Int Surg 2015;**100:**1169–1176
DOI: 10.9738/INTSURG-D-15-00012.1

Comparison of Functional Outcomes of Patients Who Underwent Hand-Sewn or Stapled Ileal Pouch-Anal Anastomosis for Ulcerative Colitis

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Total proctocolectomy with ileal pouch-anal anastomosis (IPAA) is the standard surgical treatment for patients with ulcerative colitis (UC). The purpose of this study was to investigate the long-term functional outcomes and quality of life (QOL) associated with hand-sewn and stapled IPAA. Ninety-one patients with UC had undergone IPAA using hand-sewn anastomosis with mucosectomy (32 patients) or stapled anastomosis (59 patients) from January 1988 to May 2010. Patients were evaluated according to patient characteristics, postoperative complications, functional outcomes and QOL. The QOL of patients were evaluated using the Medical Outcomes Study Short Form 36 (SF-36) and the Inflammatory Bowel Disease Questionnaire (IBDQ). Numbers of patients with colorectal cancer or dysplasia were significantly greater in the hand-sewn IPAA group ($P < 0.01$). These patients had longer disease durations and were older (both $P < 0.01$). There was no difference in the incidence of complications between the groups, except for a greater incidence of postoperative anal fistula in the stapled group ($P = 0.03$). In the early postsurgery period, both the frequency of bowel movements and the rate of soiling were significantly higher in the hand-sewn group, but in a later period, there was no difference in these events >3 years after surgery. The SF-36 and IBDQ results were similar in the two groups, indicating that hand-sewn and stapled IPAA result in similar QOL in the late postoperative

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period. Postoperative complications, functional outcomes, and long-term QOL were similar in patients who had received hand-sewn or stapled IPAA.

Key words: Ulcerative colitis – Ileal pouch anal anastomosis (IPAA) – Hand-sewn anastomosis – Stapled anastomosis – Functional outcome – Quality of life

While medical therapy is central to the management of ulcerative colitis (UC), surgical treatment plays an important role in patients whose disease is intractable to medical therapy or has undergone neoplastic transformation. It is estimated that approximately 20 to 30% of patients with UC ultimately require a surgical resection.[1–3]

Total proctocolectomy with ileal pouch-anal anastomosis (IPAA), which was first described in 1978 by Parks and Nicholls,[4] has become established as the standard surgical treatment for patients with UC. The problems with IPAA are that the excision close to the anal sphincter may result in impaired anal function that may cause neurologic damage to the rectum, in turn resulting in urinary and sexual dysfunction. The anastomosis of ileal pouch leads to diarrhea and frequent bowel movements that may adversely affect patients' quality of life (QOL). Two different anastomotic techniques are generally used in IPAA: hand-sewn anastomosis with mucosectomy, which removes all rectal mucosa to the dentate line, and stapled anastomosis (Fig. 1). Patients who undergo hand-sewn anastomosis are thought to develop impaired anal function and QOL more than that in patients who underwent stapled anastomosis.

Although some reports have suggested that the stapled anastomosis provides a better functional outcome than the hand-sewn anastomosis,[5–7] no report has investigated the difference between a hand-sewn IPAA and a stapled IPAA with regard to QOL using validated questionnaires.

We reviewed postoperative complications and evaluated postoperative function both objectively and subjectively. We compared long-term functional outcomes and QOL between these two techniques, using the Medical Outcomes Study Short Form 36 (SF-36),[8] which is a validated generic QOL instrument, and the inflammatory bowel disease questionnaire (IBDQ),[9,10] which is the standard disease-specific scale for assessing QOL in patients with IBD.

Methods

Patients

From January 1988 to May 2010, 91 patients with UC underwent staged IPAA in the Department of Surgical Oncology, the University of Tokyo Hospital. Ileal pouches were constructed using a "J" configuration. Thirty-two patients underwent hand-sewn anastomosis with mucosectomy, and 59 patients underwent mechanically stapled anastomosis without mucosectomy.

All patients gave informed consent to participate in the study. Clinicopathological data such as sex, age at operation, and duration and extent of disease, were collected from patient charts, along with information about early and late complications. The frequency of bowel movements in 24 hours and the presence of soiling were reviewed for functional results. After surgery, patients were monitored with annual endoscopy for surveillance.

Questionnaires

Quality of life was assessed using the SF-36 and IBDQ. The questionnaires were sent to all patients by mail. The quality of life of patients who had been operated upon 3 or more years earlier was evaluated to determine long-term outcomes.

Medical Outcomes Study Short Form 36

The short form 36 is a 36-item questionnaire that evaluates 8 health dimensions: physical functioning, physical role, bodily pain, general health perception, vitality, social functioning, emotional role, and mental health. This scale's validity and reliability have been well established.[11,12] According to norm-based scoring, the national standard value is 50, and the standard deviation is 10. Higher scores are associated with better QOL.

Inflammatory bowel disease questionnaire

The inflammatory bowel disease questionnaire consists of 32 questions distributed among 4 subscales: bowel symptoms, systemic symptoms, emotional function, and social function. The patients were asked about their status in the past 2 weeks, and their responses were recorded using a 7-level Likert scale, ranging from "none of the time" to "all of the time." The standard translation/back-trans-

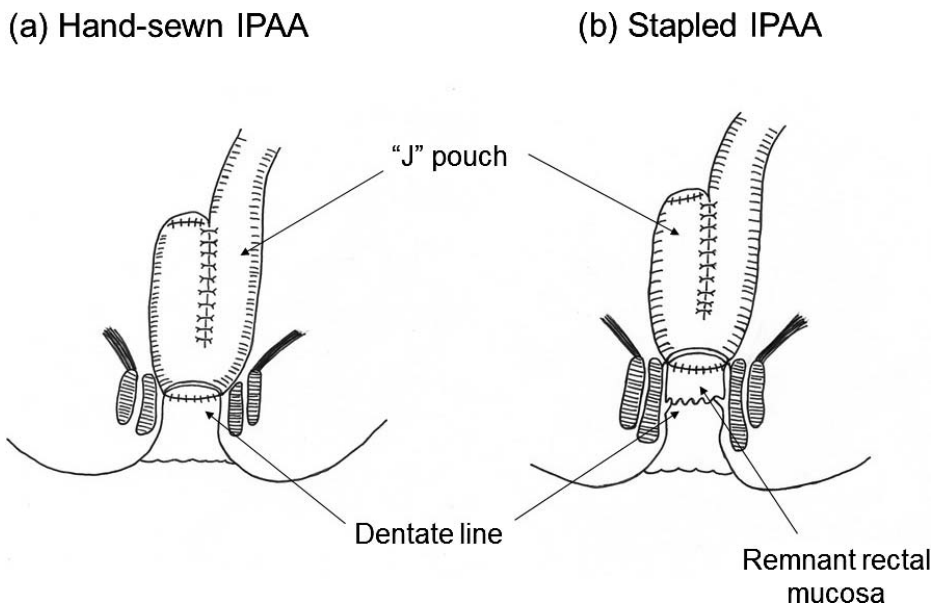

Fig. 1 A scheme illustrating the difference between (a) hand-sewn and (b) stapled ileal-pouch anal anastomosis. Note that the rectal mucosa on the anal canal is removed in the hand-sewn anastomosis while it is left behind in the stapled anastomosis.

lation method was used to translate the original IBDQ into Japanese.[10,13]

Statistical analyses

For the analysis of clinicopathological variables, unpaired *T*-tests were used for comparison of continuous variables and the Pearson χ^2 test was used for categorical variables. Comparisons of scores obtained from questionnaires were performed using the Mann-Whitney *U* test. The cumulative probability associated with ileal pouch was calculated using the Kaplan-Meier method and the log-rank test. All analyses were performed with commercial software (JMP 10.0; SAS Institute, Cary, North Carolina) and differences at $P < 0.05$ were considered statistically significant.

Results

Patient characteristics

Comparisons of the patient characteristics between hand-sewn and stapled IPAA are given in Table 1. Thirty-two of the 91 patients underwent hand-sewn anastomosis with mucosectomy, and 59 patients underwent stapled anastomosis without mucosectomy. For ulcerative colitis patients with coexisting colorectal cancer or dysplasia, hand-sewn IPAA has been preferentially performed at our institution; thus, the proportion of patients with neoplasm was significantly higher in the hand-sewn IPAA group. The disease duration in the hand-sewn group was significantly longer than in the stapled group (13.5 versus 7.3, $P < 0.01$); moreover, patients in this group were older at the time of operation than were those of the stapled group (46.3 versus 32.2, $P < 0.01$). There were no significant differences between

Table 1 Patient characteristics

	Hand-sewn	Stapled	*P* value
Total	32	59	
Sex			
Male, n (%)	14 (44)	37 (63)	0.08
Age at surgery, y	45.7 ± 13.0[a]	32.2 ± 12.9[a]	<0.01
Duration of disease, y	13.5 ± 8.8[a]	7.3 ± 5.8[a]	<0.01
Pancolitis, n (%)	28 (88)	55 (93)	0.36
Indications			
Intractable, n (%)	6 (19)	35 (59)	
Severe/emergent, n (%)	4 (13)	21 (36)	<0.01
Cancer/dysplasia, n (%)	22 (69)	3 (5)	
Follow-up duration, y (range)	7.6 (0.4–18.0)	7.7 (0.4–20.4)	0.63
SF-36			
Number of patients, n	16	31	
Follow-up duration, y (range)	7.9 (5.2–18.0)	9.3 (3.6–20.4)	0.63
IBDQ			
Number of patients, n	17	31	
Follow-up duration, y (range)	7.9 (5.2–18.0)	8.7 (3.6–20.4)	0.83

[a]Data are presented as mean ±SD.

Table 2 Postoperative complications

	Hand-sewn	Stapled	*P* value
Anastomotic leak	9% (3/32)	2% (1/59)	NS
Pelvic sepsis	0% (0/32)	2% (1/59)	NS
Wound infection	22% (7/32)	19% (11/59)	NS
Anal stricture	13% (4/32)	19% (11/59)	NS
Pouch-vaginal fistula[a]	0% (0/18)	9% (2/22)	NS
Anal fistula	0% (0/32)	14% (8/59)	0.03
Cancer/dysplasia	0% (0/32)	0% (0/59)	–

NS, not significant.

[a]The incidences of vaginal fistula were evaluated with female patients.

the groups in other clinical factors, such as sex, the proportion with pancolitis and follow-up duration.

Postoperative complications

Postoperative complications are shown in Table 2. We found no statistically significant differences in the incidence of each complication between patient with hand-sewn and stapled operations, except for the development of postoperative anal fistula: 14% patients who underwent stapled anastomosis developed anal fistula, whereas none of the patients with hand-sewn anastomoses developed this complication ($P = 0.03$). No patients in either group developed cancer or dysplasia during the surveillance period.

Ileal pouch-associated complications are shown in Fig. 2. Pouchitis developed in 44.4% (4/9) of the hand-sewn group and 33.3% (7/21) of the stapled group during the first 5 years after surgery, a statistically insignificant difference. Three patients experienced pouch failure: 1 in the hand-sewn group and 1 in the stapled procedure group required permanent diversion; 1 in the hand-sewn procedure group required pouch excision.

Functional results

The frequency of bowel movements and rates of patients with soiling at each postoperative period are presented in Fig. 3. During the first 2 years after bowel reconstruction, the frequency of bowel movements in the patients in the hand-sewn group was higher than that of patients in the stapled procedure group. However, the frequency of bowel movements in the hand-sewn group rapidly decreased; therefore, there was no significant difference between groups in bowel-movement frequency after 3 years. The rate of patients with soiling also had a similar trend, with a significantly higher rate in the hand-sewn group within 3 years, but no difference after four years.

Questionnaires

Of the 47 UC patients who completed the SF-36 questionnaire, 16 patients had undergone hand-

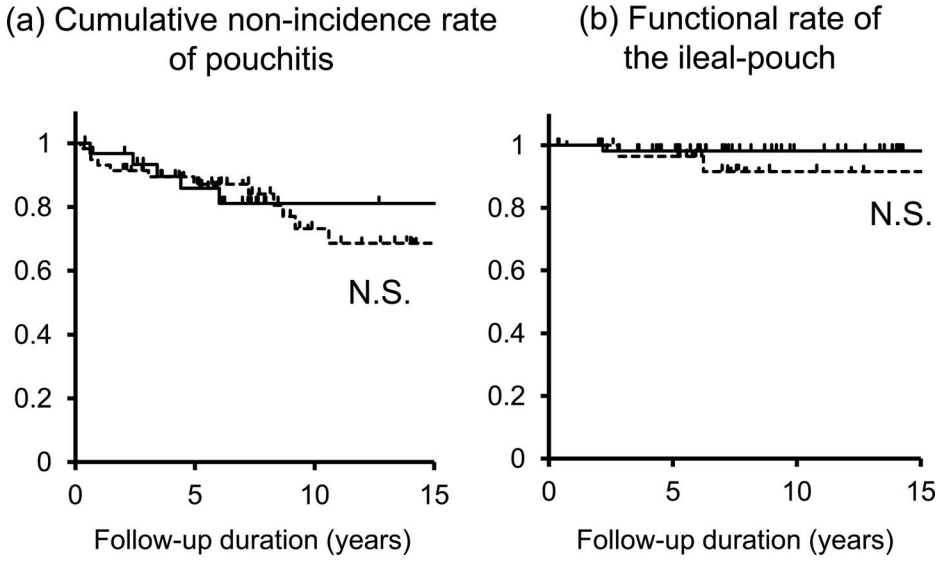

Fig. 2 Ileal pouch-associated complications of IPAA. (a) Cumulative nonincidence rate of pouchitis, and (b) Functional rate of the ileal pouch are presented using the Kaplan-Meier estimator; the solid line represents the hand-sewn group, and the dotted line represents the stapled group. We calculated *P* values using the log-rank test.

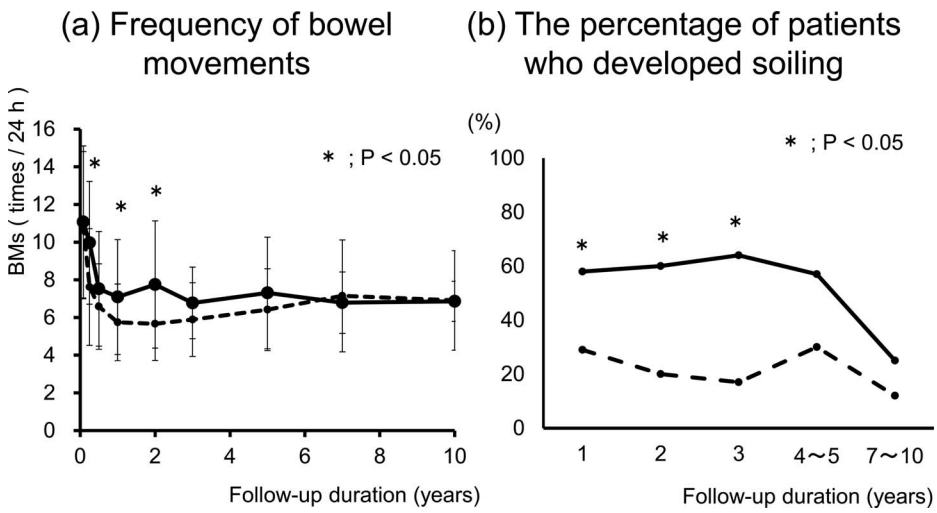

Fig. 3 Functional outcomes of IPAA. Postoperative changes in (a) the frequency of bowel movements and (b) the percentage of patients who developed soiling over time are shown. The solid line represents the hand-sewn group, and the dotted line represents the stapled group. Values in (a) are mean times per 24 hours, and the error bars represent standard deviation of the means. We calculated *P* values using the Mann-Whitney *U* test. Values in (b) are percentage of patients with soiling, and *P* values were calculated using Pearson χ^2 test

sewn anastomosis, and 31 had undergone stapled anastomosis. The first and third quartiles and the median scores of SF-36 results for patients in the 2 groups are shown in Fig. 4. The scores are expressed according to norm-based scoring, in which the national standard value is 50 and the standard deviation is 10. Higher scores reflect a better health status. The differences in the subscales between patients who underwent hand-sewn or stapled anastomosis were not significant.

Forty-eight patients completed all the items in the IBDQ, except for item 28, which asked about sex life. Japanese patients tend to avoid answering the

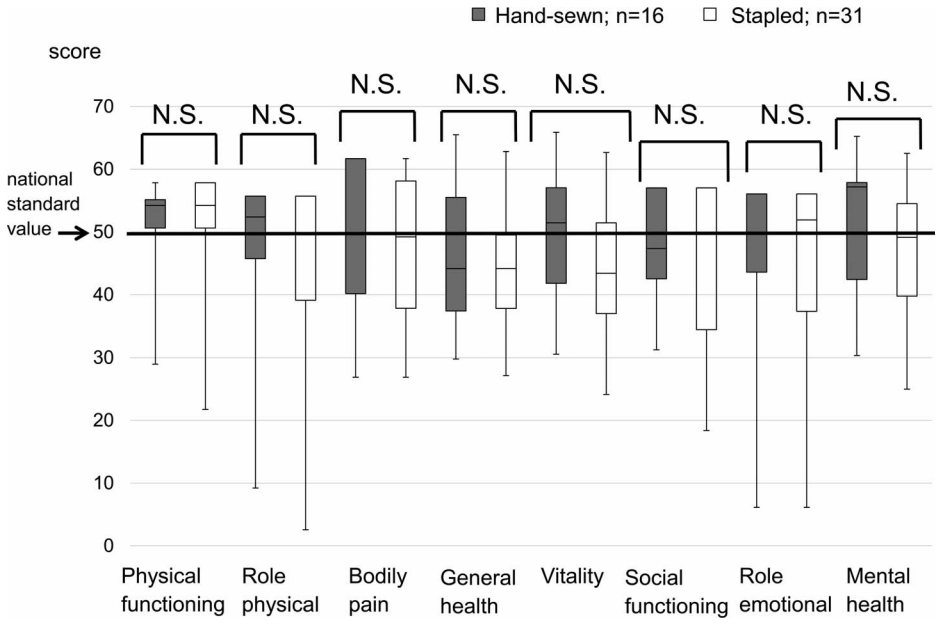

Fig. 4 Results of SF-36. The first and third quartiles and the median scores for individual scales of the SF-36. Data are represented by box-and-whisker plot: gray for the hand-sewn, white for the stapled. We calculated *P* values using the Mann-Whitney *U* test.

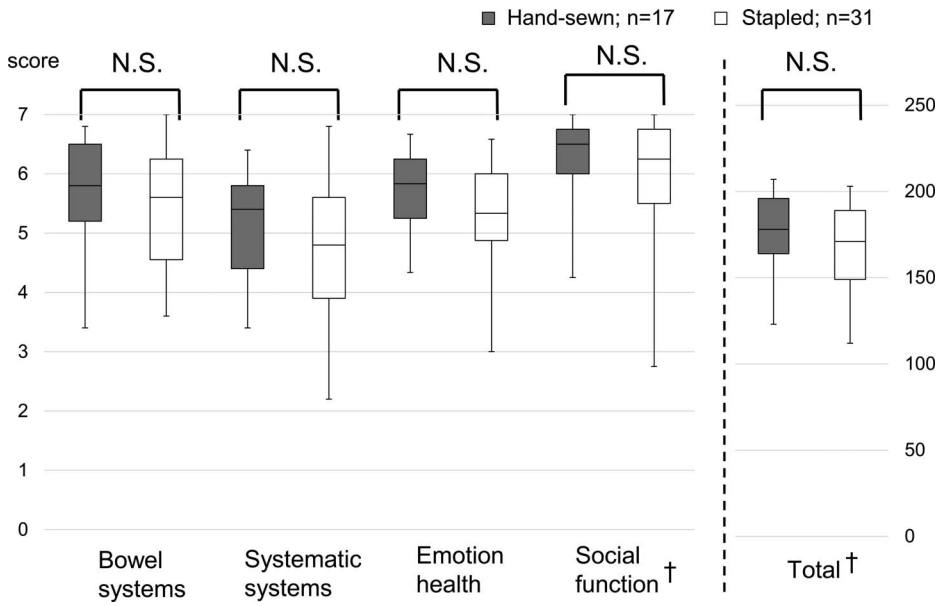

Fig. 5 Results of IBDQ. The first and third quartiles and the median scores for individual scales of the IBDQ. Data are represented by box-and-whisker plot: gray for the hand-sewn group and white for the stapled group. We calculated *P* values using the Mann-Whitney *U* test. Scales with a † symbol indicate that item 28 is excluded.

question, and the response rate to the item was 83%; therefore, the answer to item 28 was excluded from the data analysis. The results of scoring with IBDQ are shown in Fig. 5, in which 17 patients had hand-sewn anastomoses and 31 patients had stapled anastomoses; there were also no significant differences in the subscale and total scores between groups.

Discussion

Since the initial description in 1978,[4] IPAA has become the standard procedure for patients with UC who require surgical treatment. In the 1980s, the double-stapling technique was introduced and became popular rapidly. Since then, the surgical choice of hand-sewn with mucosectomy versus stapled without mucosectomy IPAA has been a subject of debate. The mucosa of anal canal is left unresected in stapled anastomosis, so colitis may persist or worsen, or neoplasms may develop in the remnant mucosa. On the other hand, the hand-sewn technique can cause the function of the anal sphincter muscles to decline, leading to impaired postoperative QOL.[5,14]

Initially, we evaluated the difference in the incidences of postoperative complications between the two techniques. There were no significant differences between the groups, except for the more frequent development of postoperative fistula in the stapled anastomosis group. Perianal fistula after IPAA has been reported to arise from the anastomotic site or anal glands,[15,16] and Araki *et al*[17] proposed that the total removal of the rectal mucosa might reduce the risk of postoperative perianal fistulae. Although several reports have described the development of dysplasia or cancer after IPAA,[14,18] we found no neoplasms in either group, during the postoperative surveillance. The incidence of postoperative pouchitis was not different between groups, and both groups maintained good pouch function, with no difference in the rate of pouch failure.

We then evaluated the functional outcomes. In the early postoperative period, both the frequency of bowel movements and the rate of soiling were significantly higher in the hand-sewn anastomosis group. However, the difference between groups rapidly decreased over time, and after 3 years, there were no differences between the 2 anastomotic techniques in the bowel-movement frequency or soiling.

Several studies have investigated the difference between both techniques to determine postoperative complications and functional outcomes. Although some studies have reported the superiority of the stapled IPAA in functional outcome,[5–7] a recent meta-analysis with more than 4000 UC patients demonstrated that both techniques had similar post-

operative outcomes.[19] As demonstrated by Michelassi *et al*,[20] the postoperative function rapidly improved during first 1 to 2 years, a result consistent with our results. Most reports include a variety of periods from the time of the operation to the time of evaluation, and this might explain the differences among reports. Therefore, we focused on the late postoperative period (more than 3 years after surgery) and conducted the evaluation of QOL using questionnaires.

In addition to the evaluation of the objective outcome, such as frequency of bowel movement or incidence of soiling, the importance of the subjective assessment of the patients' QOL by validated questionnaires has become a recent focus.[21] Although many studies have evaluated the QOL in patients after IPAA,[13,22–24] none has compared QOL after hand-sewn and stapled IPAA with validated generic and disease-specific instruments.

Short form 36 is a generic health status measure for assessment of QOL.[8] Its validity and reliability have been well established in multiple populations, including the Japanese,[11] and in patients with IPAA.[12] With SF-36, we found no significant differences between the 2 anastomotic techniques in all subscales, and the recorded scores were almost equivalent to the published norms for the general Japanese population. IBDQ is the most widely used disease-specific health-related QOL questionnaire for patients with IBD and has been shown to be reliable in a clinical setting.[9] The Japanese IBDQ also has proved to be valid and reliable for the assessment of Japanese patients with UC after IPAA.[13] We found no significant differences in any of the subscales and total scores between the hand sewn-anastomosis group and the stapled-anastomosis group. Approximately 70% of patients in the hand-sewn group underwent surgery because of the development of neoplasms, which usually occurred more than 7 years after the onset of UC.[25] Therefore, the patients in the hand-sewn group were over 10 years older than those in the stapled group and were expected to have worse preoperative anal function. However, the late postoperative anal function and QOL were not different between the two anastomotic methods, thus documenting that the hand-sewn technique was not inferior to the stapled technique according to these criteria of functional outcomes.

In conclusion, our study suggests that the postoperative complications, functional outcomes, and long-term QOL with hand-sewn IPAA were equivalent to those with stapled IPAA. Because the present study was a retrospective and nonrandomized, the results should be validated in prospective studies with a large number of patients to confirm the validity of our results.

Acknowledgments

The authors declare that they have no conflicts of interest.

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