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Combined effect of Schroth method and Gensingen brace on Cobb's angle and pulmonary functions in adolescent idiopathic scoliosis: a prospective, single blinded randomized controlled trian

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Abstract. – OBJECTIVE: To detect the of the Schroth method added to the Ger brace for six months on Cobb's angle, axi tion of the trunk, and pulmonary function in lescent idiopathic scoliosis.

PATIENTS AND METHODS: The study lowed a prospective, singlerando ized controlled trial design ne CON ucted in SORT guidelines. The stu was co Health and Rehabilitation tre. 42 les aged 10-18 years old, diagnose iopathic scoliosis with OL were recruited and n were an d into three groups: Group p B, and G **RESULTS:** < 0.001) mprovemen axial rotation of the in Cobb's and and trunk (AR7 vere noted a be treatment in the three gr s, while pulmor unction showed better sults in Group A (p < .001) when combother groups $p \ge 0.000$). o the tw par US S: Six months of Schroth meth-Brace demonstrate faod ad Gensing o's angle, thoracic trunk able in 🥻 ulmonary function in adoon an t idiopa coliosis. Scoliosis, Schroth method, Gensingen

Abbreviations

Adolescent Idiopathic Scoliosis: AIS; Schroth Method: SC; Gensingen brace: GB; Activities of daily living:

ADL; the perthopedic and Rehabilitation Treatment: SOSOK1; Posterior Anterior: PA; Forced expiracolume in one second: FEV₁; Forced vital capacity: mum voluntary ventilation: MVV.

Introduction

Idiopathic scoliosis is a type of spinal deformity that commonly occurs in adolescents¹, with no significant identifiable causes in a child who is considerably healthy². It is further referred to as the three-dimensional deformity, where the spine naturally bends³. Patients with idiopathic scoliosis outcomes are enhanced by early detection and treatment⁴. Adolescent idiopathic scoliosis (AIS) is the most common form of scoliosis, affecting approximately 2% to 4% of adolescents⁵. Weinstein⁶ outlined that the diagnosis of scoliosis is confirmed through an X-ray of the full spine, while the patient standing in full position. It is also of utmost significance to consider the importance of bone density, especially in young patients. In one of the recent studies, Weiss et al⁷ study explains that alteration of the neuromuscular system (neuromuscular scoliosis), alterations of soft tissue (Marfan's syndrome and Ehlers-Danlos syndrome), alterations of the nervous system (neurofibromatosis), failure of formation of vertebrae and ribs (congenital scoliosis) is the major cause which leads to Scoliosis. In this context, a study by Carfi et al⁸ evaluated the data on bone mineral density (BMD) from a large cohort of adults with Down syndrome. It was found that BMD decreased with age more quickly in these subjects than in the general population, exposing the adults with Down syndrome to an increased risk of osteoporosis and bone fracture.

It has been identified9 that AIS has a long-standing described history of back pain patients with severe curves have a high prevalence than normal subjects and are exposed to minor disabilities. In Chik and Weiss¹⁰ 2020 study, the majority of scoliotic curves are called idiopathic, but the reasons are not identified yet. Scoliosis can be symptomatic or syndromic scoliosis, the curve may appear very individual, sometimes bizarre, in idiopathic scoliosis, there are certain curve patterns that regularly occur¹⁰. It further initiates the development of restrictive lung disease with decreased lung volumes¹¹. The movement of the ribs is also affected by scoliosis which develops a mechanical loading on the respiratory muscles and puts various organs of the thoracic cavity out of their places. Besides, it decreases the chest wall compliance directly and the lung compliance ind ly, causing an increase in the work of br The associated respiratory muscle weakne ay lead to chronic respiratory failure³.

Clinically, the analysis of the problem is through Cobb's angle analysis where aminations related to the size bendin y. The d are undertaken radiographi rvations held through this method on the deper Cobb's angle, such a in n 120° and ated through Cobb's angle is less periodic observ whereas sis with Cobb's angle is treated by aring an ng the progress. Howorthosis resulting in reever, in *c* where Cob. gle is greater than y is recommended. 40°, su e Schroth Methis another conservative technique that imod (S wareness of their deformity and tient pro correction in a three-dimensional prome sists ensorimotor, postural, and :oach purposed at the realignment tory static/dynamic control of posnal post. of nd stability of the spine¹².

and Yousef¹³, in their randomized ntrolled study, declare that a significant decrease bb's angle and right total static plantar pressure significant increase in left total static plantar pressure post-treatment was noted with a higher effect and six-minute walk test with a decrease in the angle trunk rotation in the Schroth group¹³. Recently, the Gensingen brace (GB), is preferred for the management of scoliosis to correct individual curves with a specific brace for each treated patient and restore an approprialignment in the sagittal plane. Besider the sobrace method promises a reduced in a diment to quality of life in patients suffering to m scoliosis, especially AIS¹⁴. It is stated that the provides an acceptable correction of more than 50 more the initial Cobb's angle¹⁵.

Many studies16-18 ha ocused on the gen b tiveness of SC and G but none of d effect f both them have focused on the AIS. methods in treat refore, patien +1 ffectiveresearch is reed to deter aging adult ness and pr of bracing in icularly those with thorascoliosis _____ents columbar curves suc no objective criteria or the prescription of clea ations conce pes of braces, daily waring time, and duratl of the intervention for adult scoliosis¹⁹. The study at to draw out the combined ef-SC and C singen brace on Cobb's angle f onary ctions in AIS patients. and

Uvpothesis

Gensingen brace is effective in decreasing Cobb's angle and improving pulmonary function (VC, FVC, FEV₁, FEV₁/FVC, and MVV) in patients with AIS.

Patients and Methods

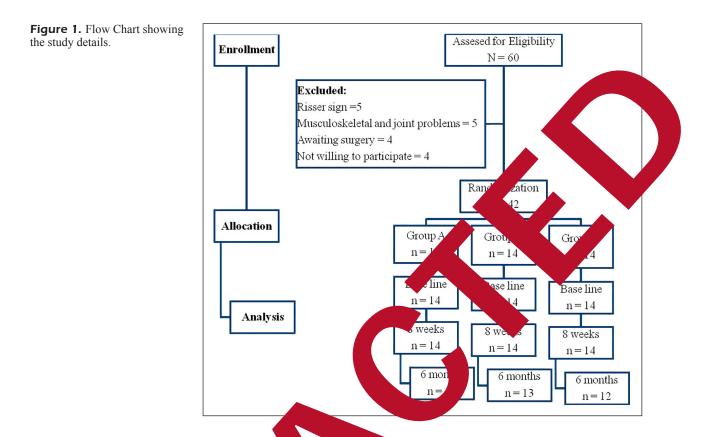
Trial Design

This study is a prospective, single-blinded, randomized controlled trial, conducted following the CONSORT guidelines. The study was conducted in Health and Rehabilitation Centre.

Study Population and Sample

The eligible participants were selected in the physical therapy department by a trained physiotherapist according to the selection criteria. The flow chart of the participants in the study at various durations is illustrated in Figure 1.

The sample of this study involved forty-two adolescents with idiopathic scoliosis, which were divided into three groups in a 1:1:1 ratio using a computer random assignment method i.e., Group A (n=14), Group B (n=14), and Group C (control group) with n=14 participants. The selection of the



participants was based on the inclusion and sion criteria, which involved male adolescents idiopathic scoliosis (AIS) diagno n ortho dician, aged between 10 and 1 startin , no hi Cobb's angle between 35 of any orthotics application, no rective is spi surgeries and consent pa r more than The participants w Riser si, four weeks, cong defects, me diseases. neuromuscular trauma, and willing to participate were excl

Interv lions

cipants in Group A were treated with Met and Gensingen brace. In the Scl ney wer first n sked to follow certain h incl d a series of training and rcises vised for a period of six months. gan with one hour of personal Th terventio g for the initial two weeks every day foltra ekly training of an hour. The exeres were given in a three-dimensional approach h consisted of the elongation of the spine, ent of the pelvis, rotation of the thorax, and correction of the shoulder. The training further included different breathing patterns in lying, sitting, and standing positions.

A provide the exercises also involved postural correction and modifications to obtain the ideal body alignment through their activities of daily living (ADL). The primary focus was on sensorimotor, breathing, and postural domain and the improvement of the spine stability. The protocol took special care of the movements required, the amount of passive support involved and the dosage recommended. Any compliance raised by the participant was noted in the logbook and verified weekly by a treating physiotherapist. The exercise performed each day was checked using a checklist. The attendance and performance of exercise during the course of the treatment were monitored continuously.

Participants in this group also received a Cheneau Gensingen Brace[™] (Scoliosis Bracing Innovations, Gensingen, Germany) if the bracing criteria were met. It can be applied at all stages of scoliosis and provides a 3D correction effect. It helps improve the posture of the participant with a more balanced appearance. The presence of expansions at the concavities decreases further spine rotation and induces spine correction. It has an open hip design which provides free hip and pelvic motions. The application of the brace did not crush the chest region and allowed free breathing. This brace was easy to wear, take off, breathe, eat and do other activities. Its positive effect on participants was its customized design according to the patient's curve pattern through its 3D scanning technology. It was recommended for patients with Cobb's angles of 45°, 50°, and more than 55° and it should be worn as indicated in the guidelines of society on scoliosis orthopedic and rehabilitation treatment (SOSORT)²⁰.

Group B only received the Gensingen brace application, while Group C received controlled conventional scoliosis exercises. These were specific exercises that are taught to patients with scoliosis. The exercises were pelvic tilt, cat-camel, double-leg abdominal press, and single-leg stance. Initially, the exercises were demonstrated by the therapist, and the subjects practiced in the presence of the therapist, and the clarifications were rectified.

These home-based exercises were printed in a hand manual in comprehensive language. The first part of the manual contains the do and don'ts during the study period. The next part of the manual contains different stretching and strengthening exercises for the back and chest muscles. They performed these exercises 10-15 reps/day for 5 days per week for 6 months. Stretching was focused on each muscle group for 3 repetition 15 seconds per muscle group²¹. In the study of the d by Weiss et al²², during the treatment of standis, no significant side effects or risks have been not conservative treatment such as active physical rehitation techniques specific to scoliotion to pattern.

Procedures Involved

Cobb's angle

the degree This angle was d to m of scoliosis on the sterior-ante A) spinal X-ray. Based e convexity can be indicated as the right t side. To obtain this angle we w a paraller respectively at the ower vertebra end lines and a verupper 2 from the parallel line that makes Cobb's tical od of measurement has good inans is m tra-ra. ter-rater biability²³.

meter be axial 1, alon of the trunk (ATR) was metered with a scoliometer (Ockendon Partthe Kewsbury, UK) in idiopathic scobiss. The participants were asked to stand in tward flexion position, while a scoliometeres placed over the spinous process, where maximum rotation of the spine occurs. It showed good to excellent reliability measurements in idiopathic scoliosis²³.

Pulmonary function test

The pulmonary values such as Forced vital capacity (FVC), forced expiratory volume (FEV), FRC/TLC, and Maximum voluntary ve (MVV) were measured by using the d PFT (COSMED, Germany). The pat was asked to sit in a comfortable position and mouthpiece was connected firmly to inspire air imum effort and then expire it with m mum h. The maneuver was repeated 10mes and the σ of the best three values considered for sis²⁴. No changes happ throug at the methy aology after the recryitme articipan

Sample Size

A pilot conducted lect a 0.5% ry variable Cobb's angle), difference the a study with two p. arms and three meaof 0.05 and a power sure me-points, o, and a sample size of 2 in each group were ulated. Assuming 10% dropouts, this implies a total pool 14 participants in each group cluded in study. G*Power version 3.1.2 v Heip niversität Düsseldorf, Düssel- (\mathbf{H}) was used for these calculations. dorf.

be blinded when providing or performing the different training protocols. However, participants were asked not to disclose their group allocation to ensure the blinding of the outcome assessor. The outcomes were measured at baseline, after six months and eight weeks. The biostatistician who conducted the data analysis was not aware of the data coding.

Statistical Analysis

All demographic characters and outcome measures were presented in form of means \pm standard deviations. Changes in the variables among the three groups were assessed using ANOVA, while pre-post changes within each group were assessed using repeated measures ANOVA. p < 0.05 indicates significant changes. All data were statistically analyzed using SPSS v. 25 (IBM Corp., Armonk, NY, USA).

Results

Final Sample After Six Months

Out of 42 participants, 38 patients were considered as the final sample and were divided as follows: 13 in Groups A and B each, while 12 in Group C as only these patients have completed

S. No.	Variable	Group A	Group B	Group C	<i>p</i> -value
1	Age (y)	13.5 ± 1.2	13.8 ± 1.5	14.1 ± 1.2	0.485*
2	Height (m)	1.48 ± 0.14	1.47 ± 0.16	1.49 ± 0.15	0.92
3	Weight (kg)	42.2 ± 1.8	41.8 ± 1.7	42.8 ± 1.9	J Josk
4	BMI (kg/m ²)	16.4 ± 0.8	15.9 ± 0.7	16.2 ± 0.7	206*

Table I. Demographic details of Group A, B and C.

*Non-Significant, BMI; body mass index

the treatment program within six months of follow-up. The basic demographic variables such as age, height, weight, and BMI did not show any significant difference between the groups ($p \ge 0.05$) at baseline (Table I).

Cobb's Angle

Patients were advised to take the brace off for a minimum of two hours before the scheduled X-ray, to allow full relaxation of the trunk in or-

Table II. Pre and post analysis of Group A, B and C.

der to obtain reliable r logical images data deformation. The ba Cobb's and anterior X-ray was collected by usin Whi scores among G no staos A, L tistical different ted. The $(p \ge 0.05)$ ons showed intra-group at various significant nange Group A and Group B (p< 0.001) after diffe. xercise training. Over of differen ning (Schroth Metheigh Jensingen brace, and Jome-based exercise) 0

S. No	Variable	Duration	Group	Group	Group C	<i>p</i> -value
1	Cobb's angle	Base liv	36.3 ± 2.4	3	36.2 ± 2.3	0.465*
	(degree)	8 we	22	33.8 ± 2.3	34.8 ± 2.3	0.001**
		6 mon	200	30.3 ± 2.1	32.3 ± 1.9	0.001**
		<i>p</i> -value	0.0	0.001**	0.00**	
2	Axial Rotation of Trunk	Base line	- 1.4	5.2 ± 1.3	4.9 ± 1.3	0.388*
	(Scoliometer)	weeks	0.8 ± 2.2	7.6 ± 1.9	5.8 ± 1.5	0.001**
		onths	6 ± 2.2	9.3 ± 1.8	6.3 ± 1.6	0.001**
		lue	01**	0.001**	0.001**	
3	Pulmonary Funct	e line	86.3 ± 5.4	87.2 ± 5.3	86.7 ± 5.1	0.902*
	TLC (% predicted va.		91.8 ± 3.7	89.8 ± 3.9	87.8 ± 4.1	0.034**
		6 months	95.8 ± 4.2	92.3 ± 4.3	88.3 ± 3.3	0.001**
		alue	0.001**	0.018**	0.596**	
	FVC Junes)	e line	76.3 ± 5.4	77.2 ± 5.3	76.8 ± 5.1	0.902*
		8 weeks	82.8 ± 4.1	81.8 ± 4.2	78.8 ± 4.3	0.042**
		6 months	90.6 ± 4.8	84.3 ± 4.3	79.4 ± 4.1	0.001**
		<i>p</i> -value	0.001**	0.001**	0.292**	
	FEV ₁ (% predicted values)	Base line	78.8 ± 7.8	79.4 ± 6.9	76.2 ± 7.3	0.478*
		8 weeks	85.8 ± 6.1	82.6 ± 6.17	79.8 ± 6.2	0.042**
		6 months	96.5 ± 7.2	88.8 ± 7.3	82.3 ± 7.3	0.001**
		<i>p</i> -value	0.001**	0.002**	0.078**	
	P. o)	Base line	44.3 ± 4.3	45.8 ± 4.6	46.2 ± 5.3	0.542*
		8 weeks	56.2 ± 5.4	48.3 ± 4.7	47.8 ± 4.8	0.001**
		6 months	61.3 ± 6.3	52.6 ± 5.4	48.2 ± 4.9	0.001**
		<i>p</i> -value	0.001**	0.001**	0.540**	
	w VV (l/min)	Base line	125.2 ± 9.8	124.9 ± 9.7	126.2 ± 9.3	0.932*
		8 weeks	136.8 ± 9.5	128.6 ± 9.4	126.8 ± 9.4	0.017**
		6 months	142.5 ± 9.2	135.4 ± 10.3	128.3 ± 9.6	0.001**
		<i>p</i> -value	0.001**	0.006**	0.832**	

*Non-Significant, **Significant, TLC; total lung capacity, FVC; forced vital capacity, FEV₁; forced expiratory volume in one second, MVV; Maximum voluntary ventilation

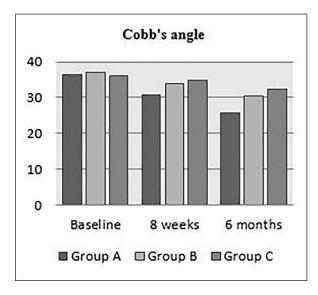


Figure 2. Mean values of Cobb's angle of Group A, B and C.

protocols, a significant difference between Group A (p < 0.001), Group B, and C at eight weeks and six months follow-up (Table II) was detected. The graphical representation showed more percentage of improvement in Cobb's angle in Group comparison with Groups B and C (Figure

Scoliometer

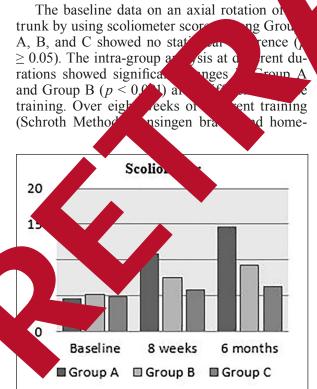


Figure 3. Scoliometer Scores of Group A, B and C.

based exercise) protocols, a significant difference among Group A (p < 0.001), Group B, and C at eight weeks and six months follow-up was detected (Table II). The graphical representation showed more percentage of improvement and rotation of the trunk in Group A than Groups Band C (Figure 3).

Pulmonary Function (PF The baseline data or almonary (VC, FEV₁, FRC/TLC MVV) scores Groups A, B, and G wed p tatistical veeks of differference $(p \ge 0.05)$ O Gensing ent training (Sch n Mei brace, exercise) 1 and home-ba signifin pulmonal cant impro ction (VC, FEV₁, FR VV) among groups (p <TLC 0.001) at eight week six months follow-up was ed (Table II) graphical represenin showed more perce, age of improvement ulmonary function (VC, FEV,, FRC/TLC & V) in Group than in Groups B and C (Fighalysis shows a little tendency The whol 11 reater in towards Group A than the tow other t

Discussion

This prospective, single-blinded, randomized controlled trial evaluated the effectiveness of the Schroth exercise in combination with the Gensingen brace on Cobb's angle, axial rotation of the trunk, and pulmonary function (VC, FVC, FEV₁, FEV₁/FVC, and MVV) in adolescent idiopathic scoliosis. We hypothesized that Schroth exercise added to Gensingen brace could have useful effects on reducing Cobb's angle, axial rotation of the trunk, and improving pulmonary function (VC, FVC, FEV₁, FEV₁/FVC, and MVV) among those adolescents. The study findings supported the hypothesis and showed that Schroth exercise added to the Gensingen brace decreased Cobb's angle significantly and further improved pulmonary function (VC, FVC, FEV, FEV,/FVC, and MVV) in patients with AIS.

Findings of the current study suggested significant improvements with respect to the percentages of the improvement in Cobb's angle in Group A, which followed the combination of both techniques. A significant improvement in the pulmonary function, and axial rotations of Group A at eight weeks and six months of follow-up were also observed. Since several treatments have been



Figure 4. Then values of Terrer g capacity (TLC), vital capacity (VC), forced expiratory volume in one second (FEV₁), functional reducing capacity/total capacity (FRC/TLC) & maximal voluntary ventilation (MVV) of Group A, B and C.

or adol ent idiopathic scoliosis sugge eatment, bracing, electri-S) suc urgic mulat physical activities²⁵, bracing d to enhance specificity confor S, is pre ig the adolescent curve pattern and keepsic agittal reposition of the deformed ne²⁶. Another important reason for bracing is oid the curve progression, minimizing the d correction of scoliosis for better cosmetic appearance. Additionally, PAs, are significant during the development to postpone or stop the need for an alternative brace as well as to keep

scoliosis likely lesser than $30^{\circ 27}$. In one study²⁸ according to the Progression factor calculation, a ten-year-old girl with a 20° Cobb's angle and a Risser sign of 0 would have a progression factor of 2. The correlating chart indicates a 90% risk of progression in a fifteen-year-old girl with a 20° Cobb's angle who might typically be 2.6 years postmenarcheal and a Risser 4, whereas in some of the cases, the progression factor is 0.53 which indicates little risk for progression²⁹. It is proved that PAs have an encouraging effect on AIS by enhancing lung function, increasing strength, and

improving postural balance. Therefore, PEs could be recommended in AIS 9³⁰.

The Schroth exercise on the other hand is highly acknowledged for improving the vital capacity in adolescents with idiopathic scoliosis. The main goal of the Schroth technique is to give powerful treatment to those patients through its treatment approach which incorporates both concentrated inpatient rehabilitation and private outpatient physiotherapy³¹. Otman et al³² executed Schroth exercises for 30 sessions, four hours each, followed by 90 minutes of home exercise each day for 50 adolescent patients with right thoracic scoliosis and concluded a 2.65° reduction in Cobb's angle after six weeks, 6.85° after six months, and to 8.25° after one year. Furthermore, Borysov and Borysov³³ applied the Schroth exercise and evaluated Cobb's angle by a scoliometer, which was significantly decreased to 2.4°. This comes in agreement with the current study which stated that there is an improvement in Cobb's angle following six months of training and supervised protocols.

The magnitude of the axial rotation of the trunk significantly relies upon Cobb's ang longitudinal axial rotation of the apical ve the higher Cobb's angle, the greater the r on angles³⁴. Additionally, the trunk rotation and minished when the acromion of the rib was tu to the opposite side by 3D rot breathi during the Schroth exercise otationa se to be breathing permitted the ex ne more 3-dimensional, which led th arrowed thoracic cage³⁵. The rre tation of the nificant improvement in the a trunk in all grou gure 4). AL nts suffer from respirato tion as a reof chest rigidity and size are wall abnormations. The also affect by the abnor onfiguration of the ribs³⁶. chese abnormalitie ld impair respirechanies²⁷. The effectiveness of Schroth rator ficant here, as it increases rib exe is 🤉 d vital acity while improving mover ing the sagittal breathing flat b incr It study showed significant se²⁷. spiratory function for the first cement h en specifically. gr

folars³⁶ exhibited positive results of throth exercises on breathing function, curve ression, and surgical need. Recently, Soumagent al²¹, concluded that after 6-month of the randomized controlled trial (RCT) that compared the viability of a supervised to non-supervised Schroth intervention in patients with AIS, the su-

pervised Schroth exercises showed better results in reducing Cobb's angles, scoliometer measures, waist asymmetry, and rib hump as compared to non-supervised and no-treatment groups. months' study period. Another study Hwangbo³ proposed similar finding where patients did Schroth exercises for tw weeks three times a week. Significant improve were observed in terms of improve trunk ation, Cobb's angle, and vital c city. These ŋġş esults proposed are in agreement with t current study.

the Gerningen With regard to the ¹ts wer positiv brace, significan tained ti in this study with othused in co ock et al³⁷ e red that 3D er exercises can be applied for tests, whole-box scan which are used for tr easurement in preparanewest development. ace, which h tion in using these scanner, for suitable measured ies, clinical progress monitoring can be conted at the st time that the patient's meaents are ol ned for providing a brace. In S spec st practices will offer to monthe face topography with spinal deitor pa. remities and its multifunction³⁷.

lar et al³⁸ in their study examined the efcus ass of Gensingen brace treatment in patients with AIS. According to the findings, the overall success rate of the Gensingen brace was 48%, while no significant association was found between the patient's age, gender, and Risser grade with the success rate of the treatment outcomes.

Another study by Weinstein et al³⁵ provided similar results, as the use of Gensingen brace in conservative brace treatment was successful in 92% of patients with AIS. The present study showed a prominent effect by adding Gensingen brace to treatment intervention for AIS in both the first and second groups.

Study Limitations

The study had a limited number of subjects with AIS and less time available for those patients to join the study because most of them were school students. In addition, the effect of treatment procedures on back pain was also not evaluated.

Conclusions

The current study focused on the treatment outcomes of Gensingen brace and Schroth Method when used in combination for patients with AIS. The influence was majorly recorded for improving Cobb's angle and pulmonary functions. The comparison among the three groups provided comparable results, however, better results were obtained for Group A which used Schroth Method and Gensingen brace in combination. The results were significant for observations related to pulmonary functions and the combined effect produced a favorable effect on adolescents suffering from idiopathic scoliosis.

The study findings may help clinicians in providing better treatment therapies for patients with AIS. They can be further implied in improving the quality of life of adolescents and can be used as a source of information for parents of adolescents in seeking guidance and support for the timely identification, diagnosis, and treatment of the disease. For future researchers, a study comparing the impacts of the Schroth exercise alone to detect its sole effect on scoliosis is recommended.

Conflict of Interests

The authors declare that they have no conflict of interest.

Ethics Approval

All methods were carried out in accordance where elevant guidelines and regulations. All experimental up of cols were approved by a named institutional and/or h ing committee. This study was approved by the Rese Ethics Committee at Prince Sattam bio and prize up in sity (No. RHPT019/42.) in accord to when upguideline of the Helsinki Declaration for the cal research involving human subjects.

Informed Conser

Informed written come was obtained and participants.

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A A, HAA, A Alysis and interpretation of data: GN, AA, HAA, A Alysis and interpretation of data: GN, W. SEBE, FAM, NAA, HAA. Drafting: SMH, SE-Supervision: SAM, FAM, HAA. Validan and finar approval of the version of the article to be pubt; SAM, GN, AEE, SMH, SEBE, FAM, NAA, HAA.

Acknowledgements

The authors would like to gratefully thank all clinicians and patients for their contribution in the study.

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Funding

The authors declared that this study has repred no financial support.



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