

## **ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE (HRQL) IN LOW-BACK PAIN PATIENTS BEFORE AND AFTER VAX-D DISC DECOMPRESSION TREATMENT. ANALYSIS USING THE COMPUTER-ASSISTED ANALYTIC HIERARCHY PROCESS (AHP)**

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### **ABSTRACT**

Since the early 1990s, the vertebral axial decompression (VAX-D) spinal disc decompression therapy has been successfully implemented in the treatment of patients with low-back pain. Multiple clinical studies have demonstrated that this non-invasive treatment is an effective therapy for the management of low-back pain due to various pathologic conditions, including failed spinal surgery. The goal of this multi-center, international study was to both evidence and quantify the impact of the VAX-D therapy on the health-related quality of life (HRQL) in a sample of 105 patients, 49 male (average age 49.06 years) and 56 female (average age 48.23 years). These patients received a minimum of three, but usually not more than ten VAX-D treatment sessions of 20-30 min duration each, prior to being assessed for HRQL outcomes. Twelve HRQL assessment criteria were chosen through health care-provider and patient-selected input, related to pain intensity, personal care, lifting, walking sitting, standing, sleeping, sex life, social life, travel, job/home-duty performance, and range of motion -- and incorporated in an AHP model using DecisionLens analytic hierarchy process (AHP) software. Our results demonstrate that this FDA-approved treatment has improved the overall HRQL in all patients, regardless of gender. The overall HRQL before treatment commenced was 0.432127 in males and 0.442481, on a ratio scale of 0-1, where 1 was the worst possible criteria assessment/outcome and 0 was the most positive. The overall HRQL after treatment ended was 0.0391147 (90.95% improvement) in males and 0.116742 (73.62% improvement) in females, the overall positive VAX-D effect being more pronounced in males. The VAX-D therapy improved the HRQL in all criteria categories, in both male and female patients. This provides evidence of significant personal and public-health benefits that this relatively low-cost, efficient treatment helps most patients with various low-back pain pathology and establishes it as a very valuable alternative to costly surgical low-back pain treatment whenever possible.

Keywords: *Health-related quality of life (HRQL), VAX-D disc decompression, AHP.*

### **1. Introduction**

Vertebral axial decompression (VAX-D) disc decompression therapy has been successfully implemented in the treatment of patients with low-back pain since the early 1990s. Multiple clinical studies have demonstrated that VAX-D is an effective treatment for the management of chronic low-back pain due to posterior facet syndromes, degenerated lumbar discs, subligament disc herniations – at one or more levels, lumbar and/or sciatic nerve compression, extruded herniations, failed back surgery (laminectomy, disectomy), bulging discs (single or multi-level), etc. The analytic hierarchy process (AHP) is a powerful general decision-making and assessment methodology, accepted worldwide. It is based on multi-criteria evaluation, where each criterion carries a specific relative weight with respect to the final assessment goal or, as in our case, health outcomes related to health-

related quality of life (HRQL) improvements. AHP has been successfully utilized as an assessment tool in industry, the military, business, as well as in medical research.

## 2. Literature Review

A retrospective outcome study on 778 patients, a Phase II Randomized Controlled Trial and a study conducted in a neurosurgery practice on 142 patients all reported approximately 70% success rates and improvements in functional outcomes for patients suffering from disc-related chronic low-back pain. Other studies, even though recruiting lesser number of patients have demonstrated patient improvements in various clinical outcomes.

## 3. Hypotheses/Objectives

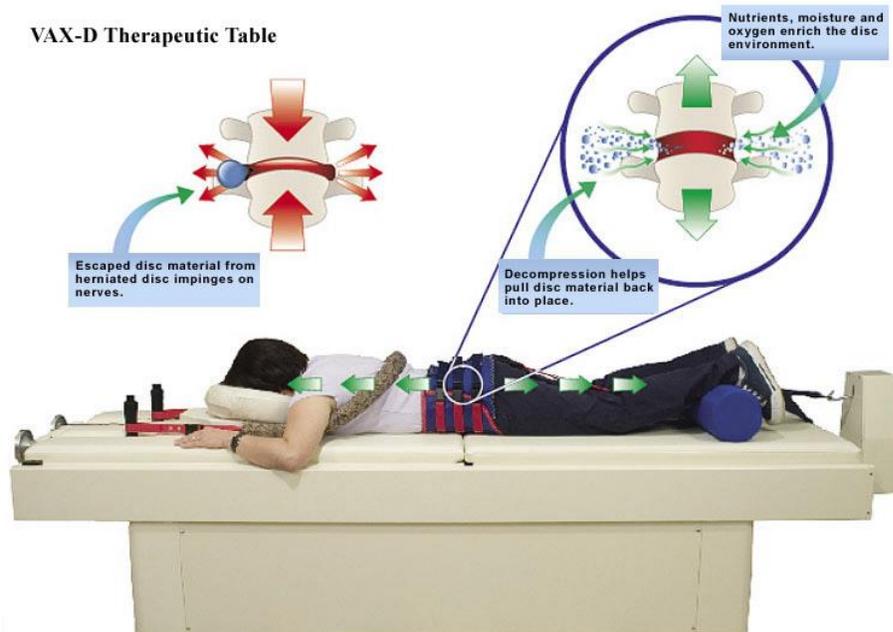
The goal of our study was to demonstrate that VAX-D disc decompression therapy improves the HRQL in patients with low-back pain, using an evidence-based approach and health outcomes. A secondary goal was to quantify the improvement in the overall quality of life and specifically HRQL for each of the 12 HRQL assessment criteria, chosen through health care-provider and patient-selected input, related to pain intensity, personal care, lifting, walking sitting, standing, sleeping, sex life, social life, travel, job/home-duty performance, and range of motion.

Hypothesis 1	The VAX-D therapy will significantly decrease the combined negative outcome of each of the HRQL criteria
Hypotheses 2-13	The VAX-D therapy will significantly decrease the negative treatment outcome of each HRQL criterion

## 4. Research Design/Methodology

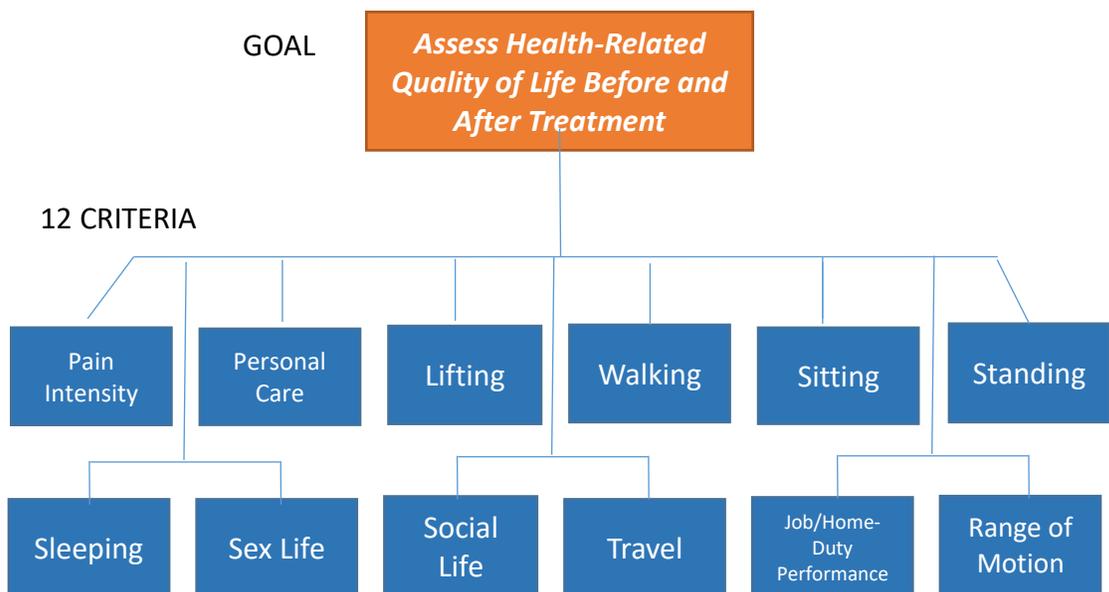
All 105 patients were treated on VAX-D tables manufactures by VAX-D Medical Technologies, Palm Harbor, FL 34685, USA. VAX-D works by interchangeably stretching and relaxing the lower spine, thereby relieving pressure on spinal structures that cause low back pain.

**Fig. 1. Illustration of a VAX-D treatment table with patient receiving a treatment**

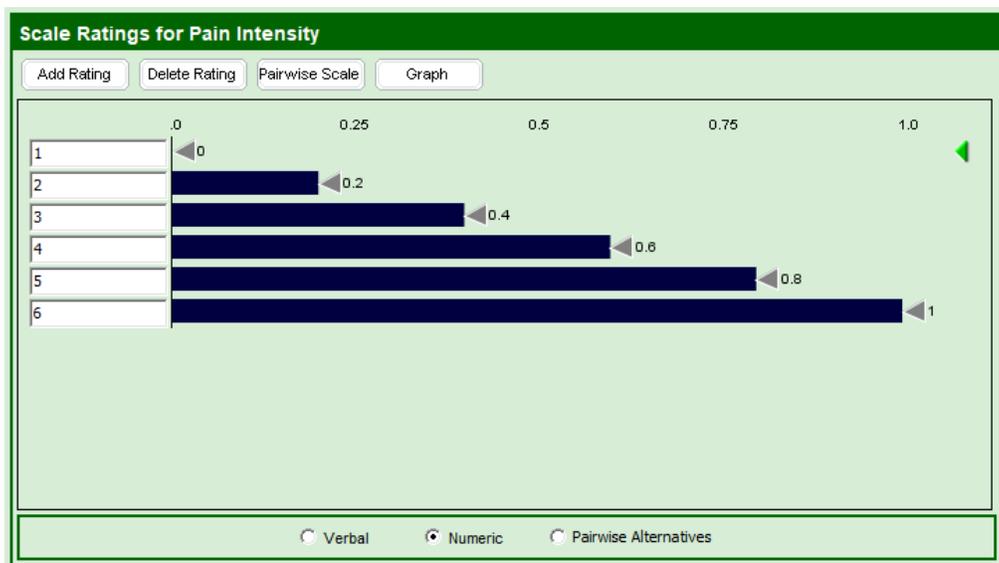


DecisionLens AHP software, created by DecisionLens, Arlington, VA, USA, was utilized in the AHP model creation and data entry. All statistical analysis was performed utilizing STATA 14 software package, developed by StataCorp, Collega Station, TX, USA. Data from the DecisionLens model was exported to Microsoft Excel for initial preliminary statistical analysis and then to STATA 14 software.

**Fig.2. The AHP model employed in the assessment of HRQL before and after VAX-D therapy, as created in DecisionLens AHP software**



**Fig. 3 The scale ratings utilized in the DecisionLens AHP model, for “pain intensity”, one of the 12 criteria**



### 5. Data/Results/Model Analysis

Table 1 and Table 2, respectively, show the correlation coefficients among the main variables of interest in the study before/after the treatment. Correlations that are statistically significant at  $p < 0.05$  are represented with an asterisk.

**Table 1. Correlation matrix of HRQL criteria/variables before VAX-D treatment**

	painin~1	person~1	lifting1	walking1	sitting1	standi~1	sleepi~1	sexlifef	social~1	travel~1	jobhom~1	rangeo~1
painintens~1	1.0000											
personalca~1	0.4419*	1.0000										
lifting1	0.1561	0.5128*	1.0000									
walking1	0.2809*	0.6572*	0.6762*	1.0000								
sitting1	0.3325*	0.5131*	0.5431*	0.4536*	1.0000							
standing1	0.0905	0.4247*	0.4067*	0.4432*	0.3131*	1.0000						
sleeping1	0.3945*	0.5538*	0.4588*	0.5300*	0.6062*	0.5570*	1.0000					
sexlifef	0.3772*	0.7409*	0.3958*	0.4732*	0.5140*	0.6152*	0.7243*	1.0000				
sociallife1	0.3189*	0.6610*	0.5980*	0.6545*	0.6145*	0.4726*	0.5901*	0.6850*	1.0000			
traveling1	0.5384*	0.6407*	0.5095*	0.6245*	0.7177*	0.4532*	0.6158*	0.7136*	0.7629*	1.0000		
jobhomedut~1	0.3690*	0.5848*	0.3310*	0.4785*	0.5196*	0.2801*	0.5863*	0.6840*	0.6847*	0.6430*	1.0000	
rangeofmot~1	0.4014*	0.6140*	0.4463*	0.5713*	0.6762*	0.2394*	0.6336*	0.6913*	0.7286*	0.7746*	0.7452*	1.0000

**Table 2. Correlation matrix of HRQL criteria/variables after VAX-D treatment**

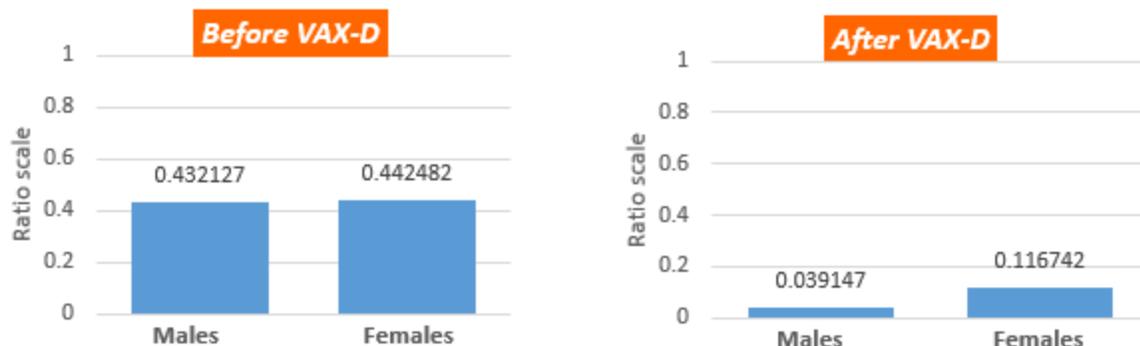
	painin~2	person~2	lifting2	walking2	sitting2	standi~2	sleepi~2	sexlifef	social~1	travel~1	jobhom~1	rangeo~1
painintens~2	1.0000											
personalca~2	0.5938*	1.0000										
lifting2	0.4701*	0.7536*	1.0000									
walking2	0.4324*	0.5996*	0.5446*	1.0000								
sitting2	0.1319	0.1552	0.2582*	0.4423*	1.0000							
standing2	0.2404*	0.4677*	0.4454*	0.6028*	0.5849*	1.0000						
sleeping2	0.3472*	0.5441*	0.4296*	0.5943*	0.4788*	0.6444*	1.0000					
sexlifef	0.1997	0.5656*	0.4580*	0.7163*	0.7550*	0.7065*	0.6746*	1.0000				
sociallife2	0.6957*	0.7669*	0.7202*	0.6786*	0.4595*	0.5373*	0.6182*	0.6076*	1.0000			
traveling2	0.3216*	0.2873*	0.4084*	0.6214*	0.7951*	0.6190*	0.6461*	0.7283*	0.6731*	1.0000		
jobhomedut~2	0.1180	0.1298	0.1871	0.4004*	0.6253*	0.4151*	0.5280*	0.6213*	0.3899*	0.6495*	1.0000	
rangeofmot~2	0.4892*	0.5554*	0.6069*	0.7926*	0.5726*	0.5327*	0.6212*	0.6579*	0.7723*	0.7154*	0.5317*	1.0000

We ran a series of paired t-tests to evaluate the effect of the VAX-D treatment comparing mean values of each criterion/variable outcome before and after the therapy. As shown on Table 3 there is a statistically significant effect of VAX-D with the mean level of pain intensity decreasing from 0.644 to 0.113 (t=15.88; p < 0.0001)

**Table 3. Paired t-test analysis evaluating the combined efficacy of VAX-D therapy in all patients**

Variable	Mean	Standard Error	Standard Deviation	[95% Confidence Interval]
Combined efficacy before VAX-D	0.644	0.026	0.266	0.593 0.696
Combined efficacy after VAX-D	0.113	0.025	0.259	0.063 0.163
Mean difference	0.531	0.334	0.342	.465 .597
Mean (diff) = Mean (Combined criteria before – Combined criteria after) t=15.88 p<0.0001				

**Fig. 4. Combined negative HRQL by gender, before and after VAX-D treatment (1=worst, 0=most positive)**



## 6. Limitations

The study was conducted both as prospective and retrospective. It is arguable that a prospective study may yield “cleaner” results. In addition, a control group receiving no treatment was not utilized, substituting for it by literature data from other studies. The ethnic/race effect was not considered in this study, nor the socio-economic status of the patients.

## 7. Conclusions

The VAX-D therapy improved the HRQL in all criteria categories, in both male and female patients. This provides evidence of significant personal and public-health benefits that this relatively low-cost, efficient treatment helps most patients with various low-back pain pathology and establishes it as a very valuable alternative to costly surgical low-back pain treatment in many clinical cases.

## 8. Key References

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