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Original Article

New Vascular-Access Intervention Assistance Plate Provides Good Operability and Safety by Preventing Accidental Falls: First Experience of 1,872 Cases

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Vascular-access interventions are necessary for the continuation of hemodialysis, and they are performed under X-ray guidance. During interventions, patients' accidental falls from the bed are a serious problem, and specialized fixation systems for hemodialysis patients to prevent their falls from the bed have been lacking. We developed a new fixation plate made of polypropylene homopolymer and tested its ability to prevent such falls retrospectively. This plate, which we named the 'vascular-access intervention assistance plate,' offers functional features such as the concurrent fixation of the body and either arm and an arm space with serrations for fixing a forearm strap. We performed computer simulations to examine the strength of the plate, and we evaluated the efficacy of fall prevention by reviewing patients' medical records. The results demonstrated that the functional design of the plate provides good operability via accurate concurrent fixations of the body and arm. The computer simulation analysis results indicated the plate's sufficient strength. The medical records analysis revealed three accidental falls before the plate's introduction (401 patients, 1,437 interventions), and none after plate introduction (683 patients, 1,872 interventions). Accidental falls were significantly prevented by use of the plate ($p < 0.05$). The dementia rate and type of procedure were not significantly different between the patients who fell and those who did not. This vascular-access intervention assisted plate provides good operability and safety by preventing accidental falls among hemodialysis patients.

Key words: hemodialysis, fall accident, incident, vascular access

Vascular-access interventions are necessary for the continuation of hemodialysis. These interventions include the creation of shunts and performing a percutaneous transluminal angioplasty (PTA), and related radiographic procedures are performed under X-ray guidance with knowledge of the blood flow and stenotic points of the vasculature. An integrated X-ray system and C-arm are often used in combination with a motorized bed for vascular-access interventions. The height of the standard motorized bed is 40-80 cm, and there is a risk of a patient falling from the bed while he or she is undergoing or has completed a hemodialysis session. Accidental falls represent one of the major types of accident in a radiology department [1,2]. The fixation of the patient to the bed is the most radical and definitive method of preventing falls, and a simultaneous fixation of the body and treated arm is also considered important to prevent falls. However, no specialized system for concurrently fixating the body and an

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arm has been available. Although integrated X-ray system providers have provided arm-support plates, these are unable to both prevent falls and fix the body and arm concurrently. Many hospitals make efforts to use the plate provided with an X-ray system or another fixation device developed for other surgeries. We hypothesized that concurrent fixation of the body and arm to the bed could provide good operability and prevent patients' falls during the protocol for hemodialysis or surgery. We describe herein the development of a new fixation plate and our retrospective validation of its efficacy in fall prevention.

Methods and Patients

Vascular-access intervention assistance plate for fall prevention. This plate is our original design. A polypropylene homopolymer plate (100 cm wide × 150 cm long) was purchased from Daiwa Kousan Corp. (Hiroshima, Japan) and processed by K-Techno Co., Ltd. (Okayama, Japan). The dimensions of the processed plate are as follows: 100 cm wide × 130 cm long × 7 mm thick; weight, 6.7 kg. The denim belt to hold the patient was purchased from Showa Co., Ltd. (Okayama, Japan). A hook-and-loop fastener is sewn to the belt to hold the body and keep the body securely on the bed. Detailed information is available in a video format (https://www.youtube.com/watch?v=CuRlsJON3R4).

Strength simulation test. The plate's strength was simulated using Marc software (MSC Software Corp., Los Angeles, CA) at the Industrial Technology Center of Okayama Prefecture (Okayama, Japan). This analysis was performed by simulating a virtual hard sphere pushing on the loading points (Fig. 1A, B, D, E). The yield stress was calculated using results from a real polypropylene plate-pressing test (Fig. 1C).

Clinical evaluation. This retrospective, non-randomized study was carried out in accordance with the Declaration of Helsinki and approved by the institutional review board at Shigei Medical Research Hospital (approval #20180618-2). We retrospectively analyzed patients' electronic medical records. The vascular-access intervention assistance plate was authorized for use as a non-medical device by the Ministry of Health, Labour and Welfare of Japan in March 2020. For the present study, an optout of the informed consent and a negative opportunity were guaranteed in the study's ethical approval.

The plate was introduced for use at our hospital on December 9, 2016. The observation periods were as follows: before plate introduction, May 1, 2015 to December 7, 2016 and after plate introduction, December 9, 2016 to December 29, 2018.

Patients. The study included 1,084 Japanese adult hemodialysis patients who underwent vascular-access interventions at Shigei Medical Research Hospital between May 1, 2015 and December 29, 2018. All patients who underwent a PTA or radiography using an integrated X-ray system (Philips Allura Xper FD20, Amsterdam, the Netherlands) during the study period were enrolled. Operations to create a shunt for vascular access were not included in this study. Shunt operations were performed in the surgical department, not in the radiology department. All clinical data were collected and analyzed at Shigei Medical Research Hospital.

Statistical analysis. All statistical analyses were performed with JMP ver. 10.0.2 software (SAS Institute, Cary, NC, USA). For two-group comparisons, Pearson's chi-squared test was used. P-values < 0.05 were considered significant.

Results

The vascular-access intervention assistance plate is designed to concurrently fix the body and arm and to assist intervention procedures. We designed the plate to prevent patient falls with the use of a belt (Fig. 2A), but the plate was designed to have additional functional features. A belt insertion port is set to hold the body and plate together by the belt. A surgical instrument space is provided for forceps, scissors, and other instruments. A handle is provided to allow easy reversal of the plate to accommodate intervention for either arm. These design features enable the plate to hold the patient's body and arm concurrently and facilitate the intervention procedure or surgery.

The vascular-access intervention assisted plate is used as follows. The plate is set on the bed of the X-ray system (Fig. 2B). The mattress and arm stand should be set on the plate (Fig. 2C). The patient lies on the bed and is held securely by the wide cloth belt through the belt insertion port (Fig. 2D). The patient cannot fall because she is held by the belt at the height of the ilium (Fig. 2E). An arm space with serrations is designed for placement of the arm and the attachment of the fore-

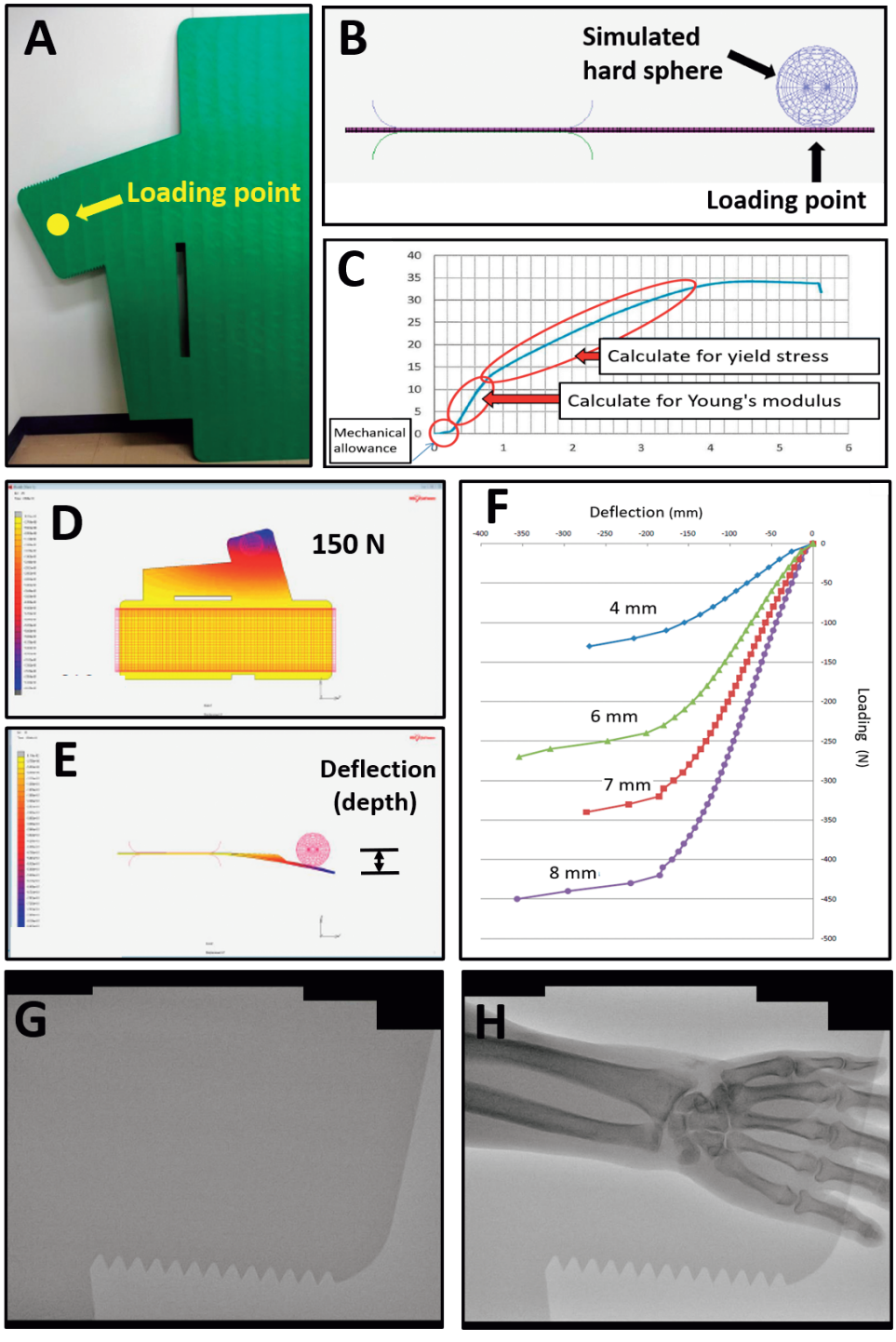

Fig. 1 Computer simulation testing for the plate's strength. Simulated loading points were set at the indicated positions (A). A simulated hard sphere was used for loading (B). Deflection was calculated according to the indicated mechanism (C). Deflection was measured as the depth of the bent plate (D, E). Each thickness of plate showed the indicated deflection curve (F). Radiolucency was confirmed under an X-ray system (G). The outline of the hand and underlying bone were clearly depicted over the plate on the X-ray system (H).

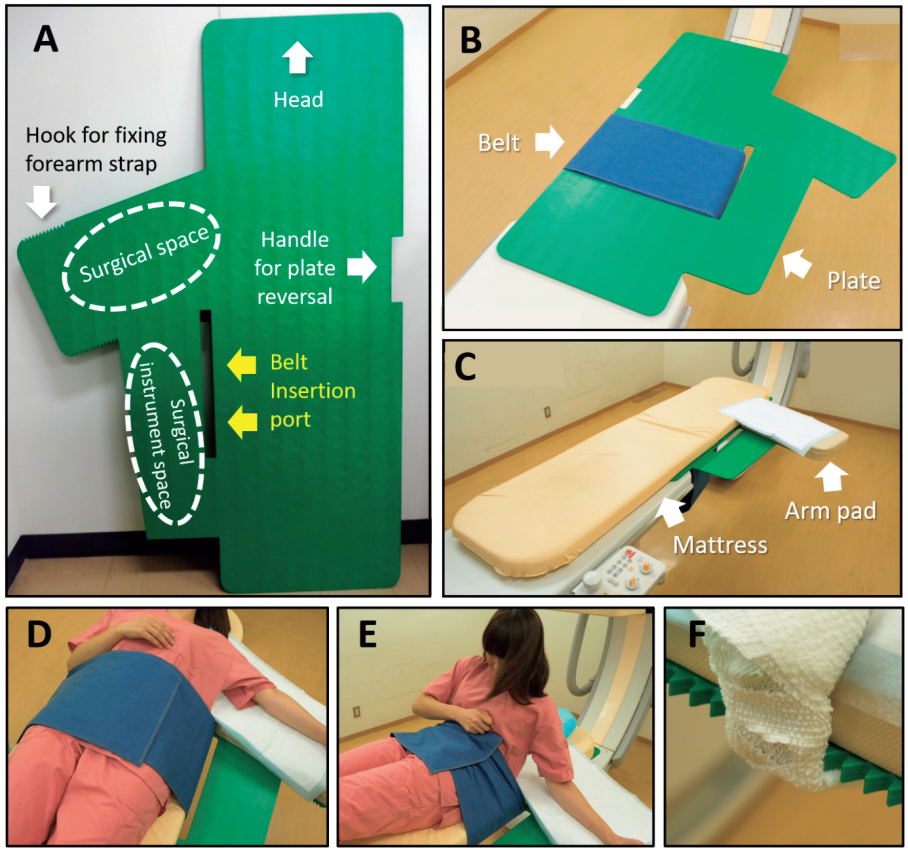

Fig. 2 Overview of the vascular-access intervention assisted plate. The plate is designed to have the indicated functions (**A**). The plate is set on the bed of the X-ray system (**B**). The mattress and arm stand are set on the plate (**C**). The patient lies on the mattress and is fixed to the plate and bed by the belt (C). Falls are prevented by fixing the belt at the height of the ilium (**D**). Serrations are provided for attachment of the forearm-fixing strap (E).

arm-fixing strap (Fig. 2F). These points of functional design provide good operability for surgeons and safety for patients.

The strength of the polypropylene homopolymer plate in the simulation analysis, and the material's radiolucency. We had considered many types of material as candidates for the plate, including polycarbonate, carbon, and polypropylene homopolymer. Polycarbonate did not offer enough strength, and carbon was too expensive and difficult to process. We speculated that a polypropylene homopolymer plate was likely to be strong enough, yet easy enough to process. The strength and weight are in proportion to the thickness of the plate. The design also affects the strength. We thus performed a computer simulation analysis of the designed plate using virtual 4-, 6-, 7-, and 8-mm-thick plates (Fig. 1F). The results of the computer simulation analysis revealed that 7- and 8-mm-thick plates had enough strength for over 250 N of loading force. We decide to use the 7-mm-thick plate to minimize the plate's weight. We also examined the radiolucency of the plate for use in X-ray systems. The polypropylene homopolymer plate exhibited sufficient radiolucency (Fig. 1G, H).

Retrospective analysis of the prevention of accidental falls. To assess the efficacy of the plate for preventing patients' accidental falls from the table, we retrospectively analyzed two groups of patient medical records: for the period before plate introduction (401 patients), and for the period after plate introduction (683 patients) (Table 1). As the patients were taken for radiographic imaging and percutaneous transluminal angioplasty multiple times, the total numbers of examinations before and after plate introduction were 1,437 and 1,872 cases, respectively (Table 2). The background of the patients did not differ significantly

Table 1 Background characteristics of patients

	Before plate introduction (n = 401)	After plate introduction (n = 683)
Age, years	68.3 ± 15.6 (23–95)	68.6 ± 9.2 (21–95)
Male	227	373
Female	174	310
Body mass index, kg/m^2	22.1 ± 0.5 (12.9–37.3)	22.0 ± 0.4 (12.5–38.7)
Dementia (+)	18 (4.5%)	27 (4.0%)
Dementia (−)	383	656

Values are given as number or mean ±standard deviation (range).

Table 2 Background characteristics of examinations

	Before plate introduction (n = 1,437)	After plate introduction (n = 1,872)
Age, years	69.2 ± 4.2 (23–95)	69.5 ± 8.5 (21–96)
Male	786	1,006
Female	651	866
Body mass index, kg/m^2	22.0 ± 0.1 (12.9–37.3)	22.1 ± 0.3 (12.5–38.7)
Dementia (+)	76 (5.3%)	132 (7.1%)
Dementia (−)	1,361	1,740
Procedure Radiographic imaging	161 (11.2%)	117 (6.3%)
Percutaneous transluminal angioplasty	1,276 (88.8%)	1,755 (93.7%)
Fall accident (+)	3 (0.2%)	0 (0%)
Fall accident (−)	1,434	1,872

Values are given as number or mean ±standard deviation (range).

Table 3 Characteristics of patients who experienced fall accidents

Patients	#1	#2	#3
Age	52	32	80
Sex	Male	Male	Male
Dementia	(−)	(−)	(+)
Procedure	PTA	PTA	PTA
Occurrence	After procedure	Before procedure	After procedure
Bone fracture	(−)	(−)	(+)

between before and after the plate introduction.

Three accidental falls occurred before the plate's introduction (0.21%), and none occurred after the plate introduction. The patients in all three accidental falls were men, and the falls occurred before or after a PTA procedure (Table 3). One of the patients had dementia and required hospital care for the bone fracture he suffered in the fall. The statistical analysis revealed that accidental falls were significantly prevented after the plate's introduction (Table 4). The PTA procedure and dementia were not statistically related to the accidental falls. These results indicate that the vascular-access intervention assistance plate can prevent patients' accidental falls from the bed.

Table 4 Analysis of fall accidents

	Fall accident (+)	Fall accident (−)	*p*-value (Pearson chi-squared test)
Before plate introduction	3	1,434	
After plate introduction	0	1,872	0.0480*
Dementia (+)	1	207	
Dementia (−)	2	3,099	0.0543
Procedure Radiographic imaging	0	278	
Percutaneous transluminal angioplasty	3	3,028	0.6012

*: $p<0.05$.

Discussion

Accidental falls are sometimes reported by hospitals [3-7]. Although these do not occur very frequently, a single fall can cause serious injuries. Many reports of patients' accidental falls have been made from wards, and few reports or descriptions of countermeasures have originated from radiology departments [1,2]. Various candidate countermeasures to prevent such falls have been considered, including the use of human resources such as careful monitoring by staff, but automatic fall prevention is the best option to avoid human error. In fact, our study revealed that all of the accidental falls occurred before or after a PTA procedure while medical staff were distracted from monitoring.

The vascular-access intervention assistance plate can also contribute to patients' safety at the peripheral time points of PTA and other procedures, such as during the patients' preparation, repositioning, and transfer. In addition, although dementia has been speculated to be a risk factor for accidental falls, our analyses revealed that the rates of dementia before and after the introduction of the intervention assistance were not significantly different at 5.3% and 7.1%, respectively (Table 2) [8-11]. Dementia was not statistically related to accidental falls (Table 4). Medical personnel might pay closer attention to dementia patients as a general countermeasure.

A long procedure time is also considered a risk factor for accidental falls, and all 3 of the accidental falls in the present study occurred before or after a PTA procedure. Compared to radiographic imaging, the PTA procedure take more time and materials. However, the results of our analyses demonstrated that the PTA procedure was not related to the incidence of accidental falls. Together our results indicate that accidental falls occurred regardless of the patients' background characteristics. Automatic fall prevention is thus an important countermeasure.

In general, a separate arm stand and attached table of a surgical bed are used to fix the patient's arm for vascular-access intervention, but these devices cannot fix the body and arm simultaneously with the adequate strength and stability. As mentioned above, we considered various candidate plate materials by considering their strength, processing features, and cost. Although a carbon plate would be very strong, it would be both very expensive and difficult to process. A normal plastic plate comprised of polyethylene would be cheap and easy to process, but not strong enough. The polypropylene homopolymer that we selected provides a suitable balance between low cost and ease of processing.

Thickness is a key feature in handling the plate. We examined 4-, 6-, 7-, and 8-mm plate thicknesses. The 6-mm plate was not strong enough, and 8 mm was a little too heavy for some medical staff. The thickness of 7 mm offered the best balance of strength and handling. According to the simulation calculation results, the 7-mm plate allows patients weighing up to 200 kg (approx. 440 lbs.).

The following limitations must be considered when interpreting the present results. We did not perform a prospective and control study to confirm the efficacy of the plate in fall prevention. We cannot fully exclude the possibility that some of the medical personnel's caution based on patients' previous accidental falls helped prevent further fall accidents. A prospective multicenter trial is thus necessary to test our findings.

In conclusion, the vascular-access intervention assistance plate provides good operability and safety, preventing accidental falls in patients undergoing hemodialysis or other procedures.

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References

1. Hashida M and Shiraishi J: Incident reports related to tasks performed by radiological technologists: an analysis of ten years of incident reports. Nihon Hoshasen Gijutsu Gakkai Zasshi (2015) 71: 99–107.
2. Mansouri M, Shaqdan KW, Aran S, Raja AS, Lev MH and Abujudeh HH: Safety incident reporting in emergency radiology: analysis of 1717 safety incident reports. Emerg Radiol (2015) 22: 623–630.
3. Chari SR, Smith S, Mudge A, Black AA, Figueiro M, Ahmed M, Devitt M and Haines TP: Feasibility of a stepped wedge cluster RCT and concurrent observational sub-study to evaluate the effects of modified ward night lighting on inpatient fall rates and sleep quality: a protocol for a pilot trial. Pilot Feasibility Stud (2016) 2: 1.
4. Lee YL, Yip WK, Goh BW, Chiam EP and Ng HP: Fall prevention among children in the presence of caregivers in a paediatric ward: a best practice implementation. Int J Evid Based Healthc (2013) 11: 33–38.
5. Cuttler SJ, Barr-Walker J and Cuttler L: Reducing medical-surgical inpatient falls and injuries with videos, icons and alarms. BMJ Open Qual (2017) 6: e000119.
6. Hempel S, Newberry S, Wang Z, Booth M, Shanman R, Johnsen B, Shier V, Saliba D, Spector WD and Ganz DA: Hospital fall prevention: a systematic review of implementation, components, adherence, and effectiveness. J Am Geriatr Soc (2013) 61: 483–494.
7. Shorr RI, Chandler AM, Mion LC, Waters TM, Liu M, Daniels MJ, Kessler LA and Miller ST: Effects of an intervention to increase bed alarm use to prevent falls in hospitalized patients: a cluster randomized trial. Ann Intern Med (2012) 157: 692–699.
8. Lach HW, Harrison BE and Phongphanngam S: Falls and Fall Prevention in Older Adults With Early-Stage Dementia: An Integrative Review. Res Gerontol Nurs (2017) 10: 139–148.
9. Bayen E, Jacquemot J, Netscher G, Agrawal P, Tabb Noyce L and Bayen A: Reduction in Fall Rate in Dementia Managed Care Through Video Incident Review: Pilot Study. J Med Internet Res (2017) 19: e339.
10. Harvey L, Mitchell R, Brodaty H, Draper B and Close J: Differing trends in fall-related fracture and non-fracture injuries in older people with and without dementia. Arch Gerontol Geriatr (2016) 67: 61–67.
11. Toots A, Wiklund R, Littbrand H, Nordin E, Nordstrom P, Lundin-Olsson L, Gustafson Y and Rosendahl E: The Effects of Exercise on Falls in Older People With Dementia Living in Nursing Homes: A Randomized Controlled Trial. J Am Med Dir Assoc (2018).