

EARLY EXPERIENCE WITH THE COPPER 7, COPPER T220C AND MULTILOAD 250 INTRAUTERINE DEVICES

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THE ADDITION OF copper to an inert intrauterine device (IUD) has been shown to enhance its contraceptive effectiveness (Tatum, 1973; Zipper *et al.*, 1971). However, problems resulting in termination of use have not been eliminated and modifications in IUD design are continuously being explored in the search for the optimal device which will not only be acceptable to the patient but which would also be sufficiently reliable for mass insertion. Evaluation of new devices cannot be made by direct comparison of data from different authors since many variables are involved (Sivin, 1973; Tatum, 1972; Mishell, 1975). A valid comparison between different devices can only be made under the same field conditions.

This paper is a preliminary study to assess the progress made in the IUD project being carried out at three University centres in Kuala Lumpur, Singapore and Medan (Inter-University Collaborative Fertility Project). Three IUD's were studied: The Copper 7 (Cu-7) and two newer devices, the Copper T220C (TCu 220C) and the Multiload 250 (MLCu 250). Only the first six months of use were analysed as the number of acceptors were still relatively small.

MATERIALS AND METHODS

The study group consisted of 574 parous women who chose the IUD as the sole method of contraception. Insertions were made in the interval period namely at least four weeks after an abortion and

eight weeks following a delivery. Allocation of the device was made on a random basis and all patients had been followed up for at least 6 months or had been terminated from study by 31st August, 1977.

The devices used are shown in Figure 1. Each device is supplied in a sterile package together with introducer and plunger. The Cu-7 with an exposed copper area of 200 sq. mm. in the form of wire coils on its vertical stem is well-known (Bernstein *et al.*, 1972; Newton *et al.*, 1975). The TCu 220C is a new model of the T-device with 220 sq. mm. of copper in the form of sleeves on both the transverse and vertical arms. The MLCu 250 has 250 sq. mm. of copper wire wound on its vertical stem. Its transverse wings are highly flexible and have barbs for anchorage within the uterine cavity (Van Os

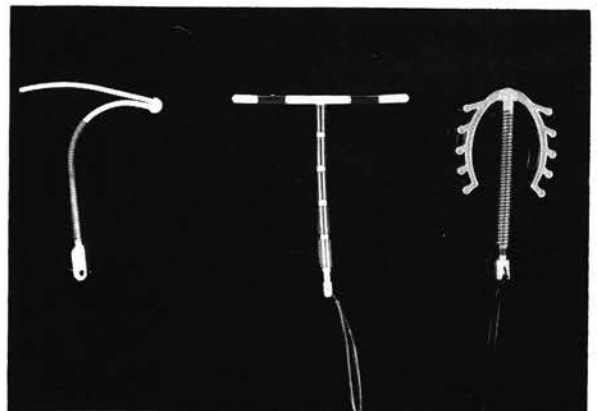


Figure 1

Cu-7, TCu 220C and MLCu 250 devices.

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et al., 1976). Figure 2 shows the devices ready for insertion. Note that no plunger is needed for the MLCu 250 and the device does not need to be manipulated into the introducer.

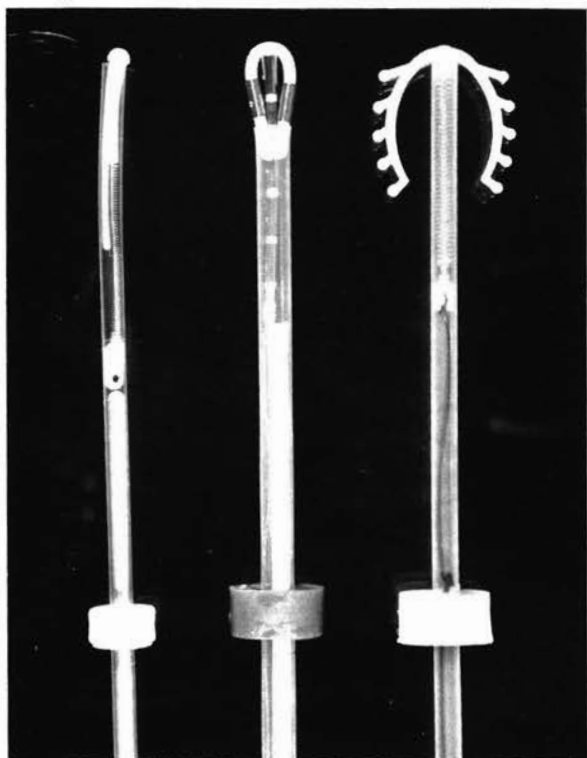


Figure 2

Cu-7, TCU 220C and MLCu 250 ready for insertion.

A full history was taken and physical examination carried out on admission to the study. A gynaecological examination including cervical Papanicolaou Smear was then performed. After swabbing the cervix with antiseptic solution, the uterine cavity was sounded to determine its depth and direction. Insertion of the Cu-7 and TCU 220C is by the withdrawal technique while the MLCu 250 is inserted directly into the uterine cavity on its applicator.

After insertion, follow-up was carried out at 6 weeks, 3 months and then at 6 months when a repeat Papanicolaou Smear was taken. Unscheduled visits were also recorded.

RESULTS

The age range of acceptors was 19-35 years. The mean age was 26.8 years and mean parity 2.6 (Table I). The three groups of patients were comparable in mean age/parity as expected from randomization. Insertion of the IUD was not possible in two patients as the uterine sound could not be negotiated into the uterine cavity.

Table I
Mean Age/Parity of IUD Acceptors

	Cu-7	Cu-T220C	MLCu 250	Total
Mean Age (yrs.)	26.6	27.0	26.7	26.8
Mean (Parity)	2.7	2.4	2.6	2.6

Of the 572 insertions made, 70 (12.2%) were terminated in the first 6 months of use. The cumulative event rates obtained (Tietze and Lewit, 1973) are shown in Table II. The overall continuation rate at 6 months was 87.7 per 100 users for a total of 3,253 woman-months of use.

Table II
Cumulative Event Rates Per 100 Users By IUD Type, 6 Months of Use

	Cu-7	Cu-T220C	MLCu250	Total
No. of First Insertions	189	191	192	572
Woman-months	1063	1096	1094	3253
Type of Termination:				
Pregnancy	1.6	0.5	2.1	1.4(8)*
Expulsion	4.2	1.6	1.6	2.5(14)
Removal:				
Pain/Bleeding	3.2	3.1	3.1	3.1(18)
Planning pregnancy	1.6	2.1	1.6	1.7(10)
Infection	0.5	0	0	0.17(1)
Other reasons	1.6	2.6	1.0	1.7(10)
Loss to follow-up	2.1	1.0	1.6	1.6(9)
Continuation rate	85.2	89	89.1	87.8

* Indicates number of patients

DISCUSSION

Being flexible and small in size, the three IUD's were generally easy to insert. The two failures of insertion out of 574 patients studied were not attributable to the device itself. The MLCu 250 is the simplest of the devices to insert and the technique does not require sterile gloves to be worn since manipulation of the device is not necessary unlike the other two devices.

The removal rate for pain/bleeding was comparable among the three IUD's. The mean of 3.1/100 users is low in contrast to the Lippes loop which is reported to have a comparative rate of 9.9 at six months (Orlans, 1974). Being small and flexible, the copper IUD's do not cause undue distortion or compression within the uterus. This may account for the low termination rate observed for pain/bleeding (Adel *et al.*, 1971; Kamal *et al.*, 1971).

The main differences between the devices lay in their rates for expulsion and accidental pregnancy. However, the data is too small at present for any tests of significance to be meaningful.

The TCu 220C appears to better retained than the Cu-7 device with expulsion rates of 1.6 and 4.2/100 users respectively. Other studies comparing the T-device with the Cu-7 have also shown that the T-device is better retained (Jain, 1975; Shaila *et al.*, 1974). This difference is attributed to the "anchoring mechanism" of the T-device whereby the tips of both its transverse arms are embedded in the myometrium whereas the Cu-7 has only one embedding arm (Timonen *et al.*, 1972; Kamal *et al.*, 1973). The barbed wings of the MLCu 250 tend to resist expulsion and this may explain the low expulsion rate of 1.6/100 which is comparable to the TCu 220C.

Partial expulsion of the device is frequently observed in pregnancies associated with the copper IUD's (Tatum, 1972; Sivanesaratnam *et al.*, 1974). Should the TCu 220C be partially expelled however, the copper on its transverse arms may still exert a significant anti-fertility effect within the uterine cavity. The accidental pregnancy rate would therefore be expected to be low (Tatum, 1975). In the present study, the pregnancy rate of 0.5/100 users of the TCu 220C is low in contrast to the MLCu 250 and Cu-7 device which have rates of 2.1 and 1.6 respectively. Tatum (1975) in a preliminary study found that the pregnancy rate with the TCu 220C was 1/3 that of the Copper T-200 which has copper wire wound only on its vertical stem. The difference observed did not reach statistical significance but is nonetheless consistent with the above hypothesis. The removal rate for planning

pregnancy and the rate of loss to follow-up were acceptably low at an average of 1.7 and 1.6 per 100 users respectively. There was no uterine perforation observed in the period of study.

Pelvic infection necessitating IUD removal was found only once, a rate of 0.17%. This low figure is significant in view of the mortality and morbidity associated with this complication (BMJ leading article, 1976). Strict adherence to insertion technique and the availability of the devices in sterile packaging are probably responsible for this finding. Similar experience is reported by Fortier *et al.*, (1973).

In the successful use of IUD's on a large scale, the ease and simplicity of insertion are important factors to consider (Mishell, 1975). This is particularly so where widespread use is made of paramedical personnel to perform the insertions (Rosenfield, 1975). The copper IUD's being easy to insert and having lower event rates may be better suited to this role compared to the larger non-medicated devices like the Lippes loop (Jain, 1975; Orlans, 1974). However, in order to make a demographic impact, an IUD must be effective in-utero for at least 3-5 years (Tatum, 1977). Copper wire tends to corrode and fragment in-utero (Tatum, 1973). Their effective life-span is therefore limited. By using the copper in the form of sleeves as in the TCu 220C, its integrity should be preserved longer and an effective life-span of 15-20 years in-utero is expected (Tatum, 1977). If field studies support this view, the TCu 220C would be established as a major advance in IUD design.

SUMMARY

The results of this preliminary study so far may be considered satisfactory but they do not warrant any firm conclusions as the data is small. However, certain trends are noted and possible explanations offered. If the present trends continue, the TCu 220C may prove to be the most effective device of the three: its potential in large family planning programmes would then be tremendous.

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