Peritoneal Dialysis International, Vol. 26, pp. 677–683
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PROSPECTIVE COMPARISON OF DOWNWARD AND LATERAL PERITONEAL DIALYSIS CATHETER TUNNEL-TRACT AND EXIT-SITE DIRECTIONS

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♦♦***Objective:*** **Guidelines for optimal peritoneal dialysis access support both downward and lateral exit-site directions. Numerous clinical reports support the superiority of downward exit sites but none substantiate lateral configurations.**

♦♦***Methods:*** **This prospective study compared infectious and mechanical complications between 85 catheters with a preformed arcuate bend to produce a downward exit site and 93 catheters with a straight intercuff segment configured to create a lateral exit site.**

♦♦***Results:*** **Kaplan–Meier survivals were not different for time to first exit-site infection ($p = 0.62$), tunnel infection ($p = 0.89$), or peritonitis ($p = 0.38$) for downward and lateral exit-site directions. Poisson regression showed no differences in rates (episodes/patient-year) of exit-site infection (0.26 vs 0.27, $p = 0.86$), tunnel infection (0.02 vs 0.03, $p = 0.79$), peritonitis (0.42 vs 0.43, $p = 0.87$), or catheter loss (0.06 vs 0.09, $p = 0.29$) for downward and lateral exit sites. Kaplan–Meier analyses of antibiotic-free intervals for exit-site ($p = 0.94$) and peritonitis infections ($p = 0.72$) were not different for the two groups. There was one case of catheter tip displacement with flow dysfunction in each group. There were no pericatheter hernias or spontaneous cuff extrusions. Catheter survival between groups was not different ($p = 0.20$).**

♦♦***Conclusions:*** **Catheter types employing downward and lateral tunnel-tract and exit-site configurations produce equivalent outcomes for infectious and mechanical complications.**

Perit Dial Int **2006; 26:677–683** **www.PDIConnect.com**

KEY WORDS: Tenckhoff catheter; swan neck catheter; exit-site infection; tunnel infection; peritonitis; cuff extrusion; catheter tip migration; catheter survival.

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Received 21 February 2006; accepted 19 April 2006.

While published guidelines by the International Society for Peritoneal Dialysis have historically supported both downward-directed and lateral-directed peritoneal catheter exit sites (1–4), there are numerous clinical reports favoring the superiority of the former (5–11) but none corroborating the latter. With few exceptions (12,13), studies regarding downwardly facing exit sites promote the use of a catheter with a preformed bend in the intercuff segment, commonly referred to as the "swan neck" design. This preformed configuration restricts exit-site options to the lower abdominal area and may not be ideal for patients with low lying belt lines or lower abdominal skinfolds (14). Therefore, there is a sense that a laterally directed exit site is still required in certain patients to emerge the catheter above the belt line or skinfold. As a result, it is important to know whether a lateral-facing exit site places the patient at any disadvantage to catheter infection risk compared to a downward-facing exit site. Furthermore, it is essential to evaluate the effects of tubing stress created by bending a catheter with a straight intercuff segment into a lateral configuration with respect to risks for external cuff extrusion or internal catheter tip migration.

MATERIALS AND METHODS

The study design was a prospective nonrandomized comparison of downward and lateral peritoneal dialysis catheter tunnel-tract and exit-site directions. The study groups were drawn from a population of 253 consecutive patients implanted with peritoneal dialysis catheters from January 2000 through March 2005. Patients enrolled in a clinical trial of silver-impregnated catheters (15), those implanted with two-piece extended catheter systems to produce presternal or upper abdominal exit sites (16,17), and subjects with buried catheters for delayed exteriorization were excluded. The remaining 178 patients implanted with two-cuff, coiled tip

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Tenckhoff catheters with either a preformed swan neck bend in the 5-cm intercuff segment or a straight 6-cm intercuff segment constituted the study population.

Catheters with a swan neck bend were implanted so that the subcutaneous tunnel tract precisely followed the shape of the tubing, with the superficial cuff located 2 – 3 cm from the downwardly directed exit wound. Catheters with a straight intercuff segment were bent with an arc in the subcutaneous tissues so that the tunnel tract and exit site were directed laterally. The lateral tunnel-tract configuration was determined by a previously validated design algorithm that placed the superficial cuff 4 cm from the exit site (18). The design algorithm compensates for shape memory effects of a straight tube bent into an arcuate configuration. The amount of tube straightening that occurs over time is a balance between the resiliency forces of the tubing and resistance offered by the tissues, and is different from patient to patient. Using the algorithm, even in the most extreme event of tube straightening, the superficial cuff will not come closer than 2 cm of the exit site.

Selection of the catheter type to be implanted was based upon specific criteria. During the preoperative evaluation, patients were examined fully dressed to mark the belt-line location. The subjects were then assessed for the appropriateness of the two catheters. The insertion site of the catheter, which coincides with the deep-cuff location, was determined with the patient supine by aligning the upper border of the catheter coil with the upper border of the pubic symphysis, and marking the upper border of the deep cuff in the paramedian plane 3 cm lateral of midline. The pubic symphysis has been recommended as a reliable landmark for ideal location of the catheter tip in the true pelvis (19), which is confirmed laparoscopically (20). After determining the deep-cuff location for each catheter, the tunnel tract and exit site were mapped on the abdominal wall as described above. Subjects were then examined in the sitting position to determine if the two catheter types produced an exit-site location that was clear of the belt line, skin creases, blindside of a skinfold, or the ridge of an abdominal pannus. Catheter selection was based upon which device produced the best fit of proper deep pelvic position of the catheter tip and an exit site that did not conflict with the belt line, skin creases, or skinfolds (14). If both catheter types were satisfactory, final selection was determined by the exit-site location that was the greatest distance from the belt line and provided the best visibility. If neither catheter was acceptable, the patient underwent placement of an extended catheter system to remotely locate the exit site away from the usual lower abdominal region without sacrificing proper deep pelvic position of the catheter tip. Subjects requiring extended catheters were excluded from the study.

Preoperatively, a single dose of cefazolin, or vancomycin in the event of cephalosporin allergy, was administered for prophylaxis. Catheter implantation was performed using a laparoscopic approach previously described in detail (20). The peritoneal catheter was inserted at a paramedian site through a port conduit that was tunneled under laparoscopic control in a craniocaudal direction through the rectus muscle and sheath. The resulting 4 – 6 cm rectus sheath tunnel promoted pelvic orientation of the catheter tip. The deep catheter cuff was positioned in the rectus muscle just below the anterior rectus sheath. The catheter was tunneled subcutaneously from the insertion incision toward the designated exit site with a stylet that was the same caliber as the catheter and advanced through the skin without making a prior incision (Faller tunneling stylet; The Kendall Company, Mansfield, Massachusetts, USA). No catheter anchoring stitches were used. Instead, the catheter was immobilized with tincture of benzoin and sterile adhesive strips.

Following catheter placement, a chlorhexidine-impregnated wafer (BioPatch; Johnson & Johnson, Arlington, Texas, USA) was left in place around the catheter tubing at the exit wound for 2 weeks, after which the patient began daily exit-site cleansing with antibacterial soap. Mupirocin 0.2% ointment was applied to the exit site 3 days weekly. Patients were permitted to resume showering 1 month following implantation if wound healing was uncomplicated. The exit site was kept covered with sterile gauze. All catheters were allowed at least 2 weeks to heal before instituting dialysis.

After institution of peritoneal dialysis, patients were generally evaluated on a monthly basis in the clinic and immediately in the event of an acute problem. Exit-site infections were diagnosed if signs of redness and purulent discharge were present (3). Tunnel infection included induration or redness over the subcutaneous course of the catheter, associated with tenderness and pain, with or without abscess formation (3). Peritonitis was defined clinically as abdominal pain and a cloudy dialysate yielding a leukocyte count greater than 100/mm^3 with greater than 50% polymorphonuclear cells (21).

Removal of peritoneal catheters for exit-site and tunnel-tract infections was generally performed if there was a failure to respond within 2 – 4 weeks to a treatment program that included appropriate antibiotic therapy, intensified exit-wound care, and unroofing of the infected tunnel tract with shaving of the superficial cuff (3,22). Removal of peritoneal catheters for refractory

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peritonitis was performed if no improvement was noted within 5 days of starting appropriate antibiotic treatment. Recrudescence of peritonitis by the same organism within 4 weeks of completing antibiotic therapy led to the removal of peritoneal catheters for relapsing disease (21). Episodes of exit-site infection and peritonitis were counted as separate events if the episode occurred more than 4 weeks after stopping antibiotic therapy or if the infection was caused by a different organism.

Antibiotic-free intervals were compared to evaluate the effect of exit-site direction on completeness of treatment response and risk of recurrent infection. Treatment-free intervals, representing the number of days between infections during which a patient was not taking antibiotics, were calculated separately for exit-site infection and peritonitis. The antibiotic-free interval for the first infection was calculated as the time interval between the onset of the infection and the day after the implantation procedure. The antibiotic-free interval between succeeding infections was calculated as the subsequent infection date minus the preceding infection date, minus the duration of antibiotic therapy. If there was no infection or no subsequent infection date, the end of the study date for that patient was used and the time interval was treated as a censored interval in the statistical analyses.

All patient data in this report were recorded prospectively in an Institutional Review Board-approved database. Fisher's exact test was used to compare nominal data. Age, body mass index, and duration of subject observation were compared using the Wilcoxon rank-sum test. Event rates were compared by Poisson regression. Correlations between time to first infection and antibiotic-free time intervals between subsequent infections used Spearman rank correlation. Probability distributions for time to first infection, antibiotic-free intervals, and overall catheter survival were estimated using the method of Kaplan and Meier. For catheter survival, all causes for loss except for infectious and mechanical complications were censored. Comparison of probability curves was performed with the log-rank test. All results were considered significant at $p < 0.05$. All analyses were performed with SAS version 9.1.3 (SAS Institute, Cary, North Carolina, USA).

RESULTS

Study population demographics are summarized in Table 1. Selection of catheter type and exit-site configuration was significantly different by gender. Subjects with belt lines above the umbilicus, typically females, were most frequently matched with a catheter with a preformed bend that produced a downwardly directed exit site below the belt. Male subjects generally had belt-line locations below the umbilicus and most often underwent implantation of a catheter with a straight intercuff segment that was bent to produce a laterally directed exit site emerging above the level of the belt. Forty-eight subjects (27%) were satisfactory candidates for either catheter type. Average follow-up was significantly less in the lateral exit-site group due to a greater proportion of subjects not completing the study for various causes listed in Table 2. Contingency table analysis using Fisher's exact test revealed no significant difference between the two groups for completing versus not completing the study ($p = 0.55$).

Survival distributions for time to first exit-site infection, peritonitis, and catheter loss from infectious complications are illustrated in Figures 1, 2, and 3. Log-rank comparisons of these survival estimates showed no significant differences between catheters with downward and lateral exit-site configurations. Survival time to first tunnel infection (data not shown) was not different for the two groups ($p = 0.89$). The results of Poisson regression of event rates (episodes/patient-year) for exit-site infection, tunnel infection, peritonitis, and catheter loss for downward and lateral exit-site groups are listed in Table 3. There were no significant differences in the rates of occurrence of any of these events between the two groups.

Spearman correlations for first and succeeding antibiotic-free time intervals between infection events were found to be small and insignificant for both exit-site infection and peritonitis (data not shown); therefore, the analyses of antibiotic-free intervals were treated as independent of the patient. Log-rank tests of Kaplan–Meier survival analyses of the length of antibiotic-free time intervals for exit-site ($p = 0.94$) and peritonitis infections ($p = 0.72$) were not different for patient groups with downward or laterally directed exit sites.

There were four cases of tunnel-tract infection in each study group. One case in each group underwent unroofing of the catheter tunnel tract and shaving of the superficial cuff for successful resolution of chronic exit-site and tunnel infection. Two catheters in each group underwent removal for tunnel-tract infection without concurrent peritonitis. One of these tunnel-tract infections in the lateral exit-site group manifested itself dramatically within the first week post-implantation and was thought to be due to an intraoperative contamination. The fourth catheter in the lateral exit-site group was removed 1.4 months after implantation due to a pericatheter leak that led to the only case of catheter infection-related peritonitis. The fourth tunnel infection in the swan neck group was cured with antibiotic therapy.

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TABLE 1
Study Population Demographics

Parameter	Downward exit-site group	Lateral exit-site group	*p* Value
Subjects (*n*)	85	93	—
Age (mean±SD) (years)	52.8±16.2	55.2±13.6	0.36
Male (%)	29.4	78.5	<0.0001
Body mass index (mean±SD) (kg/m^2)	27.1±4.9	27.8±4.7	0.30
Diabetes mellitus (%)	49.4	54.8	0.47
Follow-up (mean±SD) (months)	23.8±15.3	18.1±14.1	0.01
Total follow-up (months)	2022	1682	—

TABLE 2
Causes of Subject Loss Before End of Study

Causes	Downward exit-site group (*n*)	Lateral exit-site group (*n*)
Dialysis-related infection	10	13
Died	14	13
Elective transfer to hemodialysis (inadequate dialysis; psychosocial)	9	13
Kidney transplantation	1	5
Recovery of renal function	1	0
Moved out of service area	5	6
Removal for non dialysis-related complication	4	3
Total	44	53

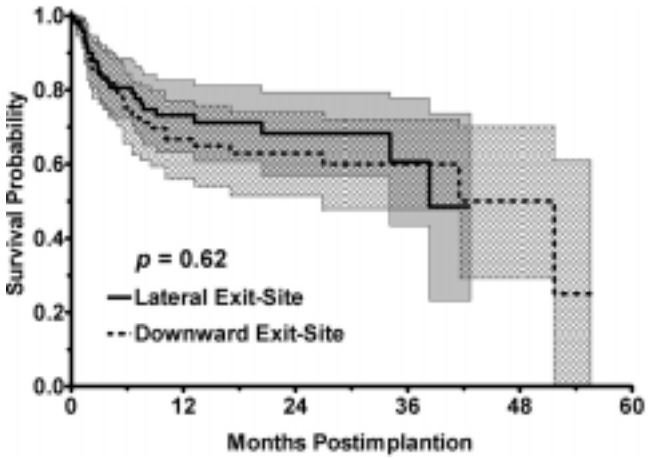

Figure 1 — Survival distributions for time to first episode of exit-site infection for lateral and downward-directed exit-site groups were not statistically different. Shaded areas indicate the 95% confidence interval for each curve.

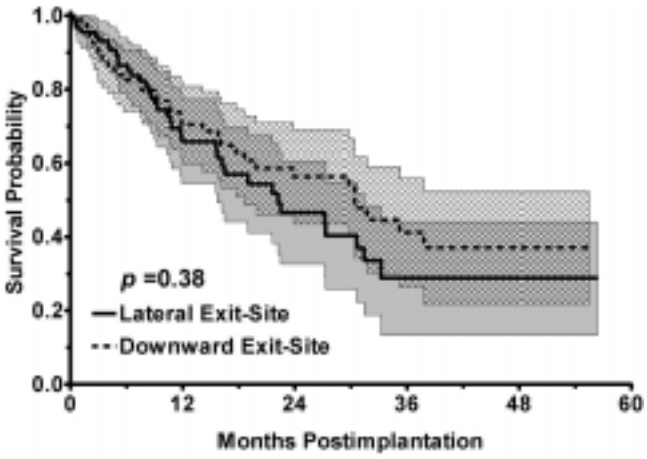

Figure 2 — Survival distributions for time to first episode of peritonitis for lateral and downward exit-site groups were not statistically different. Shaded areas indicate the 95% confidence interval for each curve.

The incidence of mechanical complications for the two catheter groups was low. Three swan neck catheters (3.6%) developed pericatheter leaks during the immediate postoperative period, while two straight intercuff catheters (2.2%) experienced a leak. Except for the one leak in the straight intercuff catheter group that led to catheter infection-related peritonitis, the remainder resolved with an additional period of catheter rest. One left-sided swan neck catheter was observed to develop left mid-abdominal tip displacement following an episode of constipation with colon distention. The patient experienced pain toward the end of dialysate drainage. Catheter manipulation was declined by the patient and symptoms were satisfactorily managed with a tidal di-

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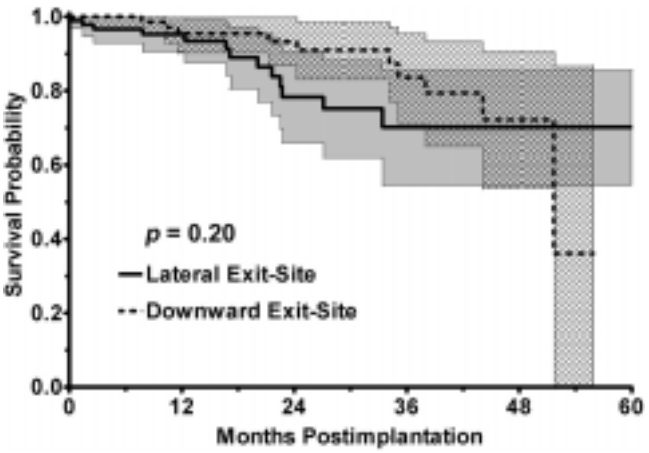

Figure 3 — Cumulative survival probability of catheter loss from infectious complications for lateral and downward exit-site groups was not statistically different. Shaded areas indicate 95% confidence interval for each curve.

alysis regimen. A left-sided straight intercuff catheter developed displacement of the catheter tip into the left mid-abdominal region following peritonitis with prolonged ileus and bowel distention. The patient experienced both inflow and outflow discomfort and low drain volumes. Laparoscopic division of a small bowel adhesion allowed the catheter to be repositioned in the pelvis; normal dialysis was resumed . Neither of these two catheter displacements can be attributed to shape memory effects. There were no pericatheter hernias, late leaks, or spontaneous superficial cuff extrusions.

DISCUSSION

Because people come in all sizes and shapes, one catheter type cannot be expected to fit all patients. The most appropriate catheter choice for the patient is the one that produces the best balance of proper deep pelvic location of the catheter tip for good hydraulic function, an exit site in an environmentally friendly zone easily visible to the patient, and a course through the abdominal wall with the least amount of tubing stress. A previous anthropometric analysis (14) demonstrated that peritoneal access can be provided for approximately 75% of patients with either a swan neck catheter employing a downwardly directed exit site or a straight intercuff segment catheter with a laterally configured exit site. Approximately 50% specifically require one of these catheter types and 25% can be served with either. Determinants of most appropriate catheter type were belt-line location, skinfolds, and skin creases. These anthropometric findings are similar to those observed in the present study, where only 27% of patients could be satisfactorily supplied with either catheter. The remaining 25% of patients in whom anthropometric measurements indicate that neither catheter is suitable, usually because of obesity, are logical candidates for extended two-piece catheter systems, permitting remote exit-site locations to the upper abdomen or chest (16,17).

The reported superiority of downward-facing exit sites stems from a retrospective study by Twardowski *et al.* (5) analyzing infectious and mechanical complications of 83 catheters with a mix of tunnel directions. Although the study continues to be widely cited in support of the swan neck catheter design, it is confounded by an assortment of one-cuff and two-cuff catheters implanted through midline and lateral approaches that were further subdivided into four tunnel directions, with group sizes numbering from 15 to 29 subjects. Approximately 24% of the subject entries were reconstructed from abdominal scars of previously removed catheters. The study concluded that infection of a downwardly directed exit site was less resistant to treatment compared to any other exit direction. In addition, straight tubing bent to produce a downwardly directed tunnel was associated with a significantly higher incidence of catheter tip migration. The subjects from this retrospective analysis also comprised a portion of the historic control group for a subsequent study of long-term experience with swan neck catheters (7). In the latter study, catheter malfunction was improved with the swan neck design compared to the historic control group; however, there were no significant differences in exit-site/tunnel infection, peritonitis, and pericatheter leak.

TABLE 3
Results of Poisson Regression Comparing Event Rates Between Catheter Groups with Downward and Lateral Exit-Site Directions

Event	Downward exit site (episodes/patient-year)	Lateral exit site (episodes/patient-year)	Poisson regression (*p* value)
Exit-site infection	0.26	0.27	0.86
Tunnel infection	0.02	0.03	0.79
Peritonitis	0.42	0.43	0.87
Catheter loss	0.06	0.09	0.29

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Most other reported studies with swan neck catheters are retrospective and historically controlled experiences (6,8,10). Implantation methodology and tunnel configurations for the historic control groups were not described. Although trends existed to support the swan neck configuration, none of the comparative differences in mechanical and infectious complications reached statistical significance. Lye *et al.* (11) performed a prospective randomized comparison of swan neck coiled-tip and straight intercuff straight-tip catheters, with 20 subjects in each group. There were no significant differences in peritonitis and mechanical complications between the two groups. Interestingly, the authors reported a significantly lower incidence of exit-site infection in the swan neck group despite the fact that the straight intercuff catheters were also configured to produce a downwardly directed exit site.

Eklund *et al.* (23,24) conducted two separate prospective randomized studies comparing swan neck catheters to straight intercuff segment catheters. One study employed one-cuff catheters in both groups (23) and the second used two-cuff devices (24). In both studies, 40 subjects were equally randomized to two groups. The tunnel tract was directed upward in the straight intercuff segment catheters. No significant differences between catheter types for mechanical and infectious complications and catheter survival were detected in either study. Three cuff extrusions occurred in two-cuff catheters with upward-directed tunnel tracts. The authors reported that the subcutaneous cuffs were positioned about 2 cm from the exit site.

Intuitively, an upwardly directed catheter exit sinus would appear to collect dirt, perspiration, and flow of water during bathing, thereby leaving the patient more susceptible to exit-site infection. Conversely, a downwardly directed exit site would seem less likely to become contaminated because of gravity flow away from the orifice of the skin sinus tract. However, no conclusive evidence exists to support the superiority of one exit-site direction over another. In the present study, catheter types employing downward and lateral tunnel-tract and exit-site configurations produced equivalent outcomes for exit-site infection, tunnel infection, peritonitis, and catheter survival.

Multiple studies show that the incidence of catheter tip migration is minimized when resiliency forces of the tubing are adequately taken into account. The preformed bend of the swan neck catheter promotes pelvic orientation by eliminating shape memory effects (7,9). Eklund *et al.* (24) successfully avoided resiliency forces by implanting the straight intercuff segment catheter in a straight configuration across the abdominal wall with an upward-directed tunnel tract. The current study and others (25–30) controlled shape memory forces by implanting the straight intercuff catheter in a long musculofascial tunnel to immobilize the transmural segment. This effectively maintains pelvic orientation of the catheter tip despite bending the straight tubing in a subcutaneous tract.

Superficial cuff extrusion can be prevented by avoiding excessive angulation of the catheter in the subcutaneous tract and appropriate distancing of the cuff from the exit site. Helfrich and Winchester (31) described a laterally directed tunnel tract in which the skin exit site was cephalad to the level of the muscle insertion site of the catheter. This tunnel-tract configuration, similar to that used in the current study, creates a gentle arch with minimal tubing stress. The subcutaneous cuff of straight intercuff catheters that are bent in an arcuate configuration should be positioned 3 – 5 cm from the exit site (12,18,31). Compared to the usual recommendation of 2 cm, this deeper positioning of the superficial cuff is less prone to extrusion and to infection spreading from the exit site (12). Just as in the case of eliminating resiliency forces with a swan neck bend for downward exit sites, consideration should be given to producing a catheter with a gentle preformed lateral bend capable of emerging the tubing above the level of the belt line for mid-abdominal exit sites.

One criticism of the current study is that the catheter assignment was not randomized. Instead, specific criteria were used to match the most appropriate catheter type to the physical characteristics of the patient. A properly performed randomized protocol would necessitate enrolling only subjects that were candidates for both types of catheters. According to previous anthropometric analyses (14) and supported by observations of the present study, only about one quarter of peritoneal dialysis patients fall into this category. The time required to accrue sufficient numbers for analysis makes randomization impractical, unless conducted as a multicenter trial.

ACKNOWLEDGMENT

Presented at the 26th Annual Conference on Peritoneal Dialysis, February 28, 2006, San Francisco, California, and published in abstract form in *Peritoneal Dialysis International* 2006; 26(Suppl 1):S36.

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