

Original Research Article

Comparative Study between Primary Fistula Repair vs. Seton Placement

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Received: 09-05-2024 / Revised: 19-05-2024 / Accepted: 26-06-2024

ABSTRACT

BACKGROUND

This study was conducted to compare the outcomes of conventional fistula repair surgery with seton placement on the basis of pain, wound drainage, duration of healing, incontinence to flatus, liquid stools, semisolid stools and recurrence.

METHODS

This was a hospital-based single-center prospective and retrospective study conducted among 50 patients in the age group of 18 to 60 years., presenting with clinical evidence of fistula, in the Department of Surgery, Lokmanya Tilak Municipal Medical College Sion Hospital Mumbai, over a period of 2 years, from December 31, 2020, to June 1, 2022, after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

RESULTS

On day 28, 16% of cases of seton were healed, while in fistulectomy, it was 0%. On day 56, 56% of cases of seton were healed, while in fistulectomy, it was 36%. The pain score p-value was <0.0001, which was very significant for seton placement. Among the 25 cases of seton, none of them had incontinence to flatus, liquid stool, or semi-solid stool, while 8% of cases of fistulectomy had incontinence to liquid stool. Among the 25 cases of seton, 12% had recurrence, while in fistulectomy, 24% had recurrence.

CONCLUSION

It is determined that seton therapy for fistula-in-ano is straightforward, safe, and easy. Seton therapy is an outpatient technique that may be performed in primary health care or even in a small operating room. The procedure did not result in a significant perineal wound or related morbidity. While the usual hospital stay after seton ranges from one to two days, it does not necessitate hospitalization. When compared to fistulectomy, the length of hospital stay for seton therapy is substantially shorter. Therefore, the use of seton is a superior alternative since it is less expensive, results in less postoperative problems, and requires fewer "off-work" days.

KEYWORDS

Primary Fistula, Seton Placement.

INTRODUCTION

One of the most prevalent colorectal conditions in the medical literature is an anal fistula (also known as an anorectal fistula). An inflammatory tube or link between the anal canal and the perianal skin is called an anal or anorectal fistula. An abscess forms and a perineal infection causes classic anal fistulas. The anal glands are the source of these infections; they first manifest as a cryptoglandular abscess near the dentate line, which spreads to the perianal skin. Either a surgical incision and drainage technique can be used to empty the abscess or infection, or they can drain naturally from the outside. Following the drainage, a chronic tract may develop, which may periodically drain or re-infect.^[1] Although they manifest as atypical fistulas, hemorrhaginitis suppurativa, trauma, cancer, TB, and Crohn's disease can also manifest as fistulas. An examination under anesthesia and abscess draining are the first treatments for any perianal discomfort and suspected perineal infections. A fistula is assumed if there is persistent leakage from a punctum or nodule at the perianal skin after the abscess has healed over time. Regarding the anatomy through which the fistula passes, there are many forms of fistula tracts. The external anal sphincter can be reached by a deep or superficial fistula tract. With a fistulotomy to the anal gland, the superficial tracts can be easily opened or unroofed, and the tract will repair secondary intention. Because unroofing the deeper fistulas would result in fecal incontinence, they enclose a larger portion of the external anal sphincter. Rather than going through the tract, a seton (a thick suture or elastic band) should be inserted through it. This will allow the tract to slowly heal as the deeper sections do, reducing the likelihood of incontinence. A flap closure of the tract with advancement flaps is the last resort for chronic fistulas.^[2] Surgeons have challenges while treating patients with complicated fistulas. Chemotherapy and radiation treatment are necessary components of an interprofessional team approach to rectal and anal malignancies in cases with malignant fistulas.^[3] In order to prevent abscess formation from jeopardizing patient care plans, seton may be employed as an adjuvant to permit drainage. Fistula patients with Crohn's disease present unique challenges. In order to ensure that there is no abscess or perineal sepsis, setons would be the first line of treatment. If necessary, adjuvant medications such as steroids and infliximab might subsequently be taken on a long-term basis to aid in the disease's remission and the fistula tract(s)' repair.^[4] After consideration of their relevant past symptomatic and surgical histories, patients undergo clinical assessment, including DRE (Digital Rectal Examination) and proctoscopy. EUA (Examination Under Anaesthesia) is done if necessitated by pain experienced by the patient due to any acute inflammatory event. Clinical assessment guides the imaging, which includes conventional fistulography, CT (Computed Tomography), EAU (Endoanal Ultrasound) and magnetic resonance imaging. (MR-Anal Fistulogram), the decision to which is influenced by institutional protocols, concerns, and preferences of the surgeon and the radiologist.^[5-6] Intraoperative assessment variably includes using a probe, injection of methylene blue dye, air, or hydrogen peroxide through the external opening for delineation of the fistula tract. Treatment is influenced by the fistula's anatomy and topography. Antibiotics are only adjuncts, beneficial otherwise in the setting of cellulitis, immunosuppressed states, prosthetic implants, or valvular heart disease.

The surgical effort is directed towards achieving a balance between the elimination of the source (the infected anal gland) and the preservation of sphincter functions. The various procedures, like setoning with or without fistulotomy, one- or two-stage fistulotomy, one- or two-stage fistulectomy, and an anorectal advancement flap, proclaim optimum results in different scenarios adapted to the course of the tract and its relation to the sphincter. Fibrin glue

and fistular plugs using porcine submucosa are other nonsurgical attempts being tried in vain. Currently, surgical therapy forms the standard of cure for fistulas in ano.^[7-9] Postoperative recurrence is essentially due to failure to remove the correct infected anal gland, inability to locate the internal opening, or in cases of Crohn's disease. In the era of growing pursuits for better technology and increasing expectations of technical expertise from the surgeon, the responsibility lies in the hands of the surgeon to aptly use the preoperative imaging modalities available, being aware of the different benefits they offer in different scenarios.

Aims and Objectives

To compare the outcomes of conventional fistula repair surgery with seton placement on the basis of pain, wound drainage and duration of healing, incontinence to flatus, liquid stools and semisolid stools, and recurrence.

METHODS

This was a hospital-based single-center prospective and retrospective study conducted among 50 patients, in the age group of 18–60 years, presenting with clinical evidence of fistula, to the Department of Surgery, Lokmanya Tilak Municipal Medical College Sion Hospital Mumbai, over a period of 2 years, from December 31, 2020, to June 1, 2022, after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

Inclusion Criteria

- Randomly selected males and females in the age group of 18-60 years, with a history of spontaneous, intermittent perianal discharge.
- No history of malignancy
- Single fistula track

Exclusion Criteria

- Patients treated on OPD basis are excluded.
- Patients with clinical diagnosis of pilonidal sinus, hiradenitis and other perianal conditions.
- Immunocompromised patients.
- Patients relative not willing to get enrolled in the study
- Recurrent fistula in ano
- Cases of rectovaginal fistula (currently diagnosed or with a recent past history of the same).

Statistical Methods

The data was entered with the help of MS Excel software. The data was represented in the form of tables for frequency analysis. Mean, SD, and median were derived for assessing central tendency and dispersion. The chi-square test and Fisher exact probability tests were used to compare percentages between two or more groups. A student's unpaired t-test was used to compare means between two groups if the data follows a normal distribution.

RESULTS

	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Pain Score - Day 0	1-3	0	0.0%	9	36.0%
	4-6	10	40.0%	15	60.0%
	7-10	15	60.0%	1	4.0%
Total		25	100.0%	25	100.0%
		Fistulectomy		Seton	

		No. of Cases	Age (%)	No. of Cases	Age (%)
Pain Score - Day 2	1-3	0	0.0%	14	56.0%
	4-6	13	52.0%	11	44.0%
	7-10	12	48.0%	0	0.0%
Total		25	100.0%	25	100.0%
		Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Pain Score - Day 7	0	1	4.0%	5	20.0%
	1-3	3	12.0%	19	76.0%
	4-6	19	76.0%	1	4.0%
	7-10	2	8.0%	0	0.0%
Total		25	100.0%	25	100.0%
<i>Comparison of Pain score on day 0,2 and 7</i>					

In the present study, we assessed the pain score on day 0 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 4-6 in 40% and 7-10 in 60% of subjects. Whereas in seton pain score was 1-3 in 36%, 4-6 in 60%, and 7-10 in 4% subjects.

The pain score on day 2 among study subjects in the fistulectomy procedure was 1-3 in 0% of subjects, 3-6 in 8% of subjects, and 7-10 in 44% of subjects. The seton pain score on day 2 was 1-3 among 56% of subjects and 4-6 among 44% of subjects.

We assessed the pain score on day 7 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 0 in 4%, 1-3 in 12%, 4-6 in 76%, and 7-10 in 8% of subjects. The seton pain score was 0 in 20%, 1-3 in 76%, and 4-6 in 4% of subjects.

	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Pain Score - Day 14	0	3	12.0%	13	52.0%
	1-3	8	32.0%	12	48.0%
	4-6	14	56.0%	0	0.0%
Total		25	100.0%	25	100.0%
	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Pain Score - Day 28	0	7	28.0%	21	84.0%
	1-3	14	56.0%	4	16.0%
	4-6	4	16.0%	0	0.0%
Total		25	100.0%	25	100.0%
	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Pain Score - Day 56	0	14	56.0%	23	92.0%
	1-3	10	40.0%	2	8.0%
	4-6	1	4.0%	0	0.0%
Total		25	100.0%	25	100.0%
<i>Comparison of pain score on day 14,28 and 56</i>					

We assessed the pain score on day 14 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 0 in 12%, 1-3 in 32%, and 4-6 in 56% of subjects. The seton pain score was 0 in 52% and 1-3 in 48% of subjects.

We assessed the pain score on day 28 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 0 in 28%, 1-3 in 56%, and 4-6 in 16% of

subjects. The seton pain score was 0 in 84% and 1-3 in 16% of subjects.

We assessed the pain score on day 56 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 0 in 56%, 1-3 in 40%, and 4-6 in 4% of subjects. The seton pain score was 0 in 92% and 1-3 in 8% of subjects.

	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Wound Score - Day 0	2	2	8.0%	1	4.0%
	3	12	48.0%	15	60.0%
	4	7	28.0%	8	32.0%
	5	4	16.0%	1	4.0%
Total		25	100.0%	25	100.0%
	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Wound Score - Day 2	2	5	20.0%	4	16.0%
	3	13	52.0%	17	68.0%
	4	7	28.0%	4	16.0%
Total		25	100.0%	25	100.0%
	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Wound Score - Day 7	1	2	8.0%	1	4.0%
	2	9	36.0%	8	32.0%
	3	9	36.0%	15	60.0%
	4	5	20.0%	1	4.0%
Total		25	100.0%	25	100.0%

Comparison of wound score on day 0,2 and 7

We assessed the Southampton wound score among subjects on day 0 in fistulectomy, which was grade 2 in 8% cases, 3 in 48% cases, 4 in 28% cases, and 5 in 16% cases. Whereas in seton wounds, the grade was 2 in 4%, 3 in 60%, 4 in 32%, and 5 in 4% cases.

We assessed the Southampton wound score among subjects on day 2 in fistulectomy, which was grade 2 in 20% cases, 3 in 52% cases, and grade 4 in 28% cases. Whereas in seton wounds, the grade was 2 in 16%, 3 in 68%, and 4 in 16% cases.

We assessed the Southampton wound score among subjects on day 7 in fistulectomy, which was grade 1 in 8% cases, 2 in 36% cases, 3 in 36% cases, and grade 4 in 20% cases. Whereas in seton wounds, the grade was 1 in 4%, 2 in 32%, 3 in 60%, and 4 in 4% cases.

	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Wound Score - Day 14	1	2	8.0%	7	28.0%
	2	10	40.0%	13	52.0%
	3	10	40.0%	5	20.0%
	4	3	12.0%	0	0.0%
Total		25	100.0%	25	100.0%
	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Wound Score - Day 28	0	0	0.0%	4	16.0%
	1	5	20.0%	9	36.0%
	2	9	36.0%	10	40.0%

	3	8	32.0%	1	4.0%
	4	3	12.0%	1	4.0%
Total		25	100.0%	25	100.0%
	Procedure	Fistulectomy		Seton	
		No. of Cases	Age (%)	No. of Cases	Age (%)
Wound Score - Day 56	0	9	36.0%	14	56.0%
	1	10	40.0%	8	32.0%
	2	2	8.0%	1	4.0%
	3	3	12.0%	2	8.0%
	4	1	4.0%	0	0.0%
Total		25	100.0%	25	100.0%
<i>Comparison of wound score on day 14,28 &56</i>					

We assessed the Southampton wound score among subjects on day 14 in fistulectomy, which was grade 1 in 8% cases, 2 in 40% cases, 3 in 40% cases, and grade 4 in 12% cases. Whereas in seton wounds, the grade was 1 in 28%, 2 in 52%, and 3 in 20% of cases.

We assessed the Southampton wound score among subjects on day 28 in fistulectomy, which was grade 1 in 20% cases, 2 in 36% cases, 3 in 32% cases, and grade 4 in 12% cases. Whereas in seton wounds, the grade was 0 in 16% cases, 1 in 36%, 2 in 40%, grade 3 in 4%, and grade 4 in 4% cases.

We assessed the Southampton wound score among subjects on day 28 in fistulectomy, which was grade 0 in 36% cases, 1 in 40% cases, 2 in 8% cases, 3 in 12% cases, and grade 4 in 4% cases. Whereas in seton wounds, the grade was 0 in 56% of cases, 1 in 32%, 2 in 4%, and 3 in 8% of cases.

	Procedure	Fistulectomy		Seton		Total
		No. of Cases	Age (%)	No. of Cases	Age (%)	
Incontinence	No	23	92.0%	25	100.0%	48
	Yes	2	8.0%	0	0.0%	0
Total		25	100.0%	25	100.0%	50
	Procedure	Fistulectomy		Seton		Total
		No. of Cases	Age (%)	No. of Cases	Age (%)	
Recurrence	No	19	76.0%	22	88.0%	41
	Yes	6	24.0%	3	12.0%	9
Total		25	100.0%	25	100.0%	50
<i>Comparison on basis of incontinence and recurrence</i>						

Among the 50 cases studied, 8% of cases from fistulectomy had incontinence, and 0% of cases from seton had incontinence. Among the studied subjects, 24% of cases of fistulectomy had recurrence, whereas 12% of cases of seton had recurrence.

DISCUSSION

Ancient Indian writings mention using Seton to cure fistula-in-ano. These stenos are similarly manufactured from plant extracts that have been layer-impregnated with latex on cotton thread. Seton can be softly knotted to allow gradual, controlled division of the contained tissue mechanism with minimum separation of the transacted end, or loosely inserted to allow track marking, encourage fibrosis, and ease short- or long-term drainage of sepsis.

There are also other reports of this procedure's variations. The bulk of the patients in our study were in their fourth decade, and the study's male preponderance is consistent with findings from other studies conducted both in India and elsewhere. Additionally, in line with

earlier research, is the distribution of single external openings, external opening situations, internal openings with respect to the anal axis, and fistula kinds. In the current study, individuals undergoing fistulectomy needed a considerably shorter hospital stay in the seton group. Similar findings were also noted in other investigations conducted by Shukla N. et al., Gouranga D. et al., and Reddy V. M. et al.^[4-6]

Research Studying 44 individuals with fistula-in-ano, Reddy V. M. et al. In the seton group, they saw that an operation required a maximum of 33.54 minutes and a minimum of 18.2 minutes. In contrast, the fistulectomy group needed a minimum of 47 minutes and a maximum of 64.6 minutes, respectively ($p < 0.05$). Despite this, the number of days "off work" in the current research was lower in the case of seton because, in contrast to fistulectomy, there was less discomfort and no open incision. As a result, patients who had a set-on surgery could resume their jobs the next day, and their regular activities were unaffected. The seton group experienced a considerably lower number of "off work" days (p -value < 0.001) than the fistulectomy group. The findings of Reddy V. M. et al. and Gouranga D. et al. are comparable to those of our investigations.^[2,5]

In the current investigation, the seton group's treatment period was noticeably longer than the fistulectomy group's. In the medicated seton group, the healing process took an average of 67.35 days. The average recovery period for the fistulectomy group was 24.9 days. Patients must visit the hospital once a week for a fresh seton placement since seton is a multistage operation. As a result, the seton group needed a lot more days to recover (p value = 0.181). Similar findings were obtained by Shukla N. et al., Gouranga D. et al., and Gupta Shyam K. et al.^[2,4,6] No patient in the seton therapy group experienced liquid, gas, or feces incontinence during the current trial. Two patients (8%) from the group that had fistulectomy experienced incontinence related to flatus, liquids and feces. A high anal fistula was seen in both incontinence patients. As a result, this study may be compared to previous Indian investigations. In the current research of 25 patients, 10% of the fistulectomy group experienced a recurrence of fistula-in-ano, whereas 12% of patients experienced a recurrence following seton therapy. It is impossible to comment on the precise recurrence rate because follow-up varied from 6 to 18 months.

When Reddy V. M. et al. examined 44 instances of fistula-in-ano, they found that the recurrence rates following seton and fistulectomy were, respectively, 0% and 20%. Madankar, S. P. et al. 114 individuals with fistula-in-ano treated with medicated seton were investigated by Mohite J. D. et al.^[7] Between six months and two and a half years of follow-up, they saw no recurrence.

In a study of sixty patients with fistula-in-ano, Gupta Shyam K. et al. found that the recurrence rate was 10% following fistulectomy and 3.33% with medicated seton. Six In their study, Shukla N. et al. found that recurrence rates were 4% with medicated seton and 11% with fistulectomy.^[4] At days 0, 2, 7, 14, 28, and 56 following surgery, post-operative pain was measured using a visual analog scale.

In comparison to the fistulectomy group, the medicated seton group experienced considerably (p value < 0.001) less discomfort after six hours. Gupta Shyam K. et al. examined 60 patients who had fistula-in-ano and used a visual analogue scale to measure postoperative pain at six hours. All patients in the medicated seton group experienced considerable discomfort.^[6] Of the individuals who developed fistulas, 77% reported moderate discomfort and 23% reported severe pain ($p < 0.001$) less discomfort than those who had a fistulectomy. As a result, this study may be compared to previous Indian studies.

Demographic Characteristics

In the present study, we assessed the age distribution among the study subjects. We observed that the majority of the study subjects belonged to the age group of 41 to 50 years (36%),

followed by 31 to 40 years (24%), and 51 to 60 years (18%). We evaluated the gender distribution of the research individuals in the current investigation. We found that 36% of fistulectomy patients were female, while 64% of participants were male. And in the seton placement study, 68% of subjects were male, whereas 32% were female. The male: female ratio in fistulectomy in the current study was 9:16, and in seton placement it was 8:17.

Pain Score Day-0

In the present study, we assessed the pain score on day 0 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 4-6 in 40% and 7-10 in 60% of subjects. The seton pain score was 1-3 in 36%, 4-6 in 60%, and 7-10 in 4% of subjects.

Pain Score Day-2

The pain score on day 2 among study subjects in the fistulectomy procedure was 1-3 in 0% of subjects, 3-6 in 8% of subjects, and 7-10 in 44% of subjects. Whereas the seton pain score on day 2 was 1-3 among 56% of subjects, 4-6 in 44% of subjects.

Pain Score Day-7

We assessed the pain score on day 7 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 0 in 4%, 1-3 in 12%, 4-6 in 76%, and 7-10 in 8% of subjects. Whereas the seton pain score was 0 in 20%, 1-3 in 76%, and 4-6 in 4% subjects.

Pain Score Day 14

We assessed the pain score on day 14 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 0 in 12%, 1-3 in 32%, and 4-6 in 56% of subjects. Whereas the seton pain score was 0 in 52% and 1-3 in 48% of subjects.

Pain Score Day 28

We assessed the pain score on day 28 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 0 in 28%, 1-3 in 56%, and 4-6 in 16% of subjects. Whereas the seton pain score was 0 in 84% and 1-3 in 16% of subjects.

Pain Score Day 56

We assessed the pain score on day 56 among the study subjects. We observed that in the fistulectomy procedure, the pain score was 0 in 56%, 1-3 in 40%, and 4-6 in 4% of subjects. Whereas the seton pain score was 0 in 92% and 1-3 in 8% of subjects.

Southampton Wound Score Day 0

In the present study, we assessed the Southampton wound score among subjects on day 0 of fistulectomy, which was grade 2 in 8% of cases, 3 in 48% of cases, 4 in 28%, and 5 in 16% of cases. Whereas in seton wounds, the grade was 2 in 4%, 3 in 60%, 4 in 32%, and 5 in 4% cases.

Wound Score Day 2

In the present study, we assessed the Southampton wound score among subjects on day 2 of fistulectomy, which was grade 2 in 20% cases, grade 3 in 52% cases, and grade 4 in 28% cases. Whereas in seton wounds, the grade was 2 in 16%, 3 in 68%, and 4 in 16% cases.

Wound Score Day 7

In the present study, we assessed the Southampton wound score among subjects on day 7 in fistulectomy, which was grade 1 in 8% cases, 2 in 36% cases, 3 in 36% cases, and grade 4 in

20% cases. Whereas in seton wounds, the grade was 1 in 4%, 2 in 32%, 3 in 60%, and 4 in 4% cases.

Wound Score on Day 14

In the present study, we assessed the Southampton wound score among subjects on day 14 in fistulectomy, which was grade 1 in 8% cases, 2 in 40% cases, 3 in 40% cases, and grade 4 in 12% cases. Whereas in seton wounds, the grade was 1 in 28%, 2 in 52%, and 3 in 20% of cases.

Wound Score on Day 28

In the present study, we assessed the Southampton wound score among subjects on day 28 in fistulectomy, which was grade 1 in 20% cases, 2 in 36% cases, 3 in 32% cases, and grade 4 in 12% cases. Whereas in seton wounds, the grade was 0 in 16% of cases, 1 in 36%, 2 in 40%, grade 3 in 4%, and grade 4 in 4% of cases.

Wound Score on Day 56

In the present study, we assessed the Southampton wound score among subjects on day 28 of fistulectomy, which was grade 0 in 36% of cases, 1 in 40% of cases, 2 in 8% of cases, 3 in 12%, and grade 4 in 4% of cases. Whereas in seton wounds, the grade was 0 in 56% of cases, 1 in 32%, 2 in 4%, and 3 in 8% of cases.

Incontinence

Among the 50 cases studied, 8% of cases from fistulectomy had incontinence, and 0% of cases from seton had incontinence.

Recurrence

Among the studied subjects, 24% of cases of fistulectomy had recurrence, whereas 12% of cases of seton had recurrence.

CONCLUSION

It is determined that seton therapy for fistula-in-ano is straightforward, safe, and easy. Seton therapy is an outpatient technique that may be performed in primary health care or even in a small operating room. The procedure did not result in a significant perineal wound or related morbidity. While the usual hospital stay after seton ranges from one to two days, it does not necessitate hospitalization. When compared to fistulectomy, the length of hospital stay for seton therapy is substantially shorter. Therefore, the use of seton is a superior alternative since it is less expensive, results in less postoperative problems, and requires fewer "off-work" days.

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