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Reliability of the Prognos Electrodermal Device for Measurements of Electrical Skin Resistance at Acupuncture Points

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ABSTRACT

Objectives: (1) To characterize and calibrate an electrodermal screening device, Prognos. (2) To replicate a previous test—retest reliability study of this device with measurements of electrical skin resistance (ESR) at 24 *Jing-well* acupuncture points (APs). (3) To determine measurement precision in three successively more exacting trial protocols on the same set of subjects.

Settings: Oregon College of Oriental Medicine and Portland State University, Portland, OR.

Instruments: The Prognos device was electrically characterized by a team of research engineers at the Biomedical Signal Processing Laboratory of Portland State University. They determined that Prognos measures the average direct-current (DC) resistance between a metallic wrist strap and an electrode probe tip. The probe tip is connected to a linear spring set to trigger with an optically generated signal at a deflection of 2.62 mm, which corresponds to an average applied force of 2.68 \pm 0.04 N (mean \pm standard deviation [SD], n = 6). They also determined that the device quantifies resistance by applying a 1.1 μ A current for an average of 223 \pm 3 ms (n = 7). When calibrated against a series of known resistors, Prognos measures accurately in the range of 150 k Ω to 14.3 M Ω with an error of less than 0.4%.

Subjects: Thirty-one (31) healthy volunteers, 17 females and 14 males, 23–63 years of age.

Results of reliability test-retest: The mean reliability of a single measurement was; 0.758 for a standard measurement protocol of four sequential sweeps of 24 *Jing-well* (*Ting*) APs; 0.851 for four sequential sweeps after ink-marking the APs; and 0.961 for four rapid repeat measurements at each inked AP. Mean absolute values of ESR decreased between the standard and marked protocols, but not between the marked and rapid repeat protocols.

Conclusions: Prognos performs accurately, against known resistors over the reported range of ESR. The reliability in the standard protocol (r = 0.758) is comparable to the reliability of 0.721 demonstrated under similar conditions by other investigators. Marking APs, and performing measurements in a rapid sequence, increases reliability of ESR measurements. Increased reliability in the second and third protocols is associated with decreased mean ESR values which may be related to increased accuracy of Prognos probe placement and/or inking the APs.

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INTRODUCTION

Littlized by clinicians worldwide (Tiller, 1989; Tsuei et al., 1995) despite the relatively few studies that have evaluated instrument and/or measuring technique reliability (Jessel-Kenyon et al., 1995; Lam et al., 1988; Treugut et al., 1998). This practice is based on an underlying assumption that the electrical resistance/conductivity at APs, although less easily defined than the electrical fields detected with electroencephalograms, electrocardiograms, and electromyograms, is nevertheless measurable and indicative of pathophysiologic changes in related organs.

Electrodermal testing of APs developed as a consequence of 1950s research in France, Japan, and Germany (Nakatani, 1953, 1972; Niboyet, 1951, 1957; Voll, 1975). These three independent investigators found that skin surface sites corresponding to APs have lower electrical resistance/impedance (and consequent higher conductance) than surrounding sites, and that "abnormal" values at APs were indicators of dysfunction in the related meridians and organs. These epidermal bioelectric properties at APs have been observed by numerous subsequent researchers (reviewed in Tiller, 1989; Zhu, 1981; Zhang 2002). Of particular interest are a range of clinical trials in animals and humans that have demonstrated correlations between alterations in electrodermal measurements at specific APs and disease states (Falk et al., 2000; Kawakita et al., 1991; Lam and Tsuei, 1983; Matsumoto and Hayes, 1973; Oleson et al., 1980; Saku et al, 1993; Sullivan et al., 1985; Tsuei et al., 1984, 1989; Zhu et al., 2001).

A cautionary outcome of research in this field is the general agreement that electrical skin resistance (ESR) measurements are vulnerable to three frequently encountered sources of imprecision: (1) instrument error resulting from the size, pressure, and duration of probe application; (2) local skin conditions such as variable thickness, hydration, and intactness of the stratum corneum; and (3) the physiologic and pathologic functional state of the organism. Several researchers even argue that because of the high potential for measurement artifact, a meaningful decrease in resistance at APs has not been adequately proved (Martinsen et al., 2001; McCarroll and Rowley, 1979; Noodergraf and Silage, 1973).

During a search for a means to assess ESR levels at APs as a potential biomarker for clinical trials of acupuncture, we became aware of Prognos, an electrodermal device developed in the USSR's space program as a health maintenance system for their cosmonauts (www.germanmedtec.com/Download/Prognos-dl1/Info.html).

The existence of promising test-retest reliability findings for Prognos also weighed in its favor (Treugut et al., 1998). Our objectives for the present study were to characterize and calibrate a Prognos device in regard to the manufacturer's specifications, to replicate the prior test-retest reliability investigation, and to perform further reliability testing under

sequentially more precise experimental conditions. A preliminary report of our findings has been presented (Colbert et al., 2003).

MATERIALS AND METHODS

Instruments

The Prognos device was reputedly designed specifically to overcome three instrument-related artifacts: probe size and pressure and duration of probe application, by utilizing a small (4.57-mm diameter) flexible, spring-loaded probe tip and by calculating an average ESR value from 400 measurements taken in approximately 200 ms (www.germanmedtec.com/Download/Prognos-dl2/Manual.html).

Prior to use in the clinical test-retest reliability studies our test instrument, a single Prognos device (version 3; software version 2.4), rented from a practitioner in southern Washington State, was characterized and calibrated by a team of research engineers led by one of the authors (J.M.) at the Biomedical Signal Processing Laboratory of Portland State University. The device is essentially an ohmmeter (MedPrevent, Waldershof, Germany) consisting of a power source connected by a cable to the measuring probe and a reference electrode (6 × 3.5 cm) that is attached with a Velcro strap to the volar surface of the forearm. Impedance measurements recorded as direct current (DC) analogue values are taken while holding the probe at a 90° angle to the AP (Fig. 1). The analogue values are fed into an amplifier in the Prognos and transformed into a digital value by an A/D converter. A digital screen on the device displays the measured resistance values in kilo-ohms (k Ω). The data are then imported to a laptop computer via a serial cable.

The probe tip, which has a maximum excursion of 6.91 mm is connected to a linear spring and lies flush in a plastic insulation at the end of a plastic cylinder (Fig. 1). Within the cylinder a light-emitting diode transmits a light beam to

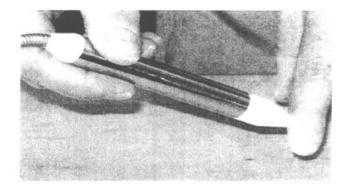


FIG. 1. Prognos measuring Jing well point, left LI 1. A linear spring probe is set to trigger at a deflection of 2.62 mm corresponding to an average force of 2.68 N.

a photodetector. The spring loaded probe disrupts the light beam and triggers a reading at an average tip deflection of 2.90 mm with an average force of 2.68 ± 0.05 N (n = 6). When triggered, the Prognos applies 1.1 μ A current from the forearm strap to the probe tip for an average of 223 \pm 3 ms (n = 7).

Device calibration focused mainly on the accuracy and repeatability of measurements over a broad range of known resistors. The resistance reported by Prognos was compared with that measured by a standard Fluke 87 multimeter over 50 different resistors ranging from 150 k Ω to 14 M Ω . The repeatability of measurements was also assessed by measuring the same resistance four separate times for n=25 different resistances. The single Prognos device tested in this study measured resistance accurately over the range 150 k Ω to 14.3 M Ω , although it appears to have a slightly positive bias for large impedances (Fig. 2).

Participants for clinical reliability testing

The research protocol was approved by the Institutional Review Board of the Oregon College of Oriental Medicine (OCOM) and by the Data Safety Monitoring Board of the Oregon Center for Complementary and Alternative Medicine, Kaiser Permanente Center for Health Research. Participants were recruited from the student body and faculty of OCOM. Potential participants were assured that their decision to participate or not would have no influence on their relationship with the college.

Written informed consent was obtained from all participants. Inclusion criteria were: 18 years of age or older, good general health, and the ability to rest calmly during measurements. Exclusion criteria were: any chronic or acute health problem, or visually observable skin irregularities

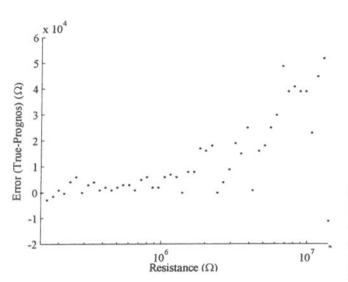


FIG. 2. Plot of the error (Fluke resistance minus the Prognos resistance) versus the "true" resistance reported by the Fluke meter.

such as cracking, lacerations, bruises, dermatologic conditions, or excessive dryness at or near the finger or toe nailbeds. Thirty-three (33) individuals met the entry criteria, 31 of whom completed the study protocol; 2 did not come on the scheduled day of testing. Participants were instructed not to eat for 2 hours prior to scheduled testing.

Procedures

All measurements took place at OCOM on February 8, 9, and 10, 2003 between 9 AM and 7 PM. Testing was not limited to certain times of the day because reliability of ESR measurements rather than absolute values was the focus of the study. Ambient temperature during testing ranged from 61°F to 72°F.

The experimenter (A.P.C.) who took all measurements, was trained in the use of the Prognos over a 2-day observation and practice session with a clinician who had been using the device for 1 year. The computer screen on which data was recorded was positioned out of the line of sight of the experimenter. A research assistant, not involved in data analysis, monitored the data input. The Prognos device was connected to a PC (Dell Inspiron 3800 laptop, Dell Inc., Round Rock, TX; Windows 98 Operating System) through a serial port; data was acquired using Medprevent's Prognos software (version 2.4). The data were saved in a software-specific format and then manually entered into Microsoft Excel for subsequent analysis. (At the time of the study the software necessary for transferring data electronically from Prognos to Microsoft Excel was not available to us.)

Participants were asked to lie quietly on an examining table for 10 minutes prior to testing. They were told that the research involved reliability testing of a device only, that measurements were not being taken for diagnostic or therapeutic purposes and that they would not be informed of their individual results. Skin preparation included cleansing the skin at the nailbeds corresponding to all Jing-well APs with a 70% ethyl alcohol swab. The 24 Jing-well acupuncture points (also called *Ting* points), located at the corners of the nailbeds on the fingers and toes, are important in acupuncture practice because they represent either the beginning or end of each of the 12 paired meridians and are used clinically to treat a variety of acute conditions. The reference electrode was secured with a Velcro strap to the right forearm 3 inches above the wrist. All measurements were taken with the participant supine on the examining tables, positioned such that they were unable to observe the recordings being made. Electrical skin resistance at all 24 Jingwell APs was recorded during three trial protocols performed consecutively on each subject. The three test protocols described below were intended to reflect: standard clinical practice (trial 1); clinical practice with the advantage of consistency of probe placement by ink-marking the APs (trial 2); and increased measuring precision with 4 rapid repeat recordings (trial 3). The series of 3 successive trials (4

recordings at each of 24 APs per trial), took between 15–20 minutes per subject.

Trial 1. The Prognos probe tip was applied sequentially to each Jing-well AP, proceeding from right hand to right foot to left foot to left hand. No conductive lubricant was used. The APs on each side were measured in the order LU 11, LI 1, MH 9, TH 1, HT 9, SI 1, SP 1, LR 1, ST 45, GB 44, KD 1, BL 67. Acupuncture point KD 1 was recorded at the medial corner of the nailbed of the small toe.

Trial 2. At the conclusion of Trial 1 on each subject, the 24 APs were marked by the experimenter with nontoxic, washable ink. The ink was allowed to dry for 1 minute and measurements were taken in the same fashion as described in Trial 1 at the marked APs.

Trial 3. At the conclusion of Trial 2, a third set of mea-

surements was taken by recording four ESR readings in rapid succession at each *Jing-well* AP before moving on to the next point. The order of points being measured was the same as in the first and second trials.

Statistical methods

Two hundred and eighty-eight (288) measurements from each of the 31 subjects were subjected to statistical analysis. The between- and within-components of variance were computed across participants at each point separately, using a standard method (Winer, 1962). The reliability of a single measurement was estimated as the ratio of the between person variance to the total variance. To assess whether there were systematic differences in the level of measurements between the three different trial protocols, paired *t* tests were applied to the individual mean resistances, separately at each point.

Table 1. Reliability and Comparisons of Mean Resistances at Twenty-Four Jing-Well Acupuncture Points in Three Consecutive Measurement Trial Protocols

Point		Standard trial (1)			Marked trial (2)			Rapid repeat trial (3)			P-values ^a		
	Side	Mean	SD^{b}	Rel	Mean	SD^{b}	Rel	Mean	SD^{b}	Rel ^c	1 vs. 2	2 vs. 3	1 vs. 3
LU	L	5610	1638	0.717	3719	892	0.750	3891	289	0.968	0.0000	0.2585	0.0000
	R	5830	1655	0.685	4060	560	0.933	4246	393	0.966	0.0001	0.2264	0.0000
LI	L	5631	1240	0.801	4101	566	0.920	4185	231	0.987	0.0000	0.4529	0.0003
	R	6510	1769	0.695	5365	1041	0.834	5212	522	0.961	0.0038	0.3809	0.0036
ST	L	4088	877	0.865	3342	427	0.929	3504	293	0.971	0.0024	0.1915	0.0369
	R	4053	919	0.837	3250	576	0.878	3715	263	0.981	0.0004	0.0018	0.2410
SP	L	3763	1112	0.739	2927	729	0.764	3457	290	0.971	0.0019	0.0058	0.3837
	R	4305	910	0.821	3145	833	0.734	3567	349	0.956	0.0000	0.0010	0.0017
HT	L	5012	1161	0.845	3888	995	0.786	3894	345	0.943	0.0001	0.9712	0.0014
	R	6382	2051	0.538	5404	413	0.690	5070	734	0.891	0.0196	0.1524	0.0013
SI	L	5306	1503	0.727	3917	814	0.823	3983	455	0.936	0.0000	0.7070	0.0026
	R	5164	1354	0.681	3937	887	0.796	3698	234	0.934	0.0001	0.0743	0.0000
BL	L	3786	848	0.870	3078	335	0.955	3322	318	0.967	0.0085	0.0458	0.1654
	R	4620	1124	0.835	3194	364	0.963	3548	424	0.950	0.0001	0.0253	0.0125
KD	L	3553	891	0.756	3241	444	0.925	3348	447	0.914	0.1412	0.3171	0.3521
	R	3817	905	0.728	3461	819	0.850	3702	325	0.981	0.2311	0.0624	0.7492
MH	L	6173	1552	0.774	4309	825	0.842	4241	338	0.969	0.0000	0.6109	0.0000
	R	7122	1803	0.669	6080	1257	0.784	5867	381	0.979	0.0146	0.3508	0.0037
TH	L	6012	1583	0.725	4704	1027	0.776	4414	385	0.965	0.0002	0.2668	0.0001
	R	6206	1675	0.733	4177	733	0.875	4197	444	0.950	0.0000	0.8771	0.0000
GB	L	4011	783	0.882	3248	466	0.931	3415	283	0.977	0.0012	0.0603	0.0246
	R	3939	1149	9.716	3342	452	0.930	3594	248	0.983	0.0176	0.0176	0.2503
LR	L	3679	988	0.753	2888	519	0.857	2910	246	0.962	0.0003	0.8548	0.0059
	R	3606	916	0.789	2868	477	0.874	3459	346	0.958	0.0000	0.0081	0.4742
Mean Reliability 0.7			0.758			0.850			0.959			anus 15	

^aPaired-sample t tests of mean resistance.

bWithin-person standard deviation.

[°]Correlation coefficient for test-retest reliability.

⁽L, left; R, right; Mean, mean resistance ($k\Omega$); SD, standard deviation; Rel, reliability of a single measurement; LU, Lung; LI, Large Intestine; ST, Stomach; SP, Spleen; HT, Heart; SI, Small Intestine; BL, Bladder; KD, Kidney; MH, Master Heart (Pericardium); TH, Triple Heater; GB, Gall Bladder, LR, Liver).

RESULTS

Clinical test-retest measurements of twenty-four Jing-well APs

The 31 healthy participants on whom ESR was measured at the 24 *Jing-well* points were 17 females and 14 males, 24 to 63 years of age (mean, 32.7 years). All completed the three trials. Mean values of ESR (in $k\Omega$) and reliability for individual APs from all three trials are presented in Table 1.

The mean reliability for Trial 1 (standard clinical protocol) was 0.758, with a range of 0.538 (right HT 9) to 0.882 (left GB 44). When the APs were marked with nontoxic washable ink and remeasured in Trial 2, the mean reliability of a single measurement increased to 0.850; range, 0.690 (right HT 9) to 0.963 (right BL 67). The highest mean reliability of 0.959; range, 0.891 (right HT 9) to 0.987 (left LI 1) was obtained in Trial 3, when four measurements at each marked point were made in rapid succession.

In general, higher reliability correlated with lower mean ESR. This trend is exemplified in Trial 1 by *Jing-well* acupuncture point left GB 44, which had the highest mean reliability and lowest ESR readings (Fig. 3) and *Jing-well* point right HT 9, which had the lowest mean reliability and highest ESR recordings (Fig. 4). In both cases, the inverse relation of ESR value and reliability was seen across subjects.

Mean ESR measurements in Trial 2, where the APs were marked for consistency of probe placement on repeat measurements, were significantly lower than in Trial 1 (unmarked points) at all but 2 APs. Means in Trial 2 were approximately 1 (within-person) standard deviation lower than in Trial 1. No further significant decrease in mean ESR was observed between Trials 2 and 3.

Among right-side measurements, there were significant differences in reliability between the *yang* and *yin* organs in both Trials 1 and 2. In both cases, the *yang* organ measurements were more reliable than the yin organ measurements (trial 1, p = 0.0014; trial 2, p = 0.0389). A comparison of the reliabilities of overall mean left side versus right side

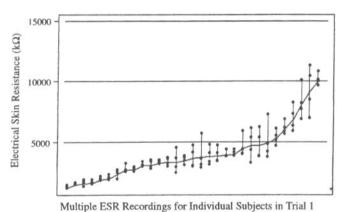


FIG. 3. Four consecutive within-person measurements at acupuncture point left GB 44 on each of 31 participants plotted against mean resistance; example of a highly reliable measurement.

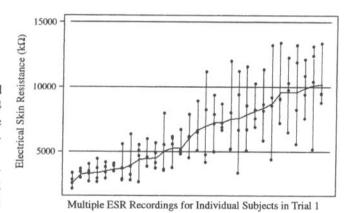


FIG. 4. Four consecutive within-person measurements at acupuncture point right HT 9 on each of 31 participants plotted against mean resistance; example of a less-reliable measurement.

measurements showed greater reliability at four of the left side points: LI, ST, HT and SI.

DISCUSSION

Characterization and calibration of a commercially available Prognos by a team of research engineers demonstrated that the device performs accurately and records repeatable measurements of known resistances. The linear spring design feature of the device improves measurement reproducibility by minimizing fluctuations in the probe's contact surface area and diminishing pressure artifacts that often confound ESR studies.

Our Trial 1 test-retest protocol, a simulation of standard clinical measuring procedure, produced comparable reliability results (0.758 versus 0.721) to those reported by Treugut et al. (1998). Marking the APs with ink for consistency of probe placement was found to give greater precision (r = 0.850 in Trial 2) than when applying the probe tip to unmarked APs (Trial 1). Furthermore, when the measurement technique was made even more precise, by performing four measurements at each marked Jing-well AP in rapid succession, the reliability of Prognos measurements again increased (0.959 in Trial 3). Within each test protocol, there was variation in both the means and the withinperson standard deviations of the ESR measurements, indicating the possibility of important variations between the different APs. Interest in the present study, however, centered on systematic differences in overall means between the three trial protocols.

The improved reliability in Trials 2 and 3 coincided with lower absolute values of mean resistance than were recorded in Trial 1. Measurements in these two trials were made on inked APs. It is possible that the markedly lower resistance measured under the Trial 2 protocol compared to Trial 1 might be related to the ink used for marking the points, despite the fact that the ink was allowed to dry prior to taking

measurements. Previous researchers found no apparent influence on subsequent ESR measurements after inking APs (Falk et al., 2000; Margolin et al., 1996). The lower ESR values that might have resulted from inking have no implications for reliability studies in which the marked AP protocol is used for all measurements, if comparisons are always made on the basis of recordings taken under the same conditions. A calibration issue, however, would arise if attempts were made to compare the absolute values of mean ESR in an unmarked protocol to the same values obtained in a marked protocol. It is worth pointing out that even Trial 1 measurements in which the APs were not inked are, by the general standard in medicine, very reliable. For example, a reliability of 0.75 exceeds the reliability of a research level repeat blood pressure measurement (average of two readings using a random zero sphygmomanometer), which lies in the 0.60-0.70 range (where within-person variability is over days in the same week based on data from the DASH study (Appel et al., 1997)

Our subanalyses differ somewhat from those of Treugut et al. (1998) who found measurements in the yin organs to be significantly more reliable than those in the yang organs and no difference between right and left sided recordings. In the present study, the yang organ measurements in Trials 1 and 2 were more reliable than the yin organ measurements. Also, greater reliability was observed for Prognos readings of the left LI, ST, SI, and HT than corresponding APs on the right. These differences between the two studies with similarly low sample sizes should be considered inconclusive and need to be further explored with substantially larger samples. Dissimilarities between left/right, upper body/lower body, and yin/yang meridians are described as having considerable diagnostic relevance (Medprevent Instruction Manual, 2000; Tsuei, 1996; Motoyama, 1997) and will be investigated in future trials.

Four major electrodermal screening procedures and instruments are in common clinical use: the Neurometer or Electro Meridian Imaging utilizing the Ryodoraku method (Amaro, 2002), the Apparatus for measuring the condition of the Meridians and their corresponding Internal organs (AMI; Motoyama, 1997), electroacupuncture according to Voll (EAV) devices using Voll's techniques (Lam, 1998) and Prognos (Treugut et al., 1998). The Ryodoraku method and Motoyama's AMI device test 28 Jing-well APs, including measurements on the lateral corner of the middle fingers and the medial corners of the middle toes not assessed with the Prognos protocol. The EAV system on the other hand utilizes a completely different set of points representing none of the classical APs (Voll, 1978). We chose to evaluate the Prognos device and system of measurement because it was the system on which at least one rigorous test-retest reliability experiment had already been performed (Treugut et al., 1998). In addition, Prognos appeared to be the most user-friendly commercially available device. Other electrodermal systems in current usage engage complex measuring techniques, requiring extensive training and

skilled interpretation of the results, and are considered to have relatively poor inter-rater reliability (Tsuei et al., 1988).

If ESR readings at APs are to be established as standard medical biomarkers, a fundamental research question to be answered is whether the instrument is accurate and reliable. The Prognos device has passed this first test. The next phase of our research will investigate physiological variability of ESR measurements at APs over time. In the present study, we sought to minimize this variability as much as possible by limiting our exploration to the three trial protocols over a 15–20 minute period in each individual.

Other larger questions to be answered are: What underlying physiologic phenomena do ESR measurements at APs actually delineate? Do they parallel galvanic skin response recordings? Are they correlates of heart rate variability measurements reflecting the state of the autonomic nervous system? Do ESR measurements at APs consistently represent pathophysiologic changes in related internal organs as demonstrated by several researchers (Bergsmann and Wooley-Hart, 1973; Matsumoto and Hayes, 1973; Motoyama, 1997, 1999; Oleson 1980; Rosenblatt, 1982; Saku, 1993; Tsuei et al., 1996; Zhu et al., 2001)? Clearly, the goal of establishing sensitivity and specificity of ESR testing at APs will be a substantial undertaking. Acknowledging the challenge, we nonetheless agree with Tiller (1989) who proposed that electrodermal diagnosis holds promise as a rapid, inexpensive, and potentially accurate diagnostic method for detecting incipient illness. The present replication of the test-retest reliability of Prognos (Treugut et al., 1998) is a first step in standardizing the research methodology needed to evaluate whether electrical measurements at acupuncture points can be developed into reliable biomarkers for early detection of disease.

CONCLUSION

A Prognos resistance detector was characterized and calibrated for accuracy and reliability. It was shown to perform in accordance with the manufacturer's specifications and when tested on 31 individuals over a 15–20 minute time span, was found to reliably measure ESR at *Jing-well* APs. We conclude that electrical resistance measurements at the 24 *Jing-well* APs, when measured with the Prognos, can be regarded as sufficiently reliable in a biomedical research setting. The Prognos appears to be the only electrodermal device for measuring acupuncture points that has been tested for reproducibility by two separate teams of researchers and proven to be reliable in both settings. This study has established the necessary foundation on which further investigations of ESR at APs can be built.

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