Non-surgical Treatment for Pectus Excavatum and Carinatum

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Frank-Martin Haecker and Marcelo Martinez-Ferro

Abstract

Pectus excavatum (PE) and carinatum (PC) are characterized by an abnormal overgrowth of sternal and costal cartilages, which result in a depression or protrusion of the sternum and costal cartilages, respectively. Both chest wall malformations are cosmetic and functional pathologies. Whereas PE is commonly associated to cardiopulmonary dysfunction, PC causes deformation of the entire thoracic cage. PE is generally corrected operatively. In contrast, due to inherent risks of a major surgery, only severe cases of PC are operated. One of the authors (FMH) will describe his 12 years experience with vacuum bells to treat PE patients conservatively. The use of vacuum bells allow significant lift of the ribs and sternum, until definitive correction of cartilage growth takes place. When employed during minimally invasive repair of PE (MIRPE), vacuum bells can also be used as a tool to enhance retrosternal dissection, advancement of the pectus introducer and insertion and flipping of the pectus bar/s. The other author (MMF) will describe his 13 years experience with the FMF® Dynamic Compressor System to treat patients with PC conservatively. When considering results, there should be little doubt that no patient would be selected as a candidate for surgery before trying a non-operative approach. Further evaluation and follow-up studies are still necessary for both conservative approaches, though.

F.-M. Haecker, MD, FEAPU (✉)
Department of Pediatric Surgery,
University Children's Hospital, Basel, Switzerland
e-mail: frankmartin.haecker@ukbb.ch

M. Martinez-Ferro, MD
Department of Surgery,
Fundacion Hospitalaria Children's Hospital,
Buenos Aires, Argentina

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Introduction

Pectus Excavatum (PE) and Carinatum (PC) are characterized by an abnormal overgrowth of sternal and costal cartilages, which result in a depression or protrusion of the sternum and costal cartilages, respectively.

Far from being an aesthetical condition, patients not only manifest psychological problems and disorders (discomfort, shame, shyness, anxiety, anguish, depression and social isolation), but also a series of physical signs and symptoms as chondrosternal and/or chondrocostal pain, sport intolerance, scoliosis, posterior asymmetry, impaired shoulders, kyphotic position, and specially in the case of PE patients, history of bronchospasms, repeated and prolonged respiratory disease, diminished stroke volume and mild to moderate heart dysfunction (in general only revealed by an echo stress test or cardiac MRI; not by usual exams). Cardio-respiratory disorders are very rare in PC patients, yet progressive thoracic cage deformation becomes evident with age.

PE is, in general, treated operatively, namely by Ravitch and variations, Nuss = Minimally Invasive Repair of Pectus Excavatum (MIRPE) or other techniques [1–8]. Among these variants, the authors prefer to operate on patients using the Nuss technique (MIRPE), described in 1998 by Dr. Donald Nuss et al. [9].

Consequent to the intrinsic risks of a major surgery, the operative treatment for PC was reserved for the most severe cases. Many PC patients remained untreated as a result.

Along the course of time, different non-operative approaches have been proposed to deal with these untreated PC patients [10–16]. One of the authors (MMF) co-invented with his partner, Dr. Carlos Fraire, the FMF® Dynamic Compressor System (DCS), and will hereby describe his 13 years experience with it [17–19].

On the other hand, the non-operative approach for PE, first published by Schier et al. consists in the utilization of vacuum bells in selected cases. The other author (FMH) will give an account of his 12 years experience with vacuum bells to treat PE patients non-operatively as well as during MIRPE [20–22].

Pectus Excavatum

Introduction

During last century, surgical repair represented the gold standard to correct PE in childhood and adolescents as well as adult patients. Previously used operative techniques to correct PE were largely based on open procedures and minimally invasive techniques. In 1998, Nuss et al. reported for the first time, their 10-year experience using a new technique of minimally invasive repair of PE (MIRPE) [9]. Today, the MIRPE technique is well established and represents a commonly used technique [23–26]. However, with its widespread use, the character and number of complications has increased [23–25, 27, 28]. Moreover, numerous recent studies report on an increasing number of near fatal complications [28–34]. Furthermore, in many cases of PE, the degree of pectus deformity does not immediately warrant surgery. Some patients are reluctant to undergo surgery because of the pain associated with the postoperative recovery and the risk of imperfect results.

In this situation, the introduction of the vacuum bell for conservative treatment of PE has made this alternative therapy a focus of interest for patients and physicians. The procedure of applying a vacuum to elevate the sternum was first used more than 100 years ago [35]. Spitzy and Lange reported their experience using a glass bell to correct PE [36]. Inadequate material and relevant side effects eliminated the routine

use of this method for conservative treatment of PE. Despite the above-mentioned risks and unsatisfactory results after operative therapy for some patients, there has been little progress in the therapeutic use of the vacuum therapy during the last few decades. In the meantime, materials have improved and the vacuum devices can now exert strong forces. In 1992, the engineer Klobe E, who himself suffered from a PE, developed a special device for conservative treatment of PE [37]. Using his device during a period of 2.5 years, he was able to elevate the sternum and to correct his funnel chest to an extent that no funnel was visible any more [37].

Preliminary results from pilot studies using this method proved to be promising [20, 21]. Information on such new therapeutic modalities circulates not only among surgeons and paediatricians, but also rapidly among patients. In particular patients who refused operative treatment by previously available procedures, now appear at the outpatient clinic and request to be considered for this method.

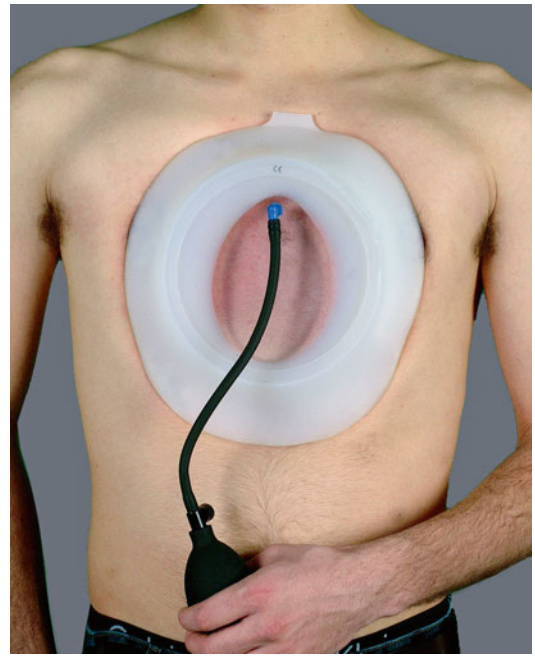

Fig. 17.1 Application of the vacuum bell

The Vacuum Bell

Description

A suction cup is used to create a vacuum at the chest wall. The body of the vacuum bell is made of a silicon ring and a transparent polycarbonate window. A vacuum up to 15 % below atmospheric pressure is created by the patient using a hand pump (Fig. 17.1). Three different sizes (16 cm, 19 cm and 26 cm in diameter) exist allowing selection according to the individual patients age and shape of the ventral body surface (Fig. 17.2). The medium size model is available in a supplemental version with a reinforced silicon wall (type "bodybuilder"), e.g. for adult patients with a small deep PE. Additionally, a model fitted for young girls and women is available (Fig. 17.3). Pilot studies performed by Schier and Bahr [20] showed that the device lifted the sternum and ribs immediately. We could also confirm this effect by thoracoscopy during the MIRPE procedure [22]. According to the user instructions and our experience, the vacuum bell should be used for a minimum of 30 min, twice per day, and may be used up to a maximum of several hours daily. The vacuum bells by E. Klobe are CE certified and patent registered. In USA, the device was approved by the food and drug administration (FDA) in May 2012.

Indication and Contraindication

Indication for conservative therapy with the vacuum bell include patients who present with mild degree of PE and/or who want to avoid surgical procedure. In particular patients under the age of 10 years with a still flexible and elastic chest wall represent good candidates to start with the application.

Contraindications of the method comprise skeletal disorders, vasculopathies, coagulopathies and cardiac disorders [38]. To exclude these disorders, a standardised evaluation protocol was routinely performed before beginning the therapy.

Complications and relevant side effects include subcutaneous hematoma, petechial bleeding, dorsalgia and transient paresthesia of the upper extremities during the application.

Fig. 17.2 Vacuum bell in three different sizes (left 16 cm, middle 19 cm, right 26 cm in diameter)

Fig. 17.3 Vacuum bell, model for adolescent girls/women

Methodology

All patients who visit our specialized outpatient clinic for chest wall deformities are informed about the option of conservative vs. surgical therapy to correct PE. Standardised evaluation includes history of the patient and his family, clinical examination and photo documentation of the PE. The depth of PE is measured in a standardized supine position. When the patient and/or the parents decide to perform the conservative vacuum therapy, meticulous family history is necessary to capture the above-mentioned contraindications. To exclude cardiac anomalies, we do routinely cardiac evaluation with electrocardiogram and echocardiography before starting the daily application in every patient.

Conservative Treatment

The first application of the vacuum bell occurs during the outpatient clinic visit under supervision of the attending physician. The appropriate size and model of the different type is defined. Patients learn the proper application of the device. In children under the age of 10 years, parents are instructed to use the device and children apply the vacuum bell under supervision of their parents or caregivers, respectively. The middle of the window should be positioned above the deepest point of the PE. Starting the application, the hand pump should be activated with 2–3 pumps. Patients are usually in a supine position for the first application. During therapy, most adolescent and adult patients apply the device in an upright position whereas parents of children under the age of 10 years prefer to continue in a supine position. With the device in position, patients may move and walk around in their home environment.

In patients with a localized deformity, it could be helpful to apply the device using the small model. In patients with an asymmetric PE or a grand canyon type PE, it could be useful to apply the device in changing positions.

When cardiac anomalies and other contraindications are excluded, patients may start with the daily application. All users are recommended to start to use the device twice daily for 30 min

each. During follow-up, some patients follow the user instructions applying the device twice daily for 30 min each. However, some of the adult patients use the vacuum bell up to 8 h daily during office hours. A group of adolescent boys apply the device every night for 7–8 h. Since there does not yet exist a detailed study protocol for the application, the duration and frequency of daily application depends on the patients' individual decision and motivation.

Patients undergo follow-up at 3–6 monthly intervals including clinical examination, measurement of depth of PE and photo documentation. Clinical examination focuses on the improvement of depth of PE as well as on relevant side effects such as persistent hematoma and/or skin irritation. If necessary, tips and tricks to optimize the application are discussed. The endpoint of therapy is defined by the patient's individual decision, which is confirmed by our clinical examination during the routine outpatient clinic visit. In addition to the daily vacuum bell application, all our patients are recommended to carry on undertaking sports and physiotherapy, so that the accompanying improvement of body control results an important factor in outcome.

Patients

Our patients group comprises applicants aged from 3 to 61 years. As mentioned previously, we observed age specific differences of success [39], and therefore the most favourable age for this treatment has still to be defined.

During the first few applications, most of the patients experience moderate pain in the sternum. Adolescent and older patients develop moderate subcutaneous hematoma, which disappears within a few hours. Temporary side effects like transient paresthesia of the upper extremities during the application and/or mild dorsalgia are reported by some patients. These symptoms disappear when lower atmospheric pressure is used during application. Analgesic medication should not be necessary and has not been reported from any patient and parents, respectively. As mentioned above, the application of the vacuum bell in children aged 3–10 years should be supervised by parents or caregivers.

Results

Within the last 11 years, 300 patients (62 female, 238 male) started with vacuum bell treatment at our institution. The median age was 16.2 years (3–61 years). When starting with the application, 67/300 patients were above the age of 17 years, 58/300 above the age of 18 years. We published preliminary results of a subset of our patients group in 2011 [38]. Latest and more detailed results were summarized in another published study [39]. Hundred and forty patients (112 males, 28 females), aged 3–61 years (median 16.05 years) used the vacuum bell for 6 to maximum 69 months (average 20.5 months). When starting with the application, patients presented with a PE with depth from 1 to 6.3 cm (average 2.7 cm). After 3 months of treatment an elevation of more than 1 cm was documented in approx. 80 % of patients.

Daily application of the whole group was 107.9 min/day (range, 10–480 min). Application was terminated after 20.5 months. In 61 patients, the sternum was lifted to a normal level after 21.8 months (range, 6–69 months) (Figs. 17.4 and 17.5).

The follow-up after discontinuation is 27.6 months (range, 1–73 months), and the success until today is permanent and still visible (Figs. 17.4 and 17.5). Patients were very well motivated and compliant which is a basic precondition for a successful therapy. At follow-up, all patients were satisfied and expressed their motivation to continue the application, if necessary. Fifty-four patients are still under treatment. However, 25/140 patients stopped the application after 15.7 months (range, 1–42 months), due to an unsatisfactory result and/or decreasing motivation. 15/25 patients underwent MIRPE. The relevance of motivation was confirmed by the fact that 15 patients who underwent MIRPE, used the vacuum bell for 160.6 min/day whereas the remaining 10 patients who stopped any kind of therapy, used the vacuum bell for 36.3 min/day. In three patients with asymmetric PE, the depth of PE has decreased after 9 months, but the asymmetry is still visible (Fig. 17.6).

Intraoperative Use

Our experience with the vacuum bell method encouraged us to use the device intraoperatively during the MIRPE procedure to facilitate the dissection of the transmediastinal tunnel and the advancement of the pectus introducer, the riskiest step of the MIRPE procedure. As already demonstrated by Schier and Bahr for the first time [20], the elevation of the sternum is obvious and persists for a distinct period of time after application of the vacuum bell. Therefore, we considered that the vacuum cup may also be useful in reducing the risk of injury to the heart and the mammary vessels during the MIRPE procedure. Since the manufacturer of the device did not apply for the approval to sterilize the vacuum bell until today, this additional use had to be considered as "Off-label". In agreement with our hospital hygienist and bearing in mind the nature of the material, we used gas sterilization for preparation of the device for intraoperative use.

Results

In a pilot study performed from 2005 to 2010, 50 patients aged from 9 to 28 years (average 14.95 years; 39 males and 11 females) were operated on for PE using the MIRPE procedure. Thirty-eight patients underwent primary surgery. Twelve patients (11 male, 1 female) used the vacuum bell for a period of 4–36 months (average 19.9 months) before surgery, and discontinued the

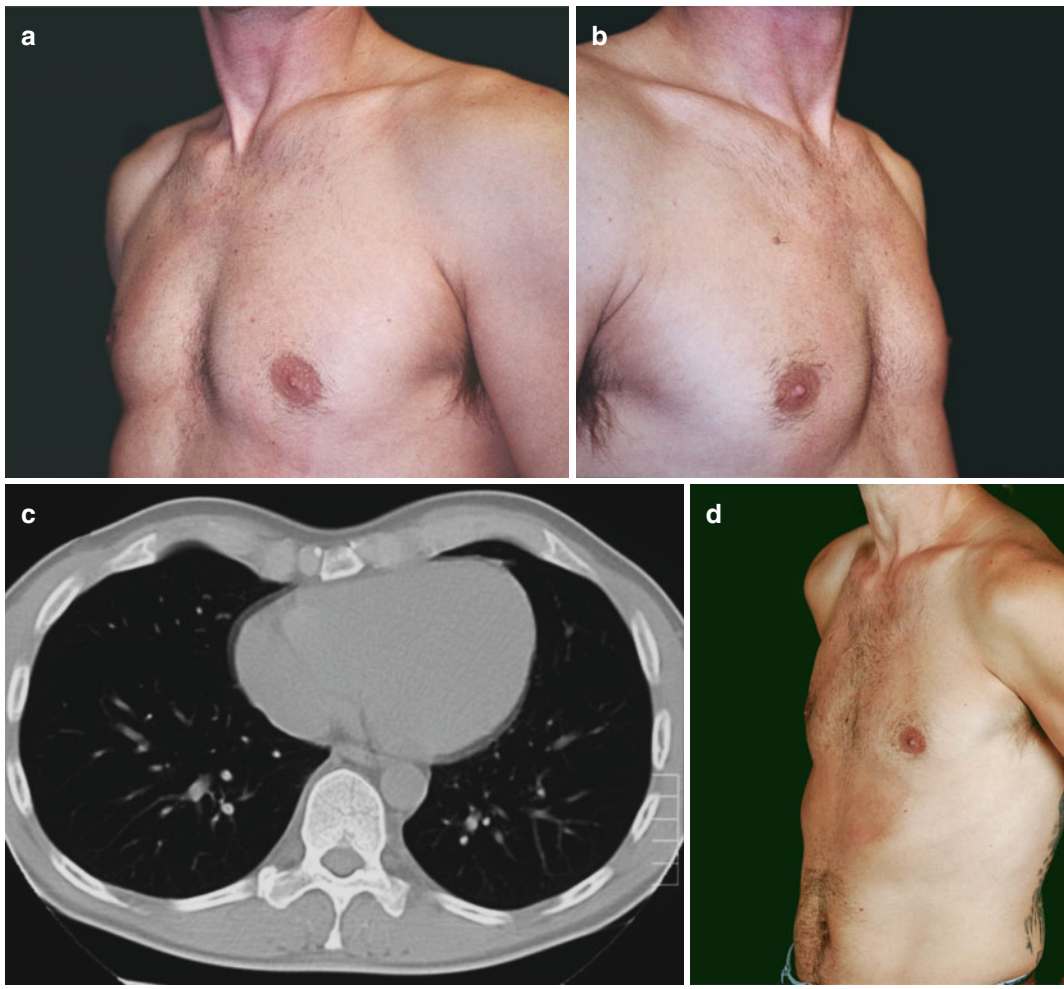

Fig. 17.4 Forty-five-year-old patient. (**a**–**c**) before (*left*: depth of PE = 2.5 cm) vacuum bell therapy and (**d**–**f**) after 12 months (*right*: depth of PE = 0.5 cm)

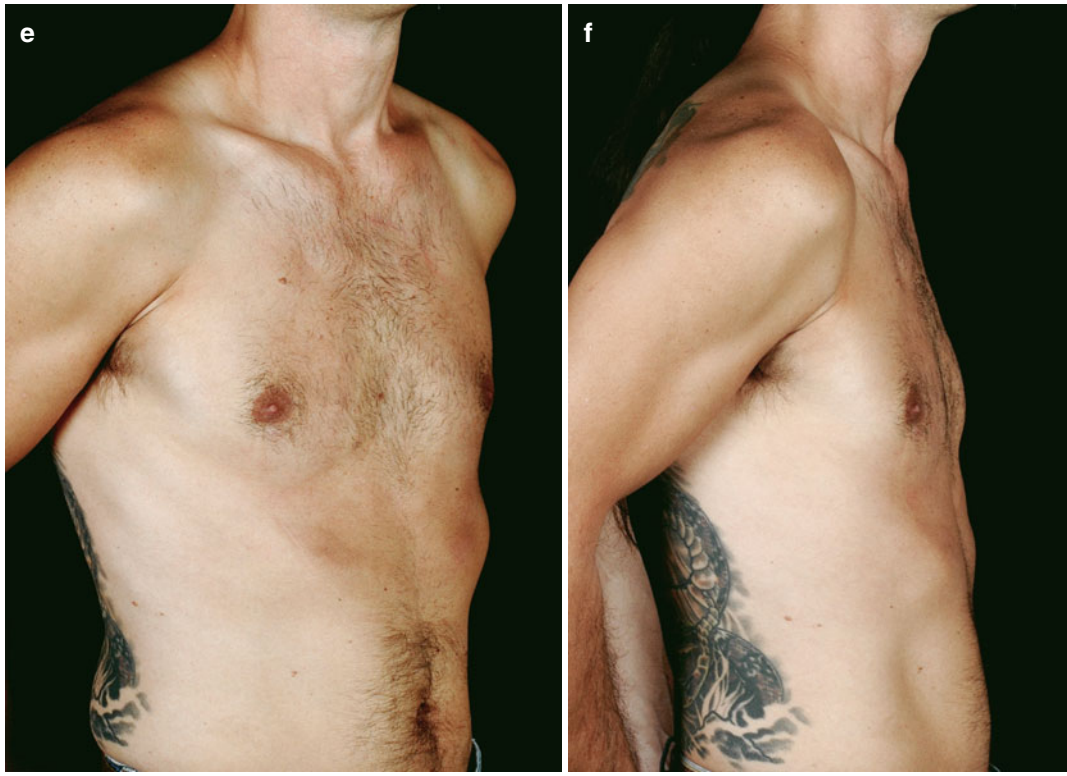

Fig. 17.4 (continued)

application due to decreasing motivation and/or insufficient success. The vacuum bell was applied for retrosternal dissection and advancement of the pectus introducer as well as placement and flipping of the pectus bar. The use of the vacuum bell led to a clear elevation of the sternum and this was confirmed by thoracoscopy (Fig. 17.7). Advancement of the pectus introducer and placement of the pectus bar was safe, successful and without adverse events in all patients. No evidence of cardiac and/or pericardiac lesions or lesions of the mammary vessels were noted intraoperatively by using right sided thoracoscopy. Additionally, no midline incision to elevate the sternum with a hook was necessary [22].

Discussion

A more differentiated analysis of our patients group will enable us "to see behind the curtain". Age and gender specific differences, depth of PE, symmetry or asymmetry, concomitant malformations like scoliosis and/or kyphosis, etc. may influence the clinical course and the success of this therapy. The influence of individual motivation on the success has been described above.

However, there still remain some unanswered questions:

Optimal age for vacuum bell therapy The optimal age for this treatment has still to be defined. We observe age specific differences of success. In our experience, growth spurt during puberty is the most important period to influence degree and depth of PE. We started a pilot study using a measuring device which might enable us to measure the correlation between patients age, the depth of PE and the elevation of the chest wall during application. With these results, we may evaluate whether beginning with the vacuum therapy before puberty will be more useful than starting during puberty or even later.

Quantitative Measurement of Pressure The success of a therapeutic procedure not only requires a

Fig. 17.5 Nine year old boy, (**a**) before (*left*: depth of PE = 2.8 cm) vacuum bell therapy, (**b**) after 10 months (*right*: depth of PE = 1.6 cm), (**c**) after 16 months (depth of PE: 0.4 cm), (**d**) 24 months after therapy and (**e**) 36 months after therapy

good technique, but also depends on an appropriate indication. It would be useful to measure the pressure that is necessary to lift the sternum during the first application. This measurement would enable us to divide patients into different groups, to identify suitable patients, and allow us to predict more accurately who of the users will benefit from this method and in whom the method will not work. As mentioned above, we are working on such a device to measure the pressure under the vacuum bell.

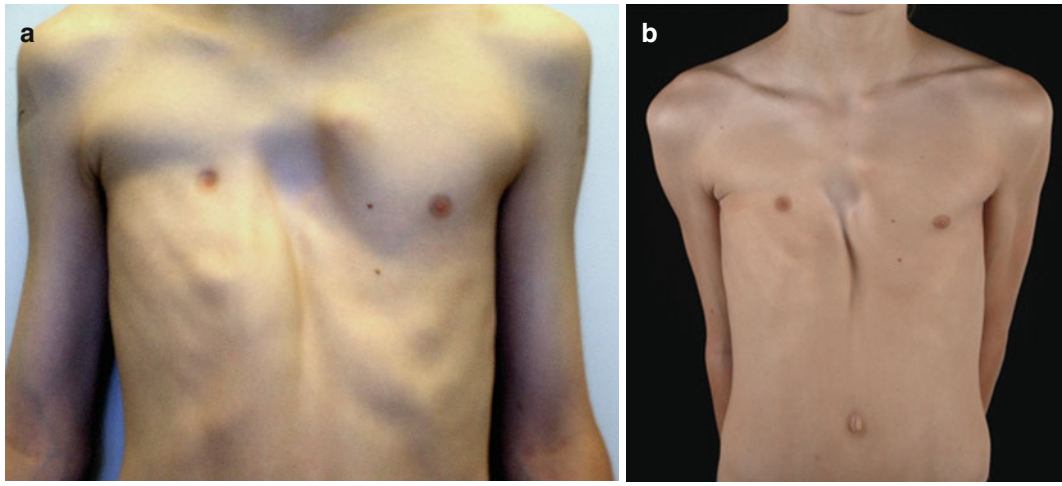

Fig. 17.6 Ten year old boy with asymmetric PE, before (**a**) vacuum bell therapy, and after 12 months (**b**)

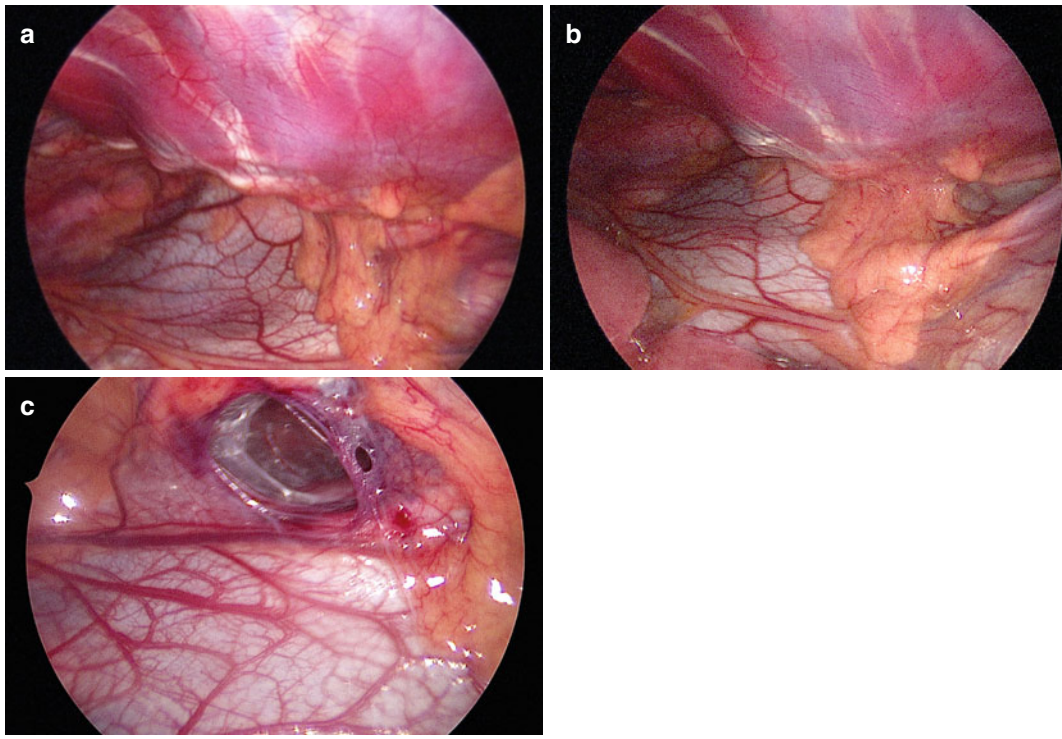

Fig. 17.7 Retrosternal space creation without (**a**) and with the vacuum bell (**b**) during the MIRPE procedure. (**c**) Note the retrosternal tunnel (**R**)

Supervision of daily application Until today, we have no possibility to supervise the frequency, the intensity and the duration of the daily application at home. Electronic devices which might be integrated into the vacuum bell, would be useful to supervise the routine application.

Long-term Results Long-term results including 10 years and more are still missing. Further studies are necessary to elucidate these facts.

Costs of Treatment In most European countries, costs of treatment have to be paid by patients and

parents, respectively. In some countries in South America, acquisition of the vacuum bell is covered by the individual national health care system or the local insurance. In USA, approval of the FDA was obtained in May 2012.

Pre-Treatment before Surgery Physicians and patients discuss about the benefit to use the vacuum bell preoperatively prior to MIRPE procedure. Since in our country the majority of patients have to pay for the device, most of our patients are not interested in this "pre-treatment". Additionally, we observed no significant difference between patients who used the vacuum bell before surgery, and patients who underwent primary surgery [22].

Objective Assessment of Depth of PE To estimate the "objective" success of this treatment modality is very difficult. The definition of success may vary considerably between individuals. Depth of PE, symmetric vs. asymmetric deformity, as well as patients' age and sex represent important variables. Various scales and measurement methods including X-rays and computed tomography have been used to quantify the degree of deformity. Our method of assessment of depth of PE is not exact enough, especially regarding the age specific differences. New methods for non-invasive assessment of chest wall growth may provide more detailed, objective information concerning the severity of PE. A 3-D laser scanner might help us to assess the degree of PE and to follow-up our patients during vacuum therapy.

Pectus Carinatum

Introduction

PC is more frequent in males than females (4:1 ratio) and can be both symmetric or asymmetric. Rarely, the defect might be associated to Currarino-Silverman, combined pectus carinatum/excavatum, and Poland, Marfan or Von Recklinghausen syndromes, among other connective tissue disorders. Even though its etiology is unknown, PC may be genetically linked considering its frequent occurrence in families [40].

Apart from the external appearance which most commonly concerns patients and families, the majority of children present with relatively mild symptoms; the most frequently reported are tenderness, bone pain or mild exercise intolerance. Even though psychosocial issues secondary to body image need to be promptly addressed in all cases, since the defect tends to become more severe during pubertal growth spurts, and may even worsen throughout adult life, the physiological concerns must take precedence without exception.

Despite the early work of Jaubert de Beaujeu et al. and Bianchi et al. [41, 42], the pioneers in non-operative treatments for PC – open surgery has been the treatment of choice over the last decades [2, 43, 44]. Most of the existing surgical procedures consist of modifications of the Ravitch technique that employ resection of the deformed costal cartilages along with sternal osteotomy [45]. Even though patients refer to be generally pleased with the improvement of their chest's shape, surgery could not address the usual problem of the flaring of ribs and a visible scar was always left. On top of that, it is well known now, that surgery does not result in complete thorax remodeling in comparison to non-operative treatments. Many different authors proposed less radical resections [46–48].

Drs. Haje DP, Haje SA and coworkers from Brazil, have shared their valuable, extensive experience in treating PC patients using a Dynamic Compressor System (DCS) [49–52]. This was the consequence of four basic facts: (1) the inherent risks of a major surgery, (2) always reserved for the most severe cases, (3) leaving a great deal of patients untreated [53], in addition to (4) anterior chest wall compliance during puberty which permits remodeling by applying external compression. Based on the latter, other authors have also suggested a wide variety of alternative non-operative approaches [10–16], too.

The FMF® Dynamic Compressor System

Foreword

The Nuss procedure for pectus excavatum introduced a paradigm shift by demonstrating that the thoracic wall is a very elastic and malleable structure in children [9]. Inspired by this concept, early in the year 1999, the author and his partner, began assessing chest wall compliance in patients with mild to moderate forms of PC by applying manual compression to the defect. Since it could be corrected without pain, a non-operative prospective study was designed and implemented (after being approved by the institution's Research Ethics Committee) at the chest wall deformities outpatient clinic. A DCS was developed and utilized for this purpose. Besides, since by that time, there were no reports about the record and analysis of pressure measurements to compare series of patients, further investigation was done on that particular topic. By the beginning of 2001, the DCS design was finished. In 2008, the initial experience with the so-called FMF® Dynamic Compressor System (FMF stands for Fraire/Martinez-Ferro) was published [17–19]. Two quantifiable variables were defined to statistically compare objective data, collected at every consultation:

- **Pressure of Correction** (**POC**): the pressure applied to the patient until the proper shape of the thorax is achieved. Basically, it is an indirect parameter to measure and quantify the patient's chest wall flexibility. It is reduced throughout the treatment and is measured initially (because one of the inclusion criterions for bracing is that the POC ought to be equal or less than 14 PSI to prevent treatment failure) and at every consultation (Fig. 17.8).
- **Pressure of Treatment** (**POT**): the pressure required to treat the patient. It is measured before and after adjusting the FMF® DCS. POT permits evaluating whether the patient has been wearing the device or if he has grown up in between consultations. A POT higher than that obtained at the last consultation, means that he has not been wearing the brace as indicated, or that he has grown up (this can be verified by checking the registered height and weight or if the brace is too tight). Variables are recorded at an evolution form (Fig. 17.9).

First Projects

At first, different kinds of plastic and then metallic orthotic devices that proved to be inefficient were developed. It could be noticed that when the

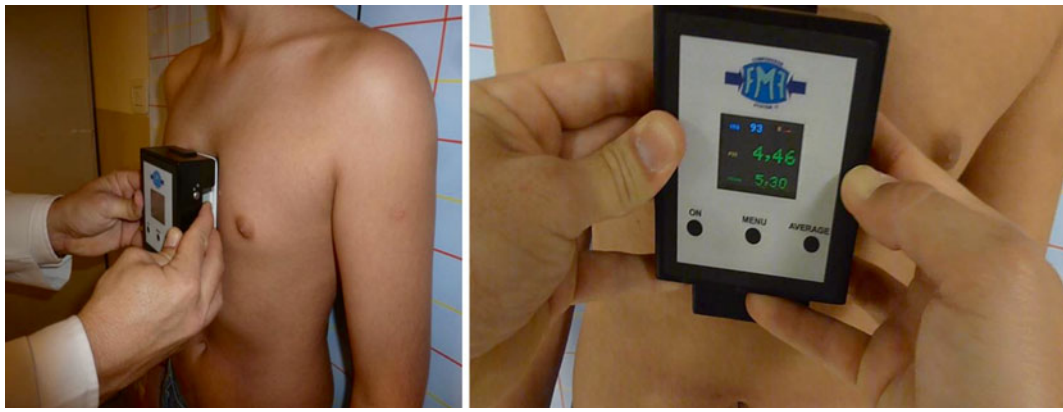

Fig. 17.8 Measurement of the **P**ressure **O**f **C**orrection (**POC**) at the first and successive consultations. The patient stands up against the wall. The pressure measuring device (PMD) is placed over the chest, where the protrusion is more prominent, and measures the pressure required to remodel the thorax. The initial POC helps to predict treatment duration and indirectly quantifies thoracic flexibility

Fig. 17.9 Measurement of the **P**ressure **O**f **T**reatment (**POT**). Before and after adjustments to the FMF® DCS. Note the three buttons for optimum performance and the digital multiparameter color display of the **P**ressure **M**easuring **D**evice (**PMD**)

Fig. 17.10 Components of the FMF® Dynamic Compressor System: (*left*) **P**ressure **M**easuring **D**evice (**PMD**) and (*right*) aluminum, lightweight brace

patient's thorax was compressed, it expanded laterally. The team concluded the reason for their failure was the fact that thoracic lateral expansion, occurring naturally during inspiration, had not been taken into account.

With the aid of mechanical and electronic engineers, an external DCS was designed, but this time loaded with an electronic Pressure Measuring Device (PMD) to measure the POC and POT. The PMD converts the mechanical energy exerted to the patient (pressure) into electrical energy visible as numbers in a screen (measurement of pressure).

The unit of measurement to quantify pressure was decided to be pounds per square inch (PSI) because it takes into consideration the pressure resulting from a force of one pound-force applied to an area of one square inch. Presently, this is the unit of pressure that is still being employed. Most of the patients can be included with a decimal scale from 1 to 14.

By that time, the FMF® DCS included an expandable aluminum brace and the PMD.

The initial results obtained from measurements of POC, age, time of usage and cosmesis were analyzed from prospective collected data. Surprisingly, by correlating the different variables, the authors found out they could predict treatment duration and prognosis. These data has been very useful since then, to assess the patient and family about the treatment from the very first day of consultation.

Throughout the following years, several modifications were introduced to the FMF® DCS. The posterior compression pad was removed as it was not useful and caused skin lesions upon the spine and dorsal tissue. Better tolerance from PC patients could be enhanced to complete the treatment. A docking mechanism was designed to attach the PMD to the brace (for regulation of POT), in addition to a locking system, to avoid patient manipulation, and a portable plate bender to model the aluminum pieces.

Today

The FMF® DCS is currently a system comprised of the following elements:

1. A custom-fitted, expandable, low-profile (invisible under the patients' shirt), cushioned aluminum brace that is adjustable to any thoracic shape or size (Fig. 17.10). Its locking mechanism is situated on the side where the prominence is most evident to enhance compression. In order to avoid referrals, the brace has been designed to be ordered, assembled and implemented at different, distant locations with ease (Fig. 17.11). It permits lateral expansion to allow thorax widening as a consequence of breathing, growth and thoracic re-shaping (Fig. 17.12).
2. Different sizes and shapes of cushioned compression plates adaptable to distinctive sternal protrusions, independently of their locations, sizes and shapes (Fig. 17.13a);
3. Different compression pads that can be adhered to the compression plate to cushion

Fig. 17.11 Components of the FMF® Dynamic Compressor System: pieces to assemble a customized brace for each patient. Format in which they are delivered in a personalized packaging

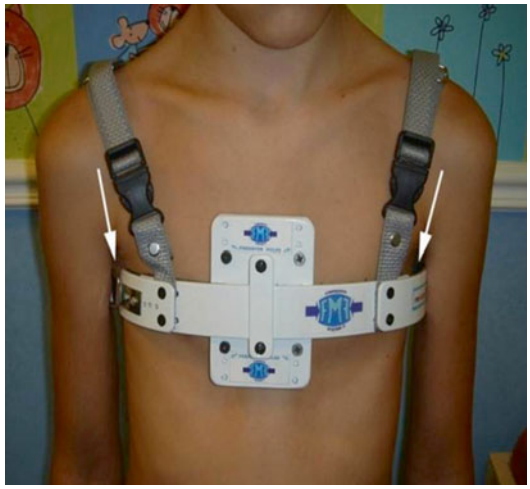

Fig. 17.12 The FMF® DCS enables lateral expansion during breathing and thoracic widening that occurs with re-shaping and growth. Note that at least a 1 cm space is left on each thoracic side. Basically the skin should not be in direct contact with the brace's undersurface to permit thoracic widening

the defect, prevent skin lesions, avoid non-compliance, increase POT in girls with breast development or when extra pressure needs to be exerted over the defect (Fig. 17.13b);

4. The PMD which can be docked to the brace's compression plate. Because of the variation of pressure when the PC patient inspires, the device latest version calculates the average POC and POT of multiple measurements taken in 5 s (Fig. 17.8).
5. Standardized measuring instruments (chest measuring ruler and metric tape) to record the data needed to assemble each brace (Fig. 17.14);
6. A portable plate bender to curve the aluminum segments according to the patient's continuous re-shaping thoracic anatomy (Fig. 17.15);
7. Specific tools as screwdrivers and screws (Fig. 17.14).

How Does it Work?

The FMF® DCS corrects PC by pushing the sternum backwards: the continuous anterior–posterior compression progressively widens and re-models the entire chest. Cartilages accommodate, grow and finally ossify in the correct position. The multiple aluminum segments can be adjusted, bent and eventually replaced at every consultation to permit proper lateral thoracic expansion, because an excessively tight brace causes non-compliance and treatment interruption.

The non-operative therapy consists of four distinct phases.

Initial Phase PC patients referred to the clinic are evaluated and those who meet the inclusion criteria (typical condrogladiolar pectus carinatum, POC < 14 PSI, consent to follow the treatment) are asked to join an institutional approved prospective study. A series of questions to reunite information for medical and academic purposes are made. Pictures are taken in six different positions (Fig. 17.16). Measurements to assemble the brace are filled in an order form.

Correction Phase Once the FMF® DCS is assembled and delivered to the patient, POT during maximal inspiration, and time of usage are set according to Table 17.1. POT over 2.5 PSI must be avoided since skin lesions can occur. The correction phase ends when the interdisciplinary team, patient, and/or family agree that the deformity has been fully repaired.

Originally PC patients were indicated to wear the brace as much as possible during the day (ideally 24 h per day). However, in order to enhance

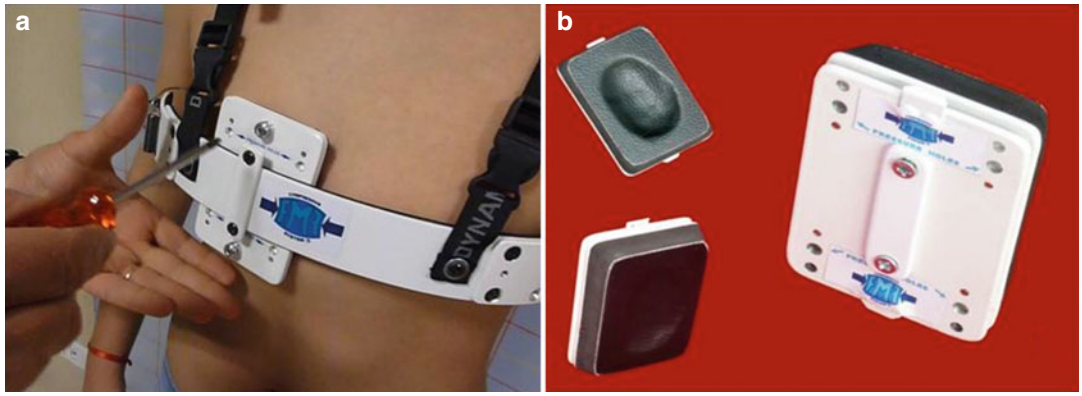

Fig. 17.13 Components of the FMF® Dynamic Compressor System (**a**) Adjustable compression plate. It is displaced frequently as the defect is compressed and its size, site and shape changes overtime. (**b**) Different sizes and shapes of cushioned compression pads designed for each type of protrusion to avoid skin lesions or to exert extra pressure (double or triple pads)

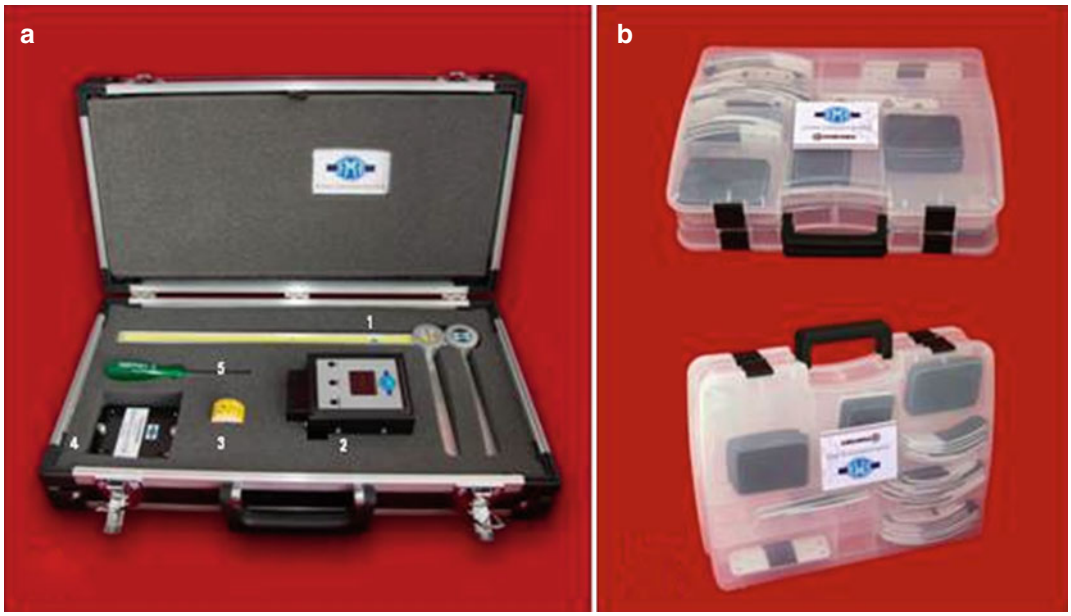

Fig. 17.14 Components of the FMF® Dynamic Compressor System. (**a**) Portable suitcase with standardized measuring instruments. Ref: (1) Measuring ruler; (2) PMD; (3) Measuring tape; (4) Removable compression plate; (5) Screwdrivers and screws. (**b**) Portable suitcases with the differently used and replacement pieces

compliance and to avoid skin lesions, PC patients have been currently classified into four distinct groups according to their initial POC. Once the patient's POC lowers to the POC range of the previous group, he is re-classified accordingly. Nonetheless, the treatment can be customized for each PC patient regarding tolerance, characteristic of the defect, skin status and age.

Following (Table 17.1) group 1 and 2 patients are instructed to wear the FMF® DCS every day, overnight and as much as possible during the day, depending on their activities. They are only allowed to remove the device during sports and while having a shower/bath. On the other hand, those PC patients belonging to group 3 and 4, commence wearing the system less hours per

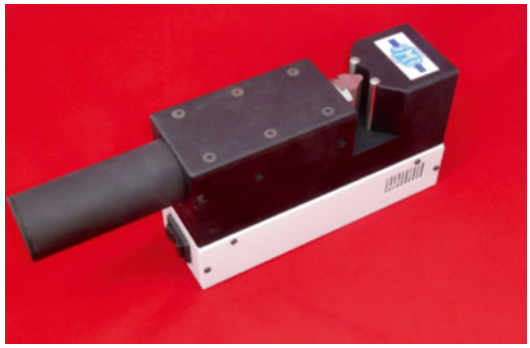

Fig. 17.15 Component of the FMF® Dynamic Compressor System. Portable plate bender to remodel aluminum lightweight pieces

day, at lower POTs, to indirectly increase the flexibility of the thoracic cage, to enhance compliance and to prevent skin lesions.

Group I and II PC patients are reminded at every consultation that the more they wear the FMF® DCS during the day and overnight, the faster their defect will be reverted.

Group III and IV are advised about the complications of overusing the brace and the need to follow medical indications.

A series of daily physical therapy exercises can be indicated, too. Swimming, playing wind instruments and inflating balloons (to treat the costal flares) are encouraged as accessory activities to complement the non-operative treatment.

A double-blinded patient-physician or family-physician survey has been implemented to assess final cosmetic results.

Basically, at the end of the correction phase, patients and/or parents (depending on age) are asked to judge the final outcome by assigning a score from 1 (poor) to 10 (excellent). Each treating physician of the interdisciplinary team submits an undisclosed judgment, too. The lowest 2 numbers are used to determine the final aesthetic result.

Printed (Fig. 17.16) and on-line historical pictures of each patient are always available at any time for consultation.

Weaning phase Once the defect is reverted, the FMF® DCS is gradually withdrawn to avoid eventual partial recurrences. PC may return mildly, in approximately 10 % of cured patients, particularly if they have been treated before pubertal growth spurts or in case they have cured very rapidly.

During the weaning phase, patients wear the brace as a "retainer" during the day or overnight (they generally prefer the latter), every day for the first month, every 2 days for the second month and every 3–4 days for the next months (range: 2–6 months). The weaning period is not contemplated in the calculation of the duration of treatment.

As aforementioned, the faster the patient gets cured, the longer the weaning phase should be. POT remains invariable in this post-correction period whilst POC is equal to cero.

Follow-up Phase Provisory treatment interruption is indicated when the weaning period ends. Patients are controlled every 6 months until they are 18 years old. In case of adults, treatment finishes when the defect is corrected. In any case, they are always indicated to call the office back if they observe any partial recurrence, that is, the appearance of a slight protrusion (never as prominent as the initial defect), which is corrected by adapting the brace to the new thoracic shape and a few more months of treatment.

Treatment Failure

Upon treatment failure or for those patients who are unlikely to be compliant with bracing, surgery is always an option (Fig. 17.17).

If the patient's chest is symmetrical and POC < 10 PSI, PC patients can be operated on with the Abramson technique which, consists of the insertion of subcutaneous and submuscular bars and stabilizers [47]. In most of the asymmetrical cases, even though an Abramson procedure can be tried, a classic thoracoplasty (using a modified Ravitch technique) is rather opted. The same is the case for those PC patients who additionally have a very stiff chest (POC > 10 PSI) or a failed previous surgery.

Results

Between April 2001 and October 2014, 500 patients were prescribed the staged, non-operative

Fig. 17.16 Patient's medical record. Six pictures are taken at the first consultation (Front, From the top, 3/4 Right Side, 3/4 Left Side, Right Side, Left Side)

Fig. 17.16 (continued)

treatment, with the FMF® DCS and counseled to follow the protocol. Three hundred and eighty were males (76 %) and the mean age of detection of the defect was 12 ± 2 years (range: 1–34 years). Thirty-two patients (6.4 %) abandoned treatment and could not be evaluated for final results. Of these, 2 declared pain and 4 reported skin intolerance as the cause of noncompliance; the other 23 claimed social discomfort, and 3 patients were lost to follow-up. Of the remaining 468 patients, 398 completed the treatment (85 %), and 70 (15 %) are still actively using the FMF® DCS.

Seventy percent of patients (n = 328) reported a familial history of chest wall deformities. Fifty percent of patients were diagnosed scoliosis, posterior asymmetry and a tendency to adopt a kyphotic position (n = 234). Forty percent of patients had asymmetric shoulders (n = 188) whereas 20 % of them evidenced costal flares (n = 94). Hundred percent of patients older than 8 years old referred social discomfort and feelings of embarrassment.

The mean time of use per patient (once adapted to treatment) was 18 ± 3 h per day for a mean period of 8 ± 5 months (range 3–24 months). When applying the satisfaction scale, 385 (97 %) patients achieved a 7- to 10-point correction (excellent, very good, and good results) and 13 (3 %), only 1- to 6 -point correction (poor and bad results). The mean initial POC value was 5 ± 1.5 PSI (range

Table 17.1 Treatment indicated at the first day of usage, until the patient tolerates the device without complications (pain, skin lesion, etc) or until the patient is re-classified into the previous group

Variables	Group 1	Group 2	Group 3	Group 4
Initial PC (PSI)	1–4	4–6	6–8	>8
Initial PT (PSI)	2.5	2	1.5	1
POT (PSI)	Reassigned according to the measured PC at every consultation until the patient tolerates full treatment			
Indicated time of usage (h)	24	24	12	6
Estimated treatment duration (months)	2	4	8	12–24

The treatment can vary among patients and be customized depending on compliance, site and height of the protrusion, sternal rotation, skin status and age

Fig. 17.17 Patient with skin ulceration caused by overusing the FMF® DCS beyond medical indication. The system was withdrawn until the lesion healed. The patient could soon employ the system as originally indicated and is currently in the weaning period

1–14 PSI). The following complications were observed in 20 of the 398 patients (5 %): back pain ($n=9$), hematoma ($n=1$), and skin lesions ($n=10$). No other complications were seen or reported. Even though complications caused a delay in completion of treatment, they were not the cause of treatment termination. Skin lesions were mild in all cases and treated by withdrawal of the FMF® DCS and/or topical skin lotions until the skin healed completely. The other complications were treated by temporary loosening the FMF® DCS to lower the POT. Some patients with sensitive skin were indicated to wear a DuoDerm® Extra Thin patch at the site of the defect and/or a cotton shirt well adjusted to the body. There was a case of an adult patient who came to the clinic with a skin ulceration (Fig. 17.18). Skin ulcerations may happen in patients with extremely sensitive skin, excessive brace usage beyond medical indication -as was the case of the aforementioned patient- or in those patients with sharp protuberances (contoured compression pads were specifically designed to prevent skin lesions in the latter cases).

Follow-up ranged from 14 years to 1 month. During the follow-up, 40 patients (10 %) presented with a partial recurrence. These were mostly observed during periods of rapid growth and typically 6 ± 2 months after treatment discontinuance. All partial recurrences were mild, and successfully treated with the FMF® DCS, by modifying its shape and size to suit the patient's larger and widened thorax. All patients responded adequately and were promptly cured. Currently, in order to reduce partial recurrences, those patients who get corrected rapidly (less than 3 months), in particular, those with a low initial POC (Group I and II patients), are indicated a longer weaning period (up to 6 months).

Analysis of Results

The statistical studies adopted were the Independent samples Student's t-test for univariate analysis and the Regression analysis for multivariate analysis. Statistical significance was set at $p<0.01$. The statistical software program employed was SAS, version 8.02.

The collected pressure data denoted several interesting facts. POC is correlated with age ($p<0.01$), final cosmetic results ($p<0.01$), and treatment duration ($p<0.01$). Younger patients have a lower POC (major thoracic flexibility) than older patients. Better final cosmesis is observed in PC patients with a lower POC. The duration of treatment could be predicted at the time of the very first

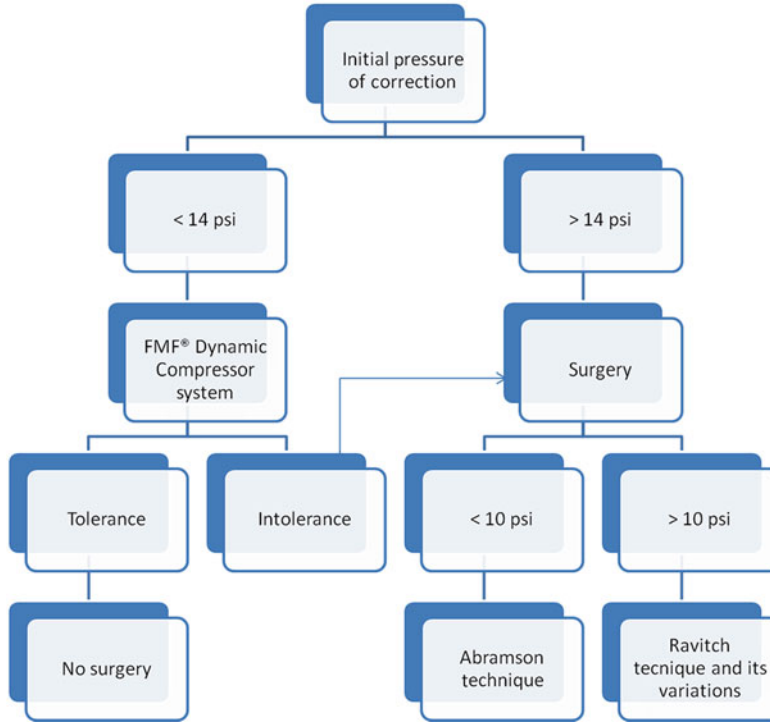

Fig. 17.18 Treatment algorithm for pectus carinatum

consultation. The duration of treatment is shorter in PC patients with more elastic and malleable thoraces (lower POCs) who wear the brace 24 h daily (except for showering, bathing and sports).

Regarding the pressure data, Group I patients can be cured in approximately 1–3 months (Fig. 17.19) whereas those belonging to Group II, get corrected in 3–4 months, and cured in 6 (Fig. 17.20). Group III patients are generally cured in 1 year (Fig. 17.21). Those in Group IV need between 15 and 24 months to revert their PC (Fig. 17.22). Upon treatment failure, the FMF® DCS softens the anterior chest and may facilitate surgery.

Correlation between POC and the duration of treatment results very useful in helping patients understand what is going to happen to them throughout the treatment.

Less than 2 % of PC patients (in particular Group I patients) show a tendency to overcorrection to PE. The treatment is immediately stopped in these cases, in whom the mild PE reverts spontaneously.

Chest X-ray, CT scan or a Chest MRI are not routinely indicated, unless the patient presents with an atypical PC, a stiff PC which demands further investigation, severe pain, or in case of an insecure family.

Throughout the correction phase, patients are monitored with a monthly frequency because of the need to adjust the brace, to verify the skin's status, to enhance the practice of complementary activities and brace wearing and to prevent overcorrection to PE.

Continuous Improvement Process

New projects are currently being developed to improve the FMF® DCS and to reduce data recollection bias. In a common project with the University of California, San Francisco, a time sensor, activated with body temperature, is being developed to measure the real "using time". An FMF® software is moreover being designed to process the measurable and applicable data, with implications for prognosis and treatment of PC [54].

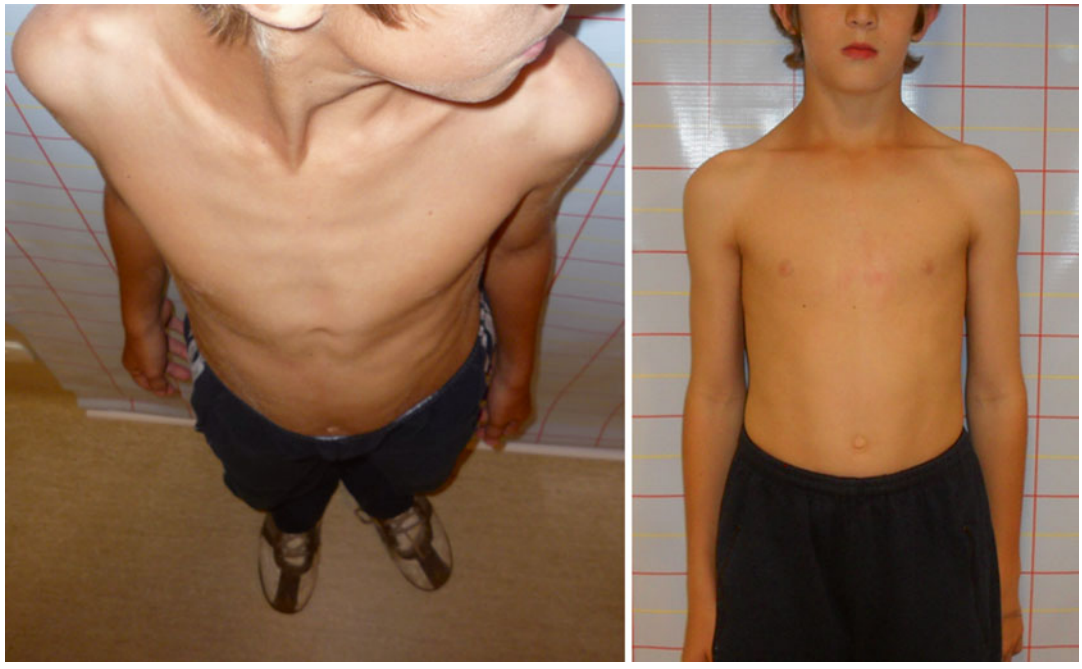

Fig. 17.19 Group 1 patient. Age: 9 years old. Initial PC = 3 PSI. 20 h of daily usage. Flat chest after 2 months

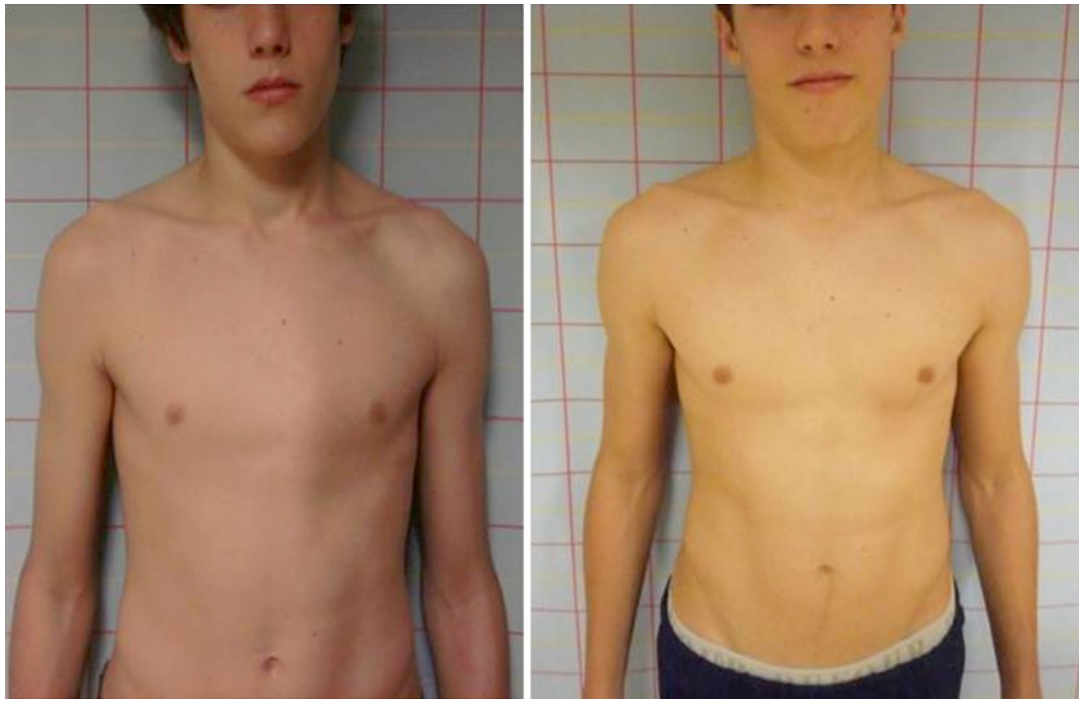

Fig. 17.20 Group 2 patient. Age: 14 years old. Initial PC = 5 PSI. 20 h of daily usage. Flat chest after 4 months

Fig. 17.21 Group 3 patient. Age 11 years old. Initial PC = 7 PSI. 15 h of daily usage. Flat chest after 8 months

Fig. 17.22 Group 4 patient. Age: 16 years old. Initial PC = 9 PSI. 18 h of daily usage. Flat chest after 1 year. Note that the higher the age and initial PC, in addition to the presence of sternal rotation, the less optimum is the cosmetic result. Anyway the patient reported a satisfaction score of 9

Discussion

The non-operative treatment for PC essentially mirrors the effects of the internal bar in PE patients, remodeling the growth pattern of the deformed chest wall cartilages [16, 55]. By the year 1999, except for the pioneer papers of Haje et al. [49–52] no other authors supported a non-operative approach for the treatment of mild to moderate cases of PC [45, 53]. Simultaneously with Dr. Haje et al, but by that time unaware of their work, the author and his partner, began developing a DCS to treat PC conservatively. As aforementioned, the DCS design was finished in 2001.

Moreover, starting almost simultaneously with the author and colleagues, several other authors have suggested a diverse variety of non-operative approaches based on the same concept: that the anterior chest wall is still compliant during puberty and permits remodeling by applying external compression [11–15], reaching to similar results and conclusions. What differentiated the FMF® DCS from other devices was essentially that the POC and POT could be objectively measured using the PMD, enabling prediction of treatment duration and prognosis.

Our initial results have been validated by other surgeons as Dr. Cohee AS and her teamwork, who are treating patients amenable to bracing with the FMF® DCS, at the Children's Hospital of the King's Daughter in Norfolk, USA [56]. They have reported very good results and observed that one of the system's advantage over other orthotics, is that it objectively measures the POC and POT to guide treatment decisions. Because the position of the compression plate is early adjusted on the aluminum frame, flattening of the sternum is enhanced in asymmetric cases is enhanced. Many other authors have recently validated our initial results [57–60].

When comparing historical open surgery results with those of the non-operative treatment, the benefits of the latter are superlative. To begin with, the FMF® DCS not only remodels the sternum and cartilaginous ribs permanently, but also results in complete thoracic re-shaping in contrast to an operation. Secondly, it totally eliminates the risks of anesthesia and of major surgeries, decreasing the complication rate, leaving no visible scar, avoiding hospital admission, avoiding activity restrictions associated to implant placing and dramatically reducing the cost of treatment. When considering the benefits of a non-operative treatment, almost no patient with a POC equal or less than 14 PSI should be selected as a candidate for surgery before trying a conservative approach.

Conclusion

The vacuum bell therapy may help to avoid surgery in some patients with PE. Specially younger patients with symmetric and mild PE may benefit from this procedure. The application is easy, and a good acceptance by both paediatric and adult patients can be noticed. However, a more differentiated analysis must focus on age and gender specific differences to help identify appropriate patients. Moreover, the time of follow-up with a maximum of 10 years is still not long enough, and further follow-up studies are necessary to evaluate the effectiveness of this therapeutic tool.

The intraoperative use of the vacuum bell during the MIRPE facilitates the retrosternal dissection and advancement of the pectus introducer as well as placement and flipping of the pectus bar. It leads to a clear elevation of the sternum without adverse events in all patients, as cardiac and/or pericardiac lesions or lesions of the mammary vessels. No midline incision to elevate the sternum with a hook is necessary. In any case, the method seems to be a valuable adjunct therapy in the treatment of PE.

The FMF® DCS permits thoracic lateral expansion (re-shaping), pressure measurement and control, prediction of treatment duration and prognosis, in-situ outpatient clinic adjustments, avoids patient manipulation and spine and dorsal injury, thereby providing increased tolerance. It can be indicated, placed and controlled by any physician at distant locations, who can additionally collect objective data to enable him adjust the FMF® DCS and perform further scientific evaluations. The implementation of a staged treatment,

consisting of four distinctive phases allows patients to be treated non-operatively with optimum reversion of their PC and complete thoracic remodeling. Upon failure, open or video-surgery are always a viable alternative. As is the case of vacuum bells further follow-up studies are needed to evaluate the effectiveness of this therapeutic tool.

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