

priority even if his routine clinical work is severely disrupted as a result.

- ¹ Adhikary, H P, Taylor, P, and Fitzmaurice, D J, *British Journal of Ophthalmology*, 1976, **60**, 717.
- ² Duke-Elder, S, *System of Ophthalmology*, vol 9, p 558. London, Henry Kimpton, 1966.
- ³ Neubauer, H, *Transactions of the Ophthalmological Societies of the United Kingdom*, 1975, **95**, 322.
- ⁴ Coleman, D J, Konig, W F, and Katz, L, *American Journal of Ophthalmology*, 1969, **68**, 256.
- ⁵ Machemer, R, Parel, J-M, and Buettner, H, *American Journal of Ophthalmology*, 1972, **73**, 1.
- ⁶ Peyman, G A, *et al*, *Acta Ophthalmologica*, 1975, **53**, 427.
- ⁷ Bronson, N R, in *Practical Management of Ocular Injuries*, ed S A Boruchoff, p 129. Boston, Little Brown, 1974.

Magnetic device to make colostomies continent

Probably no fewer than 100 000 persons in Britain have a permanent colostomy. Surgeons have often tried to render colostomies continent by various technical manoeuvres at operation; all proved unavailing, and it came to be accepted that a colostomy was inevitably an incontinent opening. Fortunately in most cases its uncontrollable activities could be dealt with satisfactorily by modern methods of management with adherent plastic bags or irrigation.¹

Then in 1974 Feustel and Hennig² of Erlangen invented a magnetic device designed to confer continence on standard iliac colostomies. A ring of samarium-cobalt (which is highly magnetic), encased in a plastic covering, is buried in the subcutaneous tissues of the abdominal wall around the emerging colon. Five or six weeks later, when the colostomy wound has soundly healed, a plastic cap with a spigot, both of which also contain cobalt, is fitted on to the colostomy, being held firmly in place by the magnetic attraction between the cobalt in the ring and that in the cap and spigot. To ensure a more secure fit, and at the same time allow flatus to escape gradually (and in a socially acceptable, relatively nonodorous way without the inconvenience of having to lift the cap off temporarily), a special charcoal filter-washer is worn between the cap and the skin. When necessary for evacuating faeces from the bowel the cap is removed and the stoma allowed to empty itself into the lavatory or a kidney dish. Alternatively, and perhaps preferably, the cap may be replaced by an adherent colostomy bag during the hour or two when experience has shown that the colostomy normally acts, or during the night and early morning till the colostomy action is over.

Early visits to Erlangen by surgeons suggested that patients provided with magnetic rings were satisfied with the results, and several hundreds have now been implanted—as either primary or secondary procedures—in different hospitals throughout Germany. But a more cautious note has been struck in the latest report from Erlangen,³ from which it appears that only 31% of the 74 patients given magnetic rings up to April 1976 have secured worthwhile continence. Nevertheless, of a further 17 patients operated on since that date 13 were considered on review to be continent. The better results in the latter cases were attributed to more careful selection of patients and greater skill in the construction of the magnetic colostomies.

More limited collective experience with the magnetic ring colostomy device in several centres in Britain during the past

12 months (see p 1269) has confirmed the paramount importance of case selection and of attention to the technical details of the operation if reasonable results are to be obtained. Certain cases are quite unsuitable for a magnetic type colostomy—and they may perhaps amount to half or more of patients having abdominoperineal excision. The device is not to be recommended for patients who are obese (with over 2.5-3.0 cm of subcutaneous fat); those who have a scar or roll of skin and fat in the region where the colostomy will be sited, making it difficult to provide a smooth flat surface against which to place the cap; and those who are unfitted mentally on account of advanced age or cerebral arteriosclerosis to learn to cope with the device. Furthermore, the construction of a colostomy incorporating a magnetic ring calls for a painstaking operative technique in some ways comparable with that employed in making an ileostomy.

The colostomy appliance firm of Coloplast International, which is now responsible for marketing the magnetic device under the name of the Maclet system, has exercised commendable restraint in not releasing this equipment to the general surgical public till the special problems and results of magnetic colostomies had been more objectively assessed by a pilot study in Denmark, Sweden, and Britain. Clearly this type of colostomy is not for every patient, nor probably for every surgeon at present. Surgeons attracted to the operation would be wise to see it performed elsewhere before undertaking it themselves or at least view the film prepared by Coloplast.

¹ Walker, F C, ed *Modern Stoma Care*. London, Churchill Livingstone, 1976.

² Feustel, H, and Hennig, G R, *Deutsche medizinische Wochenschrift*, 1975, **100**, 1063.

³ Hager, T, *et al*, Report to International Society of University Colon and Rectal Surgeons, 6th International Congress, Salzburg, September 1976.

Randomised clinical trials

The only purpose of randomising patients in clinical trials is to obtain a result that is free from bias. In certain circumstances some may think that bias, such as the unwitting allocation of healthier than average patients to a new treatment, is unlikely to have arisen—for example, in studies performed in a single centre with stable patterns of patient referral and consistent medical record keeping. Certainly many advances, such as penicillin and insulin, have been introduced without the use of randomised clinical trials (RCTs). Much of the pioneering work on the treatment of childhood leukaemia carried out by Pinkel and his colleagues¹ was based on the use of historical controls, and high-dose radiotherapy and combination chemotherapy were introduced as treatments for Hodgkin's disease largely without using RCTs.^{2 3}

Provided that the main sources of bias can be recognised and avoided, and provided that the benefits of a new treatment are expected to be so striking that it would seem inconceivable that bias alone might have accounted for them, non-randomised trials are acceptable, although some would justifiably argue that little is lost by randomising.⁴ If either condition is not met, and in practice this is likely to be so, doubt will remain about whether bias or treatment caused any apparent therapeutic benefit. In such circumstances there is no satisfactory alternative to the RCT. Some procedures that were used for many years before being judged to be valueless, such as portocaval surgery for treating portal hypertension, might never have been accepted if they had first been tested by RCTs.