Clinical comparison between CIRCUL and PSG Alice Oximeter

Zhejiang University, SRR Shaw Hospital Sleep Center ,Hangzhou China

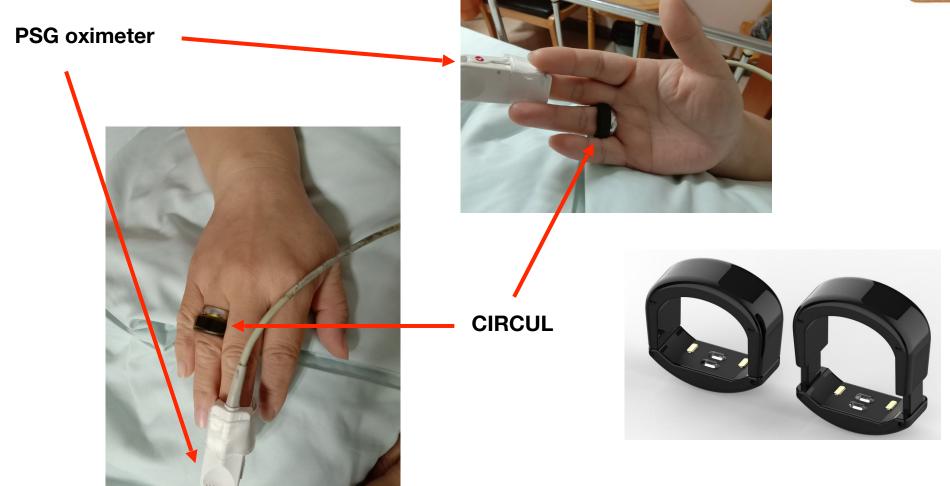


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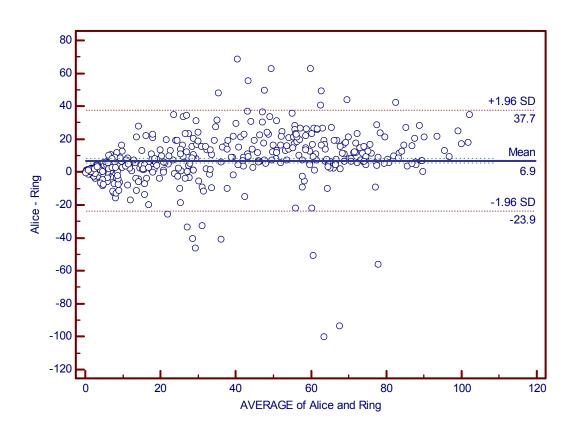
ODI3 SpO2

Sample 1		
Variable	Alice	
Sample 2		
Variable	Ring	

	Sample 1	Sample 2
Sample size	442	442
Arithmetic mean	36.9095	30.0068
95% CI for the mean	33.9867 to 39.8323	27.5084 to 32.5051
Variance	977.5287	714.2433
Standard deviation	31.2655	26.7253
Standard error of the mean	1.4871	1.2712

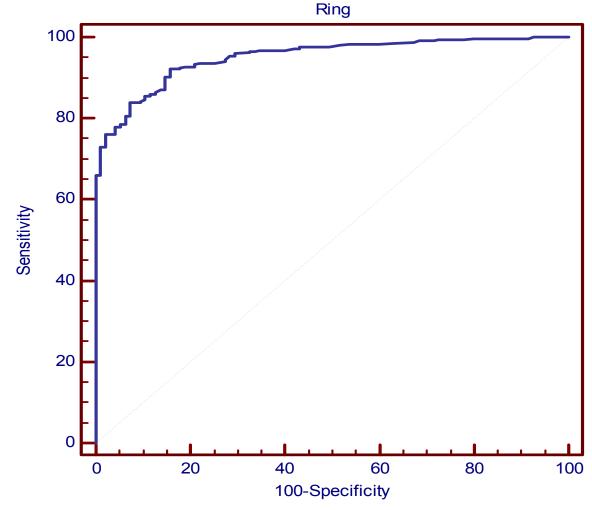
Paired samples t-test

Mean difference	-6.9027
Standard deviation	15.7079
95% CI	-8.3711 to -5.4343
Test statistic t	-9.239
Degrees of Freedom (DF)	441
Two-tailed probability	P < 0.0001



Variable Y	Alice			
Variable X	Ring			
Sample size		442		
Correlation coefficient r		0.8647		
Significance level		P<0.0001		
95% Confidence interval for r		0.8391 to 0.8865		

Variable	Ring				
Classification variable					
Sample size		442			
Positive group :	Mark = 1	347			
Negative group :	Mark = 0	95			
Disease prevalence (%	b)	unknown			
Area under the ROC c	urve (AUC)	0.951			
Standard Error ^a		0.0094			
95% Confidence Interval ^b		0.926 to 0.969			
z statistic		47.773			
Significance level P (Area=0.5)		<0.0001			
^a Hanley & McNeil, 1982					
Binomial exact					

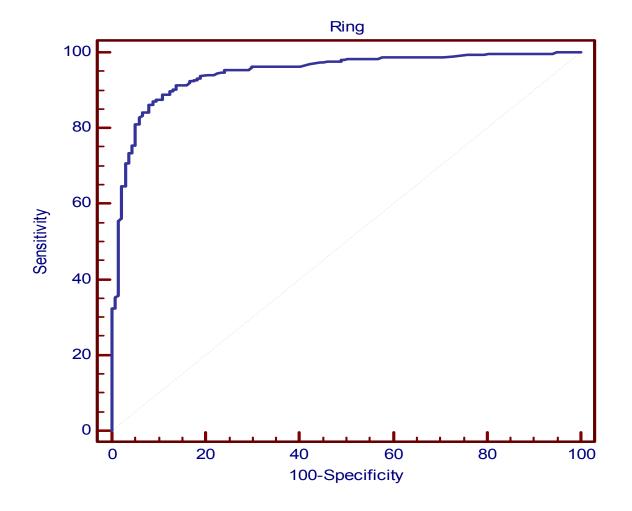


With PSG-ODI>=5 times/h as the positive standard for OSAHS diagnosis, the sensitivity of the Ring was 92% and the specificity was 84%.

The ROC curve method was used to evaluate the diagnostic accuracy of the Ring, and the area under the curve was 0.951 (P<0.001).

Variable	Ring			
Classification variable	Mark			
Sample size		442		
Positive group :	Mark = 1	305		
Negative group :	Mark = 0	137		
Disease prevalence (%)	unknown		
Area under the ROC cu	ırve (AUC)	0.947		
Standard Error ^a		0.0099		
95% Confidence Interval ^b		0.922 to 0.966		
z statistic		44.804		
Significance level P (Area=0.5)		<0.0001		

a Hanley & McNeil, 1982

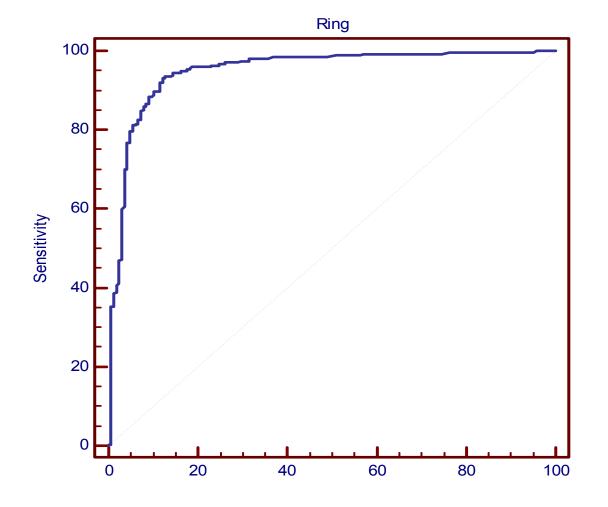


With PSG-ODI>=10 times/h as the positive standard for OSAHS diagnosis, the sensitivity of the Ring was 90% and the specificity was 87%.

The ROC curve method was used to evaluate the diagnostic accuracy of the Ring, and the area under the curve was 0.947 (P<0.001).

b Binomial exact

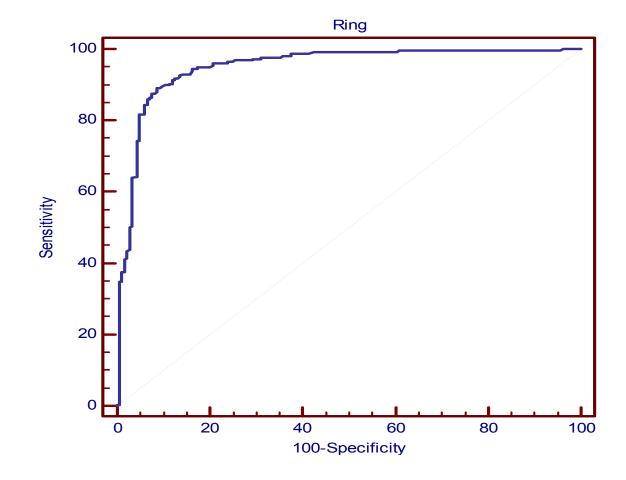
Variable	Ring				
Classification variable	Mark				
Sample size		442			
Positive group :	Mark = 1	277			
Negative group:	Mark = 0	165			
Disease prevalence (%)	unknown			
Area under the ROC cu	ırve (AUC)	0.950			
Standard Error ^a		0.00987			
95% Confidence Interval ^b		0.926 to 0.968			
z statistic		45.599			
Significance level P (Area=0.5)		<0.0001			



With PSG-ODI>=15 times/h as the positive standard for OSAHS diagnosis, the sensitivity of the Ring was 89% and the specificity was 90%.

The ROC curve method was used to evaluate the diagnostic accuracy of the Ring, and the area under the curve was 0.950 (P<0.001).

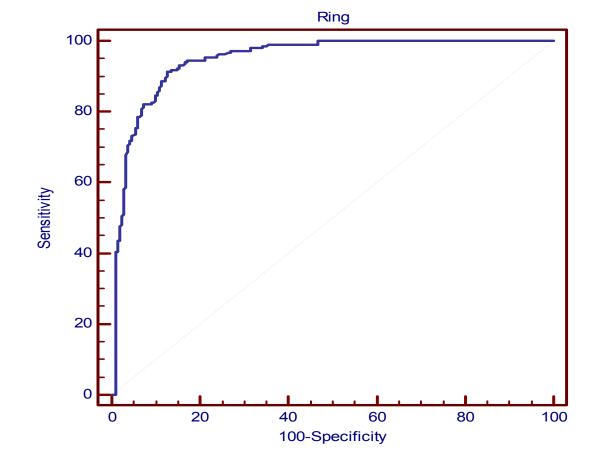
Variable	Ring				
Classification variable	Mark				
Sample size		442			
Positive group :	Mark = 1	258			
Negative group :	Mark = 0	184			
Disease prevalence (%))	unknown			
Area under the ROC cu	urve (AUC)	0.951			
Standard Error ^a		0.0100			
95% Confidence Interval ^b		0.926 to 0.969			
z statistic		44.877			



With PSG-ODI>=20 times/h as the positive standard for OSAHS diagnosis, the sensitivity of the Ring was 85% and the specificity was 94%.

The ROC curve method was used to evaluate the diagnostic accuracy of the Ring, and the area under the curve was 0.951 (P<0.001).

Variable	Ring	
Classification variable	Mark	
Sample size		442
Positive group :	Mark = 1	220
Negative group :	Mark = 0	222
Disease prevalence (%	o)	unknown
Area under the ROC co	urve (AUC)	0.950
Standard Error ^a		0.0108
95% Confidence Interval ^b		0.925 to 0.968
z statistic		41.818
Significance level P (Area=0.5)		



With PSG-ODI>=30 times/h as the positive standard for OSAHS diagnosis, the sensitivity of the Ring was 79% and the specificity was 94%.

The ROC curve method was used to evaluate the diagnostic accuracy of the Ring, and the area under the curve was 0.950(P<0.001).

ODI statistical results

		_	Exact 95% CI			Exact 95% CI		_	
	Prevalence	Sensitivity	LB	UB	Specificity	LB	UB	PPV	NPV
			M	lega versus	PSG				
ODI3, events/h									
≥5	0.79	0.92	0.89	0.95	0.84	0.75	0.91	0.96	0.75
≥10	0.70	0.90	0.86	0.93	0.87	0.80	0.82	0.94	0.79
≥15	0.63	0.89	0.85	0.93	0.90	0.84	0.94	0.94	0.83
≥30	0.50	0.79	0.73	0.84	0.94	0.89	0.96	0.93	0.81