

# THE VACUUM BELL FOR TREATMENT OF PECTUS EXCAVATUM: AN EFFECTIVE TOOL FOR CONSERVATIVE THERAPY

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## INTRODUCTION

Pectus Excavatum (PE) is the most common chest wall malformation and one of the most frequent major congenital anomalies, occurring in approximately 1 in every 300 births (1). In more than 85% of infants, the defect is already noticeable at birth. A later onset may be observed in patients with Marfan syndrome. Until the end of the last century, operations to correct PE deformities were largely based on the technique described by Ravitch (2). In 1998, a new technique of minimally invasive repair of PE (MIRPE) was first described by D. Nuss (3) to avoid several operative features of the modified Ravitch repair procedure. Today, the MIRPE technique is well established and represents a common used technique (4-9). The short operating time, smaller incisions and considerably less dissection has made the MIRPE procedure very appealing both to surgeons and patients, thereby resulting in a large increase of the number of patients requesting operative treatment, and consequently in an increase of the number of PE repairs. However, with the widespread use of the MIRPE procedure the character and number of complications has increased (4, 6-8, 10-12) (Table 1 and 2). Above all, recent studies report on an increasing number of near fatal complications (12-18). Additionally, in many cases of PE, the degree of pectus deformity does not immediately warrant surgery, yet patients may benefit from some type of nonsurgical treatment. Other patients are reluctant to undergo surgery because of the pain associated with postoperative recovery and the risk of imperfect results. Due to these facts, the introduction of the vacuum bell for

conservative treatment of PE has made this alternative therapy a focus of interest of patients.

The procedure of applying a vacuum to elevate the sternum was first used more than 100 years ago [19]. Despite the 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. Our initial results using this method proved to be promising (20). Today, we report our ongoing experience using the vacuum bell for conservative treatment of PE. Note that a subset of these patients (the first 34 patients) was reported previously [20].

## THE VACUUM BELL

A suction cup is used to create a vacuum at the chest wall. A vacuum up to 15% below atmospheric pressure is created by the patient using a hand pump (Figure 1). Three different sizes exist allowing selection

**Table 1.** Intraoperative Complications after MIRPE procedure (4-9)

Pericardial lesion
Perforation of the heart
Cardiac rhythm disorders
Lesion/rupture of intercostal muscles
(Tension)-pneumothorax
Significant blood loss
Perforation of the liver
Lesion/Rupture of the diaphragm

**Table 2.** Postoperative Complications after MIRPE procedure (4-9)

Pneumothorax (drainage ?)
Pleural effusion (drainage ?)
Pneumonia – atelectasis
Hemothorax (drainage ?)
Pericardial effusion (puncture ?)
Pericarditis
Bar shifts (requiring revision ?)
Dislocation of the stabilizer (requiring revision ?)
Wound infection
Over correction
Bar allergy
Skin erosion

according to the individual patients age (Figure 2). The medium size model is available in a supplemental version with a reinforced silicon wall (type “bodybuilder”), esp. made for adult patients with a small deep PE. Additionally, a model fitted for young girls and women is available. Pilot studies performed by Schier and Bahr (21) showed that the device lifted the sternum and ribs immediately. In addition, this was confirmed thoracoscopically during the MIRPE procedure (Fig 3). The vacuum bell should be used for a minimum of 30 minutes, twice per day, and may be used up to a maximum of several hours daily.

Indication for conservative therapy with the vacuum bell include patients who

- present with mild degree of PE
- want to avoid surgical procedure
- are reluctant to undergo surgery because of pain associated with the operation
- are afraid of “imperfect” results after surgery

Contraindications of the method comprise skeletal disorders such as osteogenesis imperfecta and Glisson’s disease, vasculopathies (e.g. Marfan’s syndrome, abdominal aneurysm), coagulopathies and cardiac disorders. 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 as well as rib fractures in rare cases what was not seen in our series.

## PATIENTS AND METHODS

93 patients (77 males, 16 females), aged from 3 to 61 years (median 17.8 years) were treated with the



**Figure 1.** Application of the vacuum bell



**Figure 2.** Vacuum bell in 3 different sizes (left 16 cm, middle 19 cm, right 26 cm in diameter)

vacuum bell for 1 to a maximum of 24 months (median 10.4 months). Standardised evaluation before starting the procedure included history of the patient and his family, clinical examination, cardiac evaluation with electrocardiogram and echocardiography and photo documentation. In addition, the depth of PE was measured in supine position. Patients underwent follow-up at 3 to 6 monthly intervals including photography and clinical examination.

The first application of the vacuum bell occurred under supervision of the attending doctor. The length of time of daily application of the vacuum bell varied widely between patients. Some patients followed the

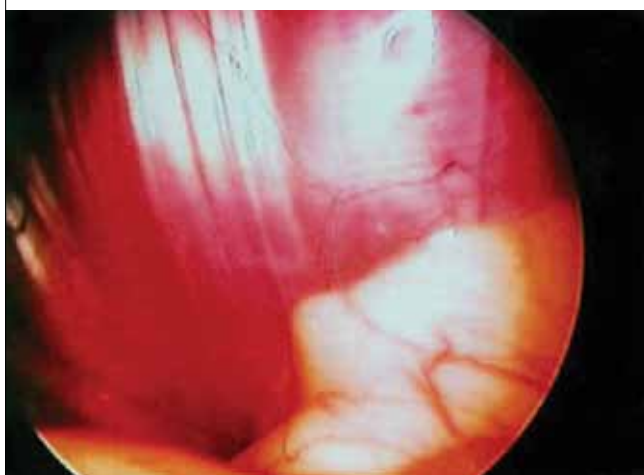
user instructions and applied the device twice daily for 30 minutes each. Patients under the age of 10 years used the device under supervision of their parents or caregivers. Some of the adult patients used the vacuum bell 4-6 hours daily during office hours. Adolescent boys applied the device every night for 7-8 hours. In fact, the duration and frequency of daily application depends on the patients individual decision and motivation.

Since 2006, the vacuum bell was used routinely during the MIRPE procedure to elevate the sternum to allow a safer passage of the Lorenz® introducer as well as the pectus bar.

### RESULTS

During the first 1-5 applications, most of the patients experienced moderate pain in the sternum and reported a feeling of uncomfortable pressure within the chest. Adolescent and older patients developed mod-

erate subcutaneous hematoma, which disappeared within a few hours. Some patients reported recurrent transient paresthesia of the upper extremities during the application. This symptom disappeared when lower atmospheric pressure was used during application. One 45 year old patient suffering from recurrent dorsalgia, reducing the application time, prevented the occurrence of discomfort. Analgesic medication was



**Figure 3.** Retrosternal space without (left) and with the vacuum bell (right) during the MIRPE procedure intraoperative use of the vacuum bell during the MIRPE procedure



**Figure 4a.** 45 year old patient, before (left: depth of PE = 2.5 cm)



**Figure 4b.** Vacuum bell therapy and after 12 months (right: depth of PE = 0.5 cm)



**Figure 5.** 9 year old boy, before (left: depth of PE= 2.8 cm) vacuum bell therapy, after 10 months (right: depth of PE= 1.6cm) and 36 months after therapy (below)

not necessary in any patient. The application of the vacuum bell in children aged 3 to 10 years was without side effects.

When starting with the application, patients presented with a PE with depth from 2cm to 5cm. In 74 patients (69%), after 3 months of treatment an elevation of more than 1.5 cm was documented. In 9 patients (10%), the sternum was lifted to a normal level after 18 months (Figures 4, 5). The longest follow-up after discontinuation is 5 years, and the success until today is permanent and still visible. In three patients with asymmetric PE, the depth of PE has decreased after 9 months, but the asymmetry is still visible. 3 patients were dissatisfied with the postoperative result (2 patients after MIRPE, 1 patient after Ravitch procedure) and started treatment with the vacuum bell. 6 patients stopped the application after 13.5 months

in average, due to an unsatisfactory result (2 patients) and decreasing motivation (4 patients). All 6 patients underwent MIRPE. At follow-up, all patients were satisfied and expressed their motivation to continue the application, if necessary.

## DISCUSSION

With the widespread use of world wide web, information on new therapeutic modalities circulate 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 new methods. From 1999 on, an increasing number of patients presented with PE at our department and asked to undergo the MIRPE proce-

cedure. The vacuum method was used as early as 1910 by Lange [19]. The vacuum bell used in our patients group was developed by an engineer, who himself suffered from PE [Klobe E, [www.trichterbrust.de](http://www.trichterbrust.de)]. We use this method since 2003. Long-term evidence of persistent effects of the treatment modality for more than 5 years are not yet available. However, initial results proved dramatic [20], and the acceptance and compliance of patients seem to be good. In many cases of PE, the degree of pectus deformity does not immediately warrant surgery, yet patients may benefit from some type of nonsurgical treatment. Other patients are disinclined to undergo surgery because of possible complications after surgery, because of the pain associated with postoperative recovery and the risk of imperfect results. Thus, the introduction of the vacuum bell for conservative treatment of PE has generated much interest among patients with PE.

The success of a therapeutic procedure not only requires a good technique, but also depends on a appropriate indication. In our study patients who presented with symmetric and mild PE, seemed to show a more successful outcome than those with asymmetric and deep PE. All patients except six were satisfied with the use of the vacuum bell, although objectively assessed improvement of PE varied between the individuals. All our patients were recommended to carry on undertaking sports and physiotherapy, so that the accompanying improvement of body control was an important factor in outcome. The participation of patients themselves in the “active” treatment of PE clearly increases motivation to maintain therapy. As demonstrated in the CT scan, the force of the vacuum bell is strong enough to deform the chest within minutes [21]. Therefore, especially in children younger than 10 years of age the application of the vacuum bell has to be performed carefully and should be supervised by an adult.

When creating the vacuum, the elevation of the sternum is obvious and persists for a distinct period of time. Therefore, the vacuum cup may also be useful in reducing the risk of injury to the heart during the MIRPE procedure, where the riskiest step of the procedure is the advancement of the introducer between the heart and sternum. Since the manufacturer of the device has not yet a license to sterilise the vacuum bell, this additional use has to be considered as a clinical trial. In accordance with our hospital hygieneist, we applied the vacuum bell during the MIRPE procedure since 2006 routinely with good experience. In addition, the vacuum bell may be useful in a way of “pre-treatment” to surgery.

In conclusion, the vacuum bell may allow some patients with PE to avoid surgery. Especially patients with

symmetric and mild PE may benefit from this procedure. The application is easy, and we noticed a good acceptance by both pediatric and adult patients. However, the time of follow-up in our series is only 5 years, and further follow-up studies are necessary to evaluate the effectiveness of this therapeutic tool. Additionally, the intraoperative use of the vacuum bell during the MIRPE may facilitate the introduction of the pectus bar. In any case, the method seems to be a valuable adjunct therapy in the treatment of PE.

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