Zinc and vitamin C supplementation in the treatment of pressure ulcers

EVIDENCED-BASED RESEARCH PRESENTATION
Overview

**IS SUPPLEMENTAL ZINC AND VITAMIN C ESSENTIAL TO THE TREATMENT OF PRESSURE ULCERS?**

- Preliminary case study
- Background information on PUs
- Research from three recent studies
- Comparison of results
- Current guidelines
- Discussion
- Conclusion
objectives

- Review the role of zinc and vitamin C in wound healing

- Examine current research (last 5 years) on supplemental zinc and ascorbic acid and their effects on wound healing time

- Integrate current research and guidelines to make appropriate interventions for populations with wounds or pressure ulcers at SSRRH
71 YOM that presents with Stage III PU Po approximately 40-50% last 3 days No current supplements are ordered WL 3 lbs since admission 7 days ago Current BMI 22.4 kg/m²

What are your general interventions as a dietitian?
Background: vitamin C

- RDA: 75-90 mg/day
- UL: 2,000 mg/day
- Role in wound healing
  - Cofactor in the cross-linkage, synthesis, and structural stabilization
  - Lysine and proline
- Dietary sources: citrus, tomatoes, potatoes, bell peppers, berries
  - In U.S. deficiency is rare
- Dietary intake 30-180 mg $\rightarrow$ 70-90% absorbed
- Doses >1000 mg $\rightarrow$ < 50% absorbed
Background: zinc

- RDA: 8-11 mg/day
- UL: 40 mg/day
- Role in wound healing
  - Cofactor in synthesis of DNA, RNA, protein
  - Formation of granulated and epithelial tissue
  - Anti-inflammatory and antimicrobial effects
- Dietary sources: red meat, seafood, whole grains, fortified cereals
  - Deficiency is rare
- Plasma zinc bound to albumin
  - Assays of zinc unreliable in state of sepsis, infection, trauma, stress
- Smaller doses more readily absorbed
- High dose supplemental zinc → immune suppression and reduced copper absorption
Background: pressure ulcers (PUs)

- When pressure on a bony site obstructs capillary blood flow, causing tissue necrosis
- Key risk factors
  - Poor nutritional status
    - Malnutrition: Presence of 2 of the 6 characteristics
    - UWL: 5% WL in 1 month or 10% WL in 6 months
    - Inadequate dietary intake
  - Infection, sepsis, trauma
    - Increases REE
    - Wounds/PUs puts greater demand on body
- Link between nutritional status and the incidence, progression, and healing of PUs
Background: pressure ulcers (PUs)

- Incidence with age
  - 27.2% of people over age 70
  - 33.8% of people over age 80

- Incidence among establishments
  - 0.4 to 38% in hospitals
  - 2.2 to 24% in SNFs
  - 0 to 17% in home health agencies

- Total cost to treat PUs in the U.S. = $11 billion annually,
  $37,800 on average to treat ONE PU
- Poses a high cost burden for hospitals to treat PUs
Interventions at Sutter

**Outdated Practice**
- 500 mg vitamin C BID
- 220 mg zinc sulfate (50 mg elemental zinc)
- Protein supplement- Ensure Complete
- Juven- HMB metabolite with glutamine and arginine

**Current Practice**
- MVI with minerals
  - 100 mg Vitamin C
  - 25 mg Zinc
- Boost Plus supplement
  - 60 mg Vitamin C
  - 4.5 mg Zinc
Let’s Examine the Research...
Specific nutritional support accelerates pressure ulcer healing and reduces wound care intensity in non-malnourished patients

van Anholt, et al.

• **BACKGROUND:**
  • PUs pose a high cost burden on health care systems worldwide
  • Patients’ risk of developing PUs is 2- to 3-fold higher when malnourished or underweight
  • Previous research has shown providing an oral nutritional supplement (ONS) improves nutritional status and lowers incidence of PU development in those malnourished
    • What about those non-malnourished?
**PURPOSE:** To investigate the potential of an arginine- and micronutrient-enriched ONS to improve healing of PUs in non-malnourished patients who would usually not be considered for extra nutritional support.

**HYPOTHESIS:** The supplement rich in protein, arginine and micronutrients will promote neoangiogenesis, stimulate collagen synthesis, and have a positive effect on wound healing.
Participants

• 47 patients recruited from 8 health care centers in 4 countries (Czech Republic, Belgium, The Netherlands, Curacao)

• Inclusion criteria:
  • 18 to 90 years old
  • At least one Stage III or IV pressure ulcer (EPUAP classification system)
  • Receiving standard care and standard diet without nutritional supplements at least 2 weeks before the study

• Exclusion criteria:
  • Malnourished
    • Age 18-70 YO: BMI <18.5
    • Age above 70 YO: BMI <21
  • Severe medical conditions, non-pressure-related ulcers, diet restrictions, life expectancy <6 mo, use of corticosteroids

• 4 subjects dropped out
Methods

- 22 subjects randomly allocated to receive a specific ONS
  - 1 serving (200 mL): 250 kcal, 20 g protein, 250 mg vitamin C, 9 mg zinc (other micronutrients)
- 21 subjects randomly allocated to receive a non-caloric, flavored placebo
- All subjects received 200 mL servings TID between meals
  - product compliance was recorded
- All received the same, standard institutional diet
  - Volume consumed was recorded
- Length of study, 8 weeks
RESEARCH STUDY 1

Methods continued

- Assessed weekly over 8 weeks
  - PU SA: measured length + width using a ruler
  - PUSH score: 0 (completely healed) to 17 (greatest severity)
    - SA, exudate, type of wound tissue
  - Total number of dressings applied in the week and time for application
- Assessed at baseline and week 8
  - Weight, BMI, Malnutrition Universal Screening Tool (MUST) score, blood parameters (vitamin C, zinc)
Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>ONS (n = 22)</th>
<th>Control (n = 21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men/women</td>
<td>8/14</td>
<td>11/10</td>
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<tr>
<td>Age (y)</td>
<td>76.2 ± 3.2</td>
<td>73.0 ± 3.3</td>
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<tr>
<td>Body weight (kg)</td>
<td>66.3 ± 4.5</td>
<td>75.6 ± 5.3</td>
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<tr>
<td>Body mass index (kg/m²)</td>
<td>23.7 ± 1.0</td>
<td>25.8 ± 1.1</td>
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<tr>
<td>MUST score</td>
<td></td>
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</tr>
<tr>
<td>Low risk</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>Medium risk</td>
<td>3</td>
<td>2</td>
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<tr>
<td>High risk</td>
<td>4</td>
<td>1</td>
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<tr>
<td>Ulcer stage</td>
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<tr>
<td>Stage III</td>
<td>17</td>
<td>14</td>
</tr>
<tr>
<td>Stage IV</td>
<td>5</td>
<td>7</td>
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<tr>
<td>PUSH tool (total score)</td>
<td>11.5 ± 0.7</td>
<td>11.4 ± 0.7</td>
</tr>
<tr>
<td>Time spent on dressings (min/wk)</td>
<td>65.5 ± 7.0</td>
<td>54.6 ± 7.3</td>
</tr>
<tr>
<td>Dressings/wk</td>
<td>5.6 ± 0.5</td>
<td>4.9 ± 0.5</td>
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<tr>
<td>7 (1–7)</td>
<td>7 (1–14)</td>
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</tbody>
</table>

*No statistical differences between the groups at baseline

*No statistical differences between PU characteristics between groups at baseline
**Results**

**Fig 1. PU Size**
ONS group healed significantly faster than the control group (P=0.016)

**Fig 2. PUSH score**
PUSH scores improved significantly in the ONS group compared to the control group (P=0.033)
Results

**Fig 3. Number of Dressings**
Significantly fewer dressings were required in the ONS group than in the control group (P=0.045)

**Fig 4. Time spent of changing dressings**
Significantly less time was required to change the dressings in the ONS group versus the control group (P=0.022)
Results

Table 3. Nutritional blood parameters
No statistically significant differences between blood parameters in the ONS and control groups with the exception of vitamin C increasingly significantly in the ONS group between baseline and the end of the study (P=0.015)

Table 4. Amount consumed of the ONS and control product
Significantly more product was consumed by the control group than the ONS group (P=0.042)

<table>
<thead>
<tr>
<th></th>
<th>ONS Group</th>
<th>Control Group</th>
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</thead>
<tbody>
<tr>
<td>C-reactive protein (mg/L)</td>
<td>18.5 (3.0–220.9)</td>
<td>13.8 (0.5–240.8)</td>
</tr>
<tr>
<td>Total leukocytes (10^{9}/L)</td>
<td>9.2 ± 0.5</td>
<td>8.9 ± 0.9</td>
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<tr>
<td>Total erythrocytes (10^{12}/L)</td>
<td>4.0 ± 0.1</td>
<td>4.3 ± 0.1</td>
</tr>
<tr>
<td>Thrombocytes (10^{9}/L)</td>
<td>398.4 ± 34.6</td>
<td>304.2 ± 27.6</td>
</tr>
<tr>
<td>Hemoglobin (mmol/L)</td>
<td>7.3 ± 0.2</td>
<td>7.8 ± 0.2</td>
</tr>
<tr>
<td>Creatinine (mg/L)</td>
<td>178 ± 16</td>
<td>190 ± 22</td>
</tr>
<tr>
<td>Zinc (μmol/L)</td>
<td>11.2 ± 1.2</td>
<td>10.6 ± 0.8</td>
</tr>
<tr>
<td>Vitamin C (μmol/L)</td>
<td>23.0 ± 5.3</td>
<td>60.2 ± 7.4[a]</td>
</tr>
</tbody>
</table>

[Table 3. Main (nutritional) blood parameters of the group receiving a specific ONS and the control group *]

<table>
<thead>
<tr>
<th></th>
<th>ONS Group (75.8 ± 3.7%)</th>
<th>Control Group (86.5 ± 2.3%)</th>
</tr>
</thead>
</table>

 agonist of TGF-β3-67
Conclusion

• The high-protein, arginine- and micronutrient-enriched ONS accelerated the healing of PUs, as indicated by:
  • Significant reduction in PU size
  • Significant decrease in PUSH tool scores
  • Significantly fewer dressings required
  • Less time required to change the dressings
• Synergistic effect between arginine, vitamin C, zinc to improve wound healing
• Supplementation will improve quality of life of non-malnourished patients and save costs by decreasing wound care
Time to wound closure in trauma patients with disorders in wound healing is shortened by supplements containing antioxidant micronutrients and glutamine: A PRCT

**BACKGROUND:**

- Ascorbic acid and zinc are attributed an important role in wound healing
- Clinical data on casual relationship was lacking between micronutrient supplementation and wound healing
PURPOSE: To investigate how dietary measures including micronutrient supplementation (including ascorbic acid and zinc) improves the wound healing process.

HYPOTHESIS: The wound closure in trauma patients with disorders in wound healing (DWH) is accelerated by supplementation of antioxidant micronutrients and glutamine.

- DWH: failure to close with continued excretion 10 days after trauma
Participants

• 20 Caucasian trauma patients with DWH were recruited from University Hospital of Bonn, Germany

• Exclusion criteria:
  • EN or TPN
  • Current supplementation with vitamins and trace minerals
  • Consumption of fortified juices
  • Extreme comorbidities
  • PUs as primary diagnosis
  • ICU stay or sepsis

• All 20 subjects completed the study
**RESEARCH STUDY 2**

Methods

- 10 subjects randomly allocated to the verum group
  - Received two sachets per day of Glutamine Plus® granulate
    - 500 mg AA, 6.6 mg zinc, 20 g glutamate
- 10 subjects randomly allocated to the placebo group
  - Received two sachets per day of tasteless, isoenergetic maltodextrine
- Both groups instructions:
  - Mix the entire sachet with yogurt, dessert or beverage and consume immediately
  - Document intake in a diary
- All received a protein-rich diet provided by a hospital caterer
  - Fortified juices were excluded
  - Subjects recorded daily intakes
- Length of study, 14 days
• Measured on d0 and d14
  • Anthropometric data
  • Nutritional status
    • Determined by a Subjective Global Assessment (SGA)
      • Well-nourished: SGA A
      • Moderately malnourished or suspected to be malnourished: SGA B
      • Severely malnourished: SGA C
    • Determined risk for malnutrition
      • Nutritional Risk Screening- 2002
  • Blood Samples
    • Ascorbic acid and zinc
• Measured on d0, d7, and d14
  • Parameters of microcirculation: oxygen saturation, blood flow, blood velocity
    • Non-invasive white light spectrometer
  • Wound temperature
  • Time to wound closure (study entry to no secretion, inflammation or infection)
Results

Table 3. Nutrient status (plasma concentrations) at d0 and d14
Median [quartiles]. Nutrient status is comparable in both groups at baseline. d0: baseline; d14: after 14-day supplementation; n.s.: not significant

- No statistical difference of zinc or ascorbic acid plasma concentrations between d0 and d14 in both the placebo and verum groups
- No statistical evaluation of zinc was performed “due to low number of patients concerned”
Results

Figure 1. Time to wound closure [days]
Significant difference in time to wound closure between groups
RESEARCH STUDY 2

Conclusion

• Supplementation of antioxidant micronutrients and glutamine is associated with an accelerated wound closure in patients with DWH
  • Speculated glutamine supplementation in the verum group maintained plasma glutamine levels; increased intracellular glutamine availability; thus supporting the healing process
    • Glutamine: major nitrogen source for rapidly proliferating fibroblasts and epithelial cells.
  • Speculated vitamin C supplementation caused reduction in inflammation in verum group

• “The underlying mechanism(s) remains debatable”
A nutritional formula enriched with arginine, zinc and antioxidants for the healing of pressure ulcers: a randomized trial Cereda, et al.

• **BACKGROUND:**
  
  • Previous trials on specific nutritional supplements for the treatment of PUs have been small, inconsistent in their formulations, or did not standardize for the protein and calorie content of the supplements.

  • No other studies evaluated the independent role of arginine, zinc and vitamin C when included in a readily available commercial formula designed to improve wound healing
PURPOSE: To perform a large, randomized trial in malnourished patients to evaluate whether supplementation with arginine, zinc and antioxidants within a high-calorie, high-protein formula improves PU healing.

HYPOTHESIS: The oral formula enriched with arginine, zinc and antioxidants is beneficial to the healing of PUs.
RESEARCH STUDY 3

Participants

• 200 malnourished adults with PUs Stage II-IV recruited from 7 sites, Italy
  • Long-term care or home care services

• Inclusion criteria:
  • Malnourished (one of the following)
    • Low BMI
      • For age < 65: BMI < 20 kg/m²
      • For age ≥ 65: BMI < 21 kg/m²
    • Recent unintentional WL
      • ≥ 10% in 3 months
      • ≥ 5% in 1 month
    • Low serum albumin
    • Reduced oral intake
      • < 60% of estimated daily energy requirements the week prior
  • Able to drink ONSs
  • Provide written consent

• Exclusion criteria:
  • Artificial nutrition, uncontrolled DM, renal or hepatic insufficiency, HF, PVD, COPD, neoplastic disease, obesity, infected wound, or sepsis

• 138 subjects completed the trial
• 200 included in analysis using linear regression models
Methods

• 101 subjects randomly allocated to the experimental formula
  • 1 serving (100 mL): 125.8 kcal, 10 g protein, 1.5 g Arginine*, 125 mg vitamin C*, 4.5 mg zinc* (other micronutrients)

• 99 subjects randomly allocated to the homemade, control formula
  • 1 serving (100 mL): 127.2 kcal, 10 g protein, 19 mg vitamin C, 2.3 mg zinc (other micronutrients)

• Calories and grams of protein equivalent in both formulas

• Both groups received two bottles (400 mL) per day of their respective formulas
  • Adherence was monitored throughout the study

• Dietary intakes not standardized

• Length of study, 8 weeks
RESEARCH STUDY 3

Methods continued

• Measured at baseline and week 8:
  • Body weight
  • Braden scale: measures risk of PU
    • Score ≤ 18 predictive for PU development
• Measured at baseline, week 4, and week 8:
  • PU area (unstated how)
• Measured at baseline and every 2 weeks:
  • Total daily energy and protein intakes (including ONSs)
    • 3-day quantitative food diary, assessed by RD
• Measured on a daily basis:
  • Amount of formula consumed
• Type of dressing and frequency of its change was individualized

All methods were standardized between facilities
The same person assessed all subjects at each facility
Experimental and control formulas contained same amount of protein and calories
Statistically different in the amount of zinc, vitamin C, arginine*

<table>
<thead>
<tr>
<th>Table 1. Nutrient Contents for 100 mL of the Intervention Formula</th>
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<tbody>
<tr>
<td><strong>Variable</strong></td>
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<tr>
<td><strong>Macronutrients</strong></td>
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<tr>
<td>Proteins, g</td>
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<tr>
<td>Milk proteins</td>
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<tr>
<td>Arginine</td>
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<tr>
<td>Carbohydrates, g</td>
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<td>Fats, g</td>
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<tr>
<td><strong>Energy</strong></td>
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<tr>
<td>Total, kcal</td>
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<tr>
<td>Percentage from proteins</td>
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<tr>
<td>Percentage from carbohydrates</td>
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<td>Percentage from fats</td>
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<tr>
<td><strong>Minerals</strong></td>
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<td>Sodium, mg</td>
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<td>Potassium, mg</td>
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<tr>
<td>Chloride, mg</td>
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<tr>
<td>Manganese, mg</td>
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<tr>
<td>Molybdenum, mcg</td>
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<td>Chromium, mcg</td>
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<tr>
<td>Iodine, mcg</td>
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<tr>
<td><strong>Vitamins</strong></td>
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<tr>
<td>Vitamin A, mcg</td>
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<td>Vitamin D, mcg</td>
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<tr>
<td>Vitamin E (α-tocopherol), mg</td>
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<td>Vitamin K, mcg</td>
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<td>Riboflavin, mg</td>
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<td>Niacin, mg</td>
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<td>Vitamin B₁₂, mcg</td>
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<tr>
<td>Biotin, mcg</td>
</tr>
<tr>
<td>Vitamin C, mg</td>
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<tr>
<td>Choline, mg</td>
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</table>

* Values indicate significant differences.
Results

**Primary end points**
- Reduction in PU area at week 8, %

**Secondary end points**
- ≥ 40% reduction in PU area at week 8, %
- Complete healing, %
- Reduction in PU area at week 4, %
- Wound infections, %
- Mean dressings, n

**X**: experimental group with significantly more %persons at **week 4**
**X**: experimental group with significantly more %persons at **week 8**
Results

- Adherence to treatment:
  - 84.8% ± 15.2% in experimental group
  - 83.7% ± 16.3% in control group
- Treatment resulted in increase BW at 8 weeks in both groups
Conclusion

• “Overall treatment was effective in improving PU healing in both the experimental and control groups”

Overall Conclusion: Additional provision of arginine, zinc and antioxidants in the nutritional support of patients with PUs was effective in improving PU healing

• Mean reduction in PU area at week 8
• ≥ 40% reduction in PU area at week 8
Comparison of studies

<table>
<thead>
<tr>
<th></th>
<th>Study 1</th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects</td>
<td>43</td>
<td>20</td>
<td>200</td>
</tr>
<tr>
<td>Tested malnourished population</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Tested non-malnourished population</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Isolated zinc and vitamin C</td>
<td></td>
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<tr>
<td>Supplement contained glutamine</td>
<td>✔️</td>
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<tr>
<td>Supplement contained arginine</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>ONS group had accelerated wound healing</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
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</table>

Accelerated wound healing exclusively caused by supplemental vitamin C & zinc
What does the *Pressure Ulcer Prevention and Treatment: Clinical Practice Guidelines* say about current research....?

-NPUAP, EPUAP, PPPIA
“methodological flaws and study size have precluded confirmation of clinically significant results...because previous studies of the individual nutrients failed to show benefit, the authors have postulated a synergistic effect among the nutrients.” –2014 Cochrane Database System Review

“The 2014 Cochrane Review...investigated the effect of nutritional supplementation on the healing of PUs [in] 14 studies.... The authors concluded there is generally no clear evidence of improved PU healing with nutritional supplements.... Most of the treatment studies were unclear and had a high risk of bias.” –NPUAP, EPUAP, 2015
Zinc:

• “High-dose zinc supplementation (>40 mg/d) is not recommended because it can adversely affect copper status... inhibit healing... induce a copper deficiency [which] may be harmful as copper is essential for collagen cross-linking.”

• “No evidence-based research exists to prove it’s beneficial to give mega doses of zinc over the upper tolerable limit of 40 mg/d to promote wound healing unless clinical signs of zinc deficiency are present, and supplementation should be stopped once deficiency is corrected.”

  - NPUAP, EPUAP 2015

• “In the presence of a confirmed or expected zinc deficiency general practice is to give ZnSO4 220 mg (50 mg elemental Zn) bid for no longer than two or three weeks.”

Vitamin C:

• “Research doesn’t support giving [routine] mega doses of vitamin C to accelerate wound healing...physiological doses should be considered [only] when dietary deficiency is diagnosed.”

• “The inclusion of fruits and vegetables in the diet can achieve the daily recommended intake”

  -NPUAP, EPUAP 2015

• “Members of the general population should not routinely exceed the UL, which...applies to intake from both food and supplements.... Doses greater than the UL may cause nausea, diarrhea or abdominal cramps.”

  -IOM’s Dietary Reference Intakes
No current research has directly and appropriately determined that supplemental zinc and vitamin C accelerate wound healing.
A dietitian’s MNT goal for PUs:

- Maintain adequate nutrition status by providing optimum dietary and fluid intake
- Identify and treat causes of poor nutritional intake
- Monitor weight status routinely to detect unexpected or unintentional weight loss
- Select nutrition interventions to improve or maintain nutritional status, including the use of oral supplements or nutrition support, if warranted

“Inadequate dietary intake may require a multivitamin/mineral supplement; however, the use of specific supplements (i.e. vitamin C and zinc) is only recommended when a true deficiency occurs.”

Detecting Deficiencies:

• Plasma zinc levels naturally decrease with inflammation, and lab testing may not represent total body stores
  • Assay is rarely done

• Physical assessment can help determine deficiencies
  • Tongue, skin, nails, hair, lips

• If pre-existing malnutrition is evident, correct deficiencies to improve nutritional status
  • Liberalize diet and encourage po intake
  • ONS- Boost
  • Suggest nutrition support, if appropriate
Assessment & Discussion:

What is one piece of information you will take away from today's presentation on PUs?
Empower yourself to...

- Use what we have learned today from this point forward to appropriately assess and make nutritional recommendations for patients with PUs
  - 2014 *Pressure Ulcer Prevention and Treatment: Clinical Practice Guideline*, from NPUAP, EPUAP, PPPIA
Summary

Is supplemental zinc and vitamin C essential to the treatment of pressure ulcers?

- Preliminary case study
- Background information on PUs
- Research from three recent studies
- Comparison of results
- Current guidelines
- Discussion
THANK YOU

QUESTIONS?