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Resumee in English of a clinical application survey of „YATHAN SECOND skin“ Heel Cushion

carried out at

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conducted by

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Our facility „Zentrum für Beatmung und Intensivpflege im Storkower Bogen GmbH“ is a Center for Artificial Ventilation and Intensive Care founded in 2006. It is located in Berlin, Germany. We have specialized in the attention of patients which require artificial ventilation and patients suffering from Unresponsive Wakefulness Syndrome (UWS) or Minimally Conscious State (MWS) in long-term rehabilitation phase F. We have a capacity for 70 patients and offer both inpatient specialized attention and outpatient service in assisted living schemes.

For more than two years, we have been using the YATHAN SECOND skin Heel Cushion made of polymeric gel in mesh structure to avoid occurrence of heel and elbow pressure ulcers in our facility. In this survey we resumed the clinical situation and outcome of 12 patients using YATHAN SECOND skin Heel Cushion Size S (Art-N° 9-21-110 F) or Size M (Art-N° 9-21-120 F) for several weeks for decubitus prevention. This survey covers patients attended in our facilities from 14 March 2014 to 16 November 2015, aged between 30 and 82 years. Most of them were totally immobilized, bed-ridden, mainly due to neurological or internal pathologies.

All of them showed a medium to very high pressure ulcer risk which was evaluated according to the BRADEN scale.

These 12 patients – when starting the application of the product - showed in total 9 pressure ulcer wounds, two of them in category III and nine of them in category I according to EPUAP. All these wounds completely healed during the application of YATHAN SECOND skin heel cushion.

Until the end of time of the survey no new pressure ulcers occurred. Moreover, the use of this heel cushion showed positive effects on the skin in general. The skin turned smoother and more elastic. Reddish areas disappeared.

Me and my colleagues in our facility did not observe any direct or indirect damage which could be induced by the product to the patients or the nursing staff.

Resuming we can state that our nursing team is very satisfied with the results of the application of this product as not only the existing pressure ulcers healed but also handling and cleaning of the YATHAN SECOND skin heel cushion turned out to be uncomplicated.

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Head of Wound Management

Place	ZBI Berlin	ZBI Berlin	ZBI Berlin
Patient	1	2	3
Period of observation	04.02.15 - 02.06.15	10.08.15 - 12.11.15	03.04.15- 06.06.15
Sex	female	female	male
Age	73	67	30
Size in cm	168	163	186
Weight in kg	62.5	63	92
Diagnose	<i>Hypoxic cerebral damage with cerebral oedema, diabetes mellitus, chronical renal disease, slack tetraparesis, dysphagia</i>	<i>Intracranial bleeding in the right front area, rupture into the ventricular system, recurring general and extended cerebral spasms</i>	<i>Multiple trauma after fall off a bridge, cerebral contusion with fracture of the left temporal bone, mid facial fracture, fracture of the lower jaw, basal skull fracture, haemorrhage in the posterior part of corpus callosum, splenic rupture, left elbow fracture, rip fracture, tetraparesis, epilepsia</i>
Pressure ulcer risk	<i>Very high risk</i>	<i>High risk</i>	<i>Medium risk</i>
Special risk factors	<i>Risk of malnutrition, blood pressure continuously instable and low, bed-ridden patient, lying on a healed but high degree pressure ulcer, totally immobilized, paralysis, spasms</i>	<i>Blood pressure continuously instable and low, bed-ridden patient, medium heavy limitations of mobility, paralysis, spasticity, pain symptomatology</i>	<i>bed-ridden patient, totally immobilized, paralysis, spasticity, contractures, pain symptomatology</i>
Existing pressure ulcer	<i>yes</i>	<i>no</i>	<i>yes</i>
Category acc to EPUAP	<i>Category I on both heels</i>	<i>Does not apply</i>	<i>Category I on both heels</i>
Healing process	<i>Positive</i>	<i>Does not apply</i>	<i>Does not apply</i>
Was there a pressure ulcer in the past?	<i>yes, on the left heel</i>	<i>no</i>	<i>no</i>

Description of the general skin conditions when starting the clinical survey	<i>Dry up to very dry skin, atrophic skin, pale, low skin tonicity</i>	<i>Normal, without special changes of colour, normal skin tonicity</i>	<i>Normal, without special changes of colour, normal skin tonicity</i>
Description of the general skin condition when finishing the clinical survey	<i>Unchanged</i>	<i>Unchanged</i>	<i>Unchanged</i>
Description of the skin conditions on the heel when starting the clinical survey	<i>Dry skin on both feet, pressure ulcers category I on both heels, size 1,6 x 1,5 cm (length x width) each</i>	<i>Redness on both heels but no pressure ulcer</i>	<i>Pressure ulcers category I on both heels (size 1,0 cm x 1,0 cm)</i>
Was the heel cushion in use over the entire time of the survey?	<i>yes</i>	<i>yes</i>	<i>yes</i>
Description of the skin conditions on the heel when finishing the clinical survey	<i>Less dry skin on both feet, skin conditions have normalized, skin was smoother and softer, pressure ulcers healed</i>	<i>No redness any longer</i>	<i>Pressure ulcers healed</i>
Comments	<i>non</i>	<i>non</i>	<i>non</i>

Place	ZBI Berlin	ZBI Berlin	ZBI Berlin
Patient	4	5	6
Period of observation	<i>30.03.15 - 14.04.15</i>	<i>09.05.15 - 01.06.15</i>	<i>20.03.15- 30.04.15</i>
Sex	<i>female</i>	<i>male</i>	<i>male</i>
Age	<i>57</i>	<i>58</i>	<i>64</i>
Size in cm	<i>161</i>	<i>164</i>	<i>168</i>
Weight in kg	<i>86</i>	<i>58.6</i>	<i>76</i>
Diagnose	<i>Acute liver failure with hepatic encephalopathy after chronic alcohol abuse, depression, arterial hypertension, patient's condition after ulcus ventriculi, hypokalaemia, acute renal failure</i>	<i>Acute respiratory insufficiency type II, COPD, pneumonia caused by Staphylococcus and E.coli, hypovolemia, MRSA, acidosis, tobacco and alcohol abuse</i>	<i>Weaning from artificial ventilation, with temporal necessity to continue artificial ventilation. Tricuspid insufficiency, severe COPD Typ IV, lung emphysema, arterial hypertension</i>
Pressure ulcer risk	<i>Medium risk</i>	<i>Very high risk</i>	<i>Medium risk</i>

Special risk factors	<i>Continuously low blood pressure, bed-ridden patient, medium severe mobility restrictions, limited sensoric abilities</i>	<i>Malnutrition, continuously low blood pressure, continuously instable circulation, bed-ridden patient lying on a healed higher grade pressure ulcer, significant mobility restrictions, limited sensoric abilities</i>	<i>Continuously instable circulation, bed-ridden patient, medium degree mobility restrictions, orthopaedic contractions</i>
Existing pressure ulcer	<i>no</i>	<i>no</i>	<i>no</i>
Category acc to EPUAP	<i>Does not apply</i>	<i>Does not apply</i>	<i>Does not apply</i>
Healing process	<i>Does not apply</i>	<i>Does not apply</i>	<i>Does not apply</i>
Was there a pressure ulcer in the past?	<i>Yes, category III on both heels</i>	<i>Yes, category IV on both heels</i>	<i>Yes, left heel with category III</i>
Description of the general skin conditions when starting the clinical survey	<i>Fatty skin, yellowish colour, skin tension high</i>	<i>Dry to very dry skin, reddish, low skin tension</i>	<i>Cortisone treatment, dry to very dry skin, atrophic skin of pale, bluish colour, low skin tension</i>
Description of the general skin condition when finishing the clinical survey	<i>unchanged</i>	<i>unchanged</i>	<i>unchanged</i>
Description of the skin conditions on the heel when starting the clinical survey	<i>Skin tension high</i>	<i>Hyperkeratosis</i>	<i>Dry atrophic skin</i>
Was the heel cushion in use over the entire time of the survey?	<i>yes</i>	<i>yes</i>	<i>yes</i>
Description of the skin conditions on the heel when finishing the clinical survey	<i>Skin of the heel became more elastic</i>	<i>Hyperkeratosis decreasing, skin condition is normalizing</i>	<i>Skin was additionally treated with an urea lotion, skin became smoother and more elastic, skin moisture increased</i>
Comments	<i>Slight imprint of heel cushion on the skin due to oedema on the lower extremities</i>	<i>none</i>	<i>Muscle tone decreased in the protected joint, reduced pain</i>

Place	ZBI Berlin	ZBI Berlin	ZBI Berlin
Patient	7	8	9
Period of observation	<i>17.09.15-02.11.15</i>	<i>10.03.14-15.05.14</i>	<i>15.10.15-16.11.15</i>
Sex	<i>male</i>	<i>male</i>	<i>male</i>
Age	<i>71</i>	<i>82</i>	<i>57</i>
Size in cm	<i>173</i>	<i>174</i>	<i>183</i>
Weight in kg	<i>62.3</i>	<i>69.5</i>	<i>71.5</i>

Diagnose	<i>Renal cell carcinoma (right) with metastatic involvement of vena cava inferior, rectal bleeding, circulatory insufficiency, respiratory insufficiency requiring artificial ventilation and weaning from artificial ventilation, pleural effusion (left), polyneuropathy as critical illness, tetraparesis</i>	<i>Acute exacerbation of known inspiratory stridor, combined with global inspiratory insufficiency, vocal folds paralyzed, symptomatic trigeminal neuralgia</i>	<i>Hypoxic cerebral damage, abscess after aortic aneurysm, dysphagia with tracheostoma</i>
Pressure ulcer risk	<i>Very high risk</i>	<i>Very high risk</i>	<i>Very high risk</i>
Special risk factors	<i>Continuously low blood pressure, continuously instable blood pressure, bed ridden patient, patient lying on a healed pressure ulcer, totally immobilized, paralyses, orthopaedic contractions, pain symptomatology, restricted sensoric abilities.</i>	<i>Very advanced age patient, malnutrition, continuously instable circulation, bed-ridden patient, totally immobilized, pain symptomatology, restricted sensoric abilities.</i>	<i>Continuously instable circulation, bed ridden patient, patient lying on a healed pressure ulcer, medium severely immobilized, paralysis, restricted sensoric abilities.</i>
Existing pressure ulcer	<i>no</i>	<i>yes</i>	<i>no</i>
Category acc to EPUAP	<i>Does not apply</i>	<i>right heel category III</i>	<i>Does not apply</i>
Healing process	<i>Does not apply</i>	<i>positive</i>	<i>Does not apply</i>
Was there a pressure ulcer in the past?	<i>Yes, on both heels, category III</i>	<i>no</i>	<i>no</i>
Description of the general skin conditions when starting the clinical survey	<i>Dry to very dry skin, pale skin, low skin tension</i>	<i>Dry to very dry skin, reddish colour, low skin tension</i>	<i>Normal to sensitive skin, pale and reddish colour, normal skin tension</i>
Description of the general skin condition when finishing the clinical survey	<i>unchanged</i>	<i>unchanged</i>	<i>unchanged</i>
Description of the skin conditions on the heel when starting the clinical survey	<i>Completely healed pressure ulcers category III on both heels, hyperkeratosis on both feet</i>	<i>right heel in category III, necrotic and red, 1.5 cm x 1.5 cm (length x width), depth not determinable due to necrosis</i>	<i>Dry skin, hyperkeratinoses</i>
Was the heel cushion in use over the entire time of the survey?	<i>yes</i>	<i>yes</i>	<i>yes</i>
Description of the skin conditions on the heel when finishing the clinical survey	<i>Hyperkeratosis decreased on both feet</i>	<i>The pressure ulcer was fully healed on 07.04.2014</i>	<i>Skin is more elastic and hyperkeratinoses are decreasing</i>
Comments	<i>none</i>	<i>Pain reduction in the wound area due to use of the heel cushion</i>	<i>none</i>

Place	ZBI Berlin	ZBI Berlin	ZBI Berlin
Patient	10	11	12
Period of observation	18.06.15-07.09.15	28.01.15-02.04.15	09.01.15-05.05.15
Sex	female	female	male
Age	80	41	47
Size in cm	168	176	173
Weight in kg	64	65.3	81
Diagnose	Traumatic subarachnoid hemorrhage, unconsciousness related to craniocerebral trauma, post-traumatic hydrocephalus, diabetes mellitus	Hypoxic cerebral damage after cardiac arrest of uncertain cause, tetraplegia with spastic and cranial involvements, spasms, agitated patient with organic brain syndrome, dysphagia	Anoxic brain damage after cardiac arrest, recurring ventricular fibrillation, acute myocardial infarction, unresponsive wakefulness syndrome, chronic respiratory insufficiency, long-term artificial ventilation
Pressure ulcer risk	Very high risk	Very high risk	Medium risk
Special risk factors	Very senior patient, malnutrition, continuously instable and low blood pressure, diabetes mellitus, bed-ridden patient, totally immobilized, orthopaedic contractions, spasms, pain symptomatology, restricted sensoric abilities.	Malnutrition, continuously instable circulation and low blood pressure, bed-ridden patient, patient lying on a healed pressure ulcer, totally immobilized, paralyzes, orthopaedic contractions, spasms, restricted sensoric abilities	Continuously instable circulation, bed-ridden patient, totally immobilized, paralyzes, spasms, restricted sensoric abilities
Existing pressure ulcer	no	yes	yes
Category acc to EPUAP	Does not apply	On both heels category I	On both heels category I
Healing process	Does not apply	positive	positiv
Was there a pressure ulcer in the past?	no	Yes, in category III on the right heel	no
Description of the general skin conditions when starting the clinical survey	Typical elderly skin, reddish and brownish skin areas, low skin tension	Normal skin, pale, high skin tonicity	Dry to very dry skin, pale, yellowish colouration, normal skin tension
Description of the general skin condition when finishing the clinical survey	unchanged	unchanged	unchanged
Description of the skin conditions on the heel when starting the clinical survey	Dry and reddish skin on both heels	Pressure ulcer category I on both heels, 2.0 cm x 2.0 cm	Hyperkeratinoses, pressure ulcer category I on both heels, 1.6 cm x 1.5 cm
Was the heel cushion in use over the entire time of the survey?	yes	yes	yes

Description of the skin conditions on the heel when finishing the clinical survey	<i>Reddish colouration disappeared, skin is smoother and more elastic</i>	<i>Pressure ulcers healed</i>	<i>Pressure ulcers healed</i>
Comments	<i>Less pain in the heels</i>	<i>none</i>	<i>none</i>

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