checked. We can only conclude that it is much more common for normal people to pass acid urine than we had previously appreciated. To further test this contention a random check was made on 54 specimens of urine from patients in a general surgical ward and on which the pH had been measured and recorded on their charts. On only one occasion was the urine specimen found to be alkaline.

If urinary pH is not as important as previously supposed, then the amount and concentration of uric acid in the urine might be more important. Again our observations showed no significant difference between the 24-hour excretion in the three groups. Though the daily output of uric acid was not changed, however, this was excreted in a significantly smaller volume of more concentrated urine in the patients with ileostomies. This may become important in an acid medium when the solubility of uric acid is greatly reduced. Though this situation may exist in patients with ileostomies it is less important in those with ileorectal anastomoses because of the greater urinary volume.

Examination of the blood samples from each of the three groups did not show any variation from normal among the postoperative patients.

It would therefore seem that a reduction in urine volume is the most important postoperative finding, and that this is sometimes associated with reduction in the amount of sodium excreted in the urine. With regard to these two parameters, differences exist between patients with ileostomies and those with ileorectal anastomoses. These variations may well account for the apparent difference in incidence of postoperative stone formation. Persistent acidity of the urine is thought to be less important than previously claimed, while variations in the total daily output of uric acid and composition of the blood do not seem to have any significance at all.

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# Clinical Experience with the Dalkon Shield Intrauterine Device

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*British Medical Journal*, 1973, 3, 143–145

## Summary

**Preliminary acceptability and reliability tests of the Dalkon Shield were done in 377 women over 17 months, amounting to 3,028 months of use. There was a 98% follow-up. The pregnancy rate of 4·7 and expulsion rate of 6·3 do not meet the claims described in initial trials by the developers of the device. Nevertheless, the Dalkon Shield seems to be an advance in intrauterine contraception since it has the advantages of a lower expulsion rate than the "first generation" inert intrauterine devices.**

## Introduction

The development of inert plastic intrauterine devices (I.U.D.s) which could be manipulated into a linear introducer and inserted in the uterus without anaesthetic has been a significant advance in contraceptive practice. However, their application had side effects which limited their extended use-effectiveness (Tietze and Levit, 1970). As some of the evidence relating to the mode of action of the I.U.D. suggested that the extent of endometrial coverage was a significant factor, a device, the Dalkon Shield, was designed with this objective as well as minimizing the risk of expulsion, while at the same time its flat shape was intended to reduce the risk of a disturbing level of abnormal bleeding (Davis, 1971). The initial clinical trials were most encouraging with a pregnancy rate of 1·1% and an expulsion rate of 2·3% and an acceptable bleeding pattern (Davis, 1970). Since these data were produced by the clinics involved in its development, however, an independent study seemed appropriate.

## The Device

The Dalkon Shield is a light, flexible device which conforms to the shape of the average uterine cavity. It consists of a thin, central shield-shaped membrane to increase endometrial contact and has lateral series of small fins, which are designed to promote retention and are thought to permit its accommodation to variations in uterine shape.

The Shield is made of polyvinylacetate and contains barium sulphate for location by *x*-ray film, together with copper powder and anhydrous cupric sulphate. The addition of copper increases the strength of the plastic. The average standard Shield contains 1·6 mg copper but only a small proportion (0·015 $mm^2$) is exposed on the surface. Dissolution studies indicate that less than 5% of the total copper is released.

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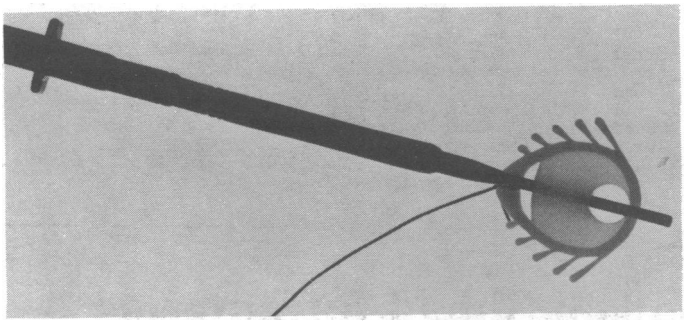
INSERTION TECHNIQUE

The Shield device is supplied preloaded on a sterilized inserter which has a notched end (see fig.). After performing a bimanual examination to check the size and position of the uterus a Cusco speculum is inserted in the vagina. The cervix is cleansed with antiseptic and a single-toothed tenaculum applied to the anterior lip. After sounding the uterus the device on the inserter is passed to the full depth of plane of the uterine cavity. The device is then disengaged in the fundus by turning the inserter through 90° and withdrawing it. In the normal-sized uterus a knot lies at the level of the external os in the cervical appendage; this is present to aid location.

In those patients who have a tight internal cervical os a cervical block with 5ml lignocaine 0·5% is made at positions 4 and 8 o'clock through the vaginal fornices. This allows an easy pain-free insertion.



Dalkon Shield on sterilized inserter.

## Patients Studied

The age and parity distribution of the 377 women involved in this survey are shown in table I. Most of the insertions were performed as an outpatient procedure by five doctors experienced in this type of work. However, about 20 were performed by doctors learning the technique. Insertion was also performed at the time of termination of pregnancy in 31 women and at the time of other gynaecological procedures under general anaesthesia in a further two. A small Shield was used in two women only, most having the standard-size device.

The women were followed up between July 1971 and December 1972 over periods ranging from three completed months to 17 months (the minimum time analysed for this study). About 5% of these patients intermittently used a spermicide in addition to the device.

TABLE I—*Age and Parity Distribution of 377 Women in Dalkon Shield Trial*

| Age in Years | No. of Women | Parity | No. of Women |
|---|---|---|---|
| 19 | 22 | 0 | 18 |
| 20–29 | 234 | 1 | 72 |
| 20–39 | 105 | 2 | 152 |
| 40+ | 16 | 3 | 92 |
| | | 4 | 26 |
| | | 5+ | 17 |

## Results

Only seven women (2%) were lost to follow-up. Of the remainder 12 had two Dalkon insertions and thus data on 370 women and 382 insertions are presented. This information covers 3,028 months of Shield use and the continuation, pregnancy, expulsion, and removal rates are shown in table II.

*Pregnancies* occurred in 12 women—that is, 4·7/100 woman-years. No special distinguishing features could be found in these women who were all parous and whose ages ranged from 23 years to 45 years. Six pregnancies occurred during the first three months of use and three during each of the two following three-monthly periods (see table III). Two of the women had already had pregnancies with other intrauterine devices *in situ*. The device was expelled in 16 women (6·3/100 woman-years), including three in whom it was found to be lying in the cervical canal at a routine follow-up visit. Most expulsions occurred within the first three months of use (see table III). Three women in this group had previously expelled other types of intrauterine device. Eight of them were refitted with a second Dalkon Shield, and of these one was again expelled, one was removed because of excessive bleeding, and the remaining six were in situ after periods ranging from four weeks to six months. Seven women in our total number had previously expelled two or more of a variety of types of I.U.D. Of these "chronic expellers" two again rejected the Dalkon Shield and the other five retained it at the time of writing, covering a period of two to 15 months.

TABLE II—*Dalkon Shield Trial*

| | No. | Rate per 100 Women-years |
|---|---|---|
| Patients fitted | 377 | |
| Insertions | 387 | |
| Lost to follow-up | 7 (2%) | |
| Women-months of observation | 3,028 | |
| Continuation rate | 304 (78%) | |
| Pregnancies | 12 | 4·7 |
| Expulsions | 16 | 6·3 |
| Removals—medical | 24 | 9·5 |
| Removals—personal | 25 | |
| Perforations | 1 | |

TABLE III—*Incidence of Pregnancy and of Expulsion and Removal of Devices*

| Months of use: | 0–3 | 4–6 | 7–9 | 10–12 | 13–15 | 15–17 |
|---|---|---|---|---|---|---|
| Pregnancies | 6 | 3 | 3 | | | |
| Expulsions | 2 | 3 | 1 | | | |
| Removals—medical | 5 | 8 | 6 | 4 | 1 | |
| Removals—personal | 9 | 5 | 7 | 4 | | |

TABLE IV—*Dalkon Shield Continuation Rates According to Duration of Use*

| Months of use: | >12 | 9–12 | 6–9 | 3–6 |
|---|---|---|---|---|
| No. of insertions | 101 | 75 | 69 | 144 |
| No. continuing | 70 | 60 | 57 | 117 |
| Rate (%) | 69·3 | 80 | 82 | 81·3 |

The Shield was removed for medical reasons, usually for pain or bleeding or both, in 24 cases (9·5/100 woman-years). Unlike the expulsion rate this removal rate showed no tailing off with increased duration of use (table III). The Shield was removed for non-medical reasons commonly because of sterilization or desire for pregnancy in 25 women. There was one perforation in the series. This was in a woman, six weeks postpartum, who experienced increasing low abdominal pain after insertion. The device was removed with the laparoscope from the Pouch of Douglas.

Included in our series are 31 women in whom the I.U.D. was fitted immediately after vaginal (vacuum aspiration) termination of pregnancy. All but two of this number were continuing with the device—in one it was removed at six months because of acute pelvic sepsis and the second asked for it to

be taken out as she wanted a further pregnancy. The overall continuation rate in our clinic is shown in table IV—after one year 69% were continuing with the Shield.

### Discussion

The reintroduction of intrauterine contraceptive devices in the early 1960's was initially followed by widespread enthusiasm and then growing dissatisfaction. The pregnancy and expulsion rates were higher than expected and side effects of pain or bleeding or both necessitated a high proportion of removals. The evidence suggested that a local endometrial action manifesting as a macrophage response, presumably chemotactically induced, prevented conception (Sagiroglu and Sagiroglu, 1970; Sedlis and Reyniak, 1970). Davis (1971) then postulated his surface interaction hypothesis that the antifertility effect of an inert I.U.D. bore a direct relation to the surface area of contact between the I.U.D. and the endometrium. Bearing these two points in mind the Dalkon Shield was developed by Davis, a gynaecologist, and Lerner, a bioengineer. Clinical trials conducted by Davis and his associates have been most enthusiastic (Davis, 1971).

This study, however, has shown a much higher complication rate than that reported by Davis. The pregnancy rate for example is much above that of 1·1/100 users at 12 months of use and corresponds more to the 3·8/100 users after one year found in the multicentre U.K. study reported by the Family Planning Research Unit of the University of Exeter (Snowden and Williams, 1973) in which there is no information about the number of women who used a spermicide in addition to the Shield. In the present report about 5% of participants who asked to use a spermicide did so intermittently.

The expulsion rate of 6·3/100 users in a year is again greater than the 2·3/100 users at 12 months reported by Davis (1971). This rate, however, is much lower than the expulsion rates ascribed to the more generally used I.U.D.s such as the Lippes Loop C and the Saf-T-Coil of 19 and Lippes Loop D of 12·7/100 users at 12 months' use (Kleinman, 1972).

The figures for medical removal rates will be greatly influenced by individual doctors' attitudes to this particular problem. Nevertheless our rate corresponds closely to that of 9·7/100 users at one year reported by Ostergard and Broen (1971) and is approaching the removal rates of 11·0/100 users at one year for the Lippes Loop (Tietze and Levit, 1970). The Exeter survey reported a much lower removal rate for the Shield (4·6/100 users at one year), while the figures of Davis again are the lowest recorded at 2/100 users at one year.

The continuation rate of 69% at our clinic after one year of use again puts the Dalkon Shield on a par with more conventional I.U.D.s (Kleinman, 1972).

### Conclusion

The information presented here from 3,028 months of use of the Dalkon Shield in 377 women suggests that this device has a pregnancy and medical removal rate similar to those ascribed to the Lippes Loop. However, the low expulsion rate seen in our study indicates that the Shield is superior in this respect. Thus we think that the Shield is an advance in intrauterine contraception but that the complication rate quoted by Davis is an under-estimation. The failure of this device, with its large endometrial contact area, to affect the pregnancy rate, must, if confirmed by other studies, question the existing hypotheses of mode of action of the so-called inert I.U.D.s.

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# MEDICAL MEMORANDA

## Cricoarytenoid Arthritis in Ankylosing Spondylitis

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*British Medical Journal*, 1973, 3, 145–146

Cricoarytenoid arthritis has been described in association with rheumatoid arthritis on numerous occasions (Montgomery *et al.*, 1955; Copeman, 1957; Pearson, 1957; Polisar, 1959), and its presence may lead to serious anaesthetic and respiratory problems (Montgomery *et al.*, 1955; Baker and Bywaters, 1957; Polisar, 1959). So far as we are aware involvement of this joint in ankylosing spondylitis has not been previously reported in the English literature.

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### Case 1

A man aged 64 with a history of ankylosing spondylitis since 1944 was seen in the rheumatism clinic in 1965. He had been subject to recurrent attacks of iritis, and *x*-ray pictures of his spine showed severe changes of ankylosing spondylitis. Both hips were involved, and a synovectomy had been performed on the left knee for recurrent effusions. The Rose-Waaler and latex tests were negative.

Since 1956 his voice had become increasingly husky and he had noticed progressive shortness of breath with a constant feeling of obstruction in the throat. Chest *x*-ray examination showed an old tuberculous focus but no other abnormality. Indirect laryngoscopy showed very little movement of the vocal cords, and on direct laryngoscopy both arytenoid cartilages appeared fixed with no abduction of the cords occurring on inspiration.

In 1966 he became dyspnoeic at rest and developed a pronounced inspiratory and expiratory stridor. A tracheostomy and subsequent left Woodman's operation was performed, and at operation gross