

**Artcure<sup>®</sup>** 

**CLINICAL STUDY SUMMARIES  
2018**



Diffusional  
Patch & Gel



## PROVIDING SUPPORT FOR THE EXISTING TREATMENTS WITH MAGNETIC DIFFUSIONAL PATCHES AT DISC HERNIAS

### CLINICAL STUDY CENTRE

DIŞKAPI TRAINING AND RESEARCH HOSPITAL

HEAD OF THE CLINICAL RESEARCH

OP. DR. MEHMET SORAR

TOTAL NUMBER OF VOLUNTEERS SCREENED

AT THE BEGINNING OF THE STUDY 80

NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 40

PLACEBO APPLICATION DURING THE STUDY 40

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Average age of the patients who took part in the study was  $41.90 \pm 8.52$ , BMI was  $25.26 \pm 4.08$ , number of the disc hernia patients was 15, number of the extrude disc hernia patients was 25. All of the patients were the ones who were previously administered medicine as well as rest treatment and physiotherapy.

### SYMPTOMS

Average VAS scores of the 40 patients intotal who were included in the study, before the treatment was  $7.85 \pm 1.39$ . At the end of 24 hours, second VAS was reported as  $3.15 \pm 2.11$  ( $P < 0.001$ , Anova) with significant decrease and at the end of 48 hours, the third VAS was reported as  $1.86 \pm 1.65$  ( $P < 0.001$  Anova) with significant decrease and the correlation between the second and the third VAS was reported as  $P < 0.01$  with significant decrease (Diagram 1). Such decrease does not show correlation with age and BMI ( $p > 0.05$ , Pearson).

CLINICAL STUDY CENTRE  
DIŞKAPI TRAINING AND RESEARCH HOSPITAL  
HEAD OF THE CLINICAL RESEARCH  
OP. DR. MEHMET SORAR

TOTAL NUMBER OF VOLUNTEERS SCREENED  
AT THE BEGINNING OF THE STUDY 80  
NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 40  
YEAR OF THE STUDY 2012

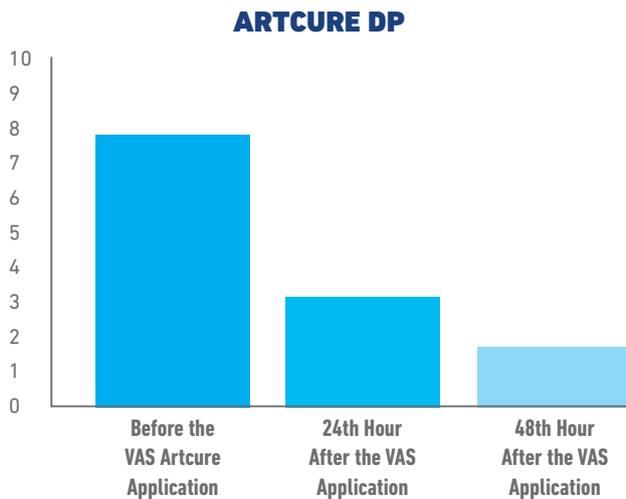
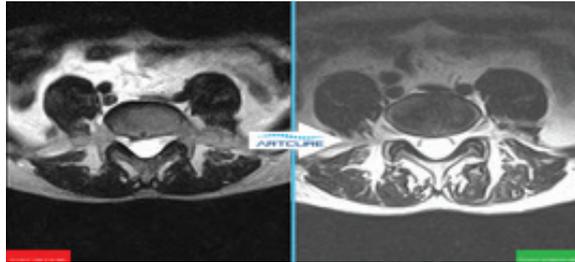


Diagram 1. Values of VAS Pain scores of the disc hernia patients at the end of 0, 24 and 48 hours.

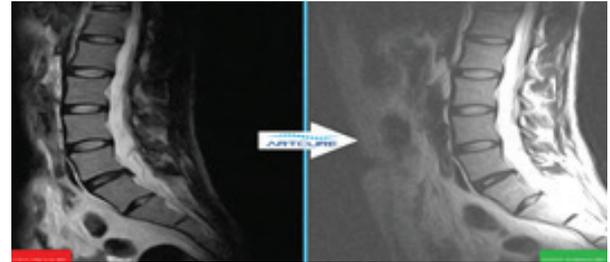
At the result of MRI imaging after 4 weeks, massive contraction is observed on the patients' herniated areas (Patient 1, 2, 3, 4, 5,6).

PATIENT 1



BEFORE

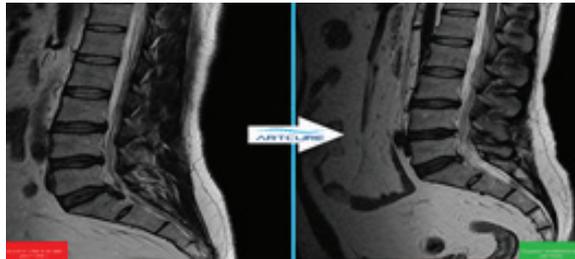
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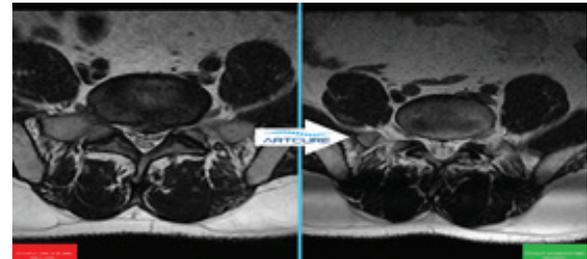
AFTER

PATIENT 2



BEFORE

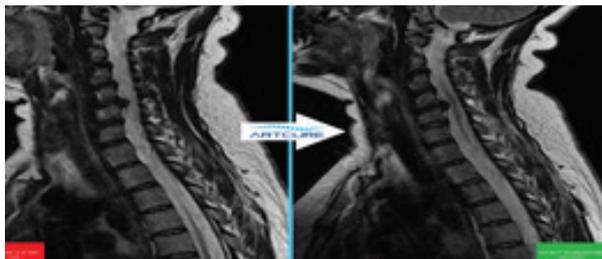
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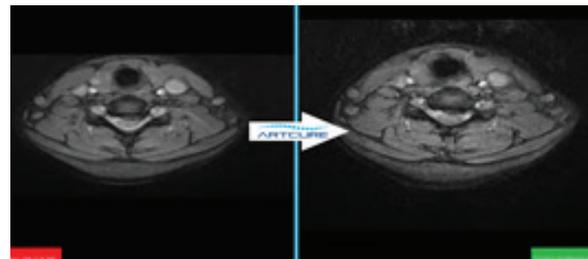
AFTER

PATIENT 3



BEFORE

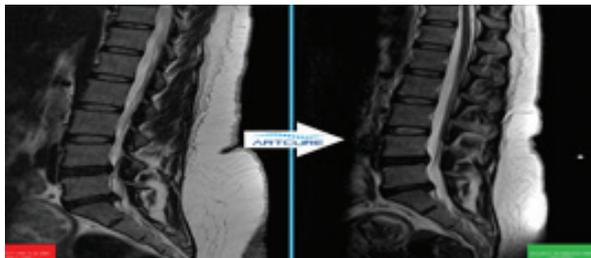
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BEFORE

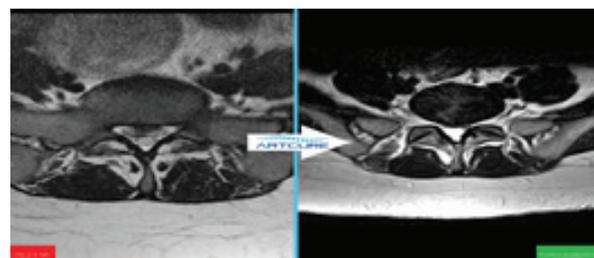
AFTER

PATIENT 4



BEFORE

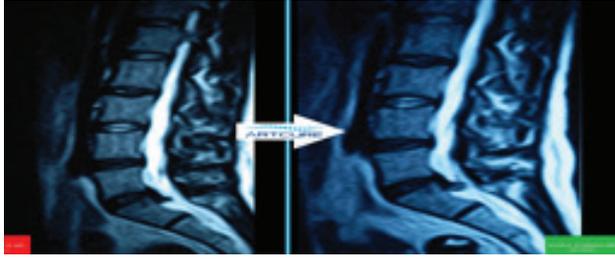
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BEFORE

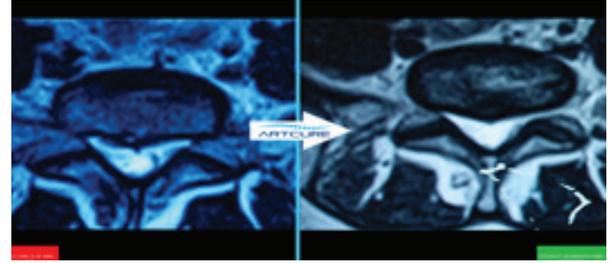
AFTER

## PATIENT 5



BEFORE

AFTER



BEFORE

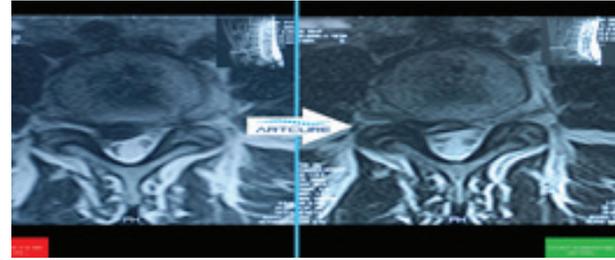
AFTER

## PATIENT 6



BEFORE

AFTER



BEFORE

AFTER

## APPLYING PLACEBO

For ARTCURE<sup>®</sup> diffusional patch which had been applied on 40 healthy individuals in the age range of  $45.40 \pm 5.20$  (20-54), VAS scores before applying placebo was declared as

follows: 0 for VAS1, 0 for VAS2 and 0 for VAS3. No difference was observed during the neurological evaluations before and 48 hours after the study.

# DETERMINING SHORT AND LONG TERM EFFECTS OF DIFFUSIONAL PATCH APPLICATION ON PAIN AND FUNCTIONAL CONSTELLATION ON THE PATIENTS WITH LUMBER DISC HERNIA

## CLINICAL STUDY CENTRE

YILDIRIM BEYAZIT ÜNİVERSİTESİ

ANKARA ATATÜRK EĞİTİM ARAŞTIRMA HASTANESİ

HEAD OF THE CLINICAL RESEARCH

YARD.DOÇ.DR. ATIF AKSEKİLİ

This study was presented at the 26th TOTBID Congress held on 25-30 October 2016

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Our main goal in this study is to show Artcure Diffusional Patch's efficiency which is in hipoosmolar lipid structure and is made from the mixture of 6 different herbal oils, and to discuss this treatment's pros and cons compared to the surgical treatment.

## METHOD

Our study includes 79 of 120 patients who have been clinically diagnosed with lumbar disc prolapsus. Clinic measurements were carried out according to the patients' protrusion and extrusion degrees shown on MRI images and to their dermatomal distribution of pain. Artcure Diffusional Patch (ADP) was applied to the treatment group and the placebo group was applied with Transdermal Diffusional Patch (TDP). Patients' functional capacities were measured with Oswestry Disability Index (ODI) scale and their pain density changes were measured with Visual Analog Scale (VAS) scale. Also to support these, criteria such as restriction degree of movement, Lasague test, femoral extension test and paravertebral muscle spasm were used. Statistical analyses include Oswestry Disability Index, Visual Analog scale, patient satisfaction and duration of resuming their professional life.

## SYMPTOMS

During the first 1 month after the study, substantial improvement and positive developments were observed in the treatment group's pain degrees, Oswestry Disability Index values and Visual Analog scale. On the evaluations which were made 3 days after the application, treatment group's physical examination symptoms and improvements of the scores turned out to be much greater in statistical sense, compared to the control group.

## INFERENCES

Compared to the placebo treatment, Artcure Diffusional Patch treatment proved substantial superiority on clinical scores, patient satisfaction, physical examination symptoms and duration of resuming their professional life for lumbar disc hernia patients with radiculopathy. According to these symptoms, Artcure Diffusional Patch treatment can be a good alternative for lumbar disc hernia patients with radiculopathy.

**Table 1:** The datas before and after application in the experiment group General Linear Model Repeated Anova (Wilks' Lambda) Post Hoc Test: LSD - Cochrans's Q Test - Post Hoc Test: nonparametrik posthoc test (Miller(1966) Average Values $\pm$ Ss(standard deviation), Median Range(Maximum-Minimum) ve n(%))

		Preoperative=I N=40	3rd Day=II N=40	1st Month=III N=40	P Value I-II	I-III	II-III	General
<b>ODI</b>		59,2 $\pm$ 13,37	44,8 $\pm$ 15,61	33,4 $\pm$ 10,13	<0,001	<0,001	<0,001	<0,001
<b>VAS</b>		9(10-3)	7(10-2)	5(10-2)	<0,001	0,042	0,016	<0,001
<b>SLR</b>	Positive	32(80,0)	16(40,0)	4(10,0)	0,001	<0,001		<0,001
	Negative	8(20,0)	24(60,0)	36(90,0)			0,016	
<b>K-SLR</b>	Positive	32(80,0)	16(40,0)	4(10,0)	<0,001	0,001		<0,001
	Negative	8(20,0)	24(60,0)	36(90,0)				
<b>Flexion</b>	Normal	15(37,5)	25(62,5)	33(82,5)	0,019	<0,001	0,085	<0,001
	Disabled	25(62,5)	15(37,5)	7(17,5)				

		Preoperative=I N=40	3rd Day=II N=40	1st Month=III N=40	P Value I-II	I-III	II-III	General
Extansion	Normal	14(35,0)	25(62,5)	2(80,0)	0,006	<0,001	0,148	<0,001
	Disabled	26(65,0)	15(37,5)	8(20,0)				
Right Lateral Flexion	Normal	17(42,5)	28(70,0)	32(80,0)	0,003	<0,001	0,704	<0,001
	Disabled	23(57,5)	12(30,0)	8(20,0)				
Left Lateral Flexion	Normal	17(42,5)	28(70,0)	32(80,0)	0,003	<0,001	0,704	<0,001
	Disabled	23(57,5)	12(30,0)	8(20,0)				
Paravertebral muscle spasm	Disabled	40(100,0)	12(30,0)	8(20,0)	<0,001	<0,001	1	<0,001
	Yes	0(0,0)	28(70,0)	32(80,0)				
Femoral Stretching Test	Positive	31(77,5)	15(37,5)	6(15,0)	<0,001	<0,001	0,082	<0,001
	Negative	9(22,5)	25(62,5)	34(85,0)				

**Table 2:** The data before application and 3rd day after application in placebo group Independent T Test(Bootstrap) - Mann Whitney U Test(Monte Carlo) - Fisher Exact Test (Exact)  
Average Values $\pm$ Ss(standard deviation), Median Range(Maximum-Minimum) ve n(%)

		Placebo Preop	3rd Day	P Value
<b>ODI</b>		61,8 $\pm$ 11,42	52,2 $\pm$ 12,5	<0,001
<b>VAS</b>		8(10-3)	7 (10-2)	<0,001
SLR	Positive	29 (74,4)	25 (64,1)	0,219
	Negative	10 (25,6)	14 (35,9)	
K-SLR	Positive	29 (74,4)	24 (61,5)	0,063
	Negative	10 (25,6)	15 (38,5)	
Flexion	Normal	17 (43,6)	18 (46,2)	1
	Disabled	22 (56,4)	21 (53,8)	

**Table 2:** The data before application and 3rd day after application in placebo group Independent T Test(Bootstrap) - Mann Whitney U Test(Monte Carlo) - Fisher Exact Test (Exact)  
Average Values±Ss(standard deviation), Median Range(Maximum-Minimum) ve n(%)

		Placebo Preop	3rd Day	P Value
Extansion	Normal	17 (43,6)	18 (46,2)	1
	Disabled	22 (56,4)	21 (53,8)	
Right L Flexion	Normal	16 (41,0)	18 (46,2)	0,500
	Disabled	23 (59,0)	21 (53,8)	
Left L Flexion	Normal	17 (43,6)	19 (48,7)	0,500
	Disabled	22 (56,4)	20 (51,3)	
Paravertebral muscle spasm	Yes	30 (76,9)	21 (53,8)	0,004
	No	9 (23,1)	18 (46,2)	
Femoral Strechthing Test	Positive	27 (69,2)	20 (51,3)	0,016
	Negative	12 (30,8)	19 (48,7)	

## CLINICAL STUDY CENTRE

YILDIRIM BEYAZIT UNIVERSITY ATATURK TRAINING AND  
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PHYSIOTHERAPY AND REHABILITATION DEPARTMENTS

HEAD OF THE CLINICAL RESEARCH

OP. DR. ATIF AKSEKİLİ

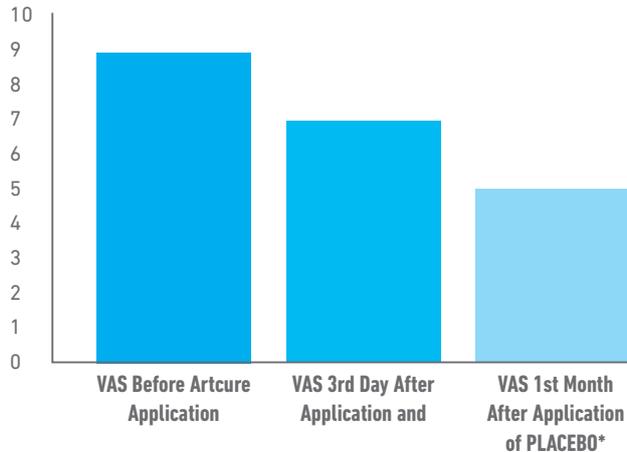
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THE STUDY 129

NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 40

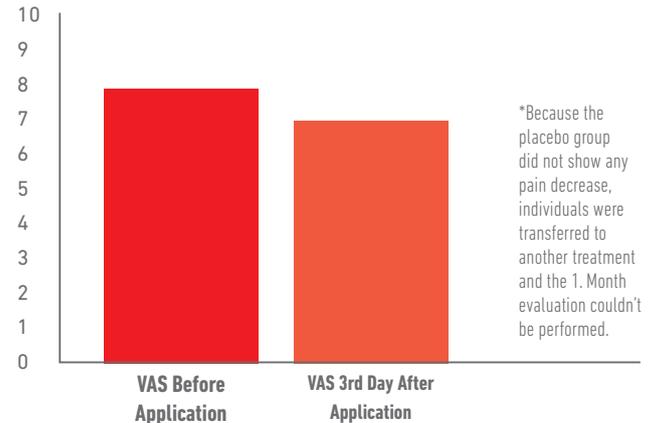
PLACEBO APPLICATION DURING THE STUDY 40

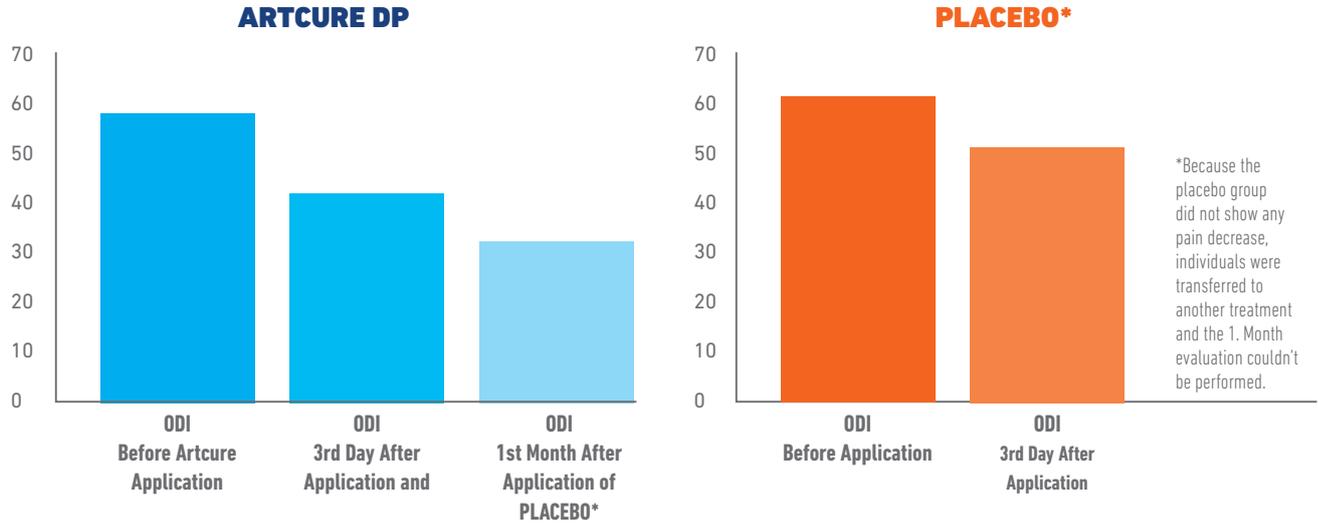
YEAR OF THE STUDY 2015

### ARTCURE DP



### PLACEBO\*





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## DIFFUSIONAL PATCH'S EFFECT ON PAIN AND FUNCTIONAL CONSTELLATION DURING LUMBER DISCOPATHY TREATMENT.

### CLINICAL STUDY CENTRE

EGE UNIVERSITY MEDICAL FACULTY DEPARTMENT OF  
NEUROSURGERY

### HEAD OF THE CLINICAL RESEARCH

PROF. DR. MEHMET SEDAT ÇAĞLI

### METHODS

This study was designed to include 60 patients, aged 24-80, with lumbar disc herniation. The Artcure patch was attached to the lumbar region with a hypoallergenic plaster, and 24-h bed rest was advised. Patients received no other treatments for 24 h. The clinical researchers removed the patch the following day. The neurological examinations were performed before treatment; 24th hour, 48th hour and first month after treatment including straight leg raise test, muscle strength, sensorial status, reflexes, range of motion at flexion, extension, lateral bending and rotation. Paravertebral spasm was also recorded if presented. Severity of pain was assessed using a visual analogue scale (VAS) and functional status using the Oswestry disability index (ODI).

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### AIM

The transdermal diffusional patch (ArtcureDP) is a novel transdermal patch of plant origin, based on essential oils, that works through diffusion. The purpose of this prospective, open label study was to examine the effect of the 'diffusional patch' on pain and functional status in the treatment of lumbar discopathy.

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## RESULTS

After the patch application the mean VAS scores were decreased statistically significantly. The range of motion in flexion was statistically significantly increased in all three assessments after treatment. Straight leg raise test was positive in 26 patients before treatment, after treatment at the first month only 14 patients were positive for straight leg raise test; this change was statistically significant. The patch treatment resolved paravertebral spasm statistically significantly. Also, decrease in ODI scores following patch application was statistically significant. Control MRI at the first month revealed disc shrinkage in 10 patients (16.7%), and the degree of shrinkage observed was statistically significant.

## CONCLUSIONS

The results of this study revealed that the transdermal diffusional patch (ArtcureDP) application caused statistically significant amelioration in pain scores and clinical condition of the patients. Furthermore, this treatment caused a statistically significant shrinkage of disc. In conclusion, the hypo-osmolar diffusional transdermal patch (Artcure) can be used in the treatment of patients with protruded, extruded and fragmented disc hernias.

**Table 1:** The results of the clinical assessments.

Variable	Pretreatment	24th hour	48th hour	1st month	p-value
VAS	8 (3-10) <sub>a,b,c</sub>	6 (1-9) <sub>a,d,e</sub>	3 (0-9) <sub>b,d,f</sub>	1.5 (0-5) <sub>c,e,f</sub>	<0.001†
ROM-Flexion	49 (81.7%) <sub>b,c</sub>	54 (90.0%)	58 (96.7%) <sub>b</sub>	58 (96.7%) <sub>c</sub>	<0.001‡
ROM-Extention	54 (90.0%)	58 (96.7%)	58 (96.7%)	56 (93.3%)	0.062‡
ROM-Rotation	58 (96.7%)	58 (96.7%)	58 (96.7%)	60 (100.0%)	0.112‡
ROM-Lateral Bending	57 (95.0%)	57 (95.0%)	57 (95.0%)	57 (95.0%)	1.000‡
SLR – positivity	26 (43.3%) <sub>a,b,c</sub>	14 (23.3%) <sub>a</sub>	10 (16.7%) <sub>b</sub>	14 (23.3%) <sub>c</sub>	<0.001‡
PVS – positivity	39 (65.0%) <sub>a,b,c</sub>	47 (78.3%) <sub>a,e</sub>	47 (78.3%) <sub>b,f</sub>	22 (36.7%) <sub>c,e,f</sub>	<0.001‡
Muscle strength	5 (4-5)	5 (4-5)	5 (4-5)	5 (4-5)	0.074†
Sensorial evaluation	5 (8.3%)	2 (3.3%)	5 (8.3%)	2 (3.3%)	0.083‡
ODI	54 (32-74) <sub>a,b,c</sub>	50 (20-61) <sub>a,d,e</sub>	42 (20-60) <sub>b,d,f</sub>	36 (18-54) <sub>c,e,f</sub>	<0.001†

† Friedman test, ‡ Cochran's Q test, a: The change between pretreatment and 24th hour is statistically significant ( $p < 0,0083$ ), b: The change between pretreatment and 48th hour is statistically significant, c: The change between pretreatment and 1st month is statistically significant ( $p < 0,0083$ ), d: The change between 24th hour and 48th hour is statistically significant ( $p < 0,001$ ), e: The change between 24th hour and 1st month is statistically significant ( $p < 0,001$ ), f: The change between 48th hour and 1st month is statistically significant ( $p < 0,001$ ).

VAS: visual analogue scale, ROM: range of motion, SLR: straight leg raise, PVS: paravertebral spasm, ODI: Oswestry disability index.

## CLINICAL STUDY CENTRE

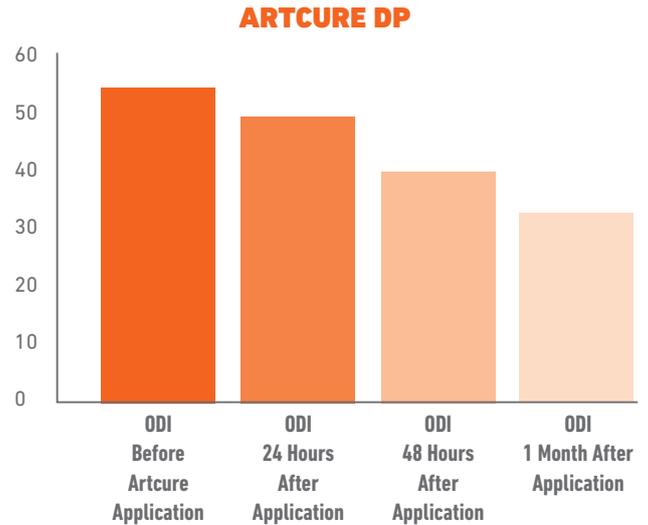
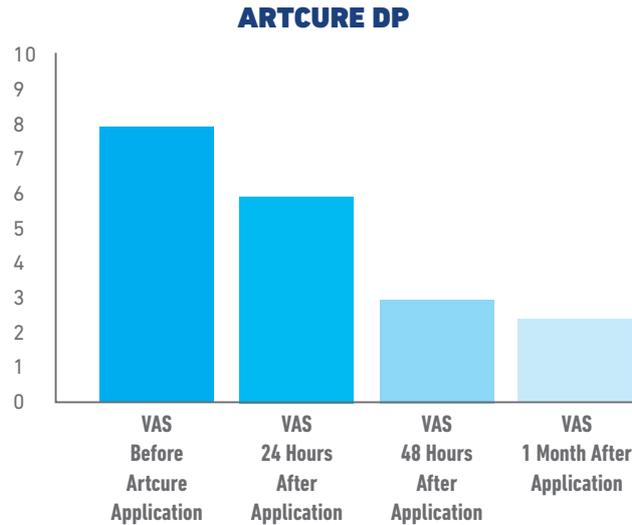
EGE UNIVERSITY MEDICAL FACULTY DEPARTMENT OF  
NEUROSURGERY

HEAD OF THE CLINICAL RESEARCH

PROF. DR. MEHMET SEDAT AĐLI

TOTAL NUMBER OF VOLUNTEERS SCREENED AT THE BEGINNING OF  
THE STUDY 60

NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 60  
YEAR OF THE STUDY 2015



## SHORT AND LONG TERM EFFECTS ON PAIN AND FUNCTIONAL CONSTELLATION OF ARTCURE DIFFUSIONAL PATCH APPLICATION ON PATIENTS WITH LUMBER DISCOPATHY.

### CLINICAL STUDY CENTRE

ANKARA TRAINING AND RESEARCH HOSPITAL AND  
HACETTEPE UNIVERSITY DEPARTMENT OF PHYSIOTHERAPY  
HEAD OF THE CLINICAL RESEARCH  
PROF. DR. PINAR BORMAN

This study was presented at 4th World Congress On Controversies, Debates And Consensus in Bone, Muscle And Joint Diseases (BMJD), in Spain, during 20-22 October.

THE EFFICACY OF A TRANSDERMAL HERBAL PATCH (ARTCURE®) IN THE TREATMENT OF LUMBER DISC HERNIATION: A RANDOMIZED PLACEBO-CONTROLLED CLINICAL and MR IMAGING-based STUDY

Pinar Borman MD, Seçil Vural MD, Pelin Kavak MD, Burcu Duyur Çakıt MD, Barış Nacır MD, Aynur Karagöz MD  
University of Hacettepe Faculty of Medicine Dept of PMR, \*Numune Training and Research Hospital, Clinic of Radiology\*\*Ankara Training and Research Hospital Clinic of PMR, Ankara, Turkey

### BACKGROUND / AIM

Low back pain due to lumbar disc herniation (LDH) is common in our routine practice. Artcure® is a recently developed transdermal patch comprising a mixture of 6 herbal oils, which has been shown to reach to the bulged out herniated disc and decrease the volume of HNP, reduce the nerve root irritation and relieve the pain (1). After wrapping the Artcure® patch to the LDH area, absolute bed rest is necessary for 24 hours. Then the patient take off the patch and turn back to routine daily activities. The product has been on the market and used among LDH patients since a few years. The aim of this randomized placebo controlled study was to investigate the effects of Artcure® patch in the treatment of LDH, with regard to pain, functional status and magnetic resonance imaging (MRI) findings.

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## METHODS

Patients with low back pain due to LDH were recruited to the study. Demographic and clinical variables were recorded and patients were randomly assigned (2:1) to either Group1 with Artcure® patch or Group2 with placebo patch. The primary outcomes were the pain by VAS, functional disability assessed by Oswestry Disability Index (ODI) which were assessed at baseline, 48 hours later and at the end of second month; the secondary outcome measures were changes in the size of HNP assessed by sagittal and axial MR images at baseline and at the end of two months.

## RESULTS

The demographic and clinical variables were similar between the groups (Table 1). Immediately after the treatment patients in both groups experienced improvements in VAS and ODI scores, appearing more significant in Group1 than in Group2. But the difference remained significant only in Artcure patch group at second month follow-up. The size of HNP visualized by MRI, were found to be decreased at 2 months follow-up in Group1 (Table 1). No serious adverse events were observed.

## CONCLUSION

Artcure® herbal patch has favorable effects on pain and functional disability both in the early period and late period (up to 2 months) of lumbar HNP, compared to placebo. It has also reduced the size of HNP, as visualized by MRI. Artcure® patch may be a non-invasive, practical, safe and longlasting alternative therapy in patients suffering from low back pain due to LDH.

## KEY WORDS

LBP, herniated nucleus pulposus, herbal patch, treatment

**Table 1:** The demographic, clinical and imaging variables in both groups

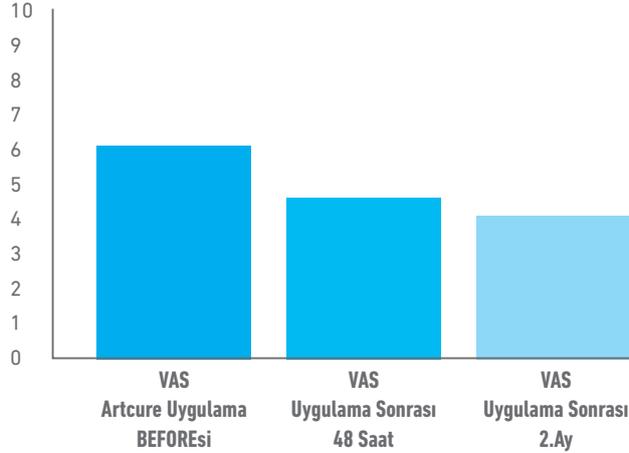
	Group 1 n=34	Group2 n=17	p
Age (years)	45.14±10.13	43.7±10.06	>0.05
Gender (female/male)	28.15±3.92	28.86±3.47	>0.05
BMI (kg/m <sup>2</sup> )	15/19	7/10	>0.05
Duration of disease (months)	21.7±27	18.29±	>0.05
<b>Pain by VAS</b>			
Baseline	6.1±1.5	5.8±1.7	
At 48 hr	4.7±1.5*	5.2±2.4*	
At 2 months	4.4±1.8*	6.1±1.5	<0.05
<b>Oswestry disability index score</b>			
Baseline	51.1±15.4	55.2±15.4	
At 48 hr	44.1±14.2*	49.4±14.9*	
At 2 months	33.8±15.3**	48.2±13.4	<0.05
<b>HNP size by axial image (mm)</b>			
Baseline	37.6±1.65	37.5±1.9	
At 2 months	35.8±1.83*	37.7±2.0	
<b>HNP size by sagittal image (mm)</b>			
Baseline	38.9±1.7	39.3±2.0	
At 2 months	37.46±1.9*	39.3±2.2	<0.05

\*inter- group difference between baseline and after treatments, p<0.05

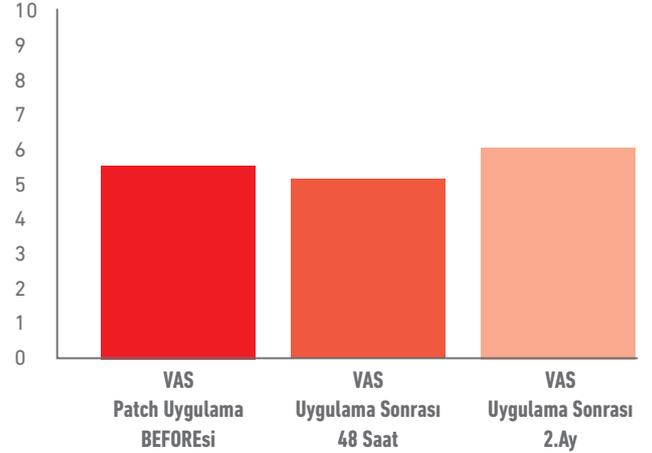
CLINICAL STUDY CENTRE  
ANKARA TRAINING AND RESEARCH HOSPITAL AND  
HACETTEPE UNIVERSITY DEPARTMENT OF PHYSIOTHERAPY  
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PROF.DR. PINAR BORMAN

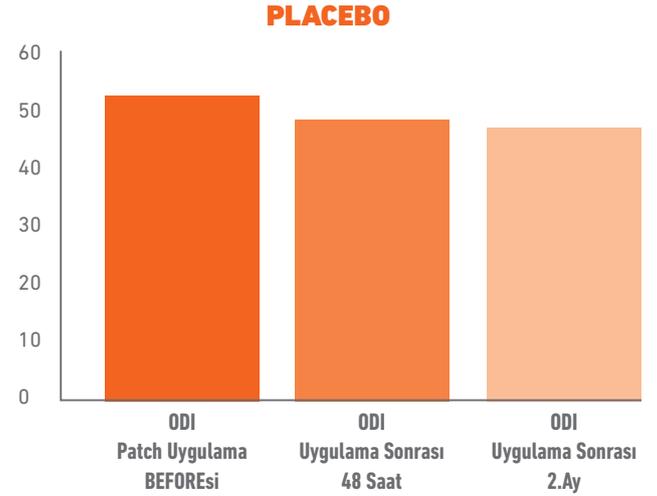
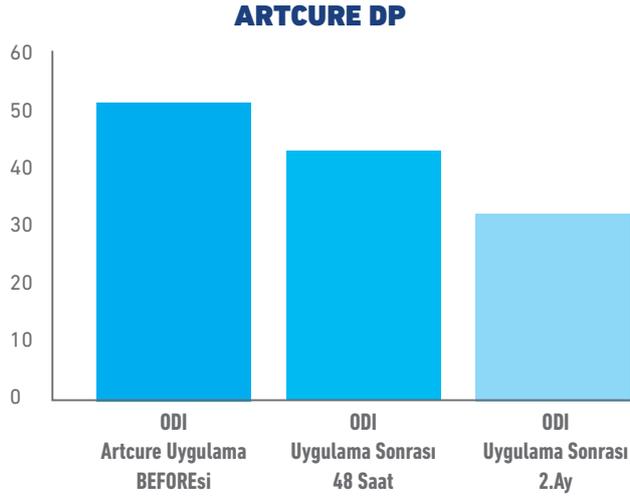
TOTAL NUMBER OF VOLUNTEERS SCREENED AT THE BEGINNING OF  
THE STUDY 80  
NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 34  
PLACEBO APPLICATION DURING THE STUDY 17  
YEAR OF THE STUDY 2016

### ARTCURE DP



### PLACEBO





4<sup>TH</sup> WORLD CONGRESS  
on Controversies, Debates & Consensus  
in Bone, Muscle & Joint Diseases  
**CONGRESS PROGRAM**



**BMJD**

Barcelona, Spain  
October 20-22, 2016  
[www.congressmed.com/bmjd](http://www.congressmed.com/bmjd)



subcutaneous daily administration, and for the Negative Control (NC) group a placebo once-a-day. After a 2 week acclimatization period, functional assessments of pain, including spontaneous (static weight bearing using an Incapacitance meter) and reflexive (Free Walking Incapacitance meter) were performed at D-1\* threshold -PWT- using an electronic von Frey (anesthesiometer) methods, were performed at D-1\* (Baseline), D7\*, D14, D21\*, D35, D49, D63, D77, D91, D105, D119, D133, D147, D161, D175, D189, D203, D217, D231, D245, D259, D273, D287, D301, D315, D329, D343, D357, D371, D385, D399, D413, D427, D441, D455, D469, D483, D497, D511, D525, D539, D553, D567, D581, D595, D609, D623, D637, D651, D665, D679, D693, D707, D721, D735, D749, D763, D777, D791, D805, D819, D833, D847, D861, D875, D889, D903, D917, D931, D945, D959, D973, D987, D1001, D1015, D1029, D1043, D1057, D1071, D1085, D1099, D1113, D1127, D1141, D1155, D1169, D1183, D1197, D1211, D1225, D1239, D1253, D1267, D1281, D1295, D1309, D1323, D1337, D1351, D1365, D1379, D1393, D1407, D1421, D1435, D1449, D1463, D1477, 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INTERNATIONAL  
MULTIDISCIPLINARY SYMPOSIUM ON  
DRUG RESEARCH & DEVELOPMENT  
IN HONOR OF PROFESSOR VURAL KALIN

OP2 NEW TREATMENT METHOD BASED ON GRADIENT ACQUIRED by the  
REDUCTION of INTRA-DISC DENSITY and OSMOTIC PRESSURE in DISC  
HERNIAS

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Treatment of the Disc Hernias consists of non-steroid anti-inflammatory drugs, and muscle relaxants, epidural steroid injections, physical therapeutic approaches like TENS and therapeutic ultrasound, and surgery. Many patients are resolved by the conservative approaches, decides some of them require surgical management.

Our new non-invasive treatment method is a novel galenic based therapeutic approach. It is a transdermal diffusional patch (TDP), releasing active ingredient to the involved segment directly. Gel content is composed of mainly 6 different oil. Product components that reach the nucleus pulposus by the transdermal patch carrier cause a considerable decrease on the weight of the hernia nucleus pulposus, which contains 90% of water by letting the water off the nucleus pulposus. The decreased nucleus pulposus applies lowered pressure on neural root and spinal canal itself. Consequently, the patient's ache significantly reduces.

The system that provides the mechanical effect is the re-formed lipid molecules inside the patch. Disc, having no vascular system, is not a blood-fed tissue which fed by diffusion. Disc which contains a jelly-like inter or has a semi-permeable outer wall. Permeability is increased at disc section that is tore or deformed by hernia and this allows the re-formed lipid molecules inside the patch migrate. TDP shall not go through the healthy disc with a non-deformed outer wall (non-Hernia) so, it only effects on hernia zone. After migration of the re-formed low-density lipid molecules to the Hernia disc zone, osmotic pressure over the hernia disc drops down and the density and viscosity of the Hernia disc zone decreases in relative with the surrounding tissues. The hypoosmotic liquid in the hernia disc displaces towards the relatively hyperosmotic surrounding tissue. Accordingly, together with its weight, hernia disc's pressure over neural tissue reduces.

In conclusion, with all these aspects, transdermal diffusional patch is a noninvasive method prior to the surgical intervention.

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Symposium on Drug Research &  
Development which took place on  
15-17 October.

## DETERMINING SHORT AND LONG TERM EFFECTS OF DIFFUSIONAL PATCH APPLICATION ON THE PATIENTS WITH CERVICAL DISC HERNIA.

### CLINICAL STUDY CENTRE

YILDIRIM BEYAZIT UNIVERSITY

ATATURK TRAINING AND RESEARCH HOSPITAL

### HEAD OF THE CLINICAL RESEARCH

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CERVICAL\_BGOF\_ORF/FTR/BC\_140606-06.06.2014

CASE REPORT FORM

VERSION NUMBER CERVICAL\_HTF\_ORF/FTR/BC\_140606

DATE 06.06.2014

ONGOING STUDY

 <http://kap.titck.gov.tr/Home/Arastirmalar?aramatext=patch&rbgrup=2>

# EXAMINATION OF THE RESULTS OF ARTCURE DIFFUSIONAL PATCH APPLICATION DURING THE TREATMENT OF RADICULOPATHY CAUSED BY LUMBER DISC HERNIA

## CLINICAL STUDY CENTRE

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DECISION NO 15/08

TARİH 23/01/2015

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ONGOING STUDY

 <http://kap.titck.gov.tr/Home/Arastirmalar?aramatext=artcure+&rbgrup=2>

## PROVIDING HYPO-OSMOLAR CONDITION WITH DIFFUSIONAL TRANSDERMAL PATCH SUPPRESS DEGENERATED INTERVERTEBRAL DISC-INDUCED PAIN POSSIBLY VIA TRANSIENT RECEPTOR POTENTIAL VANILLOID IN RABBITS

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### AIM

The aim of this study was to evaluate effects of a hypoosmolar diffusional transdermal patch containing natural essential oils as a transdermal penetration enhancer against IVD degeneration-induced pain in rabbits.

Materials-Methods: Rabbits underwent IVD degeneration with an annular stab surgical technique and were randomly assigned to sham (n=25), sham +transdermal patch (n=20), IVD degeneration (n=25), IVD degeneration +transdermal patch (n=27), and IVD degeneration +transdermal patch +ruthenium red, a transient receptor potential vanilloid (TRPV) antagonist (n=20), groups. The patch was taped on the animal's back for

24 hours at 4 weeks post-surgery. Ruthenium red was injected intraperitoneally at 1 hour before the patch was applied. Pain was assessed by the grimace scale, and IVDs were harvested at 5 weeks post-surgery, being analyzed by the measurements of density and viscosity and immunohistochemical staining. Results: Pain score was significantly worse in the IVD degeneration group, and was significantly improved by the patch, which significantly decreased density, viscosity and cellularity associated with proapoptotic cleaved-caspase-3 activation in the degenerated IVD. Ruthenium red abolished the patch's effects.

### CONCLUSION

Providing hypo-osmolar condition with diffusional transdermal patch may be a new non-surgical treatment against IVD degeneration-induced pain by decreasing viscosity, density and increasing proapoptotic effect possibly via TRPV.

### KEYWORDS

Intervertebral disc, Pain, Rabbit, Transdermal patch

This study was presented fifth medical Rehabilitation Congress.(3-6 November 2016)



**5. TIBBİ REHABİLTASYON KONGRESİ**  
03-06 Kasım 2016, Swissôtel, Ankara

**P 048 PROVIDING HYPO-OSMOLAR CONDITION WITH DIFFUSIONAL TRANSDERMAL PATCH SUPPRESS DEGENERATED INTERVERTEBRAL DISC-INDUCED PAIN POSSIBLY VIA TRANSPARENT RECEPTOR POTENTIAL VANILLOID IN RABBITS**

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**Objective:** The aim of this study was to evaluate effects of a hypo-osmolar diffusional transdermal patch containing natural essential oils as a transdermal penetration enhancer against IVD degeneration-induced pain in rabbits.

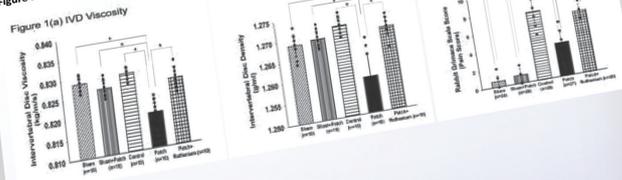
**Materials-Methods:** Rabbits underwent IVD degeneration with an annular stab surgical technique and were randomly assigned to sham (n=25), sham +transdermal patch (n=20), IVD degeneration +transdermal patch (n=20), IVD degeneration +transdermal patch +ruthenium red, a transient receptor potential vanilloid (TRPV) antagonist (n=27), and IVD degeneration +transdermal patch +ruthenium red, a transient receptor potential vanilloid (TRPV) antagonist (n=20), groups. The patch was taped on the animal's back for 24 hours at 4 weeks post-surgery. Ruthenium red was injected intraperitoneally at 1 hour before the patch was applied. Pain was assessed by the grimace scale, and IVDs were harvested at 5 weeks post-surgery, being analyzed by the measurements of density and viscosity and immunohistochemical staining.

**Results:** Pain score was significantly worse in the IVD degeneration group, and was significantly improved by the patch, which significantly decreased density, viscosity and cellularity associated with proapoptotic cleaved-caspase-3 activation in the degenerated IVD. Ruthenium red abolished the patch's effects.

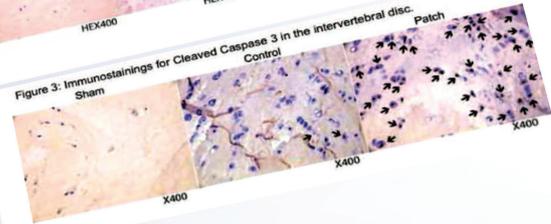
**Conclusion:** Providing hypo-osmolar condition with diffusional transdermal patch may be a new non-surgical treatment against IVD degeneration-induced pain by decreasing viscosity, density and increasing proapoptotic effect possibly via TRPV.

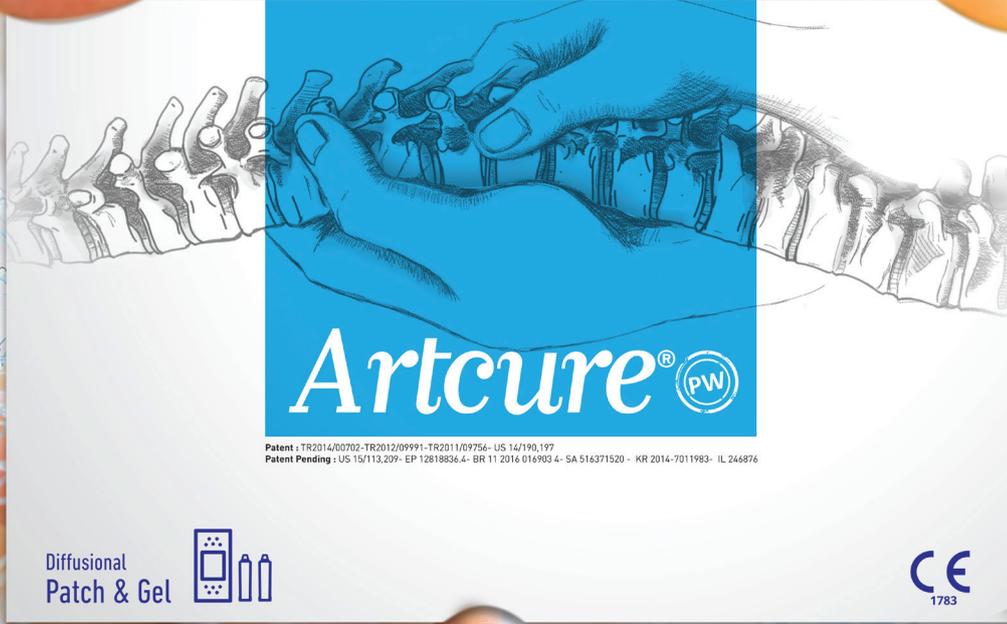
**Keywords:** Intervertebral disc, pain, rabbit, transdermal patch

**Figure 1. IVD viscosity, IVD Density, Rabbit Grimace Scale score.**



**5. TIBBİ REHABİLTASYON KONGRESİ**  
03-06 Kasım 2016, Swissôtel, Ankara





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