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Bracing Effects of the Flexpine in Scoliosis Patients

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Abstract

Although various bracing methods are used today for the treatment of scoliosis, the plaster cast seems to be the most practiced technique at the moment. 3D printed systems are on the run which allow brace adjustments without plaster but with elastic band and flexible frame. This advance of 3d printing technology is developed into the use of the Flexpine method enabling the built of a delicate 3d printed brace without an orthopaedic technician to build a systemized brace for scoliosis correction. This 'FLEXpine'' brace, developed according to the Flexpine 3d bracing principle, promises an enhanced convenience of quality of life within the uses of the brace. However, the change of pushing method and material should not result in reduced curve fixture. Therefore, the primary correction effect of various "FLEXpine" brace methods have been evaluated.

Keywords: 3d printing technology; brace evaluation; 3d bracing principle; Cobb's angle.

1. Introduction

The correction effects of the patients of scoliosis treated according to the principle of the 'Flexpine'' brace were evaluated after an average treatment time of 15 weeks by a full-body X-ray made in the standing position whilst wearing the brace and compared with the last X-ray before bracing(n=10) [1]. The average curve angle of the whole group was 15.6°, the average age was 19 years. Along with the X-Ray and scoliometer test to measure the Cobb's angle, this evaluation incorporates a muscle activity evaluation(EMG reaction) of the testing patients to see how it is after participants have used the brace during the research. Backbone Erector Spinae muscle and internus abdominus was measured as participants were in erect position [2]. As for a brace's effect with stretching exercise, evaluation was carried out 3 times during the research in two groups that were randomly divided into two groups for 12 weeks and evaluation was taken in between 4 weeks during exercise time.

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1.1 Research Method (Scoliometer & Cobb's method)

Research was conducted once according to detailed schedule in between patients and their conditions of scoliosis were determined by X-Ray results and scoliometer of a typical type. Angle was measured using Scoliometer by looking at Angle T when a line is drawn to measure at right angle (90°) from concave part from the top part of spine where it was most tilted to bottom most part of spine.

1. Group A(n=10) was chosen, Group A was separated into two random groups. One group wore FLEXpine while the other group wore a different brace.

2. Both groups regularly wore their brace for three months.

- •Evaluations were carried out three times during the research according to detailed schedule
- •Evaluations were conducted at same schedule with full participation from both groups.
- •Evaluation was conducted at the end of the research with participation from both groups.

When measuring of Cobb's angle before the research Cobb's angle was measured to compare the changes in two groups based on X-ray results. Participants' curvatures were checked to set a goal to achieve. When measuring of Cobb's angle in the middle of the research, progress made was compared with initial goal to track any changes and also setting a goal after comparing with Cobb's angle before the research was included. Lastly when measuring Cobb's angle after the research, curvature was measured at the end, and changes were tracked using statistic program to compare Flexpine with other braces [3].



Figure 1: Dorsal aspect of one of the patients with comparable curve patterns.

The right is after the patient wears a FLEXpine brace and the patient on the left wears no brace.



Figure 2: The patient is wearing a conventional brace made with plaster building technician. The special feature with this technique is that the brace is customized but still its static feature lets the user unable to wear for so long.

These patients have been treated according to the principles of the "FLEXpine" brace and were evaluated after an average treatment time of 15 weeks by a full-body X-ray taken in the standing position whilst wearing the brace and compared with the last X-ray before bracing. This brace is called 'FLEXpine" brace.

1.2 Research Method (EMG Reaction)

Evaluations were carried out three times during the research according to detailed schedule. And EMG electrodes were applied on ESM, and OIA laterally to participant's body at rest and Maximal Voluntary Isometric Contraction (MVIC) was measured three times 10 seconds at a time while participants were in position to create most voluntary force for each muscle. Rehab program was used to track changes in muscle activity levels. Muscle activity level was measured before using Flexpine and rehab program to be compared with the results after the middle and middle of the research to see if there were any effects on spine as well as muscles surrounding the area [4].

• EMG signal analysis

EMG signal data were process with EMGworks® Software EMG Analysis

Butterwort's band-pass filter method was used to analyze at Cut-off frequency of f1 450Hz, f2 15Hz which noise can be candled out by smoothing. Mean of EMG signal data which were gathered three times 10 seconds each time was used at 5 seconds each. And EMG signal data collected for 15 minutes were used to calculate the means when breathing was normalized.

1.3 Research Method (Exercise Program Following the Application of Flexpine)

Experts have gathered to pick out best exercise positions for scoliosis, and these exercises were tested to see if they are suitable for the research. Muscular exercises developed or modified for scoliosis were evaluated by experts to

determine if they are applicable for the research, then final exercise program was determined afterwards. Exercise program was then applied to 8 adult female participants along with using braces. X-ray was taken before the exercise program began. For 12 weeks, participants came for 5 days a week, one hour per day program. X-ray was taken after 12-week program has finished. X-rays were compared to prove the effectiveness of exercise on scoliosis. Following 12 weeks of exercise, 3 more consecutive weeks were followed to watch further changes afterwards totaling the final research period of 15 weeks.

1) Warm up

- 2) Marjaryasan
- 3) Virasana
- 4) Ardha Matsyendrasana

5) Plank

6) Limb twist

7) Bridge

8) Paschimottanasana

1.4 Results (Scoliometer & Cobb's method)

Scoliometer(°) when Flexpine was used resulted in 7.22 ± 1.45 which was 8.35 ± 1.82 before wearing; Flexpine. Scoliometer(°) did show improvement after wearing the brace.



Figure 3: This is picture of a patient with a correction in a Flexpine brace. Correction of a thoracic curve from 10° to 0° in a 29-year old woman with an experience of Flexpine brace. For the measurement of the corrected curve the conventional method of X-ray was used.



Figure 4: Double major scoliosis treated with a FLEXpine brace. Nearly 19 year old girl with a (40°/29° Double major AIS in the FLEXpine brace corrected to 16°/31° Cobb.)



Figure 5: This is an x-ray of a patient with another 10° thoracic curve with the correction of 10° with immediate measurement of the brace wearing. The effect of flexible brace comes to show for people within $10-20^{\circ}$.

• Change in Cobb's angle

8-week program where participants were wearing Flexpine had shown a change in Cobb's angle, and such was tested with a t-test(Paired-test) for analysis. Cobb's angle($^{\circ}$) before Flexpine was at 16.45±0.98 while result after the research has come out to be 13.23±3.24. Cobb's angle($^{\circ}$) did improve after wearing Flexpine.

Trials	Scoliometer (<i>t</i>)	Cobb's Angle (T)	P-value
First try	8.51±.82	16.45±0.98	.021
Second try	8.2±1.25	15.12±2.64	.034
Third try	7.22±1.45	13.23±3.24	.049

 Table 1: Cobb's Angle (Scoliometer & Cobb's method)

1.5 Results (Muscle Activity Level Test - EMG Reaction)

Muscle activity level was measured with first 5 minutes of Mid Frequence (MDF) after 5 hours of continuous usage of the braces.

Data values were separated as initial stage from 0-1 minute, mid-stage as 2-3 minutes, Late stage as 4-5 minutes in order to calculate the means at each stage. ESM and OIA's progress was monitored, and it did show a significance in terms of affects in muscle activity level (p<.01).

Objects	M±SD	F	Р
ESM	53.314±5.751		
OIA	51.484±8.156		
		32.3	.00
		79	0

Table 2: Muscle Activit	y Level Test	(EMG Reaction)	Result
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ESM: Erector Spinae Muscle ORA: Oblique Internus Abdominus

1.6. Results

(Exercise Program)

The research has been conducted on females with scoliosis for 12 weeks to look at the effects which exercise used with Flexpine could have on scoliosis. Yoga exercise program for scoliosis was performed and following results were obtained.

• Changes in Cobb's angle

The changes in Cobb's angle after 12-week long Flexpine Exercise program is as follow.

Cobb's Angle before 12-week Flexpine exercise program was measured at 7.65 ± 2.5 , but it has shown a result of 4.55 ± 2.32 after the program which was 3.1 degree less than before the research, significant level was p<.01 and showed significance.

Table 3:	Exercise	Program	Results
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Objects	Pre	Post	t	P-value
Experimental Exercising	7.65 ± 2.5	4.55 ± 2.32	10.84	.0001

Measurement of Cobb's Angle - Scoliometer & Cobb's Method

Change in Scoliometer angle has been studied by Boylston (2012) which showed a similar result where Scoliometer had decreased from 8.9 degree to 6.5 degree [5]. Scoliometer also showed significance in this research as well when looking at angle of lumbar vertebra and thoracic-lumbar spine as rubber band exercise has decreased the angle, and positively affected posture of participants. However, the result obtained from the research only proved the fact that Flexpine does improve the condition when Cobb's angle and Scoliometer angle were statistically tested but wider analysis on exercise programs for different causes need to be developed in the future.

Muscle Activity Evaluation (EMG Reaction) Test Result

Evidences for Flexpine's role in increasing muscle activity in the spine area were presented in the research, and actual data was obtained to show a correlation. Therefore, it could be suggested that scoliosis patients can increase their muscle activity by exercising while wearing Flexpine. This result suggests for further development of exercise program which can result in better outcomes when used with braces, and focus on flexibility of body muscle should be encouraged for optimal results.

• Exercise Program Test Result

This research was seeking to track changes in Cobb's angle through Flexpine usage and exercise program among adult participants with early to mid phase of scoliosis. It was proven that exercise program to correct posture while wearing braces do have positive impact on treatment of scoliosis, and braces which correct posture do actively support enactor muscles while strengthening abdominal and spine muscles to help patients with scoliosis.

Flexpine and its new development was to make the brace simpler, finer, easier to wear, and by this to lead a quality of life for the patients with scoliosis under brace treatment. The quality of experience and noticeable appearance from rear view for the patient may be the most concern for potential users [6], which can be deduced by the use of advanced bracing methods involving the finest possible correction available using flexible frame and elastic band [7]. The latest developments in the field of bracing, try to solely prove that there is evidence that brace treatment can stop curvature progression, reduce the frequency of surgery and improve brace wearing experience. And it is attempted by using elastic band and simultaneously with less material in contrast to current bracing systems (contrast with Fig. 1 and 2), but there has been lower attention to braces that give comfortable experience along with the curvature progression. But flexible frame, elastic band and material reduction should not result in lower effect [8]. The primary correction effect in the Flexpine brace that has been reassured and compared with that of other braces used before is the effect of exercise with the curvature correction gives a synergy effect to the brace users.

2. Conclusion

The use of the 'FLEXpine" brace leads to fixture of the curve above average when compared to the correction effects of other braces described in other case studies. The reduction of the frame size and lesser of the material

along with the powerful elastic bands seems to affect the desired correction in a positive way. Certain noticeable facts that have been noted by static braces have been included into a guideline for brace construction that is different from the custom plaster cast technique, for 3d printed designed braces, namely "FLEXpine" brace (patented) developed recently. Various bracing concepts are used today for the treatment of scoliosis. The plaster cast method worldwide seems to be the most practiced technique at the moment [9]. However, 3D printing with CAD systems are on the market which allow brace adjustments without plaster. The brightest development is the use of the FLEXpine which is made with an aim to provide flexible brace experience for scoliosis correction and to provide a more flexible and healthier treatment process.

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