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Cement Leakage in Percutaneous Vertebroplasty for Osteoporotic Compression Fractures With or Without Intravertebral Clefts

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OBJECTIVE. The purpose of our study was to compare the incidence and location of cement leakage in percutaneous vertebroplasty for osteoporotic compression fractures with and without intravertebral clefts.

MATERIALS AND METHODS. Percutaneous vertebroplasty was performed in 120 consecutive patients with 300 osteoporotic compression fractures. The cement volume injected was recorded. The cement leakage was evaluated using spinal radiography, MRI, and fluoroscopy during the procedure and CT after the procedure.

RESULTS. One hundred seven vertebrae contained intervertebral clefts, and 193 vertebrae had no clefts. The cement volume injected (± SD) was 4.0 ± 2.0 and 3.6 ± 1.6 mL into vertebrae with clefts and without clefts, respectively, with no statistically significant difference ($p = 0.14$). There was no statistically significant difference in the incidence of cement leakage between vertebrae with clefts (53 of 107) and those without clefts (78 of 193) ($p = 0.13$). Leakage occurred into the epidural veins (12 of 107), perivertebral soft tissues (7 of 107), disks (41 of 107), intervertebral foramen (1 of 107), and spinal canal (1 of 107) in fractures with clefts and into the epidural veins (47 of 193), perivertebral soft tissues (13 of 193), disks (25 of 193), paravertebral veins (5 of 193), large vein (2 of 193), lung (2 of 193), intervertebral foramen (1 of 193), and spinal canal (1 of 193) in fractures without clefts. Cement leakage into the epidural vein was significantly more frequent in vertebrae without clefts ($p < 0.01$). Disk leakage was significantly more frequent in vertebrae with clefts compared with those without clefts ($p < 0.01$).

CONCLUSION. There was no statistically significant difference in the incidence of cement leakage between vertebrae with clefts and without clefts. However, cement leakage into the epidural vein was significantly more frequent in vertebrae without clefts and disk leakage was significantly more frequent in vertebrae with clefts.

Keywords: cement leakage, clefts, osteoporosis, vertebroplasty

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WEB
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The intravertebral cleft is generally considered a radiographic sign of avascular necrosis of the vertebral body associated with impairment of the vertebral blood supply and cartilaginous nodes and normal stress placed on a weakened vertebra [1–3]. This sign is highly suggestive of osteonecrosis, although it is not specific [4] and has not been described in association with acute vertebral fractures [5]. In other words, clefts are thought to represent fracture nonunion [1, 2].

In percutaneous vertebroplasty, the existence of clefts inside fractured vertebral bodies is significant, and back pain disappears by injecting cement into clefts to relieve instability in the fractured vertebrae [6–12]. Reports have indicated that cement can be injected easily into clefts at low pressure with minimal cement leakage outside the vertebral body [13]. In addition, kyphoplasty is a technique that prepares a gap, or cleft, in a fractured vertebral body using a balloon and then cement is injected. Compared with vertebroplasty, the degree of cement leakage outside the vertebra is lower for kyphoplasty [14, 15]. However, while the cement is being injected into a cleft during percutaneous vertebroplasty, cement sometimes leaks into the intervertebral disk connected to the cleft.

Leakage into the intervertebral disk is often asymptomatic but has been reported as one cause of new compression fractures after percutaneous vertebroplasty [14, 16, 17], and therefore leakage must be minimized. The purpose of this study was to compare the incidence and location of cement leakage in percutaneous vertebroplasty for osteoporotic compression fractures with and without intravertebral clefts.

Materials and Methods

This study was conducted on 120 consecutive patients (107 women, 13 men) with painful osteoporotic compression fractures treated using percutaneous vertebroplasty. The mean patient age was 73 years (age range, 44–86 years). A total of 300 vertebral bodies were treated. Locations and numbers of treated vertebral bodies were as follows: T5, $n = 2$; T6, $n = 5$; T7, $n = 7$; T8, $n = 13$; T9, $n = 11$; T10, $n = 11$; T11, $n = 23$; T12, $n = 50$; L1, $n = 63$; L2, $n = 34$; L3, $n = 43$; L4, $n = 23$; and L5, $n = 15$.

The indication for percutaneous vertebroplasty was back pain caused by vertebral body compression fracture, with pain on percussion of the vertebral spinous process. In cases with multiple compression fractures in which percussion pain of the spinous process was unclear, physical examination was performed using fluoroscopy. Patients with back pain attributed to myelopathy or radiculopathy resulting from stenosis of the vertebral canal or narrowing of the intervertebral foramen were excluded.

Percutaneous Vertebroplasty Procedure

Informed consent was obtained from all patients before the procedure. All procedures were performed by one of the authors who had 9 years of experience in percutaneous vertebroplasty or by a fellowship trainee under the supervision of the author. Percutaneous vertebroplasty was performed under combined CT and fluoroscopic guidance (Advantx LCA plus ACT, GE Healthcare). Thirty minutes preoperatively, 10 mg of morphine hydrochloride, 0.5 mg atropine sulfate, and 25 mg hydroxyzine hydrochloride were administered intramuscularly. Local anesthesia with 10 mL of 1% lidocaine was administered from the skin to the periosteum of the pedicle using a 22-gauge Cathelin needle (Terumo Europe) under fluoroscopic guidance. After orientation of the puncture needle was confirmed on CT and aligned with the Cathelin needle, a 13-gauge bone biopsy needle (Osteo-Site Bone Biopsy Needle Murphy M2, Cook) was advanced into the pedicle of the vertebral arch. A unilateral transpedicular approach was chosen in all cases. CT was repeated, and after the orientation of the biopsy needle was confirmed, the visualization technique was changed to lateral fluoroscopy and the bone biopsy needle was advanced to the anterior third of the vertebral body close to the midline.

Intraosseous venography was performed with 1–5 mL of iopamidol (Iopamiron 300, Schering Japan) or 5–20 mL of carbon dioxide to confirm that the needle was not positioned within a direct venous anastomosis to the central or epidural veins. Subsequently, 20 g of methylmethacrylate powder (Osteobond Copolymer Bone Cement, Zimmer) was mixed with 5 g of barium sulfate powder that had been sterilized with dry heat to increase its opacity. Next, 10 mL of liquid methylmethacrylate monomer was added to the powder, and the mixture was blended to a toothpastelike consistency, producing polymethylmethacrylate (PMMA). Using 1-mL syringes, the PMMA was injected with lateral fluoroscopic guidance. PMMA injection was terminated when adequate filling of the vertebral body was achieved or if leakage occurred. When a fractured cleft was filled with cement for the cases with clefts, we stopped the cement injection. The needle was then removed, and all patients were observed in the supine position for 2 hours.

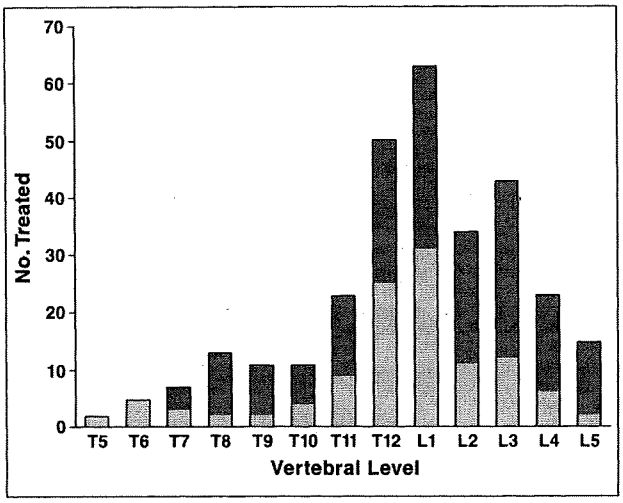


Fig. 1—Graph shows distribution of treated vertebral fractures. Light gray shading indicates without intravertebral clefts and dark gray shading indicates with intravertebral clefts.

Cleft and Leakage Diagnosis

Clefts were diagnosed on the basis of linear well-demarcated radiolucency inside a fractured vertebral body on preoperative radiography or, alternatively, using transverse signal hyperintensities on fat-suppressed T2-weighted MRI. Furthermore, linear well-demarcated radiolucency seen by intraoperative fluoroscopy and lesions in which cement was injected as compact and solid cement filling during PMMA injection were diagnosed as clefts. In addition, CT was performed immediately after PMMA injection, and compact and solid cement fillings also were diagnosed as clefts. Leakage outside vertebral bodies was assessed by CT immediately after PMMA injection, and 3D images were prepared to diagnose leakage location. Images including spinal radiography, MRI, and CT were evaluated by two of the authors who reached a consensus for each case. Chest radiographs were obtained to detect pulmonary cement embolism 1 day after percutaneous vertebroplasty. When a pulmonary cement embolism was suspected during the procedure, chest CT was performed immediately after the procedure.

Statistical Analysis

The volume of cement injection per vertebra was compared between vertebral bodies with and without clefts and analyzed using the Wilcoxon's rank-sum test. The chi-square test was used to compare occurrence rates of cement leakage.

TABLE 1: Cement Leakage Outside Vertebra With or Without Cleft

Location	With Cleft ($n = 107$)	Without Cleft ($n = 193$)	p
Epidural vein	12 (11.2)	47 (24.4)	> 0.01
Perivertebral soft tissue	7 (6.5)	13 (6.7)	0.95
Intervertebral disk	41 (38.3)	25 (13.0)	> 0.01
Paravertebral vein	0 (0)	5 (2.6)	0.09
Large vein[a]	0 (0)	2 (1.0)	0.29
Lung	0 (0)	2 (1.0)	0.29
Intervertebral foramen	1 (0.9)	1 (0.5)	0.67
Spinal canal	1 (0.9)	1 (0.5)	0.67
Total	62 (57.9)	96 (49.7)	

Note—Data are number of patients, and numbers in parentheses are percentages.
[a]Mean inferior vena cava and azygos vein.

All statistical analyses were conducted using StatView for Windows version 5.0 software (SAS Institute), and values of $p < 0.05$ were considered statistically significant.

Results

One hundred seven vertebrae contained intervertebral clefts, and 193 vertebrae had no clefts. Forty-three (40.2%) and 71 (66.4%) of 107 clefts were detected on spine radiography and MRI, respectively. On the other hand, 36 of 107 clefts (33.6%) were diagnosed on fluoroscopy during the procedure or on CT after the procedure. Locations of each vertebra are shown in Figure 1.

The mean volume of cement injected (± SD) was 4.0 ± 2.0 mL for vertebrae with clefts and 3.6 ± 1.6 mL for vertebrae without clefts, and the volumes were not significantly different ($p = 0.14$). There was no statistically significant difference in the incidence of cement leakage between vertebrae with clefts (53 of 107 vertebrae, 49.5%) and those without clefts (78 of 193 vertebrae, 40.4%) ($p = 0.13$). Leakage locations included the epidural vein (12 of 107, 11.2%), perivertebral soft tissue (7 of 107, 6.5%), intervertebral disk (41 of 107, 38.3%) (Fig. 2), intervertebral foramen (1 of 107, 0.9%), and spinal canal (1 of 107, 0.9%) in fractures with clefts; and the epidural vein (47 of 193, 24.4%) (Fig. 3), perivertebral soft tissues (13 of 193, 6.7%), intervertebral disk (25 of 193, 13.0%), paravertebral vein (5 of 193, 2.6%), large veins including the inferior vena cava and azygos vein (2 of 193, 1%), lung (2 of 193, 1%), intervertebral foramen (1 of 193, 0.5%), and spinal canal (1 of 193, 0.5%) in fractures without clefts (Table 1). Cement leakage into the epidural vein was significantly more frequent in vertebrae without clefts compared with those with clefts ($p < 0.01$). On the other hand, disk leakage was significantly more frequent in vertebrae with clefts than in those without clefts ($p < 0.01$) (Table 1).

Symptomatic cement leakage developed in only four patients. One patient had radiculopathy caused by a large cement leak into the adjacent disk. Continuous pain for about 1 month at the puncture site caused by cement leakage into subcutaneous tissue through the needle track developed in three patients. No patients had symptoms from the epidural leakage.

Discussion

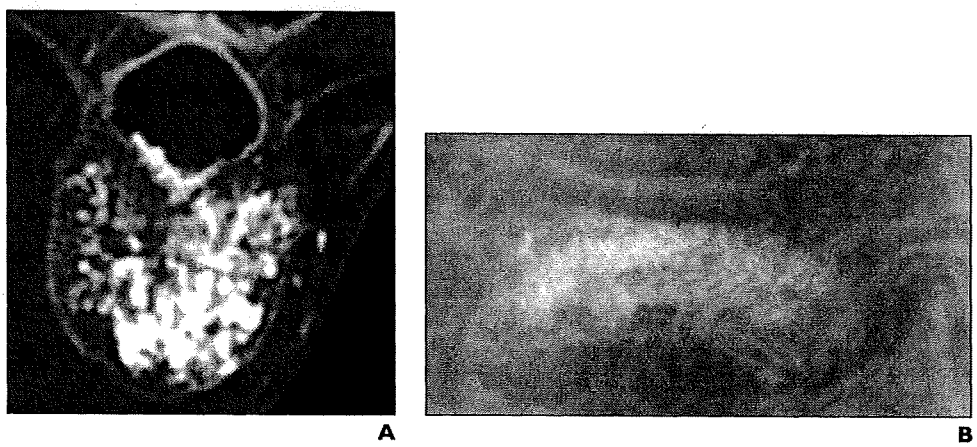
The presence or absence of clefts was diagnosed using not only preoperative radiography and MRI but also intraoperative fluoroscopy and the distribution of PMMA after injection on CT. The reason for these varying methods of detection was that the detection rate of clefts is low using preoperative diagnostic imaging alone, and in some cases clefts can be seen only after injecting PMMA [6, 17–19].

The amount of injected PMMA was greater for vertebral bodies with clefts compared with vertebral bodies without clefts, although there was no statistically significant difference in the volume of PMMA injected. In vacuum clefts containing gas or fluid, the level of resistance during cement injection was low because of low pressure inside the clefts, allowing a greater amount of cement into the cleft and increasing the cleft volume [5, 20].

There was no statistically significant difference in the incidence of cement leakage between vertebrae with clefts and those without clefts. These results agree with the report by Jung et al. [21], but Krauss et al. [15] reported that the incidence of leakage was lower for vertebral bodies with clefts than those without clefts. Krauss et al. indicated that cement leakage occurred in 18.2% (8 of 44) of clefts, whereas cement leakage occurred in 49.5% (53 of 107) of clefts in our series. The leakage rate of our series was significantly higher than in the series of Krauss et al. The mean cement volume injected by Krauss et al. was 3.1 mL, and the mean was 4.0 mL in our series. The cement volume injected was greater in our series than in that of Krauss et al. However, because Krauss et al. did not describe the end point of cement injection, the difference between their study and ours is not clear. Ha et al. [22] likewise reported that the incidence of leakage was higher for vertebral bodies with clefts compared with those without clefts.

Fig. 2—79-year-old woman with vertebral compression fracture with cleft of T12 due to osteoporosis. Sagittal CT image shows cement leakage into disk through part of destroyed endplate.

The incidence of leakage into the intervertebral disk was significantly higher for vertebral bodies with clefts than for vertebral bodies without clefts. The current study and the investigation by Jung et al. [21] were the only ones that have addressed the location of cement leakage from vertebral bodies with clefts, and our results agreed with the results obtained by Jung et al. The reason for cement leakage from vertebral bodies with clefts is



A **B**

Fig. 3—73-year-old woman with vertebral compression fracture without cleft of T7 due to osteoporosis.
A, CT scan shows bone cement in epidural vein continuing to vertebral body. Cleft is not detected in fractured vertebral body.
B, Lateral spinal radiograph shows opaque cement interspersed through trabecular space.

primarily endplate damage, which is high for vertebral bodies with clefts, allowing cement to leak into the intervertebral disk via endplate damage. Furthermore, studies have reported that the vacuum phenomenon in vertebral bodies is associated with the vacuum phenomenon in the intervertebral disk [6, 23].

For vertebral bodies without clefts, leakage into the perivertebral veins occurred most commonly. The cancellous bone of vertebral bodies contains a rich internal vasculature that communicates with the epidural plexus and segmental veins. Moreover, we applied unilateral injection of cement in all cases. At the unilateral injection, the needle-tip is positioned on the midline of the vertebra. Basivertebral veins are primarily distributed in the midline portion of the vertebra. We think that a part of the cement was injected into the basivertebral veins and then leaked into the epidural veins. Therefore, cement injected into vertebral bodies readily leaks into veins through these passages [24].

Some limitations exist in the current study. First, the study was retrospective and only examined a small number of vertebral bodies. Second, all procedures were not performed by only one operator.

Injecting cement into clefts is easy, and fluoroscopy during injection shows that the height of vertebral bodies increases during injection. This tempts operators to inject more cement. However, our findings show that the incidence of cement leakage into the intervertebral disk is significantly higher in vertebral bodies with clefts, and leakage into the intervertebral disk may induce new compression fractures [11, 13, 14]. Caution must therefore be exercised during cement injection while keeping these points in mind.

In conclusion, there was no statistically significant difference in the incidence of cement leakage between vertebrae with clefts and those without clefts. However, cement leakage into the epidural vein was significantly more frequent in vertebrae without clefts compared with those with clefts, and leakage into the intervertebral disk was significantly more frequent in vertebrae with clefts than in those without clefts.

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LABORATORY INVESTIGATION

Mechanical Characteristics of Composite Knitted Stents

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Abstract We used metal wires and fibers to fabricate a composite knitted stent and then compare the mechanical characteristics of this stent with those of a pure metallic stent of the same construction in order to develop a stent that offers a comparable degree of expandability as metallic stents but can be used for highly curved lesions that cannot be treated using metallic stents. We fabricated two types of composite knitted stent (N–Z stents), using nitinol wire with a diameter of 0.12 mm and polypara-phenylene-benzobisoxazole (PBO) multifilament fiber (Zyron AS; Toyobo, Osaka, Japan). Stents were knitted into a cylindrical shape using the same textile pattern as a Strecker stent. Two loop lengths (L) of nitinol wire were used in the N–Z stents: L = 1.84 mm (N–Z stent L = 1.84) and L = 2.08 mm (N–Z stent L = 2.08). For the sake of comparison, we fabricated a metallic stent of nitinol using the same textile pattern (N–N stent L = 1.92). We applied a radial compression force diametrically to each stent and applied a bending force diametrically at the free end of a stent with one end fixed in order to evaluate the relationship between stent elasticity and load values. In addition, we macroscopically evaluated the generation of kinks when the stent was bent 180°. The radial compressive force when the stent diameter was reduced by 53% was 6.44 N in the case of N–Z stent L = 1.84, 6.14 N in the case of N–Z stent L = 2.08, and 4.96 N in the case of N–N stent L = 1.92 mm. The composite stent had a radial compressive force higher than that of a metallic stent. The restoring force to longitudinal direction at a 90° bending angle was 0.005 N for N–Z stent L = 1.84, 0.003 N for N–Z stent L = 2.08, and 0.034 N for N–N stent L = 1.92. The restoring force of the composite stent was significantly lower. Finally, the composite stent generated no definitive kinks at a bending angle of 180°, regardless of loop length. However, the N–N stent clearly produced kinks, causing blockage of the inner cavity. In conclusion, the use of a metal and fiber composite in the construction of a knitted stent ensures an expansion performance comparable to that of metallic stents, while providing better kink resistance.

Keywords Composite stent · Fiber · Radial force · Restoring force · Kink

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Introduction

Metallic stents are made of materials such as nitinol and stainless steel. Their mechanical properties are mainly regulated by stent mesh design, properties of the metal, wall thickness, and radius. When the wall thickness and radius of some stents are comparable, stents that have a high degree of expandability tend to have a high degree of restoring force against bending deformation. Focusing on hollow organs that bend highly expandable stents, the restoring force generated during bending deformation results in excessive surface pressure being applied to tissue, and this can cause ulceration and tissue perforation [1]. In addition, during high-degree bending deformation, adjacent struts make contact and cause kinks, as they deform in a manner that allows them to protrude inwardly [2]. To resolve these

disadvantages of metallic stents, we fabricated composite knitted stents that combine two types of material, each having a different bending stiffness. With conventional stents used for the intestinal tract, biliary system, and vessels in joints, problems exist with patency and antikink properties, and we believe that the stent in the present study may be useful for stenting in such areas. Piquet et al. [3] and Hagen et al. [4] reported metal–fiber composite stents, but no studies assessing mechanical characteristics have been reported. The purpose of this study is to evaluate the mechanical properties of composite material stents fabricated by combining metallic and polymeric fibers.

Materials and Methods

Construction of Composite Material Stents

The materials used for the stents were nitinol wire with a diameter of 0.12 mm and polypara-phenylene-benzobisoxazole (PBO) multifilament fiber (ZYRON AS; Toyobo, Osaka, Japan) with a diameter of 0.18 mm. When achieving both expandability and restoring force with composite stents, shape memory treatment by heating nitinol is essential. PBO is a fibrous material but can withstand nitinol heat treatment. We knitted these in the same textile pattern (N–Z stent) (Fig. 1) as that of a Strecker stent [5].

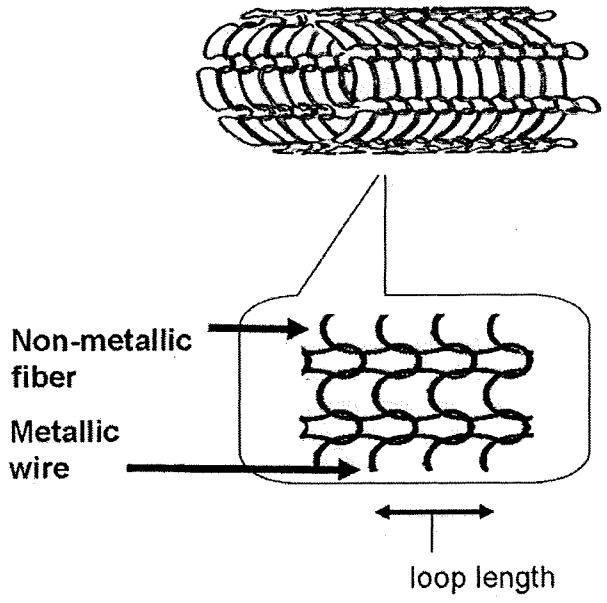

Fig. 1 Composite knitted stent. Nitinol wire and PBO fiber are alternately knitted. After being removed from the anchor, the composite stent is constricted longitudinally. We defined the distance of nitinol wires of composite stents after removal from the anchor as the loop length (L)

As composite stents are knitted with fiber materials under stretched conditions, when the anchor, which is a part of the knitting machine, is released, the length of the nitinol loops shrinks. Because stent expandability can be regulated by the loop length of the metallic wire during periods of no load, we defined the loop length of the no-load nitinol wire loop, L, as the loop length of the stent and used a 50× microscope (DS-3US; Magica, Osaka, Japan) to take actual measurements. We altered the knitting conditions and fabricated two types of composite knitted stents: an L = 1.84 mm N–Z stent (N–Z stent L = 1.84) and an L = 2.08 mm N–Z stent (N–Z stent L = 2.08). For the sake of comparison, we also fabricated an L = 1.92 mm metallic stent using nitinol alone (N–N stent L = 1.92).

The three trials fabricated stents were 15 mm in diameter and 80 mm long. After knitting, we heated the stents at 400°C for 30 min as a shape memory treatment for the nitinol alloy. Taking into account the balance between reduced PBO strength due to heating and the shape–memory properties of nitinol, a temperature of 400°C was selected.

Mechanical Strength of the Stent

With regard to the mechanical strength of the stent, we evaluated the following three items.

Radial Compressive Force

In stenting for hollow organ stenosis, we consider that patency >50% of the luminal diameter can often be achieved after stenting. As an indicator for assessing expandability after placing a stent in the body, the actual measurement range was set at compression until 53%. Even with 100% compression, however, the present stent was not deformed or destroyed. We installed two metal plates in a universal testing machine (RTC-1350A; Orientec Co., Ltd, Tokyo) and set the stent between the upper and the lower metallic plates. We lowered the upper metal plate until the stent diameter was 7 mm (47% of its original diameter) and used that as the measurement starting point. We moved the upper metal plate upward at a rate of 5 mm per minute to release compression. We then successively measured the relationship between stent distortion and load value by means of an autograph connected to the upper metal plate. After the stent reached its no-load point, we lowered the upper metal plate at a rate of 5 mm per minute and compressed the stent until reaching the measurement starting point. We considered this to be one cycle. We took an average of two cycles to measure the stent's radial compressive force [6] (Fig. 2).

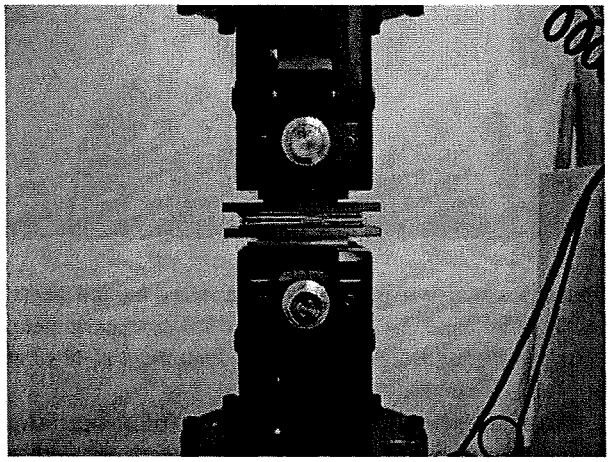

Fig. 2 Radial compressive force was measured using a universal testing machine (RTC-1350A; Orientec Co., Ltd, Tokyo)

Restoring Force

We inserted a mandrel 4 cm into one end of the stent and fixed the other end of the stent in place. We then attached a force gauge (DS2; Imada, Aichi, Japan) diametrically to the free end of the stent and applied external force through the gauge until the stent bent 90°. With the stent bent 90°, we measured the load value displayed on the force gauge. We took three measurements and took the average of these as the restoring force (Fig. 3).

Kink Resistance Performance

We inserted mandrels through both ends of the stent for a length of 2 cm and fixed both ends of the stent in place. We then bent the stent 180° until the mandrels became parallel.

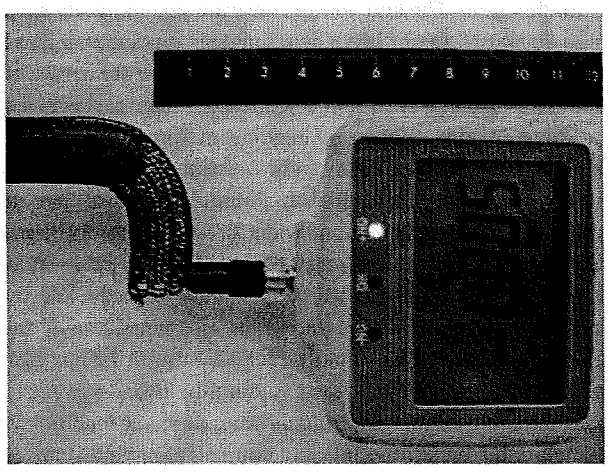

Fig. 3 Restoring force with the stent bent 90° was measured using a force gauge (DS2; Imada, Aichi, Japan)

Under these conditions, we visually assessed the kinking condition in the center of the stent (Fig. 4).

Results

Radial Compressive Force

The radial compressive forces of the stents with a compression load up to 47% of the diameter in the case of N–Z stent L = 1.84, N–Z stent L = 2.08, and N–N stent L = 1.92 increased in a curved line. The radial compressive force when each stent was compressed 9 mm (47% diameter reduction) was 6.44 N for N–Z stent L = 1.84 and 6.14 N for N–Z stent L = 2.08. The restoring force increased as the loop length of the metal became shorter and the density of the knit increased. In addition, the restoring force of N–N stent L = 1.92 was 4.96 N (Figs. 5, 6, 7). In other words, compared with the metallic stent, the composite stents showed a greater restoring force at the same metal knit density.

Restoring Force

Restoring forces when the stents were bent 90° were 0.005 N for N–Z stent L = 1.84, 0.003 N for N–Z stent L = 2.08, and 0.034 N for N–N stent L = 1.92.

Kink Resistance Performance

With N–N stent L = 1.92, we found an increase in kinking at restoring angles of $\geq 60°$. With N–Z stent L = 1.84 and N–Z stent L = 2.08, we found a slight reduction in stent diameter when bending stents 100° or more, but at that level the diameter remained within 5% of the full diameter, irrespective of the knit density. Furthermore, we confirmed macroscopically that bending up to 150° did not produce any kinks.

Discussion

In this study, we fabricated composite knitted stents using nitinol and PBO fiber. We then compared the structural characteristics of these stents with those of a knitted metallic stent of the same construction.

At compression to 47% of its diameter, the radial compressive force of the composite knitted stent indicated a load value that increased in a curved line to the amount of compression. Comparison of composite knitted stents showed that shorter loop lengths had higher load values. Wright et al. reported that for metal stents, the larger the number of vents, the greater the expandability [7]. This

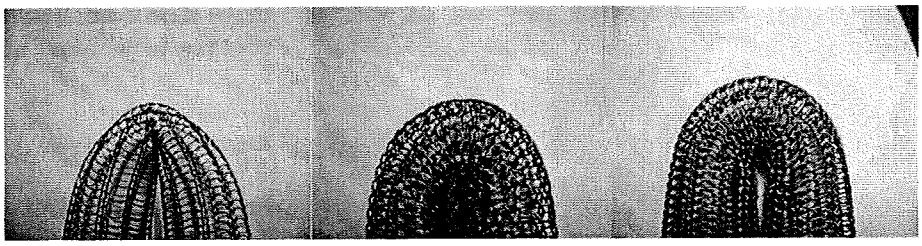

Fig. 4 Compared to the N–Z stent (*center* and *right*), the N–N stent (*left*) shows obvious kinking at bending angles of 180°

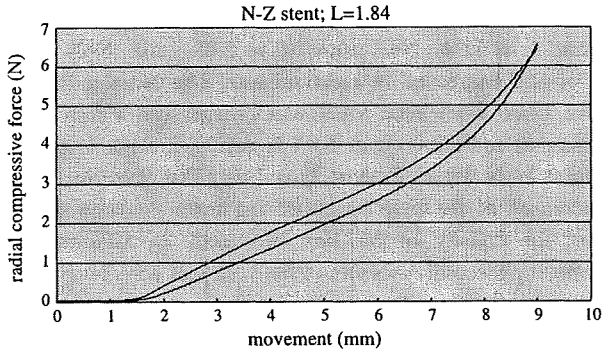

Fig. 5 Relationship between movement of upper metallic plate and radial compressive force of N–Z stent; L = 1.84

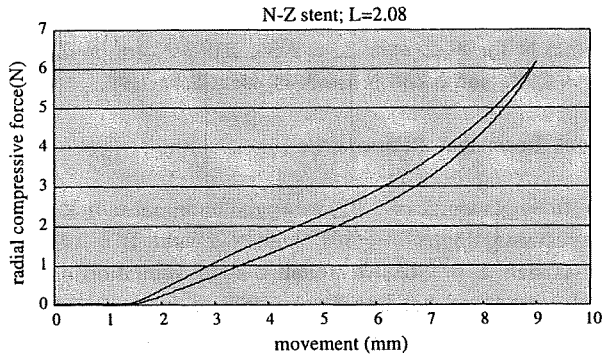

Fig. 6 Relationship between movement of upper metallic plate and radial compressive force of N–Z stent; L = 2.08

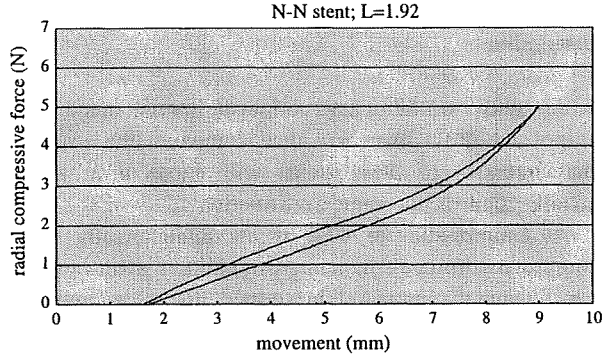

Fig. 7 Relationship between movement of upper metallic plate and radial compressive force of N–N stent; L = 1.92

tendency was also seen with hybrid material knitted stents. On the other hand, N–Z stent L = 2.08, a composite stent, showed a higher radial compressive force than N–N stent L = 1.92, a metallic stent.

We think the reason for this high radial compressive force response despite the longer loop length is because fibers knitted with nitinol prevent deformation of metallic wire. Fibers have tolerance for bending but can have longitudinal resistance for elasticity. As a result, a high radial compressive force is maintained despite the larger loop length.

With regard to restoring force, compared to a metallic stent with a similar knit density, the composite knitted stent showed lower values, and no kinks were seen macroscopically. Mori et al. investigated the mechanisms of stent kink generation using finite-element method analysis and found that the interference between struts reduces flexibility and leads to kinking [2]. In the case of a composite knitted stent, a fiber loop is adjacent to a metal loop. Even if these interfere during bending deformation, the fiber loop deforms easily and generates no restoring force because the fiber has almost no bending stiffness, therefore the main cause of restoring force during bending deformation is the recoil force related to the curvature of the metal wire. As a result, we see a low overall restoring force.

The composite stents fabricated here had a general knit weave construction, similar to that of the Strecker stent and Ultraflex stent. The knit weave construction reportedly has a high degree of flexibility in bending deformation compared with other types of knitting [8]. However, as in the results of this experiment, using a single metal construction clearly led to kinks at high degrees of bending deformation and the restoring force was also high. Solving these problems involves designing a wide loop alignment interval, but an alignment interval that is too wide will not allow for practical expandability. A composite knitted stent is believed to have mechanical properties that cannot be achieved by metallic stent construction due to the characteristics of the fiber components. We think it could be useful for the gastrointestinal tract, biliary tract, and highly flexed vessel.

Limitations of this experiment were, first, our inability to compare the metallic stents and composite knitted stents at the same loop length. This is because releasing the anchor when knitting the composite stent caused the multifilament

fibers to contract, which then caused the nitinol loop length to shrink. To fabricate a stent at the designated loop length requires clarifying the relationship between the knitting conditions and the rate of shrinkage. Second, the safety of PBO in the body has not been investigated. The possibility of foreign body reactions in the body will need to be assessed using animal studies in future.

Conclusions drawn from this study are as follows. Compared with a metal stent of the same design, a composite knitted stent comprising metal and fiber materials allows for a high radial compressive force and a low restoring force. In addition, compared with a metallic stent, the use of composite materials provides excellent resistance to kinking.

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CASE REPORT

Percutaneous translumbar inferior vena cava cannulation under computed tomography guidance

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Abstract Percutaneous translumbar inferior vena cava (IVC) cannulation is an alternative approach for central venous catheterization, but there have been sporadic reports of puncture-related complications. To avoid complications during IVC puncture, percutaneous translumbar IVC cannulation was performed under computed tomography (CT) guidance in addition to fluoroscopy in two patients. To perform chemotherapy for recurrent breast cancer, we planned subcutaneous port catheter placement for central venous access. Under CT guidance, the direction and insertion distance of a long elastor needle were adjusted, and the IVC was punctured at the level of the third lumbar vertebra while taking care to avoid the right urinary tract. A guidewire was inserted through the long elastor needle, and a catheter was placed over the guidewire. It was possible to perform central venous catheterization by percutaneous translumbar inferior vena cava cannulation under CT guidance.

Key words Translumbar · Vena cava · Catheter · Vascular access · Percutaneous

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Introduction

For central venous catheterization, the subclavian vein, internal jugular vein, femoral vein, or upper extremity peripheral vein is generally targeted. However, when these vascular accesses are unavailable, it is necessary to consider placing a percutaneous inferior vena cava (IVC) catheter by translumbar cannulation, transhepatic cannulation, or transhepatic vein cannulation as an alternative.[1–14] To avoid complications during IVC cannulation, we performed percutaneous translumbar IVC cannulation under computed tomography (CT) guidance for two patients.

Case reports

Case 1

The patient was a 60-year-old woman with a height of 151 cm and a body weight of 45 kg. She underwent left mastectomy for left breast cancer 8 years previously and had since repeatedly undergone chemotherapy and radiotherapy for bone, skin, lymph node, and liver metastases. Here, we planned subcutaneous port catheter placement for central venous access to perform chemotherapy. The patient had an invasive 12-cm tumor in the left anterior chest wall. The skin around the tumor was red, reaching the right anterior chest wall. The tumor in the left anterior chest wall reached the anterior mediastinum and was located in the vicinity of the area where the left and right brachiocephalic veins merged. Subsequently, cervical, clavicular, and upper extremity approaches were ruled out; and percutaneous translumbar IVC cannulation was selected.

Case 2

The patient was a 58-year-old woman with a height of 159 cm and a body weight of 50 kg. The patient underwent left mastectomy for right breast cancer 3 years previously and had since repeatedly undergone chemotherapy and radiotherapy for bone, skin, lymph node, and liver metastases. Here, we planned subcutaneous port catheter placement for central venous access to perform chemotherapy. The patient had multiple skin metastases in the bilateral anterior chest wall and neck. Subsequently, cervical, clavicular, and upper extremity approaches were ruled out; and percutaneous translumbar IVC cannulation was selected.

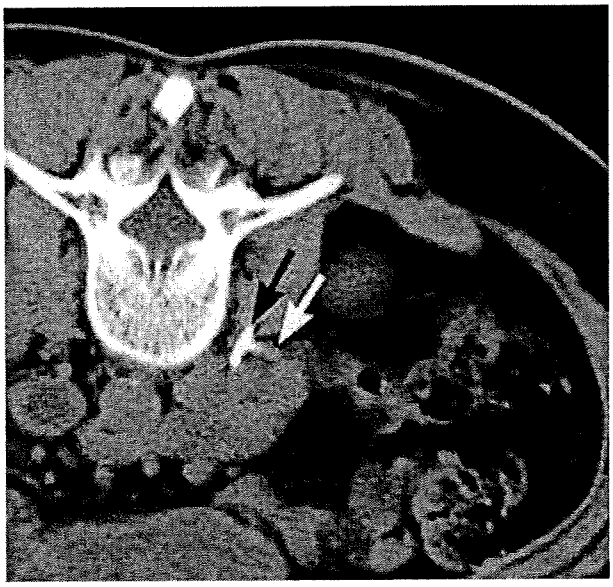

Fig. 1. Under computed tomography (CT) guidance, a 15-cm 21-gauge long elastor needle was inserted into the inferior vena cava (IVC) (*black arrow*) in a 60-year-old woman. After confirming the location of the right urinary tract (*white arrow*), caution was exercised to avoid it

Procedure

After obtaining informed consent, subcutaneous port catheter placement for central venous access was performed by percutaneous translumbar IVC cannulation in both patients.

The patient was placed in the prone position. During the procedure, electrocardiography (ECG), percutaneous oxygen saturation, and blood pressure were monitored. The maximal barrier precaution technique was employed. The procedure was performed under conscious sedation (hydroxyzine).

At the height of the iliac crest, local anesthesia was induced by injecting 1% lidocaine (Xylocaine; AstraZeneca, Osaka, Japan) 7 cm right of the dorsal midline; a 1-cm incision was then performed to serve as a temporary entry site. Under fluoroscopic guidance, a 10-cm 21-gauge needle was inserted through the temporary entry site into the right margin of the third lumbar vertebra to a depth of 8 cm to anesthetize the puncture pathway additionally. Next, a 15-cm 21-gauge long elastor needle (Medikit, Miyazaki, Japan) was inserted in the same direction to a depth of 8 cm. Then, while adjusting the direction and distance under CT guidance, the IVC was punctured at the level of the third lumbar vertebra. While advancing the needle, caution was exercised to avoid the right urinary tract in front of the iliopsoas muscle (Fig. 1). CT was performed four times in case 1 and six times in case 2 to puncture the IVC using the long elastor needle. After confirming that the tip of the long elastor needle was within the IVC, a 0.025-inch wire (fixed core wire guide Safe-T-J; Cook, Bloomington, IN, USA) was inserted through the outer cannula of the long elastor needle. The wire tip passed through the right atrium and was placed in the brachiocephalic vein. A 4F 25 cm long sheath introducer (Medikit) was inserted over the guidewire. After determining the location of the port reservoir (BardPort Titanium Low Profile; Bard, Salt Lake City, UT, USA), a subcutaneous pocket was prepared. The port was placed 4 cm dorsal to the right middle axillary line and 5 cm cranial to the 4F sheath introducer insertion site. Using the Tunneler (Bard), a tunnel was prepared from the subcutaneous pocket to the temporary entry site, and an indwelling 8F catheter (Groshong Catheter, Bard) was placed. After tunneling, a 0.035-inch wire (Amplatz Super Stiff; Boston Scientific, Natick, MA, USA) was inserted through the 4F angiosheath, and the tip of the wire was paced in the brachiocephalic vein. Using the wire, the 4F angiosheath was replaced with a 9F 25 cm long peel-off introducer (Medikit). The 8F catheter was passed through the peel-off introducer, and the introducer was then peeled away. The tip of the catheter was placed in the right atrium. The port was connected to the catheter and was then implanted in the subcutaneous pocket, and the wound was closed.

Abdominal radiography and contrast-enhanced CT were performed to check for complications (Figs. 2, 3) The contrast-enhanced CT was employed after placing the catheter in case 1 and before inserting the 9F 25 cm long peel-off introducer in case 2. The patient of case 1 was hospitalized for 2 days, and the patient of case 2 was hospitalized after the procedure continuously for chemotherapy. It was possible to perform chemotherapy using the port reservoir.

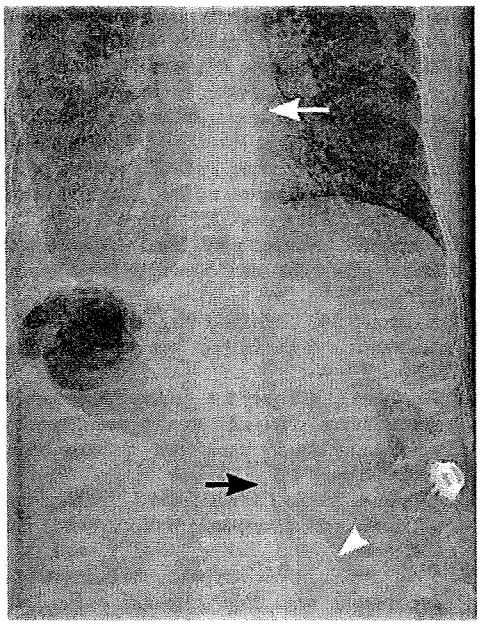

Fig. 2. Abdominal radiograph of a 60-year-old woman. The catheter tip was placed in the right atrium (*white arrow*). *Black arrow*, IVC cannulation. *White arrowhead*, temporary entry site

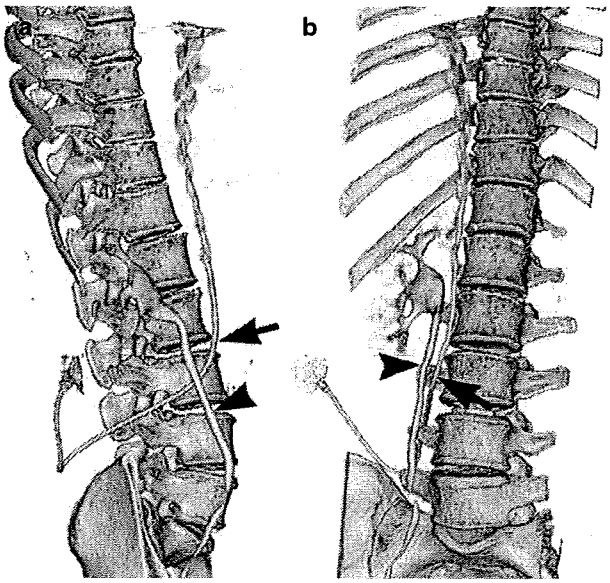

Fig. 3. Three-dimensional images reconstructed from contrast-enhanced CT scans following central venous catheterization by percutaneous translumbar IVC cannulation in a 60-year-old woman. **a** The catheter (*arrow*) and urinary tract (*arrowhead*) intersected at the level of the third lumbar vertebra. **b** The catheter (*arrow*) and urinary tract (*arrowhead*) were separated, confirmed by CT during cannulation

Discussion

When inserting a central venous catheter from the upper body, the subclavian vein, internal jugular vein, or peripheral brachial vein is used; but central vein stenosis or skin damage at the puncture site might prevent the selection of one of these veins. Although it is possible to insert a catheter from the femoral vein, several studies have found that central venous catheterization through the femoral vein should be performed only in emergencies or in children.[15,16] In addition, when involving the femoral vein, there is a risk for thrombosis in the iliac and femoral veins.[15,17] As alternative approaches to conventional cannulation, central venous catheter placement by translumbar cannulation, transhepatic cannulation, or transhepatic vein cannulation has been reported.[1–14] When cannulating the IVC using an alternative approach, studies have reported that translumbar cannulation should be used preferentially because it is associated with fewer complications than percutaneous transhepatic cannulation.[10,18,19] Translumbar cannulation was first reported by Kenney in 1985, and its use has been documented in a large number of cases with clinical results and complications in studies from the United States. [1,2,4–8,10–13]

The situations for which translumbar IVC cannulation has been selected are as follows.[20,21] First, traditional access sites other than the femoral vein cannot be used. Second, it is needed for long-term placement of a large-bore catheter used for access of infusion or dialysis even if the femoral vein approach can be used. Third, a central venous approach for interventional treatment is needed when the femoral vein approach cannot be used because of an occluded IVC, such as existence of the thrombosed IVC filter.

The incidence of late complications associated with central venous catheter access by percutaneous translumbar IVC cannulation is as follows: 0.24 episodes of infection per 100 catheter-days and 0.22 thrombosis-related catheter failures per 100 catheter-days, both which are comparable to those seen with conventional cannulation.[5,12] However, retroperitoneal hematoma, damaged renal artery branch, punctured aorta, punctured superior mesenteric vein, and damaged urinary tract have been reported as complications of central venous catheter placement by percutaneous translumbar IVC cannulation, and they are unique to translumbar cannulation.[6,13,22,23]

While conventional central venous cannulation is performed under echo guidance, translumbar cannulation is performed using radiopaque instruments such as guidewires, catheters, wire baskets, or intravascular snares as visual markers, thus resulting in the above-mentioned complications. With our method, the IVC was punctured using the interventional radiology (IVR)-CT system under fluoroscopic and CT guidance. Using

this method, it is possible to avoid accidentally damaging arteries, the urinary tract, and other organs that can be identified by CT. Particularly for cannulation under fluoroscopic guidance, it is difficult to avoid damaging the urinary tract, even if fluoroscopy is performed from two directions. When treating a damaged urinary tract, it may be necessary to place a catheter for a period of time; hence, it is clinically useful to avoid puncturing the urinary tract under CT guidance.[22,23] Contrast-enhanced CT for guidance when puncturing the IVC may be helpful for visualizing the urinary tract, artery, and IVC.

When placing the catheter through the iliopsoas muscle, CT cannot identify arteries vascularizing the iliopsoas muscle, but it can discover retroperitoneal hemorrhage at early stages during the procedure, thus enabling early therapy. According to Bennett et al., retroperitoneal hematoma was not discovered immediately after placement but was seen at 48 h after catheter placement due to flank pain and bruising, confirmed by CT.[13] Cazenave et al.[24] deduced a safe pathway for percutaneous translumbar IVC cannulation by CT and discussed the slope of the puncture needle under fluoroscopic guidance. This suggests that a safe pathway can be determined under CT guidance; however, to the best of our knowledge, there have been no clinical reports on CT-guided cannulation.

One disadvantage of our method is that IVR-CT is required for CT and fluoroscopic guidance. In addition, because CT has been performed several times to examine the area between the third lumbar vertebra and the iliac crest, the amount of radiation exposure to the patient might be greater.

In conclusion, it was possible to perform central venous catheterization by percutaneous translumbar IVC cannulation under CT guidance.

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CLINICAL INVESTIGATION

Peripheral Stent Placement in Hemodialysis Grafts

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Abstract The purpose of the present study was to evaluate the clinical outcome of peripheral stent placement after failed balloon angioplasty in patients with grafts who are on hemodialysis. We examined 30 Wallstents that were placed in 26 patients because balloon angioplasty failed or early restenosis (<3 months) occurred within 3 months. We retrospectively reviewed 267 consecutive balloon angioplasties performed in 71 patients with graft access between August 2000 and March 2007. Stent placements accounted for 30 (11.2%) of the 267 balloon angioplasties. The clinical success rate of stent placement was 93.3% (28 of 30 stent placements). The 3-, 6-, and 12-month primary patency rates were 73.3%, 39.3%, and 17.7%, respectively. The 1-, 2-, and 3-year secondary patency rates were 90.2%, 83.8%, and 83.8%, respectively. Primary patency was significantly prolonged by stent placement after early restenosis compared with previous balloon angioplasty alone ($P = 0.0059$). Primary patency after stent placement was significantly lower than after successful balloon angioplasty without indications for stent placement ($P = 0.0279$). Secondary patency rates did not significantly differ between stent placement and balloon angioplasty alone. The mean number of reinterventions required to maintain secondary patency after stent placement was significantly larger than that after balloon angioplasty alone (Mann–Whitney U test, $P = 0.0419$). We concluded that peripheral stent placement for graft access is effective for salvaging vascular access after failed balloon angioplasty and for prolonging patency in early restenosis after balloon angioplasty. However, reinterventions are required to maintain secondary patency after stent placement. Furthermore, peripheral stent placement for graft access cannot achieve the same primary patency as balloon angioplasty alone.

Keywords Stent · Graft · Balloon angioplasty · Stenosis · Vascular access

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Introduction

Percutaneous transluminal angioplasty has become the first choice of treatment for failure of vascular access. The introduction of cutting and ultrahigh pressure balloons appears to have increased the success rate of balloon angioplasty [1–4]. However, stents are still occasionally placed to treat stenosis after failed balloon angioplasty. The guidelines of the Dialysis Outcomes Quality Initiative (DOQI) and of the Society of Interventional Radiology (SIR) state that central and peripheral stent placement is useful in selected instances of failed balloon angioplasty [5, 6]. Stent placement for failed balloon angioplasty has been studied in detail and therapeutic outcomes have been documented [7–17]. The authors of these publications seem to promote stent use for failed balloon angioplasty. However, repeated reinterventions seem to be required after placement of stents, which limits their effectiveness. Thus,

the present study evaluates the clinical results of peripheral stent placement after failed balloon angioplasty and examines whether or not the primary patency of stent placement in this circumstance can equal that of balloon angioplasty alone.

Materials and Methods

Study Design

This study was a retrospective investigation. Our institutional review board approved the study protocol and all patients provided written informed consent before undergoing interventions. We investigated 30 stent placements for graft access in 26 Asian patients (12 women, 14 men; mean age, 64 ± 11 years [standard deviation]) with 30 peripheral stenoses, including 2 at the stented segment. All grafts (Thoratec; Thoratec Laboratories Co., Pleasanton, CA, USA) comprised 5-mm-diameter nontapered polyurethane. Two grafts were straight, and 24 were loops. Fifteen grafts crossed the elbow, and the others were placed at the upper arm. We retrospectively reviewed 267 consecutive balloon angioplasties performed due to access failures in 71 patients (30 women and 41 men; mean age, 64 ± 10 years) between August 2000 and March 2007. We evaluated the clinical success rates, as well as complications, primary patency, and secondary patency. We then compared the patency before and after stent placement in early restenosis and compared stent placement with balloon angioplasty for the primary patency, secondary patency, and number of reinterventions required to maintain secondary patency. All patients underwent hemodialysis at our dialysis center or at our dialysis branches connected on the medical network. Consecutive medical records and radiographic images of all patients were reviewed. The first author (a radiologist with 13 years of experience in interventional procedures as of 2007) performed all procedures at the same institution.

Indications for Balloon Angioplasty and Stent Placement

For all balloon angioplasties and stent placements, we selected interventional or surgical procedures after discussion with an interventional radiologist and access surgeon. According to DOQI guidelines [5], all angioplasties were performed on patients exhibiting >50% stenosis and clinical/physiologic abnormalities. Stents were placed after failed balloon angioplasty defined as follows:

Indication A was failed balloon angioplasty based on insufficient restoration of access flow assessed by fistulography and insufficient conversion of a continuous palpable thrill at the distal (venous) end of grafts.

Indication B was restenosis occurring within 3 months after the last balloon angioplasty for the same lesion. However, when the vascular diameter and access flow after the present balloon angioplasty were more favorable than those after the last balloon angioplasty, stent placement was excluded.

Balloon Angioplasty Procedures

All procedures were accomplished on an outpatient basis at our hospital. Patients were monitored using pulse oximetry, blood pressure measurements, and electrocardiography. An anticoagulant (intravenous heparin, 3,000 U) was administered during thrombolysis only. Fistulography was performed immediately before balloon angioplasty to measure vessel diameter. Thereafter, if a lesion was identified as requiring dilation (>50% stenosis), an appropriately 6- to 7-Fr sheath introducer (Medikit Co., Miyazaki, Japan) was positioned and balloon angioplasty proceeded. The sheath introducer was placed in the graft or outflow vein. Balloon size was determined based on the diameter of the adjacent normal vessel. The balloon catheters ranged in size from that of the normal vessel diameter to 20% larger (6–10 mm in diameter). We used Ultra-thin Diamond (Boston Scientific, Natick, MA, USA; rated burst pressure, 15 atm), Blue Max (Boston Scientific; rated burst pressure, 20 atm), or Peripheral Cutting (Boston Scientific; rated burst pressure, 10 atm) balloons. All balloons were dilated using a pressure inflation device (Everest; Medtronic, Minneapolis, MN, USA) to below the rated burst pressure until the balloon waist disappeared and then were inflated for 1 min (or for 5 min in the event of recoil). We determined whether or not a continuous palpable thrill was converted immediately after each balloon angioplasty. Fistulography was performed after balloon angioplasty to confirm whether sufficient restoration of access flow could be obtained. The entire access circuit from the arterial anastomosis to the superior vena cava was evaluated by digital subtraction angiography during the procedure.

Before balloon angioplasty, patients with thrombosis underwent thrombolysis using the lyse-and-wait technique with 60,000–180,000 U of urokinase (Urokinase; Benesis, Osaka, Japan) admixed with 3,000–5,000 U of heparin as described by Cynamon et al. [18]. Residual thrombus was dislodged using balloon catheters and sheath introducers.

Stent Placement

We positioned self-expanding stents and Wallstents (Easy Wallstent or Wallstent RP; Boston Scientific) of 6- to

10-mm nominal diameter that were adapted to the largest diameter of the segment covered with the stent so that the entire stent could touch the luminal wall. The stent was kept as short as possible but long enough to bridge the entire lesion with a slight overlap at its proximal and distal ends. Stents were dilated after deployment using the original balloon to ensure close contact with the vessel wall. We examined the conversion of a continuous palpable thrill at the distal (venous) end of grafts immediately after stent placement. Fistulography was performed to visualize access flow after stent placement. No patients underwent anticoagulation treatment for stent placement after the procedure.

Study Definitions and Follow-Up

Percentage stenosis was defined as the minimal luminal diameter determined by fistulography in the single view or the multiple view if necessary. The percentage stenosis was defined by NASCET criteria (1 − MLD/reference vessel × 100). The reference vessels were defined as graft in graft-to-vein anastomotic stenosis, graft in artery-to-graft anastomotic stenosis, adjacent normal vein in autogenous venous stenosis, and adjacent normal vein in in-stent restenosis. Clinical success after an interventional procedure was defined as the resumption of normal dialysis for at least one session, in accordance with published SIR guidelines [6]. Clinical follow-up of all patients included a physical examination, venous dialysis pressure measurements at each hemodialysis session, and monthly evaluations of dialysis dose and urea recirculation. Ultrasonography was performed when results were abnormal during clinical follow up. Follow-up findings were determined via access meetings with staff in the dialysis units. Follow-up continued until the patient died, surgical revision excluded the stent-implanted segment, or the graft was abandoned. We defined "postintervention primary patency" and "postintervention secondary patency," described in the published SIR guidelines [7], as primary and secondary patency, respectively. Loss of patency was defined as treatment of a lesion anywhere within the access circuit, from the arterial inflow to the superior vena cava-right atrial junction, according to published SIR guidelines [7].

Comparison of Primary Patency

When stent placement was successful, primary and secondary patencies were calculated after the first stent placement. We also calculated primary patency for indications A and B, as well as nonthrombotic and thrombotic access. Primary and secondary patencies were also calculated when balloon angioplasty alone was sufficient to treat stenosis. Primary and secondary patencies after successful stent placement due to failed balloon angioplasty were then compared with those after successful balloon angioplasty alone.

We compared the primary patency for stent placement with that of previous balloon angioplasty alone in the indication B group. We compared the mean number of reinterventions required to maintain the secondary patency of stent placement with that for balloon angioplasty alone.

Statistical Analysis

Primary and secondary patencies were calculated using the Kaplan–Meier method and patency rates were compared using the Breslow–Gehan–Wilcoxon test. To compare the mean primary patency periods of stent placement with those of previous balloon angioplasty alone, we used the Wilcoxon signed-rank test as a matched pair test for comparisons of the same lesions at different times. We compared the number of reinterventions required to maintain secondary patency of stent placement with that for balloon angioplasty alone using the chi-square test. Values of $P < 0.05$ were considered statistically significant.

Results

Stent Placement

Stent placements accounted for 11.2% (30 of 267 procedures), 19.2% (16 of 83), 8.8% (9 of 102), and 6.0% (5 of 82) of all procedures during the period of review, as well as between 2000 and 2003, between 2004 and 2005, and after 2006, respectively. Table 1 reports the characteristics of access and stenosis with stent placement. The insertion of one stent was sufficient to cover the entire lesion in 26 procedures, and two were required for coverage in 4 others. Thirty-four stents were placed over the course of the present study. The lyse-and-wait technique was performed for nine patients with thrombosis before angioplasty with 30 stent placements.

Clinical Success

The clinical success rate of stent placement was 93.3% (28 of 30 procedures) for all procedures, 85.7% (12 of 14 procedures) for indication A, and 100% (16 procedures) for indication B. Table 2 reports the number of stent placements and clinical successes. One unsuccessful patient underwent first stent placement for graft-to-vein anastomotic stenosis and second stent placement for artery-to-graft anastomotic stenosis. The second stent placement was not clinically successful because arterial stenosis occurred immediately after deployment and access flow was insufficient. Another

Table 1 Number of accesses and stenoses among patients with stent placement

No. of accesses[a]	
All graft accesses with stent placement	30 (100%)
Thrombotic access	9 (30%)
Nonthrombotic access	21 (70%)
Indication A[b]	14 (47%)
Indication B[c]	16 (53%)
No. of stenoses[d]	
All stenoses with stent placement	30 (100%)
Graft-to-vein anastomosis	28 (93%)
Artery-to-graft anastomosis	1 (3%)
Autogenous vein	1 (3%)
Upper arm	26 (87%)
Lower arm	4 (13%)
Stenosis without stent	28 (93%)
Stenosis at stented segment	2 (7%)

[a] Data are numbers of accesses with stent placements that were retrospectively reviewed

[b] Failed balloon angioplasty based on insufficient access flow and insufficient conversion of continuous palpable thrill

[c] Restenosis within 3 months of previous balloon angioplasty for same lesion

[d] Data are numbers of retrospectively reviewed stenoses with stent placements

unsuccessful patient underwent first stent placement for graft-to-vein anastomotic stenosis and thrombosis occurred in the graft within 24 h of stent placement. The mean minimal diameter of the placed stent and mean residual percentage diameter stenosis were 4.2 ± 0.7 mm and 14.6 ± 14.2%, respectively.

Successful stent placement was not associated with any complications.

Primary Patency

Table 3 reports the mean primary patency periods, the primary patency rates for successful stent placement, and the subgroups. During the 79 months that we retrospectively reviewed, 45 patients were treated using balloon angioplasty alone without indication for stent placement, and 44 were clinically successful. Table 3 lists the mean primary patency periods and the primary patency rates for successful balloon angioplasty alone. The mean period of primary patency after successful stent placement was significantly shorter than that after successful balloon angioplasty for stenosis without indications for stent placement (Breslow–Gehan–Wilcoxon test, $P = 0.0279$) (Fig. 1).

Table 4 reports a comparison of the access patency in indication B after stent placement and previous balloon angioplasty for the same lesions. Primary patency persisted significantly longer after stent placement than after previous balloon angioplasty alone (Breslow–Gehan–Wilcoxon test, $P = 0.0468$; Wilcoxon sign-rank test, $P = 0.0059$).

Secondary Patency and Reintervention

Table 5 reports the secondary patency rates, mean number of reinterventions required to maintain secondary patency, and mean follow-up periods for stent placement and balloon angioplasty alone. Secondary patency rates did not significantly differ between stent placement and balloon angioplasty alone. The number of reinterventions per 1,000 patency days required to maintain secondary patency after stent placement was significantly larger than that after balloon angioplasty alone (χ^2 test, $P < 0.0001$).

Seventy reinterventions for 96 lesions including stenosis at stented segments (67.7%) and stenosis without stents (32.2%) were required to maintain secondary patency after stent placement. The mean percentage stenosis was 74.5 ± 12.6% at the stented segment. Stenosis at the stented segment occurred in 78.6% of cases (22 of 28 successful stent placements) during the study periods.

Stenosis caused by delayed shortening occurred in 3.5% (1 of 28) of successful stent placements and another stent placement was required for treatment of the stenosis.

Discussion

The SIR guidelines do not recommend the routine use of stents to prevent restenosis and state that the role of stents has yet to be fully defined [6]. Three prospective randomized studies have found that stent placement does not confer an advantage over successful angioplasty [19–21]. Thereafter, some studies have described the placement of metallic stents for peripheral lesions after failed balloon angioplasty, which seems to have been effective [9–11, 16, 17]. Thus, the present study evaluates the clinical outcomes of peripheral stent placement after failed balloon angioplasty and examines whether or not the primary patency of stent placement in this circumstance equals that of balloon angioplasty alone.

We defined the indication for peripheral stent placement as failed balloon angioplasty. Stent placement has been indicated by many investigators to treat severe residual stenosis (≥30–50%) after balloon angioplasty [9, 10, 19]. The ratio (%) of stenosis in enlarged irregular veins or at the anastomosis of two very different vessels may be difficult to ascertain. Furthermore, vessel diameters cannot be accurately determined by fistulography because of unidirectional imaging. We also have occasionally observed that intimal flap and dissection immediately after balloon dilation do not improve the visualization of access flow assessed by

Table 2 Number of stent placements and clinical successes

Case no.	1st stent placement		2nd stent placement for stenosed stented segment		2nd stent placement for stenosis without stent		3rd stent placement for stenosis without stent		Total no. of stent placements	
	Success	Failure	Success	Failure	Success	Failure	Success	Failure	Success	Failure
1[a]	+		+						2	
2[b]	+					+			1	1
3[c]	+		+				+		3	
4[d]		+								1
5–26[e]	+								22	
Total	25[f]	1	2			1	1		28[g]	2
	26		2		1		1		30	

[a] Case 1 required second stent placement for stenosis at the stented segment

[b] Case 2 required first stent placement for graft-to-vein anastomotic stenosis and second stent placement for artery-to-graft anastomotic stenosis. The second stent placement was not clinically successful

[c] Case 3 required the first stent placement for graft-to-vein anastomotic stenosis, the second for stenosis at the stented segment, and the third for outflow venous stenosis without stent at the cephalic arch

[d] First stent placement was not clinically successful in case 4

[e] Cases 5–26 required only first stent placement

[f] Primary and secondary patency rates calculated for these 25 patients

[g] Clinical success rate of stent placement was 93.3% (28 of 30 procedures) for all procedures

Table 3 Primary patency of stent placements compared with balloon angioplasty alone

Category	No. of patients	Primary patency period (months)[a]	Primary patency rate (%)[b]			*P*-value
			3 months	6 months	12 months	
Stent placement	25	7.0 ± 9.8	73.3 ± 9.4 (16)	39.3 ± 10.7 (8)	17.7 ± 8.8 (3)	0.0279[c]
Subgroup						
Indication A[d]	10	6.5 ± 3.8	80.0 ± 12.6 (8)	57.1 ± 16.4 (5)	17.1 ± 14.5 (1)	
Indication B[e]	15	7.3 ± 12.5	68.4 ± 13.2 (8)	25.7 ± 12.7 (3)	17.1 ± 11.0 (2)	
Nonthromboticaccess	18	7.2 ± 11.0	81.4 ± 9.8 (12)	44.8 ± 13.3 (6)	18.6 ± 11.4 (2)	
Thrombotic access	7	6.6 ± 6.7	57.1 ± 18.7 (4)	28.6 ± 17.1 (2)	–	
Balloon angioplasty alone	44	12.7 ± 12.9	80.9 ± 6.1 (32)	72.8 ± 7.0 (27)	44.1 ± 8.4 (13)	

[a] Data are mean ± standard deviation

[b] Data are primary patency rate ± standard error. Numbers in parentheses are numbers at risk at start interval

[c] Determined by Breslow–Gehan–Wilcoxon test. $P = 0.0279$ vs. balloon angioplasty alone

[d] Technical failure of balloon angioplasty based on insufficient access flow and insufficient conversion of continuous palpable thrill

[e] Restenosis within 3 months after previous balloon angioplasty for the same lesion

fistulography and also do not achieve conversion of a continuous palpable thrill. Residual stenosis rates in these types of lesions are difficult to assess by fistulography. Therefore, for indication A, we based our judgment on restoration of access flow assessed by fistulography and the conversion of a continuous palpable thrill at the distal (venous) end of grafts immediately after balloon angioplasty. Trerotola et al. have advocated using thrill as the procedural endpoint and we support this recommendation [22].

The SIR guidelines recommend stent placement for lesions in central, but not peripheral, veins within 3 months of initially successful balloon angioplasty [6]. Some investigators have placed stents to treat restenosis within 3 months [9–11], and we have likewise done so within 3 months of balloon angioplasty. However, we have not placed stents if dilation was more favorable compared with the previous balloon angioplasty (indication B), unlike other investigators. Prolonged inflation of a larger balloon or the use of a cutting balloon achieved better dilation in some of our patients.

According to our study, the prevalence of stent placement has decreased annually, reaching 6.0% after 2006. The reasons for this appear to be recent technical improvements in angioplasty. The 85.7% clinical success rate of stent

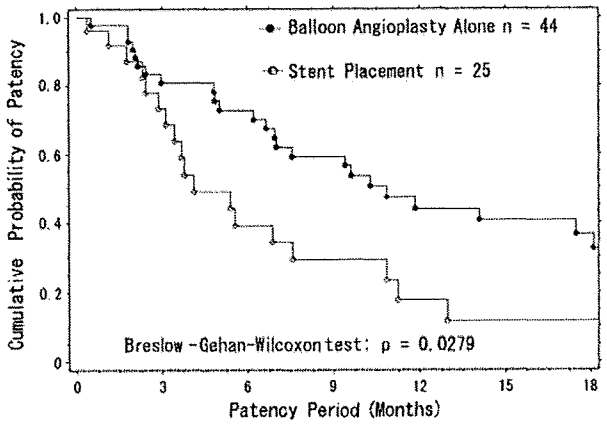

Fig. 1 Kaplan–Meier analysis of primary patency rates after stent placement ($n = 25$) and after balloon angioplasty alone ($n = 44$). *Open circles* indicate stent placement. *Filled circles* indicate balloon angioplasty alone. Primary patency after successful stent placement was significantly shorter than that after successful balloon angioplasty alone for stenosis without stent placement (Breslow–Gehan–Wilcoxon test, $P = 0.0279$)

placement for indication A in the present study indicates that peripheral stent placement is effective for salvaging hemodialysis access after failed balloon angioplasty.

We found delayed stent shortening in 3.5% of successful stent placements. Haage et al. reported that stent shortening was delayed in 6% of central Wallstent placements (3 of 50) and that angioplasty and additional stents were placed to treat uncovered segments with restenosis [14]. Delayed stent shortening should be acknowledged as a limitation of Wallstents. Vogel et al. placed Nitinol stents for graft access after failed balloon angioplasty and our indications were compatible with theirs, although they used different stents [10]. They reported 3-, 6-, and 12-month primary patency rates of 77%, 51%, and 20%, respectively, while in our study the primary patency rates for graft access were 73.3%, 39.3%, and 17.7%, respectively. These findings indicate that the Nitinol stent seems to be superior to the Wallstent, although the two stents are difficult to compare.

If early restenosis occurs, stent placement can be a useful option because the present study found that primary patency was prolonged significantly by stent placement for peripheral stenoses recurring within 3 months. However, the duration of primary patency after stent placement following failed balloon angioplasty was significantly shorter than that for successful balloon angioplasty alone for stenosis without stent placement. Even when stents were placed for stenosis after failed balloon angioplasty, the primary patency was never the same as that for successful balloon angioplasty alone. Thus, we suggest improving the success rate of balloon angioplasty and reducing the use of stents. Our results are different from those of Maya et al., who found that the primary patency rate of 14 stents placed to treat thrombosed grafts was higher than that of balloon angioplasty alone [12].

Table 4 Comparison of primary patency between previous balloon angioplasty (BA) alone and stent placement in indication B group: restenosis within 3 months after previous BA for the same lesion ($N = 15$)

Intervention	Primary patency period (month)[a]	*P*-value[b]	Primary patency rate (%)[c]					*P*-value[d]
			1 month	2 months	3 months	6 months	12 months	
Previous BA	1.9 ± 0.7	0.0468	86.7 ± 8.8 (13)	53.3 ± 12.9 (8)	0 (0)	–	–	0.0059
Stent placed	7.3 ± 12.5		93.3 ± 6.4 (13)	85.6 ± 9.5 (10)	68.4 ± 13.2 (3)	25.7 ± 12.7 (3)	17.1 ± 11.0 (2)	

[a] Data are mean ± standard deviation

[b] Determined by Wilcoxon signed-rank test. Primary patency periods after stent placement were compared with those after previous BA alone

[c] Primary patency rate ± standard error. Numbers in parentheses are those at risk at start interval

[d] Determined by Breslow–Gehan–Wilcoxon test. Comparison of primary patency rates after stent placement with those after previous BA alone

Table 5 Comparison of secondary patency and number of required reinterventions to maintain secondary patency between previous balloon angioplasty (BA) alone and stent placement

Category	No. of patients	Mean follow-up period[a]	No. of reinterventions per 1,000 patency days[b]	*P*-value[c]	Secondary patency rate (%)[d]			*P*-value[e]
					1 year	2 years	3 years	
Stent placed	25	22 ± 19	4.5	<0.0001	90.2 ± 6. (16)	83.8 ± 8. (9)	83.8 ± 8. (6)	0.0891
BA alone	44	23 ± 19	1.9		97.1 ± 2. (28)	97.1 ± 2. (14)	97.1 ± 2. (9)	

[a] Data are mean ± standard deviation

[b] Number of required reinterventions to maintain secondary patency. Data are mean ± standard deviation

[c] Determined by Mann–Whitney *U* test between stent placement and BA alone

[d] Data are secondary patency rate ± standard error. Numbers in parentheses are those at risk at start interval

[e] Determined by Breslow–Gehan–Wilcoxon test between stent placement and BA alone