JWMR

KroniKare Proof of Value (PoV) Report

Objectives

The KroniKare Wound Scanner (KWS) is a digital optoelectronic system for non-contact monitoring of adult chronic wounds by healthcare professionals. It is intended for temporary monitoring of wound dimensions, for wound tissue classification, and screening for potential wound complications. The KWS harnesses the power of custom-designed artificial intelligence (AI) engines to allow ward nurses and wound care specialists to use it to measure wound dimensions in 3 dimensions (3D), assess wound tissue types automatically, and detect wound complications. This study aimed to evaluate the accuracy of KWS in:

- 3D wound dimension measurement: length, width, and depth of the wound, which are key indicators of wound healing progression
- Wound tissue assessment: identification of tissue types on the wound bed, that help discern the condition of the wound and the appropriate treatment procedure
- Wound complication detection: detection of infection and undermining in wounds

Methodology

This was a non-randomized, blinded study performed at Changi General Hospital, St. Andrew's Community Hospital, Kwong Wai Shiu Hospital's nursing home and St. Luke's Hospital's home care over the period of January 2019 to June 2019 when trained clinical staff offered wound care to sampled patients at these sites. All the wounds included this study were assessed by both qualified clinical staff manually and with the KWS where the staff had no knowledge of the KWS outputs at the time of their assessments. Similarly, the KWS assessments did not receive any input on wound assessment outcomes by the clinical staff when performing wound measurements, wound tissue identification and wound complication detection. Prior to the start of the study, all KWS deployed in this study were factory calibrated and the clinical staff involved were trained on how to use the KWS.

During each wound care visit, the clinical staff captured images (visual, 3D laser scanned, and thermal) of the wound(s) using KWS, before performing the following assessments as part of their routine care of the wound patients:

- Wound size measurement with paper ruler and probe
- Wound bed tissue classification as necrosis, slough, granulation and epithelial based on visual inspection
- Check for complications including undermining, infection, and ischemia based on visual inspection and manual temperature inspection of tissues around the wound

Using the images captured by the KWS in this study, the embedded AI algorithm would calculate the estimated wound size, present a list of automatically detected tissue types, and offer an estimation on whether there was a "suspected" risk of infection, ischemia, or undermining complication for every wound image. The wound size measurement, tissue classification and complication assessment (i.e., presence or absence of ischemia) outcomes of the KWS were then compared against the respective outcomes determined by trained clinical staff considered as expert opinions. This comparison was done with the goal of establishing the similarity of the outcomes determined by KWS with those of experts.

Study inclusion criteria included patients admitted to the hospital, clinic, or homecare with chronic wounds. Exclusion criteria included patients with circumferential wounds, cancer wounds, or surgical wounds that were sutured and closed. If the manual assessment data was not recorded, or wound images were not captured by the KWS, the corresponding wounds were also excluded from the study. A P-value of <0.05 was considered statistically significant.

Results

The entire dataset which was compiled in this study comprised of 1,204 distinct wounds from 644 patients, with 4,904 wound reports generated and more than 15,000 images collected. Results of the statistical analysis performed to determine the wound outcome assessments by the KWS and clinical staff were summarized in the following three sections.

3D wound dimension measurement

The values of size measurements derived by the KWS and clinical staff were in real values for length, width and depth of each wound. Paired t-tests were performed based on a set of 615 wounds with dimensions measured by the KWS and clini-

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Table 1. P-values of paired t-tests performed on wound dimensions measured by the KroniKare Wound Scanner and clinical staff

Item	Institution	No. of data points	P-value		
			Length	Width	Depth
1	Changi General Hospital	207	0.670	0.929	0.138
2	St. Andrew's Community Hospital	310	0.994	0.165	0.160
3	Kwong Wai Shiu Hospital	98	0.102	0.105	0.093

Table 2. P-values of McNemar tests performed on wound tissue assessment by KroniKare Wound Scanner and clinical staff

Item	Institution	No. of data points	P-value			
			Necrosis	Slough	Granulation	Epithelizing
1	Changi General Hospital	329	0.230	0.099	0.596	0.181
2	St. Andrew's Community Hospital	983	0.286	0.230	0.755	0.461
3	Kwong Wai Shiu Hospital	321	0.386	0.845	1.000	1.000
4	St. Luke's Hospital	306	0.149	0.267	0.239	4.919E-20

Table 3. P-values of McNemar tests performed on wound complication detection by the KWS and clinical staff

Item	Institution	No. of data points	P-value		
			Infection	Ischemia	Undermining
1	Changi General Hospital	271	0.118	0.121	0.423
2	St. Andrew's Community Hospital	983	0.337	0.061	0.453
3	Kwong Wai Shiu Hospital	1,797	0.868	0.239	0.112
4	St. Luke's Hospital	306	0.0002	0.302	0.181

cal staff. The results (Table 1) showed that there were no significant differences in the measurements of wound length, width, and depth by the KWS and clinical staff.

Wound bed tissue assessment

The values of wound bed tissue classification were binary (1: presence of a particular tissue type, 0: absence of a particular tissue type; tissue type included necrosis, slough, granulation and epithelizing). McNemar test was applied on the wound tissue assessment outcomes from the KWS and clinical staff which were based on the same set of 1,939 wound images. Results demonstrated that classification of epithelizing wounds by the KWS was statistically different from that of clinical staff at St. Luke's Hospital. Nevertheless, the overall results (Table 2) showed there was no significant difference in labelling of tissues by the KWS and clinical staff.

Wound complication detection

The values of complication assessment from the KWS and clinical staff were binary (1: presence of a particular wound complication, 0: absence of wound complication). McNemar test was performed on a set of 3,357 wound images assessed by the KWS and clinical staff. The overall results (Table 3) generally showed there was no significant difference in wound complication detection for infection, ischemia and undermining type wounds by the KWS and clinical staff.

Conclusion

Overall, KWS was able to measure wound dimensions, assess wound bed tissue types and detect wound complications in similar manner as qualified clinical staff. Harnessing these capabilities of the KWS can potentially enable nurses and wound care specialists to manage their wound care load in a more efficient way.