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# Magnetic Mini-Mover Procedure for Pectus Excavatum IV: FDA Sponsored Multicenter Trial

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## Abstract

**Purpose:** The Magnetic Mini-Mover Procedure (3MP) is a minimally invasive treatment for prepubertal patients with pectus excavatum. This multicenter trial sought to supplement safety and efficacy data from an earlier pilot trial.
**Methods:** Fifteen patients with pectus excavatum had a titanium-enclosed magnet implanted on the sternum. Externally, patients wore a custom-fitted magnetic brace. Patients were monitored closely for safety. Efficacy was determined by the Haller Index (HI) and satisfaction surveys. After 2 years, the implant was removed.
**Results:** Mean patient age was 12 years (range 8-14), and mean pre-treatment HI was 4.7 (range 3.6-7.4). The device was successfully implanted in all patients. Mean treatment duration was 25 months (range 18-33). Post-treatment chest imaging in 13 patients indicated that HI decreased in 5, remained stable in 2, and increased in 6. Seven out of 15 patients had breakage of the implant's titanium cables due to fatigue fracture. Eight out of 13 patients were satisfied with their chest after treatment.
**Conclusion:** The 3MP is a safe, minimally invasive, outpatient treatment for prepubertal patients with pectus excavatum. However, the magnetic implant design led to frequent device breakage, confounding analysis. The HI indicated mixed efficacy, although surveys indicated most patients perceived a benefit.

**Key Words:** magnet, sternum, brace, Haller Index, funnel chest, chest wall

**Study Type/Level of Evidence**: Case series, treatment study. Level IV

## 1. Introduction

The Magnetic Mini-Mover Procedure (3MP) for correction of pectus excavatum was developed as an alternative to single-stage repairs such as the Nuss and Ravitch procedures. Although effective, single-stage procedures often result in significant post-operative pain, which can be challenging for patients, families, and clinicians [1-3]. Inspired by orthodontic and orthopedic braces, the 3MP applies a gradual, sustained force on the sternum to slowly remodel the malformed costal cartilages and achieve chest wall correction. We have previously described the development and design of the device, as well as simulations for feasibility and safety [4].

The 3MP device consists of 2 parts: an internal magnet (Magnimplant), which is implanted on the sternum, and an external custom-fitted anterior chest wall brace (Magnatract), which houses a second rare-earth magnet. The Magnatract is secured to the patient's chest wall by the attractive force between the coupled internal and external magnets, which produces an outward force on the sternum (Fig. 1). We previously reported the results of a Phase I trial of 10 patients, which demonstrated safety and efficacy in younger, pre-pubertal patients and prompted design revisions for both the implant and the external brace [5, 6]. To further investigate the safety of the 3MP, implement lessons learned from the initial Phase I trial, and collect preliminary data on efficacy of chest wall correction, we conducted this multi-center trial of 15 otherwise healthy patients with pectus excavatum.

## 2. Materials and Methods

Three important modifications were made based on the previous trial. First, the duration of treatment was extended from 18 to 24 months. Second, all patients received a wrist x-ray for bone age determination before treatment. Bone age was used as a proxy for skeletal maturity, as we hypothesized that patients with more immature, pliable chest walls would have a better response to treatment. Third, the Magnimplant was redesigned to simplify implantation and eliminate a weld point that had been prone to breakage. The external Magnatract device retained the functions that evolved throughout the first trial, including the screw mechanism for patient-adjustable magnet strength. An Investigational Device Exemption (IDE) was obtained from the Food and Drug Administration (FDA) for the redesigned device (G090006), and the protocol was approved by Institutional Review Boards from all 3 trial sites (UCSF 10-02970, UCD 260161, and CMH 13070228).

*2.1 3MP Device*

The Magnimplant (Hayes Manufacturing, Sunnyvale, CA and Hantel Technologies, Hayward, CA) consists of a neodymium iron boron disc magnet, (1 ½ cm diameter x 3/16 in. thick) and a ferromagnetic focusing plate encapsulated in a low-profile titanium shell. In the first generation device, the titanium implant was screwed to the back plate with a threaded stem, which was inserted through the sternum. However, the attachment between the stem and back plate was prone to weld failure, leading to 3 breakages in the Phase I trial. Thus, this redesigned, second generation Magnimplant eliminated the problematic back plate attachment. Instead, the back plate is connected to the

anterior magnet with titanium cables, which wrap around the sides of the sternum.

Prior to human use, a third-party certified test laboratory (Empirical Testing Corporation, Colorado Springs, CO) performed bench top mechanical tests of the Magnimplant under specifications and protocols designed by an external orthopedic research consultant (The Taylor Collaboration, San Francisco, CA). The Magnimplant's strength during overload testing, simulating constant anterior pull from the brace against the fixed sternum, was approximately 20 times physiological load levels. Fatigue testing, simulating 2 years of respiration and coughing, demonstrated that the device could withstand 15 million cycles of worst-case loading.

The external Magnatract brace is a custom orthotic made of polypropylene that is molded to each patient's anterior chest wall. The Magnatract houses a second rare-earth magnet that is held onto the patient's chest wall by its attraction to the implanted magnet. The patient can adjust the force exerted on the sternum using a screw mechanism to change the distance between the brace and the implanted magnet.

*2.2 Screening and Enrollment*

Fifteen otherwise healthy patients, aged 8-14 years, with pectus excavatum deformities of Haller Index (HI) ≥ 3.5 were enrolled across the three sites. We received a total of 540 inquiries regarding trial participation, of which 44 potentially eligible patients were screened, and the first 15 patients who met all criteria were enrolled. Patients were excluded if they had any of the following: other congenital anomalies (including significant skeletal anomalies)

not directly related to pectus excavatum, bleeding disorders, heart disease or arrhythmia, respiratory conditions requiring steroid treatment in the last 3 years, increased risk for general anesthesia, inability to obtain authorization for the procedure from their insurance provider, active implantable medical devices, or relative or close friend living within the same house with an active implantable medical device. A hand x-ray was also obtained from each patient during screening to document bone age; male patients with bone age greater than 14 years and female patients with bone age greater than 13 years were excluded from the study. All hand x-rays were evaluated by a single attending pediatric endocrinologist with no other affiliation with the study or investigators. Following enrollment, pre-treatment HI was assessed based on computed tomography (CT) of the chest, and an electrocardiogram (EKG) was performed to measure baseline cardiac activity.

*2.3 Implantation*

The Magnimplant was placed in all 15 patients in an outpatient surgical procedure under general anesthesia. An approximately 2-inch transverse skin-line incision was made at the junction of the sternum and xiphoid, and the soft tissue bluntly dissected. The back plate with attached titanium cables was inserted just behind the lower sternum, and the magnet placed directly on top of the sternum. The cables were then threaded through small holes in the magnet casing and secured with set screws. Intraoperative chest x-ray (CXR) was obtained to monitor for pneumothorax.

*2.4 Treatment*

Two weeks after the procedure, the external Magnatract was custom fitted to the patient's chest wall deformity, and patients started to wear the brace two weeks later. Patients were trained to adjust the strength of magnetic pull on the external Magnatract by rotating the magnet housing. This was titrated to patient comfort. Study investigators performed all other fittings and adjustments. Patients were instructed to wear the brace as often as possible, both while sleeping at night and during the day. Patients were seen twice during the month following implantation to monitor comfort, brace fit, and skin condition. Thereafter, patients were monitored through monthly clinic visits.

To determine whether the magnetic field associated with either the implanted sternal magnet or the external magnet could have any effect on cardiac electrical function, an EKG was done one month post-implant. Anterior/posterior (AP) and lateral CXRs were obtained at 1 month, 12 months, and 18 months after implant, and as needed, to monitor device integrity and positioning.

*2.5 Explant*

The Magnimplant was removed after 24 months in an outpatient procedure under general anesthesia. One month after implant removal, patients underwent repeat chest CT to evaluate chest wall correction and repeat EKG to monitor for cardiac effects. Patients are contacted by phone or email at 6, 12, 18, and 24 months after implant removal to monitor for long-term adverse events.

*2.6 Questionnaires*

Patients were asked to complete a questionnaire one month after the start of brace wear, one month after explant, and one year after explant. The questionnaire asked about brace fit, comfort wearing it at home and at school, frequency of brace wear, problems with either the magnet or the brace, pain, discomfort, disruption of activities from the magnet, general and mental health before and after the magnet was implanted, ability to get adequate rest, and energy level. The two post-explant questionnaires also asked about satisfaction with the correction of the chest deformity and whether patients would recommend the treatment to someone else with pectus excavatum.

*2.7 Data Analysis*

The number of patients in the study was limited to 15 by our IDE, for the purpose of evaluating device safety. Though not powered to determine efficacy, preliminary efficacy data, as measured by pre- and post-treatment HI, was also collected. All data were analyzed with Prism 7 for Mac OS X (GraphPad Software, La Jolla, CA). Pre-treatment and post-treatment HIs were compared using the Wilcoxon matched-pairs signed rank test. Changes in HI in patients with intact devices and those with broken devices were compared using the unpaired t-test. Linear regression and correlation analyses were performed to determine effect of patient age on change in HI. Two-tailed P values $\leq 0.05$ were considered significant. The responses to each survey question were summarized as frequency and percentage.

## 3. Results

Thirteen male and 2 female patients were enrolled in the trial. Mean patient age was 12 years (range 8-14 years), and mean pre-operative HI was

4.7 (range 3.6-7.4). Though the planned duration of treatment was 24 months, 2 patients and their families refused explant and elected to continue treatment longer - 30 and 32.5 months respectively. Patient data is summarized in Table 1.

*3.1 Safety*

The Magnimplant was successfully placed in all 15 patients. Thirteen patients were discharged home the day of the procedure and had uneventful post-operative recovery. One patient developed a post-operative pneumothorax and was admitted overnight for chest tube placement and air evacuation. A second patient was admitted for 3 days for pain control following the procedure. No abnormality was found at that time, but this same patient subsequently developed a surgical site infection 3 weeks after the procedure, which resolved with an outpatient course of sulfamethoxazole / trimethoprim. No other patients had wound complications.

During the course of treatment, there was only very mild skin erythema from brace wear, and no permanent skin damage or discoloration. One patient developed a rash on the chest wall from brace wear during warm weather, which resolved with nystatin powder. EKGs remained normal in all patients throughout the course of treatment and after explant, and there was no clinical evidence of any cardiac malfunction in any patient. There was no incident of the magnetic field interfering with another electrical implant, such as a cardiac pacemaker. All explant procedures were uneventful.

The cable connecting the magnet and back plate failed and fractured during the course of treatment in 7 patients. In 2 of these patients, the broken

cable was incidentally discovered on explant. A third patient presented to clinic with a sudden anterior movement of the chest and some mild redness of the overlying skin, and a broken cable was discovered on CXR. The implant was removed the following day. The 4 other patients were found to have broken cables on routine screening CXR. All were counseled regarding the finding and potential risks, and all elected to continue treatment. However, 1 of these 4 patients subsequently chose to undergo explant after an episode of chest pain and tightness, and 1 underwent explant after a symptomatic pericardial effusion.

Selected questionnaire data is summarized in Table 2. All patients reported wearing the brace for at least some hours of every day, suggesting that it was well tolerated. No patient reported more than occasional pain because of the implanted magnet. Two patients commented further, clarifying that they felt occasional pain only with “vigorous exercise” and during practices for “competitive gymnastics.” In the early survey, 1 patient reported that not feeling well during treatment frequently prevented him from doing his usual activities; however, by the post-explant survey, patients reported only occasional (n=5) or no interruption (n=8) in their usual activities.

*3.2 Efficacy and Patient Satisfaction*

Of the 13 patients who received post-treatment chest imaging, 5 had an improvement in HI, 2 remained the same (change in HI <0.2), and 6 worsened (Fig.2). Pre-treatment and post-treatment HIs were not significantly different (P=0.486). HI tended to improve more in younger patients, but this was not statistically significant (slope=0.089, P=0.75). There was no significant

difference in change in HI between patients with intact and broken devices (P=0.88).

The majority of patients (62% one month after explant and 57% one year after explant) were “satisfied” or “very satisfied” with the correction of their chests. Nearly all patients (85% one month after explant and 86% one year after explant) would recommend the 3MP treatment to someone else with pectus excavatum.

## 4. Discussion

The purpose of this multi-center trial was to build upon the results of our initial Phase 1 trial and further evaluate the safety and efficacy of the 3MP device. We adopted several important modifications based on experience from the previous trial: extending the duration of treatment from 18 to 24 months, adding a wrist x-ray to determine bone age as proxy for skeletal maturity, and, most notably, redesigning the Magnimplant to eliminate the weld point where the previous device had failed. Unfortunately, the cable system that replaced the welded attachment also led to device failure in nearly half of the patients, and significantly confounds our analysis.

We can still learn a great deal from this trial. Most significantly, the results support those of our Phase 1 trial in showing that the procedure and magnetic implant are safe. Though the substernal dissection during implant can lead to retained pleural air [5, 6], we screened for this with a simple x-ray on the operating table. In this trial, only one patient had evidence of post-operative pneumothorax and was discharged home the next day. There was no evidence of skin injury from the external device, nor that the magnetic field

caused any difficulty to patients or to others, such as those with implanted pacemakers.

Patients with intact devices experienced no adverse effects or symptoms. Three patients with broken Magnimplant cables were explanted due to symptoms. In two of these cases—one patient with pleural effusion and one with sudden chest wall movement—the symptoms were likely related to the broken cable. In the third patient with chest tightness, this relationship is less clear. Four patients were entirely asymptomatic from the broken cable, likely because of encapsulation that forms around the implant, preventing migration and shielding the surrounding tissue from cable fragments. In surveys, all patients reported either no pain or discomfort, or only occasional pain or discomfort from the implanted magnet. Thus, with no demonstrable effect on the heart, physiologic function, wound healing or susceptibility to infection, as well as minimal surgical complications and little to no discomfort, we conclude that the 3MP is safe.

Determining device efficacy, as measured by change in HI, was difficult for several reasons. First, since the primary goal was to ensure patient safety of this new medical device, a small sample size was chosen to minimize unnecessary risk. Therefore, the study was not powered for efficacy. Second, efficacy analysis was confounded by the fact that the devices with broken cables likely lost much of their ability to transmit the anterior magnetic force and reshape the sternum. To determine the cause of cable failure, two broken devices were taken to Christensen Material Engineering (Alamo, CA) for analysis and microscopic evaluation under a scanning electron microscope.

Striations across the individual strands, which curve outward from an originating crack, indicate fatigue fracture of the cables at transitions where they were inserted into the magnet housing or into the back plate. These stress patterns at extreme bends and transitions from flexible areas to stiff areas are similar to those seen with common cell phone charging cords. We posit that the constant movement of the chest wall with respiration, in addition to the anterior force from the external magnetic brace, created greater than anticipated dynamic stress on the implant cables, leading to frequent fatigue fractures.

In addition to the problem of device failure, our method of assessing efficacy also has several limitations. The HI (also known as Pectus Severity Index), defined as the ratio of the distance between the anterior spine and posterior sternum to the widest transverse diameter of the chest [7], has several known problems. The measurement varies significantly with respiratory cycle, which can introduce inconsistencies during imaging [8, 9]. The HI also necessarily varies with overall patient chest wall shape, as patients with rounder, or “barrel-shaped” chests have smaller transverse and larger AP diameters regardless of the degree of sternal depression. Moreover, HI does not assess asymmetry, which can significantly affect chest wall appearance and make repair more challenging [10].

The problem of quantitative assessment is compounded when attempting to track HI over time in pre-teen and adolescent patients. The pectus excavatum deformity progresses with growth, becoming exacerbated by the onset of puberty and its associated rapid growth spurt [11, 12]. Even in normal

children, the measured HI increases from ages 8 to 14 in both boys and girls [13]. Thus, we would expect our patients' defects and measured HI to worsen throughout the course of the 2-year study without intervention. The degree to which the 3MP may have changed the natural progression of the deformity is difficult to estimate without a control group.

Subjective assessment of treatment may be more informative than the imaging measurements. Most patients at one month and one year after explant (62% and 57%, respectively) were "satisfied" or "very satisfied" with the appearances of their chest walls, and nearly all (85% and 86%) would recommend the procedure to other patients with pectus excavatum. This includes patients with broken cables as well as patients whose HIs worsened on post-treatment CT. There may be some element of patients' wanting to validate the considerable time and effort of participating in the study, as well as desires to please the investigators. However, this enthusiastic response from the participants suggests that most perceived a benefit.

In the previous trial, HI improved more in younger patients (ages 8-12 years)[6], which we attributed to increased chest wall compliance due to skeletal immaturity. We did not see the same relationship between age and change in HI in this trial, despite screening with wrist x-rays to assess bone age. Our results may be confounded, however, by the fact that several patients in the 8-12 year-old age group had broken devices, and a 10-year old patient had a significant increase in HI, which weighs heavily in this small study group.

The ultimate goal of the 3MP is to give children with pectus excavatum a less painful and disruptive alternative to the traditional corrective procedures.

In the years since the 3MP was conceived, significant research efforts have focused on improving pain control after the Nuss and Ravitch procedures, especially in the areas of multimodal and regional analgesia [14-17]. We have been especially encouraged by the effects of intraoperative cryoanalgesia, and have recently begun to use it in the Nuss procedure at our institution [18].

## 5. Conclusion

The results of this multicenter trial of 15 patients further supports the 3MP as a safe, minimally invasive outpatient procedure for treating prepubertal patients with pectus excavatum. Though efficacy, as measured by HI, was mixed, most patients perceived a benefit. Unfortunately, the Magnimplant had a technical failure—frequent fatigue fracture of titanium cables—which was associated with two adverse events. The 3MP was initially conceived as a less morbid alternative to the Nuss and Ravitch procedures, but new pain control methods may significantly improve the patient experience in chest wall correction.

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## Figures

Fig. 1: **3MP Device**: A titanium-enclosed magnet is implanted onto the anterior sternum. Externally, patients wear a custom-fitted brace designed to correct the deformity using magnetic force. On lateral CXR, the implant alone is shown on the left; on the right, the implant is coupled with the external brace.

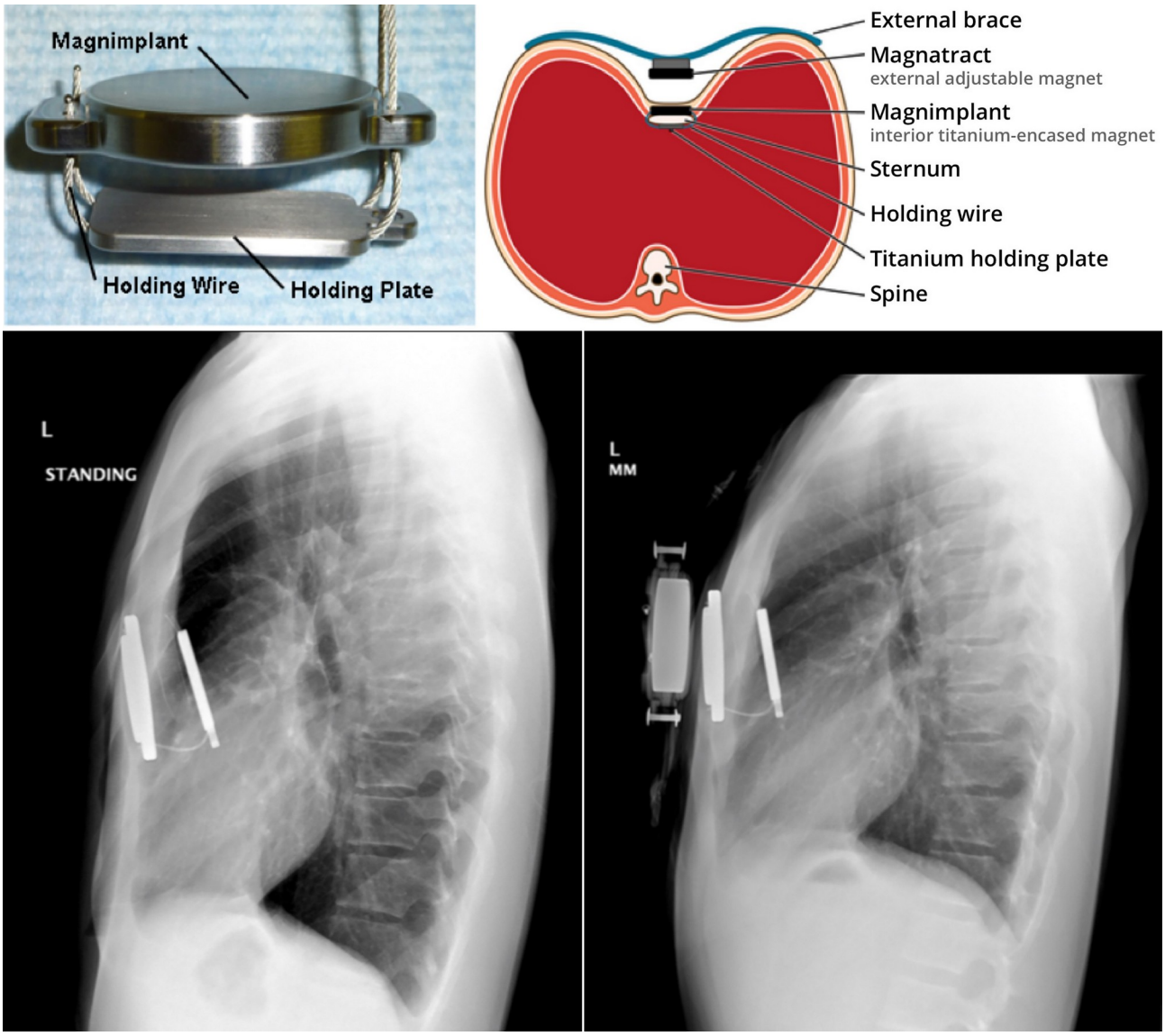
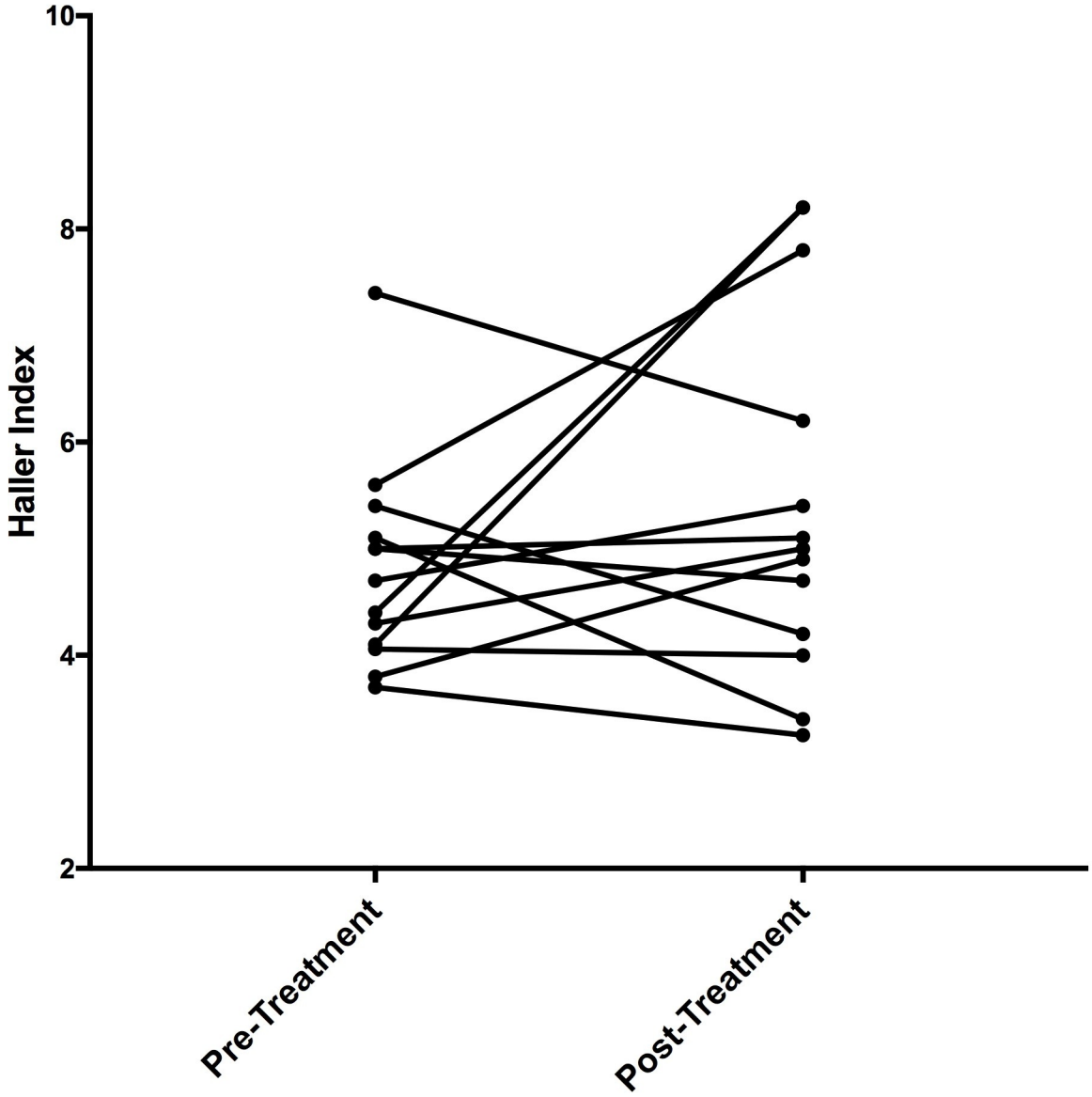


Fig. 2: **Change in HI** for each patient, determined by pre-treatment to post-treatment chest CT. There was no significant difference between pre-treatment and post-treatment HIs by Wilcoxon matched-pairs signed rank test **(P = 0.486).**



**Tables**

Table 1. Patient and treatment characteristics

| *Patient* | *Age (y)* | *Sex* | *Bone Age (y)* | *Implant Duration (mos)* | *Pre-treatment HI* | *Post-treatment HI* | *Change in HI* | *Broken cable?* |
|---|---|---|---|---|---|---|---|---|
| 1 | 13 | M | 13.5 | 24 | 7.4 | 6.2* | -1.2 | No |
| 2 | 13 | M | 13 | 24 | 4.3 | 5.0 | +0.7 | Yes |
| 3 | 13 | M | 13 | 32.5 | 5.0 | 5.1 | +0.1 | Yes |
| 4 | 12 | M | 12.5 | 30 | 5.6 | 7.8 | +2.2 | Yes |
| 5 | 12 | F | 12 | 18 | 3.8 | 4.9 | +1.1 | Yes |
| 6 | 14 | M | 13.5 | 25 | 5.0 | 4.7 | -0.3 | No |
| 7 | 9 | M | 10 | 24.5 | 5.1 | 3.4 | -1.7 | No |
| 8 | 9 | M | 11 | 22 | 5.4 | 4.2 | -1.2 | Yes |
| 9 | 8 | M | 9.3 | 26 | 4.7 | 5.4 | +0.7 | Yes |
| 10 | 12 | F | 14 | 24 | 4.1 | 4.0 | -0.1 | No |
| 11 | 10 | M | 11 | 25 | 4.4 | 8.2 | +3.8 | No |
| 12 | 13 | M | 13.5 | 25 | 4.1 | 8.2 | +4.1 | No |
| 13 | 13 | M | 14 | 24 | 3.7 | 3.25 | -0.5 | No |
| 14 | 11 | M | 12.5 | 23.5 | 3.6 | Pendin | | Yes |
| 15 | 13 | M | 13.5 | 24 | 4.9 | Pendin | | No |

Abbreviations: y = years, mos = months, HI = Haller Index

* Patient 1 post-treatment HI determined by AP/lateral CXR, as patient refused protocol CT

Table 2. Selected Questionnaire Responses

| ***Question*** | **One month into treatment N (%)** | **One month post-explant N (%)** | **One year post-explant N (%)** |
|---|---|---|---|
| *Did you feel any pain because of your implantable magnetic device?* | | | |
| No pain | 6 (40) | 5 (38) | 1 (14) |
| Occasionally | 9 (60) | 8 (62) | 6 (86) |
| Frequently | 0 (0) | 0 (0) | 0 (0) |
| Often (every day) | 0 (0) | 0 (0) | 0 (0) |
| *Did you have any physical or mechanical problem with the magnetic implant or the brace magnet when you were near other magnets or metal objects?* | | | |

| | | | |
|---|---|---|---|
| None | 10 (71) | 9 (69) | 6 (86) |
| Occasionally | 4 (29) | 4 (31) | 1 (14) |
| Frequently | 0 (0) | 0 (0) | 0 (0) |
| Often (every day) | 0 (0) | 0 (0) | 0 (0) |
| *During treatment, did not feeling well physically or mentally keep you from doing your usual activities?* | | | |
| Never | 9 (60) | 8 (62) | 4 (57) |
| Occasionally | 5 (31) | 5 (38) | 3 (43) |
| Frequently | 1 (7) | 0 (0) | 0 (0) |
| Often (every day) | 0 (0) | 0 (0) | 0 (0) |
| *How often did you wear your brace?* | | | |
| Every day, all day | 3 (23) | 3 (23) | 3 (43) |
| Every day, almost all day | 9 (69) | 7 (54) | 2 (29) |
| Every day for some hours | 1 (8) | 3 (23) | 2 (29) |
| Missed days | 0 (0) | 0 (0) | 0 (0) |
| *How satisfied are you with the correction of your chest?* | | | |
| Very satisfied | | 4 (31) | 1 (14) |
| Satisfied | | 4 (31) | 3 (43) |
| Unsure | | 2 (15) | 2 (29) |
| Dissatisfied | | 3 (23) | 1 (14) |
| Very dissatisfied | | 0 (0) | 0 (0) |
| *I would recommend this treatment to someone else with pectus excavatum:* | | | |
| Strongly agree | | 4 (31) | 2 (29) |
| Agree | | 7 (54) | 4 (57) |
| Unsure | | 2 (15) | 1 (14) |
| Disagree | | 0 (0) | 0 (0) |
| Strongly disagree | | 0 (0) | 0 (0) |