

# *Intraoperative Determination of Small Intestinal Viability following Ischemic Injury*

## *A Prospective, Controlled Trial of Two Adjuvant Methods (Doppler and Fluorescein) Compared with Standard Clinical Judgment*

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Two adjuvant techniques for the intraoperative assessment of small intestinal viability were compared with standard clinical judgment in a prospective, controlled study of 71 ischemic bowel segments in 28 consecutive patients operated on for acute intestinal ischemic disease. Each segment was independently assessed 15 minutes after surgical correction of the underlying lesion by: 1) standard clinical judgment; 2) Doppler-detected pulsatile mural blood flow; and 3) fluorescein ultraviolet fluorescence pattern. Viability endpoint for each segment was determined objectively by patient follow-up or "blinded" microscopic evaluation of histologically unequivocal resection specimens using criteria established by previous animal studies. Seventeen histologically equivocal specimens were excluded from the final results. Standard clinical judgment proved moderately accurate overall (89%) but would have led to a relatively high rate (46%) of unnecessary bowel resection. The Doppler technique did not increase accuracy in any category of evaluation. The fluorescein fluorescent pattern was correct in all 54 determinant bowel segments, and proved more sensitive specific, predictive, and significantly more accurate overall than either standard clinical judgment or the Doppler method. This controlled study suggests that the fluorescein technique is the method of choice for the prediction of small intestinal recovery following ischemic injury.

**T**HE HIGH MORTALITY RATE associated with acute intestinal ischemic conditions presents a formidable challenge to the responsible physician. A significant factor limiting the successful management of such patients is the well-recognized difficulty in accurately predicting intestinal recovery from ischemic

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injury following surgical reversal of the underlying cause.

This difficulty has fostered a wide variety of adjuvant methods, which have been proposed to achieve a more accurate intraoperative assessment of intestinal viability than is obtained using conventional clinical signs. A number of these techniques require relatively sophisticated methodology and/or expensive equipment.<sup>1-4</sup> Although several of these technically cumbersome methods have been shown to increase the accuracy of intestinal viability assessment in the experimental laboratory, they have not been reported to have found widespread clinical application, even in those centers where they have been developed.

More recently, two relatively simple approaches have been proposed. The return of pulsatile mural blood flow as detected with the Doppler ultrasonic flow probe has been reported to be accurate in both experimental animals<sup>5-8</sup> and man.<sup>9-11</sup> Although enthusiastically advocated by its proponents, the retrospective reports of the use of this technique in man have often been uncontrolled by formal comparison with other methods of assessment.<sup>6,8,10</sup> Furthermore, they fail to employ proven and objectively unequivocal viable and non-viable endpoints against which the technique could be assessed.<sup>5-11</sup> When such standards are applied to the evaluation of the Doppler technique in the experimental laboratory, we have found this method to be unreliable.<sup>12</sup> Such controlled and objective trials have not previously been reported in man.

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In 1942, Lange and Boyd proposed the assessment of tissue reperfusion as indicated by the fluorescent pattern seen under ultraviolet illumination following the peripheral intravenous administration of vital dyes, usually sodium fluorescein, as an accurate predictor of intestinal viability.<sup>13</sup> Subsequently, this approach has been advocated by others.<sup>14-17</sup> Stoler and Randolph's careful recent report<sup>18</sup> employs both formal clinical control evaluations and a definitive viability endpoint, as does our own confirmation of their findings.<sup>12</sup> Both of these studies were performed in laboratory animals. The fluorescein technique has not, however, been previously reported to have been evaluated in a formal clinical trial in patients with intestinal ischemic disease.

This report describes the outcome of a prospective, controlled, clinical trial of these two adjuvant techniques, Doppler and fluorescein, compared to standard clinical judgment as assessed with respect to objective and unequivocal endpoints for both viability and nonviability, in a consecutive series of patients operated on for acute small intestinal ischemic disease at the Johns Hopkins Medical Institutions.

### Methods

#### *Patients*

Twenty-eight consecutive patients operated on for acute small intestinal ischemic disease were initially included in the study. Patients were identified by their primary surgeon prior to operation and informed consent was obtained. Therefore not all patients with such conditions were studied, but all consenting patients about which we were notified were included if they proved to have acute intestinal ischemia for which the underlying cause could be reversed or controlled. Decisions for inclusion or exclusion on the basis of diagnosis were made prior to viability assessment. This group comprised 15 males and 13 females with a mean age of 53 years (range: 17-84 years). The vast majority of this group (23 patients) had some form of strangulated intestinal obstruction, due either to an incarcerated abdominal wall hernia (four patients) or an internal hernia or volvulus (19 patients). None had only simple (nonstrangulated) obstruction. Five patients had acute mesenteric ischemia due to arterial thrombosis (two patients) or embolism (one patient), venous thrombosis (1 patient), or nonocclusive mesenteric ischemia (one patient). Patients with mesenteric ischemia were included only if the underlying lesion could be reversed or limited by treatment. Patients with an uncorrectable lesion were specifically excluded because we did not feel any assessment technique could be expected to accurately predict the future clinical course of an untreatable underlying lesion. This study,

therefore, focused on intestinal recovery following reversal of the primary cause of ischemia, and avoided the evaluation of the natural course of relatively untreatable ischemic disease.

The protocol for this study was approved prior to its outset by the Joint Committee For Clinical Investigation of the Johns Hopkins University, School of Medicine.

#### *Viability Assessment*

At least 15 minutes following reversal of the underlying cause of the ischemic injury the small intestine was considered to be composed of several different segments, based solely on the gross clinical appearance: contiguous areas of a uniform gross appearance were considered as a single segment, and distinguished from other segments of disparate gross appearance. Uninvolved (normal) intestine was not included in the viability scoring. However, if any question whatsoever of intestinal viability could be raised with respect to a given segment, it was included. Our initial evaluation therefore included 71 separate intestinal segments in the 28 patients.

The senior operating surgeon was then asked to use whatever conventional clinical criteria he would normally employ to designate each segment separately as "viable" or "nonviable," based upon whether or not he would resect that segment if it were the only segment of bowel involved by the ischemic process. Equivocal responses were often initially tendered<sup>10</sup> but never accepted, and a definitive response was obtained prior to the use of any adjuvant techniques. In most cases the surgeons considered the return of color, arterial pulsations, and visible peristalsis as the major bases for the decision.

A sterile 9.2 mHz ¼" pencil-type probe connected to a Parks® model 821 Doppler ultrasonic flowmeter was then placed against the antimesenteric border of the bowel wall at several points in each previously designated segment. Care was taken to carefully duplicate the technique described by advocates of the use of the method.<sup>9,11</sup> The proper functioning of the Doppler unit was initially tested by application directly to the wall of a pulsatile mesenteric arterial branch outside the ischemic area. In all cases contact was assured with a sterile conductive jelly. The loop was scored as "viable" with respect to the Doppler method if all areas tested in the loop gave an audible, pulsatile, arterial-type signal. If any area failed to produce audible pulsations the segment was scored "nonviable." Attempts to analyze the tracing of the recorded Doppler wave form proved cumbersome and less reliable than the assessment of the audible signal when applied to the ini-

tial control mesenteric artery branch evaluations in the first few patients, and were therefore abandoned.

Following evaluation with the Doppler probe, the bowel was draped on the abdominal wall such that each defined segment in question would be visible in its entirety with minimal handling. Residual peritoneal fluid was aspirated and two ampoules (1000 mg) of sodium fluorescein were administered through a peripheral vein with the intravenous solution over 30–60 seconds. The room was then darkened and the operative field illuminated with a standard, hand held long wave (3600 Å) ultraviolet (“Woods”) light. Each loop was scored as “viable” or “nonviable” based upon the fluorescence pattern of the “worst” area. Criteria for this evaluation have been previously reported,<sup>12</sup> are discussed in the results section, are summarized in Table 1, and are illustrated in Figures 2 and 3. In manipulating the intestine, care was taken to avoid passively transferring dye-stained peritoneal fluid to unstained areas prior to their formal evaluation. In accordance with the protocol submitted to the Joint Committee on Clinical Investigation, the patients were followed closely during the intra- and postoperative period for evidence of adverse reactions<sup>19,20</sup> and to determine the time course of the elimination of visible dye from the body via the urine.

Following the three independent evaluations of viability for each designated segment the results were recorded. The surgeon then used whatever criteria he chose to decide as to resection. Our study was not designed to evaluate the correctness of these operative decisions, because they were, quite properly, not necessarily based on the result of any one of these, at that point, unproven methods of viability assessment. By the end of the study, some surgeons, particularly those who had previously provided several patients for the study, came to rely on the fluorescein method rather than the Doppler, and made decisions as to resection accordingly. Because the viability endpoint was objectively defined, these opinions played no role in our assessment.

#### *Determination of Endpoint*

The viability of unresected segments was determined by patient follow-up. Fortunately, all of these patients recovered or went to postmortum examination with viable intestine, indicating that no nonviable loops had been left *in situ*. These segments were all considered to be both determinant and viable. No attempt was made to study asymptomatic, recovered patients for subsequent stricture formation, although no patient developed clinical indications thereof. Immediate intestinal recovery or necrosis was considered to be the im-

portant endpoint in the acute management of these seriously ill patients.

Resected segments were taken directly from the surgeon and circumferentially sampled in those areas where the greatest question of viability had been raised by any of the three assessment techniques. Specimens were immediately placed in coded vials of formalin, and conventional hematoxylin and eosin slides were prepared. These slides were evaluated by a pathologist who was fully informed of the clinical circumstances of each patient and the anatomic location of the bowel segment, but specifically “blinded” with respect to the viability assessments. He did, of course, realize that the operating surgeon had decided, on some basis, to resect the tissue. Viability was assessed on the basis of objective criteria established in previous studies in animals<sup>12</sup> and specifically in a serial study of 125 rats followed from one to seven days following reproducible degrees of segmental intestinal ischemic injury.<sup>21</sup> Only those segments unequivocally viable or unequivocally nonviable by these criteria were considered to be determinant. When any question of histologic viability was present, the loop was scored as indeterminate and excluded from the main portion of the study. In these segments, a “best guess” was recorded and these results analyzed separately to determine whether the exclusion of these segments could have introduced significant bias to the results obtained.

#### *Management of Data*

Results were recorded for each method and compared with the viability endpoint described above. The sensitivity (percentage of nonviable loops correctly detected), specificity (percentage of viable loops correctly detected), predictive value (percentage of loops scored as “nonviable” that proved to be so), and overall accuracy (percentage of correct evaluations) were determined by standard formulae<sup>22</sup> and expressed  $\pm 95\%$  confidence limits determined by the binomial distribution. The sensitivity, specificity, predictive value, and overall accuracy of the techniques were compared by the chi squared determination, corrected for continuity in order to allow accurate evaluation of some of the smaller proportions. Probabilities equal to or less than 0.05 were considered to be statistically significant.

#### *Photography*

For purposes of illustration, the exteriorized bowel was photographed using standard strobe illumination prior to administration of the fluorescein. Fluorescein patterns were recorded by  $\frac{1}{2}$  to one second exposures at f 3.5 to f 11 on ASA 400 film. No filter was used.

These photographs were not employed for the assessment of viability.

**Results**

Of the 71 intestinal segments in 28 patients initially included in the study, 17 segments from four patients were later excluded for lack of an unequivocally determinant endpoint. The breakdown of these patients is illustrated in Figure 1. The 54 remaining segments in 24 patients were all evaluated with respect to standard clinical judgment, fluorescein fluorescence, and viability endpoint. Doppler evaluations were only made on 49 of these segments. In five segments (in 2 patients), the Doppler probe did not give reproducible signals from the visibly pulsatile mesenteric arterial branch used to confirm its proper operation and these segments were not scored for the Doppler. In one case this was due to a loose wire, and in one case to a discharged battery. In each instance the problem was corrected and the device tested before the next patient was studied.

The six fluorescein patterns observed are summarized in Table 1 and illustrated in Figures 2 and 3. These patterns were identical, except for changes in scale, to those we have previously described in animals.<sup>12</sup> The three "viable" patterns all demonstrated confluence of the dye pattern in the intestinal wall. The three "nonviable" patterns all demonstrated at least one area of confluent nonfluorescence 5 mm or greater in diameter.

Conventional clinical judgment proved fairly accurate overall (89%) but demonstrated a relatively low

TABLE 1. Patterns of Fluorescein Fluorescence

Pattern	Intensity	Texture	Predicted Outcome
Hyperemic	Increased	Uniform, "smooth"	Viable
Normal	Normal	Uniform, "smooth"	Viable
Fine granular	Normal to slightly decreased	Fine granular	Viable
Patchy	Decreased	Patches of non-fluorescence $\geq 5$ mm diameter	Nonviable
Perivascular	Decreased	Only perivascular areas stained	Nonviable
Nonfluorescent	None	None	Nonviable

predictive value (Table 2) (64%). This would lead to the unnecessary resection of viable intestine in 46% of those segments resected.

Determination of viability with the Doppler probe proved inferior to standard clinical judgment in every assessment category, although none of these differences were statistically significant. This method clearly provided no advantage, however.

The fluorescein fluorescence method proved superior in every category, and was without an error in the determinant segments. Differences in specificity ( $p = 0.05$ ), predictive value ( $p = 0.05$ ), and overall accuracy ( $p < 0.007$ ) were statistically significant when compared with the Doppler method. Fluorescein was also significantly more accurate overall than clinical assessment ( $p < 0.04$ ). Other differences were not statistically significant due primarily to the relatively small number of determinant nonviable loops. Anecdotally, however, clinical assessment missed two of nine nonviable segments and the Doppler method missed three of eight, while the fluorescein technique correctly identified all nine.

The inclusion of the "best guess" results from indeterminate loops is shown in Table 3. This made no substantial difference in any category of the results, but did provide us with our single fluorescein error: the evaluation of a (probably) viable segment as "nonviable." Predictive value was still 94% however, as 15 of the 16 loops were correctly designated as nonviable.

No adverse reactions to the fluorescein were observed. In most cases, gross evidence of the dye was cleared from the body within 12 to 24 hours via the urine. One patient with acute renal failure retained evidence of the dye for two to three days, but suffered no apparent untoward effects that could be considered fluorescein related. We observed no changes in vital

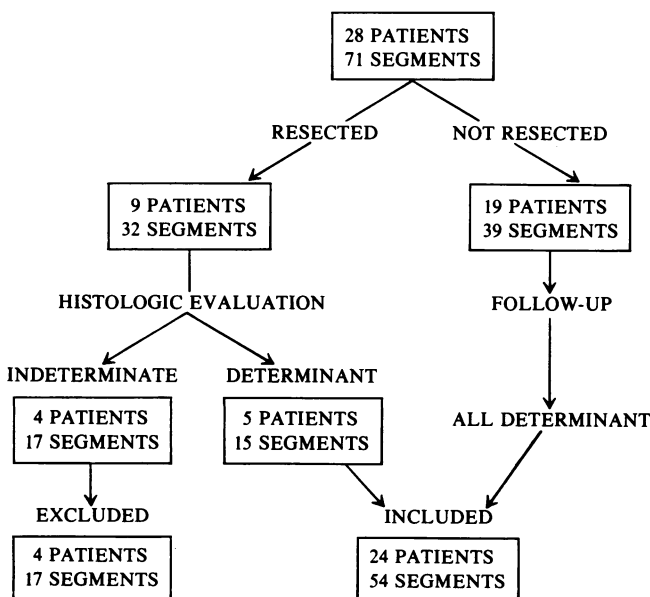


FIG. 1. Determination of Viability Endpoint

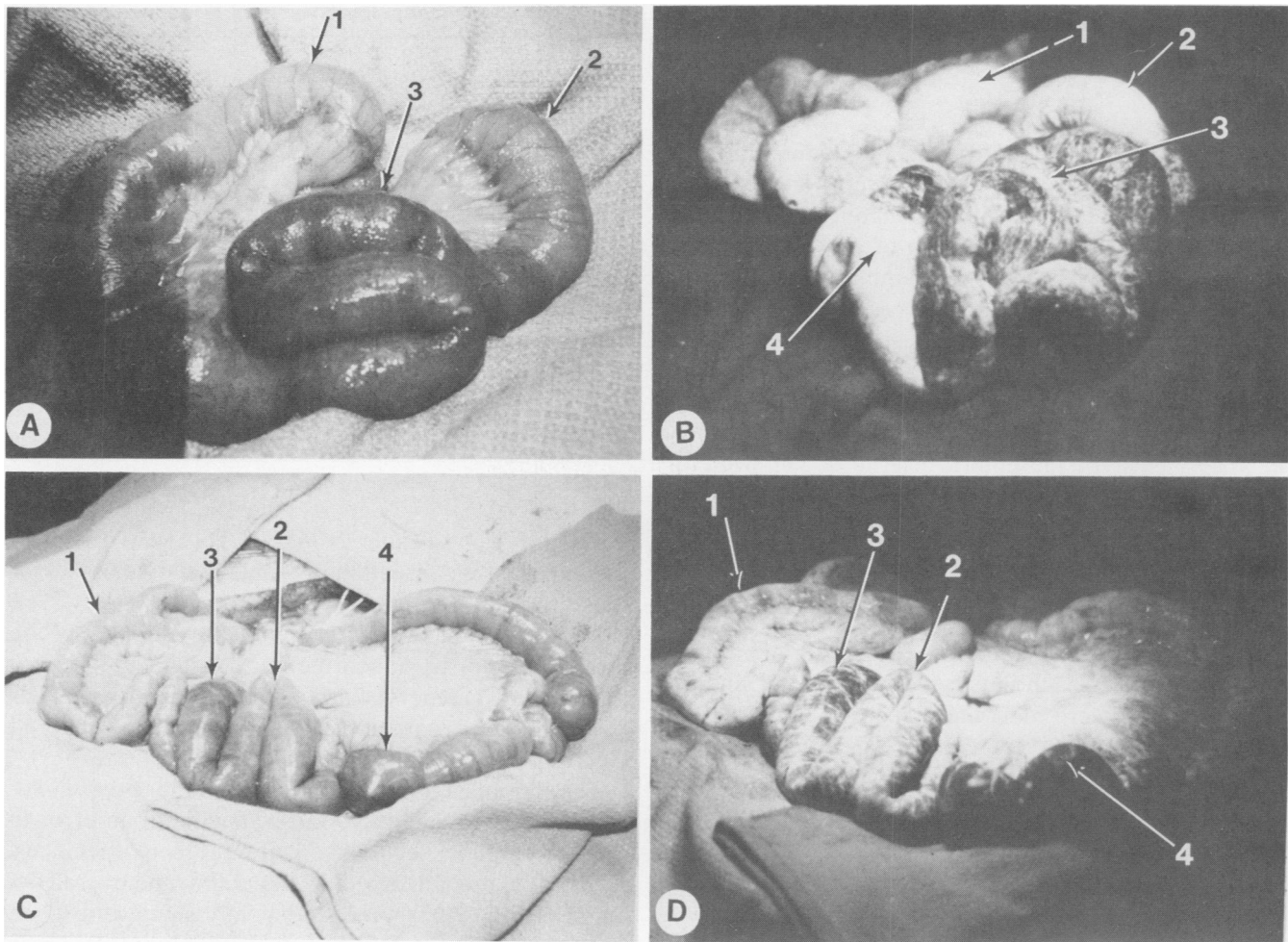


FIG. 2. (A and B) Patient with internal hernia 15 minutes following release of the underlying adhesive band viewed under standard flash (A) and 3600 Å ultraviolet light (B). B demonstrates several viable fluorescent patterns including normal (1), hyperemic (2, 4), and fine granular (3) patterns (Numbered areas in A correspond with those in B). (C and D) Patient with mesenteric embolus 30 minutes following embolectomy, viewed under normal (A) and fluorescent (B) light. B demonstrates two nonviable patterns, patchy (3) and perivascular (4) as well as two viable patterns, normal (1) and fine granular (3). (Numbered areas in C correspond with those in D).

signs or vomiting related to the administration of the dye in anesthetized patients. No clinical evidence of allergic reactions was encountered.

### Discussion

The assessment of small intestinal viability based on conventional clinical signs proved to be reasonably reliable. Sensitivity, specificity and overall accuracy were relatively high, at the expense of a lower predictive value. (Segments judged nonviable were incorrectly so designated 46% of the time.) Thus the experienced surgeon tends to err on the side of resection, preferring the unnecessary removal of viable bowel to the more dangerous error of leaving nonviable intestine *in situ*. In the absence of means to more definitively

determine viability, this would appear to be a rational approach, and is certainly in accord with conventional surgical dogma.

The relatively high accuracy of clinical judgment points up the importance of evaluating any adjuvant technique by means of a controlled trial, wherein the proposed method is compared with the traditional or other approaches, all applied to the same intestinal segments. Without such a controlled design it is impossible to evaluate the true incidence of "tough calls" in the population studied. The relatively good results obtained with clinical judgment suggest that in most situations any reasonable method of viability assessment will be correct, but may add little to the conventional approach. For example, of the 126 patients reported by Cooperman and his colleagues to have been evalu-

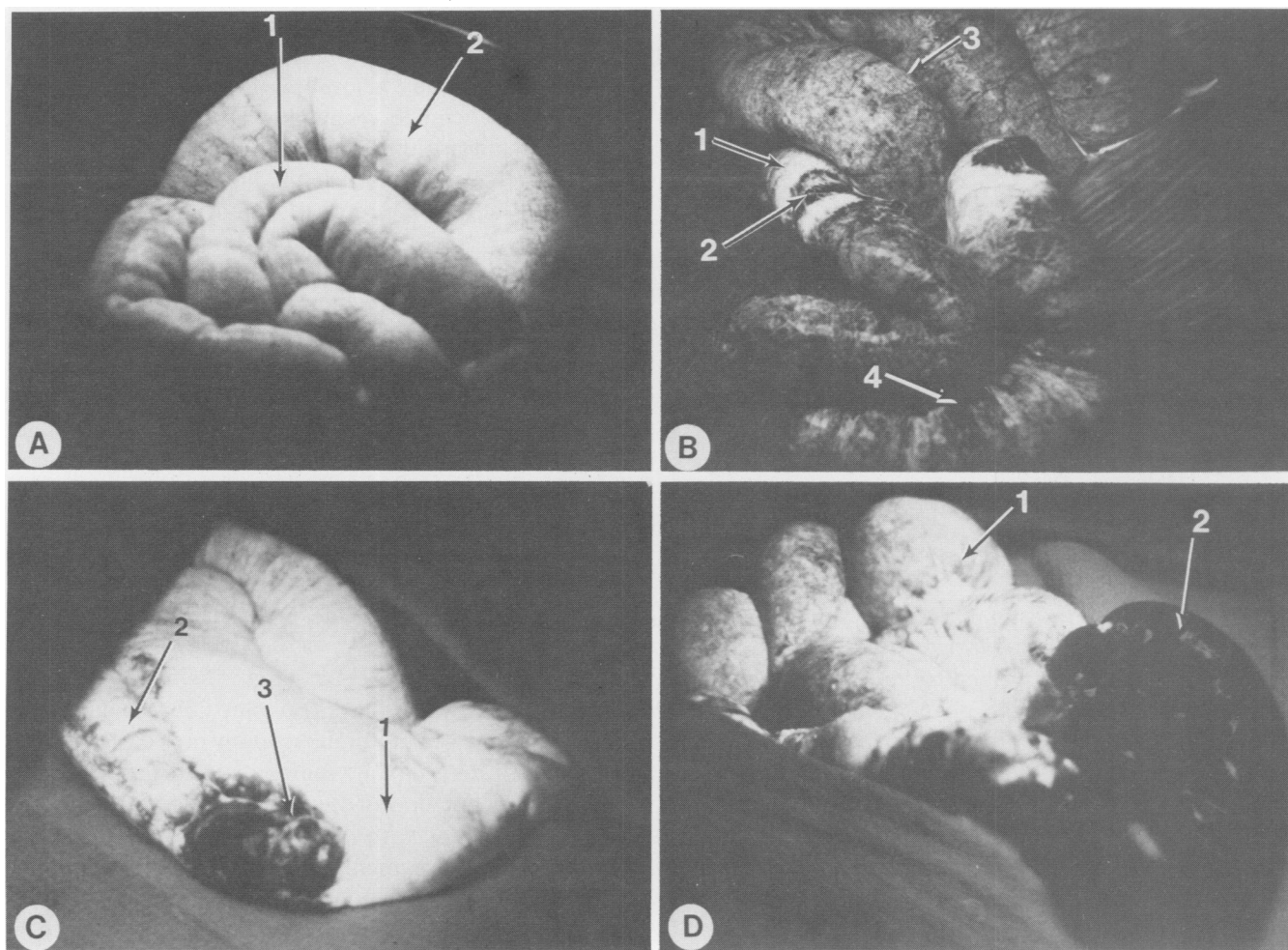


FIG. 3. Fluorescence Patterns. (A) Normal (1) and hyperemic (2) patterns are viable. (B) Normal (1) and fine granular (3) patterns are viable; patchy (2, 4) pattern is nonviable. (C) Hyperemic (1) and fine granular (2) patterns are viable. Perivascular (3) pattern is nonviable. (D) Normal (1) pattern is viable; nonfluorescent (2) pattern is nonviable.

ated by the Doppler approach, in only nine of these patients did the Doppler assessment change the clinical evaluation.<sup>9</sup> In only four of these cases was the endpoint unequivocal ("determinant" as we have defined the term for analysis of our own data) because the histologic endpoint of these resected "nonviable" segments is undefined and unclear. The difference in overall accuracy in the determinant group has no sta-

tistical significance (117/121 vs 121/121;  $\chi_c^2 = 2.29$ ,  $p > 0.14$ ).

When our human and animal<sup>12</sup> studies were simultaneously initiated, we had hoped that the Doppler and fluorescein techniques would both prove to be more accurate than clinical judgment, so that their joint application would provide the means for confirmation of difficult assessments of viability. However, in both

TABLE 2. Viability Assessment of Determinant Segments

Method	Sensitivity	Specificity	Predictive Value	Overall Accuracy
Standard clinical judgment	78 ± 27% (7/9)	91 ± 8% (41/45)	64 ± 28% (7/11)	89 ± 9% (48/54)
Doppler	63 ± 33% (5/8)	88 ± 10% (36/41)	50 ± 31% (5/10)	84 ± 10% (41/49)
Fluorescein fluorescence pattern	100% (9/9)	100% (45/45)†	100% (9/9)†	100% (54/54)*†

\* Significantly better than clinical judgment by  $\chi_c^2$  ( $p < 0.04$ ).

† Significantly better than the Doppler method by  $\chi_c^2$  ( $p \leq 0.05$ ).



TABLE 3. *Viability Assessment of Determinant, Compared with all Segments*

Method	Sensitivity	Specificity	Predictive Value	Overall Accuracy
Standard clinical judgment				
unequivocal end point	78	91	64	89
all segments	88	91	78	89
Doppler				
unequivocal end point	63	88	50	84
all segments	64	86	56	81
Fluorescein				
unequivocal end point	100	100	100	100
all segments	100	98	94	98

Numbers indicate per cent.

of these studies of intestinal recovery following control or reversal of the underlying cause of ischemia, the Doppler technique has proved to be less reliable than clinical judgment (although not significantly so), and significantly less accurate overall than the fluorescein fluorescence pattern. These findings are in apparent conflict with previous reports by the two groups advocating the use of the Doppler technique.<sup>5-11</sup> Our own inability to reproduce these apparently good results could be due to one or more of several differences in approach.

The importance of independent and controlled observations by at least two techniques has been discussed. Such a controlled approach was absent in some of these reports<sup>6,8,10</sup> but present in others.<sup>5,7,9,11</sup> These latter studies all employed conventional clinical evaluation as a control method.

A major potential cause of discrepancy is the viability endpoint employed. We have shown that clinical judgment of intestinal viability 24 hours following the initial laparotomy is surprisingly unreliable in the assessment of intestinal viability in cats<sup>12</sup> and rats (unpublished observations). (None of the patients reported in this series required second-look procedures). Nevertheless, some reports have used gross evaluation at a second-look procedure as the only viability endpoint.<sup>5,7</sup> Whereas long-term follow-up of all (viable and nonviable) intestinal segments left *in situ* provides an ideal definitive endpoint in experimental animals<sup>8,12</sup> it is not possible in clinical studies. We have therefore established histologic viability criteria based upon the serial killing of a series of 125 rats over periods of from one to seven days following graded segmental ischemic injuries. These criteria provide the basis for reproduc-

ible evaluations of viability and nonviability on resected segments by a "blinded" pathologist familiar with them.<sup>12,21</sup> They also allow the pathologist to reproducibly recognize segments that are histologically equivocal and are thus designated indeterminate. We believe such a rigorously defined endpoint is more reliable for the evaluation of resected human segments than those less clearly defined and untested for reproducibility.<sup>9-11</sup> The designation of some resected loops as "indeterminate" significantly reduces the numbers of determinant nonviable segments, but does not appear to bias the results, as shown in Table 3.

Other possible cause of discrepancy include species and/or organ variation in animal experiments<sup>5-8</sup> and somewhat differing clinical situations<sup>9</sup> in man. Technique is also a possible cause of differing results. Our approach attempted to precisely copy that of Cooperman<sup>6,9</sup> by using the antimesenteric border of the intestinal segment in question. Wright and Hobson<sup>5</sup> and O'Donnell and Hobson<sup>10</sup> described a somewhat more elaborate approach.

In this study, the presence of reperfusion at the tissue level, as assayed by the ultraviolet fluorescence pattern after fluorescein administration proved to be accurate in all determinant segments, and probably accurate in all but one of the indeterminate segments. This is consistent with our finding that intestinal recovery following segmental ischemia correlates significantly with postocclusion microvascular patency, as assayed by a silicone elastomer casting technique.<sup>21</sup> The overall accuracy of the fluorescein technique was significantly greater than clinical judgment or the Doppler method. The clear superiority of fluorescein over the Doppler technique has therefore been demonstrated in the only two studies wherein they were compared in a controlled fashion.<sup>12</sup> This superiority may be due to the fact that the eye can rapidly scan the entire surface of a fluorescent bowel segment and easily detect a nonfluorescent patch 5 mm or more in diameter, whereas it is virtually impossible to place the tip of the Doppler probe on every square centimeter of the intestinal surface. Our observation of the patchy pattern of fluorescence on many of the nonviable segments, and on all three of the determinant nonviable segments "missed" by the Doppler technique would support this explanation. The viable segments falsely designated nonviable by the Doppler technique may represent technical problems, including suboptimal contact between the probe and the bowel surface despite the use of a soluble conductive gel.

No adverse reactions to fluorescein dye were observed intra- or postoperatively. This is consistent with a long history of safety for this substance which has

been in widespread use by ophthalmologists for years, and more recently by plastic surgeons evaluating skin flap viability.<sup>23</sup> We were able to find reports of only five serious adverse reactions (three resulting in death) in the 56-year history of its use.

This study, therefore, indicates that conventional clinical judgment is fairly accurate in the assessment of intestinal viability following ischemic injury for which the underlying cause can be reversed or controlled. A significant number of unnecessary resections may be performed, however, in order to maintain this acceptable overall accuracy and to avoid leaving nonviable bowel in the patient. In our hands, the Doppler ultrasonic flow probe adds little if anything to clinical judgment. On the other hand, the fluorescein fluorescence pattern provides a useful adjuvant to the clinical assessment of intestinal viability, proving significantly more reliable than either clinical judgment or the use of the Doppler flowmeter. Therefore, while the use of fluorescein is not necessarily indicated for every determination of intestinal viability in man, it provides a reliable means of evaluation for those difficult borderline bowel segments that occasionally appear in patients with acute small intestinal ischemic disease.

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### DISCUSSION

DR. FRANK GORDON MOODY (Salt Lake City, Utah): Dr. Peter Lawrence of Utah has also come to the same conclusion that fluorescein is a useful adjunct for surgically treating ischemic bowel disease. Its advantages are obvious, it is cheap and available in our pharmacies. All that is needed is a Woods lamp in the operating room, and a circulating nurse to turn off the lights.

We've used it to advantage in patients with nonocclusive ischemic disease, especially vasculitis; and therein lies the problem, because one will identify with this technique patchy areas of apparent nonviability, especially in the colon. This is a type of lesion that wasn't addressed in this presentation. These areas, obviously, go on

to survive, if you take care of the area that has the near or frank perforation, and I would hope that the authors would discuss their use of this in the vasculitides.

I think that an additional issue is whether this particular technique will give us enough assurance to leave bowel that will heal an anastomosis. The question is: how much blood supply does the intestine need to, in fact, get the fluorescein in?

The second problem is the fact that the fluorescein sticks around, once it does get into the tissue. Can one use it two or three times during the course of a difficult revascularization, or following the use of vasodilators, once you have already given the fluorescein to see if the bowel is viable?

I wonder whether this means we should do away with the "second