博士論文

Preventing development and recurrence of skin tear in elderly patients at a long-term medical facility in Japan

- Focusing on skin properties and morphological characteristics of injuries -

(本邦の療養病床病院における高齢者スキンテア発生と再発予防

皮膚特性と創傷形態に着目して**)**

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ABSTRACT

Background: The identification of predisposing skin properties and etiology-related external forces is important for the prevention of skin tear (ST) development and recurrence. The aim of Chapter 1 was to identify skin properties that can help to predict the high risk population of STs. The aim of Chapter 2 is to define morphological characteristics of STs, to record known external causative forces and to identify which morphological characteristics of STs are associated with different external forces.

Methods: A prospective cohort study was conducted at a long-term medical facility (Chapter 1). Skin properties at baseline were measured by 20-MHz ultrasound scanner and by skin blotting. The development of STs was followed by a regular observation of the extremities and incident reports. In Chapter 2, we discuss a qualitative descriptive study to define the morphological characteristics of STs, and to extract subcategories and categories from interviews involving in external forces causing STs. Unique characteristics related to each subcategory were summarized in the correspondence table.

Results: A total of 149 participants were followed for eight months. There were 21 patients who developed STs, resulting in an incidence rate of 1.13/1000 person-days. The predictor of STs was dermis thickness (cutoff 0.8 mm). Four characteristics of STs—purpura, shape, depth of arc, and size—were found to be associated with different external causative forces.

Conclusion: The identification of skin property that associated with ST development, as well as the different external forces that cause them, may contribute to prevention of the development and recurrence of STs.

KEY WORDS: elderly, external forces, morphological analysis, nursing, skin tear

INTRODUCTION

1. Skin changes with aging

Japan is forecasted to become a super-aging society ahead of any other countries in the world [1]. The skin is the largest organ of the human body, and can contribute to the maintenance of an individual health by providing a protective barrier from the environment, for instance from heat, solar ultraviolet (UV) irradiation, infection, injury. Aging produces functional deficits within the skin due to structural changes. Therefore, as the aged population continues to increase in number, alterations in the skin's integrity with aging will produce increased risk of injuries, such as skin tears (STs) [2-4].

Skin aging results from two processes: chronological aging, which is a naturally occurring process that results in slow tissue degeneration, and photoaging, which is caused by advanced cumulative effects of UV irradiation due to sun exposure [5-7]. Both processes are cumulative and photoaging superimposes on chronological aging. In addition, decreased estrogen levels also play a role in aging of the skin, especially in women after menopause [8, 9].

Histological studies have revealed that the major alterations in aged skin are localized in the dermis layer [10, 11]. Human skin consists of two layers: the epidermis and the dermis. The epidermis is primarily composed of keratinocytes, which continually undergo terminal differentiation, a process that results in formation of the outermost protective barrier [12]. The dermis, 2 to 3 mm in thickness, is a layer composed predominantly of connective tissue and blood vessels that comprises the main bulk of the skin [13]. It supports the epidermis and binds it to the subcutaneous tissue [13, 14]. The dermal connective tissue contains elastin and collagen [10, 11]. In the dermis, a collagen-rich extracellular matrix is synthesized, organized, and maintained by dermal fibroblasts [10, 11, 13]. Dermal thickness decreases with age [15-17], with a decrease in vascularity and cellularity [3, 4]. Therefore, aging is inevitably associated with a decrease in collagen turnover due to a decrease in the number of fibroblasts and associated collagen as well as elastin synthesis [4-7, 10, 11]. The aging process is also partially due to the formation of reactive oxygen species, which are engendered by both chronological aging and photoaging, stress, and smoking [4]. Furthermore, some evidence suggests that reactive oxygen species contribute to the degradation of collagen and to the accumulation of elastin, which is emblematic of photoaged skin [6, 18]. Age-related abnormal collagen homeostasis impairs the structural integrity [4-7, 10, 11, 13] and mechanical properties of the skin [19, 20], with an increase in vulnerability to STs.

2. Epidemiology of skin tears

In Japan, the prevalence of STs in 11 general hospitals was 0.15% or 1.65% in a population under 65 years or over 75 years of age, respectively [21]. The prevalence and incidence of STs in an elderly population (median age; 89 years) at a long-term medical facility was 3.9% [22] or 3.8% [23], respectively. In United Kingdom, a retrospective review of 6-month incident reports revealed that an average of 14% of the population sustained a ST each month [24]. A previous study in Western Australia showed that STs comprised 20% of known wounds in a population predominantly over 70 years of age [25]. Although the prevalence of STs in Japan is lower than that compared with fair-skinned in Western people, the number of elderly population suffering from STs in Japan is expected to grow in aging societies, because the prevalence of STs increases with aging. Therefore, a prevention capable of more precisely detecting high risk population of STs is indispensable.

3. Definition and status of skin tears

STs are defined as wounds caused by shearing, friction, and/or blunt forces that result in the separation of skin layers [26], which most commonly occur on the extremities in elderly people [21- 30]. STs can occur accidentally due to external forces, for example, bumping into objects, shearing, or pulling in patient’s arm during routine nursing care, or during daily activities by patients themselves, [24, 27, 27-32] and are considered to be largely preventable. However, STs have been an underappreciated wound receiving very little attention and there have been few research reports on related risk factors [26]. Therefore, the occurrence of STs has not been well predicted or prevented.

When the intensity of external forces to the skin exceeds the ability of tissues to resist them, ST occurs often accompanied by terrible pain [27, 28]. Excessive external forces and tissue structures may yield a unique morphology of ST, like the linear, L type, or flap type [33-35]. For example, when patients bump their forearm against a bed rail, the skin and subcutaneous tissues are compressed against the bone and may split sideways often accompanied by a zone of surrounding purpura and skin flap. STs are sometimes preceded by bruising, such as in senile purpura or ecchymosis [24, 27, 28, 36-38]. Depending on the intensity level or type of external forces during trauma, the skin flap is sometimes partially or completely absent. In addition, a ST is predisposed to infection, which may be correlated with a larger tear size and complete flap absence [39]. While the definition of injury is different from that of ST, there are some injuries whose morphologies are similar to STs, for example, pretibial lacerations, which develop on the lower legs (Grade 1-3) [40] and dermatoporosis (stage 2-3) [41].

Elderly people with existing STs are most likely to experience additional tearing, which is referred to as ST recurrence [23, 27, 29]. Unfortunately, hospital-acquired STs have not been recognized as natural consequences of aging in elderly people but, incorrectly, as injuries caused by abuse or poor-quality care [27]. In addition, the development of a ST during routine care could threaten a trustworthy relationship between the healthcare practitioners and the patient. Therefore, the development of STs can be a constant stress not only for older patients, but also for healthcare practitioners.

4. The etiology of skin tears

STs result from a complex series of skin changes associated with chronological aging and photoaging [22, 26, 41]. In the aged skin, the epidermis is atrophic with flattening of the dermal-epidermal junction, which separates the epidermis from the dermis [42, 43]. The flattened dermal-epidermal junction results in decreased resistance to shearing forces [3, 4].

Age-related changes in the dermis contribute to the etiology of STs [2, 41]. The dermis contains elastin and collagen; elastin fibers contribute to elasticity and resilience, whereas collagen fibers are essentially responsible for the skin’s tensile strength and mechanical strength properties [3, 4, 9, 10]. As in solar elastosis, the accumulative degeneration of elastic fibers progresses during the course of photoaging, the degenerated elastic fibers come to occupy most of the reticular dermis [44]. Therefore, the aging skin is more easily stretched due to a decrease in normal elastin fibers. The total amount of collagen decreases approximately by one percent per year throughout life, resulting in a thinning of the dermis [45]. The loss of integrity of the dermis leads to decreased torsion extensibility and diminished elasticity [5-7, 13, 18-20].

In addition, loss of subcutaneous fat with aging results in a parallel decrease in the protective function of the skin of the extremities [3]. The overall volume of subcutaneous fat typically diminishes with aging. Subcutaneous fat below the dermis primarily consists of adipose tissue, which provides mechanical protection. Therefore, decreased adipose tissue may also lead to an increased risk of STs [46]. These altered skin properties which are caused by the aging process, would make the skin of an elderly patient more susceptible to mechanical trauma, such as ST.

5. The intrinsic and extrinsic risk factors involved in skin tears

Numerous intrinsic and extrinsic factors have been examined in an attempt to identify patients at high risk of ST. Intrinsic factors include age, race, sex, UV irradiation due to sun exposure, history of ST, dehydration, poor nutrition, medications, cognitive impairment, altered mobility, and skin conditions such as senile purpura or ecchymosis (bruising) [21-30, 36-39, 41, 47]. Extrinsic factors indicate an external force that causes injury and include forces that are derived from daily activities performed by patients themselves, routine care by healthcare practitioners, or those inflicted by medical devices, such as wheelchairs, compression stockings [24, 27, 29, 31-33].

Healthcare practitioners in the clinical setting have used many intrinsic factors related to ST to identify high-risk patients. Moreover, they have provided these high-risk patients with a skin care protocol focused on the minimization of external forces, such as the use of gentle cleansers, moisturizers, and protective padding on the patient's extremities [24, 29, 48-50]. However, the occurrence of ST remains despite the adoption of these preventive measures. Therefore, new direct and non-invasive methodology may be required to establish measures to prevent STs based on the identification of high-risk patients.

6. Skin properties associated with skin tears

The goal of this study was to determine the series of age-related skin changes that are associated with ST development. In master thesis, a cross-sectional study was used to explore skin properties in elderly patients at a long-term medical facility [22]. Skin properties included epidermal function (stratum corneum hydration, skin pH, transepidermal water loss) and skin elastosis. Stratum corneum hydration was measured using a capacitive method (Corneometer CM-825) [51], and skin pH was determined using the glass electrode method (Skin-pH-meter PH905) [52]. Transepidermal water loss (TEWL), which represents skin dryness, was measured using a closed chamber vaporimeter (VapoMeter) [53]. Finally, to evaluate skin elasticity parameters, we used a commercially available instrument (Cutometer® MPA 580) [54], which measures the vertical deformation of skin when it is pulled into the probe via a controlled vacuum.

Other skin-related variables were also investigated. These included the levels of certain major proteins of the dermo-epidermal junction—collagen type IV (COL4) [13, 14], fibronectin [13], and matrix metalloproteinase-2 (MMP-2) [55], a marker of solar elastosis in the papillary dermis (low-echogenic pixels: LEPs) [56, 57],—as well as tumor necrosis factor-alpha (TNF-α), a proinflammatory protein that regulates collagen remodeling [58]. Tissue levels in the skin were quantified non-invasively using engineered and molecular biological techniques, and were then compared between elderly patients with or without STs.

High-frequency ultrasonography has been used for the non-invasive visualization and quantification of age-related skin changes [15, 16, 56, 57]. In aged skin, high-frequency ultrasonography with a 20-MHz transducer showed an area of low-echogenic pixels (LEPs), not seen in young skin, which most likely represents solar elastosis and edema in the papillary dermis [56, 57]. This device is also able to measure the thickness of the dermis layer non-invasively. On the other hand, skin assessment capable of quantifying function within the skin is limited to the clinical setting. Recently, we have developed a skin blotting method that allows us to evaluate functional changes within the skin non-invasively [59]. A hydrated nitrocellulose membrane applied to the skin surface attracts cytokines from the epidermis, dermis, and subcutaneous fat layer [22, 59, 60]. Skin blotting is a method of assessing skin tissue variables related to the dermal-epidermal junction [22].

Our master thesis stated that the skin of patients with STs, compared with that of those without, would show significantly lower tissue levels of COL4 [13, 14], a major matrix protein of the dermal-epidermal junction; and MMP-2 [55], a proteolytic enzyme that degrades COL4. The thesis also identified that skin with STs would have significantly higher tissue levels of LEPs [56, 57] and TNF-α [58]. However, because of the cross-sectional study design, we were unable to determine whether these predicted findings preceded the development of STs. Therefore, a prospective cohort study will be needed to clarify which skin properties may be predictive of the development of STs.

7. Recurrence of skin tears in the elderly

As stated above in the definition of ST, elderly people with existing STs are most likely to experience additional tearing, which is referred to ST recurrence [23, 27, 29]. Identifying the etiology related to external forces is of importance in the prevention of recurrent ST. However, these injuries often accidentally develop without being noticed by healthcare practitioners, while most patients may not report any new injuries promptly because of cognitive impairment. Therefore, the external forces that have caused STs are often unknown [27, 28]. As it is difficult to identify the external forces that have caused an existing-ST, an appropriate management system for the prevention of recurrent ST has yet to be established.

Small injuries that show distinct patterns or morphologies can aid in the elucidation of the factors involved in a traumatic incident in forensic science [61]. We hypothesized that morphological characteristics of STs may assist healthcare practitioners in determining the external forces implicated. However, although morphological classifications for ST definitions have already been proposed for healing management [33-35], no morphological characteristics of ST exist with which to identify the potential external forces involved.

One promising approach to identify the external forces that cause ST is morphological analysis. This novel method was developed by our laboratory through a modification of a qualitative descriptive approach [62]. This method suggests the application of an advanced care protocol to protect against potential external forces based on morphological characteristics of individual wounds [63, 64]. The qualitative research was effective for generating in-depth descriptions of phenomena in this study [65]. Morphological analysis consists of three steps. The first is to define the morphological characteristics of STs, which we did by sketching photographic records of STs (Chapter 2: Study 1). The second is to identify the external forces that caused the STs (Chapter 2: Study 2). The third step is to develop a correspondence table that links specific morphological characteristics of STs to different types of potential causative external forces (Chapter 2: Study 3).

RESEARCH QUESTIONS

The development of a ST may be related to alterations that accompany aging in the dermis layer, which is less resistant to shearing forces. For the prevention of STs in the clinical setting, healthcare practitioners have tried to identify high-risk patients using indirect risk factors of ST. However, the occurrence of ST has not been prevented. Recent advancements in technologies have allowed clinicians to provide more direct and precise assessment of skin properties in a noninvasive manner to predict ST development.

To establish a preventive strategy for ST recurrence, identifying the etiology-related external forces that caused ST is of importance, however it is difficult because the ST could have accidentally developed without being noticed by healthcare practitioners. A morphological analysis offers a useful approach for the verification of the characteristics of wounds and the identification of the external forces that may have caused the skin injury. Therefore, the use of morphological analysis may be applicable to identify the morphological characteristics of a ST that can be used to estimate the external forces causative of an existing ST. In this thesis, two research questions were generated based on the literature review.

CHAPTER 1:

What skin properties could be used as predictors for the development of ST?

CHAPTER 2:

Are morphological characteristics of STs capable of identifying the external forces that caused the ST?

Study 1 What are the morphological characteristics of the STs?

Study 2 What were the external forces that had caused the STs?

Study 3 What morphological characteristics of STs could associate with the external forces that had caused the ST?

STUDY AIMS

The aim of this study was to establish a preventive strategy for ST occurrence and recurrence. In Chapter 1, a prospective cohort study was conducted to identify the skin properties that may be used to predict the development of the ST. In Chapter 2, a qualitative descriptive study was conducted to (1) describe the morphological characteristics of the STs among elderly patients, (2) identify the external forces that caused the STs, and (3) identify the specific morphological characteristics of STs associated with different external causative forces.

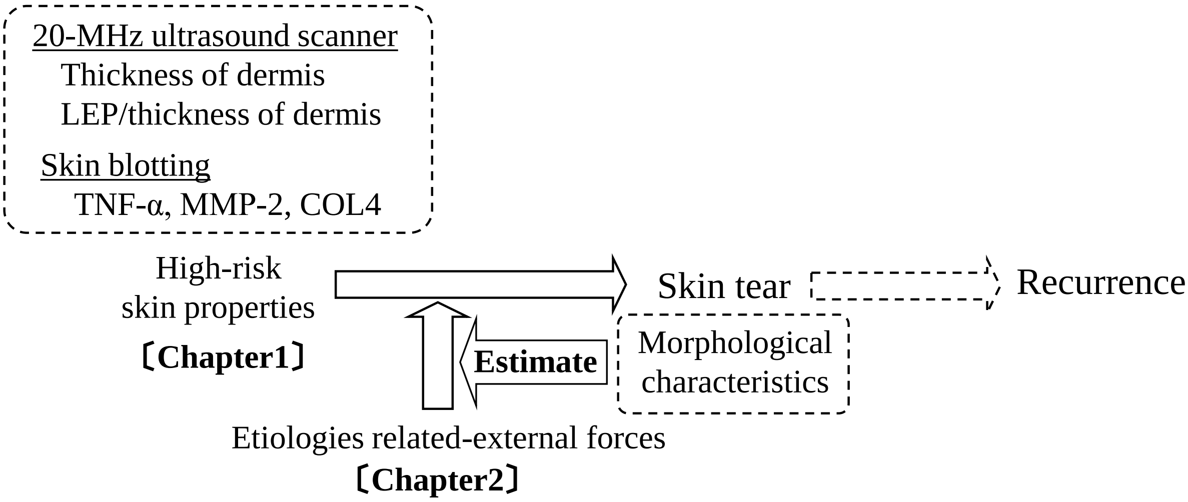


Figure 1. The conceptual framework of this study.

CHAPTER 1

Prediction of skin tear development

STUDY AIM

This prospective cohort study was conducted to identify skin properties that could be used to predict the development of ST.

METHODS

1. Study design

A prospective cohort study was conducted at a long-term medical facility that is financed by both, health insurance and long-term-care insurance. Participants in one medical unit with 50 beds were enrolled by the middle of the study period, in April 2015, because there was a possibility of decreasing the incidence of ST due to routine skin assessment of patients by the researcher.

2. Setting

Participants were recruited from a long-term medical facility with 500 beds consisting of 10 units, in Ishikawa Prefecture, Japan. Over 80% of patients in this facility were physical immobile and communication-impaired, secondary to a cerebrovascular disease. Such patients spend almost all day in bed and receive assistance for daily living tasks. Specifically, they require caregivers for bathing and showering, diaper changes, positioning changes, dressing and undressing, and eating meals. A complete survey was conducted in 3 of the 10 units. This long-term medical facility was conveniently selected for two reasons. First, healthcare practitioners in this facility could appreciate the importance of taking photographs of STs, and being interviewed about the causes of STs. Second, almost all patients received an equal measure of daily standard care support based on their individual physical condition during their hospital stay, which was ideal for the researcher to evaluate possible aged skin properties related to STs.

3. Participants

Participants were part of an open clinical cohort (entering and leaving the study at different time points) for a period of eight months (December 2014 to July 2015). The participants were elderly patients aged 65 and older, who agreed to participate. They were followed up until they developed a ST on an extremity, were discharged from the hospital, or until the final day of the survey. Patients who had evidence of cutaneous disease on the extremities at baseline, used a rigid cast on the extremities, or refused to participate in a regular assessment during the follow up period were excluded from the study. In our study, skin properties were measured on the forearm, which is the most common anatomical location for STs in Japan [22]. Skin properties may differ depending on the anatomical location [66, 67]. When analyzing the association between skin properties and STs, outcome was limited to only STs on the arm of elderly individuals. Therefore, the participants who developed a ST on any anatomical location other than the arm were excluded from the analysis of skin properties.

4. Evaluation of skin tears

The researcher obtained the incidence of ST during the follow-up period in two ways: 1) regular skin assessment on the extremities of patients repeated every four days and 2) information collected from incident reports. STs of elderly patients on the extremities were observed during the survey in order to identify the incidence of skin tears, because STs of elderly patients was developed on the extremities [21-30]. After finding wounds suspected to be STs, the researcher took photographs and obtained detailed information concerning external forces that may have contributed to the ST from healthcare practitioners who knew something about the circumstances of the tearing incident. After collecting data, a wound, ostomy, and continence nurse assessed all photographs of the STs and information concerning external forces that had caused STs. This was done to correctly discriminate STs from stage II pressure ulcers or other skin wounds that share a similar morphology. Each ST was classified according to the Skin Tear Audit Research (STAR) Classification system [34] shown in Table 2.

The STAR consists of a treatment guide and a classification system with a glossary. The treatment guide discusses six topics related to the care of the wound and the surrounding skin. The classification system has five categories that evaluate color and the presence or absence of a skin flap. The STAR classification is comprehensive but simple and easy to use, with confirmed content validity and inter-rater reliability [34].

5. Procedures

Demographic data and general nursing care for potential external force factors of individuals contributing to ST were evaluated at baseline. Skin properties including LEPs and dermis thickness measured by a 20-MHz ultrasound scanner, and soluble proteins related to ST (COL4, MMP-2, and TNF-α) measured by skin blotting were also evaluated at baseline on the posterior forearm (posterior midpoint between the lateral epicondyle and the radial styloid process). This is because that forearm is the most susceptible to tearing among elderly patients [22]. The right or left side of forearm was randomly decided. The researcher conducted skin observations on the next day after measurement in order to confirm the presence or absence of any skin manifestations, and none described any erythema or pain on the forearm during the survey. After collecting data concerning skin properties, the researcher obtained information of the incidence of ST. This study protocol was approved by the Ethical Committee of the Graduate School of Medicine, The University of Tokyo, Tokyo (#10694) and the participating institution. Proxies provided signed informed consent to participate in the study.

6. Data collection

1) Demographic data

Patient demographics including age, sex, length of stay (months), history of ST, body mass index, paralysis, contracture in the extremities, Braden Scale [68], medication (number of medicines, steroid use, antithrombotic therapy including anticoagulants and anti-platelet agents), and diseases were collected from the medical charts and the nursing charts. A history of ST was defined if there was any description concerning the presence of a ST in the nursing record three months before the baseline. Cutaneous atrophy with systemic treatment tends to be dose-related and is more common in older patients after prolonged use of prednisolone [69]. Therefore, patients who had systemic corticosteroid therapy were included as 'steroid'. Presence or absence of contracture in the extremities was determined by direct confirmation of joint mobility by the researcher. The Braden Scale is widely used to predict the risk of pressure ulcers, and requires the examination of six criteria—sensory perception, moisture, activity, mobility, nutrition, and friction and shear [68]. This score has a range of 6 to 23, where 6 indicates a high risk and 23 indicates no risk of pressure ulcers [68]. A lower Braden Scale score is associated with physical immobility, which is a state in which individuals spend almost all day in bed. A lower Braden Scale score and history of STs were significantly associated with development of STs in previous study [23]. The number of medicines was counted as internal use per oral, gastrostomy, or nasal tube administration. Diseases were classified according to the International Classification of Diseases-10 categories. Comorbidities were evaluated by the Charlson Comorbidity Index, which consists of 17 weighted items [70]. The Charlson comorbidity index predicts the ten-year mortality risk for a patient with a range of different comorbid conditions, such as heart disease, AIDS, or cancer. Each condition is assigned a score of 1, 2, 3, or 6, depending on the risk of dying associated with each one. Scores are summed to provide a total score (0–30) which is used to predict the mortality risk. Higher scores indicate a greater burden of disease and a higher risk of mortality.

2) Skin properties measured by 20-MHz ultrasound scanner

A 20-MHz ultrasound scanner (Dermascan C, Cortex Technology, Hadsund, Denmark) with a sharp-focusing transducer was used to obtain cross sectional, two-dimensional (B-mode) images of the skin [16, 71]. The ultrasonic wave is partially reflected at the boundary between adjacent structures and generates echoes of different amplitudes. The intensity of the reflected echoes (echogenicity) is evaluated by a microprocessor and visualized as a two-dimensional color image. For the ultrasound scanner, echo amplitudes were transformed into a numerical pixel scale (range of pixels, 0 to 255); low-echogenic pixels (LEPs) are defined as those with an echogenicity of 0 to 30 [15, 16, 57, 72]. The color scale of echogenicity is white > red > yellow> green > blue > black. The dermis layer, or superficial fascia, and purpura or subcutaneous tissues were visualized as having a higher echogenicity and lower echogenicity, respectively. If participants displayed any senile purpura or ecchymosis on these regions, the probe was attached at the peripheral points from the senile purpura or ecchymosis.

Ultrasound images were obtained twice (gain level 3) by moving the probe at 1-cm intervals in the direction of the long axis in order to avoid measuring a similar area. The cutoff between the dermis and the subcutaneous tissue was determined by the A-scan function (one-dimensional measurements) on the B-mode image. A rapid drop in the peak height on A-scans in the lower dermis indicated the interface between the dermis and subcutaneous tissue [16]. In some cases, interface between the lower dermis and superficial fascia was beyond identification because of thinned subcutaneous tissue in aged skin. For the accurate measurement of dermis thickness, the researcher decided the interface between the dermis and subcutaneous tissue, or superficial fascia by moving the forearm of all patients while taking the image of 20-MHz ultrasound scanner; mobile or immobile high echogenicity area of image was superficial fascia, or lower dermis, respectively. This method also allowed easier determination of the interface between the dermis and the subcutaneous tissue.

The dermis thickness was measured at three standard points over the width of one image; the average of six measurement sites in a total was used to determine the dermis thickness. To quantify the LEPs area, the number of LEPs in the area that extended about 0.75

mm [57, 72] or the interface between the dermis layer and subcutaneous tissue under the skin surface was calculated using MATLAB2012a software (MathWorks Inc., Natick, MA; 17). Additionally, LEPs was divided according to individual dermis thickness.

3) Skin properties measured by skin blotting (COL4, MMP-2, and TNF-α)

Skin blotting was performed on the day when the patient did not receive any hygiene care and ointment application on the forearm, because these can affect protein collection during skin blotting. Skin blotting was conducted at similar regions as those subjected to 20-MHz ultrasound scanning. A piece (12 mm × 22 mm) of nitrocellulose membrane (Bio-Rad, Hercules, CA) was moistened with 20 μL of normal saline and attached to the skin surface delicately with nonadhesive medical tape (Nitto Medical, Osaka, Japan) for 10 min. The blotted membranes were stored at 4 °C until staining process.

The following immunostaining procedure was performed by the SNAP i.d. 2.0 system (Merck Millipore, Billerica, MA). To inactivate endogenous peroxidases, the membranes were incubated with 20% methanol supplemented with 0.3% hydrogen peroxide at room temperature for 10 min. Following inactivation of endogenous alkaline phosphatase and blocking with blocking buffer (Nacalai Tesque, Kyoto, Japan) supplemented with 500 μg/mL of levamisole hydrochloride (Sigma-Aldrich, St. Louis, MO) at room temperature for 10 min, membranes were reacted with primary antibodies and secondary antibodies for 10 min each. The primary antibodies for COL4 (Merck Millipore), MMP-2 (Thermo Fisher Scientific, Waltham, MA), and TNF-α (Santa Cruz Biotechnology, Dallas, TX) were diluted with blocking buffer at dilutions of 1:1000, 1: 200, and 1:250, respectively. The dilutions of both secondary antibodies including alkaline phosphatase-conjugated anti-goat IgG (Jackson ImmunoResearch, West Grove, PA) and horseradish peroxidase-conjugated anti-rabbit IgG (Jackson ImmunoResearch) were 1:1000. Immunoreactivities were visualized by incubating with chemiluminescent substrates for alkaline phosphatase (DuoLux, Vector Laboratories, Burlingame, CA) for 5 min and peroxidase (Luminata Forte, Millipore) for 2 min, and captured by LumiCube (Liponics, Tokyo, Japan).

The color images were separated into RGB channels by Image J (National Institutes of Health, Bethesda, MD). The blue channel of each three proteins was selected for the image processing. The mean brightness of the luminescence was measured using Image J.

7. Statistical analysis

The ST incidence rates were calculated as follows: (the number of patients with all STs/follow-up days of each patient)×1000. Descriptive data was expressed as median (top 25th percentile and bottom 25th percentile) for continuous variables and n (%) for categorical variables. All statistical analyses were performed using IBM Statistical Package for the Social Sciences (SPSS) version 20. The statistical significance level was set at $p < 0.05$. Based on a previous study of hospitalized patients [22], 410 patients are needed when differences in LEPs between two groups with a power of 90% and alpha error of 5%.

A comparison between the presence and absence of STs as outcome was conducted using the chi-squared test or Fisher's exact test for categorical variables and Mann-Whitney U test for continuous variables. We defined the analysis time as the period from when the patients entered the study to the development of a ST, or the end of this survey (no development of ST), or censoring. If participants left the hospital due to death, or changed hospital during the follow-up period, they were regarded as censored. The multivariate Cox proportional hazard model was used to calculate the hazard ratio (HR) and 95% confidence interval (95% CI) of skin properties in a crude model. Before the analyses, correlations between potential independent variables were examined in order to avoid multicollinearity. If the correlation coefficients exceeded 0.6, either variable was selected. Covariates at baseline were forced into the adjusted models as non time-dependent variables including age [23], sex [30], steroid use [37, 41, 47], history of STs [23, 27, 29], Braden Scales total scores [23], and the Carlson

Comorbidity Index, which showed an association with ST development in a previous study. The proportionality of the hazard assumption was examined by plotting the log of the negative log of the estimated survivor function against the log of time. To determine a cutoff point of a skin property which best associated with ST, a logistic regression model was used to calculate the odds ratio (OR) and 95% CI of covariates including sex, age, steroid use, history of STs, Braden Scales total scores, and the Carlson Comorbidity Index in Model 1. Because the median of the follow-up period was 101, ST development at both day 100 and 200 were defined as an outcome of the early type and delayed type, respectively. In order to determine the effects of skin properties, variables were subsequently added to Model 2 and 3. The fitness of the model was assessed by the area under the curve (AUC). The cutoff point was defined from this univariate model as the point where the sum of the sensitivity and specificity showed the maximum value. In addition, we reevaluated the validity of the obtained cutoff points in the Kaplan-Meier and log-rank test. Kaplan-Meier estimates of the cumulative non-ST rate of occurrence according to the cutoff points were calculated and the log-rank test was performed to compare survival time.

RESULTS

1. Characteristics of patients

A total of 152 patients in three medical wards were recruited. Of these, one patient with a rigid cast on the left lower leg due to fracture and two patients who refused to participate in regular skin assessment were excluded. The remaining 149 were followed-up (Table 1); The median length of hospital stay was 10 (4-23) months. The median follow-up period was 101 (58-224) days. The median age was 87 (81-91) years, and 68.5% patients studied were female. Patients who had a history of ST before starting the survey were 18.1%. Median of the Braden Scale total score and Charlson Comorbidity Index was 12 (11-14) and 3 (2-4), respectively.

2. Incidence rates and characteristics of skin tears among 149 patients

Of the 149 patients enrolled, 21 patients developed STs. The incidence rate of ST was found to be 1.13/1000 person-day. The median follow-up period of ST development from baseline was 48 (33-97) days. A total of 52 STs were recorded among the 21 patients over the 8-month period (mean = 2.47 STs/patient SD±2.59, range = 1-10). Characteristics of 52 STs was shown in Table 2. STs were found on the extremities, neck, and face, but the most frequent anatomical location was the posterior forearm (34.6%) followed by the dorsal hand and fingers (19.2%) and the anterior lower leg (19.2%). Of the patients with STs, 36.5% were classified as Category 2b based on the STAR Classification System.

3. Types of external forces causing skin tears

The causative external force in 40.4% of STs was unknown (Table 2). The cause of STs were found to be consequent to events such as falls (7.7%) and self-inflicted injuries (25%) including the patient bumping into something, scratching by the patient, self-inflicted nail lacerations; routine nursing care (13.5%); adhesive tape removal (1.9%); and medical device-related injuries (11.5%), including patient wristbands, nasal catheters for oxygen inhalation, and cotton bandages. The location where STs most commonly occurred was the patient's bedroom (50%). All other locations including the bathroom or lounge represented less than 10% of overall ST incident locations.

4. Skin properties related to skin tear development

An additional seven patients were excluded because seven patients developed STs only on the lower legs, neck, or face (Figure 2). Therefore, a total of 142 patients were included in the analysis of skin properties. Of the 16 patients who developed STs on the arms (upper arms, elbows, forearms, hands and fingers), the incidence rate of ST was found to be 0.87/1000 person-day. Baseline characteristics and risk factors in the presence and absence of ST are shown in Table 3. The median follow-up period between the presence and absence of STs was 50.5 (35.8-108.3) days and 101 (72.5-224) days, respectively. Significant differences were observed in patients with a history of STs and steroid use.

Boxplots show the distributions of dermis thickness, LEP/dermis thickness and the intensity level of three marker proteins including COL4, MMP-2, and TNF-α measured by the skin blotting method (Figure 3). Values of skin properties related to STs on the forearms in the presence and absence of STs are summarized in Table 4. A significant difference was observed in dermis thickness between the two groups. The median (interquartile range [IQR] 1 to IQR3) dermis thickness of participants with or without STs was 0.64 (0.51-0.70), and 0.89 (0.75-1.01), respectively (p = 0.002). The crude and adjusted HRs in the Cox proportional hazard model are shown in Table 5. According to the crude model, only the thickness of dermis layer was significantly associated with development of ST (HRs 0.44, 95% CI 0.283-0.685). For dermis thickness, being 0.1 mm thinner over any period was positively associated with a higher probability of developing STs, where adjusted the HR (95% CI) was 0.519 (0.330–0.815).

Table 6 and 7 show the effects of dermis thickness, when the development of ST at day 100 or 200 was defined as outcome. According to the logistic regression analysis in Table 6, Model 1 including intrinsic factors related to STs and Model 2 including dermis thickness alone were significantly associated with ST (AUC 0.847, 95% CI 0.703-0.991, AUC 0.889, 95% CI 0.799-0.979, respectively). Moreover, Model 3 including intrinsic factors and dermis thickness was also significantly associated with STs (AUC 0.948, 95% CI 0.889-1.000). According to Table 7, Model 1 including intrinsic factors related to STs and Model 2 including dermis thickness alone were significantly associated with STs (AUC 0.883, 95% CI 0.794-0.973, AUC 0.794, 95% CI 0.672-0.917, respectively). Moreover, Model 3 accounting for intrinsic factors plus dermis thickness was significantly associated with STs (AUC 0.935, 95% CI 0.866-1.000).

Table 8 shows the cutoff points defined from the univariate model as the point where the sum of sensitivity and specificity showed maximum value at day 100, or 200. Receiver operating characteristic (ROC) analysis for identifying the cutoff for dermis thickness showed that the greatest points of the AUC at day 100 and day 200 were 0.67 mm (0.839; 95% CI, 0.722-0.956), and 0.8 mm (0.701; 95% CI, 0.557-0.844), respectively. However, the cutoff point 0.67 mm (at day 100) was too sensitive to be practical in a clinical setting. Therefore, the AUC and 95% CI of dermis thickness of 0.7 mm and 0.8 mm at day 100 and day 200 were used. Figure 5 shows the estimated ST-free proportion of the cutoff point according to dermis thickness of 0.7 mm, and 0.8 mm. Overall, the ST-free proportion was significantly higher above the cutoff points than below the cutoff points over any period (0.7 mm: p = 0.002, 0.8 mm: p = 0.003; log-rank test).

DISCUSSION

This clinical study represents the first effort to identify skin properties that can be used to predict the development of STs among Japanese elderly patients at a long-term medical facility and determine the cutoff point of dermis thickness.

The ST incidence during eight months was 1.13/1000 person-day (mean = 2.47 STs/patient SD ± 2.59, range = 1-10). A previous study in Western Australia that was similar to mean (SD) age (86.43 (7.56) years old), and sex (female 65.8%) to our results showed that a total of 1396 STs were recorded among the 424 residents (mean = 3.29 STs/resident SD ± 3·99, range = 1-36) for six months [29]. Thus, mean STs per patient in Japan were lower than that for people with fair skin in Western Australia. This could be explained not only by a different medical system, but also by skin properties predisposed towards STs.

As shown in Table 2, the type of external forces that caused STs was classified into six categories, but in half, the causes were unknown, and were found most frequently on the forearm. As shown in Table 3, of the patients with ST, 93.8% had stroke, and they correlated completely with lower total scores in the Braden Scale (median score 12). As the main reason, these injuries often accidentally develop without being noticed by nurses, and not all hospital residents will report new injuries to them promptly. A previous study suggested that STs occurred more frequently on the lower limbs among the more independent residents with reduced care requirements, which could be assumed to relate to bumps and falls suffered by frail ambulant individuals [29]. It is proposed that the forearms are more at risk when dependent residents are being maneuvered during routine nursing care, which may easily generate causative shear and friction, or by patients themselves due to disturbing behavior [25, 28, 31, 32].

We identified that the dermis thickness associated with the development of STs in univariate analysis. In Table 4, the median dermis thickness at baseline in patients with ST (0.64 mm) was considerably less compared to that in patients without ST (0.89 mm), which corresponded to about half of the normal skin thickness (1.24-1.31 mm) on the dorsal forearm in those aged 60–90 years in a previous study, measured using B mode in 20-MHz ultrasound scanners [15]. In addition, the multivariate model in Table 5 showed that the dermis thickness at baseline remained to be significantly associated with ST, even after adjusting for covariates in a single cohort of elderly patients. This finding provided further support to the notion that aged-related changes in the dermis impair the skin's resistance to external forces [13, 19, 20]. Although COL4, a major matrix of the dermo-epidermal junction, showed no association with ST in this study, the dermo-epidermal junction of a patient with ST may be flattened by an accompanying thinning dermis layer [42, 43].

As shown in Tables 6 and 7, our data indicate that the AUC at day 100 and 200 were higher for model 3 including that in model 1 plus dermal thickness than model 1 alone. This study revealed that systemic risk factors including dermal thickness were the best variables for predicting ST. Moreover, in model 3 at day 200, we identified sex, the history of ST and dermis thickness as significant predictors of ST development. ROC analysis for identifying the cutoff for dermal thickness showed that the greatest point of the AUC was 0.67 mm (0.839; 95% CI, 0.722-0.956) compared to other cutoff values of 0.7 mm or 0.8 mm. However, the purpose of measuring dermal thickness is to identify a patient who is prone to develop tearing without overlooking any patient at risk for ST. As shown in Table 8, a sensitivity of dermal thickness of 0.7 mm and 0.8 mm are almost similar for predicting day-100 ST development, however, the sensitivity of dermal thickness of 0.7 mm for predicting day-200 ST development is low. Therefore, we recommend the cutoff point of 0.8 mm as a clinically relevant predictor of STs on the forearm in elderly patients.

Healthcare practitioners in the clinical setting have used many intrinsic factors related to ST in attempts to identify high-risk patients. Although a lower Braden Scale score was shown to be predictive of STs in a previous study [23], there was no association between it and the development of STs in our results. This was attributed to the fact that almost all the participants in our study were dependent. Our results suggest that measuring the thickness of the dermis using a 20-MHz ultrasound scanner at the time of hospital admission is an easy and accurate way to identify a high-risk patient. In addition, beginning general ST preventive practices for the high-risk patient at hospital admission may help decrease ST incidence.

While COL4, MMP-2, and TNF-α, measured by the skin blotting method, and LEPs/dermis thickness, measured by a 20-MHz ultrasound scanner, have been shown to associate with STs in a cross-sectional study [22], the current study did not find any significant association with STs. A possible explanation for these findings might depend on the physical irreversibility of biomarkers. The intervals in which these soluble proteins may affect the outcome could be narrow due to concentration-dependent properties, and their concentrations may vary in response to different internal and external physiologic stimuli [55, 58]. Therefore, we need to narrow the prediction interval to, for example, one week, and measured these soluble proteins frequently during that interval.

A limitation of this study was the small sample size, which may have decreased the statistical power in stratified analyses. In addition, the patient's clinical status and the specific measurer may directly affect the actual or recorded dermis thickness, respectively. In addition, the cutoff point (dermis thickness 0.8 mm) used for the elderly population of a long-term medical facility, may not allow generalization to other groups and settings. Additional studies involving other patient care settings, like nursing homes or acute care hospitals, are required. Despite these limitations, our findings provide a better understanding of possible predictors of STs in long-term medical facility, especially for the Asian aged population.

In this study, we found that many general preventive practices for ST at baseline were performed most frequently in those patients who developed at least one ST during the follow-up period and in those who had a history of ST (Table 9) [29, 31, 32]. However, many cases of STs still occurred in spite of these preventive measures. Patients with an existing ST are predisposed to recurrent STs. The incidence of ST may decrease according to thickening of the dermis layer; however, it is nearly impossible to preventively thicken the dermis layer in elderly populations. Consequently, we suggest that new preventive measures focused on known causative external forces are essential for patients with ST recurrence.

Table 1. Characteristics of participants at baseline

	n = 149
Age (years)	87 (81-91)
Sex	
Male	47 (31.5)
Female	102 (68.5)
Length of stay (months)	10 (4-23)
Follow up period (days)	101 (58-224)
History of ST	27 (18.1)
Body mass index	17.6 (15.7-19.7)
Paralysis	46 (30.9)
Contracture of the arm	102 (68.5)
Contracture of the leg	123 (82.5)
Braden Scale	
Total score	12 (11-14)
Sensory perception	3 (2-4)
Moisture	2 (2-3)
Activity	1 (1-2)
Mobility	2 (2-2)
Nutrition	3 (3-3)
Friction and shear	1 (1-1)
Medications	
Steroid	7 (4.7)
Antithrombotic	33 (22.1)
Number of mediations	3.5 (1-6)
Diseases	
Stroke	138 (92.6)
Dementia	49 (32.9)
Cardiac disease	42 (28.2)
Parkinson's disease	7 (4.7)
Cancer	20 (13.4)
Renal failure	5 (3.4)
Diabetes	33 (22.1)
Hypertension	19 (12.8)
Charlson Comorbidity Index	3 (2-4)

Values are median (IQR1-IQR3) or number of patients (%).

Table 2. Characteristics and type of external forces involved in skin tears

		n* = 52
Anatomical location		
Upper arm	Anterior	0 (0)
	Posterior	1 (1.9)
Elbow		2 (3.9)
Forearm	Anterior	1 (1.9)
	Posterior	18 (34.6)
Dorsal hand and fingers		10 (19.2)
Knee		2 (3.9)
Lower leg	Anterior	10 (19.2)
	Posterior	3 (5.8)
Neck or face		5 (9.6)
STAR classification		
1a		1 (1.9)
1b		17 (32.7)
2a		0 (0)
2b		19 (36.5)
3		15 (28.9)
Type of external forces which have caused STs		
Outcome of fall		4 (7.7)
Self-inflicted		15 (25)
Routine nursing care		7 (13.5)
Adhesive tape removal		1 (1.9)
Medical device-related injury		4 (11.5)
Unknown		21 (40.4)
Location in which ST occurred		
Patient's bedroom		26 (50)
Bathroom		4 (7.7)
lounge		1 (1.9)
Unknown		21 (40.4)

ST, skin tear; n*, number of skin tears

Values are number of patients (%).

Self-inflicted includes patient bumping into something autonomously, patient scratching, and patient nail-biting.

Medical device-related injury includes wristbands, nasal catheters for oxygen inhalation, and cotton bandage.

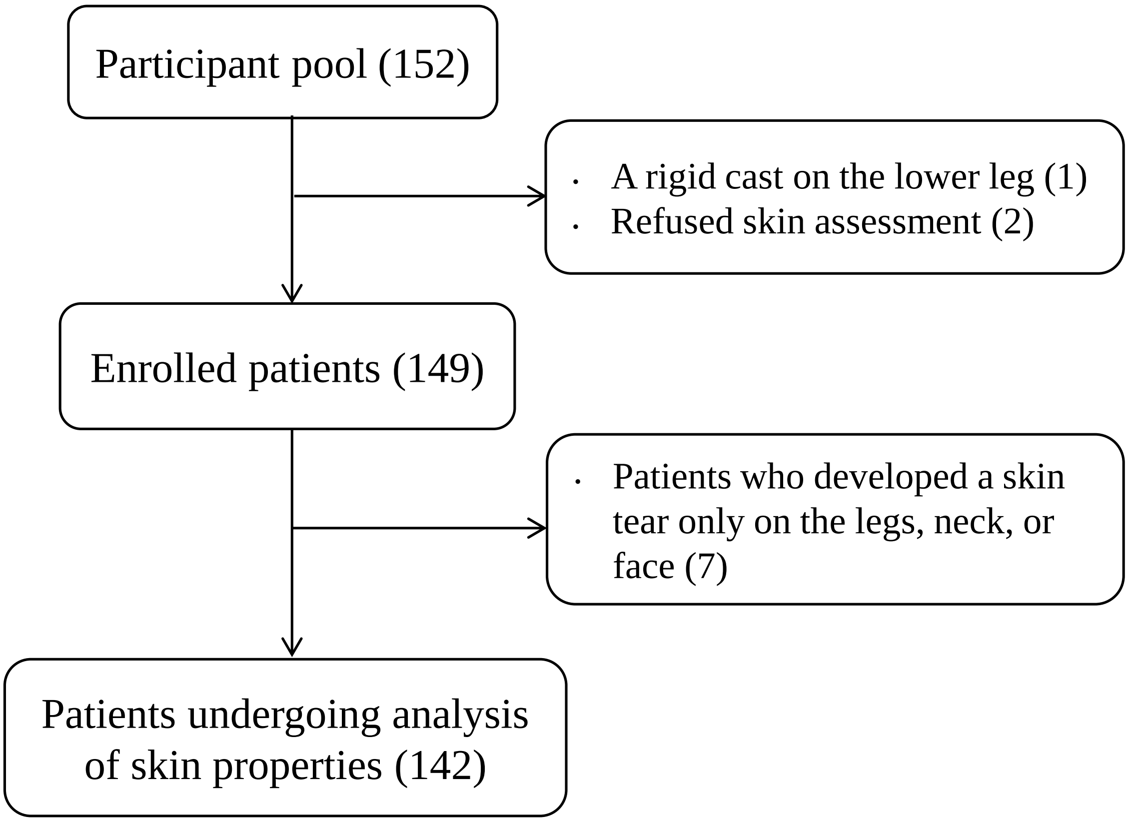


Figure 2. Flowchart of participants analyzed in the study described in Chapter 1

Table 3. Characteristics and risk factors related to skin tears of participants at baseline

	Patients with ST (n = 16)	Patients without ST (n = 126)	*p-value*
Age (years)	86 (81.8-90)	87 (80.3-91.8)	0.760
Sex			
Male	8 (50)	36 (28.6)	0.092
Female	8 (50)	90 (71.4)	
Length of stay (months)	6 (4-10)	11 (4-26)	0.26
History of ST	10 (62.5)	15 (12)	<0.001
Body mass index	16.9 (15.5-18.9)	17.7 (15.8-19.7)	0.507
Paralysis	3 (18.8)	40 (31.7)	0.392
Contracture of the arm	12 (75)	87 (69)	0.776
Contracture of the leg	13 (81.2)	105 (83.3)	1.000
Braden Scale			
Total score	12 (11-14)	12 (11-14)	0.912
Sensory perception	3 (2-4)	3 (2-4)	0.606
Moisture	2 (2-3)	2 (2-3)	0.589
Activity	1 (1-2)	1 (1-2)	0.781
Mobility	2 (1.8-2.3)	2 (2-2)	0.744
Nutrition	3 (2-3)	3 (3-3)	0.368
Friction and shear	1 (1-1)	1 (1-1)	0.931
Medications			
Steroid	2 (12.5)	3 (2.4)	0.003
Antithrombotic	2 (12.5)	29 (23)	0.523
Number of medications	3.5 (1-6)	3.5 (0.75-6)	0.910
Diseases			
Stroke	15 (93.8)	118 (93.7)	1.000
Dementia	6 (37.5)	38 (30.1)	0.571
Cardiac disease	4 (25)	37 (29.4)	1.000
Parkinson's disease	1 (6.3)	6 (4.8)	0.572
Cancer	3 (18.8)	17 (13.5)	0.471
Renal failure	0 (0)	5 (3.9)	1.000
Diabetes	3 (18.8)	26 (20.6)	1.000
Hypertension	1 (6.3)	17 (13.5)	0.693
Charlson Comorbidity Index	2 (2-4)	3 (2-4)	0.390

ST, skin tear;

Values are median (IQR1- IQR3) or number of patients (%).

Differences in interval variables were assessed using a Mann-Whitney U test.

Differences in categorical variables were assesseed using a chi-square test or Fisher's exact probability test.

Table 4. Skin properties of participants at baseline

	n	Patients with ST (n = 16)	n	Patients without ST (n = 126)	*p-value*
Dermis thickness (mm)		0.64 (0.51-0.70)		0.89 (0.75-1.01)	0.002
Dermis thickness according to age (years)					
65 - 69			3	1.18 (1.17-1.30)	
70 - 79	3	0.61 (0.55-0.67)	22	0.84 (0.74-1.06)	
80 - 89	8	0.60 (0.51-0.67)	52	0.86 (0.72-0.95)	
90 - 99	5	0.68 (0.61-0.73)	41	0.75 (0.62-0.88)	
100 - 104			5	0.66 (0.65-0.67)	
LEP/dermis thickness		2620.80 (1632.8-3956.2)		2669.4 (1506.9-4713.9)	0.896
COL4 (a.u.)		14.02 (11.16-15.54)		11.84 (10.69-20.15)	1.000
MMP-2 (a.u.)		18.16 (11.81-37.27)		15.44 (11.68-26.33)	0.580
TNF-α (a.u.)		14.15 (12.57-17.30)		16.36 (13.58-19.42)	0.269

ST, skin tear; LEP, low-echogenic pixels; COL4, collagen type IV; MMP-2, matrix metalloproteinase-2

TNF-α, tumor necrosis factor-α

Values are median (IQR1- IQR3)

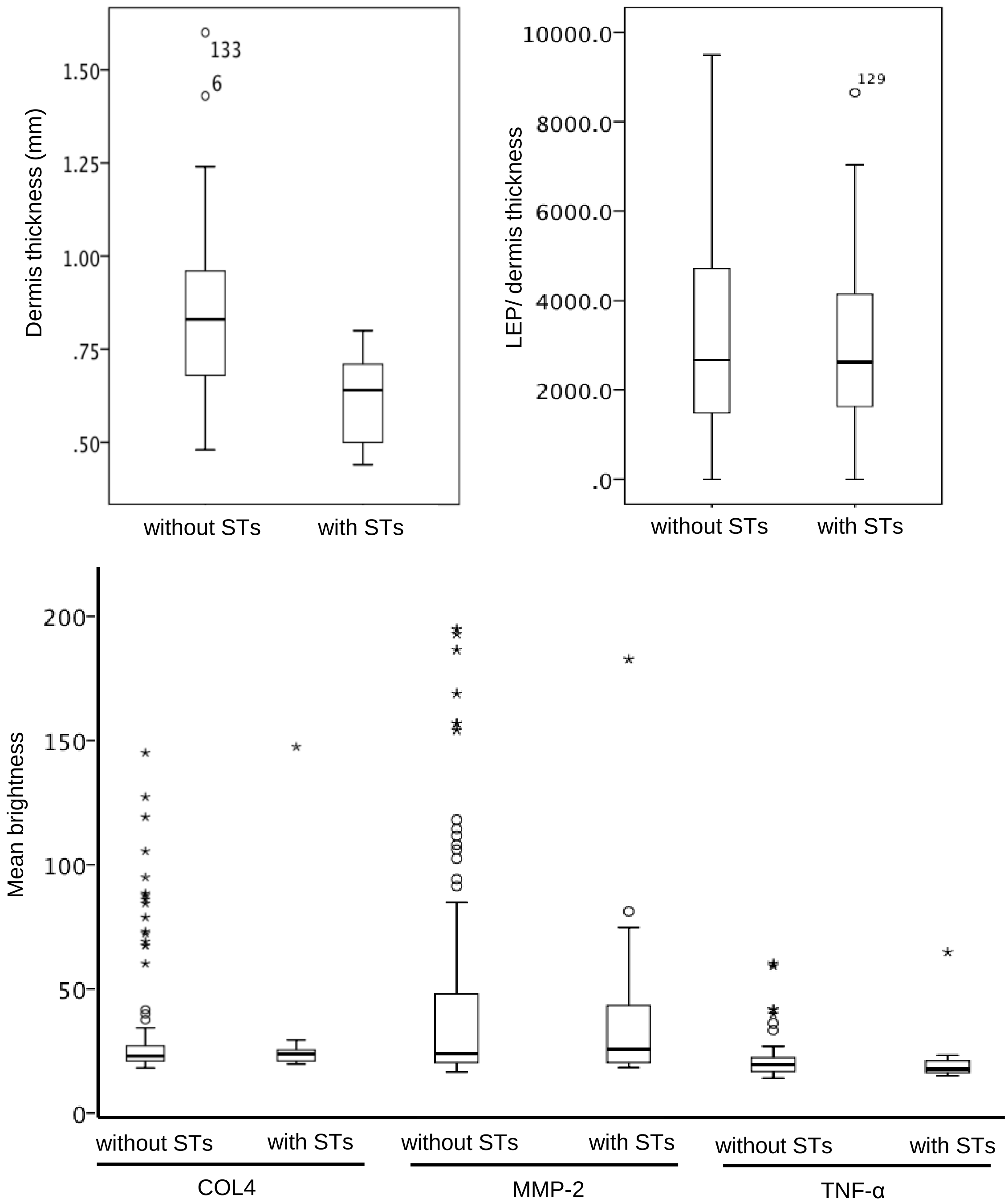


Figure 3. Box plots showing thickness of the dermis layer, LEP/dermis thickness (upper), and intensity levels of COL4, MMP2, and TNF-α (Lower). In the lower, the Y-axis indicates the mean brightness representing as intensity level of proteins, which can be captured by the nitrocellulose membrane. Bottom, middle, and top lines of each box correspond to the 25th percentile, the 50th percentile (median), and the 75th percentile, respectively. The circle or star-shaped asterisk indicate extreme outliers over 1.5 or 3 times of box, respectively.

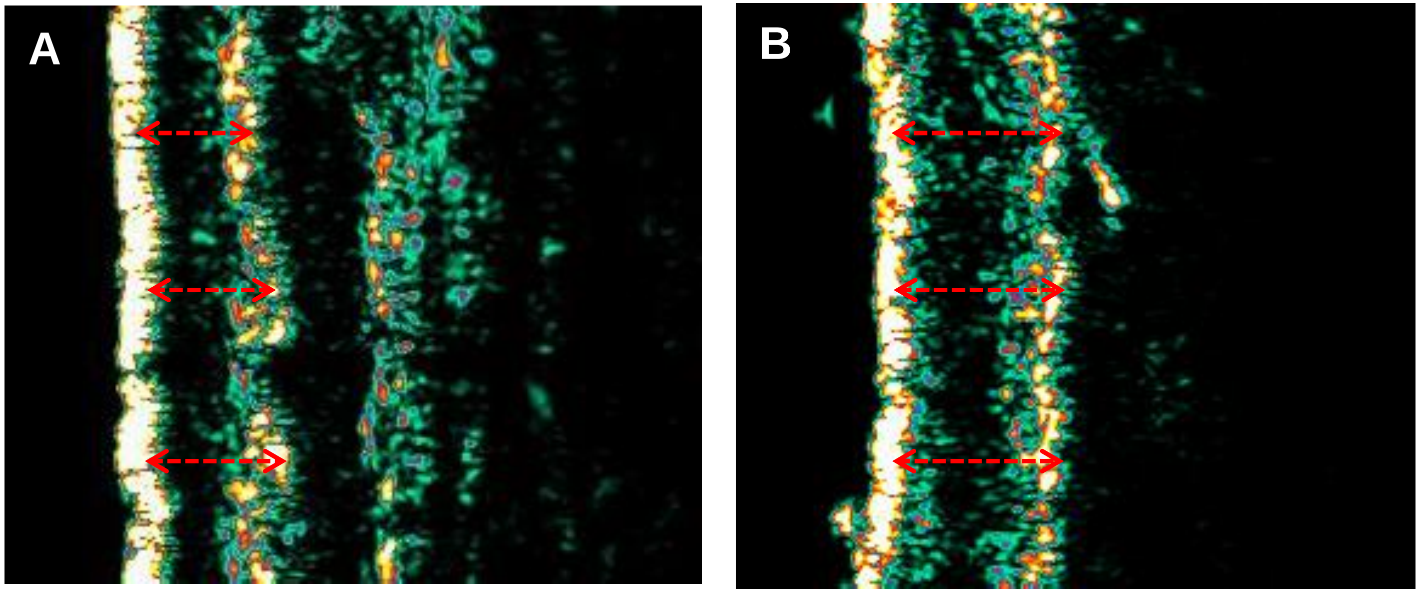


Figure 4. Dermis thickness of the posterior forearm measured by 20-MHz ultrasound scanner. (A) 0.64mm thickness in an elderly patient with skin tear (84-year-old, female), (B) 0.89 mm thickness in an elderly patient without skin tear (94-year-old, female). The dermis thickness was measured at three regular sites (red arrows) over the width of one image from under the epidermis to the interface between the dermis and the subcutaneous tissue.

Table 5. Multivariate Cox proportional hazards model for skin tear incidence

Variables	n	Crude HR	(95% CI)	*p-value*	Adjusted HR*	(95% CI)	*p-value*
Dermis thickness	139	0.44	(0.28-0.68)	<0.000	0.52	(0.33-0.81)	0.004
LEP/ dermis thickness	139	1.00	(1.00-1.00)	0.979	1.00	(1.00-1.00)	0.877
COL4	118	1.00	(0.98-1.01)	0.845	1.00	(0.98-1.01)	0.817
MMP-2	118	1.00	(0.99-1.01)	0.622	1.00	(0.99-1.01)	0.689
TNF-α	118	1.03	(0.97-1.08)	0.328	1.03	(0.97-1.08)	0.240

HR, hazard ratio; CI, confidence interval

LEP, low-echogenic pixels; COL4, collagen type IV; MMP-2, matrix metalloproteinase-2

TNF-α, tumor necrosis factor-α

*Adjusted hazard ratio for age, sex, steroid, histrory of skin tear, Braden Scale total scores, Charlson Comorbidity Index

Table 6. Logistic regression model for risk factors associated with skin tear development at day 100

	Model 1			Model 2			Model 3		
Variables	OR	(95% CI)	*p-value*	OR	(95% CI)	*p-value*	OR	(95% CI)	*p-value*
Age	0.97	(0.88-1.09)	0.799				0.94	(0.81-1.08)	0.416
Sex	0.70	(0.11-2.68)	0.467				0.53	(0.05-5.53)	0.595
History of ST	32.27	(3.94-90.49)	<.000				13.65	(1.65-112.73)	0.015
Braden Scale total scores	0.98	(0.81-1.33)	0.720				0.83	(0.57-1.19)	0.316
Steroid	4.73	(1.44-116.00)	0.022				1.33	(0.04-44.41)	0.875
Charlson Comorbidity Index	0.95		0.839				1.07	(0.50-2.28)	0.860
Dermis thickness				0.26	(0.11-0.57)	0.001	0.35	(0.15-0.81)	0.014
AUC	0.85	(0.70-0.99)	<0.000	0.89	(0.79-0.97)	<0.000	0.95	(0.88-1.00)	<0.000

ST, skin tear; OR, odds ratio; CI, confidence interval; AUC, area under the curve

n=100 (12 with STs, 88 without STs)

Table 7. Logistic regression model for risk factors associated with skin tear development at day 200

	Model 1			Model 2			Model 3		
Variables	OR	(95% CI)	*p-value*	OR	(95% CI)	*p-value*	OR	(95% CI)	*p-value*
Age	1.01	(0.91-1.12)	0.798				0.98	(0.86-1.10)	0.709
Sex	0.28	(0.05-1.44)	0.128				0.11	(0.01-0.93)	0.043
History of ST	21.82	(3.85-123.63)	<.000				27.03	(2.34-311.07)	0.008
Braden Scale total scores	0.93	(0.67-1.27)	0.641				0.70	(0.44-1.10)	0.123
Steroid	3.53	(0.17-70.66)	0.409				1.09	(0.01-105.60)	0.971
Charlson Comorbidity Index	0.90	(0.51-1.58)	0.723				0.64	(0.28-1.45)	0.291
Dermis thickness				0.45	(0.25-0.77)	0.004	0.35	(0.15-0.77)	0.010
AUC	0.88	(0.79-0.97)	<0.000	0.79	(0.67-0.91)	0.001	0.94	(0.86-1.00)	<0.000

ST, skin tear; OR, odds ratio; CI, confidence interval; AUC, area under the curve

n=61 (15 with STs, 46 without STs)

Table 8. Cutoff points of dermis thickness at day 100 and 200 for predicting skin tear development

Outcome	Cut off	sensitivity+specificity	Sensitivity	Specificity	AUC	(95% CI)	*p-value*
STs development at day 100	0.67	1.67	0.90	0.77	0.84	(0.72-0.95)	<0.000
	0.7	1.62	0.90	0.72	0.81	(0.68-0.93)	0.001
	0.8	1.52	1.00	0.52	0.77	(0.65-0.87)	0.006
STs development at day 200	0.7	1.42	0.77	0.65	0.73	(0.57-0.87)	0.013
	0.8	1.48	1.00	0.48	0.70	(0.55-0.84)	0.028

ST, skin tear; AUC, area under the curve; CI, confidence interval

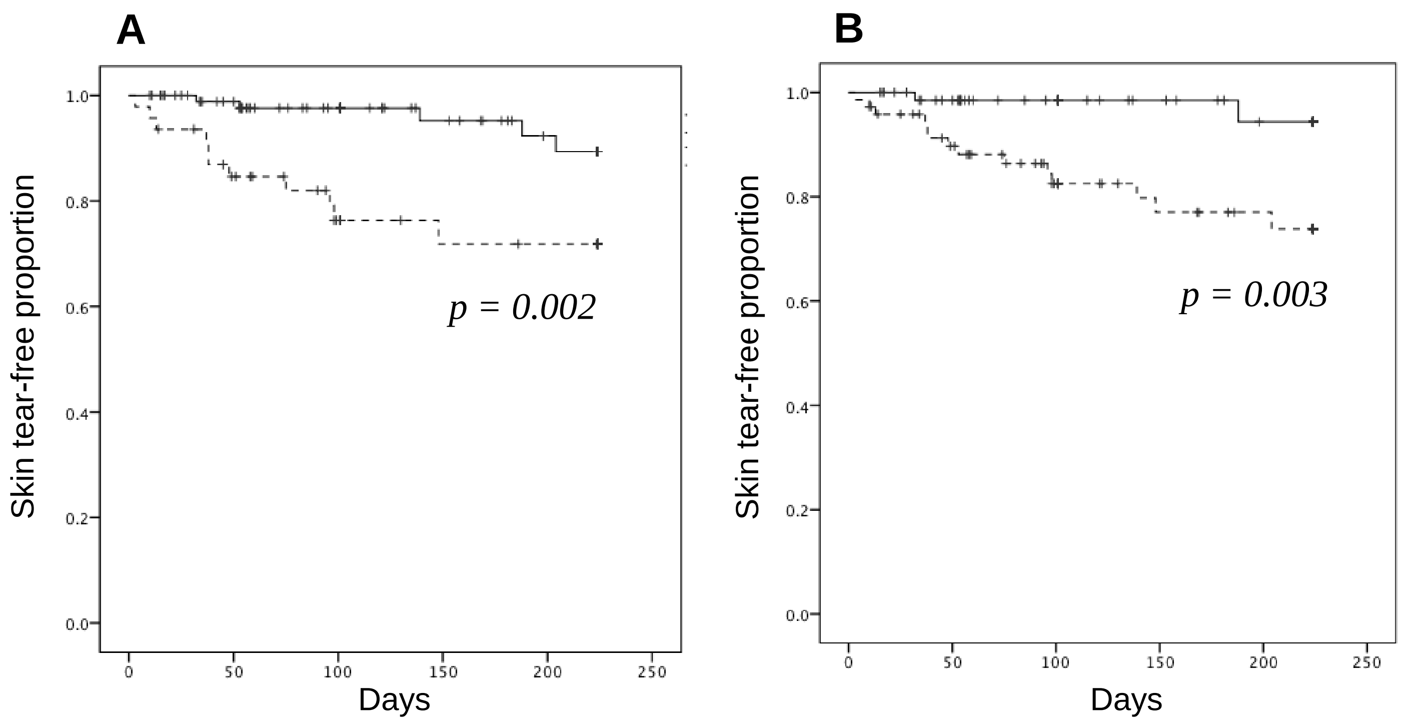


Figure 5. Skin tear-free proportion according to cutoff points of the dermis thickness. (A) Survival curves by dermis thickness of 0.7mm, (B) 0.80mm. Dotted lines represent skin tear occurrence rates below the cutoff points for dermis layer. Black lines represent skin tear occurrence rates above the cutoff points for dermis layer.

Table 9. General nursing care against external forces contributing to skin tear at baseline

	Without ST& without HST (n=111)	Without ST& with HST (n=15)	With ST& without HST (n=7)	With ST& with HST (n=9)
Clothing with stretchable fibe	66 (59.4)	4 (26.6)	3 (42.8)	8 (88.9)
Arm cover	1 (0.9)	0 (0)	0 (0)	3 (33.3)
Leg cover	7 (6.3)	3 (20)	0 (0)	1 (11.1)
Pad over bed rail	17 (15.3)	0 (0)	0 (0)	3 (33.3)
Moisturising	33 (29.7)	5 (33.3)	3 (42.8)	5 (55.5)
Floor leaving sensor	10 (9)	0 (0)	0 (0)	2 (22.2)
Wristband off	23 (20.7)	3 (20)	1 (14.3)	3 (33.3)
Mitton, or glove	14 (12.6)	1 (6.7)	1 (14.3)	4 (44.4)

ST, skin tear; HST, history of skin tear

CHAPTER 2

Identification of a prevention strategy for skin tear recurrence

(Study 1)

STUDY AIMS

Identification of the suspected causative external forces of an existing ST is the most suitable approach to prevent a recurrence. However, it is difficult to identify such external forces because these injuries can develop accidentally without detection by healthcare practitioners. A morphological analysis offers a useful approach to document wound characteristics and identify the potential causally related external force. In order to determine a preventive strategy for ST recurrence, qualitative descriptive studies were conducted; these are described in Chapter 2. The aim of the first study was to describe the morphological characteristics of STs among elderly patients (Study 1), and that of the second was to identify the external forces that caused specific STs (Study 2). Finally, the aim of the third study was to identify the morphological characteristics of STs associated with each specific identified external force (Study 3).

METHODS

1. Study design

We chose to perform a qualitative descriptive study because it is suitable for describing specific clinical conditions related to STs and for generating categories of morphological characteristics of ST in elderly people.

2. Setting

Participants were recruited the same facility as that used for the study discussed in Chapter 1, a long-term medical facility with 500 beds consisting of 10 units, in Ishikawa Prefecture, Japan. Follow-up for identification of STs was conducted by the researcher at 8 of 10 participating units (400 beds) from August 2012 to October 2012.

3. Participants

The study participants were patients aged 65 years and older who had at least one ST on the extremities. The STs, which were classifiable under the STAR classification [34], were included even if the etiology related- external forces that caused the ST were unknown. After a discussion with the primary researcher and the wound, ostomy, and continence nurses, STs in which the wound had already undergone complete re-epithelialization or engraftment of the skin flap were excluded from the study for defining the morphologies involved in development of ST.

4. Evaluation of skin tears

Evaluation of STs was performed in the same way as that described in Chapter 1. Each ST was classified according to the STAR classification system [34] shown in Table 10.

5. Data collection

The researcher and an assistant nurse conducted a direct inspection of all the patients' extremities and photographed the regions bearing STs using a digital camera (Lumix GM5; Panasonic, Osaka, Japan) in order to confirm the presence of tearing. Moreover, the information involving the possible external forces that caused the injuries was collected by the researcher from the healthcare practitioners.

Demographics of patients with STs including age, sex, body mass index, Braden Scale score [68], paralysis, contracture, medications, and disease, were collected from the medical charts and nursing charts.

6. Data Analysis

Data analysis was conducted with the use of morphological analysis [63, 64]. This novel method offers a useful approach for qualitative verification of the details of wounds [62]. The morphological characteristics of STs were inductively generated by verbalization of clinical features of STs and surrounding skin through the sketching of photographs by the researcher (Figure 6). Unitizing, categorizing, and constant comparison were used in the analysis [65, 74, 75].

The descriptions generated with ST photographs alone were limited the extraction of morphological characteristics of wounds. The descriptions generated by sketching the ST photographs helped the researcher comprehensively analysis through clarification of the phenomenon which may have been overlooked. An established sketching technique is indispensable to success in qualitative morphological analysis. First, the primary researcher sketched photographs of a few STs and verbalized clinical features. A wound, ostomy, and continence nurse with extensive experience of qualitative morphology analysis verified the technique of researcher's sketching and verbalization in a few samples. After researcher's sketching technique was established, the remaining samples were sketched and verbalized. Figure 6 shows an example of a detailed description of a ST with the use of the sketching technique. In addition to the sketching sample, clinical features of individual samples were summarised (Figure 6).

First, we analyzed the summaries generated by the researcher, and then dividing the sentences into simple codes. The researcher examined all codes and compared them for any similarities and differences, and sorted the codes to identify clusters of codes, then extracted subcategories. These subcategories were compared for any similarities in order to extract categories. Sub-subcategories were also generated from the codes constituting a particular subcategory (Figure 7-2). The other two researchers examined this process and confirmed that all extracted categories fitted the sketch descriptive data. Categories, subcategories, and sub-subcategories were divided into inner and external force factors. The inner factors such as skin senescence were excluded from the draft of conceptual diagram. Finally, the draft of conceptual diagram including morphological characteristics representing the external forces factors contributing to ST development was developed.

7. Analytical rigor

Lincoln and Guba's (1985) four criteria of credibility, applicability, consistency, and confirmability were followed to ensure rigor [76]. To establish credibility, member-checking was conducted among three primary nurses who were experienced in the management of STs in a long-term medical facility. However, as originally, we should have confirmed contents of conceptual diagram to patients with STs as members, we selected the primary nurses because almost all of those patients' ability to communicate was impaired as a result of cerebrovascular accident. The final sub-subcategories, subcategories, and categories were confirmed by consensus among the three primary nurses on the basis of the process for extracting each description and summary. All of them agreed with the results and gave the researcher advice regarding additional ST morphology. The revised version of the conceptual diagram was accomplished with the addition of one new category; this may be attributed to the intensity of the applied external forces. To establish the applicability of revised version, other wounds, including two cases of pressure ulcers, two venous leg ulcers, and two diabetic foot ulcers, were verified with the three primary nurses. No characteristics of these other types of wounds were applicable to the all shape subcategories and sub-subcategories and skin flap subcategories of STs. Five other skin photographs of STs, obtained from some nursing homes, that represented STs in an elderly people, were verified by two experts of wound care. The morphological characteristics of all five STs fit with subcategories and sub-subcategories. To establish consistency, the research team recorded observational and interpretive field notes throughout the research process. Confirmability was enhanced through discussion by the primary researcher and two experts of wound care.

RESULTS

1. Characteristics of patients

Two samples that satisfied the exclusion criteria were excluded from the original 22 samples for a total of 18 patients with 20 STs in the final study population. Table 10 shows the characteristics of the study participants, and STs. The median age (interquartile range) of participants was 87 years (84–93 years), and 61.1% of the participants were women. STAR classification 1b (skin tear with a pale, dusky, or darkened flap whose edges can be realigned to the normal anatomical position without undue stretching) was dominant (70%).

2. Morphological characteristics of skin tears in conceptual diagram

Five categories, fourteen subcategories, and three sub-subcategories emerged from the data analysis (Figure 7, 8): 1) ‘anatomical location’, with two subcategories, 2) ‘shape’, with two subcategories, three sub-subcategories, 3) ‘skin flap’, with four subcategories, 4) ‘purpura’, with four subcategories, 5) ‘size’, with two subcategories.

1) Category ‘anatomical location’

The category ‘anatomical location’ was defined as the area where the ST developed with two subcategories (Figure 7-1). The subcategory ‘bony prominence’ was defined as areas where the skin is in close proximity to underlying bone or the skin around the joints, including the pretibial region, elbows, wrist, dorsal surface of the hand, and the knees. The definition of ‘long bones’ was ‘skin surface over the long bones except for the joint area or bony prominences.’

2) Category ‘shape’

The category ‘shape’ was defined as the visible shape of ST, with two subcategories and three sub-subcategories (Figure 7-2). The subcategory ‘linear-shaped’ was defined as a linear laceration without a skin flap. All cases involved a wrinkle of skin over a long bone. The subcategory ‘crescent-shaped’ was defined as an arc-shaped laceration accompanied by a skin flap or by loss of a skin flap.

The subcategory ‘crescent-shaped’ was subdivided into three further sub-subcategories based on the features of the arc: ‘direction of arc’, ‘symmetry of arc’, and ‘depth of arc’. The sub-subcategory ‘direction of arc’ was defined based on the direction of the arc’s apex against the head. The arc’s apex was said to be directed toward the head, to the right side, to the sole, or to the left side with the following designations twelve, three, six, or nine, respectively. The sub-subcategory ‘symmetry of arc’ was based on the wound’s appearance: ‘symmetry’ indicated a symmetrical arc, and ‘asymmetry’ indicated that an arc was not symmetrical. The sub-subcategory ‘depth of arc’ was defined based on the fraction between a vertical line drawn from the arc’s apex and the bisectrix linked to both ends of the wound edge. An arc for which the vertical line drawn from the apex was shorter or longer than its bisectrix was designated a ‘shallow type’ or ‘U type’, respectively.

3) Category ‘skin flap’

The category ‘skin flap’ was defined by the thin flat piece of skin that develops during an original trauma and was subdivided according to four subcategories (Figure 7-3). The ‘without skin flap’ subcategory was defined as an ST without a skin flap, and is linear-shaped. The subcategories ‘skin flap present’, ‘partial flap absence’, and ‘complete flap absence’ were defined based on the degree of skin flap covering the dermis layer. ‘Skin flap present’ indicated a tear whose flap covered the dermis within 1 mm of the wound edges and could be realigned to its normal anatomical position. ‘Partial flap absence’ indicated a tear whose flap partially covered the dermis and could not be realigned to the normal anatomical location. ‘Complete flap absence’ indicated a tear where the skin flap was completely absent.

4) Category ‘purpura’

The category ‘purpura’ was defined as the discoloration of the skin due to extravasation of red blood cells [77, 78], with four subcategories (Figure 7-4). Purpura, known medically as ecchymosis, is more commonly known by laypeople as bruising. The lesions vary in color from purple to bluish-red with evolution (chemical degradation of hemoglobin) through a greenish-yellow or brownish-yellow hue [77, 78]. The subcategory ‘without purpura’ was defined as a ST without bleeding. The subcategory ‘localized purpura’ was defined as bleeding having clear and limited margins around a skin split. The subcategory ‘Purpura around the skin in contact with medical implements' was defined as bleeding having non-clear margin spreads around the medical implements. The subcategory 'discrete purpura' was defined as bleeding having an unclear margin or a margin marked by irregularly shaped bleeding dotting over the arm or leg including ST, and included bruises present over the entire body that were caused by underlying disease.

5) Category 'size'

The category 'size' was defined as a lacerated area caused by an original trauma, which was determined based on the appearance of tearing into two subcategories. The subcategory 'large' and 'small' was defined on the basis of the wound area of the ST marked by (a) a tangential line linked to the flap edge (mm) times the (b) vertical line drawn from the arc's apex (mm). The subcategory 'small' defined a ST as large as a half of an adzuki bean (4 mm × 6 mm) to half of quail egg (25 mm × 15 mm). The subcategory 'large' defined a ST as large as half of a chicken egg (30 mm × 20 mm) to half of a fist (40 mm × 45 mm).

DISCUSSION

To our knowledge, this is the first study to describe the morphological characteristics of STs in detail as a means of estimating the external forces that cause STs in elderly people. Existing morphological classifications generally represent two types of lacerated morphology proposed for healing management: the linear and flap type [33-35]. Our conceptual diagram partially overlaps with the wounds described as two types of tearing shape. However, no classifications of STs exist that include the following: site of wound, direction, symmetry and depth of arc's apex of skin flap, bruising area surrounding wound, and wound size. We believe these features are important to identify the relationship between the morphological characteristics of a ST and the potential external forces involved.

As shown in Table 10, the proportion of STs was highest among patients with stroke, and these were completely concordant with the results of lower total scores in the Braden scales (median score; 11). STs were located primarily on the forearms and might occur during routine care, or by patients themselves due to disturbing behavior. This anatomical location for a ST is relatively consistent with the findings of White et al [24] and Malone et al [27]. Excessive external forces and aged skin properties may yield a unique shape of ST. The shape subcategories and sub-subcategories were different from those of skin wounds resulting from exposure to persisting forces (e.g., pressure ulcers [63], diabetic foot ulcers, venous leg ulcers). Every nurse, on member-checking, agreed completely with the differences in shape between STs caused accidentally. Factors such as pressure duration and skin extensibility against impact due to pressure may be reflected in different wound shapes.

In addition, the sub-subcategory 'depth of arc' or 'crescent-shaped' may be more reflective of the underlying anatomical structures, and type of external force. Skin resistance to traction predominates in the direction of Langer's lines and varies with site [71, 79-81]. As already noted, the extensibility of the skin varies in degree of stiffness and thickness with the anatomical location [19, 20, 76, 77]. Langer's lines correspond to the alignment of collagen fibers within the dermis and the direction in which the skin is under the highest tension and has the least extensibility [79-82]. Thus, skin movement is more likely to occur across Langer's lines where the skin tension is lower [81, 82]. Therefore, the type of external force applied across or along Langer's lines may be a factor in the development of crescent-shaped tearing, specific to the depth of arc.

Decreased perivascular support with chronological aging and photoaging may explain the easy development of senile purpura with skin tearing or senile purpura alone in response to slight shear forces on the extremities [2, 36, 37, 41]. The weakened binding force in the skin with senile purpura was not sufficient to resist biaxial and tangential tension, causing skin to tear [36]. The presence of discrete purpura, or around pupura skin contacting medical implements, which may have been present before ST development, may contribute to distinguish whether STs are preceded by purpura, or not. The intensity and direction of external forces that cause ST may vary in the presence or absence of bleeding. Therefore, the type of purpura may provide important clues about the type of external forces involved in ST. Multiple morphological assessments based on anatomical location, shape, skin flap, size, and range of purpura may be effective to estimate the type of external forces, including intensity and direction of impact, contributing to ST development.

In forensic science, Whittele, *et al.* have already described a few wound morphologies within sub-dermal tissue, such as the Y-shape, linear, stellate, and double crescent, due to actual blunt-force using a synthetic skin model (silicone layer and polyurethane sponge), and analyzed the relationship between energy of external forces and these wound morphologies [83]. These morphologies were partially similar to our results. However, almost all STs in older Japanese people developed within the dermis layer and were caused by both blunt forces and shearing forces. Briefly, the status of STs in elderly people were different from injuries on the synthetic skin model with respect to wound deepness and cause of external forces, these wound characteristics on the synthetic skin model are not applicable to ST of elderly people. Therefore, collecting information in detail regarding external forces implicated in STs is indispensable in Study 2, when investigating the relationship between morphological characteristics defined in Study 1 and the type of external forces that cause ST.

Our study has some limitations. First, although we collected various ST samples, the study participants were taken from just one long-term medical facility. Our study population dominantly comprised dependent and elderly patients with below-standard body mass indices; analysis of ST samples from independent and obese elderly patients is needed. Second, regarding the category ‘skin flap’, the skin flap may be lost during not only the potential etiology of ST, but also during subsequent trauma, like cleansing due to necrosis or sloughing, or tape removal [33]. We need to verify whether these morphological categories may be effective for estimation of the etiology related to external forces in study 2, including the effect of subsequent trauma.

Table 10. Characteristics of participants and skin tears in Study 1

		Patients with ST (n = 18)
Age (years)		87 (84-93)
Sex	Male	7 (38.9)
	Female	11 (61.1)
Body mass index		17.7 (14.5-19.5)
Paralysis		3 (16.7)
Cotracture of the arm		15 (83.3)
Contracture of the leg		15 (83.3)
Braden Scale		
	Total score	11 (11-12)
	Sensory perception	3 (2-3)
	Moisture	2 (1.25-2)
	Activity	1 (1-2)
	Mobility	2 (1.25-2)
	Nutrition	3 (2-3)
	Friction and shear	1 (1-1)
Medications		
Steroid		2 (11.1)
Antithrombotic		5 (27.8)
Diseases		
Stroke		14 (77.8)
Dementia		2 (11.2)
Cardiac disease		1 (5.5)
Parkinson's disease		1 (5.5)
Anatomical location (n* = 20)		
Upper arm		2 (10)
Elbow		2 (10)
Forearm		9 (45)
Dorsal hand		3 (15)
Knee		1 (5)
Lower leg		3 (15)
STAR classification (n* = 20)		
	1a	1 (5)
	1b	14 (70)
	2a	1 (5)
	2b	2 (10)
	3	2 (10)

ST, skin tear;

Values are median (IQR1- IQR3) or number of patients (%).

n*; number of skin tears

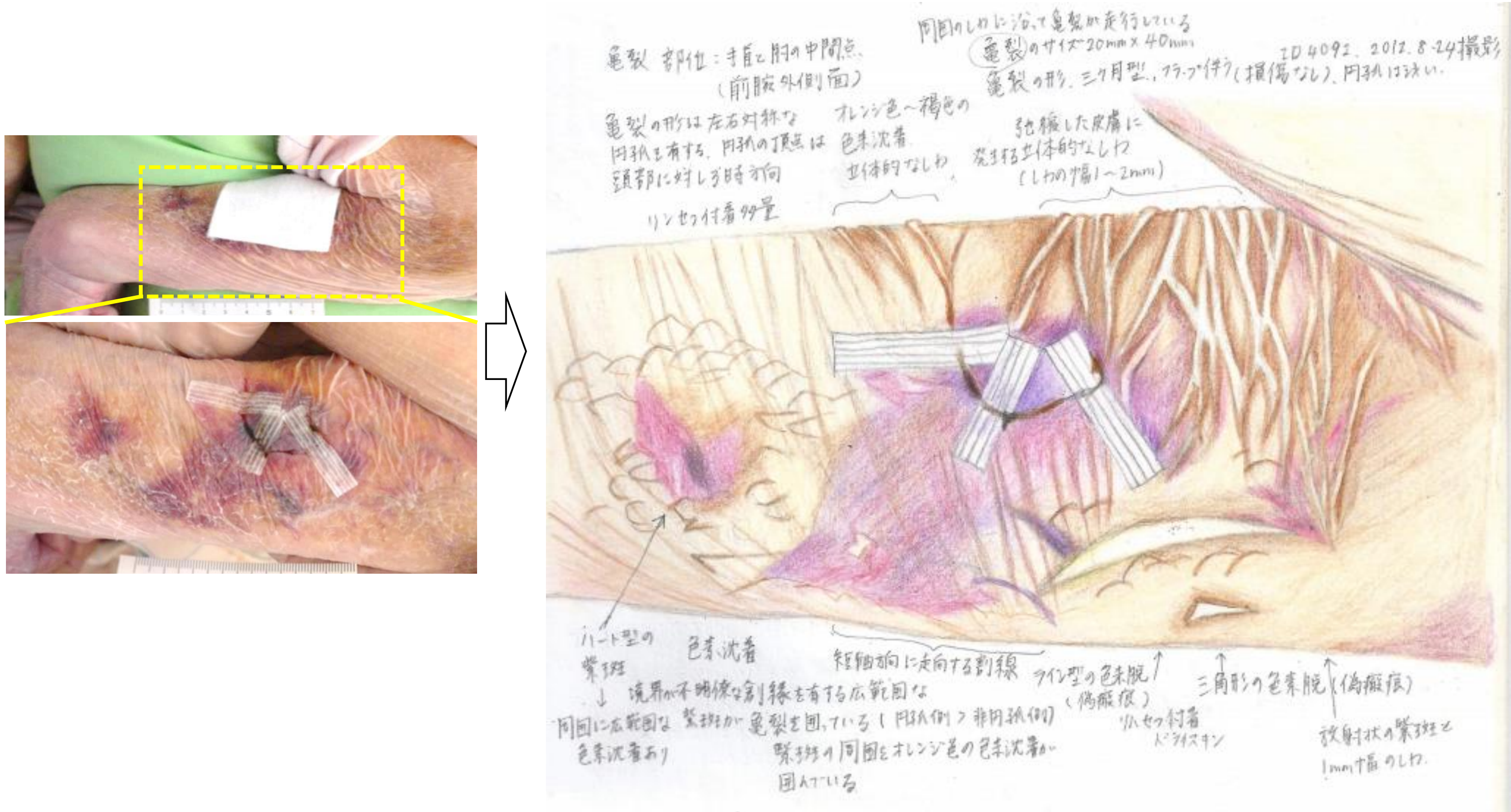


Figure 6. An example of the detailed description and summary of skin tear in a 95-year-old resident woman. Skin tear that did not appear to involve an etiology-related external forces. This skin tear, with skin flap, was located midway between the wrist and elbow on the patient's posterior forearm. The tear was developed along with the three-dimentional wrinkle, a dark-purple symmetrical arc, and split involved the dermis. The tear measured about 20 mm × 40 mm. The apex of the arc of the crescent-shaped flap was directed toward the three. The tear was surrounded by poorly marginated radial purpura. Pseudoscars (appearing as whitish lines and three-pointed stars) were accompanied by senile purpura and pigmentation in the surrounding skin. An extensive orange-colored pigmentation around the three-dimentional wrinkle, bleeding may be varying in color from purpura to orange due to chemical degradation of hemoglobin. Therefore, orange-colored pigmentation may expresses there was any purpura around the three-dimentional wrinkle. The skin flap side of purpura sorrounding tear is more extensive than the non-flap side. The surrounding skin was also marked by a three-dimentional wrinkle, 1 to 2 mm wide, and cleavage, with dry silver scales.

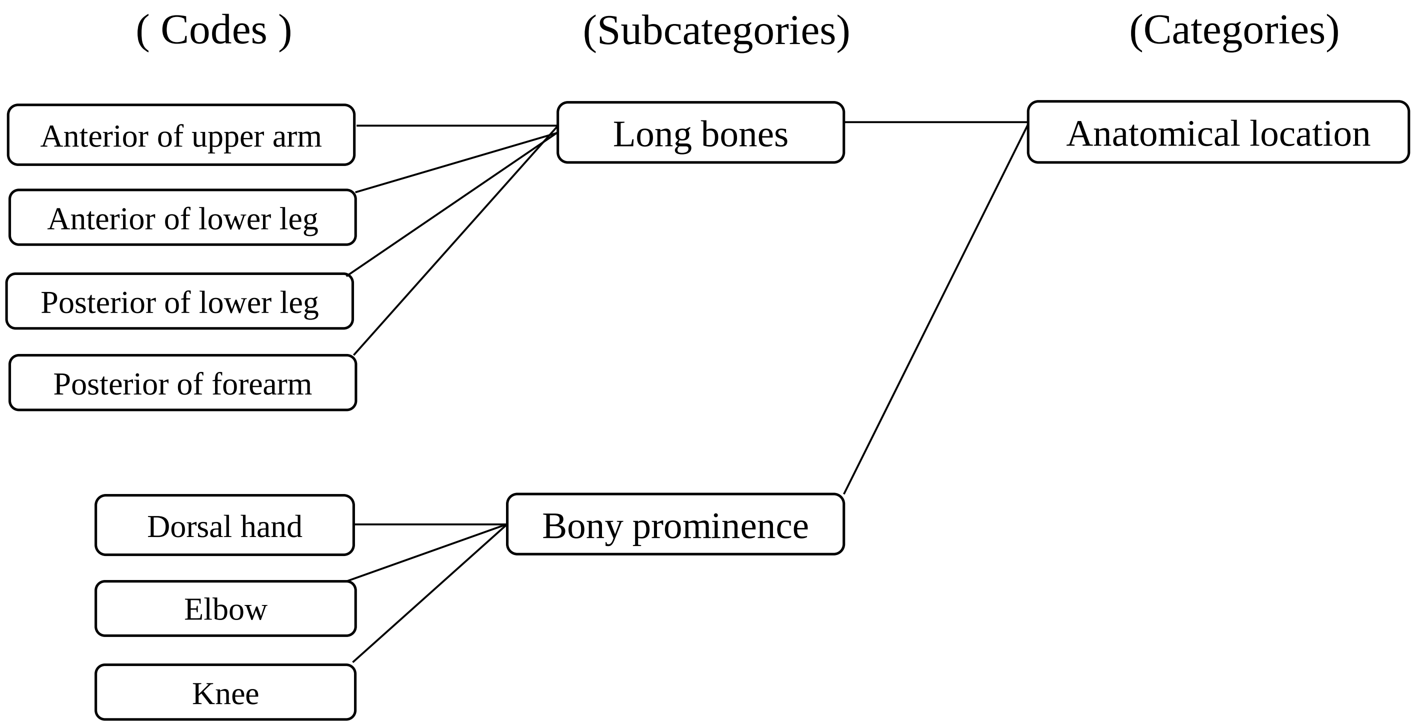


Figure 7-1. Codes, subcategories, sub-subcategories and categories of morphological characteristics of skin tears in anatomical location.

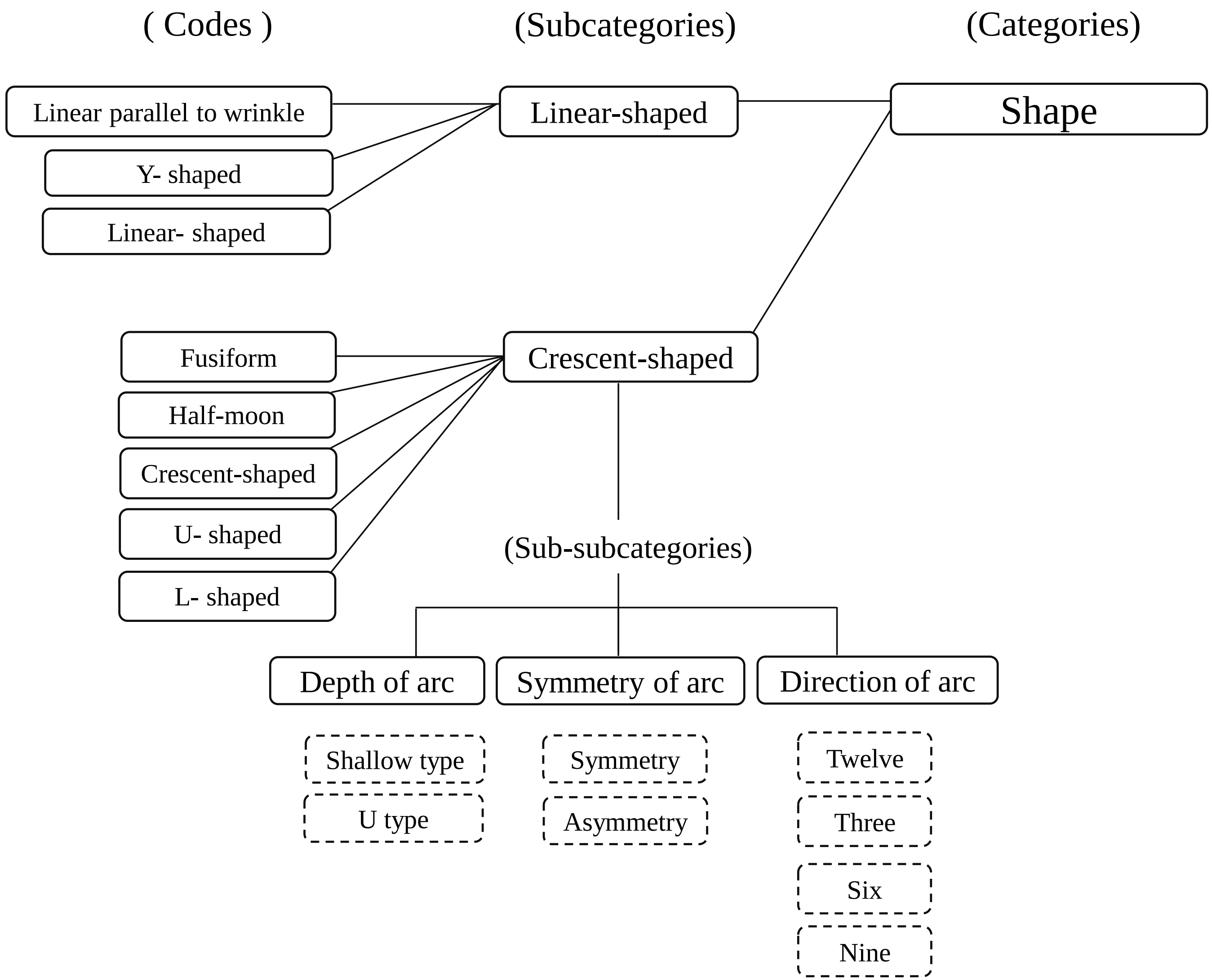


Figure 7-2. Codes, subcategories, sub-subcategories and categories of morphological characteristics of skin tears in shape.

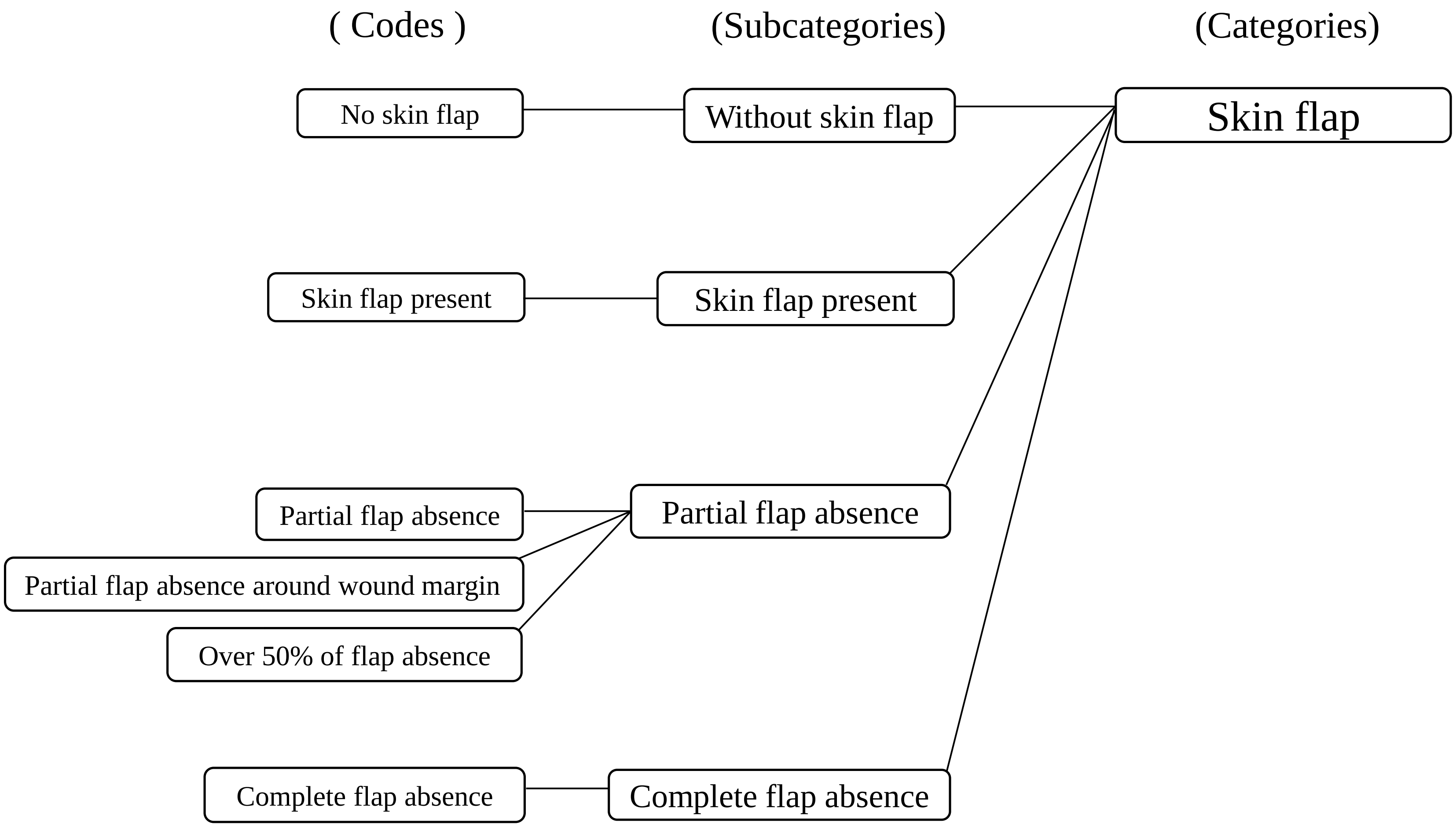


Figure 7-3. Codes, subcategories, sub-subcategories and categories of morphological characteristics of skin tears in skin flap.

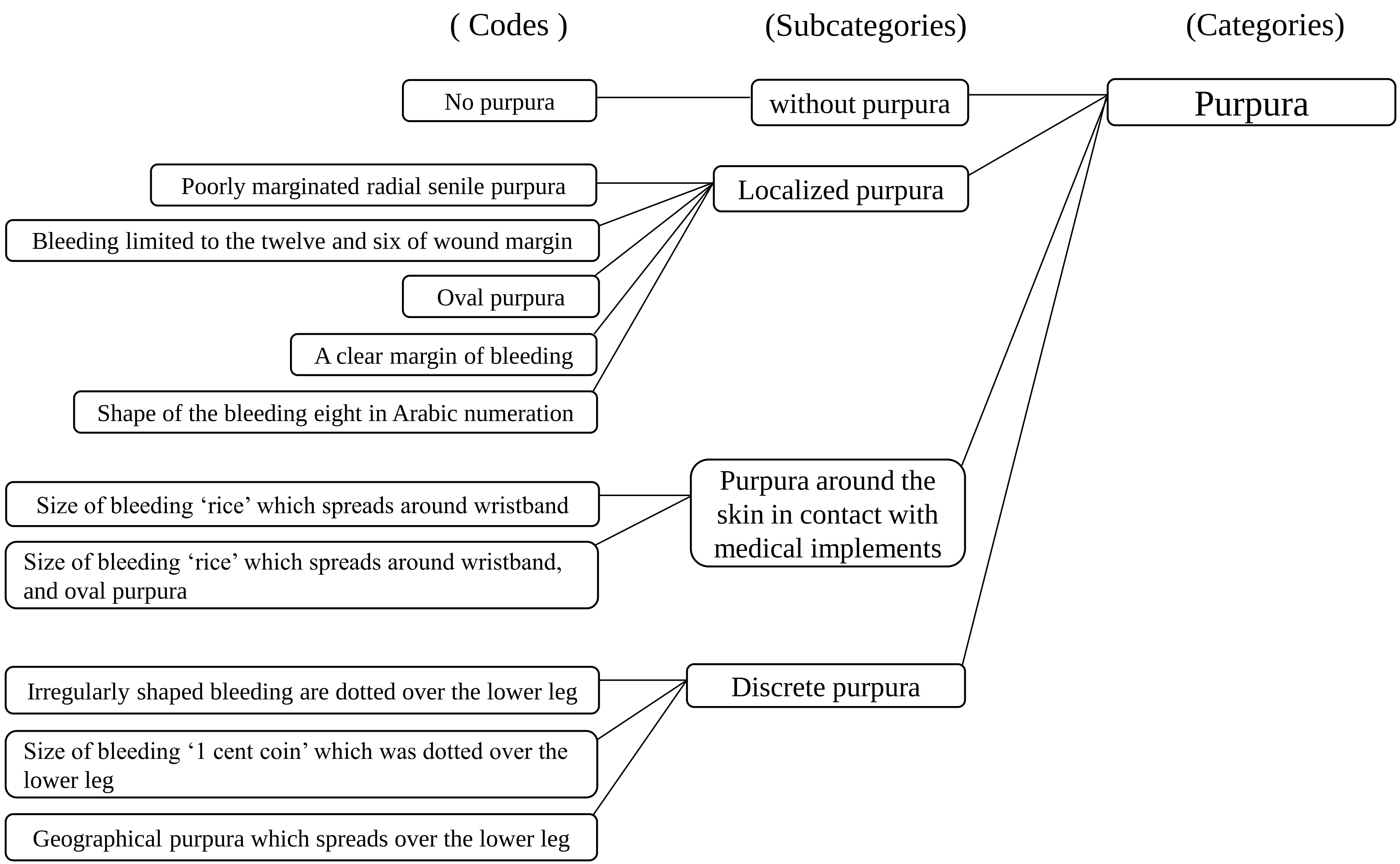
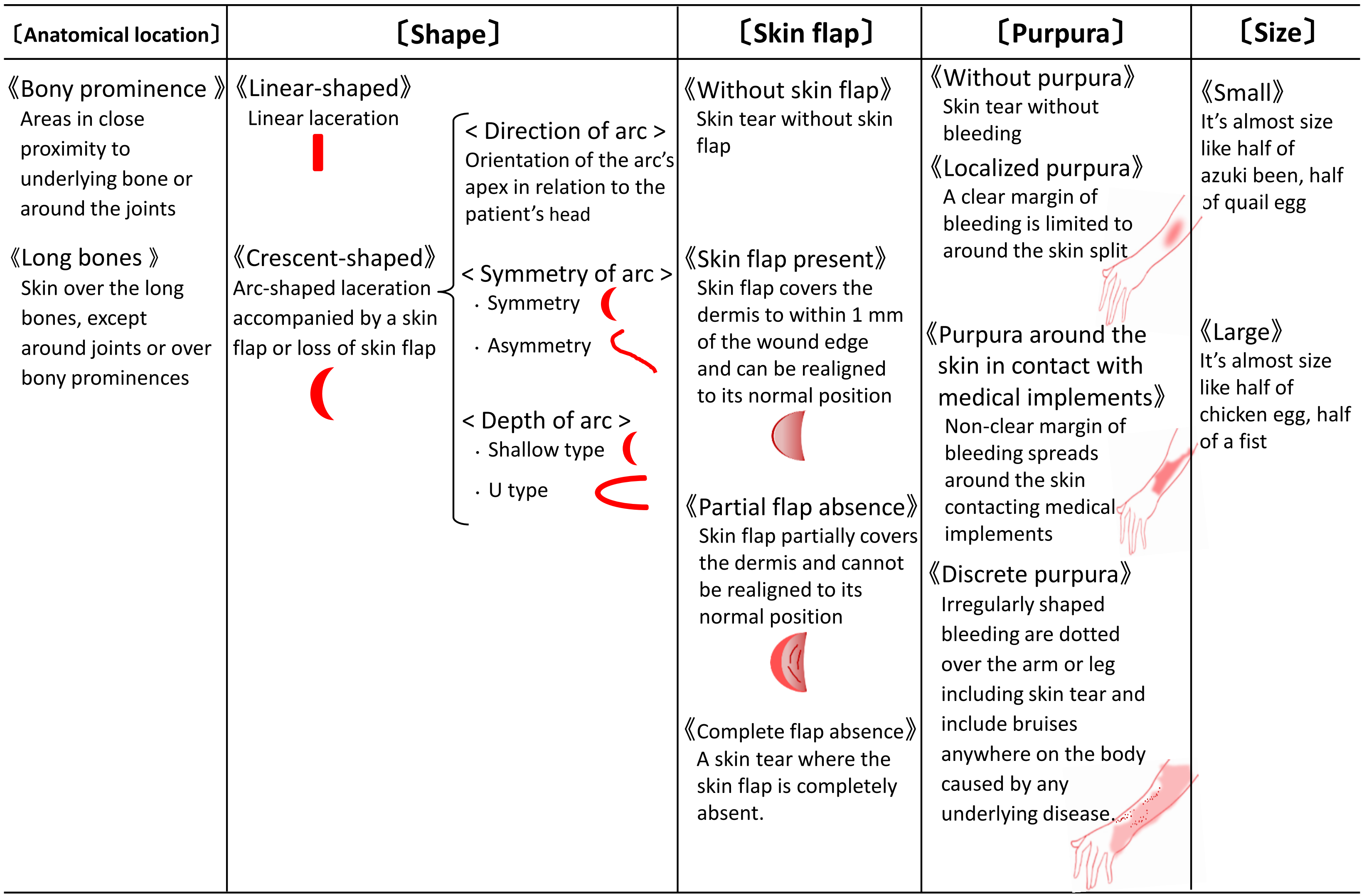


Figure 7-4. Codes, subcategories, sub-subcategories and categories of morphological characteristics of skin tears in purpura.



〔 〕, Category; 《 》, Subcategory; 〈 〉, Sub-subcategory.

Figure 8. Conceptual diagram with morphological classification of skin tears. Five categories—anatomical location, shape, skin flap, purpura, and size were generated.

CHAPTER 2

Identification of a prevention strategy for skin tear recurrence

(Study 2)

STUDY AIM

The aim of study 2 was to identify the external forces that caused the STs.

METHODS

1. Study design

We chose a qualitative descriptive study because it is suitable for describing the etiology-related external forces that cause the STs in elderly people from healthcare practitioners.

2. Setting

Participants were recruited from the same facility and units as those in the study discussed in Chapter 1 which was carried out from December 2014 to July 2015.

3. Participants

The study participants were patients aged 65 years and older who were hospitalized and had at least one ST episode during the study period. The analysis samples by morphological analysis were limited to STs on the arm. Because a different extensibility of the skin depends on the anatomical location [76, 77] and may affect the morphologies of a ST even when it is caused by similar external forces. The current analysis included only STs on the arms for which the etiology-related external forces contributing to ST could be clarified. Exclusion criteria were STs for which the etiology-related external forces or the date of the ST development was unknown, or if more than four days had passed after the development of the ST.

4. Evaluation of skin tears

Evaluation of STs was performed in the same way as that in Chapter 1. Each ST was classified according to the STAR classification system [34] as shown in Table 11.

5. Procedure

All healthcare practitioners in this facility are required to report the occurrence of any ST as a medical accident. At the beginning of the survey, to establish an intimate relationship with the healthcare practitioners, the researcher described the purpose of our study to every healthcare practitioner in the three participating wards, and particular attention was paid to their concern that interviews involved in STs should not cause any disadvantage to them. After identifying the presence of an ST on a patient's extremities, the researcher gathered information regarding the external forces that contributed to the ST. This study protocol was approved by the Ethical Committee of the Graduate School of Medicine, the University of Tokyo, Tokyo (#10694) and the participating institution and conformed to the ethical guidelines of the 1975 Declaration of Helsinki. Proxies provided written informed consent.

6. Data collection

To investigate the relationship between ST morphology and etiology-related external forces, two major sources of data contributed to this investigation: (i) photographs of STs and (ii) semi-structured interviews concerning development of the ST. After identifying a wound suspected as being an ST during the survey, photographs of the ST and the context in which the ST occurred, such as the bed or wheelchair, were taken from different viewpoints by the researcher. The wound area was concurrently measured using a scale: a tangential line linked to the flap edge (mm) times the vertical line drawn from the arc's apex (mm) was used to determine the wound area of the ST.

Given that a ST develops instantaneously or accidentally, healthcare practitioners tend to forget the specific details of the external forces involved in the ST incident. Thus, a participant observation was conducted over 50 days before starting the survey to design an interview guide. This guide allows the researcher to precisely collect all of the information relative to the external forces causative of STs from healthcare practitioners during routine care including bathing and transferring which are considered as high risk situations for STs [23, 24, 31,32]. The external force factors related to the onset of a ST from both the point of view of the patient and of the medical institution were collected by talking with healthcare practitioners. In order to guarantee the safety of all bedside routine nursing care procedures including dressing, positioning, bathing, and transferring, routine cares were conducted between two or more healthcare practitioners in this facility. Therefore, semi-structured interviews were collected from all members who may have participated in the situation of tearing. Sixty-two interviews for 52 tearing episodes were conducted by the researcher and each interview lasted 10 to 20 minutes. Almost all interviews were recorded by hand on paper. The following questions were the focus of the interviews:

(1) In what type of process did the ST develop?

(2) Where did you touch or grab the patient's body during the development of the ST? Was there any simultaneous resistance by the patient?

(3) What kind of clothing was worn on the surface of the patient's skin surrounding the ST?

(4) What type of protection was used against bleeding on the surface of patient's skin before the generation of the ST?

(5) What was the body position of the patient and were there any objects located near the ST?

Other questions were formulated following-up on individual participants' responses. There were cases where the cause of a ST was a medical device, such as a wristband, or the patient's fingernails, or by bumping due to a patient falling on his own. In these cases, the individual shape and size of the ST and object involved was directly verified to determine whether the reports corresponded.

Patient demographics including age, sex, body mass index, paralysis, contracture in the extremities, Braden Scale [62], medication, and diseases were collected from the medical charts and the nursing charts.

7. Data Analysis

Reports of the interviews describing the circumstances of the ST were read carefully and the content was analyzed by scrutinizing each sentence and then the sentences were coded. The researcher compared all codes for any similarities and differences and extracted subcategories representing the external force factor (Figure 11). These subcategories were compared for any similarities in order to extract categories.

8. Analytical rigor

To establish consistency, the research team recorded observational and interpretive field notes throughout the research process. This procedure was confirmed as acceptable based on consultations between the primary researcher and three experts in the area of wound care.

RESULTS

1. Characteristic of patients

Thirty-two STs that satisfied the exclusion criteria were excluded from the original 52 STs identified for the study. Three additional STs on thr forearms for which causes were known from a previous study (Study 1) were added as analysis objects, because the number of STs for morphological analysis was too small. Therefore, a total of 23 STs which developed on the arms (upper arms, elbows, forearms, dorsal hands) among 15 patients were selected for the morphological analysis (Figure 9). Table 11 shows the characteristics of participants and STs. The median age (interquartile range) of participants was 89 years (82-90 years), and 66.7% of the participants were women. STAR classification 1b (ST with a pale, dusky, or darkened flap whose edges can be realigned to the normal anatomical position without undue stretching) and 2b (ST with a pale, dusky, or darkened flap whose edges cannot be realigned to the normal anatomical position without undue stretching) were dominant (30.4 and 34.8%, respectively).

2. Interview results on external forces causing STs

Two categories and nine subcategories emerged from the data analysis of interview contents (Figure 11): 1) ‘origin’, with three subcategories and 2) ‘type of external forces’, with six subcategories.

1) Category ‘origin’

The category ‘origin’ was defined as the origin from which external forces were applied, with three subcategories (Table 12-1). The subcategory ‘caregiver’ was defined as a person who assists with any of the patient’s activities of daily living. The definition of ‘patient’ was a person who requires medical care. The definition of ‘skin contacting medical implements’ described wearing something on the patient’s extremities, including wristbands, bandages, the patient’s watch.

2) Category ‘type of external forces’

The category ‘type of external forces’ was defined as the external force that caused ST, and consisted of six subcategories (Table 12-2)**.** The subcategory ‘bumping’ was defined as bumping the patient’s skin against something by a caregiver during care or by the patients themselves due to accidental falling. The subcategory ‘wiping’ was defined by the caregiver’s wiping off the patient’s skin with a towel. The subcategory ‘pulling’ was defined as a caregiver giving the patient’s skin a strong pull. The subcategory ‘fingernail lacerations’ was defined as the caregiver’s or patient’s fingernail lacerating the patient’s skin during care or that inflicted by the patients themselves. The subcategory ‘scratching’ indicated patients vigorously scratching off their skin. The subcategory ‘friction’ was defined as that caused by a wristband or, any medical device, on the arm against the skin surface of patients.

DISCUSSION

To the best of our knowledge, this is the first study to identify the etiology-related external forces causative of STs in detail from healthcare practitioners who knew something about the circumstances of the tearing incident. Our results partially overlaps with the external forces causative of tearing in the previous study, such as ‘bumping by caregiver’, ‘accidental fall by patient themselves’, and ‘pulling by caregiver’ [23, 24, 29, 31, 32, 38, 39, 84]. On the other hand, no previous study related to external forces causative of existing STs include the following: ‘patient or caregiver fingernail laceration’, ‘persisting friction due to patient wristband’, and ‘wiping with towel by caregiver’.

In the clinical setting, the identification of etiology-related external forces causing an existing ST is the most important, because the prevention of recurrent ST was selected based on the kinds of external forces. However, a ST is considered a skin lesion due to a medical accident [23, 24, 32] and the cause of tearing was often unknown [23, 24]. Thereby, collecting accurate information involving external forces such as ‘patient or caregiver fingernail laceration’, ‘persisting friction due to patient wristband’, and ‘wiping with towel by caregiver’ has been almost impossible by the traditional means. Data collection by semi-structured interviews based on participant observation must succeed in identifying the accurate etiology of an individual’s skin tearing incident.

As shown in Table 11, the proportion of STs was highest among patients with stroke, and they were completely concordant with the lower total scores in the Braden Scales (median score; 13). About 70% of STs were located on the posterior area of the forearm, which indicated etiologies consistent with injuries inflicted during routine care or by patients themselves [23-25]. In addition to this, we newly identified that medical implements placed on the forearm in elderly patients, such as a wristband or bandage may contribute to develop a ST.

Our study has several limitations. Firstly, although we collected many ST samples with various kinds of etiology, the study participants were taken from just one long-term medical facility. Our study population dominantly comprised dependent residents, therefore, these etiologies-related external forces causative of STs may not yet been saturated among another elderly patients, like an independent. Indeed, a ST caused by adhesive tape removal, a standard etiology of ST at the intensive care unit of general hospitals in Japan [21], did not develop among our participants during the survey period. If patients need to receive the intravenous fluids, an insertion of central venous catheter through the internal jugular vein was selected. Therefore, there was no factor related to tape removal on the arm among elderly patients because no one received any intravenous fluids on the arm or dorsal hand.

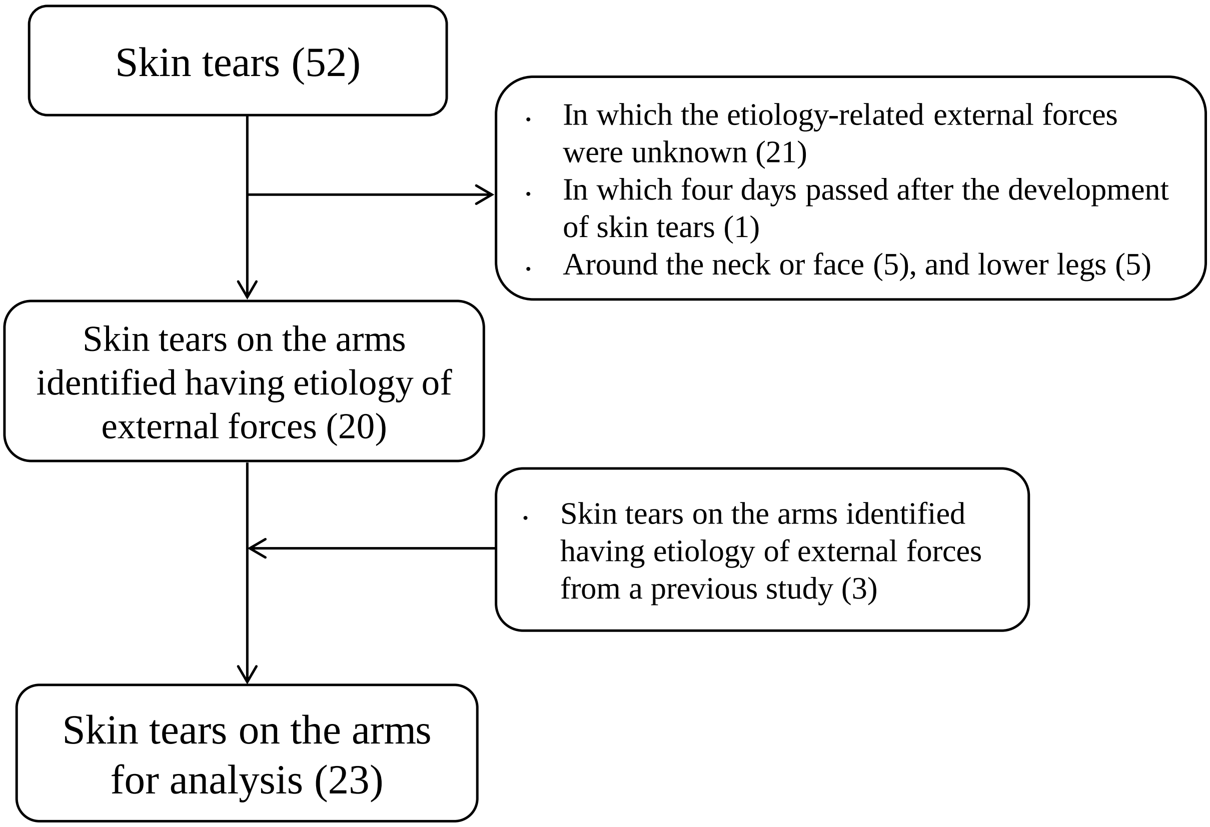


Figure 9. Flowchart of analysis objects in Study 2, Chapter 2

Table 11. Characteristics of participants and skin tears in Study 2

		Patients with ST (n = 15)
Age (years)		89 (82-90)
Sex	Male	5 (33.3)
	Female	10 (66.7)
Body mass index		16.1 (15.5-18.2)
Paralysis		2 (13.3)
Cotracture of the arm		11 (73.3)
Contracture of the leg		11 (73.3)
Braden Scale		
	Total score	13 (11-14.5)
	Sensory perception	3 (2-4)
	Moisture	3 (2-3)
	Activity	1 (1-2)
	Mobility	2 (2-3)
	Nutrition	3 (2-3)
	Friction and shear	1 (1-1.3)
Medications		
Steroid		3 (20)
Antithrombotic		0 (0)
Diseases		
Stroke		12 (85.7)
Dementia		6 (42.9)
Cardiac disease		2 (14.3)
Parkinson's disease		1 (7.1)
Cancer		2 (14.3)
CCI		2 (2-4)
Anatomical location (n* = 23)		
Upper arm	Anterior	0 (0)
	Posterior	1 (4.3)
Elbow		1 (4.3)
Forearm	Posterior	16 (69.7)
	Anterior	1 (4.3)
Dorsal hand and fingers		4 (17.4)
STAR classification (n* = 23)		
1a		2 (8.7)
1b		7 (30.4)
2a		2 (8.7)
2b		8 (34.8)
3		4 (17.4)

ST, skin tear; CCI, Charlson Comorbidity Index

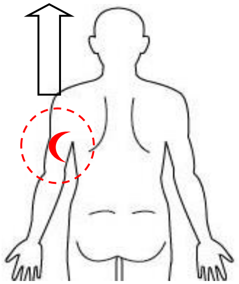
Values are median (IQR1- IQR3) or number of patients (%).

n*: number of skin tears

Interview contents related to development of skin tear

Interview was the night shift nurse who found a skin tear (skin tear ID: 6) at pm 22:30, 18th February, 2015.
Interview day; 23th February, 2015

When I (nurse) visited patient A's bed room, because he was shouting in a loud voice, I found him fallen from a bed (no pain) and lying on his back. There was a skin tear on the posterior of his left upper arm. I asked him "Did you accidentally fall from bed, and bump your upper arm against the bed railing, or the edges of the tabletop? He replied that, "When I fell on my way to the bathroom carrying a bath towel, I bumped my arm against something at the bed side."
I (nurse) also think "he might fall due to stumbling against the stand for drip infusion near the bed railing, or bumped his arm against the edge of the tabletop, or the stand for drip infusion.



Classification of morphology based on conceptual diagram of skin tear, which was defined in Study 1

The morphological characteristics of skin tear was divided into 'long bones', 'crescent-shaped', 'partial flap absence', 'localized purpura', and 'large'. In addition, 'crescent-shaped' was divided into 'shallow type', 'symmetry', and 'three'.

Figure 10. An example of interview content of skin tear and classification of morphological characteristics using a photograph of a skin tear. Description of etiology causing skin tear in a 92-year-old independent male resident.

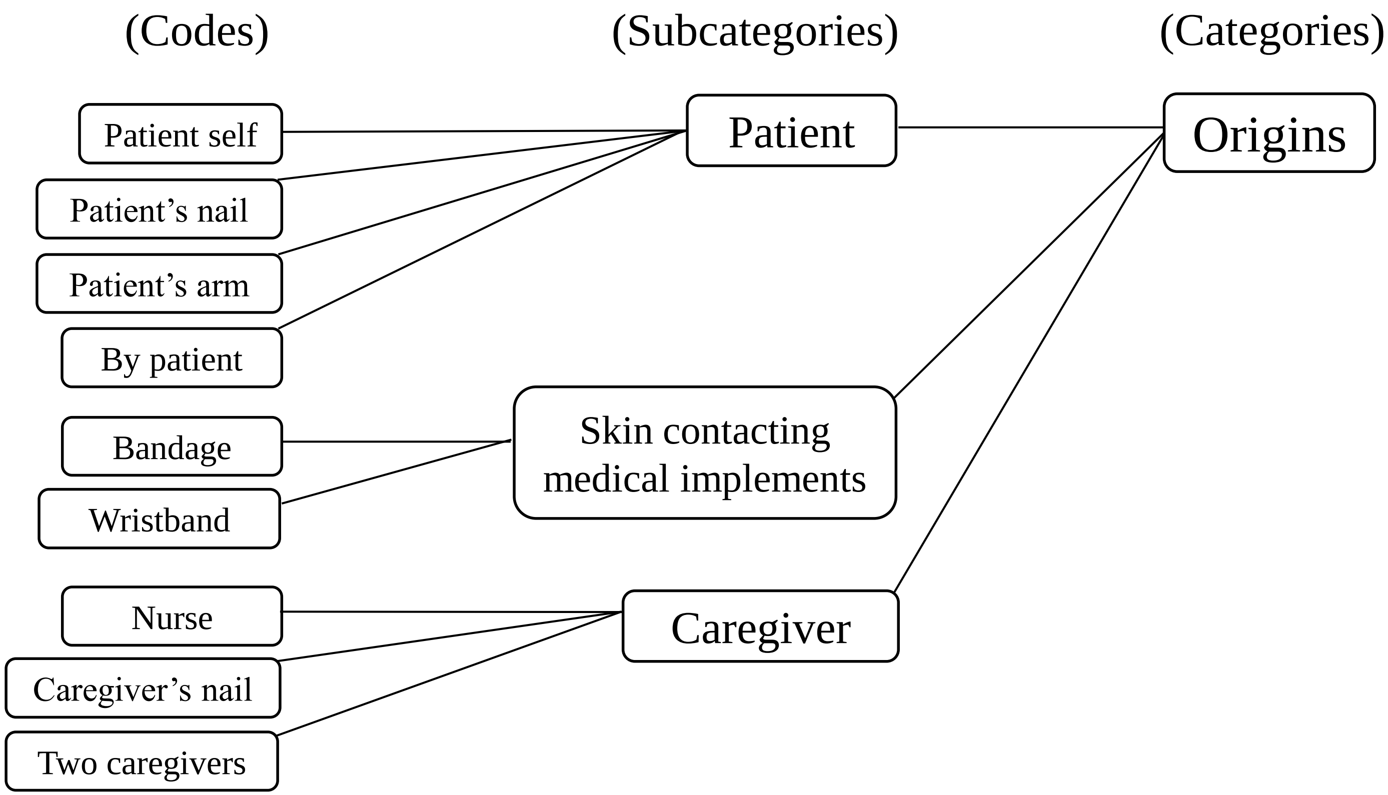


Figure 11-1. Codes, subcategories, and categories derived from interview reports, origins.

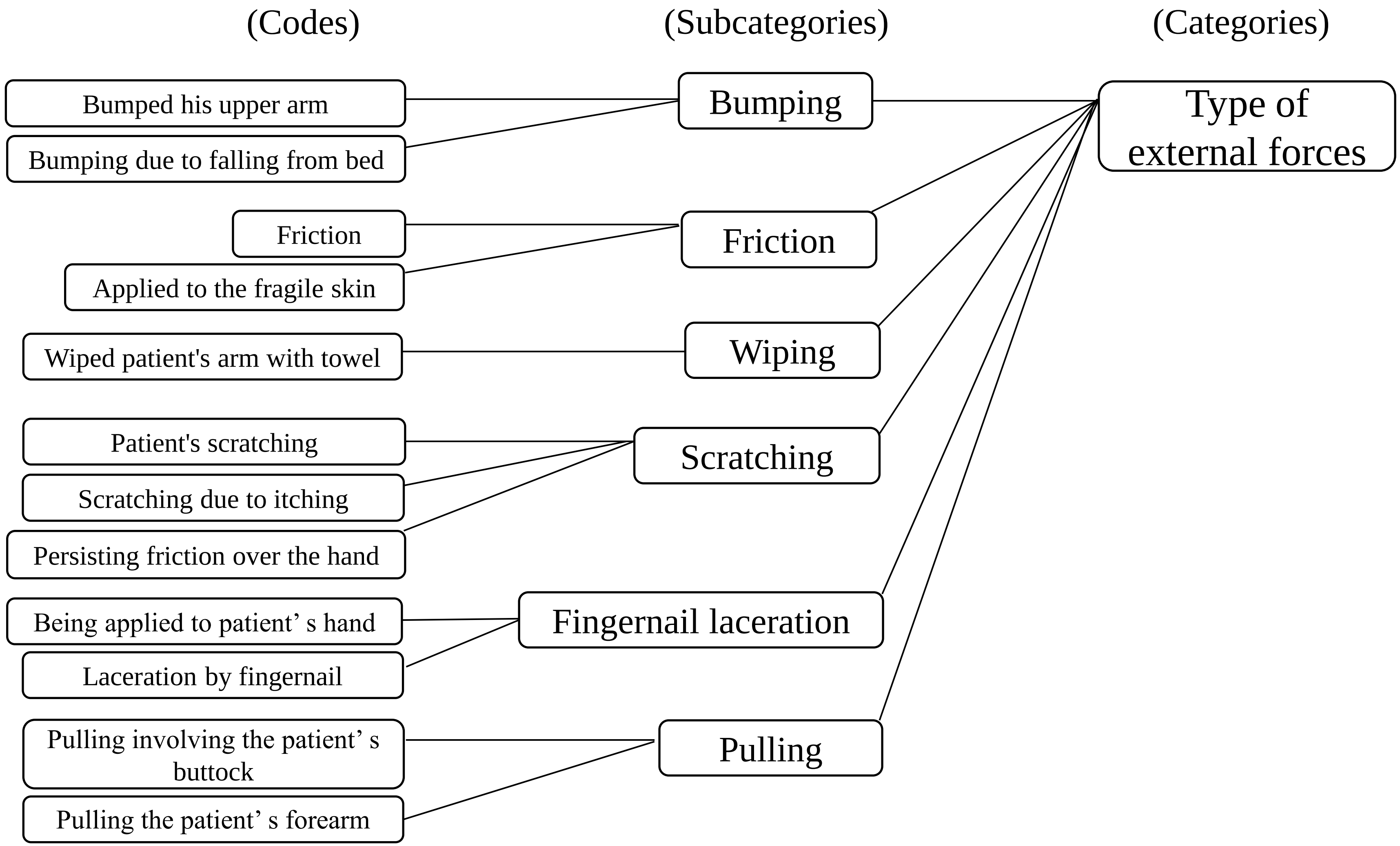


Figure 11-2. Codes, subcategories, and categories derived from interview reports, type of external forces

CHAPTER 2

Identification of a prevention strategy for skin tear recurrence

(Study 3)

STUDY AIM

The aim of study 3 was to identify the morphological characteristics of STs associated with external causative factors.

METHODS

1. Study design

We chose a qualitative descriptive study because it is suitable for associating the etiology-related external forces, which were identified in Study 2, with the morphological characteristics of STs, which were identified in Study 1. The study setting, participants, and data were same as that used for the study 2.

2. Data Analysis

Data analysis was conducted by qualitative morphological analysis [59, 60] and was implemented in three phases. Firstly, the morphological characteristics of 23 STs were divided into five categories, fourteen subcategories, and STs with crescent-shaped was also divided into three sub-subcategories (direction of arc, symmetry of arc, depth of arc) (Figure 10) according to the findings from Study 1. Second, the morphological characteristics of all STs were classified according to the same nine subcategories of external forces, which were identified in Study 2 (Table 12). For identifying the unique characteristics for each category and subcategory of external forces, each morphological characteristic of STs was compared within and across each category and subcategory of external forces. Third, unique characteristics related to each subcategory were summarized in a specific correspondence table (Table 13). In the correspondence table, only the morphological characteristics of STs that were associated with external forces were stratified according to ‘origin’ and ‘type of external forces.’ The morphological characteristics that contained the following piece were excluded from correspondence table: it was common in all subcategories of external forces, or had no association with identifying ‘origin’ and ‘type of external forces’.

3. Analytical rigor

To ensure the validity of the results, we enlisted the opinion of three experts in the area of qualitative morphological analysis and wound care. They examined the process used and confirmed that all the extracted categories fitted the interview data. The researcher held discussions with the experts until a consensus was reached in each phase.

RESULTS

1. Unique characteristics in each subcategory of ‘origin’ and ‘type of external forces’

1) Category ‘origin’

In five cases of ‘caregiver’, localized purpura, and crescent shaped lesions were the most prominent features. In fourteen cases of ‘patient’, discrete or localized purpura was the most prominent variables. In four cases of ‘skin contacting medical implements’, purpura around the skin in contact with medical implements and linear shape were the most prominent features. The orientation of the arc’s apex in relation to the patient’s head, which indicates direction of the arc, was divided into ‘caregiver’ and ‘patient’ categories. In the five cases that were caused by a caregiver, the number (proportion) of three or nine, and twelve or six in direction of the arc were 3 (60%) and 2 (40%), respectively. On the other hand, in fourteen cases which were caused by patients themselves, were 9 (64.3%) and 5 (35.7%), respectively.

2) Category ‘type of external forces’

In ‘bumping’, the shallow type arc and localized purpura were the most prominent variables. Among bumping, the U type arc and localized purpura were also prominent variables when the cause was accidental falling by the patients themselves. In ‘wiping’, the shallow type arc, large, and localized purpura were prominent variables. In ‘pulling’, the U type arc, large, and localized purpura were the most prominent variables. In ‘fingernail lacerations’, the shallow type arc, skin flap present, small, and localized purpura were prominent variables. In 'scratching', crescent-shaped, complete flap absence, and discrete purpura were prominent variables. In 'friction', linear- shaped, shallow type arc, and purpura around the skin in contact with medical implements were the most prominent variables.

2. Correspondence table estimating the etiology-related external forces of STs

This correspondence table included four morphological characteristics (purpura, shape, depth of arc, and size) corresponding to the different external forces causative of ST. There are seven subcategories: localized purpura, discrete purpura, purpura around the skin in contact with medical implements, linear- shaped, crescent-shaped, small size, and large size. Lastly, there are two sub-subcategories—shallow type and U type (Table 13). Anatomical location, direction of the arc, symmetry of the arc, and skin flap did not reach the level of significance for inclusion in the correspondence table. The different illustrations combining different characteristics, which were associated with different etiologies-related external forces causing ST, were inserted into correspondence table. When if healthcare practitioners found the ST by unknown cause, they could estimate the external forces causing ST corresponding to special morphological characteristics represented in a direction from purpura (left) to size (right).

DISCUSSION

To the best of our knowledge, this is the first study to develop a novel concept whereby a healthcare practitioner could estimate the cause of a ST from the morphological characteristics of STs as a preventive strategy against their recurrence. This correspondence table includes the four characteristics (purpura, shape, size, and depth of arc) identified as factors able to estimate the cause of ST based on morphological analysis.

The first split of the correspondence table is purpura morphology because it is a significant feature able to estimate the origin of external forces. During the follow-up period, localized purpura occurred accompanied by a ST as consequence of nursing care activities or accidental falls by patients almost simultaneously. On the other hand, discrete purpura or purpura around the skin in contact with medical implements was developed prior to STs due to bumping, or shearing by the patient's own actions or by something placed on the patient's extremities, respectively. Discrete purpura on the arm has been reported to be a potential risk factor for ST development because bleeding under the epidermis enables the skin to lift off more easily when friction or slight pressure is applied on the extremities, thus resulting in tearing [2, 36-38, 41, 77]. This same mechanism may be responsible for the association between ST due to a medical device. Although bleeding including senile purpura, ecchymosis, or hematomas has already been described by Lewin et al. (2015) as a predictor for the development of ST, it has yet to be elucidated what kind of bleeding can be used to predict tearing [38]. However, our correspondence table could be used to estimate the external forces causing tearing based on the individual's morphology of purpura.

The subcategory 'shape' and sub-subcategory 'depth of arc' have been identified as contributors to clarify the direction of external forces. The type of external forces applied on the fragile skin may influence the shape of the lesion (crescent or linear) and the depth of arc (shallow or U type arc) of the tearing since these morphological categories reflect the combined effect of vertical force, and shear force [61, 83].

The category 'size' representing strength of the applied external forces was included in Table 13 for the correct estimation of etiology. In some STs presenting with a similar crescent-shape, shallow type arc, wound size was different according to the cause of the ST. For example, one cause of tearing was wiping with a towel by caregiver (size; large) and the other was a self-inflicted abrasion by the patient's fingernail (size; small). Different kinds of external forces may have an appreciable effect on wound size even when the ST presents with a similar shape. Previous studies have not included an evaluation of the intensity of the sustained external forces [63, 64]. However, size is a critical concept for determining etiology from morphologies of accidentally generated injuries, such as ST.

Table 13 shows STs characterized by localized purpura, small, crescent-shaped lesions with a shallow type arc caused by 4 types of external forces, ‘laceration of the patient’s or caregiver’s fingernail’, ‘bumping by caregiver’, ‘accidentally falling by patient’. These 4 types of external forces have a greater impact on the vertical force than shear force. For the orientation of the arc’s apex in relation to the patient’s head with these STs (twelve, three, six, and nine), they were applied both across (three or nine) and along Langer’s lines (twelve or six). The compression between objects and bone under the strong influence of vertical forces would likely transform tears into a shallow type arc tearing, regardless of the direction of Langer’s lines. This is because tearing occurs under a condition of little extensibility [61, 71]. When this correspondence table is clinically applied, it may be somewhat difficult to determine the correct origin and type of causative external forces involved in causing STs with these particular morphological characteristics. Furthermore, in STs caused by accidental falling by patients, wound size or depth of the arc may be influenced by the magnitude of the impact or the shear force generated during the fall.

There was only case with a ST caused by the patient’s wristband characterized by a linear-shaped tearing. The diameter of button on the patient wristband was in close agreement with all sizes of the three STs that were caused by patient’s wristband. Thus, the linear-shaped injury with 10 mm diameter may be caused by persisting friction of the patient’s wristband button on the surface of fragile skin.

Four characteristics, ‘anatomical location’, ‘skin flap’, ‘symmetry of the arc’ and ‘direction of the arc’ were not included in our correspondence table. The skin flap was not adequate as tearing predictor because of effects by not only the potential external forces and but also during subsequent trauma. Regarding the anatomical location (long bones or bony prominence) and symmetry of arc (symmetry or asymmetry), all causes of tearing were applied to both sides. The skin tension along Langer's lines is the highest [79-82]. Thus, skin movement is more likely to occur across Langer's lines where the skin tension is lower [81, 82]. In the direction of the arc, the proportion of STs with an arc of three or nine orientation (across Langer's lines) was expected to be increased in cases caused by patients than in those caused by caregivers. However, the proportion of arc type for the two groups was similar. Consequently, we conclude that direction of the arc is not associated with origin of causative external force in STs.

With traditional prevention protocols against ST recurrence, when an elderly person developed a skin tear of unknown cause on the forearm, the recommended care included the use of an arm cover and the application of moisturizer to the forearm to improve the skin integrity around the ST. These measures were based on the assumption that the external force involved was bumping against something. In the future, healthcare practitioners can estimate the external forces from observable morphological characteristics of the STs in such cases. Moreover, depending on the kind of suspected external force, they can focus their attention on preventing ST recurrence. As described above, a recurrent ST poses a problem in the clinical setting, and in some cases, it is incorrectly being recognized as an injury caused by abuse or poor-quality care [25]. Therefore, recurrent STs can be a source of constant stress not only for older patients, but also for healthcare practitioners. Accurate prevention of additional STs may contribute to decreasing ST recurrence and help patients and healthcare practitioners maintain a trusting relationship.

Our study has a limitation. Our results may be insufficient to estimate etiology-related external forces of STs on the anatomical location other than for arms. This is because the extensiveness of the skin in elderly individuals may be different particularly depending on the anatomical locations concerned [66, 67], which may ultimately affect the morphology of the ST.

To widen the ability of the correspondence table to accurately estimate the external forces, additional analysis of STs which are developed various kinds of anatomical locations among elderly people is required.

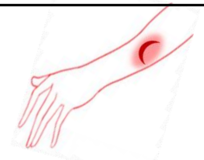
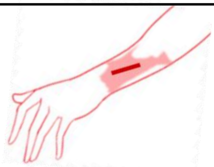
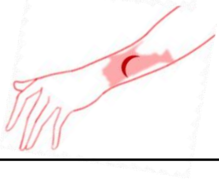
Table 12-1. Morphological classification of skin tear based on **origin**

	Anatomical location	Shape	Skin flap	Purpura	Size
Caregiver (5)	《 Long bone 》 (3, 5, 21) 《 Bony prominence 》 (16,20)	《 Crescent 》(3,5, 16,20,21) <Depth of arc> Shallow (3,5,16) U-type (20,21) <Symmetry of arc> Symmetry (16, 21) Asymmetry (5,3,20) <Direction of arc> Twelve (20,21) Six (3) Nine (5,16)	《 Skin flap present 》 (3,16,21) 《 Partial flap absence 》 (5,20)	《 Localized 》 (3,5,16,20,21)	《 Small 》 (16) 《 Large 》 (3, 5, 20,21)
Patient (14)	《 Long bone 》 (6,7,8,9,11,12,13,14, 15,17,18,19) 《 Bony prominence 》 (2,4)	《 Crescent 》(2,4,6,7,8,9,11,12,13,14,15,17,18,19) <Depth of arc> Shallow (2,4,6,9, 11,12,14,17,19) U-type (7,8,13,15,18,) <Symmetry of arc>Asymmetry (4,7,8,12,14) Symmetry (2,6, 11,13, 15,18,19,9,17) <Direction of arc> Twelve (2,8,11,13,14,18) Three (4,6,9,17) Six (7,15,19) Nine (12)	《 Skin flap present 》 (2,8,9,11,17) 《 Partial flap absence 》 (4, 6,7,12,15,14) 《 Complete flap absence》 (13,18,19)	《 None 》 (18) 《 Localized 》 (2,4,6,7,9,17) 《 Discrete 》 (8,11,12,13,14,15,19)	《 Small 》 (2,4,8,9,11,12,13 ,14,15,17,18,19) 《 Large 》 (6,7)
Wristband/ bandage (4)	《 Long bones 》 (10, 22, 23) 《 Bony prominence 》 (1)	《 Linear 》(10,22,23) 《 Crescent 》(1) <Depth of arc>Shallow (1) <Symmetry of arc> Asymmetry (1) <Direction of arc>Six (1)	《 Without flap 》 (10,22,23) 《 Partial flap absence 》 (1)	《 Around skin contacting medical implements 》 (1,10,22,23)	《 Small 》 (1,10,22,23)

Table 12-2. Morphological classification of skin tear based on **type of external forces**

	Anatomical location	Shape	Skin flap	Purpura	Size
Bumping (5)	《 Long bone 》 (3,6,7) 《 Bony prominence 》 (2,4)	《 Crescent 》 (2,3,4,6,7) <Depth of arc> Shallow (2,3,4,6) U-type (7) <Symmetry of arc> Symmetry (2,6) Asymmetry (3,4,7) <Direction of arc> Twelve (2) Three (4,6) Six (3,7)	《 Skin flap present 》 (3,2) 《 Partial flap absence 》 (4,6,7)	《 Localized 》 (2,3,4,6,7)	《 Small 》 (2,3,4) 《 Large 》 (6,7)
Wiping (1)	《 Bony prominence 》 (5)	《 Crescent 》 (5) <Depth of arc> Shallow (5) <Symmetry of arc> Asymmetry (5) < Direction of arc> Nine (5)	《 Partial flap absence 》 (5)	《 Localized 》 (5)	《 Large 》 (5)
Pulling (2)	《 Long bones 》 (20) 《 Bony prominence 》 (21)	《 Crescent 》 (20,21) <Depth of arc>U-type (20,21) <Symmetry of arc> Symmetry (21) Asymmetry (20) <Direction of arc> Twelve (21) Six (20)	《 Skin flap present 》 (21) 《 Partial flap absence 》 (20)	《 Localized 》 (20,21)	《 Large 》 (20,21)
Fingernail laceration (3)	《 Long bones 》 (9,17) 《 Bony prominence 》 (16)	《 Crescent 》 (9,16,17) <Depth of arc> Shallow (9,16,17) <Symmetry of arc> Symmetry (16) Asymmetry (9,17) <Direction of arc> Three (9,17) Nine (16)	《 Skin flap present 》 (9,16,17)	《 Localized 》 (9,16,17)	《 Small 》 (9,16,17)
Scratching (8)	《 Long bones 》 (8,11,12,13,14,15,18,19)	《 Crescent 》 (8,11,12,13,14,15,18,19) <Depth of arc> Shallow (11,12,14,19) U-type (8,13,15,18) <Symmetry of arc> Symmetry (11,13,15,18,19,) Asymmetry (8,12,14) <Direction of arc> Twelve(8,11,13,14,18) Six (15,19) Nine (12)	《 Skin flap present 》 (11) 《 Partial flap absence 》 (8,12,15,14) 《 Complete flap absence 》 (13,18,19)	《 None 》 (18) 《 Discrete 》 (8,11,12,13,14,15,19)	《 Small 》 (8,11,12,13,14,15,18,19)
Friction (4)	《 Bony prominence 》 (10,22,23) 《 Bony prominence 》 (1)	《 Linear 》(10,22,23) 《 Crescent 》(1) <Depth of arc> Shallow (1) <Symmetry of arc> Asymmetry (1) <Direction of arc>Six (1)	《 Without flap 》 (10,22,23) 《 Partial flap absence 》 (1)	《 Around skin contacting medical implements 》 (1,10,22,23)	《 Small 》 (1,10,22,23)

Table 13. Correspondence table between morphological characteristic and etiology-related external forces of skin tears

Morphological characteristics of skin tears										
Purpura			Shape		Depth of arc		Size			Etiologies-related external forces of skin tears
Localized	Discrete	Skin in contact with medical implements	Linear	Crescent	Shallow	U type	Small	Large	Illustrations combining different characteristics	
○				○	○		○			Laceration by the caregiver's fingernail (2/6) Laceration by the patient's fingernail (1/6) Bumping by caregiver (1/6) Accidental fall by patient (2/6)
○				○	○			○		Wiping with towel by caregiver (1/2) Accidental fall by patient (1/2)
○				○		○				Pulling by caregiver (2/3) Accidental fall by patient (1/3)
	○									Scratching by patients (8/8)
		○	○							Friction of wristband (3/3)
		○		○						Friction of bandage (1/1)

CONCLUSION

In Chapter 1, the author's aim was to identify the skin properties, which could be used as predictor of STs among elderly patients for prevention of STs. The 149 participants were followed for eight months. The predictor most associated with ST was the thickness of dermis layer (cutoff point; 0.8 mm). For the prevention of ST, this cutoff value may contribute in the identification of a high-risk patient for ST at hospital admission. However, there are still many cases of STs despite the activation of preventive measures at this facility. A patient with an existing ST is predisposed to a recurrent ST. Consequently, we suggest that new preventive measures are indispensable for patients at high risk of ST recurrence.

In Chapter 2, in order to develop a correspondence table for estimating etiologies-related external forces causing ST, we suggested the following approach using a qualitative descriptive study: describe the morphological characteristics of STs among elderly patients by sketching photographs of wounds (Study 1), identify the external forces that had caused the STs (Study 2), and identify the morphological characteristics of STs associated with the specific external forces known to have caused them (Study 3). In Study 1, the characteristics, were divided into five categories, fourteen subcategories, and three sub-subcategories as follows: 1) 'anatomical location' with two subcategories, 2) 'shape' with two subcategories and three sub-subcategories, 3) 'skin flap' with four subcategories, 4) 'purpura' with four subcategories, and 5) 'size' with two subcategories. In Study 2, semi-structured interviews were conducted in order to identify the potential external forces that resulted in the development of the STs. In Study 3, a correspondence table that included four characteristics (purpura, shape, depth of arc, and size) was developed for factors that act as a guide to estimate the cause of STs. Then, depending on the kind of external forces, healthcare practitioners can focus their attention on the prevention of ST recurrence.

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APPENDIX

Silver Chain

STAR Skin Tear Classification System

Curtin University of Technology

STAR Skin Tear Classification System Guidelines

1. Control bleeding and clean the wound according to protocol.
2. Realign (if possible) any skin or flap.
3. Assess degree of tissue loss and skin or flap colour using the STAR Classification System.
4. Assess the surrounding skin condition for fragility, swelling, discolouration or bruising.
5. Assess the person, their wound and their healing environment as per protocol.
6. If skin or flap colour is pale, dusky or darkened reassess in 24-48 hours or at the first dressing change.

STAR Classification System

Category 1a
A skin tear where the edges **can** be realigned to the normal anatomical position (without undue stretching) and the skin or flap colour **is not** pale, dusky or darkened.

Category 1b
A skin tear where the edges **can** be realigned to the normal anatomical position (without undue stretching) and the skin or flap colour **is** pale, dusky or darkened.

Category 2a
A skin tear where the edges **cannot** be realigned to the normal anatomical position and the skin or flap colour **is not** pale, dusky or darkened.

Category 2b
A skin tear where the edges **cannot** be realigned to the normal anatomical position and the skin or flap colour **is** pale, dusky or darkened.

Category 3
A skin tear where the skin flap is completely absent.

Skin Tear Audit Research (STAR). Silver Chain Nursing Association and School of Nursing and Midwifery, Curtin University of Technology. Revised 4/2/2010.