

An Experiment Comparing the Postabortal Performance of the Lippes Loop, Copper T, and Dalkon Shield

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The Red Cross Hospital in Pusan, Korea, undertook an experiment in June 1973 to compare the performance of the Lippes Loop, the Copper T, and the Dalkon Shield when inserted post-abortally. An offer of an immediate IUD insertion was made to all women receiving induced abortion at the hospital's outpatient facilities, about 400 cases per month. Of these about half accepted, and the three devices were inserted, before departure from the hospital, in strict rotation among individuals. Thus on each day the numbers receiving the three devices could differ by one at most, and the various personal characteristics, pregnancy/abortion experience, and medical histories of the women were equalized within chance limits.

The experiment continued until 900 cases were inserted, 300 for each device. Table 1 describes the groups and shows their equality on a number of major characteristics.

Follow-up data were obtained through the usual returns to the clinic, and through home interviews¹⁾. Insertions ran from June 1 through mid-October 1973, and home interviews were conducted during June 1974 (used as the cut-off month for all cases). Interviews were not attempted on the relatively small number of cases already known to have terminated from clinic entries.

Most (72%) of known terminations were un-discovered except through the home interviews (Table 2): 73% for removals and 67% for expulsions and pregnancies in situ. However although the interviews were valuable in discovering terminations they did not in many cases establish dates. (Instructions to the interviewers were quite firm that for any termination they should accept only a precise date from the respondent, and not record vague responses.) Otherwise the success of interview contact (82%) and the relatively high rate of known terminations are reassuring on the adequacy of the follow-up effort. Overall the aggregated clinic and interview data show 310 terminations, of which 49% are of unknown date due the interview data show 310 terminations, of which 49% are of unknown date due to the interview problem mentioned.

Insertions occurred from June 1, 1973 until the 900 total was attained in October. Observation time was ten months, from early August as the midpoint of insertions to

1) Before the home interviews, an effort by mail was made to determine the current status of cases not yet terminated in the clinic, but this was largely unsuccessful.

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Table 1. Summary of Basic Characteristics of Acceptors

	Loop	T	Shield
1. % living in "Gu" (District) of Pusan surrounding hospital	60.0	62.3	59.7
% living elsewhere in Pusan	35.7	32.7	36.0
2. % never entered middle school	64.0	58.7	63.0
3. Mean age at insertion	36.05	36.20	35.80
% under age 30	26.7	24.0	26.7
% aged 30-39	62.0	67.7	61.7
4. Mean pregnancy order	5.31	5.52	5.35
% 1-3 pregnancy	25.0	21.0	21.7
% 4-6 pregnancy	44.3	44.7	47.0
5. Mean no. of live births	3.36	3.26	3.23
% 0-3 L. B.	56.3	58.7	62.3
% 4-6 L. B.	42.3	40.7	36.7
6. Mean no. of induced abortions before Index abortion	2.17	2.43	2.23
% Zero	27.3	20.0	19.7
% 1-2	38.0	41.0	45.3
% 3-5	25.7	28.0	28.7
% 6+	9.0	11.0	6.3
7. Mean No. Living sons	1.75	1.89	1.88
% 0-1	38.7	32.0	35.1
% 2	45.7	47.1	42.8
% 3+	15.7	20.9	22.1
8. Mean No. Living Daughters	1.58	1.35	1.36
% 0-1	51.0	58.6	62.5
% 2	30.0	28.6	22.7
% 3+	19.0	12.8	14.7
Difference (7)-(8)	.17	.54	.52
9. Mean No. Living Children	3.33	3.23	3.24
% 0-2	26.7	25.3	28.3
% 3	30.3	34.7	34.3
% 4+	43.0	40.1	38.0
10. % never used contraception before	52.7	45.7	42.3
% ever used contraception before	47.3	54.3	57.7
% used pill	19.3	15.0	14.7
% used loop	24.3	36.7	40.7
% used other	3.7	2.3	2.3
11. Side-effects reported by returnees at 1st return visit (within 8 days)			
% bleeding light	70.3	68.3	71.8
medium	2.6	2.9	1.8
heavy	.9	2.1	1.8
% pain	10.0	8.8	8.8
% pain and bleeding	9.6	9.6	7.0
% backache	4.4	6.2	5.7
No symptom	2.2	2.1	3.1
	100.0 (76.3%)	100.0 (80.0%)	100.0 (80.7%)

Table 2. Follow-up Information by Device

	Loop	T	Shield	Total
% contacted by interview	83.0	82.0	80.7	81.9
% returned to clinic within first 8 days				
% making a first visit	76.3	80.0	75.7	77.3
% making a second visit	54.3	55.3	52.7	54.1
% making a third visit	9.7	11.3	10.0	10.3
% returned to clinic later				
never	58.0	54.7	57.0	56.6
once	37.7	39.7	40.3	39.2
twice	4.3	5.7	2.7	4.2
A. % of terminations recorded in clinic data only				
all terminations	14.2	10.5	15.7	13.7
removals	12.4	11.3	18.0	14.1
expulsions and pregnancies in situ	20.8	6.7	5.3	12.1
B. % of terminations recorded in interview data only				
all terminations	75.2	75.6	64.8	71.7
removals	79.8	73.2	65.2	72.7
expulsions and pregnancies in situ	58.3	86.7	63.2	67.2
C. % of terminations recorded in both clinic and interview data				
all terminations	10.6	14.0	19.4	14.7
removals	7.8	15.5	16.8	13.3
expulsions and pregnancies in situ	20.9	6.6	31.5	20.7
A+C % in clinic or both				
all terminations	24.8	24.4	35.2	28.3
removals	20.2	26.8	34.8	27.3
expulsions and pregnancies in situ	41.7	13.3	36.8	32.8
B+C % in interview or both				
all terminations	85.8	89.5	84.3	86.3
removals	87.6	88.7	82.0	85.9
expulsions and pregnancies in situ	79.2	93.3	94.7	87.9

early June as the midpoint of the home interview effort. Because of the design, the distribution of starting (insertion) times was identical for the three devices, as were the "ending times" produced by the mechanisms for knowing the status of each case close to the cut off date. These mechanisms operated similarly for the 3 devices, as indicated in Table 2. Thus it is possible to use the percentage who terminated as a continuation measure at 10 months, without bias to any of the three devices, and as a very close approximation to a life table result. The life-table as usually calculated is not possible due to the cases that terminated at unknown dates. While these cases could be included at arbitrary time points in a life table calculation, only the final percentage Continuing would be valid, not the time curve. Therefore the percentage is used directly.

The basic design, of rotation of the three devices among individual clients, appears to

Table 3. Percent Terminating by end of 10 Months (Average) of Observation

	Loop	T	Shield
Unstandardized	38.6	29.0	36.3
Standardized for Age ^a			
To Loop Age Distribution	38.6	29.4	36.1
T " "	37.8	29.0	34.8
Shield " "	38.4	29.6	36.3
Standardized for No. Living Children ^b			
To Loop No. Living Children Distribution	39.1	29.3	35.8
T " " "	39.4	29.3	36.3
Shield " " "	39.4	29.2	36.5
Standardized for No. Living Sons ^c			
To Loop No. Living Sons Distribution	38.6	29.2	36.7
T " " "	39.1	29.0	40.0
Shield " " "	38.7	29.4	36.3
Standardized for Previous Contraceptive Use ^d			
To Loop Distribution	38.6	28.8	36.3
T "	38.2	29.1	36.4
Shield "	38.1	29.1	36.4

a Categories used: 5-yr age groups 20-44

b " " : 0-2, 3, 4+

c " " : 0-1, 2, 3+

d " " : none, pill, loop, other

Note: For each basic distribution, i. e. age, NLC, and NLS, a very few "unknown" cases exist. These produce slight differences in percentages that would otherwise be the same.

Table 4. Percent Terminating by end of 10 Months by Characteristics

	Total			Removal			Expulsion			Pregnancy in situ		
	L	T	S	L	T	S	L	S	T	L	T	S
Age												
25-29	43.1	24.1	40.7	40.0	19.0	35.6	1.5	3.4	0	1.5	1.7	5.1
30-34	39.4	31.6	41.3	25.3	22.1	36.5	10.1	7.4	2.9	4.0	2.1	1.9
35-39	34.9	28.7	25.9	27.9	26.9	19.8	5.8	.9	4.9	1.2	.9	1.2
40-44	40.6	—	—	34.4	—	—	3.1	—	—	3.1	—	—
No. Living Children												
0-2	35.4	26.7	38.1	28.8	22.7	32.1	3.7	2.7	1.2	2.5	1.3	4.7
3	43.3	29.2	43.1	31.9	20.4	37.3	6.6	7.8	2.9	4.4	1.0	2.9
4+	37.5	31.1	29.2	29.7	28.6	22.1	7.0	0.8	5.3	.8	1.7	1.8
No. Living Sons												
0-1	33.0	29.5	38.1	23.5	26.3	33.3	6.1	2.1	2.9	3.5	1.1	1.9
2	43.1	27.9	36.7	35.0	22.1	31.2	5.8	4.3	3.1	2.2	1.4	2.3
3+	39.1	32.3	33.3	32.6	25.8	22.7	6.5	4.8	4.5	0.0	1.6	6.1

have been followed closely by clinic personnel, with only one variable, previous contraceptive use, being mildly disquieting. It indicates that 24.3%, 36.7% and 40.7%

of the loop, T, and Shield cases respectively reported previous loop experience. Re-stated, of 300 cases (out of 900) having used the loop before, only 23.9% received another loop while 36.1% and 40.0% received the T and Shield. This could be simply a chance correlation, or it could reflect a tendency to yield to requests by women with an unsuccessful previous loop experience to avoid another one. However the data contain no indication that damage was done. The cases on the three methods are very similar, as noted, on all the personal characteristics in Table 1, and results below are in any case standardized by age and family size. A special check was made to see if the termination rates varied according to previous contraceptive history, but no pattern could be discerned:

Percentage Terminating				
	Loop	T	Shield	Total
<u>Previous contraceptive history</u>				
None	38.6	30.7	37.8	35.8
Pill	41.4	22.2	36.4	34.0
Loop	36.6	30.0	36.1	34.0
Other	(36.4)	(28.6)	(14.3)	(28.0)
Total	38.6	29.0	36.3	34.6

() : small base: only 11, 7, and 7 cases for the 3 cols. For other cells in the first three rows base varies from 44 to 158.

Women with previous loop experience use all three methods as successfully as other women, and when assigned to the loop actually have slightly fewer terminations than others. This result, and the Table 1 similarities, argue that no important bias entered in from the modest dissimilarity in the assignment of past loop users to the three methods. As a further safeguard, results were standardized for previous contraceptive use (Table 3, bottom panel).

The figures just given, total line, show the unstandardized results by method, with an advantage of 7-10 percentage points, at 10 months, in favor of the T over the loop or Shield in this post abortal group.

Table 3 provides further detail, and shows that standardization on basic characteristics does not change the outcome. Table 4 provides the percentage terminating by sub groups.

人工流産直後 子宮內裝置 挿入에 대한 考察

權 豪 淵·존 로스

이 報告書는 1973年 6月 4日부터 4個月間 美國 人口協會, ICARP 資金 支援 및 家族計劃協會 行政支援을 얻어 釜山 赤十字病院에서 人工流産直後에 3가지 子宮內裝置 즉 Lippes Loop, Dalkon Shield, Copper T를 각각 300名에게 挿入하여 1974年 6月 中순까지 그 經過를 考察한 것이다.

人工流産直後 子宮內裝置를 挿入하는 것이 醫學的으로 安全한 것인가는 이미 同 研究와 비슷한 여러가지의 實驗結果 무난한 것으로 立證되어 왔고 同 研究는 위에 말한 3가지 중 醫學的인 副作用 및 使用效果가 어떻게 다른가에 대한 점에 力點을 두었다.

本 研究의 結果로는 副作用(表 1—11) 및 使用期間(表3)에서 比較的 Copper T가 좋은 것으로 나타나고 있다.

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