

### PD catheters: evolution towards optimal design



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#### ABSTRACT

The first peritoneal accesses were devices that had been used in other fields (general surgery, urology, or gynecology) for flush or irrigate: trocars, rubber catheters, and sump drains. The majority of cases were treated with the continuous flow technique; rubber catheters for inflow and sump drains for outflow were commonly used. These early devices, used for short-term peritoneal dialysis, were plagued with multiple complications, such as pressure on intestines of rigid tubes, plugging of openings, leakage of fluid around the access, and difficulties in fixation of the tube on the abdominal wall. In the late 1940s, after World War II, multiple peritoneal accesses were tried, and first accesses specifically for peritoneal dialysis were designed. In the 1950s and particularly 1960s new access features solved most of the problems and eliminated most complications of peritoneal dialysis performed in the supine position. The invention of silicone rubber catheter with polyester cuff(s) was a greatest breakthrough in peritoneal dialysis access development. Unfortunately, none of the currently used catheters is trouble free; poor dialysate drainage, pericatheter leaks, exit site and tunnel infections, and recurrent peritonitis episodes are frequently encountered. Therefore, there is an incessant search for new technological solutions, including new shapes of intraperitoneal and intramural catheter segments, and new catheter materials are tried.

**KEYWORDS:** Peritoneal access, Abdominal drains, Cannulas, Catheters, Peritoneal lavage, Peritoneal irrigation, Peritoneal dialysis

#### Introduction

This paper will present a brief history of peritoneal access development and describe the designs of most commonly used devices. More complete history (seven times longer) has been described in my previous paper published in 2006 (1). For more details one can go to this paper.

Celsus in his treatise, *De Medicina*, written about 30 AD, described the drainage of fluid from the peritoneal cavity using a hollow cane stalks (in Latin *canna* – hence the name cannula) introduced after the incision of the abdominal wall. Since the 17th century the tube, usually metal, was introduced on trocar. In surgery the cannulas were used to flush (*lavare*), to hydrate or irrigate (*irrigare*) for bladder, gall, pleura, and peritoneum. Cannulas were also called probes or catheters (from Greek *καθιεναι* – to send down, to introduce). For almost two centuries there were no publications on peritoneal dialysis in humans; however, the properties of peritoneum were studied in animals. Georg Wegner, from the University of Berlin, perfused the peritoneal cavity of rabbits. For the access he used a cannula with multiple side perforations that was introduced into the peritoneal cavity on the right side and exited on the left. He noted that hypotonic solutions were absorbed and hypertonic solutions increased in volume (2). Putnam from John Hopkins University, Baltimore, Maryland, USA, repeated many previous experiments and determined that the peritoneum behaves like a semi-permeable membrane (3).

Georg Ganter from Würzburg, Germany, is commonly credited with the first peritoneal dialysis in humans for the purpose of treatment of uremia. In his paper from 1923 (4) Ganter described several experiments of peritoneal dialysis in guinea pigs, where he infused normal saline into the peritoneal cavity and drained it after a short period of time. His first attempt of sodium chloride infusion into serous

cavity was done in Greiswald, Germany, in 1918. In a patient with terminal uremia he drained 3/4 liters of effusate from the right pleural space and replaced it with normal saline. He did not drain the solution, but observed improvement in the patient's condition. In the same paper he reported on two cases of normal saline infusion into the peritoneal cavity; in the first case with bilateral ureteral obstruction due to uterine carcinoma, he infused 1½ liters of normal saline, in the second case he infused "3 liters of normal saline to a diabetic patient, who lay totally unconscious in coma; the patient's condition improved temporarily so the relatives could communicate with him". In all cases he used a needle commonly used at that time for abdominal and pleural punctures. In patients, he did not drain the fluid as he did in guinea pigs, so it was not dialysis as we understand it now; however, there was some dialysis into the saline solution. In his paper he speculated on the possibility of using two puncture needles for simultaneous infusion and drainage of the rinsing fluid.

Rosenak from Budapest, working as a volunteer in Bonn, and Siwon, from the Surgery Department at the University of Bonn, Germany, performed several experiments on continuous dialysis in nephrectomized dogs in 1926 (5). They inserted two glass cannulas through laparotomy. The inflow cannula tip was placed below the liver, the outflow in the Douglas cavity. Simple glass tubes, used in early experiments, were frequently obstructed so they decided to provide "cannulas with flask shape, multi-perforated, sprinkling can rose-like tips". These were manufactured by Geissler from Bonn. If the cannula became obstructed despite this modification, they performed omentectomy before inserting new cannulas.

The first continuous flow peritoneal dialyses in humans with acute renal failure caused by poisoning with mercury bichloride were performed in two patients by Balazs and

Rosenak from St. Rochus Hospital in Budapest, Hungary in 1934 (6). For peritoneal access they used glass cannulas distended globularly at the tip and having multiple holes (similar to those used previously by Rosenak and Siwon (5) or cannulas made of fine wire. The inflow cannula was introduced between the liver and the diaphragm, the outflow cannula was inserted into the Douglas cavity. Both cannulas were introduced by laparotomy under local and light ethyl chlorine anesthesia. In the first patient the continuous dialysis lasted 1/2 hour and 12 liters of 4.2% glucose were used, in the second patient 19 liters of 0.8% saline were used during 1½ hours of continuous dialysis. Both patients died.

The first case of a patient who survived after peritoneal lavage for the treatment of uremia in April, 1937, was reported by Wear, Sisk, and Trinkle from the Wisconsin General Hospital, Madison, Wisconsin, USA (7). "The procedure was carried out by morphine and nembutal anesthesia. A standard gall bladder trochar was introduced in the upper abdomen. The trochar introduced into the lower abdomen was modified by placing numerous small holes in the distal third to avoid occlusion of a single opening by the omentum and intestine. From an insulated reservoir the fluid was introduced into upper cannula. The lower cannula was attached to rubber tubing which hung dependent to a bottle on the floor and acted as syphon". The authors used the procedure in five cases, but only one patient survived. This was a case of reflex anuria superimposed on obstructive uropathy due to kidney and bladder stones. In spite of urethral catheterization the patient's condition deteriorated and continuous peritoneal lavage with Locke-Ringer's solution was performed. No details of the amount of fluid were given. After the lavage, the urine output gradually increased and the bladder stone was successfully removed. It is difficult to say whether the single peritoneal lavage was important for patient's survival. The authors treated four more patients with continuous peritoneal lavage, using up to 33 L of fluid for a session, but none survived.

No papers on peritoneal lavage, irrigation or dialysis appeared during World War II, but the number of renal failure cases after war trauma must have accelerated research on renal replacement therapies. Seligman, Frank, and Fine from the Surgical Research Department, Beth Israel Hospital and the Department of Surgery, Harvard Medical School, Boston, Massachusetts, USA, performed a series of experiments on nephrectomized dogs to determine suitable peritoneal access, optimal flow of continuous flow peritoneal irrigation, and proper irrigation fluid. The access was a mushroom-tip type catheter inserted through an incision or whistle-tip (urethral catheter with a terminal opening as well as a lateral one) type inserted using a trocar. Both types had added perforations. Mushroom type catheters drained more effectively than the whistle-tip type catheters. "To help maintain patency of the irrigating catheters in long term experiments, omentectomy was performed at the time of nephrectomy". "Ringer's solution containing glucose, used in the early experiments, was changed later to Tyrode's solution. In addition, the irrigation fluid contained sodium penicillin and sodium sulfadiazine for prophylaxis against infection, and the sodium salt of heparin in order to minimize the intraperitoneal formation of fibrin and adhesions" (8). The same group of authors reported the use of this method for treatment of patients. Four patients were presented at the meeting of the American Surgical Association, Hot Springs, Virginia, USA, April 2-4, 1946, by Jacob Fine and published in November 1946 (9). One patient with acute renal failure due to "parenchymatous injury to the kidneys from sulfathiazole administration" was also reported

separately in more detail (10). The mushroom catheter and the sump drain were used in this case. The patient ultimately recovered kidney function. Although in the discussion the authors stated that "(w)e cannot state with finality that the patient would have died without peritoneal irrigation", the severity of the case, fifteen days of oliguria/anuria, and improvement during peritoneal lavage seem to justify the assumption that this was the first patient who survived because of peritoneal dialysis. The report in JAMA of successful use of peritoneal irrigation in acute renal failure prompted others to implement this method.

The major problems encountered by clinicians treating patients with peritoneal irrigation were related to peritoneal access. Rosenak, working with Oppenheimer at the Mount Sinai Hospital in New York, New York, USA, in a paper published in Surgery in 1948 (11) listed the five most troublesome complications of peritoneal drains used for fluid outflow: "1) Rigidity of the tube with resulting pressure on the intestines, 2) Constant suction of contaminated air into the peritoneal cavity, 3) Occasional plugging of the small openings, 4) Leakage of lavage fluid into the dressing, which is a potential source of infection and which make exact determination of nitrogen output difficult, 5) Difficulties of proper fixation of the tube on the abdominal wall". For the first time they developed a drain specifically for peritoneal dialysis. Made of stainless steel the tube provided a rigid extra-abdominal portion, but flexible intraperitoneal portion made of a spiral, stainless steel spring wire with a rounded tip. An adjustable plate was screwed to the outer portion of the steel tube and served for fixation to the abdominal wall by means of adhesive plaster. The straight inner tube was located inside the extra-abdominal rigid tube and extended about half an inch into the flexible intra-abdominal tube. This inner tube was fitted with a rubber tube connection for suction aspiration for fluid outflow. There was an air space between the inner and the outer tube which was connected with the right angle air inlet tube further connected with a glass funnel covered with several layers of sterile gauze. Because of this connection with air, no significant negative pressure could develop. The authors believed that this would prevent omentum from being drawn into interstices of the spring coil. The access was used in dog experiments and, according to the authors, performed satisfactorily. This peritoneal access was factory-built (Speedo Manufacturing Company, New York, New York, USA.) Compared to the sump drain, the access introduced two important improvements: flexible tube made of spiral wire instead of rigid network of cords and the plate for fixation to the abdominal wall.

By permission of Oppenheimer, a second version of the Rosenak-Oppenheimer access was described by Ferris and Odel from the Mayo Clinic, Rochester, Minnesota, USA (12). The improved version had two accesses, one for inflow and one for outflow. They found the inflow tube to be entirely satisfactory. However, they experienced considerable difficulty in fluid outflow, because the flexible steel spring appeared to be wound too tightly. They were also concerned with the foreign body reaction to metal and rubber tubes. Accordingly, they improved the Rosenak-Oppenheimer access by changing the intra-abdominal portion of the outer tube. Instead of the spring coil they used a polyvinyl tube with multiple perforations. This tubing was "sweated" into the stainless steel portion of the tube with acetone. The tips of the tubes were provided with plugs consisting of bendaloy completely encased in the polyvinyl. The tubes were weighted with these plugs to insure they would hang dependently in the peritoneal cavity. This was particularly important for the outflow tube to keep the tip in the true

pelvis, the place of a fluid reservoir. Francis and Odel introduced two important ideas in their access: 1) use of plastic (polyvinyl) for the intra-abdominal segment of the access, and 2) use of weights to keep the tip of the tubing in the true pelvis. Both ideas were emulated later by other inventors.

Rapid progress in peritoneal dialysis was made in the 1950s. Grollman, from the Southwestern Medical School of the University of Texas, Dallas, Texas, USA, and his collaborators reported their experience with intermittent peritoneal lavage in nephrectomized dogs and 5 patients. The fluid was infused and drained from the peritoneal cavity through a single polyethylene tube placed through the anterior abdominal wall, "(a) trocar was inserted as in the routine removal of ascitic fluid, the stylet replaced with the polyethylene plastic tube, and the trocar removed" (13).

The next major progress was made in the late 1950s when Maxwell, Rockney, Kleeman and Twiss from the University of California in Los Angeles, California, USA, reported their experience with 76 peritoneal dialyses (14). Seemingly minor improvements in the technique provided major improvements in results. The catheter was introduced with a technique similar to that of Grollman et al (13) but the semirigid catheter was made of nylon (polyamide) instead of polyethylene, had rounded tip, and had numerous very tiny perforations (80 holes of 0.2 inch diameter (0.508 mm) instead of larger openings at the distal 3 inches. The authors believed that the use of nonirritating plastic prevented omentum and intestines from clinging to the catheter, and that the small diameter of perforations prevented particles of omental fat from plugging the catheter. They used a 17F Duke trocar set for insertion of the catheter. Two liters of solution, available in 1 L bottles, were warmed to body temperature, and connected through a Y-tubing to the catheter. The fluid dwelled in the catheter was manufactured by the Medical Development Corporation, Miami, Florida, USA. The catheter was introduced surgically under direct vision deep into the posterior pelvis or through a 22 G gallbladder trocar in the midline directly below the umbilicus. The drainage of fluid from the peritoneal cavity was markedly improved compared to sump drains, but leakage and pericatheter infections continued to plague the access.

The next major progress was made in the mid-1960s. Weston and Roberts made a small improvement by providing Maxwell catheter with a pointed stylet, thus eliminating the need of insertion through the cannula. A sharp stainless steel stylet ("three-sided trocar point") inserted through the nylon catheter was used to penetrate the abdominal wall. As a result, the abdominal opening fitted snugly around the catheter, thereby preventing leakage (15). The stylet catheters soon became commercially available (Trocat) from Don Baxter Inc., Glendale, California, USA, and McGraw Laboratories, Milledgeville, Georgia, USA. Only local anesthesia was used for catheter insertion. Before catheter insertion the abdomen was filled with dialysis solution via a 14 or 15 gauge needle inserted through the linea alba below the umbilicus. Then a small incision was made in the skin, the catheter with the stylet was pierced through the abdominal wall.

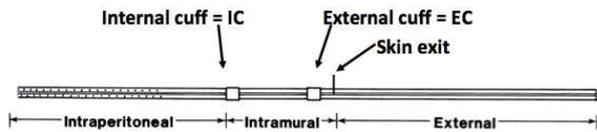
However, the major progress was made by applying a silicone rubber as a material for peritoneal catheter. Silicon rubber was flexible so it did not press on the intestines, and was inert, not causing peritoneal membrane irritation. In 1964 a preliminary communication appeared in the *Lancet* describing the use of silicone rubber peritoneal catheter in two patients (16). Palmer, not satisfied with the available

catheters, and Quinton, already successful in manufacturing silicone rubber shunts for hemodialysis (W.E. Quinton Instrument Co., Seattle, Washington, USA), developed a catheter, which is the prototype for currently used catheters. It was 84 cm long and had internal diameter of 2 mm. The intraperitoneal part of the catheter was coiled and had numerous perforations in the distal 23 cm. In the middle the catheter had a triflange step for locating in the deep fascia and the peritoneum.

In 1968, Henry Tenckhoff and H. Schechter from the University of Washington, Seattle, Washington, USA, published the results of their studies on a new catheter (17). Their catheter was an improved version of the Palmer catheter. An intraabdominal flange was replaced by a Dacron® felt cuff, which allowed tissue growth into it, fixing the catheter in the tunnel and restricting penetration of bacteria (Figure 1). A subcutaneous tunnel was shortened and a second, external cuff was used to decrease the length of the catheter sinus tract. The external cuff was not protruding through the skin, but was located just below the skin surface. To keep both exits (external and internal) down the intramural silicon tubing was bent. The intraperitoneal segment was open ended and the size of the side holes was optimized to 0.5 mm to prevent tissue suction. As mentioned above, the small diameter of side holes was recommended by Maxwell et al. (14) 19 years earlier. A shorter subcutaneous tunnel and a straight intraperitoneal segment facilitated catheter implantation at the bedside. To avoid excessive bleeding, the catheter was inserted through the midline. The initial results in six patients were excellent with 5 catheters functioning for 4-14 months.

The Tenckhoff catheter has become the gold standard of peritoneal access. Some of the original recommendations for catheter insertion such as an arcuate subcutaneous tunnel with downward directions of both intraperitoneal and external exits are still considered very important elements of catheter implantation. Few complications were reported in patients treated with periodic peritoneal dialysis in the supine position. However, in patients treated with continuous ambulatory peritoneal dialysis (CAPD), complications became more frequent, due to high intra-abdominal pressure in the upright position and numerous daily manipulations. The most common complications were: exit/tunnel infection, tip migration out of the true pelvis predisposing to obstruction, external cuff extrusion, pericatheter leak, and peritonitis.

To decrease the rate of tip migration modifications of Tenckhoff catheter were made in Toronto, Canada by Oreopoulos and his collaborators and manufactured as TWH (Toronto Western Hospital) catheter by Zellerman company (18). The intraperitoneal portion of the catheter was provided with three silicone discs. Six years later to prevent pericatheter leaks, from the same institution, a TWH-2 catheter was described (19). This catheter inserted through the rectus muscle had two Dacron cuffs, but the deep cuff was provided with a Dacron disc (flange) and a silicone ring (bead) at the deep cuff to create a better seal and prevent pericatheter leaks. The intraperitoneal portion was provided with two silicone discs (Figure 1). The retrospective analysis of complication rates with Tenckhoff and Toronto Western Hospital catheters at the University of Missouri, Columbia, Missouri, USA, (20) showed that the lowest complication rates were with double cuff catheters implanted through the belly of the rectus muscle and with both internal and skin exits of the tunnel directed downward; however, the resulting arcuate tunnel led to frequent external cuff extrusions.



**Toronto Western Hospital (TWH - 2) Catheter**

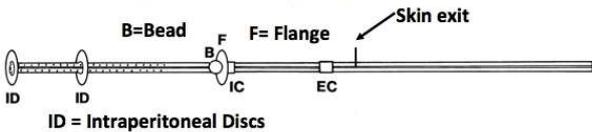


Figure 1 - Tenckhoff Catheter Oreopoulos Zellerman or TWH catheter is shown at the bottom. To decrease leaks they strengthen the seal at the internal cuff by providing a flange and a bead. A purse string suture between the bead and the flange provides an extremely strong seal almost completely preventing pericatheter leaks. Intra-peritoneal tubing was provided with two silicone rubber discs to prevent catheter migration, omental wrap and obstruction.

To avoid this complication a permanent bend between cuffs was postulated and such a catheter was manufactured by Accurate Surgical Instruments, Toronto, Ontario, Canada. The catheter was dubbed “swan neck” because of its shape (20). Because of this design, catheters can be placed in an arcuate tunnel in an unstressed condition with both external and internal segments of the tunnel directed downward (Figure 2).

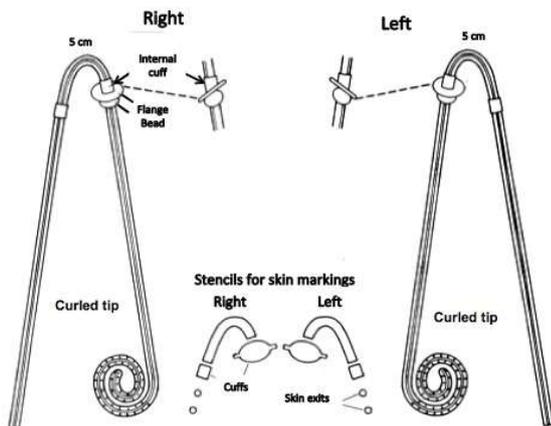


Figure 2 - Swan Neck Missouri Catheters Swan neck Missouri catheters for left and right side have permanent bends between cuffs. A permanent bend between the cuffs eliminates the silicone rubber resilience force or “shape memory”, which tends to extrude the external cuff. The downward peritoneal entrance tends to keep the tip in the true pelvis, reducing its migration. Stencils for skin markings help proper localization in the abdomen.

The downward directed exit, two cuffs, and optimal sinus length reduce exit/tunnel infection rates. A permanent bend between the cuffs eliminates the silicone rubber resilience force or “shape memory”, which tends to extrude the external cuff. The downward peritoneal entrance tends to keep the tip in the true pelvis, reducing its migration. Similar to TWH-2 catheter Swan Neck Missouri (Figure 2) catheter has a flange and bead circumferentially surrounding the catheter below the internal cuff but the flange and bead are slanted approximately 45° relative to the axis of the catheter (Figure 3). This feature helps to maintain downward direction of the intra-peritoneal segment. Insertion through the rectus muscle decreases pericatheter leaks. Lower exit/tunnel infection rates curtail peritonitis episodes.

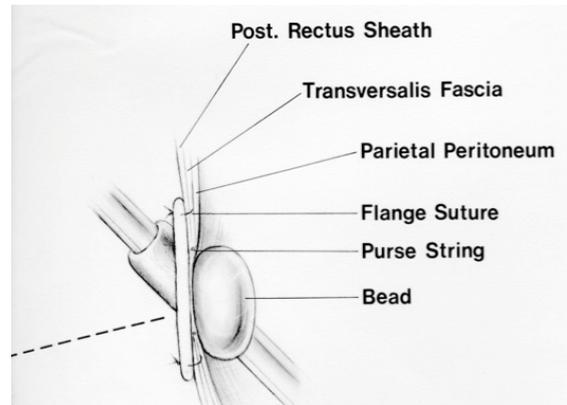


Figure 3 - Bead/flange relation to the peritoneum This slide shows the bead/flange relation to the peritoneum. A purse string between the flange and the bead creates an extremely tight seal around the catheter. A slanted bead and flange preserve better downward direction of the intra-peritoneal segment of the tubing. Downward direction of the intra-peritoneal entrance decreases the rate of catheter migrations.

Finally, swan-neck catheters with a coiled intra-peritoneal segment (Figure 2) minimize infusion and pressure pain. Slanted flange and curved intratunnel part requires different catheters for the right and left side (Figure 2). Swan neck catheters are designed to have an exit in the abdominal integument (swan-neck abdominal, Missouri, catheters) or in the chest (swan-neck presternal catheter – Figure 4).

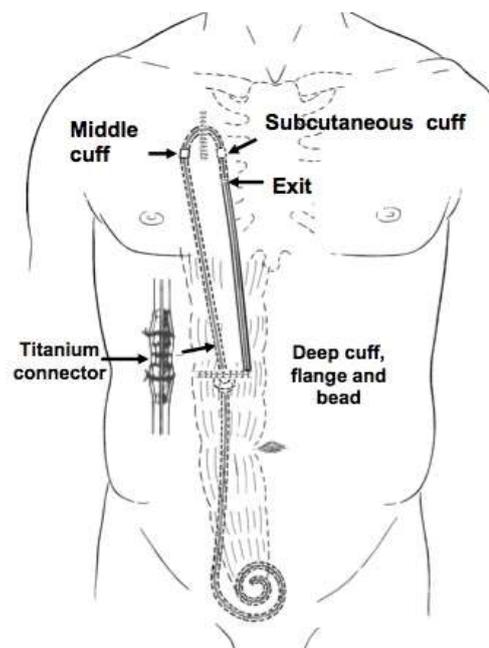


Figure 4 - Presternal catheter post implantation in relation to body structures The presternal catheter after implantation. A six-year experience with these catheters in one center showed reduced complications compared to other catheters. Survival probabilities of 95% and 86% at two and three years respectively are the best results ever reported.

The idea of a presternal exit location stemmed from several observations indicating that this location may decrease exit infections (21). The chest is a sturdy structure with minimal wall motion; the catheter exit located on the chest wall is subjected to minimal movements decreasing chances of trauma and contamination. Also, in patients with abdominal ostomies and in children with diapers, a chest exit location decreases chances of contamination. Moreover, a loose

garment is usually worn on the chest and there is less external pressure on the exit. Clinical surgical experience indicates that wounds heal better after thoracic surgery than after abdominal surgery; this may be related to less chest mobility or some other reasons. Obese patients have higher exit site infection rates and a tendency to poor wound healing, particularly after abdominal surgery. The subcutaneous fat layer is several times thinner on the chest than on the abdomen. If fat thickness *per se* is responsible for quality of healing and susceptibility to infection then the chest location may be preferred for obese patients. The catheter is particularly useful in obese patients (BMI>35), patients with ostomies, children with gastrostomy tubes, diapers, and fecal incontinence, and patients who want to take tub baths without the risk of exit contamination. Many patients prefer a presternal catheter because of better body image.

To accommodate these principles, the swan-neck peritoneal catheter was modified to have an exit on the chest but preserving all advantages of the swan-neck Missouri coiled catheters; minimizing catheter obstruction, cuff extrusion, pericatheter dialysate leak and infusion pain. The major differences from the swan-neck Missouri catheter are the length of the subcutaneous tunnel and three instead of two cuffs. The presternal peritoneal dialysis catheter is composed of two flexible (silicon rubber) tubes, which are connected end to end with a titanium connector in the tunnel (Figure 4).

In conclusion, technological evolution never ends. Many improvement of Tenckhoff catheter provided better results. Nevertheless, even today, almost five decades after first use, the Tenckhoff catheter in its original form is widely used catheter type. More information on peritoneal catheters and their implantation is available in the recent book chapter (22).

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