Instrumentation of a Tablet Breaking-Strength Tester

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Abstract □ The instrumentation of a tablet breaking-strength tester, for the automatic recording of hardness values, is described. A comparison is made between a computerized hardness tester and another identical model hardness tester from the same manufacturer ("standard"). Three lots of placebo tablets at different hardness values were compared. No significant difference was observed between the computerized unit compared with the "standard" unit.

Keyphrases □ Tablet-hardness tester—computerized *versus* unaltered models □ Breaking strength—tablets, computerized *versus* unaltered hardness values

The measurement and recording of tablet-hardness values is an important and necessary measurement during the processing of tablets. This project was initiated with the purpose of automating the measurement process in order to allow more measurements to be taken in a given period of time, to eliminate the chances of operator error and bias, and to incorporate the data automatically in a data base for long term storage and statistical treatment.

EXPERIMENTAL SECTION

The hardness tester[1] (Fig. 1), consists of the following: a rotary shaft encoder[2], a tablet-break signal, filters and a gate, and a microcomputer[3]. A table of values was programmed into the computer relating input counts to hardness values. The test button on the hardness tester was pushed to start the hardness measurement cycle. This opened a gate which allowed pulses from the rotary shaft encoder attached to the counterweight shaft, to enter the microcomputer. When the tablet broke, the signal generated by the hardness tester was to turn off the shaft encoder gate. The hardness value of the tablet was then locally displayed and sent to a terminal or computer.

Placebo tablet hardness values obtained over the working range of the instrument were: 5 kiloponds (kp) for round tablets, 10 kp for oval tablets, and 15 kp for capsule-shaped tablets. These tablets were used to validate the computerized tablet-hardness tester. Prior to these tests, each hardness tester had been modified and calibrated according to procedures previously described (1).

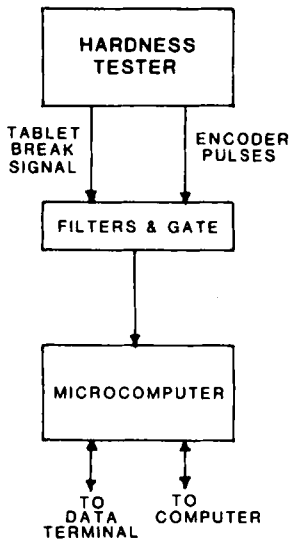

Figure 1—*Computerized hardness-tester block diagram.*

Twenty-five tablets of each hardness value were tested on both the computerized tablet-hardness tester and another identical model tablet-hardness tester, from the same manufacturer ("standard"). The scale reading and digital reading were taken from the computerized instrument after each of the 25 tablets were tested. Also, the scale reading was recorded from the "standard" tablet-hardness tester after another 25 tablets were tested. Tablets

Table I—Tablet-Hardness Values, 5 kp

"Standard" Tester	Computerized Tester	
C1	C2	C3
5.40	5.20	5.10
5.20	6.60	6.36
5.50	5.20	5.38
5.30	5.50	5.60
5.80	5.45	5.47
5.60	6.05	6.10
5.80	5.65	5.38
5.20	5.50	5.75
5.60	5.30	5.38
5.60	5.30	5.38
5.60	5.85	5.99
5.70	5.80	6.10
5.60	5.20	5.38
5.50	5.90	6.10
5.70	4.90	5.00
5.60	6.05	5.99
5.70	5.50	5.75
5.60	5.30	5.47
5.70	5.40	5.38
5.40	5.50	5.60
5.40	5.30	5.47
5.40	5.00	5.10
5.00	5.35	5.47
5.80	5.40	5.47
5.40	5.50	5.85

Table II—Tablet-Hardness Values, 10 kp

"Standard" Tester	Computerized Tester	
C1	C2	C3
10.40	10.00	10.31
10.80	9.80	9.90
9.50	9.80	10.05
10.10	10.60	10.70
9.20	9.40	9.52
9.00	9.40	9.52
10.00	9.20	9.23
9.50	10.60	10.70
9.20	10.20	10.05
9.70	10.00	10.20
10.00	10.20	10.42
9.60	9.40	9.39
10.20	9.05	9.00
9.20	10.40	10.55
10.40	9.00	9.23
10.00	8.90	8.90
9.70	10.20	10.42
9.80	9.80	9.90
9.80	9.60	9.77
9.90	9.30	9.39
9.90	8.80	8.90
10.10	8.90	8.90
10.30	9.40	9.39
9.80	9.85	9.90
10.40	10.40	10.42

[1] Model 2E; Dr. K. Schleuniger & Co., Zurich, Switzerland.
[2] Model ME20-1000; Elm Systems, Wauconda, Ill.
[3] Model 8085; Intel, Santa Clara, Calif.

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Table III—Tablet-Hardness Values, 15 kp

"Standard" Tester	Computerized Tester	
C1	C2	C3
14.90	14.55	14.38
15.70	14.70	14.61
14.80	15.40	15.60
14.90	15.50	15.42
15.60	14.20	14.38
17.50	16.00	15.90
15.80	15.10	15.32
16.00	15.50	15.72
15.10	14.20	14.21
15.00	14.10	14.21
14.10	16.50	16.70
14.20	15.95	15.90
15.30	14.70	14.95
16.00	14.50	14.38
14.20	13.30	13.25
15.20	15.50	15.60
16.60	14.50	14.50
14.50	15.20	15.18
16.40	14.45	14.50
13.50	14.85	15.04
15.30	14.05	14.21
15.40	14.20	14.38
15.40	15.75	15.72
15.30	14.90	14.76
15.10	15.80	16.00

tested on both tablet-hardness instruments, for each hardness group, were from the same lot of tablets. One operator ran the tablets on the computerized tablet-hardness tester and recorded the scale readings; the digital results were recorded on a digital printer. Tablets for the "standard" unit were tested, and scale readings were recorded by a second operator.

RESULTS AND DISCUSSION

Tables I, II, and III show the results of the approximate 5, 10, and 15 kp placebo tablets tested on both the computerized and the "standard" tablet-hardness testers. Column C1 contains the analog data from the "standard" tester, while columns C2 and C3 contain data from the computerized unit. Column C2 data are the analog readings and column C3 data are the readings from the printer. The data were analyzed by the AOVONEWAY, program for the one-way analysis of variance. To compare the means of these populations, a random sample with a normal and independent distribution and equal variance was assumed for each population. The analyses of data from Tables I, II, and III, by the MINITAB B program (2) are listed in the *Appendix*.

Therefore, we questioned whether all of the populations had the same mean. To answer this question, a null hypothesis, that the variation between the tablet-hardness testers is not greater than the variation due to random error, was established.

The F ratio is a useful statistic when determining whether the variation between the computerized tablet-hardness tester and the "standard" tablet-hardness tester is greater than the variation due to random error (3). The corresponding value from an F table for all sets of data for the F ratio to be checked against is 3.1. The F ratios were 0.74, 0.66, and 1.25 for placebo tablets of 5, 10, and 15 kp, respectively. Since all of the F ratio values are <3.1, we accept the null hypothesis and conclude that there is no significant difference between the tablet-hardness testers.

APPENDIX

AOVONEWAY Analysis of 5 kp Data:

		All Data	C1	C2	C3
	−	1		1	
6.4	+	1			1
	−				
	−	5		2	3
	−	5		2	3
	−	9	6	1	2
5.60	+	10	7	1	2
	−	26	7	8	11
	−	6	1	5	
	−	8	3	3	2
	−	4	1	2	1

Analysis and Variance

Due to	DF	SS	MS = SS/DF	F-Ratio
Factor	2	0.150	0.075	0.74
Error	72	7.337	0.102	
Total	74	7.487		
Level	N	Mean	SD	
C1	25	5.504	0.211	
C2	25	5.508	0.370	
C3	25	5.601	0.352	

Pooled SD = 0.319

AOVONEWAY Analysis of 10 kp Data:

		All Data	C1	C2	C3
10.80	+	1	1		
	−	5		2	3
	−	8	3	2	3
	−	7	2	3	2
	−	9	5	2	2
9.90	+	6	2	1	3
	−	9	5	3	1
	−	6	3	1	2
	−	8		5	3
	−	6	3	1	2
9.00	+	4	1	2	1
	−	6		3	3

Analysis of Variance

Due to	DF	SS	MS = SS/DF	F-Ratio
Factor	2	0.372	0.186	0.66
Error	72	20.329	0.282	
Total	74	20.702		
Level	N	Mean	SD	
C1	25	9.860	0.442	
C2	25	9.688	0.554	
C3	25	9.786	0.588	

Pooled SD = 0.531

AOVONEWAY Analysis of 15 kp Data:

		All Data	C1	C2	C3
	−	1	1		
	−				
	−	2	1		1
	−	2	1	1	
16.0	+	9	3	3	3
	−	14	4	5	5
	−	12	7	2	3
	−	10	3	4	3
	−	19	3	7	9
14.0	+	3	1	2	
	−	1	1		
	−	2		1	1

Analysis of Variance

Due to	DF	SS	MS = SS/DF	F-Ratio
Factor	2	1.617	0.809	1.25
Error	72	46.426	0.645	
Total	74	48.043		
Level	N	Mean	SD	
C1	25	15.272	0.859	
C2	25	14.936	0.762	
C3	25	14.993	0.784	

Pooled SD = 0.803

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