Evaluation of the SPIT Booklet for At-Home Salivary Hormone Collection

BIOS 6624 - Project 0
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Research Questions & Statistical Hypotheses

Q1: Agreement

Do Booklet times agree with MEMs times? Is there systematic bias?

H_0: No systematic bias; H_1: Bias exists

Q2: Adherence

Do subjects adhere to protocol timing windows (+30 min, +600 min)?

Descriptive: % within ±7.5 and ±15 min

Q3: Diurnal Hormone Patterns

Do cortisol and DHEA exhibit expected patterns: initial rise (0–30 min) then gradual decline?

H_0: (a) No change waking→30 min; (b) No decline after 30 min | H_1: Significant changes exist

Significance level: α = 0.05 for all hypothesis tests

Analysis Methods

Q1: Agreement Analysis

Linear mixed effects model: Booklet time ~ MEMs time + (1|Subject)

Perfect agreement: slope = 1, intercept = 0 • Systematic bias assessed via intercept

Q2: Adherence Assessment

Deviation from target times calculated using MEMs time since waking

Reported: % within ±7.5 min and ±15 min windows with 95% confidence intervals

Q3: Diurnal Hormone Patterns

Piecewise linear mixed effects model with knot at 30 minutes

Model: log(Hormone) ~ Time1 + Time2 + (1|SubjectID)

Time1 = min(Time, 30) — awakening response slope

Time2 = max(Time − 30, 0) — post-30 min decline slope

Data Overview

Study Design

- 31 healthy subjects
- 4 samples/day × 3 days = 372 observations
- Samples: waking, +30 min, before lunch, +600 min
- SPIT booklet stored in MEMs bottle cap

Descriptive Statistics

Variable	Mean (SD)
Cortisol	5.95 (6.95) nmol/L
DHEA	0.98 (1.03) nmol/L

Missing Data & Exclusions

Variable	Missing	Exclusions (Q3)
MEMs clock time	61 (16.4%)	—
Booklet clock time	35 (9.4%)	—
Cortisol	5 (1.3%)	1 (>80 nmol/L lab error)
DHEA	5 (1.3%)	6 (detection limit); 1 subject excluded

Results

Q1: Agreement (n = 285)

Slope = 0.995 (95% CI: 0.981–1.009)
CI contains 1
→ **No proportional bias**
Intercept = −6.5 min (95% CI: −12.2, −0.8)
p = 0.026
→ **Subjects recorded ~6.5 min earlier than MEMs**

Q2: Adherence

Sample	±7.5 min	±15 min
+30 min	75.9%	87.4%
+600 min	45.0%	55.0%

Good adherence for +30 min; poorer for +600 min

Q3: Diurnal Patterns (Log-transformed hormones)

Hormone	0–30 min slope	p-value	Post-30 min slope	p-value
Cortisol	+0.6%/min	0.241	−0.22%/min	<0.001
DHEA	−2.5%/min	<0.001	−0.15%/min	<0.001

Key Findings: Cortisol showed no significant awakening response but significant post-30 min decline. DHEA showed continuous decline (not expected rise-then-fall pattern).

Discussion & Limitations

Conclusions

Q1: Agreement

Strong agreement between methods; small ~6.5 min systematic bias is modest relative to sampling range

Q2: Adherence

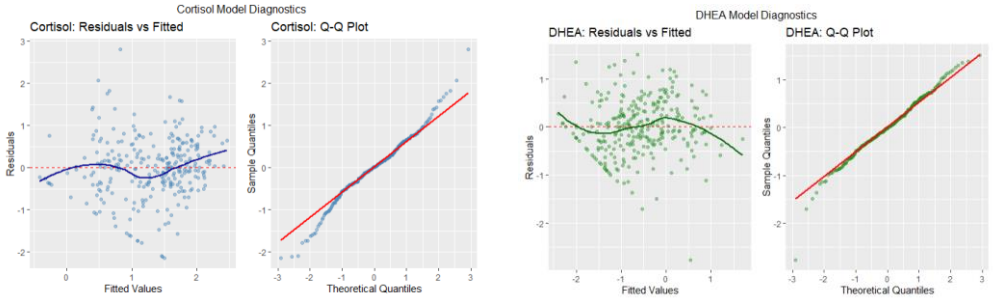
Good for +30 min (87%); poorer for +600 min (55%)—later samples more challenging at home

Q3: Patterns

SPIT captured cortisol decline but not awakening response; DHEA showed continuous decline

Limitations

- Diagnostic plots showed residual curvature—piecewise linear model may not fully capture complexity
- Fixed knot at 30 min may not capture individual variation in awakening response timing
- Q-Q plot for DHEA showed deviation from normality in lower tail
- Subject exclusions and detection limit handling may affect generalizability



SPIT device shows promise for at-home collection. Consider reminder systems for later samples. Point estimates provided for comparison with standard methods.