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Missing IUS arms?

We want to describe a couple of cases that serve to demonstrate that the hormone capsule of the Mirena® intrauterine system (IUS) can dislodge during removal thus changing its appearance, As a result, careful examination of the device is required to prevent further unnecessary investigations.

A 58-year-old woman presented to her general practitioner for removal of a Mirena IUS as it was no longer required. It had been inserted at the practice 7 years previously to provide the progestogen component of her hormone replacement therapy.

At the time of removal the cervix and the IUS threads were visualised. More traction than usual was required on the threads to remove the device. On inspection it appeared that the horizontal arms had become detached as they were not evident and the vertical main stem of the IUS had been removed with the hormone release capsule attached.

The patient was asymptomatic and was allowed home. A transvaginal ultrasound scan was performed on an outpatient basis. The scan demonstrated echogenic specks at either end of the endometrium in longitudinal section, and in cross-section specks were noted within the lateral walls of the uterus. It was queried whether these represented the arms of the IUS. The patient was then referred to the gynaecology department, for consideration for operative hysteroscopy to remove the retained arms.

A 50-year-old woman presented to the colposcopy clinic with moderate dyskaryotic smears. She had undergone two previous large loop excision of the transformation zone (LLETZ) procedures for cervical intraepithelial neoplasia (CIN) with complete excision at each. On this occasion colposcopy examination was limited because of unsatisfactory views of the squamo-columnar junction. It was decided the patient would have a further LLETZ treatment with removal and reinsertion of the Mirena IUS under general anaesthesia.

At the time of the procedure it was noted that the IUS threads were visible and the internal cervical os was tight. Again more traction than usual was required on the threads to remove the device. On inspection it was thought that the arms had become detached; the long stem of the device with the hormone release capsule present was attached to the threads. A saline hysteroscopy was therefore performed to locate the IUS arms. Good views of the entire cavity failed to demonstrate the presence of IUS pieces or perforation. The LLETZ procedure was performed and a new IUS inserted. The patient underwent an uneventful post-operative recovery.

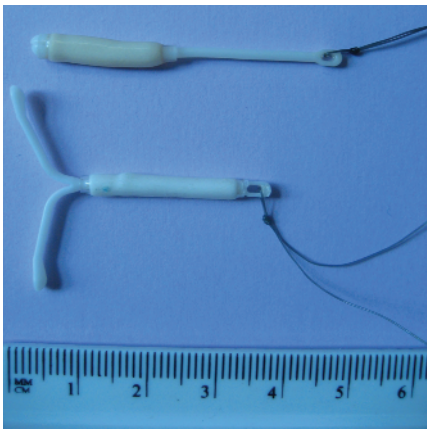

Figure 1 The intrauterine system (IUS) shown in the upper part of the photograph has been removed entirely but its appearance is atypical. The IUS in the lower part of the photograph has a normal appearance

In both cases, when the removed IUS was re-examined, it became apparent that the entire device had been removed from the uterine cavity. The arms were still attached to the main stem of the IUS. The hormone release capsule, usually situated at the base of the vertical stem, had migrated up the shaft, trapping the arms and bringing them together in the midline, making it appear as if they had been detached (Figure 1).

The majority of IUS are removed without difficulty. There are no published cases of IUS arms becoming detached. However, an intrauterine-retained hormone release capsule following IUS removal has been documented.[1]

The common theme in the two patients described above and Forrest *et al*.'s patient[1] is difficult retrieval of the device requiring more traction on the threads than normal. This presumably led to the hormone capsule being dislodged, either migrating up the device and getting stuck covering the arms or becoming detached altogether. Clinicians should always check IUS devices after removal. They should also be aware that after a difficult removal the capsule can migrate and obscure the arms but the device remains complete. Knowledge of this possibility will prevent patients being subjected to unnecessary investigations and interventions to find 'missing' IUS arms and for appropriate investigations and interventions when the capsule has detached completely.

The whole of the IUS device is radio-opaque and can be located with either X-ray or ultrasound.[2] Transvaginal ultrasound is the first-line investigation because it provides the best images to help determine whether or not the IUS is correctly sited within the uterus. The vertical stem of the IUS is visualised in the sagittal plane with multiple reflective parallel planes and in the axial plane as a single echogenic focus.[3] However, in the cases reported here the vertical stem was missing. Horizontal arms are rarely seen in the uterus unless it is possible to obtain a coronal view.[3] In view of this difficulty abdominal X-ray would confirm whether or not the horizontal arms of the IUS were within the pelvis. This would be useful, especially prior to embarking on hysteroscopic investigation.

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Reply

We would like to take the opportunity to respond to Dr Torbe *et al*.'s letter.[1]

Extremely rare, isolated case reports of hormone cylinder dislocations in the Mirena® intrauterine system (IUS) similar to the ones described by the authors have been received by the company's Pharmacovigilance and Quality Assurance Unit. The company's investigations have shown that these cases could not be attributed to a quality defect of the product. Difficult removal has been found as the underlying cause, and no further adverse effect in the Mirena user are mentioned in the majority of cases.

To make physicians aware of this extremely rare situation, and to avoid unnecessary interventions in search of 'missing' Mirena arms, the company has recently introduced the following statement into the Core Safety Information for Mirena: "After removal of Mirena®, the system should be checked to be intact. During difficult removals, single cases have been reported of the hormone cylinder sliding over the horizontal arms and hiding them together inside the cylinder. This situation does not require further intervention once completeness of the IUS has been ascertained. The knobs of the horizontal arms usually prevent complete detachment of the cylinder from the T-body".

Implementation of this statement into the local product information is currently ongoing in all countries where Mirena is marketed, and it was submitted at the beginning of December 2008 to the Medicines and Healthcare products Regulatory Agency (MHRA) to be implemented in the UK.

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Serious morbidity with long-term IUD retention

We have recently encountered four patients with serious intraperitoneal sepsis over an 18-month interval (2007/2008). Each was associated with long-term retention of a copper intrauterine device (IUD), which was identified as the likely source of infection. The IUDs had been *in situ* for 8, 15, 18 and 20 years, respectively. Three women were several years into their menopause. All four women presented as systemically unwell with a complex pelvic mass. One had ureteric obstruction at the site of the abscess, simulating gynaecological malignancy. In all cases laparotomy was technically difficult owing to the inflammatory pelvic mass adhering to bowel. Intermediate or prolonged hospitalisation resulted and, without intensive care, two of the women would probably have died.

Pelvic actinomycosis was reported in the two patients' histology. Cultures of frank pus grew *Actinomyces* sp. in a third. Actinomyces-like organisms (ALOs) had been reported on the last smear of the fourth woman. In 2004 she had undergone appendicectomy, which showed