# 2008 IRB Approved MRI Study of the Effects of Axial Linear Traction and Expanding Ellipsoidal Decompression (EED®) via Posture Pump® on Cervical Curve, Disc Protrusions and Disc Height

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**Abstract:**
Thirty-six (36) individuals with complaints of cervical pain were evaluated with MRI's at rest, as well as during the application of Axial Linear Traction and Expanding Ellipsoidal Decompression (EED®). Both devices significantly decreased the magnitude and instance of anterior subarachnoid protrusions: EED® in 86% of subjects, Linear Traction in 71%. Ranges of motion were improved by both devices with the greater improvement generally being attributed to the device applied last.

EED® expanded disc height on average over twice as much as Linear Traction. While both EED® and Linear Traction increased the posterior disc height an average of 19%, Linear Traction frequently compressed the anterior and center of the disc in relation to the neutral (no device applied) scan. In contrast, EED® expanded the entire disc including the central and anterior regions in a balanced ratio that seems to mirror the natural wedged shape found in normal cervical discs.

Cervical pain is one of the most common complaints. When there are no neurological deficits, symptomatic relief of pain is often sought with either non-steroidal analgesics, or various physical therapy modalities, including cervical traction. Most traction has consisted of axial linear distraction employing various head/chin straps and weights of 20 to 25 pounds. Such traction tends to straighten and/or reverse the cervical spinal curve and often results in TMJ pain.

The undamaged cervical spine normally defines a forward or lordotic curve of about 43° (measured from C2-C7) [²A] whereby weight is distributed on hard individual bony articular surfaces in the posterior and soft intervertebral discs to the anterior. Without such a forward curve in the cervical spine, weight of the head transfers forward onto the soft non-bony intervertebral discs and vertebral bodies causing discs to dehydrate, wear, degenerate and protrude into the anterior subarachnoid space. As vertebral bodies bear uneven stress, spurs and osteophytes form [¹A]. Additionally, individuals with lost or reversed (buckled) cervical spinal curves eventually exhibit a significant loss of natural joint movement, further limiting the normal canaliculus seepage and imbibition of adjacent fluids via vertebral end plates and annuli. Without such nutrient rich fluids the discs continue to dehydrate, further weakening the discs, resulting in a further loss of mobility, degeneration and possible nerve damage. Active nutrient transport is particularly important because the intervertebral discs' indigenous vascular supply often disappears at approximately 20 years of age.

Further, as the cervical spine is forced into flexion and the lordotic curve is reversed, "the dura, cord and nerve-roots are *drawn out*; the root-sleeves *come into contact* with the pedicles, and the nerve-roots with the inner surfaces of the sleeves. During extension *(lordotic curve recovery)* the dura, cord and nerve-roots in the cervical canal are slack; the root-sleeves have lost contact with the pedicles and the nerve-roots with the inner surfaces of the sleeves." **Fig 2** [⁴A].

Axial/Linear/Longitudinal traction has long been employed to decompress cervical joints of the spine. Typically the head is pulled, pried, lifted or otherwise separated from the thorax along the Y axis (+Y axis translation or elevation translation) [²B]. Ostensibly, to pry the joints apart at the posterior, forward flexion (+X axis rotation) is often employed in conjunction with or as an unavoidable component of linear traction. Logically one would assume that linear traction or elevation translation applied to a curved column would decrease or remove the curve. It is likewise logical to assume that adding the component of flexion or + rotation about the X axis, would apply a buckling force to the cervical spine and have the effect of reversing the curve (-Z axis translation). These forces, powerful enough to separate the spinal joints, are unfortunately antithetical to the natural geometry and biomechanics of the human cervical spine.

Health care professionals, aware of lordotic curve necessity, have searched for alternatives to axial/linear/longitudinal traction for disc, joint and nerve decompression. Expanding Ellipsoidal Decompression (EED®) was developed in order to maintain normal lordosis while providing distraction/traction on the disc spaces and avoiding pressure on the TMJ joints. In an earlier IRB study EED® showed an ability to draw disc material back into the disc proper and away from the subarachnoid space and spinal cord after one 20 minute treatment (Shealy Study, 2006) **Fig 3**. Patients reported symptomatic relief of cervical pain.

Expanding Ellipsoidal Decompression (EED®) via Posture Pump® is a process in which joints of the lordotic spinal regions (cervical or lumbar) are decompressed and simultaneously aligned in a curved or lordotic configuration. Elliptical air cells direct expansive forces from within the posterior spinal concavity, forward in translation along the +Z axis and simultaneously up and down in + and - Y axis translation. The head is stabilized in the cervical device as joints expand in 3 directions. Separation occurs at the posterior, center and anterior aspect of the vertebral bodies in a ratio coinciding with the discs' natural wedged spacing.

Continuous expansion and contraction of the air cells can be employed to create alternating hydration and milking of the intervertebral discs, activating their sponge-like imbibition action [¹B]. Holding the air pressure constant over a period of 15 to 20 minutes has the effect of simultaneously molding the spine into a curved or elliptical shape, decompressing discs and relaxing the dura, cord and nerve-roots in the cervical canal [⁴A].

## Protocol:

In this IRB approved study, 36 individuals were enrolled for a comparative MRI study with a baseline MRI and then during either EED® and/or Axial Linear Traction. Presenting complaint was chronic neck pain with no neurological symptoms. In addition to the 36 subjects chosen for the study several were ruled out because of excessively severe degenerative changes. One individual rejected for the study was found to have rheumatoid spondylitis with virtual fusion of the cervical spine. Another was found to have a large epidural neurilemoma and was referred for surgery. One of the 36 study patients had a huge ruptured cervical disc but responded well to the EED® treatment. He had no neurological deficit.

In this comparative study of 36 subjects, Absolute Rotation Angle Analysis [²C] was employed from C2-C7 to determine the cervical curve classification and magnitude of arc on lateral MRI views of each. Disc and other soft tissue protrusions into the anterior subarachnoid space or the lack thereof were noted and disc height was measured at the posterior, center and anterior portion of each disc with digital calipers: a) with no device applied, then in alternating order, b) during EED® and c) during Axial Linear Traction. Manufacturer's instructions were closely followed and great care was taken to properly position each subject for the three MRI scans. Study subjects during Axial Linear Traction were tractioned to their maximum tolerance level and carefully fitted to one of three sizes per manufacturer's instructions. The air cell under all study subjects during EED® via Posture Pump® was expanded to 8 PSI. Posture Pump® is a one size fits all device. A warm-up was done on both devices prior to full application, knee bolster and warm blankets were used on every patient for maximum comfort.

## Lordotic Curve Restoration and Destruction

Dramatic examples of lordotic curve restoration, i.e., *from* a straight or backward curved neck, to a forward or lordotic curved neck were noted. However, vivid examples of lordotic curve destruction were plentiful and plainly visible. As a general rule, when the head was separated or pried away from the body in Axial Linear Traction, joints were decompressed as the cervical lordotic curve was ***reduced, removed*** or ***buckled posterior*** into kyphosis. Multiple harmonics were created. When the cervical spine was lifted and simultaneously expanded from within the lordotic concavity during EED® via Posture Pump®, joints were decompressed and the lordotic curve was ***enhanced*** or ***restored*** to a single harmonic [²E]. During Axial Linear Traction, cervical curves were compromised in 30 of 36 subjects. By contrast, the cervical curve during EED® via Posture Pump® was ***improved*** in 26 of the 36 subjects.

**Cervical Curve Changes**
*(Compared to no device applied)*

| During EED® | During Linear Traction |
|---|---|
| Improved: 26 of 36 = 72.2% | Improved: 3 of 36 = 8.3% |
| Maintained: 6 of 36 = 16.6% | Maintained: 3 of 36 = 8.3% |
| Compromised: 4 of 36 = 11.1% | Compromised: 30 of 36 = 83.3% |

***Table 1***

## Results:

None of the patients experienced any significant discomfort during the procedure. All of them requested a Posture Pump® (EED® device) for home use. Following are the combined general MRI results of 36 Study subjects comparing the geometric configuration of their neutral lateral cervical spine (no device applied) to the geometric configuration during EED® via Posture Pump® as opposed to Linear Traction ***(see Table 1)***:

During Linear Traction, 21 of 36 subjects had their cervical curves removed, forced backward into kyphosis or had kyphotic increases. While there was slight curve reduction in some of the EED® subjects, depending on where the air cell (fulcrum) was fitted to allow for the MRI coil, there was *no instance* where the cervical curve was removed or forced into kyphosis during EED®.

In all 36 subjects the geometric configuration of the cervical spine was superior during EED® via Posture Pump® as compared to Linear Traction. Also during EED®, stair-stepping of the vertebral bodies was ameliorated in a variety of subjects.

**Specific detailed findings and explanations of this portion of the study are found in Appendix A under '**Geometric Cervical Spine Alterations**'.*

## Protrusions, Reduction of Protrusions, Disc Hydration and Joint Damage

Disc and other soft tissue protrusions into the anterior subarachnoid space were noted on the initial scan in 35 of 36 subjects. Protrusions were reduced by each device in multiple subjects. During EED® via Posture Pump®, subarachnoid protrusions were reduced in 30 of 35 subjects or 86%. During Axial Linear Traction subarachnoid protrusions were reduced in 25 of 35 subjects or 71%.

Though many spines were buckled into kyphosis under Axial Linear Traction, it was remarkable to see only one protrusion significantly increase from posterior buckling and this was subsequently ameliorated during EED®. This phenomenon and the fact that protrusions were reduced and eliminated by the decompressive actions of both devices in such a large percentage of subjects; seems to support the belief that disc expansion creates a "bellows like action" [3A] possibly imbibing fluid ***into*** the disc proper, hydrating the disc.

Disc damage expressed as bulging (protrusions into the anterior subarachnoid space) and compression (visible loss of disc height) was most prevalent at the **C4/5, C5/6,** and **C6/7** intervertebral discs. In this "**zone of compression**" lies the fulcrum of the cervical spine with its apex generally measured at the superior aspect of the C5 vertebral body in the normal lordotic spine [2D]. While disc damage was observed at disc levels above and below the zone of compression, its frequency and magnitude dropped off significantly, especially at the C2/3 and C7/T1 levels. The adult head weighing approximately 15 pounds is balanced atop the relatively frail cervical spine. Acceleration/deceleration injuries (whiplash type) frequently buckle the cervical spine in this vital zone **(C4 - C7)**. This zone is where many of the study subjects exhibited visible disc and bone damage accompanied by diminished, lost or reversed lordotic curves. ***(see Tables 2 & 3)***

### Disc Damage by Level in Initial Scan

*(36 Study Subjects)*

| | Protrusions | Disc Most Compressed | Largest Protrusion (or equal to) |
|---|---|---|---|
| C2/3: | 6 | 0 times | 0 times |
| C3/4: | 18 | 3 times | 0 times |
| C4/5: | 29 | 7 times | 7 times |
| C5/6: | 29 | 21 times | 16 times |
| C6/7: | 29 | 8 times | 20 times |
| C7/T1: | 4 | 0 times | 1 time |

***Table 2***

### Changes in Anterior Subarachnoid Protrusions

*(Compared to no device applied)*

| During EED® | During Linear Traction |
|---|---|
| Reduced in: 30 of 35 = 85.7% | Reduced in: 25 of 35 = 71.4% |
| Unchanged: 5 of 35 = 14.3% | Unchanged: 9 of 35 = 25.7% |
| Increased: 0 of 35 = 0% | Increased: 1 of 35 = 2.9% |

Additional specific detailed findings of this portion of the study are found in Appendix B under **'The Effect on Subarachnoid Protrusions'.**

***Table 3***

## Disc Expansion/Joint Separation

Intervertebral disc height was measured at the anterior, center and posterior of each disc using digital calipers, measuring to 100th of a millimeter. Measurements were taken from MRI scans with no device applied and during the applications of both Linear Traction and EED®.

*(continued on next page)*

### Average Disc Height Change by Level in 35 Subjects

*(Zone Of Compression)*

***C4/5, C5/6 & C6/7***

| | During EED® | During Linear Traction |
|---|---|---|
| C4/5: | 15.9% Increase | 9.96% Increase |
| C5/6: | 13.5% Increase | 2.53% Increase |
| C6/7: | 10.2% Increase | 6.00% Increase |
| *Average Change:* | | |
| | **13.2%** Increase | **6.16 %** Increase |

***Table 4***

The average percent disc height change obtained by each device was calculated by comparing the cumulative baseline measurements (no device applied) of each disc to the cumulative individual disc height changes measured during the application of each device. Average disc height percent changes by device, level and point of measurement are listed 1st for the critical **Zone of Compression** (C4/7) and then by device for discs C2/3 and C3/4. One of the 36 subjects was omitted from this portion of the study due to cervical fusion in the zone of compression. Disc height changes listed by the order in which each device was applied are found in Appendix C under **'Disc Height Changes'**.
***(see Tables 4,5 & 6)***

**Average Expansion by Disc Area**
***(C4/5, C5/6 & C6/7)***

| | During EED® | During Linear Traction |
|---|---|---|
| Anterior Disc | 17.18% Increase | 2.97% Increase |
| Center Disc | 10.15% Increase | 4.02% Increase |
| Posterior Disc | 18.93% Increase | 19.02% Increase |

*Please note: Individual disc height increases of over 80% were recorded by each device in several instances. The average disc height increase during EED® was over twice as much as that during Linear Traction. This was primarily due to the fact that Linear Traction compressed the anterior and center portions of discs while expanding the posterior aspect. Though both devices separated the posterior portion of the disc an average of 19%, EED® recorded a balanced expansion throughout the entire disc, doubling the increase of disc height and hydration [¹C] obtained by Linear Traction.*

***Table 5***

**Average Disc Height Change at C2/3 and C3/4**
*(35 Study Subjects)*

| | During EED® | During Linear Traction |
|---|---|---|
| C2/3: | 5.2% Increase | .06% Increase |
| C3/4: | 9.8% Increase | .78% Increase |
| *Average Change:* | | |
| | **7.5%** Increase | **<1%** Increase* |

**Linear tractions' results were influenced by negative disc height changes recorded at discs where +X axis rotation (flexion) produced compressive buckling effects (-Z axis translation).*

***Table 6***

## Observations, Discussion and Conclusions:

The findings of rheumatoid spondylitis in one applicant for the study and of a benign intraspinal tumor in another suggest that clinicians should be extremely cautious in applying mechanical therapy to patients with chronic cervical pain. In any patient who does not respond well to EED®, an MRI should be done. The striking number of postural and degenerative changes in patients presenting with chronic cervical pain is perhaps well known to most clinicians. The disc bulges or protrusions in 35 of the 36 patients present clinicians with the dilemma of unequivocal pathological findings. On the other hand, when there are no neurological symptoms, no weakness, numbness of reflex changes, conservative management is always the wisest approach!

Axial Linear Traction typically separates joints and expands discs in translation along the +Y axis, frequently with a +X axis rotation (flexion) component which induces a –Z axis translation (kyphosis) of some cervical segments, tensioning the dura, cord and nerve-roots while forcing contact with the root-sleeves and pedicles. In contrast, Expanding Ellipsoidal Decompression (EED®) via Posture Pump® separates joints and expands discs simultaneously in 3 directions of translation along the +Z axis, +Y axis and –Y axis. Flexion and –Z axis translation are eliminated while the dura, cord and nerve-roots are relaxed. *(continued on next page)*

**Observations, Discussion and Conclusions** *(continued)*:

Axial Linear Traction reduced the cervical lordotic curve or buckled it into kyphosis in 83% of subjects. In contrast, 72% of subjects whose spines' were buckled into kyphosis by Axial Linear Traction and/or exhibited initial curve loss, improved or recovered to a lordotic curve configuration during EED®.

Ranges of motion were improved by both devices with the greater improvement generally being attributed to the device applied last.

Both devices significantly decreased the magnitude and instance of anterior subarachnoid protrusions: EED® in 86% of subjects, Linear Traction in 71%.

EED® expanded disc height on average over twice as much as Axial Linear Traction. While both EED® and Linear Traction increased the posterior disc height an average of 19%, Linear Traction frequently compressed the anterior and center of the disc in relation to the neutral (no device applied) scan. In contrast, EED® expanded the entire disc including the central and anterior regions in a balanced ratio that seems to mirror the natural wedged shape found in normal cervical discs.

While Linear Traction effectively separates the posterior portion of the disc, it does so at the expense of the natural biomechanics of the cervical spine. EED® was observed to separate the posterior disc equally as well without compressing the center and anterior disc or compromising the lordotic curve. EED® was often able to overcome the compressive and buckling effects induced by Linear Traction on the cervical spine. It is therefore recommended that if Linear Traction is applied to the cervical spine, a follow-up course of EED® is instituted.

Expanding Ellipsoidal Decompression (EED®) via Posture Pump® is an excellent alternative or essential follow-up modality to cervical Linear Traction for clinicians seeking uniform disc expansion while protecting or improving the biomechanics of the cervical spine.

**References**


1. Cailliet, R., M.D., Low Back Pain Syndrome, Edition 4, Pain Series, Copyright 1994 [[1]A] pg 5, [[1]B] pgs 6-8, [[1]C] pgs 6-8
2. Donald D. Harrison, Ph.D., M.S., D.C., The Physics of Spinal Correction, Copyright 1994 [[2]A] Fig 3-3. [[2]B] Fig 1-21. [[2]C] Fig 3-3 and Fig 7-6, [[2]D] Fig 3-6. [[2]E] Fig 7-2, 7-3
3. Kirkaldy-Willis, M.A., M.D., F.R.C.S., (Edin), F.A.C.S., Managing Low Back Pain, Copyright 1988, [[3]A] page 306
4. Alf Breig, M.D. Adverse Mechanical Tension in the Central Nervous System, Copyright 1978 pg 17 Fig A and B [[4]A]

# 2008

# Effects of Axial Linear Traction and Expanding Ellipsoidal Decompression (EED®) via Posture Pump® on Cervical Curve, Disc Protrusions and Disc Height

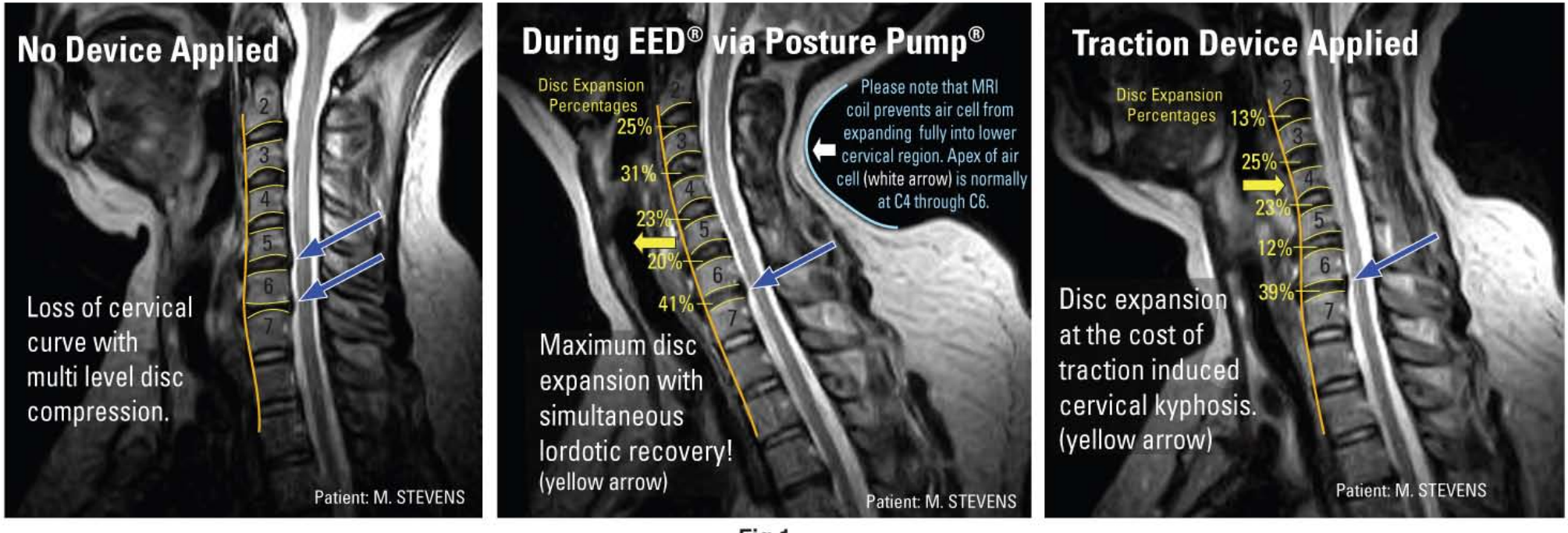
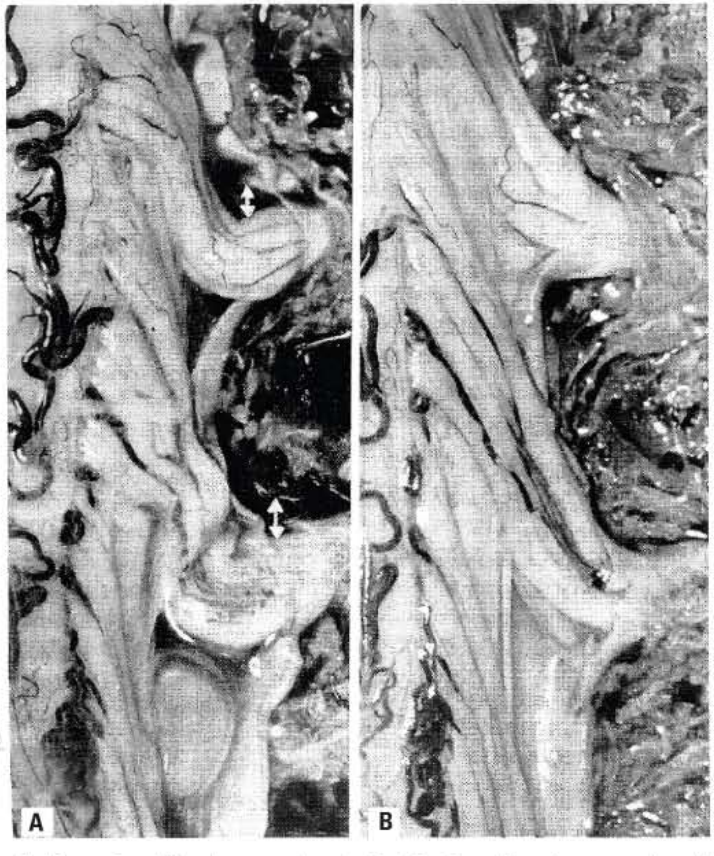



**Fig 1**

Above is a typical example of the results obtained in this 2008 MRI Study of 36 candidates comparing the effects of Expanding Ellipsoidal Decompression (EED®) via Posture Pump® and Axial Linear Traction. Please note that during EED®, disc expansion and reduction of anterior subarachnoid protrusions (blue arrows) is obtained while the cervical lordotic curve is *enhanced* (yellow arrow). Further note that during Axial Linear Traction the spine is buckled into kyphosis (yellow arrow). EED® *enhanced* the cervical curve in 72% of the subjects and reduced protrusions in 86% of subjects. Axial Linear Traction *compromised* the curve in 83% of subjects and reduced protrusions in 71% of subjects.

**Normal deformation of dura, cord and nerve-roots in the cervical canal in the cadaver due to full extension and flexion of the cervical spine.**
**(A.** *Indicative of EED®.* **B.** *Indicative of Axial Linear Traction.)*



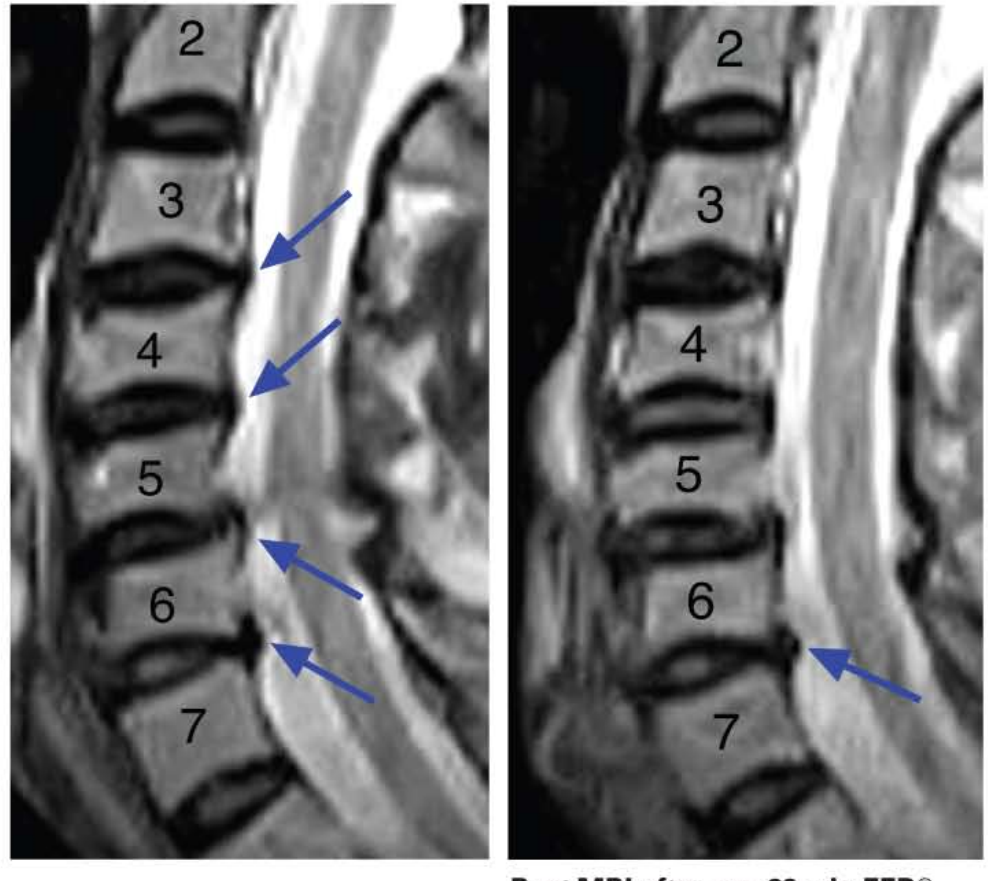

**A. *Extension.*** The dura, cord and nerve-roots in the cervical canal are slack; the root-sleeves have lost contact with the pedicles *(lower arrows)*, and the nerve-roots with the inner surfaces of the sleeves *(upper arrows)*.

**B. *Flexion.*** The dura, cord and nerve-roots are drawn out, the root-sleeves come into contact with the pedicles, and the nerve-roots with the inner surfaces of the sleeves.



**Fig 2**

## SHEALY 2006 APPROVED IRB STUDY




**Pre EED® via Posture Pump® treatment** *(Patient # C20)*

Note bulges/protrusions into the anterior subarachnoid space at C3/4, C4/5, C5/6 and C6/7 (at arrows). Compare these bulges to the **20-minute post MRI**.

**Post MRI after one 20 min EED® treatment** *(Patient # C20)*

Bulges/protrusions at C3/4 and C4/5 are no longer visible. The stair stepping at C5/6 is reduced while the C6/7 bulge is still prominent after one 20-minute session of **Expanding Ellipsoidal Decompression (EED®) via Posture Pump®**. *(See arrow and compare with arrows on pre MRI)*

**Fig 3**

**EED® via Posture Pump® applied prior to Linear Traction**

Nineteen (19) of the 36 subjects were scanned supine **1st** from the lateral aspect with **no device applied, 2nd** scanned **during EED®** via Posture Pump® and **3rd** scanned while **during Linear Traction**. The following results were observed:

On the initial or neutral scan, 11 of the 19 subjects exhibited varying magnitudes of lordotic or forward cervical curves without buckled or reversed angles. Eight (8) of the 19 subjects exhibited kyphotic (reversed) curves or no cervical curve.

**EED® via Posture Pump®** applied ***prior*** to **Linear Traction, *improved*** the cervical geometrical configuration in 13 of the 19 subjects; ***maintained*** it in 4 subjects; and ***compromised*** it in 2 subjects, 1 of which presented with a **hyper**-lordosis. Eight (8) of the 19 subjects exhibited kyphotic buckles (reversed curves) or straight necks (no cervical curves). During **EED® application,** 6 of these 8 subjects **developed forward** (lordotic) **curves.** One (1) of the remaining 2 exhibited a significant decrease in kyphosis and 1 (fused from C-5 to T-1) had no geometric change. Of the 11 subjects initially presenting with forward cervical curves, 6 exhibited improved lordotic configurations under **EED®**, 3 maintained the initial curves and 2 had slight decreases in lordosis. There was ***no instance*** where the cervical curve was removed or forced into kyphosis during **EED®**.

**Linear Traction** applied after **EED®, *compromised*** the cervical geometrical configuration in 16 of the 19 subjects; **maintained** it in 2 subjects; and ***improved*** it in 1 subject. Eight (8) of the 19 subjects exhibited kyphotic buckles (reversed curves) or straight necks (no cervical curves). Two (2) of the 8 subjects exhibited no cervical curve and were buckled into kyphosis during Linear Traction. Of the remaining 6 exhibiting kyphotic buckles, 3 had increases in kyphosis, 2 had no change and 1 had a reduction in kyphosis. Of the 11 subjects initially presenting with forward cervical curves, 5 were buckled into kyphosis, 5 exhibited lordotic curve loss (1 of which presented with a **hyper**-lordosis) and 1 curve was pulled to 0° or no curve. ***None*** of the subjects with kyphotic buckles (reversed curves) or zero degree curves (straight necks) developed forward (lordotic) curves from the application of **Linear Traction** and 11 of the 19 subjects had their cervical curves removed, forced backward into kyphosis or had existing kyphotic buckles increase.

In ***all*** 19 subjects the geometrical configuration of the cervical spine was ***superior*** during **EED® via Posture Pump®** when compared during **Linear Traction.**

## Appendix A
## Geometric Cervical Spine Alterations

Following are the detailed Study results categorized by the order the tests were performed. That is 17 subjects during Linear Traction 1st then during EED® 2nd and 19 subjects during EED® 1st then during Linear Traction 2nd.

**Linear Traction applied prior to EED® via Posture Pump®**

Seventeen (17) of the 36 subjects were scanned supine **1st** from the lateral aspect with **no device applied, 2nd** scanned **during linear traction** and **3rd** scanned **during EED® via Posture Pump®**. The following results were observed:

On the initial or neutral scan, 4 of the 17 subjects exhibited varying magnitudes of lordotic or forward cervical curves without buckled or reversed angles. Thirteen (13) of the 17 subjects exhibited kyphotic (reversed) curves, lordotic S (reversed) curves or no cervical curves.

**Linear Traction** when applied ***before*** **EED®, *compromised*** the cervical geometrical configuration in 14 of the 17 subjects; ***improved*** it in 2 subjects; and ***maintained*** it in 1 subject. Five (5) of the 14 subjects exhibited a straight or military neck. Four (4) of these 5 were ***buckled*** into kyphosis during Linear Traction. Eight (8) of the 17 subjects exhibited kyphotic buckles and lordotic S curves. Six (6) of these 8 experienced ***increased*** buckling during Linear Traction. The 4 of 17 subjects who initially presented with forward (lordotic) curves, exhibited ***lordotic loss*** during Linear Traction. Two (2) of the 17 subjects exhibited a ***reduction*** in buckling as their kyphotic spines were pulled-straight into a "military neck" posture. One subject exhibited no measured geometric change. ***None*** of the subjects with kyphotic buckles (reversed curves) or zero degree curves (straight necks) developed forward (lordotic) curves during the application of **Linear Traction** and 10 of the 17 subjects had their cervical curves removed, forced backward into kyphosis or had existing kyphotic buckles increase.

**EED® via Posture Pump®** applied ***after*** **Linear Traction, *improved*** the cervical geometric configuration in 13 of the 17 subjects; ***maintained*** it in 2 subjects; and ***compromised*** it in 2 subjects. Thirteen (13) of the 17 subjects exhibited kyphotic buckles (reversed curves) or straight necks (no cervical curves). During **EED®** application, 9 of these 13 subjects **developed forward** (lordotic) curves while 4 had measurable improvement in geometric configuration. Two (2) of the remaining 4 had no measurable change and 2 exhibited slight curve reduction as compared to the initial neutral scan. There was ***no instance*** where the cervical curve was removed or forced into kyphosis during **EED®**.

In ***all*** 17 subjects the geometrical configuration of the cervical spine was ***superior*** during **EED® via Posture Pump®** when compared during **Linear Traction.**

## Appendix B
## Anterior Subarachnoid Protrusions

Protrusions/bulges into the anterior subarachnoid space were noted in **35** of **36** Study Subjects. Many protrusions were slight and may have been due to buckling or laxity of the posterior longitudinal ligament. Many were obvious disc bulges as nearly all Study Subjects had damaged cervical spines. Most Subjects exhibited multiple protrusions.

Listed first are the combined MRI results of 35 Study Subjects comparing existing anterior subarachnoid space protrusions on pre lateral cervical scans (no device applied) to the anterior subarachnoid space during Linear Traction as opposed to Expanding Ellipsoidal Decompression (EED®). Following are the detailed Study results categorized by the order the tests were performed. That is, 17 subjects during Linear Traction 1st then during EED® 2nd and 19 subjects during EED® 1st then during-Linear Traction 2nd.

**The Effect on Subarachnoid Protrusions When Linear Traction Was Applied Prior to EED® via Posture Pump®**

Seventeen (17) of the 36 subjects were scanned supine **1st** from the lateral aspect with **no device applied, 2nd** scanned **during linear traction** and **3rd** scanned **during EED® via Posture Pump®**. The following results regarding **anterior subarachnoid protrusions** were observed: On the initial or neutral scan, **17** of the **17** subjects exhibited varying degrees of anterior subarachnoid protrusion(s).

During **Linear Traction** when applied ***before*** **EED®**, 12 of the 17 subjects **(71%)** exhibited **protrusion reductions**, 4 subjects ***(24%)*** had no reductions and 1 (6%) had an increase.

During **EED® via Posture Pump®** applied ***after*** **Linear Traction**, 15 of the 17 subjects **(88%)** exhibited **protrusion reductions** and 2 subjects **(12%)** had **no** reductions. There were **no** increased protrusions under EED®.

**The Effect on Subarachnoid Protrusions When EED® via Posture Pump® Was Applied Prior to Linear Traction**

Nineteen (19) of the 36 subjects were scanned supine **1st** from the lateral aspect with **no device applied, 2nd** scanned **during EED®** via Posture Pump® and **3rd** scanned while **during Linear Traction**. The following results regarding **anterior subarachnoid** protrusions were observed: On the initial or neutral scan, **18** of the **19** subjects exhibited varying degrees of anterior subarachnoid protrusion(s).

During **EED® via Posture Pump®** applied prior to Linear Traction, 15 of 18 subjects **(83%)** exhibited **protrusion reductions** and 3 subjects **(17%)** had **no** reductions. There were **no** increased protrusions during EED®.

During **Linear Traction** applied after **EED®**, 13 of 18 subjects **(72%)** exhibited **protrusion reductions** and 5 subjects **(28%)** had **no** reductions. There were **no** increased protrusions during this sequence during Linear Traction.

## Appendix C
### Disc Height Changes (Compared to neutral scan/no device applied)
### (C-4/5, C-5/6, and C-6/7)
### Linear Traction applied *prior* to EED® (17 subjects)

**During Linear Traction Applied 1st –**
average anterior, center & posterior disc height changes from neutral scan:

| | |
|---|---|
| Anterior | 2.2% increase |
| Center | 2.6% increase |
| Posterior | 16.0% increase |

**During EED® Applied 2nd -**
average anterior, center & posterior disc height changes from neutral scan:

| | |
|---|---|
| Anterior | 18.8% increase |
| Center | 10.6% increase |
| Posterior | 18.6% increase |

**EED® applied *prior* to Linear Traction (18 subjects)**
During EED® Applied 1st - average anterior, center & posterior disc height changes from neutral scan:

| | |
|---|---|
| Anterior | 15.6% increase |
| Center | 9.7% increase |
| Posterior | 19.3% increase |

**During Linear Traction Applied 2nd –**
average anterior, center & posterior disc height changes from neutral scan:

| | |
|---|---|
| Anterior | 3.8% increase |
| Center | 5.4% increase |
| Posterior | 22.1% increase |