Intrauterine Contraception with the Copper 7: Evaluation after Two Years

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Summary

From 1,156 insertions of the copper 7 contraceptive device with 15,044 women-months of use we conclude that it offers advantages in intrauterine contraception. Continuity is improved for all users. It is a useful method for those who have not been pregnant and as an exchange device for patients having problems with other intrauterine devices or contraceptive methods. These advantages must be set against the necessity of replacing the copper 7 after a limited life span. In no cases in our series did cervical cytological examination show anything abnormal, and a 98.1% follow-up was achieved.

Introduction

The reports of the Co-operative Statistical Programme by Tietze (1962 a, b) and Tietze and Lewit (1970) indicated a need to develop new intrauterine devices (I.U.D.) that were more effective in preventing pregnancy and at the same time had an acceptable incidence of side effects.

The use of copper on a small plastic delivery system first reported by Zipper *et al.* (1969) showed promise as an effective medicated intrauterine device. Two devices were then developed, the copper T and the copper 7. Studies on the copper T have been recently assessed by Tatum (1973), and we previously reported our preliminary observations on the copper 7 (Newton *et al.*, 1972).

We report here a two-year evaluation of the device after 1,156 insertions in parous and nulliparous women and comment on a modified insertion technique and the possible causes of some side effects.

Patients

Patients were recruited from the King's College Hospital Family Planning Brook Centre clinics. These clinics have special sessions for youth advisory work (Newton *et al.*, 1971) and general family clinics (Newton *et al.*, 1973). All patients were seen one, two, and three months after insertion of the device and thereafter every three months. If a patient failed to attend contact was established by a domiciliary visit, thus ensuring a complete follow up. No patients were lost to follow up but 1.9% refused follow up. Thus at the end of the two-year study period a 98.1% follow up was obtained. At each visit a detailed questionnaire was completed both to assess acceptability to the patient and to evaluate the medical criteria recorded for Tietze-Potter life table analysis (Potter, 1966, 1967; Tietze, 1967).

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Insertion Technique for Copper 7

In our previous report (Newton *et al.*, 1972) we emphasized the need for correct fundal placement of the copper 7 to prevent unnecessary expulsion. Further work has emphasized the importance of this technique. We inserted copper 7 devices under x-ray control with different insertion techniques and found that due to the normal "waisted" shape of the uterine cavity a simple "pull" technique may lead to incomplete extension of the transverse arm and the likelihood of subsequent expulsion.

We therefore recommend the following procedure: set the cervical stop to the depth of the uterine cavity; insert the loaded device into the uterus; withdraw the outer sheath about 25 mm to free the transverse arm; the outer sheath is now held steady and the rod gently pushed to ensure that the device is at the fundus of the uterus. The withdrawal of the sheath is then completed and the rod and then the tube removed, and the thread is cut about 2 cm from the cervical os. This modified insertion technique allows the device to be correctly placed with a fully open transverse limb at the fundus of the uterus.

Results

A total of 1,156 insertions were completed—805 in parous patients and 351 in patients who had never been pregnant. The results of 15,466 woman-months of use are now reviewed.

The net cumulative event rate and the 95% confidence limits (± 2 S.D.) for the copper 7 at six, 12, 18, and 24 months are shown in table I for use-related terminations, as defined by Tietze and Lewit (1970).

The results are given for all insertions (group 1), for insertions in those who had never been pregnant (group 2), and for those in the parous patients (group 3). The results for group 2 cover 4,051.5 woman-months of use and are statistically significant at 16 months; those for group 3 cover 9,597 woman-months of use and are statistically significant at 20 months.

ACCIDENTAL PREGNANCY

There were 21 pregnancies with the copper 7 in utero giving a pregnancy rate (table I) of 1.9% at 24 months of use for group 1, 1.7% at 16 months for group 2, and 2.0% at 20 months for group 3. These months are the last significant months of use (more than 100 women continuing in the study (Tietze and Lewit, 1970)).

EXPULSION

The total expulsions rose rapidly to 88 at six months and then more slowly to 96 at 12 months and 113 at 24 months. Most were partial expulsions (66%) with the vertical arm in the cervical canal and the tip protruding through the cervical os. This represents an expulsion rate of 10.3% at 24 months for group 1, 9.9% at 16 months for group 2, and 8.8% at 20 months for group 3.

Early and late expulsions with the copper 7 are shown in table II). There were 113 first expulsions of which 72 were events and 41 closures. Seventy-two second insertions led to 20 second expulsions and of these two were events and 18 were closures. After a second insertion 52 patients had no further problems with expulsion. There were two third insertions one

TABLE I—Net Cumulative Termination Rates (%; ± 2 S.D.; 95% Confidence Limits)

Significant Months of Use	Accidental Pregnancy	Expulsion	Bleeding and Pain	Other Medical Reasons	Planned Pregnancy	Other Personal Reasons	Total Terminations	Total Continuation Rate
<i>Group 1</i>								
6	1.2 $\pm$ 0.6	7.7 $\pm$ 1.6	2.1 $\pm$ 0.8	1.5 $\pm$ 0.7	0.5 $\pm$ 0.3	0.9 $\pm$ 0.5	13.9 $\pm$ 2.0	86.1 $\pm$ 2.0
12	1.8 $\pm$ 0.7	8.4 $\pm$ 1.7	4.1 $\pm$ 1.2	1.8 $\pm$ 0.8	1.8 $\pm$ 0.8	1.3 $\pm$ 0.6	19.2 $\pm$ 1.9	80.8 $\pm$ 2.8
18	1.9 $\pm$ 0.7	9.4 $\pm$ 1.8	5.6 $\pm$ 1.5	2.1 $\pm$ 1.0	3.5 $\pm$ 1.3	1.5 $\pm$ 0.7	23.9 $\pm$ 2.7	76.1 $\pm$ 4.6
24	1.9 $\pm$ 0.8	10.3 $\pm$ 1.9	6.5 $\pm$ 1.6	2.1 $\pm$ 1.0	5.2 $\pm$ 1.7	5.1 $\pm$ 2.0	31.1 $\pm$ 3.2	68.9 $\pm$ 7.9
<i>Group 2</i>								
6	1.7 $\pm$ 1.4	7.6 $\pm$ 2.8	3.8 $\pm$ 2.3	3.1 $\pm$ 1.9	0.2 $\pm$ 0.2	1.2 $\pm$ 1.2	17.7 $\pm$ 4.2	82.5 $\pm$ 4.2
12	1.7 $\pm$ 1.4	9.0 $\pm$ 3.0	6.5 $\pm$ 2.8	3.1 $\pm$ 1.8	1.8 $\pm$ 1.5	1.5 $\pm$ 1.5	23.6 $\pm$ 5.6	76.4 $\pm$ 4.6
16	1.7 $\pm$ 1.4	9.9 $\pm$ 3.2	8.5 $\pm$ 3.3	3.1 $\pm$ 1.8	3.7 $\pm$ 2.4	1.5 $\pm$ 1.5	28.4 $\pm$ 5.1	71.6 $\pm$ 5.1
<i>Group 3</i>								
6	0.9 $\pm$ 0.6	7.6 $\pm$ 1.9	1.6 $\pm$ 0.9	0.9 $\pm$ 0.7	0.6 $\pm$ 0.5	0.9 $\pm$ 0.8	12.5 $\pm$ 2.3	87.5 $\pm$ 2.3
12	1.8 $\pm$ 0.8	7.9 $\pm$ 1.9	3.3 $\pm$ 1.3	1.3 $\pm$ 0.8	1.8 $\pm$ 0.8	1.4 $\pm$ 0.8	17.3 $\pm$ 2.3	82.7 $\pm$ 2.3
18	2.0 $\pm$ 1.0	8.8 $\pm$ 2.0	4.6 $\pm$ 1.6	1.5 $\pm$ 0.9	3.3 $\pm$ 1.5	1.6 $\pm$ 0.9	21.6 $\pm$ 3.1	78.4 $\pm$ 3.1
20	2.0 $\pm$ 1.0	8.8 $\pm$ 2.0	4.6 $\pm$ 1.6	1.5 $\pm$ 0.9	3.3 $\pm$ 1.5	3.2 $\pm$ 1.7	23.4 $\pm$ 3.2	76.6 $\pm$ 3.2

TABLE II—Expulsions of Copper 7 after First, Second, and Third Insertions

Insertion	No.	No. of Expulsions			No. of Continuing Users
		Events†	Closures	Total	
First	1,156	72	41	113	52 (72%)
Second	72	2	18	20	
Third	2	0	1	—	

†not leading to closures

of which was subsequently expelled and the patient started on oral contraception.

MEDICAL REMOVALS FOR BLEEDING AND PAIN

There were 58 removals for bleeding (menorrhagia or intermenstrual bleeding) or bleeding and pain; giving a rate of 6.5% at 24 months for group 1, 8.5% at 16 months for group 2, and 4.6% at 20 months for group 3.

The total numbers of these medical removals for bleeding, pain, or a combination of both are broken down by month of occurrence in fig. 1. In both the never pregnant and the parous patient bleeding was the main problem, showing a steady increase over the first eight months. The combination of pain plus bleeding was the next most common symptom though pain alone was a problem for the first four months after insertion of the device in both the non-pregnant and the parous patients.

FIG. 1—Monthly cumulative rates for bleeding and pain.

REMOVALS FOR OTHER MEDICAL REASONS

The removal rate for other medical reasons is shown in table III. Devices were removed from 22 patients for such reasons, and of these 12 removed for a "tender" uterus. In only two of these 12 (0.2% of all insertions) was there definite evidence of an intra-uterine infection, and both responded to antibiotic therapy. The indication for removal in the remaining 10 was the finding of uterine tenderness on pelvic examination together with, in some cases, a vaginal discharge; in none of these cases was infection proved.

TABLE III—Removals of Copper 7 for Medical Reasons other than Pain and Bleeding in 22 Patients

Reason for Removal	No.	Month of Event after Insertion
Tender uterus (n = 12)	2	1
	1	2
	1	3
	1	5
	1	7
	3	9
Displacement of device (n = 4)	1	13
	2	16
	1	7
	2	13
Pregnant before insertion (n = 4)	1	1
Venereal disease requiring treatment (n = 1)	1	2
	1	9
Perforation of uterus (n = 1)	1	2

In four cases transverse or oblique displacement of the device had occurred (as seen on a pelvic x-ray examination), in each case associated with pain. These I.U.D.s were removed and replaced, and there were no further problems. Four patients had the device inserted late in the luteal phase of the cycle and were already pregnant. In none of these did a spontaneous miscarriage occur. Two requested termination of pregnancy, and the other two continued to term. One patient contracted gonorrhoea and the device was removed while she was treated. In one other case the uterus was perforated during insertion and the copper 7 had to be retrieved by laparoscopy.

The results about termination rates have so far been quoted as the net cumulative termination rate (as calculated by multiple decrement analysis). This includes the probability of any event occurring when taking into account the risk of another event occurring. The net rate is not suitable for comparison of different devices but is useful for the calculation of the performance of a given device for various criteria. The overall continuation rate at 12 months was 80.8% and at 24 months 68.9%. For the never-pregnant group at 16 months it was 71.6% and for parous patients at 20 months 76.6%.

COMPARISON FOR NEVER-PREGNANT AND PAROUS PATIENTS

The three main criteria of expulsion, medical removals for pain and bleeding, and accidental pregnancy are compared as net

cumulative monthly termination rates in fig. 2. The probability of accidental pregnancy was similar in both groups at the last significant month of use. But in the never-pregnant group it was more likely to occur in the first four months and seemed to be correlated with the expulsion rate.

The overall expulsion rate was similar for both groups, showing a rapid rise during the first four months of use. The analysis of bleeding and pain showed a higher rate at each month of use for the never-pregnant group, and in fig. 2 this is seen to be mainly due to menorrhagia or intermenstrual bleeding.

FIG. 2—Monthly cumulative termination rates for pregnancy, medical removals, and expulsion in never-pregnant and parous patients.

GROSS TERMINATION RATES

For comparison of use-related events of one device with those of another device gross rates should be used. The gross termination rates for the copper 7 in groups 1, 2, and 3 to the last significant month of use are compared in table IV. Gross rates (single decrement probability analysis) are by definition higher than net rates.

TABLE IV—Gross Cumulative Termination Rate (%)

Significant Months of Use	Accidental Pregnancy	Expulsion	Bleeding and Pain	Other Medical Reasons	Planned Pregnancy	Other Personal Reasons
Group 1						
6	1.3	5.5	2.2	1.5	0.6	0.8
12	2.3	6.3	4.5	1.9	2.1	1.3
16	2.5	8.1	5.9	2.2	3.5	1.5
18	2.5	8.4	6.3	2.2	4.2	1.5
20	2.5	8.4	6.3	2.2	5.3	2.6
24	2.5	9.7	7.6	2.2	6.6	2.6
Group 2						
6	1.9	8.1	3.5	3.0	0.3	1.0
12	1.9	9.7	6.6	3.3	2.2	1.3
16	1.9	10.7	9.1	3.3	4.7	1.3
Group 3						
6	1.5	18.4	1.7	2.1	0.6	0.9
12	2.4	18.8	3.6	2.5	2.1	1.5
18	2.7	19.9	5.0	2.9	4.3	1.9
20	2.7	21.9	5.0	2.9	5.4	3.7

The gross termination rates were compared after two years for the copper 7 in our series with those in the reported data for the copper T (Sivin, 1973), Lippes D, and Lippes C (Tietze and Lewit, 1970; table V). The pregnancy rate for the copper 7 was lowest at 2.5%. The expulsion rate—9.7%—was also lower than that of the copper T, which was similar to the Lippes D, and both these were better than the Lippes C. The removals for pain and bleeding for the copper T and copper 7 were less than for both sizes of Lippes loop, and the copper 7 removals were half those of the copper T (7.6% against 15.6%). The copper 7 also had the

lowest rate of removals for other medical reasons at 2.2%. The copper 7 in our series and the copper T, as quoted, had similar removal rates for planned pregnancy, which were higher than those for the Lippes loops. This was possibly due to the lower parity of patients using the copper devices.

TABLE V—Gross Cumulative Termination Rates (%) at Two Years of Use

	Copper 7	Copper T	Lippes D	Lippes C
Accidental pregnancy	2.5	4.4	4.9	5.1
Expulsion	9.7	12.0	12.1	18.1
Medical removals:				
Pain and bleeding	7.6	15.6	19.0	17.7
Others	2.2	5.2	6.2	6.3
Planned pregnancy	6.6	7.1	3.2	3.8
Other personal reasons	2.6	5.0	5.0	4.4

Discussion

This report confirms our early impression of the copper 7 device (Newton *et al.*, 1972), namely, that with the 7-shaped as with the T-shaped device there are increased acceptability and fewer side effects than with the classical plastic I.U.D.s. These results, particularly in nulliparous patients, are encouraging. As the diameter of the introducer tube is less than that of a uterine sound there is rarely any major problem with insertion. The low pregnancy rate, 1.7% at 16 months, offers a nulliparous patient a reasonable alternative to oral contraception.

These results have been obtained in youth advisory and family clinics in a hospital training clinic where insertions of the device have been carried out by both highly experienced clinic doctors and trainees. There were no significant differences between their results. This emphasizes that in a training clinic or where doctors may not be used to inserting small active intrauterine devices results of this order can be achieved within a short space of time.

Some doctors in training experience difficulty with the acutely flexed uterus due to kinking of the introducer tube at the unsupported junction between the foot of the device and the tip of the inserter rod. This problem can almost always be overcome by adequate traction on the cervix using a vulsellum, and, with the acutely anteverted uterus, easier angulation and access to the cervix can most often be obtained in the left lateral position rather than the dorsal.

Infection, common in some parts of the world after intrauterine device insertion, did not seem to be a problem in our series. Only two patients had evidence of pelvic inflammatory disease after insertion of the device, and they both responded to treatment with antibiotics. One criticism often levelled against the intrauterine device is that it is not suitable for nulliparous patients due to the problem of infection rendering the patient infertile. This did not seem to be the case in our series.

The problem of expulsion is common to all types of I.U.D.s. Due to its shape one would expect the 7 to be expelled more easily than the T device but the results (see table IV) suggest that this is not the case. Recent work (Westrom and Bengtsson, 1970) has indicated that expulsion is related to uterine motility, which might account for the high expulsion rate in the first four months. Nevertheless, some of our early expulsions at the beginning of this series were due to failure of the device to open completely inside the uterine cavity. Such failure can be prevented by the modified insertion technique described earlier. The pregnancy rate paralleled the increase in expulsion rate during the first few months of use. In the never-pregnant patient this seemed to occur over the first four months, and in the parous patient a more gradual rise in pregnancy rate was seen over the first eight to 12 months but, again, it seemed to be related to expulsion. As partial expulsion may occur without symptoms, particularly in the nulligravid patient, the use of a spermicidal cream for the first four months after insertion may help to reduce the pregnancy rate. If a first expulsion does occur, either partial or complete, it is worth trying a second

insertion of a copper 7 as 72% (52 patients) had no problems after a second insertion.

A higher incidence of ectopic pregnancy has been recorded in certain instances related to I.U.D. use. We did not find this to be the case in our series, all pregnancies being intrauterine.

Bleeding in association with an I.U.D. is a major cause of removal. It may in part be related to the size of the device; the copper T being larger than the copper 7 has a higher medical removal rate for pain and bleeding.

Like Tatum (1973) we also found an acute reaction to the presence of copper in the peritoneal cavity. Thus a copper 7 should be removed as soon as is practicable after inadvertent perforation of the uterus. If done at an early stage the laparoscope can be used, but later on a laparotomy will be necessary.

In considering any particular I.U.D. discontinuing use of the device for any particular reason is best expressed as a net closure rate as it expresses the probability of this reason occurring in relation to all the other reasons for which closure might be necessary. In considering, however, the probability of a closure for any particular reason happening with one device compared with other devices gross termination rates are preferable. They express the probability of the particular event happening in relation to the total number of people and are always individually higher than the corresponding net rate and cumulative termination rates cannot be used (Tietze, 1967). In order to compare our experience with the copper 7 with the reported data for copper T (Lewit, 1973), Lippes D, and Lippes C (Tietze and Lewit, 1970) gross cumulative termination rates were reported in table IV for the combined, never-pregnant, and parous patients. The combined rates were then compared (table V) with the rates for the other devices. Apart from a higher discontinuation rate for planned pregnancy, which probably reflected the lower parity of patients using the copper devices, the incidence of side effects of the copper 7 in our series was substantially less than in the reported series for the copper T, Lippes D, and Lippes C devices.

The present recommendation of the manufacturers is to change the device after two years of use. Observation of the monthly pregnancy rate shows no further increase after 12 months of use. This suggests that a longer duration of action is probable without adversely influencing the contraceptive efficacy of the device. There were no cases of massive erosion of the copper wire or fragmentation of the coil in the devices removed during the period of study. This is in agreement with the results of Tatum (1973) with the copper T, and we are

currently investigating the use of the copper 7 up to three years of use.

All 1,156 patients had a preinsertion cervical cytological examination, which was repeated annually. No cases of cervical dyskaryosis or atypical cervical cells were reported. In agreement with Tatum's findings there seems to be no added risk of cervical neoplastic change. The two intrauterine pregnancies continued to term with the device in situ. Both pregnancies resulted in normal children without congenital abnormalities. In one the device was spontaneously expelled at 36 weeks, and the other was delivered in the first stage of labour.

Conclusions

From 1,156 insertions of the copper 7 contraceptive device with 15,044 women-months of use we conclude that it offers advantages in intrauterine contraception. Continuity is improved for all users. It is a useful method for those who have not been pregnant and as an exchange device for patients having problems with other intrauterine devices or contraceptive methods. These advantages must be set against the necessity of replacing the copper 7 after a limited life span. In no cases in our series did cervical cytological examination show anything abnormal, and a 98.1% follow up was achieved.

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MEDICAL MEMORANDA

Nephrotic Syndrome with Oat-cell Carcinoma

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The association between the nephrotic syndrome and extrarenal malignancy (Galloway, 1922; Lee *et al.*, 1966; Miller, 1967; Ghosh and Muehrcke, 1970; Lewis *et al.*, 1971; Loughridge

and Lewis, 1971; Couser *et al.*, 1973; Gault *et al.*, 1973) suggests an immunological pathogenesis (Lewis *et al.*, 1971; Loughridge and Lewis, 1971; Couser *et al.*, 1973; Gault *et al.*, 1973), possibly related to the glomerular deposition of antibody to tumour antigen (Avrameas and Ternynck, 1969; Lewis *et al.*, 1971; Loughridge and Lewis, 1971; Couser *et al.*, 1973; Gault *et al.*, 1973). We report a case of oat-cell carcinoma of the lung presenting as the nephrotic syndrome. The latter was associated with the presence of antinuclear antibody (A.N.A.) in the serum and glomerular deposition of IgG and complement. The presence of large amounts of extracellular DNA in necrotic tumour tissue and Feulgen-positive deposits within the glomerular basement membrane suggested the possibility that tumour-induced anti-DNA might have resulted in this immune-complex glomerulonephritis with nephrosis.

Case Report

A 42-year-old white man presented with a four-week history of dyspnoea, cough, back pain, increasing abdominal girth, and pedal oedema. He was pale and had bilateral pulmonary basilar rales, an

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