this follow-up study confirm these contentions in the vast majority of patients.

Summary

A series of 138 patients have been reviewed for an average of just under five years after haemorrhoidectomy by the ligature-and-excision method.

Recurrence of haemorrhoids sufficient to cause symptoms was noted in seven (5%). Three required subsequent injections, but none needed further operation.

Anal stenosis, sufficient to prevent the passage of a proctoscope of $\frac{1}{4}$ -in. (2-cm.) diameter, but allowing an ordinary digital examination of the rectum, was present in 6 patients (4%). In the other 132 patients proctoscopy with a full-sized instrument was unimpeded.

Minor defects of anal control occurred in 26% of patients, consisting of impaired continence for flatus (9%) or faeces (6%), or of frequent soiling of underclothes

(17%). Sometimes more than one defect was present in the same patient.

A total of 128 patients were highly pleased with the result of the operation, and the other 10 had only minor reservations regarding their satisfaction with the outcome.

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TREATMENT OF "REFRACTORY OBESITY" WITH "FORMULA DIET"

BY

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The difficulty of securing a satisfactory and lasting reduction of weight in obese patients is reflected in the use of so many and varied dietary regimens. Despite these, a considerable number of obese out-patients fail to lose weight on subcaloric diets. Such patients we have defined previously as having "refractory obesity" (Duncan *et al.*, 1960), and they form an admirable group for evaluating any new weight-reducing diet or drug.

Recently, powdered food preparations, or "formula diets," have been introduced for the treatment of obesity. It was hoped that by replacing the patient's usual cooked and appetizing meals with a palatable but satisfying drink of known caloric value the patient would be less tempted to overeat.

We report the results of a 12-weeks trial of one of these preparations in a group of patients having refractory obesity.

Methods and Materials

Forty-six women, mostly middle-aged housewives, were chosen, all of whom (1) were clinically obese and with one exception overweight by at least 20% of their ideal weight (U.S.A. Medico-Actuarial Investigation, 1912); (2) had attended the dietetic out-patient department throughout the previous year and had not responded satisfactorily to the prescribed conventional diet containing 900–1,400 calories; (3) had not lost weight significantly in the three months before the trial; and (4) were not known to have any cardiac disease and had no clinical evidence of oedema.

Fifteen were mild diabetics who required neither insulin nor oral hypoglycaemic drugs and showed only minimal and occasional postprandial glycosuria.

Nine patients did not complete the 12-weeks trial. Two of these went on holiday, one became oedematous, one developed an acute exacerbation of peptic ulcer symptoms, and two were unwilling to continue because of nausea or severe constipation; three made little or no attempt to follow the recommended regimen and ate large quantities

of ordinary foods, but their failure could have been predicted from previous knowledge of their personalities.

The relevant data of the 37 patients who completed the twelve-weeks trial are set out in Table I. Most had taken part in previous trials of phenmetrazine and methylcellulose (Duncan *et al.*, 1960) and/or diethylpropion (Seaton *et al.*, 1961), but none had taken any anorectic agents in the year prior to the present study.

The Product.—Each $\frac{1}{2}$ -lb. (227-g.) tin of formula diet, containing 70 g. of protein, 20 g. of fat, and 110 g. of carbohydrate, provides about 900 calories. The preparation is fortified with various vitamins and minerals and is supplied in several flavours—plain, vanilla, butterscotch, orange, and chocolate. It is prepared for use by adding about 2 pints (1,140 ml.) of water to the contents of one tin and stirring to obtain a smooth mixture. This provides four large glassfuls, each of which replaces a main meal.

Conduct of the Trial.—The purpose of the study was explained to all patients about one month before it was started. They were asked initially to try to eat nothing but the formula diet but were allowed water and other non-caloric drinks to satisfy thirst. If they could not adhere to this strict regimen they were to be permitted, in addition to the formula diet, small quantities of low-calorie foods and drinks, a list of which was supplied to them. They were warned that constipation might occur and were asked to take a simple aperient if necessary.

Each reported at fortnightly intervals for 12 weeks, and was weighed in almost the same indoor clothing, interviewed by one of us, and given two weeks' supply of formula diet in the flavours preferred. The degree of adherence to the recommended regimen was ascertained (formula diet alone, formula diet plus permitted foods, formula diet plus prohibited foods). Because the patients knew the doctors well they freely confessed when they had eaten prohibited foods and gave their reasons. They were catechized regarding the occurrence of side-effects due to the diet, such as constipation.

Results

Stunkard and McLaren-Hume (1959) reviewed the vast literature on the treatment of obesity; they considered that only eight reports gave sufficient detail of individual patients for the effects of therapy to be properly evaluated. Because of this criticism the required data of the 37 patients who completed the 12-weeks trial are set out in Table I.

Only 5 of the 37 patients were heavier at the end of the study than at the start. The other 32 lost an average of 14.9 lb. (6.76 kg.).

Table I shows also that only 10 patients were able to adhere to the formula diet alone for the first two weeks; 10 had started to take low calorie foods and 17 had already taken prohibited foods. However, the will-power and enthusiasm of these first two groups rapidly waned, and all but two patients were taking prohibited foods by the end of 10 weeks.

Table II sets out the mean weight loss in each two-weekly period of the three groups of patients who were at that time taking the formula diet only, formula diet and permitted low-calorie foods, or formula diet and prohibited foods. In all groups the rate of weight loss in general declined with time and less weight was lost by those taking prohibited foods than by those avoiding them.

Side-effects.—Apart from constipation, about which direct questions were asked, the other side-effects were attributed spontaneously to the formula diet by the patients and are recorded in Table III. All of the 46 patients who

TABLE III.—*Side-effects Attributed to the Formula Diet by 46 Patients*

Side-effect	No. Affected	Side-effect	No. Affected
Hunger	5	Vomiting	2
Sleepiness	1	Constipation	19
Nausea	6	Lassitude	2

started the trial are included in this table; as two failed to complete the trial period because of severe nausea and constipation it would be artificially favourable to the product to exclude those patients. In all other patients the side-effects were not troublesome except for constipation, for which 12 of the 19 patients so affected required medication.

Discussion

All patients selected for this study had failed to lose weight on conventional subcaloric diets despite regular supervision and encouragement. Thus the formula diet was subjected to a severe test in respect of, firstly, the capacity of the patients to adhere to it, and, secondly, its efficacy as a reducing diet.

TABLE I.—*Data on 37 Patients who Completed 12-weeks Trial of the Formula Diet*

No.	Age (Yrs.)	Weight (lb.)				Excess Weight (%)	Progressive Weight Change in lb. (Weeks)						Total Weight Change (lb.)	Weight Change (% Excess)	Final Weight (lb.)	Weight 1 Year After (lb.)
		Ideal	3 Months Before	At Start	Excess		2	4	6	8	10	12				
3	65	138	196	198	60	43	-7	-2	-1	0	0	-2	-12	-20	186	200
5	47	138	196	212	74	54	-11	-6	-4	-2	-1	-1	-25	-34	187	210
6	46	144	244	244	100	69	-6	0	-3	-2	+2	0	-9	-9	235	238
7	68	144	201	203	59	41	-6	-2	-2	-1	-2	-3	-16	-27	187	Died
8	52	143	180	183	40	28	-9	-6	-4	0	-1	-1	-21	-53	162	191
9	65	130	174	182	52	40	-6	-2	-1	-5	0	-4	-18	-35	164	191
10	65	138	183	189	51	37	-7	-3	-4	-1	0	-3	-18	-35	171	197
11	34	132	248	262	130	99	-14	-11	-2	+1	+1	-2	-27	-21	235	Not traced
12	65	141	208	210	69	49	-9	-5	0	-1	-4	+2	-17	-25	193	215
13	30	127	210	208	81	64	-7	-12	-1	-3	+2	-5	-26	-32	182	Not traced
14	58	144	233	238	94	65	-5	0	-3	+2	-3	-3	-12	-13	226	242
15	45	151	203	211	60	40	-5	-3	-2	-4	-1	-2	-17	-28	194	200
16	59	141	188	192	51	36	-4	-3	-4	0	+1	-1	-11	-22	181	198
17	54	138	198	203	65	47	-7	-7	-11	-7	-4	-4	-40	-62	163	201
18	44	163	335	333	170	104	-4	-2	-2	-2	-7	+4	-13	-8	320	302
19	60	138	185	178	40	29	+1	+2	0	+1	0	+1	+5	+13	183	196
20	65	129	180	184	55	43	-7	-1	0	0	0	-1	-9	-16	175	150
21	67	135	188	187	52	39	-4	-3	+1	-4	0	-2	-12	-23	175	182
22	64	138	205	208	70	51	-7	+1	-8	-4	0	-2	-20	-29	188	207
23	57	140	225	228	88	63	-6	-6	-1	0	0	0	-13	-15	215	227
24	52	137	220	218	81	59	-2	-2	-4	-2	+1	-1	-10	-12	208	220
26	57	153	211	209	56	37	-1	-5	-1	-2	-3	0	-12	-21	197	225
27	52	137	166	173	36	26	-6	-4	-2	-2	-4	+1	-17	-47	156	171
28	49	135	258	270	135	100	-4	+1	-1	-2	+1	-1	-6	-4	264	272
29	61	133	175	175	42	32	-5	-1	-1	0	0	0	-7	-17	168	180
30	54	152	188	187	35	23	-2	-4	+6	-1	+1	+1	+1	+3	188	189
31	66	142	181	190	48	34	-9	-6	-3	-6	-2	-5	-31	-65	159	158
32	60	142	196	192	50	35	-6	-2	-5	-1	+4	0	-10	-20	182	192
34	35	127	224	230	103	81	-9	-1	-2	-1	0	0	-13	-13	217	230
39	60	141	182	187	46	33	+1	0	+1	+2	0	0	+4	+9	191	176
40	54	133	168	168	35	26	-4	0	-1	+1	-3	+2	-5	-14	163	162
41	65	134	167	163	29	22	-3	0	0	+3	-2	0	-2	-7	161	161
42	65	134	172	172	38	28	-3	+3	+1	-1	+1	-2	+1	+3	173	191
43	49	126	147	147	21	17	-4	-3	0	-3	-1	+4	-7	-33	140	144
44	58	127	205	205	78	61	-4	-3	-1	-2	-2	-1	-13	-17	192	197
45	42	128	190	187	59	46	+3	-2	+1	+1	0	+3	+6	+10	193	188
46	59	154	219	220	66	43	-4	-3	-1	-1	0	0	-9	-14	211	252
Mean	56	139	201	204	65	47	-5.3	-2.8	-1.7	-1.3	-0.7	-0.8	-12.5	-20.4	192	202

Progressive weight change: Bold figures = Formula diet alone. Italic figures = Formula diet + permitted foods. Ordinary figures = Formula diet + prohibited foods.

TABLE II.—*Weight Loss of Patients Adhering to the Three Regimens as Estimated at Intervals of Two Weeks*

Two-weekly Periods	Formula Diet Alone			Formula Diet + Permitted Foods			Formula Diet + Prohibited Foods		
	No.	Weight Loss (lb.)	Average Loss (lb.)	No.	Weight Loss (lb.)	Average Loss (lb.)	No.	Weight Loss (lb.)	Average Loss (lb.)
1	10	75	7.5 (-4 to -14)	10	69	6.9 (-4 to -11)	17	48	2.8 (+3 to -6)
2	5	32	6.4 (-3 to -11)	10	42	4.2 (0 to -12)	22	29	1.3 (+3 to -5)
3	2	19	9.5 (-8 to -11)	8	26	3.3 (-1 to -5)	27	20	0.74 (+6 to -4)
4	2	11	5.5 (-4 to -7)	2	9	4.5 (-3 to -6)	33	27	0.82 (+3 to -5)
5	1	4		1	2		35	20	0.57 (+4 to -7)
6	1	4		1	5		35	19	0.54 (+4 to -5)

Although nearly all the patients found the formula diet to be palatable, they succumbed, sooner rather than later, to the temptation to eat substantial amounts of prohibited natural foodstuffs; when they did so, effective weight loss ceased more or less. Nevertheless, those who persisted with the formula diet alone or supplemented by permitted low-calorie foods only, lost weight at the expected rate of 2 to 3 lb. (0.9 to 1.4 kg.) each week.

The results of this study may justifiably be compared with those of previous trials in which the same or similar patients, all having refractory obesity, were treated with anorectic agents. After taking the formula diet for eight weeks the 37 patients studied had lost an average of 11.1 lb. (5 kg.) in weight; in contrast the mean weight loss was only 3.1 lb. (1.5 kg.) for 40 patients treated with diethylpropion (Seaton *et al.*, 1961) and 4.2 lb. (1.9 kg.) for 85 persons given phenmetrazine (Duncan *et al.*, 1960) over the same period of time.

The use of powdered "formula diets" has been condemned on several grounds. The criticisms that it may cause major psychological disturbances or, when taken for long periods of time, nutritional deficiencies are scarcely justified (Antos, 1959; Roberts, 1960; Tullis *et al.*, 1960). Nevertheless, a formula diet does not help to establish proper dietary discipline and habits, and this study has confirmed the view that the majority of patients again put on excessive weight on resuming a natural though supposedly restricted diet (Table I).

Formula diets would seem to have a limited place in the treatment of obese persons for whom conventional subcaloric diets have been ineffective. As loss of weight was greatest in the first few weeks only, short-term therapy may be justified though repeated courses may be necessary. Low-calorie foodstuffs do not materially influence the rate of weight loss and can be allowed in restricted amounts as they make the diet more acceptable.

Summary

A twelve-weeks trial of a formula diet in the treatment of 46 women having "refractory obesity" is reported.

Of the 37 patients who completed the study, 32 lost weight. The mean loss was much greater than that achieved by anorectic agents in similar patients.

Nine patients failed to complete the trial period and 33 of the remaining 37 admitted taking prohibited natural foods before the end of eight weeks.

Low-calorie foods make the diet more acceptable, do not greatly influence weight loss, and should be allowed in restricted amounts.

One year after completion of the trial most patients had regained their original weight while on conventional subcaloric diets.

Our results suggest that a formula diet should generally be given for periods of a few weeks only and repeated as required.

We are grateful to Sir Derrick Dunlop for his encouragement and advice and to the patients who so willingly co-operated in this study. Our thanks are also due to Mrs. R. McMillan for considerable secretarial assistance. The formula diet used in this trial, "metercal," was supplied through Dr. A. O. Zink, of Mead Johnson Limited.

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AN XX HERMAPHRODITE WITH MALE SOCIAL SEX

BY

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The chromosome complement in several hermaphrodites is now known. A simple XX sex chromosome arrangement was reported by Hungerford, Donelley, Nowell, and Beck (1959); Harnden and Armstrong (1959); de Assis, Epps, and Bottura (1960); Sasaki and Makino (1960); and Gordon, O'Gorman, Dewhurst, and Blank (1960). Ferguson-Smith, Johnston, and Weinberg (1960) reported two further cases with a probable XX complement although, in each, additional chromosome material was found in some of the cells examined. Sandberg, Koepf, Crosswhite, and Hauschka (1960) reported briefly one case whose karyotype was XY. XY/XO mosaics in whom there is some histological support for the diagnosis of hermaphroditism have been described by Hirschorn, Decker, and Cooper (1960) and Miller (1961). A further mosaic not yet fully elucidated has been described by Waxman, Kelley, Gartler, and Burt (1962).

More information is known about the nuclear chromatin state in hermaphrodites since Grumbach and Barr (1958) reported on a group of 25 such patients, 19 of whom were

chromatin-positive and six chromatin-negative; it is not, however, known if these patients had a simple XX and XY sex chromosome complement respectively. In order that a more complete picture may be obtained of the chromosome complement in these cases we believe it to be important to report others in whom full investigation has been possible. We describe here a further case of a hermaphrodite with an XX sex chromosome complement.

Case Record

A 40-year-old married man presented himself for treatment of a right inguinal hernia on March 16, 1962. In October, 1961, he had been found to be diabetic and was receiving 36 units of insulin zinc suspension daily. At the time of the investigation into his diabetes he was recognized as having a genital deformity about which he was so sensitive that he failed to keep a further appointment at which it was hoped to investigate this aspect of his case. For this reason he was not questioned further about his marital relationship at the time of admission for the hernia operation. Neither he nor his wife volunteered any further information about the matter, and it