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**Gakken**

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## Introduction

Recently, medical facilities have been strongly urged to take countermeasures against hospital-acquired infections. It is a great challenge for them to prevent infection caused by catheters placed in blood vessels. CDC guidelines recommend using sterile gauze or dressing material made of transparent film for protection of catheter insertion sites.

Transparent film dressing material has advantages over sterile gauze; for example, it protects the site of central or peripheral venous catheter insertion, allows continuous observation of the site, and permits patients to shower. On the other hand, the adhesive agent of the dressing may occasionally cause skin irritation because it is in contact with the

entire skin surface area of the insertion site.

In this paper, we report on an application study we made to check the efficacy of the transparent dressing material (brand name: YU-KI Perme-Aid) that was developed by Nitto Denko Corporation and is distributed by Nitto Medical Corporation, in the light of its fixation capability and skin irritation.

## Methods

### 1. Subjects

The study included 90 inpatients who gave informed consent to participate in the study at the surgery ward of our hospital over the period from September 2001 to January 2002, excluding those who had had a drug of any kind applied

or attached to the site subject to observation within one week before the start of the study.

### 2. Materials

YU-KI Perme-Aid, which was used in the study, is superior in moisture permeability and adherence. Its properties allow free flow of air and vapor, but do not allow bacteria, or liquids such as water to permeate (**Table 1**). On one side of the product, an acrylic gel adhesive has been applied to enable adhesion of the product and fixation of catheters to the skin.

The adhesive is the same type as that applied to the surgical tape YU-KI BAN, manufactured by Nitto Denko Corporation. Because it minimizes the peeling of corneous cells when the tape is removed, it has earned a reputation for

**Table 1. Basic Physical Properties**

	Thickness ( $\mu\text{m}$ )		Adhesive strength to human skin (N/20mm)		Moisture Permeability ( $\text{g/m}^2/\text{day}$ )
	(Film)	(Adhesive)	0.5 hours	6 hours	
YU-KI Perme-Aid	30	30	0.71	0.64	1130
Control product T	25	25	0.77	0.97	580

**Table 2. Safety of YU-KI Perme-Aid**

Results	
Primary skin irritation test	Classified as negligible (P.I.I = 0).
Cumulative irritation test	Cumulative irritation is low.
Contact sensitization test	No sensitizing property.
Cytotoxicity test	No clear sign of cytotoxicity (IC50 = 67%).
Patch test in humans	No primary irritation in all 20 patients.

rarely causing skin irritation by physical stimulation. The safety of this product has also been fully confirmed through primary skin irritation tests (in guinea pigs and humans) and contact sensitization tests (in rabbits,) etc. (**Table 2**).

The product is provided in two sizes: 6 cm x 9 cm, which is mainly suited for fixation of peripheral venous catheters, and 10 cm x 13.5 cm, which is primarily suited for fixation of central venous catheters. Both these products are pack-

aged separately and sterilized by gamma irradiation.

### 3. Test method

The insertion site of a central venous catheter that had been placed in the subclavian vein or internal jugular vein was sterilized with 10% povidone iodine solution and dried. Subsequently, YU-KI Perme-Aid (10 cm x 13.5 cm) was applied to the site. The product was left untouched for one week as long as there were no complications, and replaced

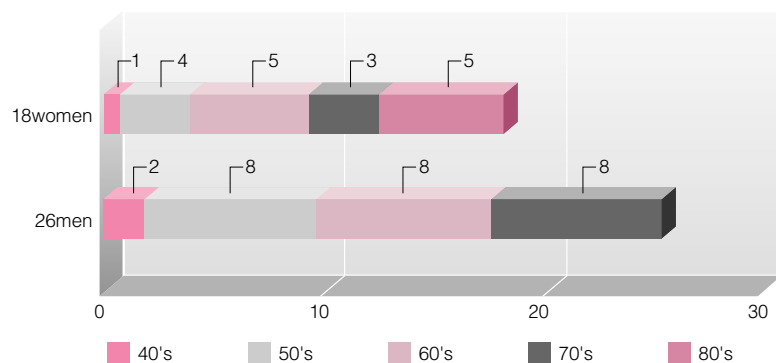
with a fresh dressing every Wednesday. Commercially available product was used concurrently as the control product T.

The insertion site of a central venous catheter that had been placed in the forearm, cubital joint, or dorsum of the hand was sterilized with 10% povidone iodine solution and dried. Subsequently, YU-KI Perme-Aid (6 cm x 9 cm) was applied to the site. The product was replaced with a fresh dressing as required.

To examine the degree of tearing of corneous cells, small pieces of YU-KI Perme-Aid and control product T were applied to the chest of 10 patients who gave informed consent, and the pieces were removed on days 1 and 7 after application. The adhesive surface of the film collected was then stained and analyzed to determine the degree of skin tearing.

### 4. Evaluation method

YU-KI Perme-Aid and control product T were clinically evaluated in terms of the catheter fixation and skin condition of the application site according to the following five evaluation criteria:



**Figure 1. Patient Demographic Data (fixat central venous catheters, n=44)**

#### Catheter fixation

The presence of space between the skin and catheter was graded according to the following three ranks:

**A:** Good. There is almost no space between the catheter and skin, and the catheter is fixed sufficiently.

**B:** Fair. Although there is small space between the catheter and skin, it does not affect the fixation of the catheter.

**C:** Poor. There is some space between the catheter and skin, and the product needs to be replaced with a new one.

#### Peel force

The presence of peeling due to perspira-

tion or friction was graded according to the following three ranks:

**A:** Good. There is almost no peeling of the product.

**B:** Fair. Although there is slight peeling of the product, it does not affect the fixation of the catheter.

**C:** Poor. There is peeling of the product, and the product needs to be replaced with a new one.

#### Skin redness

The skin immediately after the removal of the product was observed, and redness of the skin was graded according to the following three ranks:

—: There is no redness.

±: The skin is slightly red.

+: The skin is clearly red, and edema is also present.

#### Itchiness of the skin

We asked the patients whether the skin itched each time we replaced the product, and the presence of itching was graded according to the following three ranks:

**A:** The patient hardly complained of itching both during the treatment and after removal.

**B:** The patient complained of some itching during the treatment and/or after removal.

**C:** The patient complained of frequent or severe itching during the treatment and/or after removal.

#### Pain on removal of the product

We asked the patients whether they felt pain each time we replaced the product, and the occurrence of pain was graded according to the following three ranks:

**A:** The patient hardly complained of pain at the time of removal.

**B:** There was slight pain at the time of removal.

**C:** The patient complained of severe pain at the time of removal.

**Table 3. Fixation of Central Venous Catheters (YU-KI Perme-Aid)**

				Endpoints																																										
	Subjects	Sex	Age	Fixability								Adhesion								Skin redness								Itching								Pain on removal										
				1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8			
				Weeks								Weeks								Weeks								Weeks								Weeks										
1	H.S.	M	60	A	B	B	A	A	A	A	A	A	A	A	A	A	B	±	±	±	±	±	±	±	±	C	B	B	A	A	A	B	A	B	A	A	A	A	A	A	A	A	A	A	A	
2	H.M	M	71	A	A	A	A					A	A	A	A			±	±	±	±	±	±	±	±	B	B	B	B					D	D	D	D									
3	T.S.	M	54	A	A	A	A					A	A	A	A			±	±	±	±	±	±	±	±	D	D	D	D					D	D	D	D									
4	T.Y.	W	49	A	A	A	A					B	B	B	A			±	±	±	±	±	±	±	±	C	B	B	B					A	A	A	A									
5	K.N.	M	58	A	A	A	A					A	A	A	A			±	±	±	±	±	±	±	±	A	A	A	A					A	A	A	A									
6	M.I.	W	55	A	A	A	A					B	B	B	B			±	±	±	±	±	±	±	±	B	C	B	A					A	A	A	A									
7	S.M.	M	50	A	A	A	A	A	A	A	A	A	A	A	A	A	A	±	±	±	±	±	±	±	±	B	B	A	A	A	A	A	A	B	B	B	B	A	A	A	A	A	A	A	A	
8	T.H.	M	52	A	A	A	A					A	A	A	A			+	±	±	±	±	±	±	±	B	B	C	C					A	A	A	A									
9	K.O.	M	61	A	A	A	A	A	A	A		A	A	A	A	A	B	+	±	±	±	±	±	±	±	C	A	A	A	B	A	A		B	A	A	A	A	A	A	A	A	A	A	A	
10	Y.U.	M	73	A	A	A	A	A	A	A	A	A	A	A	A	A	A	±	±	±	±	±	±	±	±	A	A	A	A	A	A	A	A	A	A	B	A	A	A	A	A	A	A	A	A	
11	Y.K.	M	66	B	A	A	A	A	A	A	A	A	A	A	A	A	A	±	±	±	±	±	±	±	±	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	
12	Y.Y.	M	64	A	A	A	A	A	A	A		A	A	A	A	A	A	±	±	±	±	±	±	±	±	A	A	A	A	A	A	A		A	A	A	A	A	A	A	A	A	A	A	A	
13	A.S.	M	66	A	A	A	A	A	A			A	A	A	A	A	A	±	±	±	±	±	±	±	±	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
14	T.N.	W	81	A	A	A	A	A	A	A	A	B	B	A	A			±	±	±	±	±	±	±	±	A	A	A	A					A	A	A	A									
15	K.Y.	M	73	A	A	A	A					A	A	A	A			±	±	±	±	±	±	±	±	A	A	A	A					A	A	A	A									
16	I.N.	M	75	B	A	A	A					C	A	B	A	B		±	±	±	±	±	±	±	±	A	A	A	A	A	A			A	A	A	A									
17	T.S.	M	78	C	A	A	A	A	A			A	A	B	A			±	±	±	±	±	±	±	±	B	A	A	A					A	A	A	A									
18	T.S.	M	66	A	A	A	A	A				A	A	A	A	A		±	±	±	±	±	±	±	±	A	A	A	A	A				A	A	A	A	A								
19	T.N.	M	59	A	A	A	A	A	A	A	A	A	A	A	A	A	A	±	±	±	±	±	±	±	±	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	
20	K.Y.	W	59	A	A	A	A					A	A	A	A			±	±	±	±	±	±	±	±	B	A	A	A					A	A	A	A									
21	M.F.	W	64	A	A	A	A					A	A	A	B			±	±	±	±	±	±	±	±	A	A	A	A					A	A	A	A									
22	S.E.	W	77	A	A	A	A	A	A	A	A	A	A	A	A	B	A	A	±	±	±	±	±	±	±	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	

**Table 4. Fixation of Central Venous Catheters (Control product T)**

				Endpoints																																								
	Subjects	Sex	Age	Fixability								Adhesion								Skin redness								Itching								Pain on removal								
				1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8	
				Weeks								Weeks								Weeks								Weeks								Weeks								
1	H.F.	W	58	A	A	A	A	A				A	C	A	A	B				+	+	-	-	±			C	C	B	B	C				B	B	A	A	A					
2	A.I.	M	60	A	A	A	A					A	A	A	A					±	-	-	-				B	A	A	B					A	A	A	A						
3	I.I.	W	87	A	A	A	A	A				A	A	A	A	B				±	±	-	-	±			A	A	A	A	A					A	A	A	A	A				
4	I.M.	M	56	A	A	A	A					A	A	A	A					-	±	-	±				B	B	B	B					A	A	A	A						
5	E.H.	W	53	B	A	A	A					A	A	B	A					-	±	-	±				A	B	A	A					A	A	A	A						
6	K.S.	M	76	A	A	A	A	A	A	A	A	A	A	B	A	A	A	A	A	±	-	-	-	-	-	-	A	B	A	A	C	C	B		A	A	A	A	A	A	A	A	A	
7	N.S.	W	69	A	A	A	A					A	A	A	A					+	-	-	±				C	C	C	C	A				C	A	A	A	A					
8	M.N.	W	76	A	A	A	A	A	A			A	A	A	A	A	A			-	±		±	-	-	-	B	A	B	A	B	A			A	A	A	A	A	A		A		
9	S.S.	M	70	A	A	A	A	A				A	A	A	A	A				±	±	±	±	±	±		A	A	A	A	A				A	A	A	A	A					
10	S.K.	W	85	A	A	A	A	A	A	C		A	A	B	A	A	A	B		-	-	-	-	-			A	A	A	A	A	A	A		A	A	A	A	A	A	A	A	A	
11	Y.N.	M	72	A	A	A	A					A	A	A	A					-	-	-	-				A	A	A	A					A	A	A	A						
12	T.Y.	W	64	A	A	A	A					A	A	A	A					-	-	-	-				B	A	B	B					A	A	A	A						
13	M.Y.	W	70	A	C	A	A	A				A	C	A	A	A				-	-	±	±	±			C	C	C	C	C				A	A	A	A	A					
14	M.H.	W	89	A	A	A	A					A	A	A	A					-	-	-	-				A	A	A	A					A	A	A	A						
15	M.K.	W	64	A	A	A	A	A	A	A		A	A	A	A	A	A	A		-	-	-	-	-	-		A	A	A	A	B	B	B		A	A	A	A	A	A	A	A		
16	Y.M.	M	49	B	A	B	B	A	B			B	B	B	A	B	B			±	±	±	±	±	±		B	A	A	B	A	B			A	A	A	A	A	A		A		
17	H.T.	M	53	A	A	A	A	A				A	A	B	A	A				-	-	-	-	±			B	B	B	B	B				A	A	A	A	A					
18	R.S.	W	66	A	A	A	A					A	A	A	A	A				-	+	±	±	-			B	C	C	C	B				A	A	A	A	A					
19	S.I.	W	88	A	A	A	A	A	A			B	A	A	A	A	B			±	±	±	±	-	-		A	A	A	A	A	A			A	A	A	A	A		A			
20	K.N.	M	66	A	A	A	A	A				A	A	A	A	A				-	-	-	-	-			C	C	C	B	B				A	A	A	A	A					
21	M.I.	M	49	A	A	A	A					A	A	A	A					±	±	±	±				A	B	B	B					A	A	A	A						
22	Y.F.	M	58	A	A	A	A					A	A	A	A					-	-	-	-				A	B	B	B					B	A	A	A						

Table 5. Results Comparison of the Evaluation Test

P: YU-KI Perme-Aid T: Control product

Endpoints	Weeks	Material	A(—)	B(±)	C(+)	Dropouts	All patients	Eligible patients	A(—)	B(±)	C(+)
Fixability	1	P	19	2	1	0	22	22	86%	9%	5%
		T	20	2	0	0	22	22	91%	9%	0%
	2	P	21	1	0	0	22	22	95%	5%	0%
		T	19	0	1	2	22	20	95%	0%	5%
	3	P	21	1	0	0	22	22	95%	5%	0%
		T	17	1	0	4	22	18	94%	6%	0%
	4	P	22	0	0	0	22	22	100%	0%	0%
		T	17	1	0	4	22	18	94%	6%	0%
Adhesion	1	P	17	4	1	0	22	22	77%	18%	5%
		T	20	2	0	0	22	22	91%	9%	0%
	2	P	18	4	0	0	22	22	82%	18%	0%
		T	17	1	2	2	22	20	85%	5%	10%
	3	P	18	4	0	0	22	22	82%	18%	0%
		T	13	5	0	4	22	18	72%	28%	0%
	4	P	20	2	0	0	22	22	91%	9%	0%
		T	18	0	0	4	22	18	100%	0%	0%
Skin redness	1	P	17	3	2	0	22	22	77%	14%	9%
		T	13	7	2	0	22	22	59%	32%	9%
	2	P	20	2	0	0	22	22	91%	9%	0%
		T	10	8	2	2	22	20	50%	40%	10%
	3	P	22	0	0	0	22	22	100%	0%	0%
		T	12	6	0	4	22	18	67%	33%	0%
	4	P	22	0	0	0	22	22	100%	0%	0%
		T	11	7	0	4	22	18	61%	39%	0%
Itching	1	P	12	6	3	1	22	21	57%	29%	14%
		T	10	8	4	0	22	22	45%	36%	18%
	2	P	15	5	1	1	22	21	71%	24%	5%
		T	11	6	3	2	22	20	55%	30%	15%
	3	P	17	3	1	1	22	21	81%	14%	5%
		T	11	6	1	4	22	18	61%	33%	6%
	4	P	18	2	1	1	22	21	86%	10%	5%
		T	10	7	1	4	22	18	56%	39%	6%
Pain on removal	1	P	18	3	0	1	22	21	86%	14%	0%
		T	19	2	1	0	22	22	86%	9%	5%
	2	P	20	1	0	1	22	21	95%	5%	0%
		T	19	1	0	2	22	20	95%	5%	0%
	3	P	19	2	0	1	22	21	90%	10%	0%
		T	18	0	0	4	22	18	100%	0%	0%
	4	P	20	1	0	1	22	21	95%	5%	0%
		T	18	0	0	4	22	18	100%	0%	0%

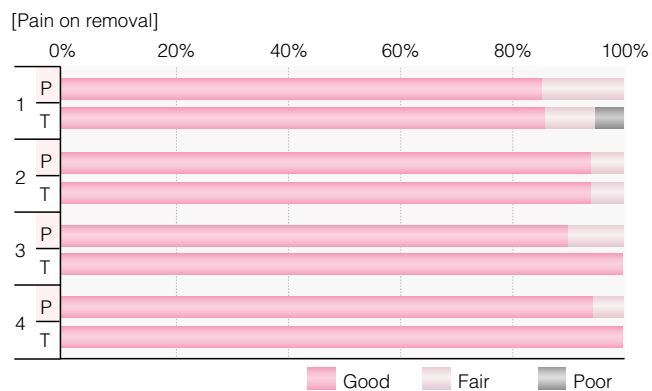
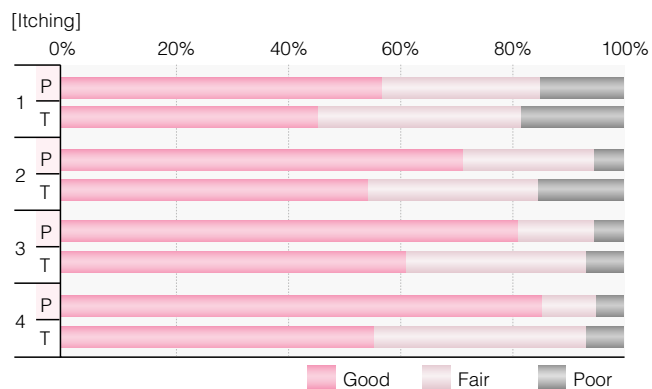
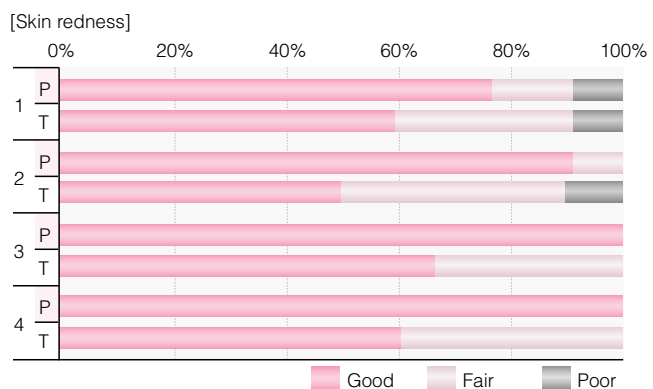
\*Dropouts: Impossible to evaluate, or changed from T to P.

(In the case of patients with low levels of consciousness, items 4 and 5 above were ranked as "D" (unable to be evaluated).)

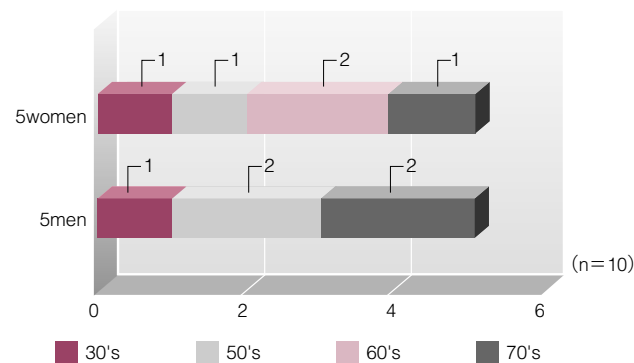
Regarding the area of peeled corneous cells, corneous cells adhering to the peeling face of the film after removal were stained, and the percentage of the area was calculated by the image analy-

sis method<sup>1)</sup> according to the following formula:

$$\frac{\text{Area of corneous cells adhering to the film}}{\text{Area to which the film was applied}} \times 100 (\%)$$



**Figure 2. Evaluation Results by the Fourth Week (P: YU-KI Perme-Aid, T: Control product T)**



**Figure 3. Patient Demographic Data (fixation of peril venous catheters, 10)**

**Table 6. Fixation of Peripheral Venous Catheters (YU-KI Perme-Aid)**

Endpoints								
	Subjects	Sex	Age	Fixability	Adhesion	Skin redness	Itching	Pain on removal
1	S.T.	W	68	A	A	—	A	A
2	F.A.	M	76	A	A	—	A	A
3	K.F.	M	32	A	A	—	A	C
4	T.I.	W	64	B	A	—	A	B
5	F.K.	W	70	A, A	A, A	—, ±	A, A	A, A
6	T.M.	W	30	A	A	—	A	A
7	W.N.	M	57	A	A	—	A	A
8	S.N.	W	59	A	A	—	A	A
9	M.K.	M	55	C	B	—	A	A
10	M.K.	M	78	A	A	—	A	A

## Results

**Figure 1** shows the demographic data of the patients. To evaluate the fixation of central venous catheters, 22 patients (16 men and 6 women) used YU-KI Perme-Aid and 22 patients (10 men and

12 women) used control product T. With regard to their age distribution, the majority of the patients were in the 50s to 70s age bracket. Of the female subjects, 5 were in their 80s. Although the period of catheterization differed from patient to patient, patients who were able to be evaluated at least 4 times (patients

in whom catheters were placed for at least 4 weeks) were regarded as eligible.

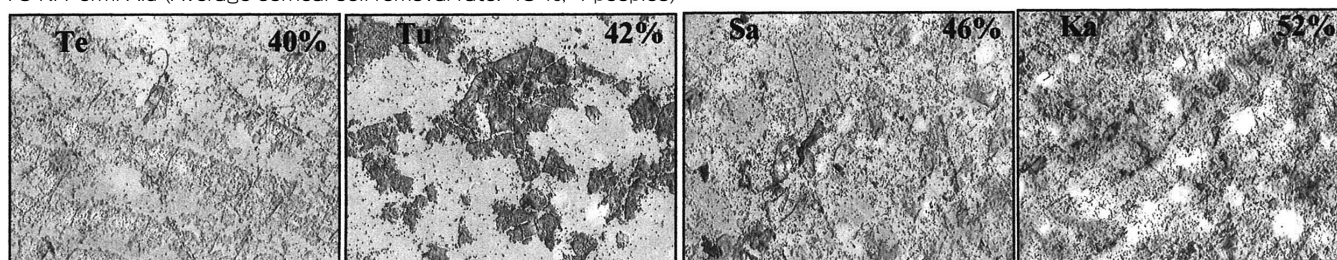
**Tables 3** and **4** show the results of the evaluation.

In the YU-KI Perme-Aid group, only one patient required replacement of the film due to peeling, although fixation

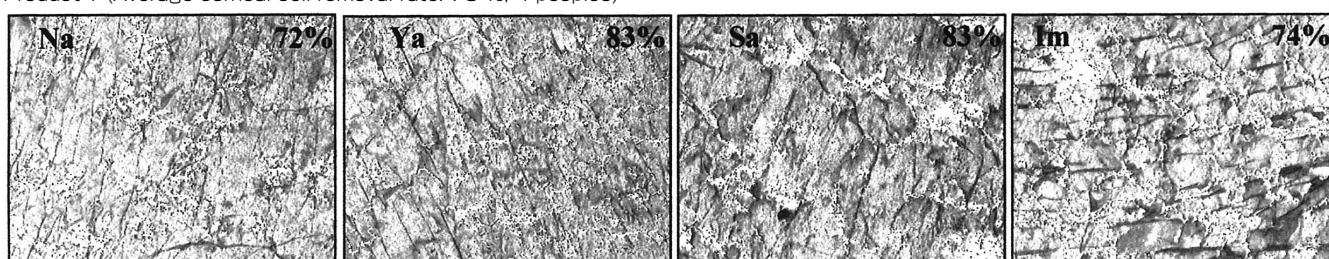


**Figure 4. Comparison of Corneal Cell Removal (IVH patients: applied on chest for 7 days)**

YU-KI Permi-Aid (Average corneal cell removal rate: 45 %, 4 peoples)



Product T (Average corneal cell removal rate: 78 %, 4 peoples)



and adhesion were satisfactory. With regard to skin redness, itching, and pain at the removal of the film, only 5 patients (from case Nos. 10 to 22) were graded  $\pm$  or B, and these patients recovered from the symptoms within 2 weeks. At the same time, 5 patients (from case Nos. 1 to 9) were graded + or C in the evaluation of skin redness or itching, but they also gradually recovered from these symptoms.

In the control (product T) group, on the other hand, 15 patients were graded + or

$\pm$  in the evaluation of skin redness, and two of them even developed blisters. Six patients, including those graded C, complained of itching. Peeling or a gap between the film and skin surface was observed in 3 patients. Of these patients, 4 patients (case Nos. 1, 7, 18, and 20) complained of severe itching and developed blisters, and requested discontinuation of use of product T. Therefore, YU-KI Perme-Aid was used for them from midway through the application period.

In these patients, skin redness and itching were slightly relieved after the film was switched to YU-KI Perme-Aid.

Of the results of evaluation of the patients listed in **Tables 3** and **4**, the results to the fourth week are summarized in **Table 5**.

**Figure 2** shows these results in graphical format. There are clear differences in skin redness and itching between YU-KI Perme-Aid and control product T, which tended to become more pro-

nounced over time. In particular, there was a significant difference in skin redness between the YU-KI Perme-Aid and control groups ( $p < 0.01$ , Mann-Whitney's U-test) from the second to the fourth week.

On the other hand, regarding the fixation of peripheral venous catheters using YU-KI Perme-Aid, **Figure 3** shows the demographic data of the patients and **Table 6** shows the evaluation results of 10 patients. The fixation condition and skin condition of the applied site were satisfactory, with the exception of one patient in whom the catheter partially came off.

**Figure 4** is a set of images of the stained cells attached to the adhesive face of the film after removal. The percentage at the right upper corner of each picture represents the area covered with peeled corneous cells. The percentages of the areas of peeled corneous cells in the YU-KI Perme-Aid group remained at 40% to 50% even 1 to 7 days after application, while the percentages in the control product T reached 70% to 90%. These percentages correlate well with the clinical evaluation results of patient skin conditions (redness and itching).

## Discussion

In this study, we evaluated the practical performance of the transparent film dressing material YU-KI Perme-Aid manufactured by Nitto Denko

Corporation when used for the fixation of catheters.

### 1. Stable fixation

It was confirmed that YU-KI Perme-Aid was equivalent to control product T in performance when used for the fixation of central venous catheters.

### 2. Breathable film with a low probability of causing tearing of corneous cells

It was confirmed that YU-KI Perme-Aid was superior to control product T in terms of the skin condition at the application site, with respect to symptoms such as redness and itching.

It is clear that YU-KI Perme-Aid has an advantage over the control product, because none of the patients in the YU-KI Perme-Aid group dropped out of the study for reasons such as blisters or itching. The advantage of YU-KI Perme-Aid is largely attributable to its breathability due to the high permeability of the film and a low probability of causing tearing of corneous cells due to the use of a unique, soft gel adhesive.

### 3. Improvement of skin condition

Regarding case Nos. 1 to 9, which scored relatively low on the evaluation of itching or pain on removal, these subjects used YU-KI Perme-Aid after using other film dressing materials. That is, they did not use YU-KI Perme-Aid immediately after the insertion of a catheter. Because all of these patients showed improvement in skin condition

with time, it was suggested that skin irritation caused by the previous products had an affect on the condition of the skin.

## Conclusion

We conducted a practical evaluation of the transparent film dressing material YU-KI Perme-Aid when used for the fixation of catheters (mainly central venous catheters) utilizing the commercially available product T as a control. Although YU-KI Perme-Aid was equivalent to the control product in terms of performance (i.e., fixation of catheters), it was clear that it had an advantage over the control product in terms of the low probability of causing skin irritation (skin condition at the application site).

Thus, it is indicated that YU-KI Perme-Aid can contribute to the assurance of safety and improvement of patients' QOL, fulfilling its original purpose, fixation of catheters, effectively.

### Reference

- 1) Nakano Yoshihisa: How to evaluate skin irritation caused by adhesives for medical use. Nitto Denko Technical Report 28 (1) : 50, 1990