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A less intensive bracing protocol for pectus carinatum

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ABSTRACT

Objectives: Despite the widespread use of bracing to correct Pectus carinatum (PC) there is no consensus in the number of hours per day patients are instructed to wear the brace. In our practice, we use a less rigorous protocol of 8–12 h/day. We sought to evaluate our results and those in the literature to determine whether more intensive usage is necessary.
Study design: We reviewed the outcomes of patients with PC treated at our institution between 2012 and 2015. We searched MEDLINE, EMBASE and Web of Science for studies describing the use of bracing to correct PC.
Results: Seventy-five patients presented with PC at our institution. Among those who were offered bracing and had adequate follow-up (n = 32), the success rate (full correction or improvement) was 90.6%. The compliance rate was 93.8%. Fifteen studies met our inclusion criteria. Our pooled data combining our results with those of other published data showed that less intensive brace usage (<12 h/day), when compared to more intensive usage (≥12 h/day), is associated with higher patient compliance (89.6% vs. 81.1%) with a similar time to correction (7.3 vs 7.1 months) and success rate (85.3% vs. 83.5%).
Conclusions: Implementing a less intensive bracing protocol for PC is successful, efficient and improves compliance.
Type of study: Clinical Research.
Levels of evidence: Oxford Centre for Evidence-Based Medicine Level-of-Evidence rating: **Level IV.**

Pectus carinatum (PC) is a protrusion of the anterior chest wall which affects 1:1500 births [1]. It is more common in males and typically presents during childhood and develops dramatically during pubertal growth [1]. In most patients, PC is a cosmetic concern with few symptoms reported [1,2].

Whereas various surgical techniques were once the standard of care [3,4], external compression by an orthotic brace has been found to be a prominent safer and cost-effective alternative with improved cosmetic results and similar success rates [5,6]. Bracing has now gained considerable traction in the literature and clinical practice. A surge of publications started 10 years ago by articles such as Kravarusic et al.'s ("The Calgary protocol") [5] brought bracing into the mainstream of the literature and a study by Emil et al. [7] in 2012 found that the majority of Canadian pediatric surgeons now use bracing for the majority of their PC patients. The study however found that despite widespread use, there was a lack of agreement on bracing protocols among surveyed surgeons. A review of the literature reveals a similar pattern of widely variable protocols. Most commonly, bracing consists of two phases; (1) a correction phase (CP) during which the patient wears the brace until flattening of the chest followed by (2) a maintenance or retention phase (MP) during which the patient continues to wear the brace for a shorter period of time. Nevertheless, bracing end-points, wear time per day and progress surveillance techniques all vary and even this two-phased approach is not featured in all publications.

While bracing results are excellent and side effects tend to be minimal, it requires long-term patient compliance to achieve success [8,9]. In our experience patients tend to have difficulty with the number of hours per day they are instructed to wear the brace. Other centers face this same challenge. Multiple studies in the literature suggest wearing the brace "all the time" during the CP which, in our clinical experience, can be insurmountable for some patients and induce discomfort, pain, social anxiety and skin breakdown due to excessive wear. Consequently, we have been instructing our patients to wear the brace only 8–12 h/day during the CP and then 8 h/day during the MP based on our hypothesis that intensive bracing may not necessarily improve outcomes and may actually hinder compliance. Here we review the results of bracing at our institution and compare them with those in the literature to elucidate the relation between brace wear time per day and treatment success, compliance and time to correction.

1. Methods

1.1. Bracing protocol at our institution

Beginning in January 2012, PC patients referred to the pediatric surgery clinic at the Children's Hospital of Eastern Ontario (CHEO) were

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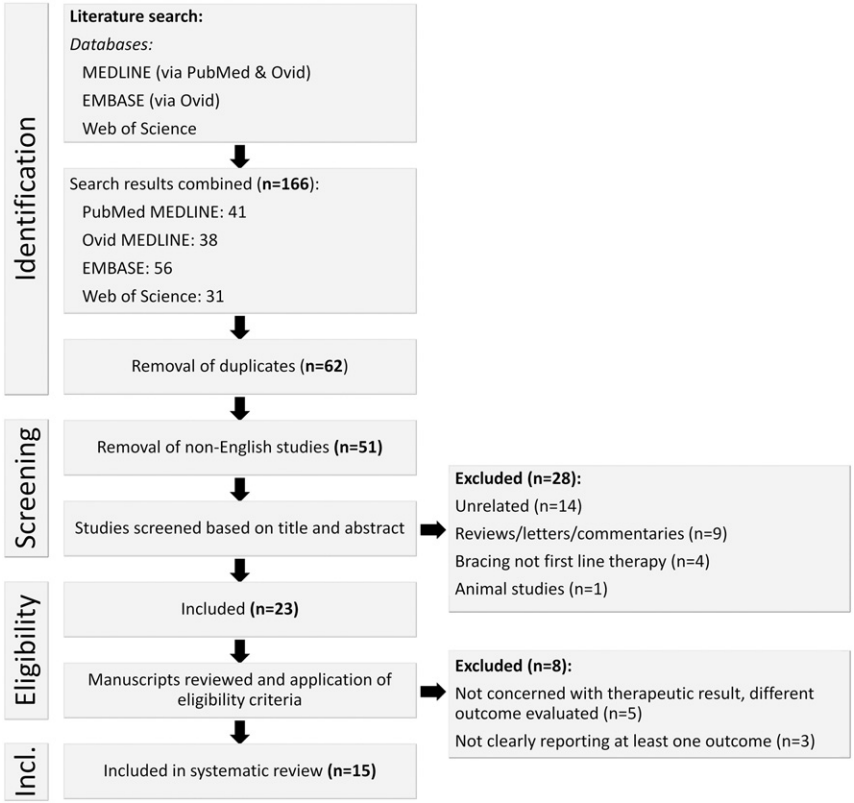

Fig. 1. Flow chart demonstration of study selection for systematic review. Incl. = Included.

offered bracing as the primary therapeutic option. The only exceptions being younger patients with chests too small for the brace and patients with a non-bothersome mild deformity; in these patients, observation was recommended instead. Surgery was reserved as a last-line option.

Patients having accepted brace therapy were given a non-custom-fitted brace, manufactured by Trulife®, and then fitted by a certified orthotist. The first phase of treatment was the CP during which patients were instructed to wear the brace 8–12 h/day until flattening of the chest as determined by surgeon assessment at follow-up. Patients were told that they did not necessarily have to wear the brace continuously as long as they fulfilled 8–12 h/day of bracing. After full correction of the deformity, patients entered the MP and usage could be reduced initially to night time wear or 8 h/day and phased out progressively over 6 months with gradual reduction in wear time. Patients were asked to follow-up 1 month after initiating bracing and then every 6 months to monitor progression and probe for complications and issues with compliance. Patients and parents were also instructed to contact the clinic and/or the orthotist if complications arose and if there was need to refit the brace. Patients were encouraged to wear the brace over a tight shirt (dry fit, no cotton recommended) and to avoid having the brace on too tight.

1.2. Retrospective institutional chart review

To assess outcomes of bracing in PC we performed a retrospective chart review of patients presenting with PC at our institution, CHEO, from January 2012, when our institution first began using bracing for PC, until July 2015. This review was done with approval from the CHEO Research Ethics Board Committee. All patients presenting with PC were included in the study irrespective of co-morbidities. First, we collected the following information from each chart: patient sex, first consultation date, follow-up dates, age at consultation, past medical history and comorbidities, recommended therapy by surgeon and therapy chosen by the patient. In patients who were offered bracing and accepted, we also collected: age at initiation of bracing, progress of treatment and outcomes based on surgeon assessment at follow-up, length of treatment phases, compliance as assessed by surgeon, complications and side effects and any other additional pertinent notes.

1.3. Systematic review search

1.3.1. Systematic review guidelines

This systematic review was completed following the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [10].

1.3.2. Systematic review identification

Studies were identified by electronic search queries. We searched MEDLINE (through both OVID and PubMed), EMBASE (through OVID) and Web of Science (all databases) (see Supplementary Table 1 in the online version at http://dx.doi.org/10.1016/j.jpedsurg.2017.01.057 for search terms). Emtree or Medical Subject Heading (MeSH) terms were utilized when available. These search inquiries were made in December 2015. No limits were placed on publication dates. We found a total of 166 combined results following all these queries. Following elimination of duplicates, 62 results remained (Fig. 1).

1.3.3. Screening and eligibility criteria

The eligibility criteria for this systematic review are as follows:

- **Population:** Human pediatric patients (0–18 years of age) treated for PC.
- **Intervention:** Usage of an external non-invasive orthotic brace as the primary therapeutic option to flatten the PC deformity.
- **Control:** *Undefined.*
- **Outcomes:** Primary outcome was therapeutic success. Secondary outcomes were compliance and length of bracing until correction.

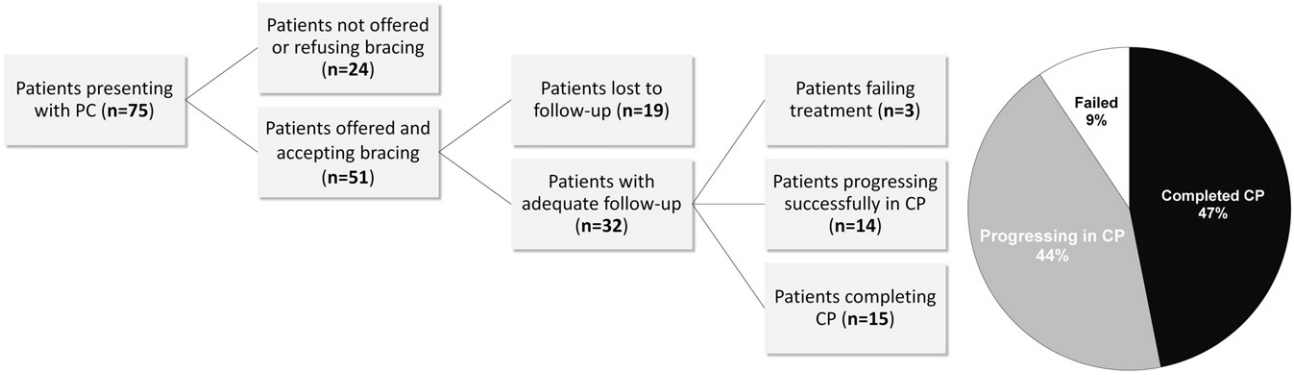

Fig. 2. Breakdown of patients from our retrospective chart review covering all patients presenting with PC at our institution between January 2012 and July 2015. A pie chart is shown at the right displaying treatment outcomes among treated patients with adequate follow-up.

We included all studies that reported clearly on one or more of these outcomes.

- **Study Design**: Included are primary research articles including case reports, case series, case control studies, cohort studies, controlled trials and gray literature.

Excluded from this study are non-English articles, unrelated articles, articles that did not contain original research data (letters, editorials, commentaries, reviews and lectures), animal studies and articles focused on diagnostic or follow-up tools and markers and not adequately evaluating or concerned with therapeutic outcomes.

Titles and abstracts were initially screened and 39 articles were removed based on the above criteria. The remaining 23 articles were read and 8 were eliminated for not meeting the eligibility criteria leaving 15 articles selected for inclusion in this review. The flow chart presented in Fig. 1 gives a detailed breakdown of this selection process. Reference lists in included articles were also surveyed but no additional articles were found to have been missed by the initial search queries.

1.3.4. Information extracted

The final included articles were assessed and the following data was extracted when available:

- Sample size, including number of patients braced
- Patient breakdown: number of patients treated, untreated and lost
- Hours of bracing per day recommended by surgeon and as reported by patients
- Time to correction
- Treatment success, either by subjective or objective measures
- Compliance
- Side effects of treatment
- Author's conclusions

In cases of unclear or inadequate information in the articles, we contacted the corresponding authors.

1.3.5. Assessment of articles

Study methodological quality was assessed by application of the Methodological Index for Non-Randomized Studies (MINORS) [11] criteria to all studies identified from the systematic review.

1.4. Pooling of data

We sought to assess the effect of less versus more intensive bracing on treatment outcomes. We pooled patients from studies identified from the systematic review into two groups, a "more intensive bracing" group and a "less intensive bracing" group, based on the number of hours per day of bracing reported by the authors of each respective article. As we instruct our patients to brace for 8–12 h/day, we defined more intensive bracing as 12 or more hours of bracing per day and less intensive bracing as less than 12 h/day. When clearly and accurately reported by the authors, we used the number of hours reported by patients in this analysis; otherwise we used the number of hours instructed by the surgeons to the patients in each respective article.

Following pooling, we calculated treatment success, patient compliance and time to correction in the two groups. Lost patients were excluded from pooling. Treatment success was defined as the sum of pooled patients having achieved a flattened chest (completing the CP) or successfully progressing in the CP phase of their treatment protocol, as reported by the treating physician, divided by the total number of braced patients pooled in each group. To allow for direct comparison of studies, only studies where patients wore the brace until correction were included in the calculation of treatment success (studies where patients wore the brace for a fixed length of time were excluded). Patient compliance was defined as the sum of pooled compliant patients, as reported by the author of each article, divided by the total number of braced patients pooled in each group. Time to correction was defined as time needed to achieve a flat chest, e.g., the length of the CP. Time to correction for each group was calculated as an average of the time reported in each study, weighted to the number of patients corrected in each article. It is to be noted that not all articles reported all three variables adequately so the number of studies included for the calculation of each variable, and hence the total number of pooled patients for each variable, varies within each group.

2. Results

2.1. CHEO retrospective chart review

Between January 2012 and July 2015, 75 patients presented with PC at the pediatric surgery clinic at our institution (Fig. 2). Sixty-four of these patients were male (85.3%) and 11 (14.7%) were female. The average age at consultation was 13.0 ± 3.2 (2–17) years.

Among the total 75 patients, 24 (32%) were not given a brace prescription; these patients were either too young and were instructed to wait (n = 7), had mild PC (n = 9), refused treatment (preferred observation; n = 6) and the remaining two patients had to wear another brace for another orthopedic disorder and could not wear the PC brace simultaneously. Among the 51 patients (68%) who were offered and accepted bracing, 19 patients (25.3%) received a brace prescription but did not obtain it and never followed-up after the initial consultation and were deemed as "lost." We elected to count these patients as "lost" rather than treatment failures as these patients never began the treatment protocol. Among the remaining 32 patients (42.7%) who followed-up adequately, 15 have achieved a flattened chest and thus completed the CP, 14 were noted at sequential follow-ups to have improvement of their deformity, by surgeon assessment, but have not yet achieved complete correction and 3 patients failed treatment. Among the patients who failed treatment, all but one, were non-compliant. Among

Table 1
Patient breakdown from studies identified in systematic review.

Study	Hours/day	Braced[a]	Corrected	Progressing	Failed	Compliant	Time to correction (mo)	MINORS Score (/16)
Patients instructed/reporting bracing ≥12 h/day								
Mielke [11]	24	1	1	0	0	1	7	-[b]
Lee (2008) [12]	24	141	N.I.[c]	N.I.[c]	N.I.[c]	119	N.I.[d]	7
Stephenson [13]	23	36	28	0	8	28	N.I.[d]	11
Lee (2013) [14]	23	70	44	10	16	56	N.I.[d]	11
Kravarusic [15]	23	24	19	2	3	21	4.3	12
Haje [16]	23	37	N.I.[c]	N.I.[c]	N.I.[c]	25	N.I.[d]	6
Colozza [17]	23	25	20	0	5	22	4.5	10
Banever [18]	23	20	3	12	5	12	24.3[e]	9
Jung [19]	20	18	13	0	5	13	4.9	11
Lopez [20]	19	61	47	14	0	61	10	12
Frey [21]	15	29	26[f]		3	26	N.I.[d]	10
Wong [7]	12	40	N.I.[g]	N.I.[g]	N.I.[g]	23	N.I.[d]	12
Patients instructed/reporting bracing <12 h/day								
Cohee [22]	11.4[h]	117	37	67	13	106	7.25[h]	11
Sesia [23]	10	13	2	11	0	13	N.I.[i]	-[j]
Martinez-Ferro [5]	7.2	205	99	68	38	180	7	9
Our institution	*10*	*32*	*15*	*14*	*3*	*30*	*9.63*	-

N.I., Data not included in analysis due to lack of availability or quality.
[a] Lost patients were excluded.
[b] Case report; MINORS score was not calculated.
[c] Only patient satisfaction scores were reported.
[d] Brace wear length given as time to follow-up and time to correction not reported. These studies were excluded from calculation of the success rate.
[e] Outlier, not considered in pooling.
[f] Reports the number of successful patients, does not report number of corrected and progressing patients separately.
[g] Only radiographic data was reported.
[h] Personal communication.
[i] Not reported.
[j] Abstract; MINORS score was not calculated.

the patients who completed the CP, time to correction was 9.6 ± 5.0 (1–19) months. There was one case of recurrence in a patient who completed therapy; he briefly re-wore the brace and re-achieved correction. No surgery for PC was performed over the studied period. Fig. 2 illustrates these results.

Compliance was defined as daily usage of the brace for at least 8 h/day in patients who began the protocol treatment. Of the 32 patients who braced and had adequate follow-up, 30/32 (93.8%) were compliant. The two non-compliant patients failed treatment.

Ten of the 32 patients (31.3%) who braced and had adequate follow-up complained of complications of bracing. All of these were slight side effects: discomfort (n = 4), social anxiety (n = 2), erythema (n = 2), sleep disturbance (n = 2), pain (n = 1) and breathing difficulties (n = 1) (2 patients had two simultaneous complaints each). Most of these cases were successfully managed with re-fitting of the brace and/or decreasing brace wear time per day. Treatment was not abandoned in any case and no analgesics were used.

2.1.1. Systematic review results

Fifteen studies met our criteria and were included in our study [5,6,8,12–23]. All studies identified were case series with no comparative groups. The extracted data from these articles and our institutional review is shown in Table 1.

We pooled the data from these studies into two groups according to the number of hours per day patients reported wearing the brace (or if not available, were instructed); an intensive bracing group (12 or more hours/day) and a less intensive bracing group (less than 12 h/day). We found that less intensive bracing, when compared to more intensive usage, was associated with a similar success rate (85.3% vs. 83.5%). We found that compliance was superior with less intensive bracing (89.6% vs. 81.1%). Finally, less intensive usage was not associated with prolonging of the time needed to achieve correction, which was similar compared to more intensive usage (7.3 vs. 7.1 months). These results are summarized in Table 2.

3. Discussion

External brace compression has now become the first line of treatment for PC given its potential for excellent results and its low-risk profile compared to surgery. However, it is hindered by poor compliance and any effort or innovation towards improved compliance would be highly beneficial. Our current finding, then, that increased compliance is correlated with less intensive brace usage, all while preserving success rates and the time needed to correct, is of great significance. We hypothesize that this could be due to increased burden and increased complications with more intensive bracing. Kang et al.'s study [9] demonstrated decreased compliance with increased number of complications in bracing patients. Thus, we also tried to correlate the number of hours per day of bracing with complication rates in our pooled data but complications were not reported often and similarly enough in the different studies to make any conclusions. Nonetheless, in our experience, excessive bracing per day leads to increased discomfort, social anxiety, and skin irritation. We instruct patients who experience these side effects to wear the brace less and to-readjust the brace and this does successfully alleviate these complications.

Table 2
Pooled data comparing bracing outcomes.

Patients instructed/reporting bracing ≥ 12 h/day		Number of pooled patients for variable analysis
Success rate (%)	83.5	255
Failure rate (%)	16.5	255
Compliance (%)	81.1	502
Time to correction (months)	7.1	144
Patients instructed/reporting bracing <12 h/day		
Success rate (%)	85.3	367
Failure rate (%)	14.7	367
Compliance (%)	89.6	367
Time to correction (months)	7.3	151

Taken altogether, this data illustrates that intensive bracing protocols are not necessary. Interestingly, Cohee et al. [22] reported that fully corrected patients wore the brace slightly more than failed patients and another study by Loff et al. [24] (which was not included in our systematic review due to not meeting our inclusion criteria) reported a similar finding. The significance of these findings though is unknown. We found no correlation in our pooled data between failure rates and the intensity of bracing per day (Table 2). A probable explanation may be that individual patients who achieve success/flattening are encouraged to wear the brace more (although not necessary). This theory is substantiated by Kang et al.'s study [9] which showed that initial therapy success correlates with increased compliance in braced patients.

We considered success of treatment based on subjective assessment by the treating surgeon which is the most commonly used success assessment metric in the studies we identified. A minority of studies only used patient satisfaction scores [13,16] or radiographic methods [8]. As there were few studies using these and quantification methods varied, they were excluded from our quantitative analysis of success rates. That said, a more widespread use of better-validated standardized objective radiographic markers can allow for better comparison between studies but this is limited by cost, institutional access and radiation exposure.

Our analysis is also ultimately limited by the fact that all identified studies used in our study were case series with no comparative groups. In addition, there may be a gap between the number of hours patients are instructed to wear the brace and how much they actually wear it in practice. We privileged the number of hours reported by the patients, when clearly and accurately reported by the authors, as the ultimate goal of this study was to describe the relationship between wear time and treatment success and compliance. However, this data was not always available. As well, different studies used different orthotic braces and some may be, in theory, more advantageous than others. For example, Lopez et al. [20] and Martinez-Ferro et al. [6] both feature a dynamically compressive brace which the patient can adjust to their comfort, presumably reducing discomfort and skin irritation. Both of these studies resulted in excellent compliance and therapeutic success rates despite the fact that one stated that patients reported bracing for an average of 19 h/day and the other, 7 h/day. Moreover, some studies pre-selected patients who were believed to have higher chances of benefitting from brace treatment based on the initial pressure needed to correct their deformity (either based on a formal pressure measurement or subjective estimation by the surgeon attempting to compress the deformity at clinical assessment) [16,20,22]. Although these add confounding factors that limit our analysis, they illustrate additional important variables which must also be considered when prescribing the brace to optimize patient comfort and hence compliance and success. Conversely, in our practice, we used a simple non-custom brace (with mechanical re-fitting as needed) and all patients regardless of the stiffness of their deformity were braced. Nonetheless, we achieved similar excellent results and compliance demonstrating that, although beneficial, these expensive and complex innovations may not be necessarily required. We hypothesize in our case that reducing the intensity of bracing per day along with asking patients to wear the brace comfortably and not too tightly sufficiently improved compliance.

It is to be noted that this study focused only on the CP. The majority of identified studies feature an additional MP phase following completion of the CP. The protocol of the MP is very variable; while in most studies, as in our practice, it is recommended for a few months, some studies do not feature it all [6,13,18,19] and some go as far as instructing the brace be worn until axial growth stops [15]. The exact purpose of the MP and its effect on treatment outcomes has not been studied or even well defined. In this present study, we could not compare the MP between different studies due to how widely protocols differed.

In conclusion, implementing a less rigorous bracing protocol for patients presenting with PC achieves equal success rates with improved compliance and does not prolong the time needed to correct the deformity. This less intensive protocol can be used to improve compliance for bracing and reduce the need for riskier surgical interventions.

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Disclosure

Conflicts of interest: none.

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