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Original Article

Outcome of Pectus Carinatum Treatment with the FMF® Dynamic Compressor System

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Abstract

Background: The use of the FMF dynamic compressor system for managing pectus carinatum (PC) has recently gained popularity. However, its efficacy and factors affecting treatment success are under investigated. The objective was to evaluate the outcome of PC treatment using an FMF dynamic compressor system.

Methods: This retrospective cohort study included 56 patients aged 13–17 years diagnosed with PC and managed using compression braces. A custom-made brace was made and applied. Patients were instructed to wear the brace to the greatest extent possible for optimal outcomes. Subsequent visits were scheduled, first every 6-8 weeks and thereafter every 3-4 months, until chest correction was achieved. The study outcomes were treatment success and complications.

Results: 46 (82.14%) had successful treatment. The pressure at initial correction was significantly lower in the successfully treated group than in the unsuccessfully treated group (6.8 ± 3 vs. 9.4 ± 3.84 psi, p=0.022). The successfully treated group had a significantly greater initial pressure of treatment than the unsuccessfully treated group (4.3 ± 1.19 vs. 2.9 ± 1.07 psi, p=0.001). The mean time to correction in the successfully treated group was 4.02 ± 1.72 months. Regarding self-assessment of the chest in the successfully treated patients, there was significant improvement after 6 (5.4 ± 1.47) and 12 months (5.5 ± 1.7) compared to the baseline assessment (2.2 ± 1.22) (p<0.001 for both), with no significant difference between the assessments after 6 and 12 months (p=0.743). Age (β: 0.132; p=0.01), the pressure of initial correction (PIC) (β: -0.214; p= 0.024), and high PIC (β: 2.092; p= 0.001) were significant risk factors for correction time.

Conclusions: A chest wall brace for treating PC with a compressive mechanism to correct this chest wall deformity might be a viable option in children and young adolescents with a high success rate.

KEYWORDS

Pectus Carinatum; FMF® Dynamic Compressor System; Pressure Treatment

Article History

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Introduction

Pectus carinatum (PC) occurs when the chest wall protrudes anteriorly as a consequence of a spectrum of chest wall abnormalities. PC is the second most common chest wall deformity and occurs more commonly in males. It is characterized by outward angling of the sternum and its neighboring costal cartilages, and it has

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two primary subgroups: chondrogladiolar and chondromanubrial [1]. PC defects tend to worsen throughout pubertal development spurts and into adulthood. Patients with PC are at risk for a diminished quality of life and a distorted body image [2].

Surgery for PC has several drawbacks, including pain, discomfort, hospitalization, infection, and risk of complications. Therefore, using a chest wall brace, an FMF dynamic compressor system, is the primary nonsurgical method for treating PC patients [3]. The FMF® Dynamic Compressor System (DCS) was jointly developed by Martinez-Ferro and colleagues in Argentina in 2001. Presently, it is widely utilized on a global scale [4]. The FMF® DCS corrects the PC gradually by widening and remodeling the whole chest and cartilage by constant anterior-posterior compression. The cartilage is then adjusted, expanded, and ultimately ossified to the proper position [3].

Despite the increasing use of the FMF dynamic compressor system, its efficacy and factors affecting treatment success have yet to be investigated. Therefore, this study aimed to assess the outcome of PC treatment using FMF® DCS.

Patients and Methods

Design

This retrospective cohort study included 56 patients aged 13–17 years diagnosed with PC and instructed to wear the compressive brace as long as they could or could wear it for 24 hours daily. Patients were recruited between March 2022 and March 2023. Before treatment, all patients provided written consent to use their medical data. The institutional ethical committee approved the study (Reference Ethical Number: REC675).

Patients

The study included patients aged 13-17 years diagnosed with PC. The exclusion criteria included patients older than 17 years and patients with very large deformities with a pressure of initial correction (PIC) greater than seven psi. These patients are usually associated with poor outcomes, as bone growth stops after 17 years of age, and it is very difficult to remodel the deformity. Additionally, with a highly increased PIC for very large deformities greater than seven psi, it is very difficult for the deformity to remodel.

Technique

A custom-made brace was made and applied in conjunction with the instructions for use. To achieve optimal outcomes, patients were instructed to wear the brace for as long as possible. Subsequent visits were scheduled at initial intervals of 6-8 weeks and every 3-4 months thereafter until the chest had been properly corrected (correction phase: time to correction). Following chest correction, patients entered the retainer mode, also known as the weaning phase, during which they progressively reduced the duration of brace usage until the conclusion of therapy [5, 6]. The combined duration of the corrective and weaning phases was known as the "total treatment duration." The surgeon and the patient established the time the chest had fully corrected, and therapy was concluded (after assessing the chest wall together). When patients expressed dissatisfaction or lost motivation to adhere to the brace, brace therapy was discontinued.

All patients were subjected to a full medical history, clinical examination, and radiological examination via chest CT and echocardiography.

All patients were treated with FMF-DCS (made by Pampamed Buenos Aires, Argentina). It is a custom-made aluminum brace with a pressure-measuring device affixed to the front plate for compression. Sideways movement of the plate can correct asymmetrical or symmetrical abnormalities. The FMF® DCS corrects pectus carinatum gradually by using continuous anterior-posterior compression to widen and remodel the entire chest and cartilages, which accommodate, grow, and finally ossify in the correct position.

The PIC denotes the cumulative pressure, expressed in pounds per square inch (psi), necessary to achieve the sternum's anatomically normal or intended position. The measurement involves applying pressure to the patient's anterior chest wall while the patient is upright

against a wall, with the pressure-measuring instrument being pressed until full correction is achieved. The height of the deformity was determined by measuring the distance from the protrusion to the correction site. A daily maintenance pressure of 2.0 to 3.0 psi constitutes the pressure of treatment (POT) utilized during brace therapy. Initially, the brace was adjusted by the surgeon only. Occasionally, patients were given guidelines on incrementally raising the POT at their residence when they gained confidence in the device [3].

Patients resumed their initial fitting visit once the brace had been delivered. The treatment pressure was adjusted to an acceptable psi, often between 1.5 and 2.5 psi, and the brace was fitted to the patients. Patients who were equipped with the brace continued to ambulate within the clinic to make any necessary changes. Patients were instructed to wear the brace for 23 hours each day, over a T-shirt or on the bare chest, depending on their comfort and preference. They were advised to remove the brace before physical activity or showering. The patients were motivated to engage in an exercise regimen with the dual purpose of enhancing their posture and strengthening the chest wall muscles to initiate the active phase of bracing therapy for these individuals. Re-evaluation by an advanced practice nurse or surgeon was scheduled for the patients every 6 to 8 weeks after an initial follow-up visit one month after the beginning of the bracing.

The brace was adjusted as necessary following the measurement and recording of the treatment pressure. The patient's chest had to be in a neutral or flat posture, while a treatment pressure of 0.0 to 0.5 psi was applied for successful bracing treatment. Once the deformity had been initially corrected, the patients were advised to wear retainers for eight to twelve hours each night while maintaining a neutral chest posture (retaining mode). The same brace was utilized during both the active treatment period and the retainer phase. The timelines for the bracing and retainer procedures were specified [7].

Patients were monitored every two to three months until the conclusion of therapy while in retainer mode. Once the patient's chest maintained a neutral or flat posture without using a brace, the treatment was considered fully complete. Following the conclusion of treatment, the brace was removed, and the patients were assessed annually.

Follow-up

Outpatient follow-up was conducted every two to three months after applying the compressive brace. We attempted to perform a follow-up chest CT for comparative purposes. Chest CT of the PC was performed during the follow-up, and both the axillary straps' fastening and the brace's effectiveness were assessed. The appropriate tension was applied to the axillary straps if they were slack.

Assessment of chest

For clinical follow-up during appointments, pressure monitoring by measuring the PIC was our clinical method for monitoring improvements in treatment outcomes.

Data and outcomes

The following variables were collected for the study: age at presentation, age at onset, sex, body mass index, type of PC, presenting symptoms, pressure of initial correction, carinatum height, time to correction, and time of use per day. The study outcomes were treatment success and complications. Self-assessments were conducted at 6 and 12 months using a score from 1 to 10, with 10 indicating the highest satisfaction.

Statistical analysis

SPSS v28 (IBM Inc., Armonk, NY, USA) was used for the statistical analysis. The chi-squared test or Fisher's exact test, as applicable, was used to analyze qualitative variables expressed as frequencies and percentages (%). Quantitative variables expressed as the mean and standard deviation (SD) were compared between two groups using the independent-sample Student's t-test. A paired sample t-test is a statistical method utilized to compare the means of two populations when there is a correlation between two samples. Linear regression was utilized to examine the relationship between a single dependent variable and several independent variables. A two-tailed P

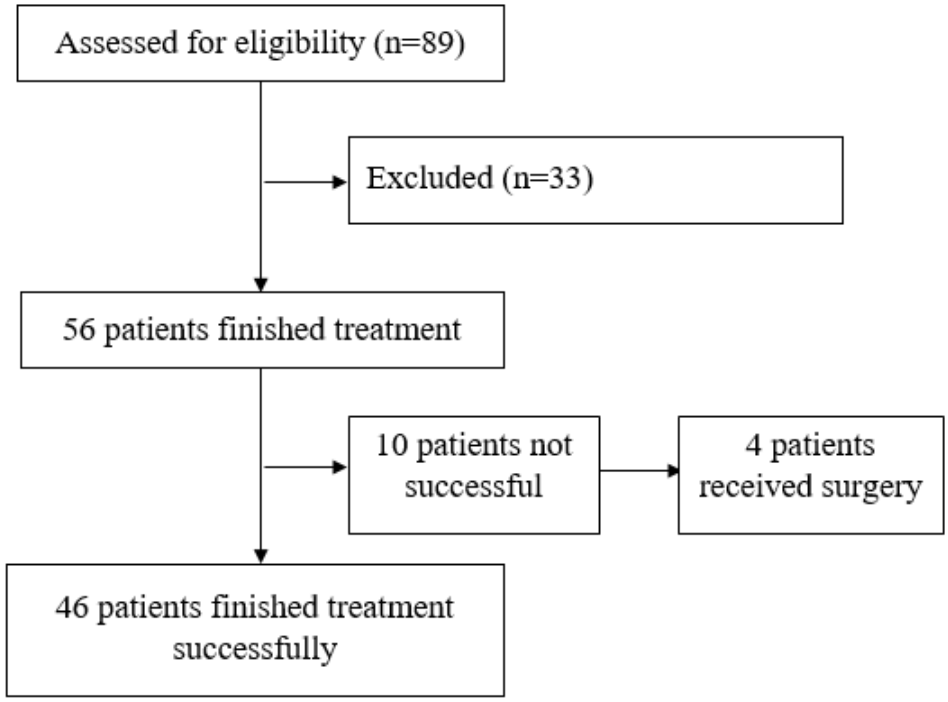

Figure 1: The study flowchart

value < 0.05 was considered to indicate statistical significance.

Results

Patients

The study included 56 patients who completed the treatment. Figure 1 shows the study flowchart.

Baseline data

Most of the included patients were males (n= 50, 89.29%), and 6 (10.71%) were females; their mean age was 15.7 ± 5.44 years, and the mean patient age at onset was 10.98 ± 2.57 years. The mean weight was 35.3 ± 5.84 kg, the mean height was 1.5 ± 0.03 m, and the mean body mass index (BMI) was 15.8 ± 2.63 kg/m2. The defect type was chondrogladiolar in 42 (75%) patients and chondromanubrial in 14 (25%) patients. Among the studied patients, 40 (71.43%) had symmetric deformities, and 16 (28.57%) had asymmetric deformities. Regarding the symptoms at presentation, we noted that many patients had more than one symptom, 21 (37.5%) patients had a physical appearance (asymptomatic), 13 (23.21%) patients had chest tenderness, 10 (17.86%) patients had shortness of breath, 8 (14.29%) patients had exercise intolerance, and 4 (7.14%) patients had chest pain (Table 1).

Table 1: Baseline characteristics, clinical data, and symptoms at presentation of the study sample. The data are presented as the mean ± SD or frequency (%)

Variables	(n=56)
Age (years)	15.7 ± 5.44
Patient age at onset (years)	10.98 ± 2.57
Male	50 (89.29%)
Weight (kg)	35.3 ± 5.84
Height (m)	1.5 ± 0.03
BMI (kg/m^2)	15.8 ± 2.63
Defect type	
Chondrogladiolar	42 (75%)
Chondromanubrial	14 (25%)
Symmetry of deformities	
Symmetric	40 (71.43%)
Asymmetric	16 (28.57%)
Symptoms at presentation	
Physical appearance (asymptomatic)	21 (37.5%)
Chest tenderness	13 (23.21%)
Shortness of breath	10 (17.86%)
Exercise intolerance	8 (14.29%)
Chest pain	4 (7.14%)

BMI: Body mass index

Correction data

The mean PIC was 7.4 ± 3.21 psi, the mean carinatum height was 3.8 ± 1.3 cm, the mean initial

POT in PSI was 4.1 ± 1.28, the mean time to correction was 3.9 ± 1.7 months, and the mean duration of use every day was 20.1 ± 2.64 (Table 2).

Table 2: Correction data for the study sample. The data are presented as the means ± SDs

Variables	Total (n=56)
Pressure of initial correction	7.4 ± 3.21
Carinatum height (cm)	3.8 ± 1.3
Initial pressure of treatment in PSI	4.1 ± 1.28
Time to correction (months)	3.9 ± 1.7
Time of use per day	20.1 ± 2.64

PSI: Pounds per square inch

Outcomes

Forty-six (82.14%) patients were successfully treated. Aside from the early discomfort that accompanied the application of the compressive brace, no severe complications occurred. Skin rashes occurred in 4 (7.14%) patients, and discolorations occurred in 2 (3.57%) patients; they were temporary and normalized after the brace was removed.

There was an insignificant correlation between the PIC and age of the studied patients (r=0.116, p-value = 0.396). When comparing successfully treated and unsuccessfully treated patients, we found no significant differences between the groups regarding baseline characteristics (age, patient age at onset, sex, weight, and height). The successfully treated group had significantly lower PIC than the unsuccessfully treated group. The initial correction rate pressure was significantly greater in the successfully treated group than in the unsuccessfully treated group. The mean time to correction in the successfully treated group was 4.02 ± 1.72 months. There was no significant difference between the two groups regarding the abundance of Carinatum (Table 3).

Regarding self-assessment of the chest in the successfully treated patients, there was significant improvement after 6 (5.4 ± 1.47) and 12 months (5.5 ± 1.7) compared to the baseline assessment (2.2 ± 1.22) ($p<0.001$ for both), with no significant difference between the self-assessments after 6 and 12 months (p=0.743). Age (β: 0.132; p=0.01), PIC (β: -0.214; p= 0.024) and high PIC (β: 2.092; p= 0.001) were significant risk factors for correction time (Table 4).

Table 3: Comparison of baseline and correction data between successfully and unsuccessfully treated patients. The data are presented as the means ± SDs or frequencies (%).

Variables	Successfully treated group (n=46)	Unsuccessfully treated group (n=10)	P value
Baseline data			
Age (years)	16.02 ± 5.57	14.1 ± 4.77	0.316
Patient age at onset (years)	10.8 ± 2.51	11.7 ± 2.83	0.334
Male	42 (91.3%)	8 (80%)	0.152
Weight (kg)	34.8 ± 6.03	37.4 ± 4.55	0.209
Height (m)	1.5 ± 0.03	1.5 ± 0.04	0.254
Correction data			
Pressure of initial correction	6.8 ± 3	9.4 ± 3.84	0.022
Pressure of initial correction			
Low (≤ 5.0 PSI %)	27 (58.7%)	2 (20%)	
Intermediate (5.1–7.5 PSI %)	15 (32.61%)	3 (30%)	0.004
High (≥7.6 PSI %)	4 (8.7%)	5 (50%)	
Carinatum	3.8 ± 1.3	3.96 ± 1.37	0.739
Initial pressure of treatment in PSI	4.3 ± 1.19	2.9 ± 1.07	0.001
Time to correction (months)	4.02 ± 1.72		

PSI: Pounds per square inch

Table 4: Linear regression analysis of risk factors for the time for correction in patients who successfully completed treatment

Variables	β	P
Age (years)	0.132	0.010
Patient age at onset (years)	0.142	0.197
Sex (female)	0.485	0.700
Pressure of initial correction	-0.214	0.024
Pressure of initial correction (intermediate vs. low)	0.276	0.374
Pressure of initial correction (high vs low)	2.092	0.001
Carinatum	0.040	0.856
Initial pressure of treatment in PSI	-0.264	0.198

PSI: Pounds per square inch

Discussion

PC occurs when the chest wall protrudes anteriorly because of a spectrum of abnormalities [8]. Although several surgical treatments have been documented, excision of all damaged cartilage and osteotomy of the sternum are the most common. The outcomes of this procedure were deemed good, with a postoperative recurrence rate of approximately 2% [9]. Nevertheless, some patients with PCs and their guardians decline surgery due to concerns about anesthesia, aesthetic issues at the surgical site, postoperative discomfort, and complications associated with the procedure. As a result, a compressive brace was created as a nonsurgical therapy [10].

Although brace therapy, which involves applying pressure to the anterior sternum to correct the projecting sternum, has been used since the 1970s, it did not receive widespread recognition until the dynamic compression system was introduced in 2008 [11-15]. Former braces frequently resulted in dropout rates of up to 40%, most of which were attributable to undesirable side effects such as skin lesions and pain, mostly caused by the high pressure employed [12-14].

Regarding the success rate, 46 (82.14%) patients were successfully treated, and 10 (17.86%) patients were unsuccessfully treated. According to Beer and associates [3], treatment was successfully completed in 85% of patients, while 24% of patients experienced a failed therapy or were lost to follow-up. A greater number of asymmetrical abnormalities were observed in this group, which may indicate that prolonged brace therapy is related to asymmetrical deformities.

Bracing was effective in most patients in the short and medium term, with few complications, according to the findings of Poola et al. [7]. Although this is not the case for every patient, their data suggested that an increase in the duration of brace treatment and a reduction in the PIC increased the likelihood of successful treatment. We observed that the successfully treated group had significantly reduced PIC in comparison to the unsuccessfully treated groups. The successfully treated group had a significantly greater initial POT rate than the unsuccessfully treated group. The mean time to correction in the successfully treated group was 4.02 ± 1.72 months.

Beer and associates [3] reported a significantly greater PIC in patients who were unsuccessfully treated (7.6 ± 1.8 psi) than in patients who were successfully treated (6.7 ± 1.7 psi). A total of 53.3% of the unsuccessfully treated patients exhibited a high PIC, while 35.2% of the patients in the successful group exhibited a high PIC. We found an insignificant correlation between age and PIC. Regression analysis revealed that age and high PIC were significant risk factors for prolonged correction duration.

Four hundred and sixty patients composed the largest cohort of patients who underwent dynamic compression bracing, as described by Dekonenko et al. [16]. However, no correlation was detected between the time to correction and the initial correction pressure or pectus height.

A reduced PIC and an extended brace time were deemed to affect the resolution probability significantly. It is logical to assume that extended periods of active brace use might result in a greater percentage of success. A prior report has documented this finding [11]. Patients with a PIC greater than 7.5 psi were first advised against using DCBs [15, 17]. Nonetheless, other investigations have failed to establish a correlation between bracing failure and a high PIC [13, 18, 19]. The bracing program developed by Poola and colleagues [7] incorporated seven individuals with a PIC above seven.

Regarding complications, we observed skin rashes in 4 (7.14%) patients and discolorations in 2 (3.57%) patients. Both were temporary and normalized after brace removal. Lee and colleagues [12] showed that, aside from initial pain while starting to wear the compressive brace, none of the 119 patients experienced any unusual complications. A total of 84 individuals developed skin rashes on the anterior compressed chest area (70.6%). Chest wall compression can cause skin lesions to develop. Skin discoloration developed in 18 patients (15.1%) due to the rapid corrective technique involving severe compression. Poola and coworkers [7] examined 52 patients (23%) who reported difficulty using a brace. Skin erythema or disintegration, which occurred in 22 individuals without indications of infection, was the most prevalent (10%). Eighteen patients (8%) experienced brace mechanical problems, which impeded their progress and necessitated the replacement of components. Subjective complaints of tightness were reported by seven patients (3%), whereas pain associated with the brace was experienced by five patients (2%). Over 75% mentioned no complications during their bracing time.

We reported significant improvement after 6 and 12 months compared to the baseline assessment, with no significant difference between the self-assessments between 6 and 12 months.

According to a previous study, patients visually evaluated their chests with a scale of 1–10 prior to and throughout therapy. A significant improvement in scores was observed following six months of bracing. Prior to the initiation of brace treatment, the average chest score determined by self-assessment was 4.0. This score improved to 7.8 after six months of therapy. The scores were stable and significantly improved after 12, 18, and 24 months compared to the initial assessment. [3]

Limitations of the study

This research was a single-center study with a relatively small sample size. We did not compare PC treatment using the FMF® dynamic compressor system with surgical intervention. We recommend further studies with larger sample sizes and comparing the FMF® dynamic compressor system with surgical intervention.

Conclusion

A chest wall brace for the treatment of PC with a compressive mechanism to correct this chest wall deformity might be a viable option in children and young adolescents with a high success rate. The complications are mild and can easily be resolved. Additionally, it permits in situ outpatient clinic adjustments and avoids the need for referrals.

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