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Original Article

Reliability and validity of skin elasticity meter to measure skin mechanical properties in patients with lower extremity cancer-related edema

Yudai Fujimoto, OTR, MS[1, 2]*, Yoshimi Yuri, OTR, PhD[2], Miki Fujii, OTR, MS[1], Yuji Kato, RPT, MS[1], Shota Kinoshita, RPT[1], Yurika Tsujimoto, RPT[1], Reina Kato, RPT[1], Atsuko Nodomi, OTR[1], Emiko Matsumoto, NS[1], Hironari Tamiya, MD, PhD[1]

[1] *Osaka International Cancer Institute: 3-1-69 Otemae, Chuo-ku, Osaka 541-8567, Japan*
[2] *Morinomiya University of Medical Sciences, Japan*

Abstract. [Purpose] This study aimed to clarify the reliability and validity of a skin elasticity meter for evaluating the skin mechanical properties. [Participants and Methods] We conducted a prospective observational study using data from 35 patients diagnosed with unilateral lower extremity edema caused by cancer-related. We evaluated the skin's mechanical properties (relative parameter; R0, distensibility; R2, gross elasticity; R5, net elasticity; R6, viscoelasticity; R7, biological elasticity) of the thigh and lower leg using a skin elasticity meter. Intra-rater reliability was calculated using interclass correlation (ICC). Validity was also examined by comparing the edema and non-edema sides of the data obtained using a skin elasticity meter and correlating them with the circumferential diameter difference. [Results] ICC values ranged from 0.787 to 0.997 for each site. A significant difference in skin mechanical properties (offset + R0, R2, R6, and R7) of the upper extremities was observed between the lymphedema and non-lymphedema groups. A correlation was found between the R0 + offset between the R0 + offset parameter and the difference in circumference. [Conclusion] This study suggested that the skin elasticity meter is a reliable and valid method for evaluating the mechanical properties of the skin in patients with lower extremity cancer-related edema.

Key words: Lower extremity cancer-related edema, Skin elasticity meter, Skin mechanical properties

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INTRODUCTION

Cancer-related edema is a chronic disease that presents as a result of cancer treatments such as surgery, radiation therapy and chemotherapy[1]. A risk of developing edema in various cancer type, including breast cancer, gynecological cancer, prostate cancer, head and neck cancer and melanoma etc. Various studies estimate the incidence to range from 5% to 83%[2–4]. In addition, in particular, patients with severe lower extremity edema have been reported to fear falling, walking slower, and have reduced physical activity and function, which is the role of rehabilitation[5].

In patients with cancer-related edema, changes in the skin mechanical properties, such as fibrosis, are a serious problem. The reason is that changes in skin mechanical properties indicate progression of the edema stage. As a matter of fact, the ISL (International Society of Lymphology)[6] defines the severity of lymphedema in terms of the skin's mechanical properties. However, in clinical practice situations, therapists depend on subjective assessments such as traditional palpation techniques. One reason for this is lack of clear consensus on how to quantitatively and objectively assess skin mechanical properties in patients with cancer-related edema.

*Corresponding author. Yudai Fujimoto (E-mail: y.1025.fujimoto@gmail.com)

The skin elasticity meter (Cutometer®; Courage & Khazaka Electronic GmbH, Cologne, Germany) is a non-invasive suction device developed to perform objective and quantitative measurements of the mechanical properties of the skin[7)]. This device can obtain quantitative data on kin mechanical properties by optically measuring the amount of evaluation as the skin is suctioned and the amount of restoration after the suction is released. In a previous study, inter- and intra-rater reliabilities were demonstrated when measuring skin mechanical properties in healthy individuals[7)]. Although this device is considered a quantitative and objective method for measuring the skin mechanical properties of patients with cancer-related edema, however its reliability and validity in actual patients have not been verified.

Therefore, in this study, we aimed to determine the reliability and validity of measuring skin mechanical properties in patients with lower extremity cancer-related edema using the skin elasticity meter.

PARTICIPANTS AND METHODS

This prospective observational study included 35 patients diagnosed patients with lower extremity cancer-related edema at the Osaka International Cancer Institute between January 2023 and December 2023. The inclusion criteria were unilateral lower extremity edema, cancer-related edema diagnosis, and initiation of edema treatment. The diagnosis of cancer-related lower extremity edema was made by the physician based on (1) history of cancer treatment, (2) physical examination findings, (3) denial of cancer metastasis or recurrence, and (4) exclusion of other edema-causing diseases besides lymphedema. In addition, none of the included patients had any impairments, such as orthopedic or neurosurgical disorders, in either lower extremity. The exclusion criteria were bilateral lower extremity edema and patients who disagreed with the study's purpose and edema treatment. The reason for including only unilateral lower extremity edema in this study was to compare between the edema and non-edema sides. The required sample size for the correlation analysis was calculated to provide a magnitude of the coefficient (p) of 0.8, a correlation coefficient (r) of 0.5, and a power of 80%, with a two-sided alpha level of 0.05. Based on the previous assumptions, at least 30 patients were required to achieve statistically significant and clinically important differences.

Using Cutometer®, a probe with a diameter of 2 mm, Mode 1 setting (vacuum of 450mbar on the skin surface for three seconds, followed by three seconds of normal pressure), six examiners evaluated the skin mechanical properties of thigh and lower legs. According to the measurement sites in the Japanese lymphedema guidelines[8)], (1) thigh: 12 cm proximal to vertical to thigh from the midpoint of the medial and lateral patella bone; and (2) lower leg: the largest part of the lower leg circumference, approximately 3 cm outside the tibial ridge. The parameters of skin elasticity meter are expressed as absolute (Ua, Ue, Uf, and Uv) or relative (R0–R9). In this study, the commonly reported parameters R0 (distensibility), R2 (gross elasticity), R5 (net elasticity), R6 (viscoelasticity), and R7 (biological elasticity)[7)]. Incidentally, R0 was summed with the offset value[9)]. The units of the parameters are mm for offset + R0 (distensibility) and % for R2 (gross elasticity), R5 (net elasticity), R6 (viscoelasticity), and R7 (biological elasticity). In addition, lower values are better only for R6 (viscoelasticity), whereas higher values were better for the other parameters. Measurements were performed three times at each edema and non-edema side sites, and each rater was blinded to the previous measurements to avoid any bias. In short, for the 35 different participants, each of the six independent examiners measured each of the four sites. The measurement environment was set at a room temperature of 23.0 ± 2.0°C and humidity of 50–60%.

Demographic data were presented as the mean ± standard deviation. Intra-rater reliability was evaluated using intraclass correlation coefficients (ICC) with 95% confidence intervals (CI). Intra-rater reliability was determined using the ICC (1,1) method. ICC values were interpreted as follows: <0.50, poor reliability; 0.50–0.75, moderate reliability; 0.75–0.90, good reliability; >0.90, excellent reliability[10)]. Precision was calculated using the standard error of measurement (SEM). Absolute reliability was assessed using Bland–Altman analysis to determine intra-rater reliability. In addition, we calculated a 95% confidence interval for the mean difference between the two measures and determined that a fixed error was present if the resulting interval did not contain zero. We also tested for the presence of a proportional error by calculating the T-value, and the significance level was 5%, indicating the presence of a proportional error. When fixed and/or proportional errors were present, the limit of agreement (LOA) was determined. In addition, when random error was present without systematic error, the minimum detectable change at 95% confidence level (MDC95) was calculated.

The validity was data obtained from the edema and non-edema lower extremities were compared between the two groups using the Wilcoxon signed-rank test. Furthermore, the difference in circumference between the edema and non-edema sides and the numerical difference between the data obtained with the skin elasticity meter were evaluated using Spearman's rank correlation coefficient. Validity is typically assessed by correlation with a gold standard assessment; however, as there is no gold standard for measuring lower extremity cancer-related edema[8)], we examined the validity by comparing measurements of the edema and non-edema sides and correlated them with circumferences commonly used in clinical practice. All statistical analyses were performed using R (version 4.2.3) software, with the level of significance set at 5%.

The present study was carried out in accordance with the principles of the Declaration of Helsinki regarding investigations including humans and was approved by the ethics committees of the Osaka International Cancer Institute (approval number 24048) and Morinomiya University of Medical Science (approval number 2024-031). Each participant received an explanation of the purpose of the study and provided written informed consent before inclusion.

RESULTS

Among the 35 patients who were initially included, no exclusions were made, and the final study included all patients. The patient characteristics are shown in Table 1.

The results of the intra-rater reliability analysis are shown in Table 2. The ICC (1,1) values for the thigh and lower leg measurements ranged from 0.787–0.997 for each parameter, with a higher moderate reliability and 95% CI of 0.663–0.999. The SEM was small in the offset + R0 (distensibility), R2 (gross elasticity), and R7 (biological elasticity) for both the thigh and lower leg and high in R5 (net elasticity) and R6 (viscoelasticity). Based on the results of the Bland–Altman analysis, there were no fixed and proportional errors.

The results of the comparison between edema and non-edema sides for each thigh and lower leg parameter are shown in Table 3. There were significant differences in the offset + R0 (distensibility) and R2 (gross elasticity), R6 (viscoelasticity), and R7 (biological elasticity) parameters for both the thigh and lower leg between edema and non-edema groups. However, R5 parameters did not differ significantly.

The results of the correlation between the difference in the values of the parameters on edema and non-edema sides and the difference in circumference are shown in Table 4. A significant negative correlation was found between the difference in circumferential diameter and offset+R0 (distensibility). However, no significant correlations were observed for other parameters, and these correlations were similar for the thigh and lower leg.

DISCUSSION

In this study, skin mechanical properties were measured in patients with lower extremity cancer-related edema using a skin elasticity measuring device, demonstrating its high reliability. Furthermore, the validity was further examined by comparing the values of skin mechanical properties on the edema and non-edema sides and by correlating them with circumferential diameter differences. Studies on the reliability of skin elasticity meter have been reported to be acceptable in healthy individuals[7)] and several skin disease[11–14)]. However, no previous studies have examined this subject in patients with lower extremity cancer-related edema. Therefore, the usefulness of the clinical application of skin elasticity meter in patients

Table 1. Patient characteristics

Characteristics	Value (%) n=35
Attribute	
Male/Female	9 (25.7)/26 (74.3)
Age, years	65.0 ± 12.0
Body mass index, kg/m^2	22.4 ± 3.6
Diagnostic cancer name	
Gynecologic cancer	18 (51.4)
Bone and soft tissue tumor	6 (17.1)
Urological cancer	6 (17.1)
Skin cancer	2 (5.7)
Other	3 (8.6)
Therapy of cancer (duplication)	
Surgery	32
Chemo therapy	18
Radio therapy	11
ISL stage	
I	0 (0.0)
II early	25 (71.4)
II late	8 (22.9)
III	2 (5.7)
Site of lymphedema affect	
Right	11 (31.4)
Left	24 (68.6)

Descriptive statistics are presented as the number of people (%), and mean ± SD.
ISL: International Society of Lymphology.

Table 2. Intra-rater reliability of measurement of skin mechanical properties using skin elasticity meter (n=35)

		Relative reliability			Absolute reliability							
					Fixed error			Proportional error				MDC_{95}
		ICC (1,1)	95% CI	SEM	95% CI	result	LOA	T value	p	result	LOA	
Thigh	Offset+R0 (mm)	0.997	0.996 to 0.999	0.015	−0.03 to 0.01	No	—	0.24	0.39	No	—	0.03
	R2 (%)	0.837	0.893 to 0.907	5.412	−15.34 to 7.43	No	—	−0.71	0.79	No	—	16.35
	R5 (%)	0.907	0.845 to 0.948	9.341	−23.44 to 11.42	No	—	−1.67	0.44	No	—	25.03
	R6 (%)	0.857	0.767 to 0.919	9.484	−19.10 to 19.13	No	—	0.32	0.71	No	—	27.45
	R7 (%)	0.824	0.718 to 0.900	6.443	−16.19 to 7.48	No	—	−1.55	0.39	No	—	17.00
Lower leg	Offset+R0 (mm)	0.983	0.970 to 0.991	0.055	−0.15 to 0.02	No	—	0.32	0.82	No	—	0.18
	R2 (%)	0.787	0.663 to 0.877	0.708	−14.93 to 16.29	No	—	1.68	0.11	No	—	22.41
	R5 (%)	0.893	0.823 to 0.940	10.408	−19.08 to 24.68	No	—	1.67	0.17	No	—	31.42
	R6 (%)	0.867	0.782 to 0.925	10.841	−19.63 to 23.31	No	—	0.22	0.85	No	—	30.82
	R7 (%)	0.838	0.739 to 0.908	6.005	−12.22 to 14.21	No	—	1.63	0.13	No	—	18.98

ICC: interclass correlation; 95% CI: 95% confidence intervals; SEM: standard error of measurement: LOA: limit of agreement; MDC_{95}: minimum detectable change at 95% confidence level.
Parameter: offset + R0 distensibility; R2: gross elasticity; R5: net elasticity; R6: viscoelasticity; R7: biological elasticity.

Table 3. Comparison of measurements between edema and non-edema side (n=35)

Thigh	Lymphedema	Non-lymphedema	p	r
Offset + R0 (mm)	1.20 ± 0.37	1.21 ± 0.36	<0.01	0.71
R2 (%)	72.81 ± 15.34	78.78 ± 14.43	<0.01	0.59
R5 (%)	84.14 ± 31.78	87.23 ± 35.52	0.45	0.13
R6 (%)	41.87 ± 25.68	38.10 ± 23.16	0.03	0.35
R7 (%)	56.10 ± 16.81	64.20 ± 15.58	<0.01	0.66
Lower leg	Lymphedema	Non-lymphedema	p	r
Offset + R0 (mm)	1.13 ± 0.42	1.15 ± 0.41	0.01	0.40
R2 (%)	67.78 ± 13.97	75.07 ± 11.81	<0.01	0.57
R5 (%)	74.85 ± 30.29	75.33 ± 26.21	0.89	0.02
R6 (%)	44.11 ± 27.98	33.96 ± 24.94	<0.01	0.66
R7 (%)	50.12 ± 13.08	56.45 ± 12.96	<0.01	0.51

Parameter: offset + R0, distensibility: R2, gross elasticity: R5, net elasticity: R6, viscoelasticity: R7, biological elasticity.

Table 4. Correlation between the difference in values of the parameters on the lymphedema and non-lymphedema side and the difference in circumference (n=35)

	Parameter	Correlation	p
Thigh	Offset + R0	−0.39	*
	R2	−0.17	
	R5	−0.13	
	R6	−0.16	
	R7	−0.13	
	Parameter	Correlation	p
Lower leg	Offset + R0	−0.42	*
	R2	−0.19	
	R5	−0.20	
	R6	−0.12	
	R7	−0.18	

*p<0.05.
Parameter: offset + R0, distensibility: R2, gross elasticity: R5, net elasticity: R6, viscoelasticity: R7, biological elasticity.

with lower extremity cancer-related edema has been unclear. The novelty of this study is that we examined the intra-rater reliability and validity of a skin elasticity meter in patients with lower extremity cancer-related edema and demonstrated the cornerstone of its use in future clinical practice and research. In the future, we are confident that the skin elasticity meter can be used to measure skin mechanical properties in patients with cancer-related lower extremity edema to provide quantitative data on skin condition for use in treatment strategies such as drainage, loosening, and selection of elastic garments.

For patients with lower extremity cancer-related edema, measurement of skin mechanical properties using a skin elasticity meter was highly reliable, with ICC values ranging from 0.787–0.997. In particular, offset + R0 (distensibility) was very reliable for both thigh and lower leg. Offset + R0 (distensibility) measures skin distensibility under negative pressure suction at the start of the measurement. These results are generally consistent with previous studies[7, 15, 16]. In other words, they suggest that offset + R0 (distensibility) is the most reliable result for measuring skin mechanical properties in patients with lower extremity cancer-related edema. On the other hand, parameters R2 (gross elasticity), R5 (net elasticity), R6 (viscoelasticity), and R7 (biological elasticity) were somewhat lower than offset + R0 (distensibility). This could be due to the possible influence of the rater's operating skill in holding the probe in place for a certain period, the patient's movement, or edema characteristics, since these parameters are values measured after the offset + R0 (distensibility)[17–20]. However, all parameters showed moderate or better ICC values, and the results of the present study are sufficient to be used in clinical applications.

The validity of the skin mechanical property measurements using a skin elasticity meter was determined based on a comparison of the relative parameters between the edema and non-edema sides and the correlation with the circumferential diameter difference. These methods of analysis were employed in this study because there is no gold standard method for assessing the skin mechanical properties of patients with lower extremity cancer-related edema. As a result, we found for the parameters of offset + R0 (distensibility), R2 (gross elasticity), R6 (viscoelasticity), and R7 (biological elasticity), significant differences in values between the edema and non-edema side. Regarding the characteristics of the parameters, R2 (gross elasticity) reflects delayed recovery after the suction phase, R6 (viscoelasticity) is the ratio of viscoelasticity to elasticity in the suction phase, and R7 (biological elasticity) reflects immediate recovery after the suction phase. These results are consistent with the reduction in skin tightness and viscoelasticity observed in the pathophysiology of cancer-related edema[21]. Hence, these indicate that the differences in skin mechanical properties between the cancer-related edema side and the non-edema side are captured. In contrast, the R5 (net elasticity) parameter revealed no significant difference between the edema and non-edema side. R5 (net elasticity) is characterized by comparing the elastic part of the suction phase versus the immediate recovery during the relaxation phase. Based on these results, it was hypothesized that cancer-related edema is often associated with slow skin return after compression or aspiration, and that the immediate response during the relaxation phase is similar to that of the healthy side.

The correlation with circumferential diameter difference was significantly different only for offset + R0 (distensibility), which is a relative parameter of distensibility and could reflect the increase in circumferential diameter difference and edema. For future clinical application, we suggest that the skin elasticity meter be used to measure skin mechanical properties in patients with lower extremity cancer-related edema, and that the parameter Offset + R0 (distensibility) be used as the basis for the measurement of skin mechanical properties.

This study has several limitations. First, because this was a single-hospital study, the possibility of unintended bias in patient selection could not be completely ruled out. Second, the reliability of this study was only intra-rater; inter-rater reliability could not be considered. However, we previously reported the intra- and inter-rater reliabilities of a skin elasticity meter in healthy individuals[7]. In the current study, only intra-rater reliability was used because we were considering the clinical application of a skin elasticity meter in patients with lower extremity cancer-related edema. Finally, as noted in the text, there is no established gold standard for measuring the extent of lymphedema or mechanical properties of the skin in lower extremity cancer-related edema. Therefore, in this study, we compared the lymphedema and non-lymphedema sides and analyzed the parameter values obtained from the measurements in correlation with the circumferential diameter difference, which is commonly used worldwide in daily clinical practice.

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Conflict of interest

The authors report no conflicts of interest.

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