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Introduction

Accurately identifying microbial burden, especially in biofilm-encased organisms, is crucial for managing chronic wound infections and guiding antimicrobial use. Swab sampling, while common, may underestimate the presence of pathogens below the surface of the wound. Tangential biopsy with a nylon fabric curettage brush offers a promising alternative, capturing both surface and subsurface organisms for a comprehensive tissue overview. In this study eight blinded, paired-samples, were assayed at Modus Laboratories in Houston, TX using YouSeq PCR assays.

Methods

A total of eight patient wound samples collected in duplicate were tested using the Wound PCR assay developed at Modus Laboratories. For each patient one sample was collected with a flocked swab (ESwab®, COPAN Diagnostics) and another with a nylon fabric curettage biopsy device (Kylon® fabric, SoftBiopsy® device, Histologics, LLC). Flocked swab collections were obtained using the Levine swab method, and the curettage collection was obtained using the pressurized twisting curettage collection method. Nucleic Acid extraction was performed using the ThermoFisher MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit on the automated ThermoFisher KingFisher™ Flex platform. Extracted DNA was subsequently amplified with YouSeq PCR assays on the ThermoFisher QuantStudio™ 12K Flex real-time PCR System. The Modus Wound PCR assay converts cycles threshold (Ct) values to CFU/mL according to their proprietary validation.

Results

Pathogen concordance was 65%. The biopsy device had slightly higher sensitivity (84%) than the swab (81%). Kylon® produced 30% more nucleic acid, with 71% showing lower cycle thresholds. In 41% of targets, Kylon® changed interpretation from colonization to infection. In 50% of study subjects, biopsy results changed infection classification.

Comparison of Detected Pathogens Between Collection Methods and Measured Ct Values

Samples	PCR Cycle	Kylon®	ESwab®	dCt	Yield %
		(Ct)			
Sample 1	RNaseP	22.52	17.75	4.78	23.73
	S.aureus	24.89	14.49	10.41	52.85
	Paeruginosa	13.38	22.63	-9.25	51.37
	Sul	13.17	21.61	-8.43	48.50
	S. agalactiae	21.333	ND	N/A	N/A
	K. oxytoca	9.091	ND	N/A	N/A
	P.mirabilis	11.46	ND	N/A	N/A
	C.albicans	ND	24.371	N/A	N/A
Sample 2	A.baumannii	ND	11.182	N/A	N/A
	RNaseP	21.41	22.22	-0.81	3.73
	S. aureus	18.38	32.81	-14.44	56.39
	TET	16.43	31.12	-14.70	61.82
	E. cloacae	14.145	ND	N/A	N/A
Sample 3	K.pneumoniae	19.904	ND	N/A	N/A
	P.aeruginosa	ND	12.671	N/A	N/A
	RNaseP	23.34	19.52	3.82	17.83
Sample 4	P.aeruginosa	14.57	20.54	-5.96	33.97
	erm	16.11	10.21	5.90	44.87
	RNaseP	21.97	15.54	6.43	34.28
	S. aureus	27.58	11.08	16.50	85.38
Sample 5	S. agalactiae	20.58	21.41	-0.83	3.95
	P.aeruginosa	ND	16.901	N/A	N/A
	C.albicans	ND	25.225	N/A	N/A
	RNaseP	19.70	18.32	1.38	7.24
	erm	26.46	26.55	-0.09	0.35
Sample 6	E.coli	20.954	ND	N/A	N/A
	S. aureus	22.474	ND	N/A	N/A
	RNaseP	22.71	32.00	-9.30	33.98
	S. aureus	18.20	17.38	0.82	4.61
	P.mirabilis	29.12	33.23	-4.12	13.20
	M.morganii	13.98	9.57	4.41	37.45
	erm	23.57	17.93	5.64	27.18
Sample 7	MecA	20.83	18.10	2.73	14.00
	S. agalactiae	18.226	ND	N/A	N/A
	C.albicans	ND	18.682	N/A	N/A
	RNaseP	15.69	20.04	-4.35	24.33
	S. aureus	22.28	14.75	7.53	40.65
Sample 8	P.mirabilis	20.98	17.18	3.80	19.91
	S.pyogenes	14.66	14.54	0.12	0.79
	MecA	23.40	15.46	7.94	40.88
	RNaseP	16.10	23.07	-6.97	35.59
Sample 8	erm	14.64	14.58	0.07	0.45
	B.fragilis	22.865	ND	N/A	N/A

Detection Summary for Kylon® and ESwab® Devices

Device	Positives Detected	Concordant Positives	Combined Positives	Detection Sensitivity (%)
Kylon®	37	28	43	86
ESwab®	34	28	43	79.1

Kylon® Device and Flocked Swab Comparison



Specimen in Kylon® array for lab transport

Results

Yield and Clinical Interpretation Impact of Kylon® versus ESwab® Devices

Metric	Value
Average ΔCt (Kylon® - ESwab®)	0.11
Average Yield % (all paired targets)	29.26
Proportion of targets with higher yield by Kylon®	42.90%
Targets reclassified from Medium to High CFU/mL	41%
Patients with colonization to infection reclassification	50%

Statistical analysis was performed using categorical methods to compare organism detection between sampling modalities. Detection sensitivity for each device was calculated as the proportion of total combined positive detections identified by that devices (positives detected divided by combined positive across both modalities). The fact that each wound target was evaluated using both sampling techniques meant that differences were assessed using McNemar's test for paired nominal data. The present test evaluates discordant pairs (target detected by one modality but not the other) to determine whether there are statistically significant differences in detection rates between methods. A continuity correction was applied to the modest number of discordant observations. Statistical significance was defined as a two tailed p value <0.05. Given the exploratory nature of this retrospective case series and the limited sample size, statistical analysis was intended to assess trends in paired detection performance rather than to establish definitive superiority of one sampling method over the other.

Conclusions

Both sampling methods detected wound pathogens; however, the nylon curettage biopsy brush demonstrated superior nucleic acid recovery and diagnostic yield. By more accurately measuring microbial burden, this minimally invasive biopsy technique may enhance infection detection and support targeted therapy in chronic wound care.