

COMPARISON OF THE LIPPES LOOP D
AND TAPERED LIPPES LOOP D
INTRAUTERINE DEVICES

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ABSTRACT

The tapered Lippes Loop D (LLD) is compared to the standard LLD to evaluate efficacy and termination events. The tapered device was designed with the intention of lowering the expulsion rate below the rate for women with standard Lippes Loops. The two devices were randomly assigned to 989 women in two studies. Expulsion rates for the tapered device were lower at six months ($p < 0.10$) and at 12 months ($p < 0.05$). When the women were divided into groups by uterine measurement, the differences continued to be significant for women with larger uteri but not for those with smaller uteri. Comparison of other pertinent event rates showed no significant differences. Analysis of the data indicates that the tapered LLD represents an improvement in expulsion rates over the standard LLD.

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INTRODUCTION

Since 1975, the International Fertility Research Program (IFRP) has evaluated a number of different IUD configurations with the intention of improving IUD performance with regard to expulsion rates. One effort involved design changes to a standard Lippes Loop D (LLD), resulting in the tapered LLD. An analysis is presented of data from two comparative studies in which the tapered and standard LLDs were randomly allocated to acceptors.

MATERIALS AND METHODS

The standard LLD has been the most widely used of all IUDs in the Western World. The tapered LLD involves dimensional changes in the standard loop. Device thickness is increased at the fundal end to .105 to .125 inches and reduced at the cervical end from .105 to .085 inches. The 10% increase in vertical compliance of the lower portion of the tapered loop was expected to decrease expulsion rates because of better accommodation to different uterine lengths. Flexibility of the device in the plane of the uterus was expected to improve efficacy.

From February 1977 to April 1979, 989 tapered and standard LLD devices were randomly allocated to women who had not been pregnant in the preceding month. The insertions were performed in clinics in Egypt (N = 493) and Yugoslavia (N = 496).

RESULTS

Continuation and termination event rates for patients receiving either a standard or a tapered LLD are shown in Table I. Although the differences were not always significant, results at the two sites were consistent with those using the pooled data. Gross life-table event rates (per 100 women) were evaluated according to the method of Potter (1). Over 90% of the women were followed-up for at least one year after insertion of their IUDs, with some 85% continuing use for that period. At six months, the expulsion/displacement rate was higher ($p < 0.10$) for women with the standard LLD, 5.7 compared with 3.0 for the tapered LLD. At 12 months, the

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Table I. Gross continuation and pertinent event rates per 100 women receiving Lippes Loop D and tapered Lippes Loop D devices

	Lippes Loop D Rate (N = 497)	Tapered LLD Rate (N = 492)
Pregnancy		
3 months	0.2 + 0.2	0.2 + 0.2
6 months	0.2 + 0.2	0.4 + 0.3
12 months	0.5 + 0.4	1.7 + 0.6
Expulsion/displacement		
3 months	3.5 + 0.8	2.1 + 0.7
6 months*	5.7 + 1.1	3.0 + 0.8
12 months**	7.1 + 1.2	3.2 + 0.8
Removal for bleeding/pain		
3 months	3.1 + 0.8	2.7 + 0.7
6 months	5.5 + 1.1	4.2 + 0.9
12 months	6.9 + 1.2	6.3 + 1.1
Removal for other medical reasons		
3 months	0.0 + 0.0	0.4 + 0.3
6 months	0.2 + 0.2	0.4 + 0.3
12 months	0.5 + 0.3	1.4 + 0.6
Continuation		
3 months	93.3 + 1.3	94.6 + 1.1
6 months	88.7 + 1.5	91.9 + 1.4
12 months	84.5 + 1.8	86.5 + 1.9
Follow-up		
3 months	97.9	97.7
6 months	96.2	96.3
12 months	92.5	91.0

*p < 0.10

**p < 0.05

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difference was even greater ($p < 0.05$), 7.1 for the standard LLD and 3.2 for the tapered device. Comparison of other pertinent event rates (pregnancy, bleeding/pain and medical removals) showed no significant differences, even though the thicker cross-section of the tapered loop at the fundal end might be expected to reduce accidental pregnancies.

When the women were divided into two groups by uterine measurement, the difference in the expulsion rates of the two devices was evident for women with larger uteri (external os to fundus, ≥ 70 mm), but not for women with smaller uteri (Table II). The twelve-month rates were 7.4 for the LLD and 3.4 for the tapered LLD ($p < 0.05$) for the larger uteri. The same pattern of higher expulsion rates with the standard device did exist for smaller uteri, but the difference was not statistically significant. (It should be noted that far fewer women in the study fell into the small uterus category).

No differences were noticed, either in the overall comparison or in the comparison by uterine measurement, for other termination event rates.

DISCUSSION

The relationship between uterine size and intrauterine device size has been demonstrated in several studies, (2, 3, 4). In one study, the most significant determinant of expulsion was found to be device size (4). Experience has shown that the smaller size of the Copper 7 and Copper T IUDs has made them more resistant to expulsion. The tapered LLD was developed by the IFRP in an effort to decrease expulsion rates with the double loop configuration.

Analysis of the data does indicate that the tapered LLD is better tolerated than the standard LLD, particularly in the larger uterus. The number of women with smaller uterine measurement in the study is too small to provide significant results, but the pattern of higher expulsion rates for the standard device continues. It does appear then that the tapered IUD offers an improvement in the expulsion rate over the standard LLD, although contrary to expectation, this improvement is not most apparent in smaller uteri.

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Table II. Gross expulsion/displacement and follow-up rates per 100 women receiving Lippes Loop D and tapered Lippes Loop D devices by uterine measurement

	<u>External Os to Fundus < 70 mm</u>	
	LLD (N = 53)	Tapered LLD (N = 60)
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Expulsion/displacement		
3 months	2.1 + 2.1	1.7 + 1.7
6 months	4.2 + 2.9	1.7 + 1.7
12 months	4.2 + 2.9	1.7 + 1.7
Follow-up		
3 months	96.0	100.0
6 months	93.5	100.0
12 months	90.7	94.2
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	<u>External Os to Fundus > 70 mm</u>	
	LLD (N = 444)	Tapered LLD (N = 432)
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Expulsion/displacement		
3 months	3.7 + 0.9	2.2 + 0.7
6 months*	5.9 + 1.1	3.2 + 0.9
12 months**	7.4 + 1.3	3.4 + 0.9
Follow-up		
3 months	98.1	97.4
6 months	96.5	95.8
12 months	92.7	90.5
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*p < 0.10		
**p < 0.05		

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REFERENCES

1. Potter, R.G. Use-effectiveness of intrauterine contraception as a problem in competing risks. In *Family Planning in Taiwan* (R. Freedman and J.Y. Takeshita, Editors) Princeton University Press, Princeton, 1969, p. 458-484
2. Hasson, H.M., Berger, G.S. and Edelman, D.A. Factors affecting intra-uterine contraceptive device performance. *Am J. Obstet Gynecol* 126:973-981 (1976)
3. Tejuja, A. and Malkani, P.K. Clinical significance of correlation between size of uterine cavity and IUCD. *Am J Obstet Gynecol* 105:620-627 (1969)
4. Wheeler, R.G., Duncan, G.W. and Spicdel, J.J., Editors. *Intrauterine Devices: Development, Evaluation and Program Implementation*. Academic Press, New York, 1974