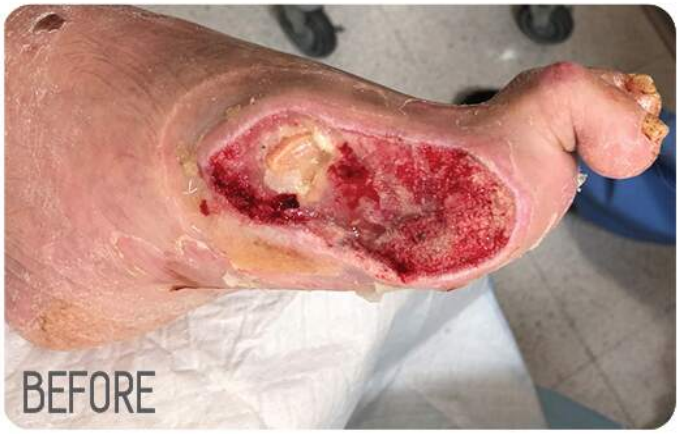
SkinTE®

Nothing heals acute wounds like human skin.

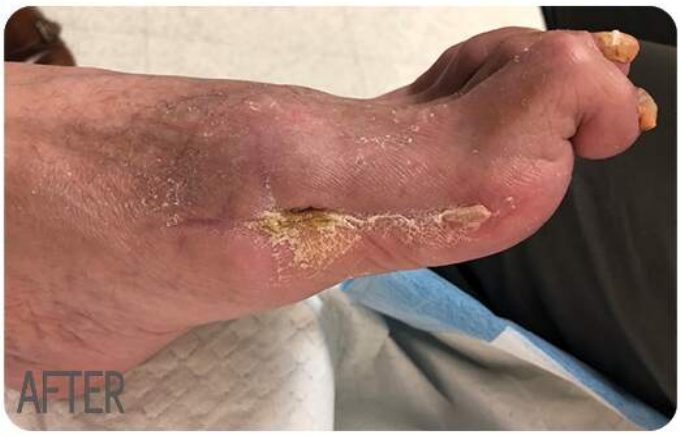
That's why SkinTE is made from the patient's own skin.

Take a revolutionary approach to skin regeneration with SkinTE.

Created from your patient's own skin, SkinTE regenerates full-thickness skin with all of its layers (epidermis, dermis, hypodermis) and appendages (hair follicles, sweat, sebaceous glands), resulting in function such as sensation, moisture production, and pliability.[1,2]



A 69 year-old male with multiple comorbidities required a left hallux amputation resulting in exposed bone and cartilage.



At four months, following a single application of SkinTE, full-thickness functional skin was generated within the wound bed and covered the previous defect including exposed critical structures.

Clinical use of SkinTE or to place an order

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833-631-9954

More About SkinTE
polarityte.com

Reimbursement information

Reimbursement@PolarityTE.com
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PolarityTE®
Where Self Regenerates Self®

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About SkinTE®

SkinTE is a human cellular and tissue based product derived from a patient's own skin (autologous) intended for the repair, reconstruction, replacement or supplementation of skin tissue and the integumentary system. Aseptic surgical procedures and handling during skin harvest, wound preparation and SkinTE deployment are mandatory.

Important Safety Information

SkinTE is donated human tissue for autologous, single application use only. SkinTE has not been evaluated for infectious substances. SkinTE may contain trace amounts of antibiotics (e.g., gentamicin), which may potentially cause an adverse effect in patients who are hypersensitive or allergic to antibiotics. For patients sensitive to or allergic to gentamicin, alternative processing is available with prior notice. Patients with multiple comorbidities, or who have any condition that could compromise recipient site vascularity and wound healing, should be carefully evaluated prior to using SkinTE. Such conditions may prevent successful outcomes or lead to suboptimal results. Failure to ensure proper aseptic technique may result in contamination of the harvested skin, donor site, tissue product and/or wound bed, and could result in potential adverse events including local, regional, or systemic infection, failure of the graft to take upon deployment, failure of skin to heal and/or regenerate, deleterious effects on potential surrounding or adjacent reconstructions including infection, failure of adjacent grafted material to take and heal, the need for further surgical operations(s), and/or debridement or other serious injuries or death. Failure to follow instructions may lead to suboptimal outcomes, product failure and/or patient harm. Outcomes may vary. Risks also include those associated with skin grafting such as graft failure, infection, and/or effects adjacent tissue or reconstructions.

Received: 28 September 2020 | Accepted: 20 October 2020

DOI: 10.1111/iwj.13520

LETTER TO THE EDITOR

IWJ WILEY

Comment on "International consensus on pressure injury preventative interventions by risk level for critically ill patients: A modified Delphi study"

Dear Editors,

With great interest, we read the recent paper by Lovegrove et al who developed pressure injury (PI) preventive interventions based on risk categories of the Consciousness, Mobility, Heamodynamics, Oxygenation, Nutrition (COMHON) Index.[1] PI prevention in clinical practice is a complex and challenging task, and initiatives aimed at guiding and improving setting-specific PI prevention are highly welcome. Because the authors use the latest International Guideline for prevention and treatment of PIs[2,3] as background for their work, some assumptions and statements should be put into context:

First, citing the International Guideline,[3] the authors state: "PI prevention begins with risk assessment, which should be undertaken using a structured risk assessment scale combined with clinical judgement."[1] We would like to clarify that such a statement does *not* exist in the International Guideline.[3] We feel very concerned about this wrong and misleading citation, which Lovegrove et al[1] used to justify their risk assessment approach. We invite the authors and all guideline users to study the comprehensive 35 pages "Risk Factors and Risk Assessment" chapter in the International Guideline[3] in detail, which presents a comprehensive summary of PI risk assessment evidence of the last decades, to ensure correct citations and appropriate interpretations.

Second, the International Guideline does state that when performing a comprehensive PI risk assessment, a structured approach that includes a comprehensive skin assessment and clinical judgement should be used. The structured approach must ensure that *all* relevant risk factors for the particular patient group and clinical setting are considered. Standardised risk assessment tools (scales, indices) may be used as one part of the risk assessment; however, a risk assessment tool does not replace a comprehensive structured approach. When a risk assessment tool is used, additional risk factors must be also considered, because the currently available tools do not include *all* relevant factors for individual patients and clinical situations.[3]

Third, for years it has been widely accepted that total (sum) scores of PI risk assessment tools and corresponding "risk levels" are neither reliable nor valid,[4] and there is no evidence that their use improves clinical decision-making.[5] Evidence supporting instrument measurement properties such as reliability or (predictive) validity does not indicate whether using a PI assessment tool to conduct a risk assessment improves clinical practice and patient outcomes.[6] Therefore, concepts such as "effectiveness" or "effects" of PI assessment tools should only be used when there is appropriate intervention studies investigating risk assessment tool effects.

Finally, while we fully understand the desire to develop prevention protocols that are more specific than described in the International Guideline,[3] the output of recommended interventions listed in Table 4 is disillusioning. The International Guideline cautions,[3] "Do not rely on a total risk assessment tool score alone as a basis for risk based prevention" (page 60). Every PI preventive intervention must address the *individual* risk factors, with a direct link between exposures to direct PI risk factors (such as immobility) and interventions directly addressing these factors. Subscale scores from risk assessment tools may be useful in identifying some (but not all) modifiable risk factors. However, by definition, the total score from a risk assessment tool cannot provide the details necessary for focused risk-based preventive interventions, resulting in over-, under-, or inappropriate use of preventive services and supplies. For example, classifying an individual as "low risk" based on the total COMHON score does not justify not using heel off-loading devices or specialised cushions when sitting out of bed. PI prevention planning should be determined based upon the level of mobility, the duration of sitting, and the

cutaneous response to loading and other factors such as the presence or absence of peripheral vascular disease. For example, there is no reason to apply preventive dressings at the trochanter region in "high-risk" patients when this area is not exposed to pressure (eg, during prone, supine, or 30° lateral position).

We agree with Lovegrove et al[1] that the overall evidence regarding (frequencies of) risk assessment and repositioning is weak and that pressure-related tissue damage can occur very fast. It is impossible to recommend any specific periods because individual susceptibilities and clinical situations are too heterogeneous. We also agree that recommended interventions must be regarded as a baseline, with more or less intervention implemented as needed, if appropriate, feasible and not contraindicated. However, this leads to the question regarding advantage and clinical benefit of a "minimum PI preventive intervention set,"[1] when there is international agreement that PI prevention must be based on individual risk factors rather than risk categories derived from non-specific numerical scores.[3]

DATA AVAILABILITY STATEMENT

There are no data to share.

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