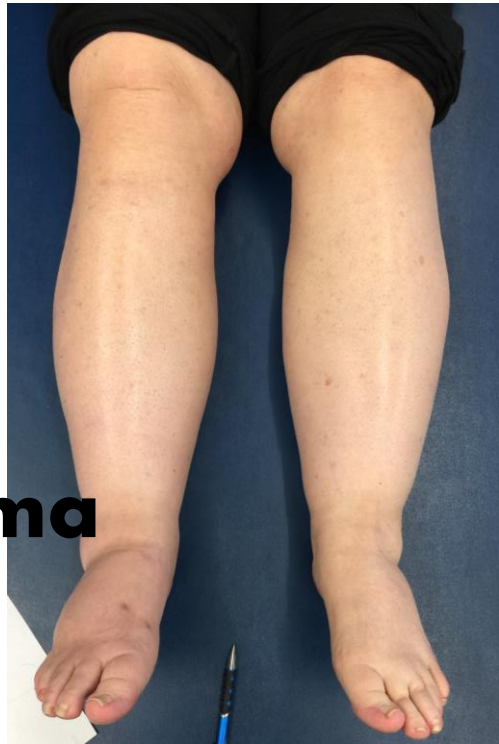
## New Frontiers in Wound **AND** Edema Management



**Stasis Ulcer**



**Edema**

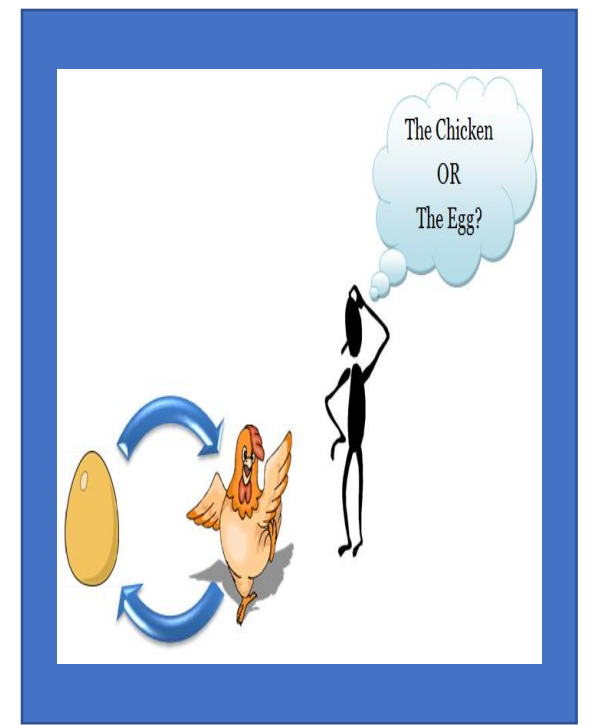


**Swelling**





# Impaired Functional Mobility



**Edema**

**Stasis Ulcer**



**Swelling**



## Edema and Co-existing disease



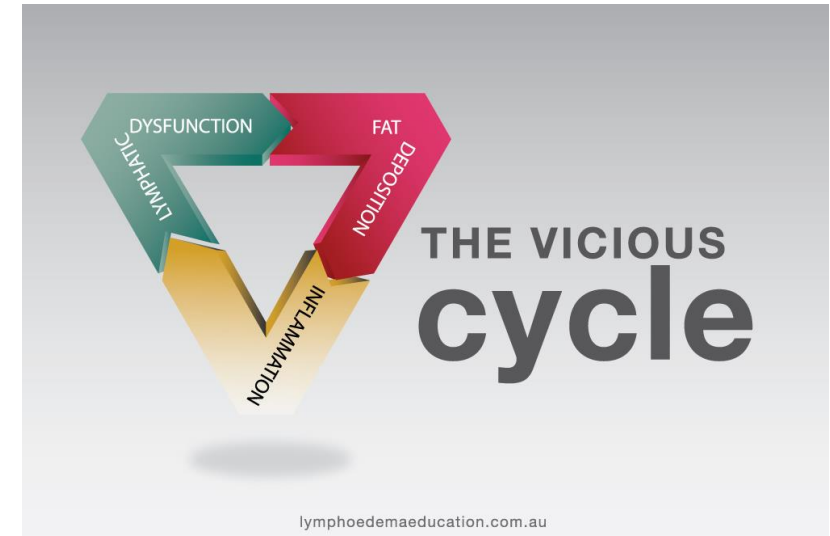
## Elective Orthopedic procedures



## Elective Orthopedic procedures complicated by infection



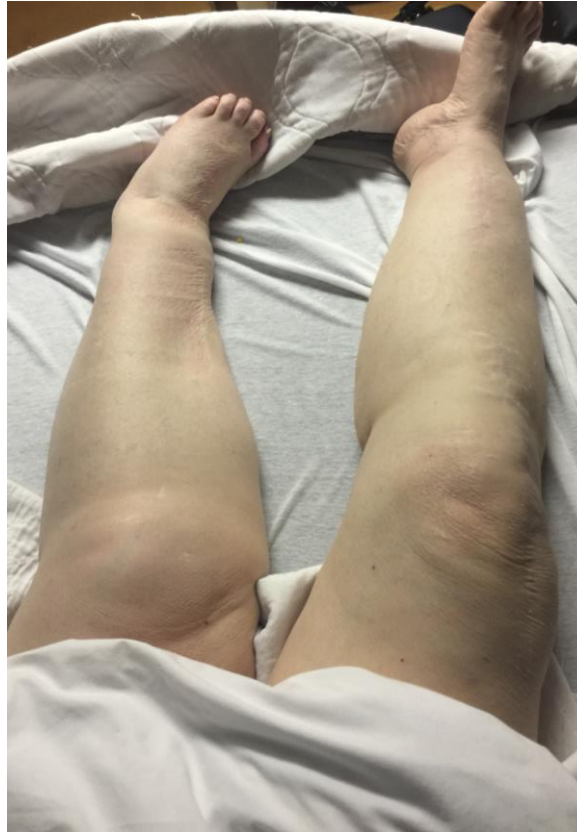
# Morbid Obesity and Chronic Edema



# Immobile Aging Population



Elderly with decline in mobility



Dense hemiplegia following CVA



Post Polio Syndrome

# Opportunity for improvement



**Opportunity  
is Knocking!**

~~~~~

**Answer  
the Door!**

- What is the impact of chronic edema?
- How are we assessing/measuring chronic edema?
- What is the impact of chronic edema management ?
  - What is the potential for prevention of edema formation?
  - Impact of edema management intervention on overall cost of care?
- What is the best way to measure the outcomes of edema management intervention?
- How do we match edema management products to a particular presentation?



# Impact of Chronic Edema

- Delays wound healing
- Contributes to infection
- Decreased quality of life
- Impaired mobility - edematous limb shifts center of gravity which when combined with difficulty finding footwear result in increased risk of falls
  - Limits range of motion
  - Impaired footwear
  - Increased fall risk
  - Impaired ability to exercise



# What does the research say?

- Specifically on impact of chronic edema more subjective report
  - 53% people with chronic edema reported having problems which affect his/her ability to exercise

Lymphedema Framework 2006 Best Practice for the management of Lymphedema. International Consensus.

Green A, Meskell P(2016) The Impact of lower limb chronic oedema on patients' quality of life. *Int Wound J* 4 Aug

- Pain free walking distance and effects on activities of daily living improved significantly following treatment for chronic edema

Baker Y et al. Complete Decongestive Physiotherapy for Older People with Chronic Venous Insufficiency. *Topics in Ger Rehab* 2010;26(2):164-70.

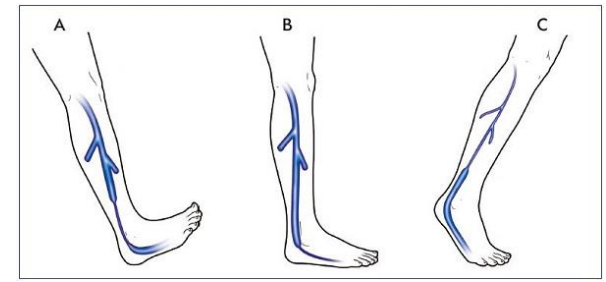
- Evidence looking at other disease processes associated with chronic edema
  - VLUs – limited ankle ROM, pain, poorer balance and mobility scores than control group participants suggesting higher risk of falls

- Many problems associate with living with VLUs are in themselves known risk of falling

Humphreys C, Moffatt C, Hood V. Risk of Falling for people with venous leg ulcers: a literature review. *Wound Central* 2017;1(2):65-69.



# Impact of ankle ROM



- Calf muscle pump efficacy is dependent on two factors: the power of the moving ankle joint and the competency of the veins

- 70% of those with VLU have impaired calf muscle pump

Orsted HL, Radke L, Gorst R. The Impact of Musculoskeletal Changes on the Dynamics of the Calf Muscle Pump. *Ostomy Wound Management* 2001;47(10):18-24

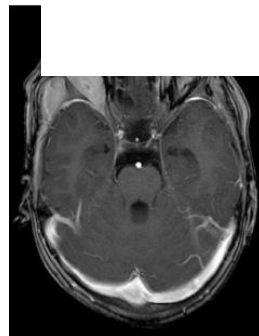
- Many healthcare professionals center their care of venous leg ulcers around dressings and topical treatments rather than on managing the hemodynamic events that may predispose patients to venous ulceration.

- Reichardt reports that 86% of all venous ulcers will heal with little or no topical treatment if venous HTN is managed

Reichardt LE. Venous ulceration: compression as the mainstay of therapy. *Journal of WOCN*. 1999;26:39-47

# How are we assessing edema?

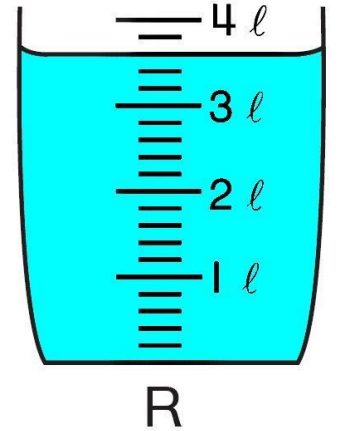
- Water displacement
- Laser perometer
- Bio-impedence
- Tissue dialectic constant
- Diagnostic imaging
- Tape measure





# What does volume tell me?

- Volume measurements objective starting point
  - What is 'normal'?
  - What % change is significant for individual patient?
- Change in volume may reflect impact of treatment intervention
- Volume DOES NOT provide information about tissue texture or impact of swelling on daily routines
  - Stage of dysfunction
    - Tissue
    - Functional level



# Beyond the volume measurement

- Change in tissue texture



Initial presentation



2 weeks of bandaging



1 week flat knit garment



6 months flat knit garment



# Volume is NOT Function

- Federal Payers (Medicare) looking at outcomes (G-codes) - NOT VOLUME (cm<sup>3</sup>)
  - Physician Quality Reporting System (PQRS)
  - Functional Limitation Reporting (FLR)

## Functional Limitation Severity Modifier Codes

| Modifier | Impairment Limitation Restriction                                |
|----------|------------------------------------------------------------------|
| CH       | 0% impaired, limited, or restricted                              |
| CI       | At least 1% but less than 20% impaired, limited, or restricted   |
| CJ       | At least 20% but less than 40% impaired, limited, or restricted  |
| CK       | At least 40% but less than 60% impaired, limited, or restricted  |
| CL       | At least 60% but less than 80% impaired, limited, or restricted  |
| CM       | At least 80% but less than 100% impaired, limited, or restricted |
| CN       | 100% impaired, limited, or restricted                            |



# Functional Scales

| General Function             | Balance                          | Lower Extremity                  | Spine                                           | Upper Extremity                            | Lymphedema                          |
|------------------------------|----------------------------------|----------------------------------|-------------------------------------------------|--------------------------------------------|-------------------------------------|
| Barthel Index                | Tinetti Mobility Test            | Lower extremity functional scale | Neck Disability Index Questionnaire             | DASH                                       | Lymphedema Life Impact Scale (LLIS) |
| Dynamic gait index           | BERG                             |                                  | Oswestry Low Back Pain Disability Questionnaire | Hand Profile                               | Lymphedema QOL Tool (LymphQOL)      |
| Dizziness Handicap Inventory | Fullerton Advanced Balance Scale |                                  | The Quebec Back Pain Disability Scale           | Shoulder Pain and Disability Questionnaire |                                     |
| Functional Reach             | Motion Sensitivity Score         |                                  |                                                 | Upper Extremity Functional Index           |                                     |
| Mini Mental State Exam       |                                  |                                  |                                                 | Upper Extremity Quick DASH                 |                                     |
| Timed Up and Go (TUG)        |                                  |                                  |                                                 |                                            |                                     |
| 4 meter walk test            |                                  |                                  |                                                 |                                            |                                     |



Performance Based Outcome Measures

Patient Reported Outcome Measures

## Venous disease

DVT – venous ulceration- PTS – IV drug use

## Medical Co-morbidities

Cardiac – renal - neurological - SE medications – cancer – trauma and tissue damage

## Aging

- ↓ flexibility and muscle mass
- ↓ agility/balance
- ↓ endurance
- ↓ activity level

# Chronic Edema

## Lymphatic Impairments

Impaired proper foot wear

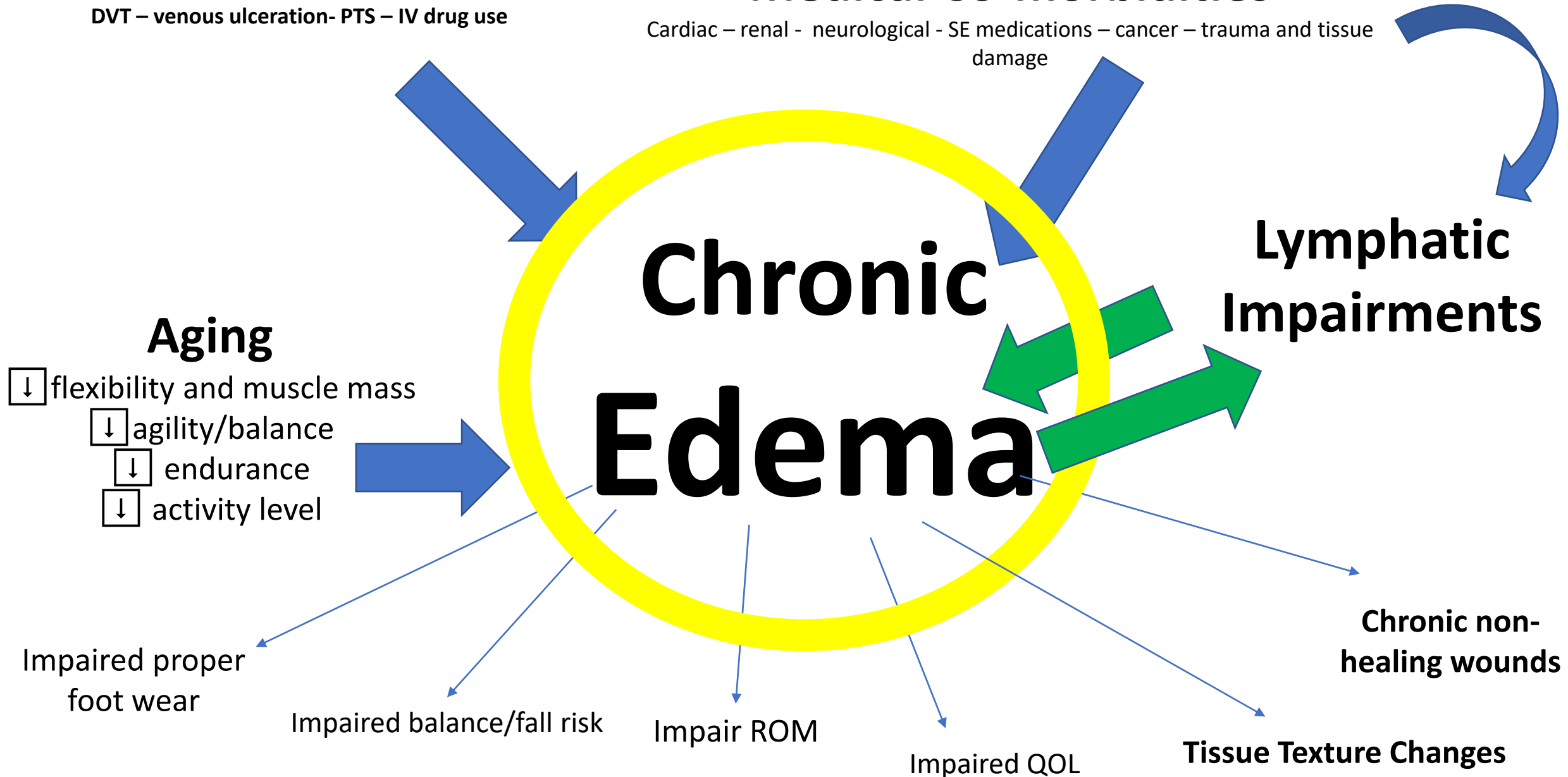
Impaired balance/fall risk

Impair ROM

Impaired QOL

Tissue Texture Changes

Chronic non-healing wounds





# Opportunity for Improvement

- Impact of edema management regiments
  - Volume
  - Function
  - Tissue texture
- Matching edema management solutions to individual patient presentations
  - Development of products to address tissue texture changes
  - Enhance compliance/concordance
  - Proactive vs. reactive approach to edema management



# Better management of Chronic Edema

- Collaborative research looking at not only causes of swelling but impact of swelling on function
- Need to look at benefit of edema management beyond volume reduction
  - ROM improve
  - Balance score
  - Reduce risk of falls
  - Improved QOL
- Effectiveness of a compression regiment
  - More than Volume containment
  - Improvement in Function
  - Improvement in tissue texture
  - Compliance/concordance with program



Carolinas HealthCare System

# PROVIDING COMPRESSION OPTIONS: THE KEY TO BETTER COMPLIANCE AND CONCORDANCE FOR PATIENTS LIVING WITH CHRONIC EDEMA

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## ABSTRACT

Compression remains the gold standard for long-term management of chronic edema<sup>1</sup>. Reviews have shown that the benefits of compression diminish according to levels of non-adherence.<sup>2</sup> Reasons commonly stated for non-adherence to compression include inconvenience, heat, cost, and pain.<sup>3</sup> We hypothesize that offering compression options will have positive impact on patients' compliance and concordance with compression regimens.

## Material and Methods

Observational study performed at 2 different edema management clinics. Ten patients presenting with lower extremity swelling and history of non-compliance with previous compression regimens were observed.

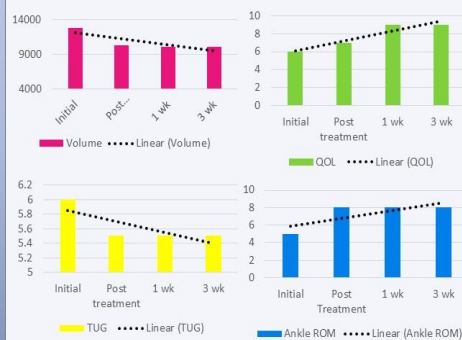
Objective data measured included the following:

- Limb volume (cm<sup>3</sup>)
- Range of motion (ROM)
- Functional activity status
  - Timed Up and Go (TUG)
  - 4M Walk Test (4MWT)
- Quality of life (QOL) using the Lymphoedema QOL Tool (LYMQOL-LEG).<sup>4</sup>

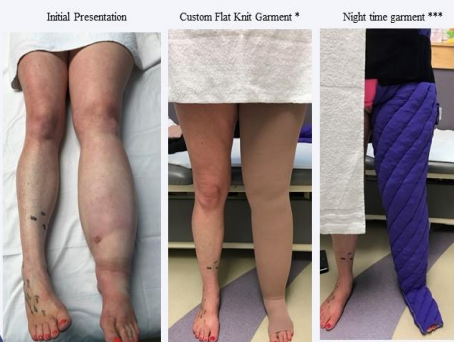
Measurements were taken at four different intervals over a minimum of 3 months. Compression options were individualized to each patient's physical presentation and lifestyle for long term management of their edema. Presented here are focused case studies with photos and individual outcomes, as well as group data.

## Results – Case I

Subject is 42 year old female with secondary lymphedema following treatment for melanoma.  
**Previous treatment:** Prescribed circular knit OTC thigh high; garment did not contain swelling and was uncomfortable  
**Intervention:** Complete decongestive therapy including manual lymphatic drainage, multi-component lymphedema wrap, exercise for approximately 2 ½ wks.  
**Long term management options:** Measured/fitted with custom day and night time garments.

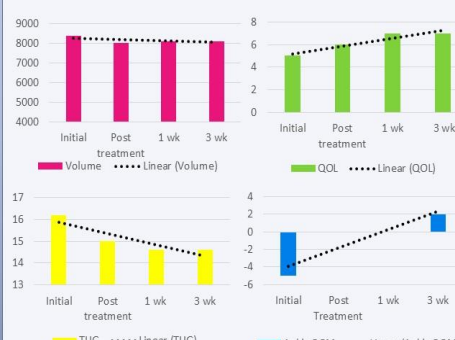


- Treatment had a positive impact on all outcome measures.
- These results were maintained over the observation period.
- Patient comments included: "I am so relieved to finally finding a way to manage my swelling"; "those other stockings just didn't work"



## Results – Case II

82 year old male with history of CVI, LE edema, recurrent stasis ulcerations both LE  
**Previous treatment:** patient had been issued elastic tubular stockinette The stockinette rolled/cut into skin so patient cut it. The wounds left leg re-ulcerated.  
**Treatment:** 2 layer cohesive to reduce volume and achieve 90% wound closure. Then fit with Velcro® Adjustable wrap and OTC flat knit garment.  
**Long term management options:** Velcro adjustable wrap and OTC flat knit, alternating use

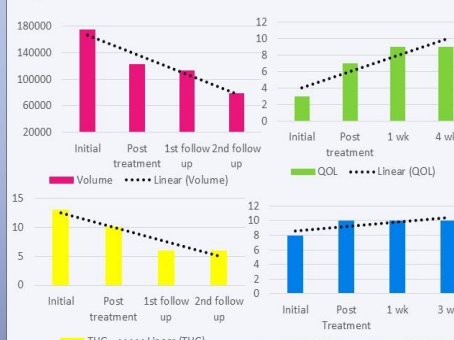


- Treatment had a positive impact on all outcome measures.
- Volume continued to reduced post intervention with ongoing use of OTC flat knit\*
- Patient comments included: "having the option to choose makes it easier on me."



## Results – Case III

46 year old male secondary lymphedema exacerbation due to contrast exposure; history of previous kidney transplant. **Previous treatment:** OTC 20-30mmHg circular knit thigh high left LE  
**Treatment:** Multi-component short-stretch for 2wks and then transition to OTC, flat knit thigh high\*; 3 months follow-up continue wearing OTC flat knit however had to go down a size due to decreased volume; total weight decreased 25 lbs over this time  
**Long term management options:** OTC Flat knit thigh\* high



- Treatment had a positive impact on all outcome measures.
- Volume continued to reduced post intervention with ongoing use of OTC flat knit\*
- Patient comments included: "like the new stocking better – seemed to manage swelling better"



## Conclusion and Discussion

Compression therapy had a positive impact on all outcomes measured during the intensive phase of therapy. Follow-up outside the intensive phase of therapy demonstrated further volume loss in 6/10 subjects; Volume remained constant 3/10, increased slightly 1/10. LYMQOL scores and functional performance level maintained stable during the follow-up period.

Offering multiple compression options including custom and over the counter (OTC) flat knit stockings\*, Velcro® adjustable wrap\*\* and night-time compression options\*\*\* had a positive impact on patients' adherence<sup>6</sup> to compression regimens during the study period compared to single compression modalities offered previously. Individualizing the compression regimen to each patient's lifestyle improved their adherence to chronic edema management.

## References

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4. Davies JA, Bull RH, Farrelly IJ, Wakelin MJ. A home based exercise programme improves ankle range of motion in long-term venous ulcer patients. *Phlebology*. 2007; 22(2):86-9
5. Keeley V. Lymphedema Quality of Life Tool-Leg (LYMQOL-LEG). Registered September 2017 and used with permission.
6. Aronson JK. Editor's view: compliance, concordance, adherence. *BR J Clin Pharmacol* 63(4): 383-384

\*L&R ExoStrong™  
\*\*L&R ReadyWrap™

\*\*\* L&R Solaris TributeNight™  
^ Rosida® TCS





Carolinas HealthCare System

# Measuring the impact of edema management – more than just a volume reduction

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## Introduction

Chronic edema of the lower leg has a negative impact on functional performance.<sup>1</sup> Chronic edema impairs foot wear use and normal gait patterns, impedes calf muscle pump function and most importantly limits the patient's ability to interact with his/her environment.<sup>2,3,4</sup> This negative spiral of progressive edema and progressive decline in functional status can be reversed simply by addressing the edema.

## Compression Material and Methods

Observational study performed at two separate outpatient edema management clinics. Eight people were referred for lower extremity edema management to a physical therapist. Objective data measured included the following:

- Limb volume (cm<sup>3</sup>)
- Range of motion (ROM)
- Functional activity status
  - Timed Up and Go (TUG)
  - 4 M Walk Test (4MWT)
  - Lower Extremity Functional Scale (LEFS)
- Quality of life (QOL) using the Lymphoedema QOL Tool (LYMQOL-LEG).<sup>5</sup>

Measurements were taken at initial evaluation, upon completion of treatment and 2 weeks post treatment. Patients received modified complete decongestive therapy. Gait training was performed during the sessions for safety with assistive device when appropriate.

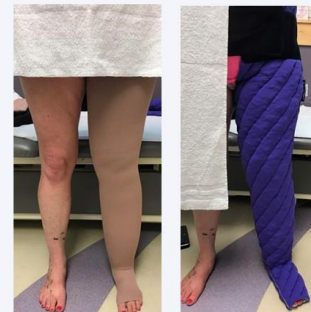
## Subjective Patient report



Patient thrilled to be back in her shoes.

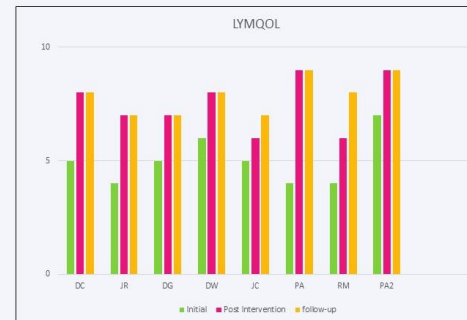
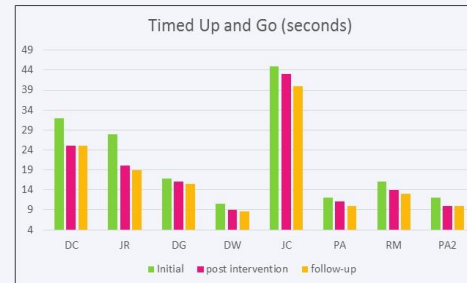
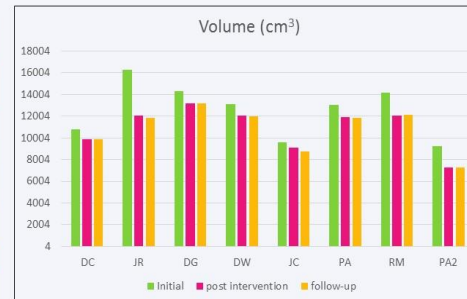


Patient able to manage swelling at home independently

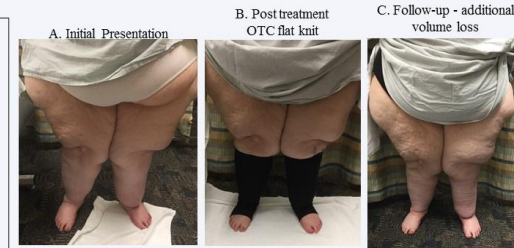


Patient expressed it was easier to manage her swelling when she had something for day and night

## Results



## Detailed Cased Presentation



SB: 5% volume reduction, 33% improvement in self reported QOL; 4MWT improved 0.5m/sec to 0.62m/sec; ROM remained the same



KE:

- 25% volume reduction
- LEFS improved from 85% to 48.5% disability
- 66.6% reduction pain
- ROM improved : 70 to 118 degrees knee flexion
- QOL 166.7% improvement



PA2

- TUG –improved from 12 to 10sec
- Volume reduced 21%
- 33% improvement in self reported QOL
- Ankle ROM improved: 0 to 10 degrees ankle dorsiflexion
- Pain reduced 8/10 to 5/10.

## Discussion and Conclusions

Reduction of swelling had a direct positive impact on all outcomes measured. LYMQOL-Leg scores and functional performance scores (TUG and 4MWT) improved by 15% and 0.1m/sec respectively. Functional performance continued to improve after active therapy had been discontinued with further increased TUG scores at the 2-week follow-up assessment. The reduced edema allowed for normal footwear use, normalized gait patterns which increased mobility and enhanced QOL.

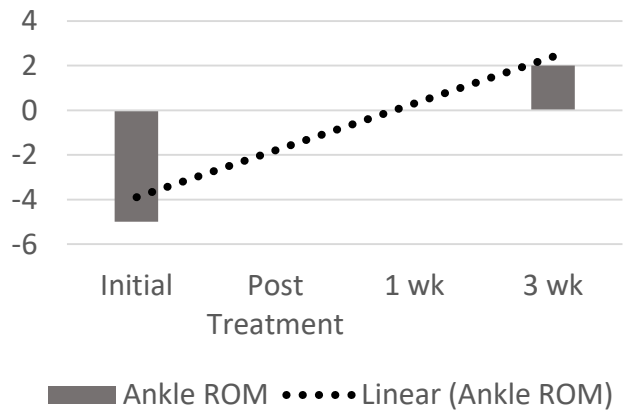
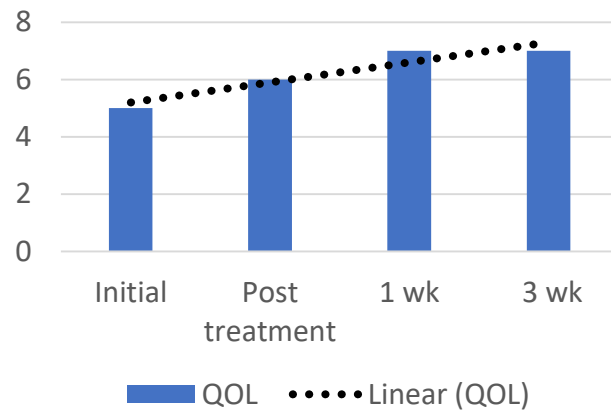
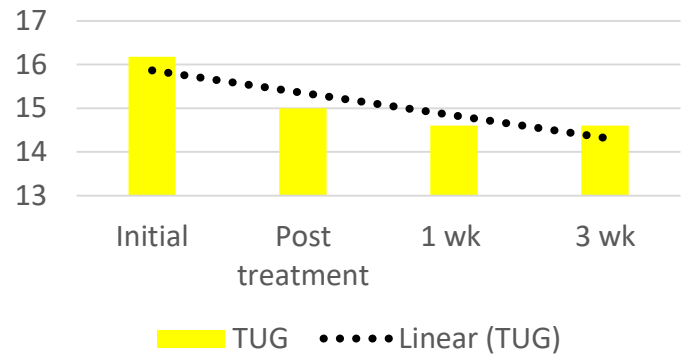
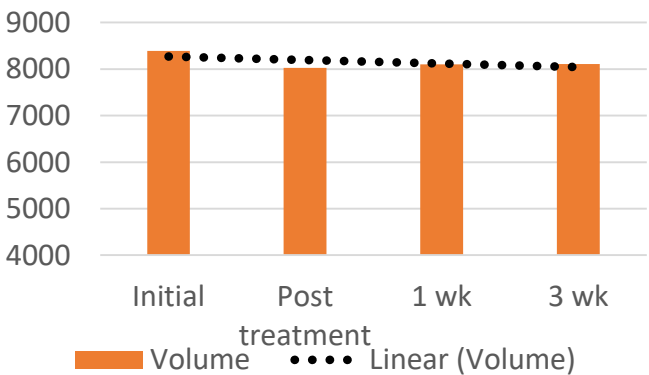
The impact of chronic edema encompasses many physical, psychological and social domains. Assessing the effect of edema management should also include assessment of these other domains including both patients' functional status and QOL in order to accurately quantify outcomes that are individualized to each patient.

## References

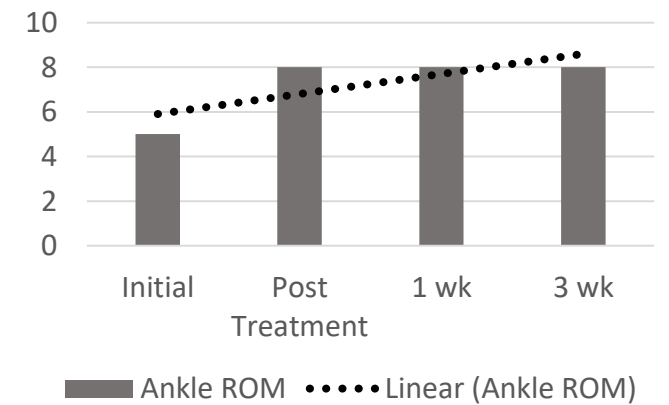
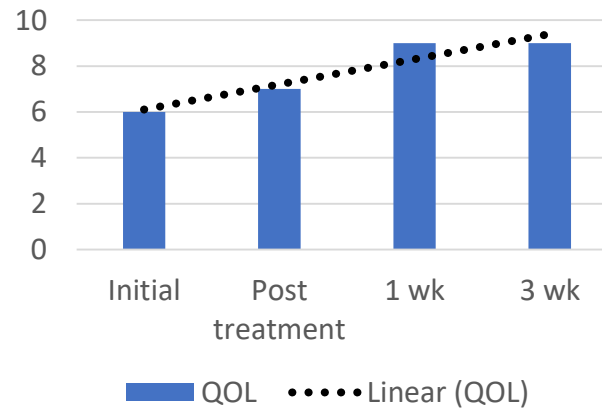
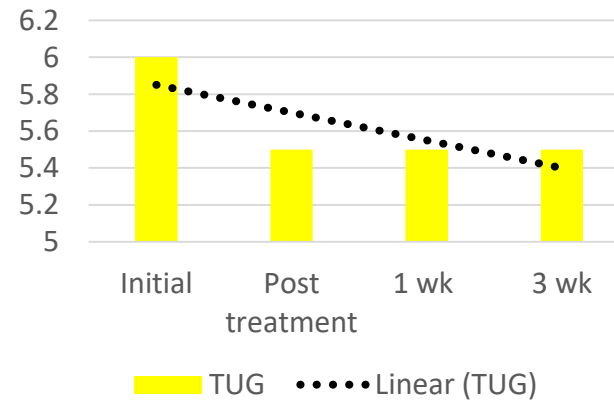
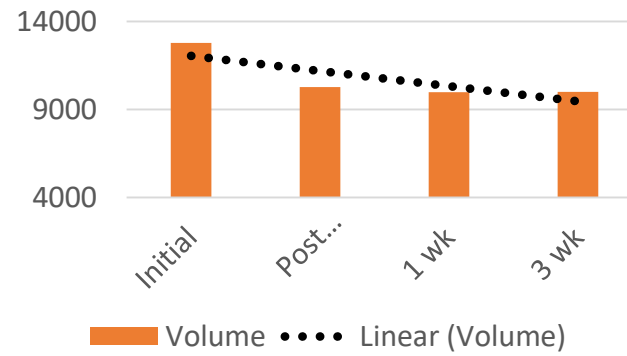
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2. Farrelly I. The importance and function of footwear in managing lymphoedema. *Chronic Oedema*. 2008 Oct:S10-14.
3. Mosti G, Partsch H. Improvement of venous pumping function by double progressive compression stockings: higher pressure over the calf is more importance than a graduated pressure profile. *Eur J Vasc Endovasc Surg*. 2014 47(5):545-549
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5. Keeley V. Lymphoedema Quality of Life tool Leg (LYMQOL-LEG). Registered September 2017 and used with permission.



# Case Study I

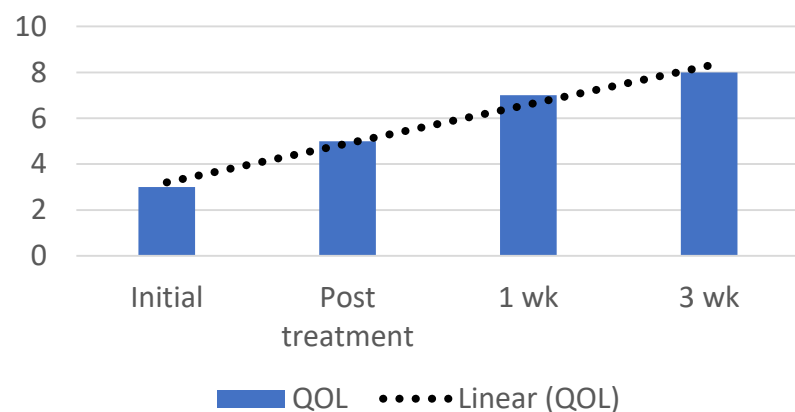
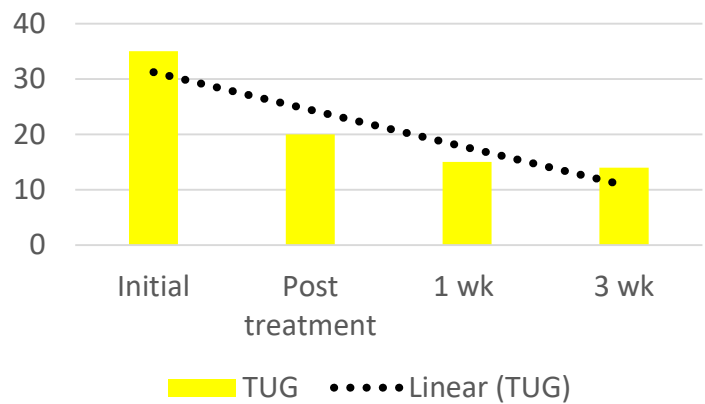
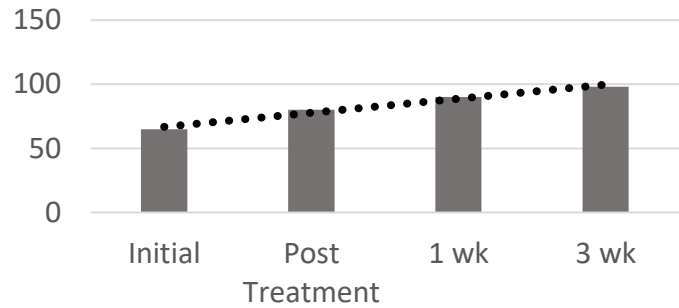
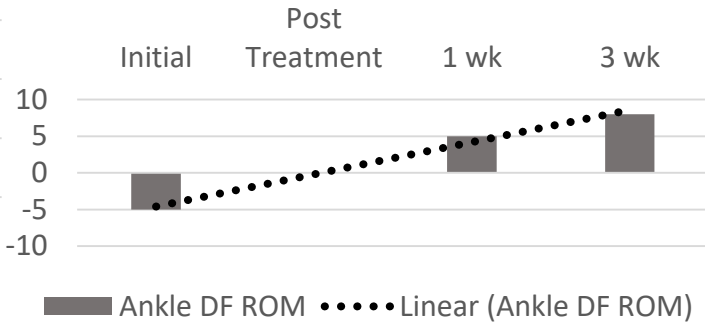
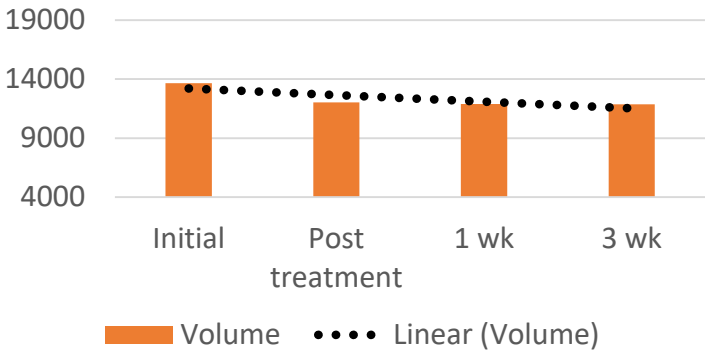


# Case Study II





# Case III





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# EWMA 2018

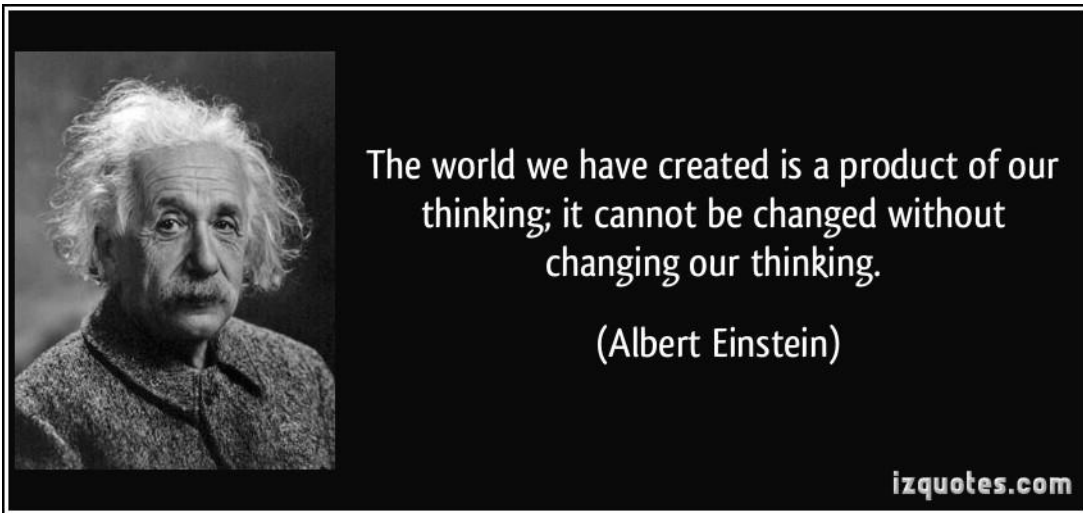
9-11 MAY 2018 · KRAKOW, POLAND



## New Frontiers in Wound AND Edema Management

- Measuring the Impact of Edema management
  - Not just Volume
    - Wound healing
    - Tissue Texture
    - Functional Level
    - QOL
- Compression Options are the key
  - Matching compression option to individual characteristics
    - Need for compression algorithm to direct health care providers
    - Studies to demonstrate long term impact of compression regiments
  - Opportunities for product development
    - Utilizing textile science to engineer compression products
    - Development of products that more easily managed by patient and health care providers

# My challenge to you...

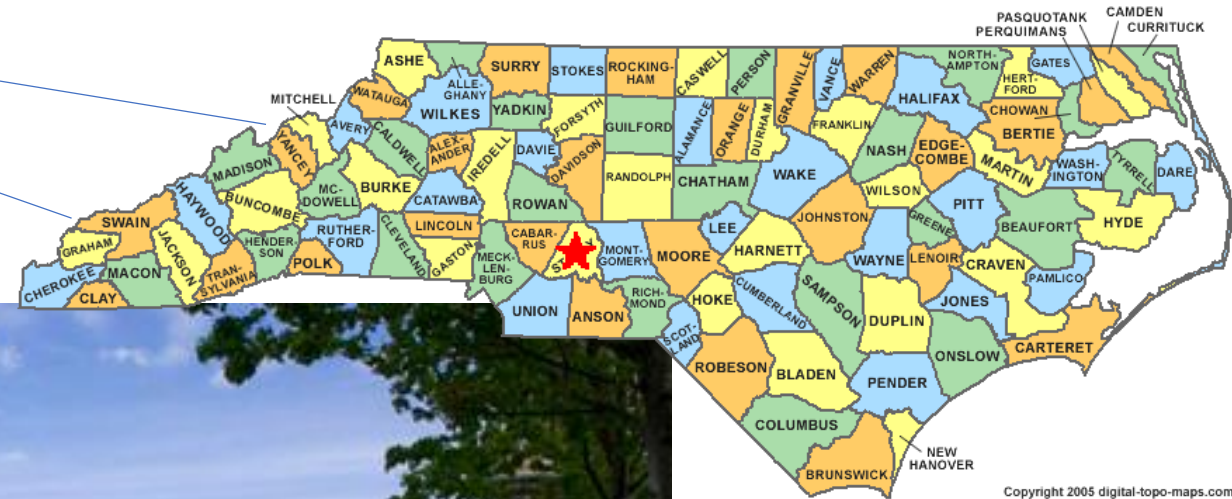


- Swelling is more than volume
  - Tissue texture
  - Function
- Edema management is KEY to wound healing and reduced recurrence
- Options for edema management is KEY to long term success



# Thank You!!

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