Treatment Methods to Reduce Pain and Cobb Angle for Patients Diagnosed with Adolescent Idiopathic Scoliosis

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Disciplines
Physical Therapy

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Title: Treatment Methods to Reduce Pain and Cobb Angle for Patients Diagnosed with Adolescent Idiopathic Scoliosis

Clinical Scenario: There are two patients who lead me to pursue this clinical question. Both were adolescent females, one was 13 years old and the other 15 years old with a diagnosis of moderate Adolescent Idiopathic Scoliosis (AIS). Both were referred to physical therapy for back pain. Medical treatment included general lumbar and thoracic stabilization exercises, stretches of concave areas, a home exercise program, and patient education on posture. Both patients were non-athletic and were not compliant with their home exercise program. Neither patient returned to physical therapy after their third appointment.

Brief Intro: It seems if patients diagnosed with AIS are referred to physical therapy the standard treatment is patient education and general back exercises. I say ”if” patients are referred to physical therapy because it appears there is controversy if physical therapy is an effective treatment option for patients with AIS. The American Academy of Family Physicians states that no studies have shown that physical therapy has been successful in the treatment of scoliosis and recommends observation, bracing, or surgery depending on the severity of the scoliosis (Reamy B. & Slakey B., 2001). The International Society on Scoliosis Orthopedic and Rehabilitation Treatment states there are not enough quality studies to draw a conclusion about physical therapy treatment (Negrini S., et al. 2012). In addition, a systematic review also noted poor levels of evidence for all AIS treatment options (Weiss H. & Goodall D., 2008). I wonder if the low efficacy that physical therapy treatment has shown so far is due to a lack of a standard treatment protocol for AIS. In my clinical experience, it seems that physical therapists treat AIS just like another back condition although AIS is obviously more complicated. During the 2013 Combined Sections Meeting (CSM), the American Physical Therapy Association (APTA) was pushing for the use of the Schroth Method of treatment for this condition (Vernon D., 2013). The Schroth Method appears to address the three-dimensional complexities of the spine that are associated with scoliosis. However, upon my review of the research cited to support this method, the literature appears weak. Most of the research has been performed within the Schroth clinics (several locations in the United States and Europe) and/or performed by Dr. Weiss, the grandson of Dr. Schroth (developer of the Schroth method). Thus, it is possible that the research could be biased. For the purposes of my clinical question, I want to know if there are any treatment options for AIS that have been shown to reduce back pain and/or lessen the severity of scoliosis.

Clinical Question: Does the use of modalities or specific exercises as compared to the standard treatment of general back strengthening and stretching reduce and prevent reoccurrence of back pain, and/or reduce the Cobb angle of the patient?

Population: Adolescents ages 10-18 years diagnosed with Adolescent Idiopathic Scoliosis

Intervention: Specific physical therapy interventions

Comparison: Generic physical therapy interventions
**Outcome:** Reduction in back pain and decreased Cobb angle

**Overall Clinical Bottom Line:**
Based on the results from the two studies by Diab and Zakaria et al., scoliosis-specific stretches and exercises can be considered a low-cost and effective treatment intervention for AIS when comparing these to mechanical traction and forward head posture correction. Zakaria et al. compared the effects of scoliosis-specific stretches to general low back mechanical traction in 40 female adolescents with AIS and found that the scoliosis-specific stretch group had significant improvements in pain (as measured by the Visual analog scale (VAS)) and in Cobb’s angle after performing four scoliosis-specific exercises three times per week for three months. The scoliosis-specific stretching group demonstrated a clinically meaningful mean (95% CI) reduction in pain (as measured by VAS scores) of 4.53 (4.01 - 5.04) points and a measurable reduction in Cobb’s angle of 9.15° (7.41 - 10.89). Mechanical traction also produced a clinically meaningful reduction in mean VAS scores with 4.20 (3.70 - 4.70) points within-group mean difference but, did not produce any actual measurable change in Cobb’s angle (2.4°; 0.65 - 4.17). The between-group results showed the scoliosis-specific stretching group had statistically significant improvement compared to the mechanical traction group with a between-group mean difference of 5.95° (95% CI, 4.32 - 7.58) in Cobb’s angle but, neither group outperformed one another with their VAS between-group mean difference of 0.27 (-0.09 - 0.63) points. In addition, I have determined that use of mechanical traction would be more costly and would have a higher risk to administer than using a scoliosis-specific stretching program. Diab’s study consisted of 76 adolescents diagnosed with AIS who were randomized into a scoliosis-specific exercise group (control group) who performed their exercises three times a week for 10 weeks to a group who performed four additional exercises to correct for forward head posture four times a week for 10 weeks. Diab found that the forward head posture group had statistically significant improvements at 10 weeks and three months post-treatment for lateral deviation and statistically significant improvements at three months for the functional rating index (FRI) when compared to the control group. However, Diab did not provide any statistical support to conclude that the scoliosis-specific exercises (control group) or the addition of forward head posture treatment contributed to the reduction of pain or scoliosis severity when analyzing the within and between-group differences at 10 weeks or three months post-treatment. At three months, the forward head posture treatment group’s within-group mean difference was 2.10 (0.94 – 3.26) and the control group within-group mean difference was 0.40 (-.48 – 1.28). I was unable to draw a conclusion from these data due to the absence of unit labeling, no reporting of accuracy for the measurement tool, and lack of minimal clinically important differences (MCID). The FRI scores at the three-month mark showed that the forward head posture group was able to maintain their improvement gained at week 10 (within-group mean difference of 3.90% (3.22 - 4.58), while the control group scores increased to pretreatment (within-group mean difference of 2.30% (1.40 – 3.2)) resulting in a between-group mean difference of 3.8% (3.05 - 4.55) in favor of the forward head posture treatment group. These differences were not enough to meet the FRI MCID of 15% and therefore the improvement would likely not be clinically meaningful. Both studies had fair to good internal validity (Diab PEDro score (7/10), Zakaria et al (6/10)). While Diab had several threats to internal validity especially with the lateral deviation outcome measure, assumptions had to be made regarding internal validity for the Zakaria et al. article, who left out information as to study losses, intention to treat, power analysis, and blinding.
In conclusion, I would not include additional interventions to correct forward head posture in patients with AIS to specifically address reduction of Cobb’s angle or decrease low back pain (LBP) based on the Diab results. However, I would include a scoliosis-specific stretching protocol over manual traction to address the concave curvature of a patient’s spine and decrease pain based on the information presented in the Zakaria et al. study and my own clinical experience and academic training that a scoliosis-specific stretching protocol is more cost-effective and less risky to administer than mechanical traction. I would like to see additional studies performed in the United States or England that compare general back strengthening exercises and stretches to scoliosis-specific exercises and stretches. Studies should be mindful to ensure adequate sample size and use meaningful outcome measures to ensure the data can produce statistically meaningful results.

Search Terms: Adolescent Idiopathic Scoliosis, scoliosis, treatment, exercises, modalities

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Rationale for your chosen articles:

Research articles that addressed the clinical question were limited. Several databases including EBSCOHost, PEDro, and Google Scholar were used. Three articles were found that closely matched the population, intervention(s), comparison, and outcome(s) (PICO) and had relatively high PEDro scores. They are listed below:


Table 1 compares the PEDro score, and PICO of each article and the clinical PICO. The PEDro score is an analysis tool used to determine internal validity of research articles. Table 2 shows in detail how each of the articles were scored and compares each of the articles.

The article by Negrini et al. had the least similar comparison group and outcome measures to the clinical PICO. Their comparison group was “standard Italian treatment”. This usually consisted
of group exercise for 45-90 minutes. Group exercise is not the standard treatment for scoliosis in the United States. In addition, the researchers stated that group exercises were usually but not always performed by the patient because the patient could choose any physical therapist they wanted to perform the treatment and the physical therapist could use whatever treatment they thought would work best. One of their outcome measures (brace prescription) related to patient comfort, but did not address it directly with pain or function, which is the intent of the clinical question. In addition to the PICO dissimilarities between the article and clinical question, the specific exercise protocol determined by the Scientific Exercises Approach to Scoliosis (SEAS) was not described in any detail, making it impossible to replicate the work performed by the researchers. The article scored a 7/10 on the PEDro (based on my analysis using the PEDro criteria).

The article by Diab also scored 7/10 on the PEDro scale (as scored by the PEDro database and by my own analysis), but this article more closely matched the clinical PICO. Though the researcher did not specify the age range for the population, the mean age was 13 years. Diab clearly described the methods so that they can be reproduced. The outcome measures for patient improvement were measured via the FRI and three-dimensional (3-D) posture parameters. Due to the lack of a gold standard to measure pain, it appears that the Function Rating Index is sufficient in measuring pain. The Cobb angle is the gold standard for measuring scoliosis. However, the researcher’s 3-D measurement is currently being researched for accuracy and has the potential to be the new gold standard for scoliosis. Since scoliosis affects the spine at all three planes and Cobb’s angle only measures one plane and until research verifies that this type of measurement is inaccurate, the 3-D measurement was considered acceptable for helping answer the clinical question.

The article by Zakaria et al. scored one point lower on the PEDro scale (6/10, scored via my own analysis) than the other two. However, its PICO most closely matched the clinical PICO. The only variant was the age range for the adolescent population was a little older then the clinical population with a range of 15-25 year instead of 13-18 years. The methods were well described and appear to have adequate statistics performed.

Based on this analysis, the articles by Diab and Zakaria et al. were chosen to perform the critically appraised topic on. Though Zakaria et al. has a lower PEDro score, the article by Negrini et al. had too many issues concerning the comparison group, outcome measures, and reproducibility.
### Table 1. Comparison of the PEDro scores and PICOs of each article and clinical topic

<table>
<thead>
<tr>
<th>Authors</th>
<th>PEDro</th>
<th>Population</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Outcome(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zaporowski K.</td>
<td></td>
<td>Adolescents ages 10-18 diagnosed with mild to moderate AIS</td>
<td>Specific exercises or modalities</td>
<td>Standard exercise/stretching treatment</td>
<td>Patient reported pain and Cobb Angle</td>
</tr>
<tr>
<td>Clinical PICO</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diab A. 2012</td>
<td>7/10</td>
<td>Adolescents diagnosed with AIS</td>
<td>Specific exercises and stretches for correcting forward head posture</td>
<td>Standard exercise/stretching treatment</td>
<td>Functional Rating Index and 3-D posture parameters</td>
</tr>
<tr>
<td>Negrini S. et al.2008</td>
<td>7/10</td>
<td>Adolescents diagnosed with mild AIS</td>
<td>SEAS specific exercise protocol</td>
<td>Standard group exercise/stretching treatment</td>
<td>Cobb angle and brace prescription</td>
</tr>
</tbody>
</table>

### Table 2. Detailed comparison of PEDro Scores (based on my analysis using the PEDro criteria)

|--------------|-----------------------|------------------------|
| 1) Eligibility Specified  
(not included in total score) | Yes | Yes | Yes |
| 2) Randomization | Yes | Yes | No |
| 3) Concealed allocation | Yes | Yes | Yes |
| 4) Baseline comparability | Yes | Yes | Yes |
| 5) Blind subjects | No | No | No |
| 6) Blind therapists | No | No | No |
| 7) Blind Assessors | No | No | Yes |
| 8) Adequate Follow-up | Yes | No | Yes |
| 9) Intention to Treat | Yes | Yes | Yes |
| 10) Between Group | Yes | Yes | Yes |
| 11) Point Estimates | Yes | Yes | Yes |
| **Total Score** | 7/10 | 6/10 | 7/10 |

**Clinical Bottom Line:** Based of this non-blinded, randomized control study consisting of 76 adolescents diagnosed with AIS, statistically significant improvements were found at 10 weeks and three months post-treatment for lateral deviation in the forward head posture treatment group that performed four additional exercises to correct for forward head posture compared to a control group that did not perform these exercises. In addition, the forward head posture treatment group showed statistically significant improvement at three-months post-treatment for FRI scores as compared to the control group. The mean difference between-groups (95% CI) for lateral deviation was 0.2 (-0.76 to 1.16) at 10 weeks, in favor of the control group and 0.8 (-0.27 to 1.87) at three months, in favor of the forward head posture treatment group. I was unable to draw a conclusion about whether this was a real or clinically meaningful difference due to the absence of unit labeling, no reporting of accuracy for the measurement tool, and lack of MCID. The FRI scores showed the forward head posture treatment group scored lower than the control group at week 10 with a between-group mean difference of 1.2% (.45 - 1.95). However, at three months, the forward head posture treatment group was able to maintain its average score while the control group scores increased to pretreatment scores resulting in a between-group mean difference of 3.8% (3.05 - 4.55) in favor of the forward head posture treatment group. These differences were not enough to meet the FRI MCID of 15% and therefore the results did not have any clinical meaning. This study had fair to good internal validity (PEDro score 7/10). The threats included no blinding and the gold standard to access scoliosis severity (Cobb’s angle) was not used. Based on the analysis of this article, I would not include additional treatment to correct forward head posture in patients with AIS to specifically address reduction of Cobb’s angle or to decrease LBP in my initial plan of care. However, if other treatment options within my plan of care are not producing sufficient results, I may include the described exercises in a revised plan since the forward head posture treatment group showed improvement overall, there is minimal cost to administer the additional four exercises, and no harm resulted from this addition. I believe that application of this treatment should not be written off and that further research with measures that can provide more clinically meaningful information should be performed.

**Article PICO:**

- **Population:** Adolescents diagnosed with AIS (n=76)
- **Intervention:** Specific exercises and stretches for correcting forward head posture
- **Comparison:** Standard/generic exercise and stretching treatment
- **Outcomes:** Functional Rating Index (FRI), 3-D posture parameters and craniovertebral angle
Blinding: The researcher who obtained the outcome measures was also the same person who administered the treatment for both groups. This could have biased the results of the 3-D posture parameters and the craniovertebral angle measurements since the researcher knew taking measurements requires some degree of decision making and the results may not have been objective. In addition, since the same researcher administered treatment to both groups, there could have been unintentional bias to the quality of treatment administered to the patients. For example, if the researcher had a preconceived idea that the control group would have poorer outcomes, he may not have put as much effort into providing the best treatment to that group, intentionally or unintentionally. It was not stated if the subjects were blinded to which group they were a part of. If they were not blinded, there is the possibility that the Hawthorne effect could occur because if the subjects knew they were in the forward head posture treatment group they could have biased the FRI results.

Controls: The control group received the same basic treatment as the experimental group did, except for the independent variable. There were no significant differences between the two group’s demographics with regards to subject age, height, weight, gender, and past physical therapy was performed. A placebo group was not included.

Randomization: The allocation of the subjects into the control or experimental group was randomized using a random number generator, an independent person, and sealed envelopes. The randomization was successful for both the subject demographics and baseline outcome measurements as there were no significant differences reported between groups (95% CI).

Study: This randomized control study consisted of 76 subjects who were referred from the Cairo University outpatient clinic in Egypt. The inclusion criteria included a diagnosis of AIS with a Cobb angle between 10°-30°, a Risser grade of 0, 1, or 2, a craniovertebral angle of less than 50°, and a Lenks category of 1A. Subjects were excluded if they had any pervious spinal surgery or any lower limb pathologies that could affect the subject overall spinal alignment, including leg length discrepancy. The subjects were divided equally (38 subjects in each). All subjects received the same conventional treatment for AIS three times a week for 10 weeks and were discouraged to participate in any other exercise program. The conventional treatment included stretches for the muscles that are tight and strengthening for the muscles that are weak (with emphasis on the muscles on the convex side of the curvature). The experimental group received four additional exercises to help correct forward head posture; supine deep cervical flexor strengthening, shoulder retraction strengthening using a Theraband, cervical extensor stretching in sitting, and manual supine pectoralis major stretches for all three pectoralis major insertions. These additional exercises were to be performed four times a week for 10 weeks. The strengthening exercises included three sets of 12 repetitions and could be progressed if the patient met specific criteria. The stretches were to be held for 30 seconds each.

Outcome measures: All measures were taken before treatment, post-treatment (week 10 of study), and three months after treatment. The outcome measures analyzed include the FRI and
lateral deviation (one of the seven 3-D postural parameter measurements taken using a Formetric II device). Though there were six other 3-D postural parameter measurements and a craniovertebral angle taken, none these outcome measures match my clinical PICO and were therefore not included in this analysis. I chose lateral deviation because it most closely resembles Cobb’s angle, which is considered the gold standard for measuring scoliosis (Patias P., et al. 2010). The author did not cite the reliability of lateral deviation or an MCID for this outcome measure. However, my own independent literature search has shown that if a specific protocol is used to obtain the 3-D measurements they can be considered to be reliable but not as accurate as Cobb’s angle in regards to inter-rater reliability (Patias P., et al. 2010). The author of the study referenced the specific protocol used to obtain lateral deviation and can therefore be considered reliable. The authors provided citations supporting FRI as a valid measure for low back pain; therefore, I decided this met my clinical PICO. There is not a gold standard for low back pain measurement. The MCID for FRI was not reported by the author, but through my own literature search, I found the MCID for the FRI to be a change of 15 points for people with low back pain (Childs M. & Piva S., 2005).

Study Losses: All subjects completed the 10-week treatment and post-treatment measurements. Eight subjects were lost at the three-month follow-up (three from the control group and five from the forward head posture treatment group) due to “family reasons”. An intention-to-treat analysis was performed. In addition, a power analysis was performed to determine an adequate sample size for the study and showed that the study needed at least 30 subjects in each group to be valid. The study met this criterion even with its losses.

Summary of Internal Validity: I found the internal validity of this study to be fair to good due to the article’s PEDro score being a 7/10 and I identified two major and three minor threats to internal validity. One of the major threats is that it appears only one researcher conducted the entire study. This design allows for rater bias throughout the study procedures. Another major threat is that the gold standard for measuring scoliosis severity (Cobb’s angle) was not used. Though the lateral deviation 3-D parameter provides information regarding how the spine is aligned in the frontal plane, it has not been accepted as a measurement that can show the progression or regression of scoliosis (Patias P., et al. 2010). In addition, the author provided no information on the intra-rater reliability for these measurements. One minor threat was that the experimental group received one extra day of treatment. Though the treatment was exclusively for forward head posture (the independent variable), this extra time with the therapist could affect patients’ perception of treatment and outcomes for the self-assessed FRI. The second minor threat is that a longer follow-up period would have better shown if treatment results lasted. Scoliosis is a slow and progressive disorder and therefore more than three months would seem appropriate to determine if the treatment was a lasting solution. Another minor threat is that there was not a placebo group. A placebo group allows us to determine the progression of AIS. Though studies show AIS is usually a progressive disease up to a certain age with some people, it is possible that some individuals may have reached the point where their AIS was no longer
progressing. This could have skewed the results at the three-month time point since these individuals would not have shown AIS progression. It is acknowledged that it would be considered unethical in the Middle East to withhold AIS treatment as the Middle East medical system takes a proactive approach with AIS (Bettany-Saltikov J. & Paz-Lourido B. 2012).

**Evidence/Discussion:** The author used ANOVA to determine between-group significance for lateral deviation and FRI. The forward head posture treatment group produced statistically significant improvements at both 10 weeks and three months compared to the control group. On the FRI, the forward head posture treatment group was only significantly different from the control group at the three-month marker. I was able to calculate the mean differences within and between groups and the between-group effect size. The mean differences within-group was analyzed because they show how well each group performed individually. The between-group differences are important to determine how much better one group performed overall as compared to the other. The between-group effect size can provide information on the magnitude of difference between groups.

In interpreting the results, it is important to remember that a decrease in lateral deviation and a decrease in FRI scores show an improvement in AIS. The units of measurement, measurement accuracy of the Formetric II device, and MCID were not provided for lateral deviation. In performing a Google search, I found lateral deviation measurement to be inconsistent as it was reported in millimeters, centimeters, and degrees. I also tried obtaining the referenced protocol in this study but could not find it. Units help determine the size of the change (e.g., a 0.5mm change is a lot different than a 0.5cm change). The instrument accuracy lets us know if the change could be due to measurement error (e.g., if an instrument is accurate to only 0.5cm, a 0.5cm change does not mean anything). Therefore, only a general interpretation of the results can be made and no definite conclusion can be drawn. In addition, because there is not a MCID for lateral deviation, we cannot determine if there is any clinically meaningful change either.

**Table 3. Mean Difference Within and Between Groups, and Between-Group Effect Size at 10 weeks for Lateral Deviation**

<table>
<thead>
<tr>
<th></th>
<th>Within Group Mean Difference (95% CI)</th>
<th>Between Group Mean Difference (95% CI)</th>
<th>Effect Size Between Group (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.60 (-.23 - 1.43)</td>
<td>0.2 (-0.76 - 1.16)</td>
<td>0.1 (-0.35 - 0.55)</td>
</tr>
<tr>
<td>Forward Head Posture</td>
<td>2.50 (1.38 - 3.62)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3 shows the within- and between-group differences and between-group effect size at 10 weeks for lateral deviation. The between-group difference was minimal with a mean difference of 0.2 (95%CI, -0.76 – 1.16) in favor of the control group. The within-group results show that the forward head posture treatment group had a 2.5 (1.38 - 3.62) improvement between baseline
and 10 weeks, whereas the control group had an average 0.6 (-0.23 – 1.43) improvement. One reason for this discrepancy in overall improvement could be because the forward head posture treatment group started out with a larger mean lateral deviation, so more improvement was necessary in order to reach an equal playing field with the control group. The 95% CIs surrounding the within- and between-group results were small; however, for the control group change and the between-group difference, the CIs crossed zero. This indicates that for the within-group change, the control group could potently get worse and that for the between-group change, the forward head posture treatment group may perform better. The effect size between groups is 0.1 (-0.35 - 0.55). This effect size is very small with a CI crossing into the negative range, indicating a small treatment effect and a potential that some members of the control group improved more than some members of the treatment group.

Table 4. Mean Difference Within and Between Groups, and Between-Group Effect Size at 3 months for Lateral Deviation

<table>
<thead>
<tr>
<th>Within Group Mean Difference (95% CI)</th>
<th>Between Group Mean Difference (95% CI)</th>
<th>Effect Size Between Group (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.40 (-.48 – 1.28)</td>
<td></td>
</tr>
<tr>
<td>Forward Head Posture</td>
<td>2.10 (0.94 – 3.26)</td>
<td>0.8 (-0.27 – 1.87) .38 (-0.09 - 0.86)</td>
</tr>
</tbody>
</table>

Table 4 shows the mean differences and between-group effect size for lateral deviation at three months. The within-group mean difference for the control group was 0.4 (-0.48 - 1.28). This shows that the lateral deviation for the control group got worse at the three-month time point compared to baseline. For the same time period, the forward head posture treatment group had a mean improvement of 2.1 (0.94 - 3.26). The between-group results showed that the forward head posture treatment group had 0.8 (-0.27 – 1.87) less lateral deviation than the control group. The effect size is medium at 0.38 (-0.09 - 0.86). The negative CI here is minimal and therefore not as concerning as it was at 10 weeks.

Table 5. Mean Difference Within and Between Groups, and the Between-Group Effect Size at 10 weeks for FRI

<table>
<thead>
<tr>
<th>Within Group Mean Difference (95% CI)</th>
<th>Between Group Mean Difference (95% CI)</th>
<th>Effect Size Between Group (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>4.20% (3.30 – 5.10)</td>
<td></td>
</tr>
<tr>
<td>Forward Head Posture</td>
<td>1.2% (0.45 - 1.95)</td>
<td>0.77 (0.31 - 1.24)</td>
</tr>
</tbody>
</table>

Table 5 shows the 10-week within- and between-group comparisons and the between-group effect size for the FRI scores. The within-group mean differences showed that both groups
decreased their mean FRI scores, but the control group had more of a decrease with 4.2% (3.3 - 5.3) difference compared to a 3.2% (2.54-3.86) difference in the forward head posture treatment group. However, the between-group difference of 1.2% (0.45 - 1.95) favors the forward head posture treatment group. Even though the control group had more improvement over all (as noted by the within-group differences), the forward head posture treatment group had a lower 10-week score. The effect size between groups is medium to large with a 0.77 (0.31 - 1.24).

**Table 6. Mean Difference Within and Between Groups, and the Between Group Effect Size at 3 months for FRI**

<table>
<thead>
<tr>
<th></th>
<th>Within Group Mean Difference (95% CI)</th>
<th>Between Group Mean Difference (95% CI)</th>
<th>Effect Size Between Group (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>2.30% (1.40 – 3.2)</td>
<td>3.8% (3.05 - 4.55)</td>
<td>2.59 (1.95 - 3.23)</td>
</tr>
<tr>
<td>Forward Head Posture</td>
<td>3.90% (3.22 - 4.58)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 6 shows the within- and between-group mean differences and the between-group effect size for the control and forward head posture treatment group FRI scores at three months. The within-group data show that the forward head posture treatment group maintained more of a difference from pretreatment to three months post-treatment than the control group with differences of 3.9% (3.22 - 4.58) and 2.3% (1.4 - 3.2), respectively. The mean difference between groups is 3.8% (3.05 - 4.55), showing that the forward head posture treatment group maintained lower FRI scores then the control group. The between-group effect size of 2.59 (1.95 - 3.23) is very high even when considering the low end of the 95% CI.

In summary, Tables 3 and 4 shows the forward head posture treatment group had greater mean improvement in lateral deviation at 10 weeks and three months (0.2 and 0.8, respectively) compared to the control group. However, because units, instrument accuracy, and MCID are unknown, it cannot be determined if these improvements are real (i.e., changes beyond the level of instrument accuracy) or clinically meaningful. Tables 5 and 6 show that even though the control group showed more percent improvement with the FRI scores at 10 weeks and three months (4.2% and 3.2%, respectively), the control group was not able to maintain these improvements as compared to the treatment group at three months (2.3% and 3.9%, respectively). The MCID for FRI has been reported as 15 points. It appears the author reported the mean results in percentages. Since the FRI score is out of 100, we may assume an increase in 15 points equals an increase in 15%. None of the results from Tables 5 or 6 showed this much of a difference. Therefore, these results are not clinically meaningful.
Applicability of study results:

**Benefits vs. Costs:** The cost to add forward head posture treatment is physical therapist and patient time. With the added time to the physical therapist, this will increase the patient’s medical bills. If the patients can perform these additional exercises on their own, additional physical therapist time would be minimal. Minimal benefits were seen from performing these additional cervical exercises, but none were clinically meaningful and none showed to cause any harm.

**Feasibility of treatment:** It appears the treatment can easily be administered and is feasible for patients to perform. The author described the added treatment well enough that it can be re-performed in a clinical setting. One drawback is that the forward head posture treatment should be performed four days a week instead of three with the standard treatment. The addition of the extra day increases the potential that the patient may not perform the exercises enough to produce the same results. Also, the more exercises assigned to a person, the less likely they are to perform them.

**Summary of external validity:** The main concern with the external validity is that the population used to obtain the sample was from only one clinic in Egypt and not randomly chosen. The study’s population matched my clinical PICO population. However, AIS patients in the United States are not typically seen until the disorder has progressed such that it is impinging on the patient’s function. In the Middle East, the medical system uses a preventive approach and therefore the AIS patients seen in the study sample may not have had as much of a decline in function at the start of treatment.
Clinical Bottom Line: Based on this non-blinded, randomized study consisting of 40 female adolescents diagnosed with AIS, statistically significant within-group improvements were found for Cobb’s angle (gold standard for measuring scoliosis progression) and pain (as measured by the VAS) for both the scoliosis-specific stretching group and mechanical traction group. Both groups performed four exercises three times a week for three months. The difference between the groups was that the scoliosis-specific stretching group performed a stretch focused on lengthening the concave side of the subject’s spine and the mechanical traction group received mechanical traction (instead of the scoliosis-specific stretch). With regards to Cobb’s angle, the scoliosis-specific stretching group had statistically significant improvement compared to the mechanical traction group with a between-group mean difference of 5.95° (95% CI, 4.32 - 7.58). The instrument accuracy for Cobb’s angle is +/- 4° to 8°. Thus, the within-group mean improvement for the stretching group showed real improvement 9.15° (7.41-10.89), but the between-group mean difference suggest that there was no real difference between the groups.

With regards to pain, both groups produced clinically meaningful results in improvement of pain, 4.53 (4.01 - 5.04) points and 4.20 (3.70 - 4.70) points on the VAS for the scoliosis-specific stretching group and the mechanical traction group, respectively. When comparing the between-group difference 0.27 (-0.09 - 0.63), there was not a clinically significant difference because the VAS has a MCID of three points. This study had good to fair internal validity (PEDro score 6/10). The threats included no blinding, potentially not enough subjects to produce reliable results, no patient protocol, lack of control and placebo group, and no follow-up period after conclusion of treatment. Based on the analysis of this article, neither of these treatment protocols produced adverse effects and neither was better than the other with respect to pain improvement. However, I would choose the scoliosis-specific stretching protocol to address the concave curvature of a patient’s spine over the manual traction group because there was some real improvement in the reduction of Cobb’s angle, there is minimal cost to administer this treatment, and there was no risk to the patient. To obtain similar results to this study, patients would need to perform not only the scoliosis-specific stretch, but also side crunch lying on the patient’s concave side, a supine abdominal crunch, and a general low back stretch three times per week for three months. Additional studies should include a larger sample size with females and males and a control group to further verify these results.

Article PICO:

Population: Adolescent females ages 15-25 diagnosed with AIS (n=40)

Intervention: Side crunch lying on the patient’s concave side, a supine abdominal crunch, a general low back stretch and patient education for posture, and stretching of muscles on concave side of scoliotic spinal curve
Comparison: Side crunch lying on the patient’s concave side, a supine abdominal crunch, a general low back stretch and patient education for posture, and mechanical traction for 15 min

Outcomes: Cobb’s angle, visual analog scale (VAS) for pain, and forward trunk flexion

Blinding: The authors did not state if any of the researchers were blinded. If the researchers were not blinded, this may have biased Cobb’s angle and forward trunk flexion results since taking these measurements require some degree of decision making. The subjects were not blinded. They were told about testing process for the study. This allows risk for the Hawthorne effect, since the VAS is subjective.

Controls: The study did not have a single control group. Instead, each group had an independent variable, which was either a scoliosis-specific stretch or mechanical traction. An accurate control group for comparison to these two groups would have consisted of the baseline treatment (side crunch lying on the patient’s concave side, a supine abdominal crunch, a general low back stretch and patient education for posture). The scoliosis-specific stretch matches my clinical intervention as it is a specific physical therapy intervention for scoliosis. The mechanical traction group matches my clinical comparison as mechanical traction is a more generalized physical therapy treatment for back pain.

Randomization: The subjects were randomly assigned to either the traction or stretching group. The average age for the stretching group was 18.21 years old and for the traction group, 17.88 years old. The pretreatment outcome measures for Cobb’s angle and VAS had a 0.8° and 0.05 points difference respectively. Since p-values were not reported for these data, I cannot definitively conclude whether the groups were similar at baseline with respect to outcome measures. However, the mean values (and standard deviations) appear similar from the data provided in the tables.

Study: Forty subjects diagnosed with AIS were obtained from various Cairo University outpatient orthopedic clinics. All subjects were female and were 15-25 years old with a Cobb’s angle between 20° to 40°. No specific inclusion or exclusion criteria were conveyed. Both groups received three sessions of treatment per week for three months. The treatment consisted of patient education on posture and activates of daily living, two exercises, a stretch, and the treatment being tested. Both groups performed the two exercises and the first stretch the same way and received the same patient education. The first exercise was strengthening of muscles on the convex side of the scoliosis by having the subject lying on the concave side and trying to lift her upper trunk up. This was done for three sets of 10 with a six-second rest between each repetition and a one-minute rest after each set. The second exercise was an abdominal crunch. The subject was to lie in a hooklying position and try to bring her hands to her knees. The sets, repetitions, and rest periods were the same as the first exercise. Both exercises could be progressed by increasing resistance. The third exercise was a stretch for the back muscles. The
subject was to lie in hooklying and the therapist lifted the subject’s legs and brought them to the subject’s chest. The stretch was held for 30 seconds and was done five times with a 30-second rest between each repetition. After this the treatment differs between the groups. The stretching group received a stretch for the muscles of the concave side of the scoliosis. The subject was to lie on their convex side and hold that position for 30 seconds. They were to do this five times with a 30-second rest in between each repetition. The traction group received mechanical lumbar traction in supine for 15 minutes instead of the stretch.

Outcome measures - Outcome measures (Cobb’s angle, VAS, and forward trunk flexion) were taken before treatment began and immediately after the three month study. My analysis will focus on Cobb’s angle and the VAS used to measure pain, since Cobb’s angle matches my clinical PICO and VAS is a tool that measures pain, which also matches my clinical PICO. Forward trunk flexion was not analyzed because it did not meet any elements of my clinical PICO. The authors did not state the accuracy or the MCID for either outcome measure. In my literature search, I found that Cobb’s angle is the gold standard for measuring scoliosis (Langensiepen S., et al. 2013) but, I could not find a MCID for AIS. The intra- and inter-observer accuracy of Cobb’s angle is +/-4° to 8° (Gstoettner M., et al. 2007). There is not a gold standard for the measurement of back pain. The VAS has been shown to be a reliable tool for pain measurement and has a MCID of 30 mm (Lee J., et al. 2003).

Study Losses - The authors did not state if there were any losses and not enough raw data were provided to determine if there were drop-outs. It was assumed that there were no drop-outs.

Summary of Internal Validity: I found the internal validity to be good to fair. It had a fairly good PEDro score of 6/10 but I identified six threats: two potentially major threats and four minor threats. I say potentially because, due to omission of specific information, I am forced to assume the worst-case scenario. One of these threats is that study losses were not reported and it was not stated if an intention to treat analysis or a power analysis was performed, leading to the risk that there were not enough subjects to provide an accurate analysis of the data. Another potential major threat is that the authors did not state whether or not blinding of the researchers was performed so, it must be assumed that it was not. If the researchers were not blinded, this could lead to bias of Cobb’s angle results, of the statistical analysis, and statistical interpretation since all require some degree of judgment. A potentially minor threat is a lack of protocol for the subjects to follow. The researchers did not state if they provided any instructions to their subjects about avoiding other treatments or participating in certain activities (e.g., bracing, chiropractors, analgesics, additional exercises, yoga, etc). Another minor threat is that the subjects were not blinded. This could have biased the results of the VAS since this tool is based on judgment (i.e., if a subject who was in the stretching group thinks that mechanical traction would have helped her more then she may “perceive” her pain to be higher than it really is). Another minor threat is that a longer follow-up period would have better shown if treatment results lasted. Scoliosis is a slow and progressive disorder and therefore more than three months would seem appropriate to determine if the treatment was a lasting solution. Not having a control group is another minor
threat. Each group received a different independent variable. Having an independent variable in each group makes it difficult to determine how much better or worse a treatment really is when there is not a baseline to compare it to. It could be the other interventions in both groups contributed to the majority of the improvement (i.e., if there was a study looking at weight loss, one group had to run for 60 minutes and the other had to walk for 90 minutes, but both groups were only allowed to eat 2000 calories. You cannot conclude that either activity contributed the majority of the weight loss without looking at what happens when there is a calorie limit without a change in activity). Another minor threat is that there was not a placebo group. A placebo group allows us to determine the progression of AIS. Though studies show AIS is usually a progressive disease up to a certain age with some people, it is possible that some individuals may have reached the point where their AIS was no longer progressing. This could have skewed the results as some individuals would not have shown AIS progression.

Evidence/Discussion: The researchers ran a one sample paired t-test for each group and a two-sample unpaired t-test to compare the groups at a 95% CI. When looking at pretest and posttest results, the researchers reported significant improvement for all within-group outcome measures. When analyzing the between-group posttest results, the stretching group had significant improvement in the Cobb’s angle as compared to the mechanical traction group. I was able to calculate the mean differences within- and between-groups and the between-group effect size. The mean differences within-group was analyzed because they show how well each group performed individually. The between-group differences are important to determine how much better one group performed overall as compared to the other. The between-group effect size can provide information on the magnitude of between-group results. In interpreting the results, it is important to remember that a decrease in Cobb’s angle and a decrease in VAS scores show an improvement in AIS.

Table 7- Mean Difference Within and Between Groups, and Between-Group Effect Size for Cobb’s angle (deg)

<table>
<thead>
<tr>
<th></th>
<th>Within Group Mean Difference (95% CI)</th>
<th>Between Group Mean Difference (95% CI)</th>
<th>Effect Size Between Group (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stretching Group</td>
<td>9.15 (7.41 - 10.89)</td>
<td>5.95 (4.32 to 7.58)</td>
<td>2.46 (1.64 - 3.28)</td>
</tr>
<tr>
<td>Traction Group</td>
<td>2.4 (0.65 - 4.17)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 7 shows the within- and between-group differences and between-group effect size for Cobb’s angle after three months of treatment. The MCID for Cobb’s angle could not be found and the accuracy for measuring Cobb’s angle is +/-4°-8°. The within-group mean difference for the stretching group shows that there was 9.15° (7.41-10.89) improvement in Cobb’s angle after three months of treatment. This is more than the accuracy of Cobb’s angle and therefore one can conclude that the stretching group had some real improvement in Cobb’s angle. The traction
group only had a 2.4° (0.65 - 4.17) within-group improvement, suggesting that there was likely no improvement since the degrees are below the accuracy of the measurement. The mean difference between groups was 5.95° (4.32 – 7.58), in favor of the stretching group. However, this result falls within the accuracy range of the measurement meaning neither group had more improvement over the other for Cobb’s angle. The between-group effect size is high with a 2.46 (1.64 – 3.28).

| Table 8. The Mean Difference Within and Between Groups, Between-Group Effect Size, and MDIC Results for VAS (points) |
|-----------------|-----------------|-----------------|-----------------|
|                 | Within Group    | Meet MCID of 3 cm? | Between Group | Meet MCID of 3 cm? | Effect Size Between Group |
|                 | Mean Difference (95% CI) |                   | Mean Difference (95% CI) |                   | (95% CI) |
| Stretching Group | 4.53 (4.01 - 5.04) | Yes             | 0.27 (-0.09 - 0.63) | No                   | 0.5 (-0.13 - 1.13) |
| Traction Group   | 4.20 (3.70 - 4.70) | Yes             |                   |                     |                     |

Table 8 shows the within- and between-group differences and between-group effect size for VAS after three months of treatment as well as whether or not the differences met the three centimeter MCID. The study analyzed the VAS data using a 10-point scale on a 10cm line. Since each centimeter equals one point, I can say that three centimeters equals three points for the MCID. Both the stretching and traction groups showed improvement for the VAS and exceeded the MCID with their within-group mean differences of 4.53 points (4.01-5.04) and 4.20 cm (3.70 – 4.70), respectively. The between-group mean difference was 0.3 points (-0.6 – 0.66), in favor of the stretching group but because this result is less than a one-point increase and does not meet the MCID, there was likely no real difference between the two groups for pain as measured by the VAS. The effect size is medium with 0.5 (-0.13 – 1.13). The 95% CI crossed into the negatives meaning that there is a potential that some members of the traction group could improve more than some members of the stretching group.

In summary, Table 7 shows that improvement was gained in Cobb’s angle with the stretching group but when comparing the between-group mean differences there was no real difference between the groups, but there was a real difference in the reduction of Cobb’s angle for the within-group results for the stretching group. In Table 8, both groups produced clinically meaningful results in improvement of pain, as measured by the reduction in VAS scores. When comparing the between-group score, there was no difference so both groups improved about the same amount.

**Applicability of study results:**

**Benefits vs. Costs:** The costs to use mechanical traction outweigh the costs of teaching scoliosis-specific stretching. Costs for mechanical traction include: additional time for patient to be at the physical therapy clinic, additional time for the therapist to setup the machine, and cost
to the therapist or patient to obtain a traction machine. The only cost with stretching is taking up
the physical therapist’s time to teach the stretch and the patient’s time to learn and perform the
stretch. Neither treatment resulted in adverse effects. The benefits of either treatment were about
the same for pain improvement; each group demonstrated clinically meaningful reductions in
pain as measured by VAS scores. However, there were no clinically meaningful benefits
between groups. The stretching group showed improvement in Cobb’s angle reduction exceeding
instrument accuracy but when comparing the between-group mean differences there was no real
difference between the groups. Overall, there may be a slight benefit to the scoliosis-specific
stretching group.

**Feasibility of treatment:** Either treatment is easily administered and feasible with exception of
the treatment time. The treatment time for both treatments was three times a week for three
months. This is likely not feasible for the United States as most insurance companies would not
cover this number of visits. Both exercise programs can be performed at home, if the patient is
trained appropriately and is 100% compliant with their home program (since the assumption was
made that the subjects were 100% adherent to the exercise program in this study). However, it is
not feasible to expect that an adolescent will be 100% compliant with their exercises. The
stretching treatment is more feasible than the traction treatment for several reasons. Not all
clinics have a traction machine, but all physical therapists can learn to appropriately teach the
stretch. Procedures for the stretch were described well, but the amount of force used with traction
was omitted. There is potential that some patients may not be able or willing to undergo
mechanical traction.

**Summary of external validity:** There is some threat to external validity, mostly due to two
features of the subject sample. The internal validity does not compromise the ability to
generalize the results. The main threat is that the population used to obtain the sample was from
Egypt. AIS patients in the United States are not typically seen until the disorder has progressed
such that it is impinging on the patient’s function. In the Middle East, the medical system uses a
preventive approach and therefore the AIS patients seen in the study sample may not have had as
much pain at the start of treatment as compared to patients form the United States. In addition,
the article population was all females ages 15-25. My clinical PICO had an age range of 10-18
years old and was more general to include both females and males. Studies have shown that the
majority of scoliosis progression for patients with moderate AIS occurs during their growth
spurts (Weinstein S. & Ponseti I.1983). Since females typically have their growth spurts earlier
than males and both typically stop growing by age 16 there is a potential that the majority of the
study’s subjects stopped growing and therefore did not have any further progression their
scoliosis. The subjects in my clinical PICO have more potential to have scoliosis progression and
therefore the results of the study may be different if performed on this population.
Synthesis/Discussion:

These two articles differed in outcomes because they used different treatment methods, populations and outcome measures. The Diab study evaluated the effects of scoliosis-specific exercises versus the addition of exercises to correct forward head posture. In contrast, Zakaria et al. evaluated the effects of scoliosis-specific exercises versus mechanical traction. The subjects for both of the articles were obtained in Cairo, Egypt, but Diab’s study sampled 76 subjects from one clinic, whereas Zakaria et al. obtained the population from multiple clinics but only chose 40 females. Zakaria et al. did specifically state any inclusion or exclusion criteria so it appears selection of the subjects was a convenient sampling that resulted in all females diagnosed with AIS. Diab’s inclusion criteria were: diagnosis of AIS with Cobb angle between 10°-30°, Risser grade of 0, 1, or 2, craniovertebral angle less than 50°, and Lenks category of 1A. Diab’s outcome measures (FRI and lateral deviation from a 3-D posture parameters machine) did not have a MCID and no reliability of measurements was reported. Specifically, for lateral deviation, units of measurement were not reported and this is also not the gold standard (i.e., Cobb’s angle) used to determine scoliosis severity. Zakaria et al. used validated outcome measures (VAS and Cobb’s angle) that were more useful for drawing conclusions because the VAS has an MCID and Cobb’s angle is the gold standard and has measurement reliability.

Neither study matched my clinical PICO specifically in that neither study had a subject group that just received general back treatment and the populations for both studies were obtained in the Middle East where it appears that a more proactive approach to scoliosis treatment is taken and therefore initial back pain may be less for the study subjects then for subjects in the United States. In addition, Zakaria et al. had all females and my PICO included both genders.

Internal validity for both articles was fair to good. Table 2 shows the overall PEDro scores were similar (Diab 7/10; Zakaria 6/10) and the criteria met for scoring was also similar as neither article met the blinding criteria for items 5, 6, or 7. However, I identified other internal validity threats in the Diab article that were not captured in the PEDro criteria: not using the gold standard to access scoliosis severity, extra treatment time for the experimental group, no placebo group, and follow-up period not long enough. Zakaria et al. also included additional threats: potentially not enough subjects to produce reliable results, no patient protocol, lack of control and placebo group, and no follow-up period after conclusion of treatment. Though these studies had methodological flaws, I do not believe these flaws were significant enough to disregard the results of the studies. However, they should be taken into consideration when extrapolating these results to a broader population with AIS.
References:


