In spite of the authors' excellent results, this study and those of others must still be regarded only as interval reports. It still must be learned how well these patients will fare in the future. In addition, new approaches need to be pursued. The wrapping procedure of Wilkinson and Peloso³¹ deserves further testing, although the early failure rate of 10% and the requirement for a large mass of foreign body are worrisome. It is, however, important, no matter what the approach, that uniform methods of reporting results be adopted and that the new operations are tested against the accepted procedures with prospective controlled blinded studies.

The reason for the superiority of the gastric bypass is probably due to the exclusion of the antrum and duodenum. Because the size of the gastric pouches and the characteristics of the anastomosis were the same in both operations, the difference should be due to interference with the neural, hormonal and enzymatic mechanism of the proximal gut. Little information on these matters is available at present. Both the fasting and postprandial levels of gastrin are reduced in patients after gastric bypass according to Shamos and associates, 32 but Huseman, 33 in contrast, found no significant changes. Villar and his associates³⁴ have shown striking alterations in the motility of the fundus after both gastric partition and bypass. Comparison of the two hormonal mileaus produced by these two operations should be a fruitful area of gastrointestinal endocrine research.

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DISCUSSION

DR. EDWARD E. MASON (Iowa City, Iowa): This is a well-designed, double-blind, randomized, prospective study that shows that a gastroenterostomy is better than a gastrogastrostomy when an 8 mm stoma is created with two rows of running, locked 3.0 monofilament polypropylene sutures. A small gastrogastrostomy, so sutured, is predisposed to develop early obstruction, because of the edema and inflammatory reaction, and late dilatation because the sutures are then

lost into the lumen. Some of the same loss of suture and dilatation of the stoma occurs with the Roux-en-Y gastric bypass, but it is less apparent because the Roux-en-Y gastric bypass provides other mechanisms for weight control besides the small pouch and a small stoma.

If we are to find a simpler operation than gastric bypass, what is needed is a nontraumatized, nonsutured, nonobstructed 11 mm diameter stoma that will not change in size, and is separated from the stapled partition by a well-healed divided stomach wall. (slide) You need to keep the stoma out of the zipper.

Let me illustrate how such a stoma was created, beginning seventeen months ago. This has now been used in 76 patients at the University of Iowa.

Vertical-banded gastroplasty, as this has been termed, has eliminated the early obstruction and late dilatation, and has produced a weight loss comparable with Roux-en-Y gastric bypass in our historical controls

I hope that Dr. Pories and others will repeat this study and use the vertical-banded gastroplasty instead of gastrogastrostomy. If he does, I would predict that he will find that the bypass of the stomach is not necessary. My interpretation of all the different results seen by all of us is that they are caused by the rather simple technical details in the performance of the operation.

(slide) So far, a comparison of the vertical-banded gastroplasty shows weight loss at six months and at 12 months, which is much better than with a horizontal gastroplasty, in which a nonabsorbable suture is used to reinforce the outlet. The weight loss with vertical banded gastroplasty is comparable with the weight loss seen with either a loop or a Roux-en-Y gastric bypass. We have eliminated so far the necessity for reoperation, and the course of these patients is excellent.

(slide) We are not having the problems with early obstruction that are present with all of the other forms of gastroplasty, gastrogastrostomy, or nonbypass gastric reduction operations.

DR. EDWARD R. WOODWARD (Gainesville, Florida): The variety of procedures being tried in bariatric surgery attests to the uncertainty as to the best operation. Controlled clinical experimentation gives us facts upon which to base a logical decision.

We too have noticed a greater weight loss with gastric bypass. Weight loss in the gastric partition patient levels off at six months, whereas the bypass patient continues to lose until 18 months.

We can confirm also the striking difference in behavior of the two anastomoses. Gastrogastrostomy tends to stenose early, usually at about three weeks. We have found it possible to dilate these endoscopically using a balloon catheter. On the other hand, gastrojejunostomy tends to remain patent. Unfortunately, gastrogastrostomy also tends to dilate later, usually three to six months. This probably accounts for the relatively high failure rate. Late dilatation seems to much less frequent with gastrojejunostomy.

Gastric bypass has an element of malabsorption to the restricted food intake, and this probably accounts at least in part for the increased weight loss. Failure of ingested fat to promptly mix with bile salts interferes with micelle formation with a resultant relative steatorrhea.

This impressive study implies strongly that gastric bypass should be seriously considered in the morbidly obese patient in whom maximal weight loss is medically indicated.

DR. WALTER J. PORIES (Closing discussion): Concerning Dr. Wylie's thoughtful questions about whether we tested for rennin levels in these patients, we have not done that, but I assure you we will.

I agree with Dr. Moody about the importance of a study group. His second question is particularly important. How do we follow up these patients? I don't think you can do this all by yourself. It takes a team. It takes a good team of dedicated people to track patients and to make sure you get good follow-up.

As you may have noticed, the number of patients listed in the abstracts is one less than the numbers reported here. This discrepancy is explained because we thought we had lost one patient and his chart forever. We finally recovered it between the time of submitting the abstract and today. We were delighted to put it back. So follow-up is difficult and hard.

I agree with Dr. Woodward that patients with gastric bypass develop some degree of malabsorption, but it seems to be well tolerated, far better than the malabsorption of intestinal bypass.

We are obviously interested in looking at a variety of new operations because this is still a new surgical approach. Our length of follow-up so far is 18 months, and more time is needed, perhaps years. Perhaps vertical-banded gastroplasty and other procedures will prove better. I do hope that we will, with each new approach, continue to do prospective controlled studies.

My associate, Dr. Flickinger, who is in the audience, has evaluated

a number of anastomoses with the endoscope. We did see some enlargement on the gastrogastrostomies and none so far on this version of the gastric bypass; but again, the time of observation is still brief. I believe that Dr. Mason is correct: some of the sutures may cut through and disappear.

We are interested in the intragastric balloon that Dr. Forrest mentioned, and I doubt that it will be successful, if our thesis is correct. Dr. Forrest, there is an extensive literature on the increase in estrogen levels in obese patients. There are several studies now in the NCI that are examining the influence of these estrogens on various cancers. I will be glad to share this literature with you, Dr. Forrest.

DR. LLOYD D. MACLEAN (Montreal): We are not accustomed to randomized trials very often in this area, and I would like to report on a small series that I have followed personally. It is only 117 patients, but I do have 100% follow-up; there was one late death in this group, but I do have to admit that in these 117 patients I have done 165 operations, and not all of them are even as yet close to thinness.

I have been impressed with the importance of orifice size as the determining factor of success, and to support that, in 59 of these patients the orifice on endoscopy done at three-month intervals over the first year was less than 10 mm, and remained so for at least that 12-month period. In 58 of the 59 patients there was at least a 25% weight loss at one year; and I like and I agree with Dr. Pories' classification of success. It was as high as 50%, and was not related to gastric bypass or gastroplasty, as long as that orifice remained small.

In contrast, in only eight of 42 patients who had an orifice larger than 10 mm during the first postoperative year was a 25% weight loss achieved. It is of interest that in four out of the eight it was gastric bypass that had been done.

(slide) This is an operation that we thought would ensure against dilatation: 18-gauge catheter, circumferential, nonabsorbable proline suture, with Teflon® reinforcement at the staple line level. Followed after two years, the enlargement in this group is well over 30%, and is no longer effective.

(slide) This led us to doing this kind of operation. I believe Dr. Mason is the first one to say that a nonsutured envelope around the anastomosis is important, and this is what we have done in two kinds of operations over the last 15 months or so.

There is a gastrostomy here, with a running anastomosis and a silicone tubing put through behind. You can see that, at staple line, when we put the staples on simultaneously, we leave a space behind there through which one can slip a silicone tubing, which this is supposed to show, and we tighten that anastomosis down on an 18-gauge catheter.

(slide) We also do the same thing with a gastric bypass procedure, and have the silicone tubing around that as well.

(slide) I would like to make a point that we should express our results in some way in which we can compare what is happening, and I liked Dr. Pories' presentation in this regard as well. We would consider a good result a patient who lost greater than 25% of preoperative weight, and is within 30% of ideal, because it is at that point that patients start to have physical problems from obesity. A satisfactory result is a weight loss greater than 25% but not within 30% of ideal, and an unsatisfactory result a weight loss less than 25% of preoperative weight.

I have two or three questions I would like to ask. Does he have data on endoscopic orifice size in the two groups at one year?

Secondly, is there any late weight gain, and is this related to an increase in orifice size? And I suppose you did show that there was a failure in the partition group, and I would like to know what those orifices looked like, if you know that. And does gastric bypass have a wider tolerance zone for orifice size than gastroplasty, which I think is really quite limited? The operation has to end up somewhere between 5 and 10 mm, and it has to stay there if you are going to get a good result, in our experience.

DR. KENNETH G. SWAN (Newark, New Jersey): I have a question regarding the graphic presentation of the per cent weight loss, which was on the ordinate against time on the abscissa. You had indicated that with the gastric partition procedure there was a plateau that was

not seen with the gastric bypass, and at 18 months the former continued to fall.

Theoretically, it would have to stop somewhere, otherwise there would be some dangers involved in that operation (gastric bypass). Can you tell us when that plateau does occur?

DR. FRANK G. MOODY (Salt Lake City, Utah): Dr. Pories has presented very strong evidence that gastric bypass, indeed, is superior to gastric partitioning for weight reduction in patients with chronic morbid obesity.

When I entered this field a couple of years ago, that was not at all clear, but the evidence now is certainly very strongly in favor of that.

We selected the lesser procedure because we wanted to study why people developed this problem in the first place, and we felt that if one is going to do preventive or prophylactic surgery, you had better have an operation that is absolutely safe, or, at least, as safe as you can get it.

For that purpose, then, we did a double staple line gastric partition, 50 ml pouch, 20 cm water, 1 cm opening on the greater curve, as judged by the passage of a no. 10 Hagar dilator, snugged up around with vertical sutures, but no circumferential suture.

I surrounded myself with a variety of professionals to tell me what was going on, and we learned very quickly that these particular pouches empty normally. They empty liquids rapidly, so they are not obstructive. We also learned from nutritionists that they lose fat. They lose some protein initially, but then gradually the bulk of their weight loss is in fat.

We also learned they had to be on a 600-calorie diet, or at least a low 800-calorie, in order to gain a significant amount of weight loss. We also learned from the nutritionists that, as a function of time, they began to increase their intake up to around 1000 to 1200 calories, and then started to fail to lose weight.

(slide) In the 244 cases that we have studied thus far, we have a male-female ratio of 5:1. This operation tends to work quite well in the male, for reasons that are not quite clear to us, but, you notice,

the males are a little bit heavier. And I noticed that you had a little bit heavier patients in one of your randomized groups that you might comment upon.

The males are heavy eaters—we call them "gorgers"—one or two large meals a day. The females tend to eat a little bit all day long; so possibly that is the difference.

We had no mortality in this group, and rather minimal morbidity. So at least we did accomplish the safety part of the procedure.

(slide) But the tailing off is as you see it here at the end of a year. This is 70 lbs, 50% of the excess weight lost in this particular population

My question relates to the fact that we had a devil of a time following these people, for whatever reason, even with the army of people I had involved in the study. So I might ask Dr. Pories, how did he conduct his follow-up?

In addition, did they study caloric intake? Were the intakes the same in both populations, so that, indeed, he could support his thesis that the reason patients with gastric partition tend not to lose much weight, and maintain weight loss, is that they have their antrum and their duodenum intact?

PROFESSOR A. PATRICK M. FORREST (Edinburgh, Scotland): A recent report in the British literature (Taylor TV, Pullan BR. Gastric balloons for obesity. Lancet 1982; i:750.) described the use of an intragastric balloon, which was inflated through an endoscope and formed a 'bezoar.' It was reported as giving good initial weight loss. Have you had any experience with this method?

If it does lead to weight reduction, it goes against your thesis that antral and duodenal exclusion is an important factor in gastric partitioning.

Secondly, may I enquire about the evidence for your statement that the incidence of carcinoma of the breast, stomach, and uterus is increased in morbidly obese women and that circulating oestrogens are increased. Presumably, this is a result of enhanced peripheral aromatization of steroids as a result of the increased bulk of fat?