Heliyon 8 (2022) e11942

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon

Research article

The effect of the design of the orthosis on the axial load transmission of two flexion abduction orthoses used in treating congenital hip dysplasia

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HIGHLIGHTS

- This axial load has been measured and linked to weight and movement.
- Comparison of the Tübinger to Superior splint shows big differences in axial forces.
- Different designs are proven to have significant biomechanic effects.

ARTICLE INFO

Keywords:
Developmental hip dysplasia
Biomechanics
Abduction orthoses
Tübinger orthosis
MittelmeierGraf orthosis
Axial force

ABSTRACT

Background: With an incidence of 2–4% in all newborns, developmental dysplasia of the hip, DDH, represents the most frequent congenital disorder of the skeletal system in Germany. The therapy options are deduced with the help of a sonography. The conservative therapy approach includes the application of flexion abduction orthoses, which lead to a development of the child's hip through abduction and flexion angle. The overall structure of the orthoses puts a strain on the axial skeleton of the children. The following work is intended to clarify what role the design of the orthoses plays in this respect.

Methods: Inclusion criterion for the study was fully developed newborns without an indication of skeletal malformations with Type I hip joints according to Graf verified by ultrasound. A total of 19 newborns were recruited and included in the period 3/2013–01/2015. Two types of orthoses used in treating developmental dysplasia of the hip (Tübinger splint, Otto Bock; hip flexion abduction orthosis (Superior orthosis) according to Mittelmeier-Graf, AIDAMED e.K (Kreuz et al., 2012; Mittelmeier et al., 1998; Schmitz et al., 1999), constructions differ, were used. Force was measured with the help of three force sensors, which were even able to be integrated into these without changing the design of the orthosis. In this closed system, force transmission was measured for the duration of a fixed period of two minutes.

Findings: The greatest axial force development (overall force) is in the Tübinger splint with an average force of 15.1 N (min. 0.59 N, max. 53.09 N, mean 15.1, SD 2.46). 4.09 N (min. 0.96 N, max. 20.99 N, mean 4.09, SD 0.65) resulted in the Superior orthosis. Significant correlations between body weight and resulting axial traction – on average during the entire measurement period and in movement – can be taken from the statistical analysis regarding the Tübinger splint. Such a correlation cannot be depicted for the Superior orthosis.

Interpretation: The analysis of the load transmission of the examined flexion and abduction orthoses reveals differences between the models. The construct of the orthoses in itself appears to play a significant role. Long-term effects of orthosis therapy on a child's axial skeleton have not been studied to date. Furthermore, it seems reasonable to expand the test series to orthoses, the design of which is configured in a similar matter compared to the examined aids.

Conclusion: This study proves that the orthotic design has an influence on the infant's axial load.

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https://doi.org/10.1016/j.heliyon.2022.e11942
Received 31 May 2022; Received in revised form 16 November 2022; Accepted 21 November 2022

1. Introduction

Congenital hip dislocation or DDH (developmental dysplasia of the hip) is defined as a congenital dysgenesis of the acetabulum [1, 2, 3] and is a global problem. It is a highly prevalent condition and has significant medical impacts globally [4, 5]. If DDH is overlooked and/or not treated, long-term deformities of the hip with gait disorders and premature arthrosis can result [2, 3, 6, 7].

As early as 1980, Graf et al. published a classification [8] for ultrasound examinations of the infant hip, with a division into four main types [9, 10]. Meanwhile, the Graf method is standard throughout Europe and has been established by law as a preventive measure in line with the 4–6 week screening after birth [11, 12]. This screening is already conducted during the first week after birth in the Orthopedic Clinic and Polyclinic of the University Medical Centre Rostock because dysplastic hips then already have a 6-week advance in therapy.

If hip dysplasia is diagnosed, a flexion abduction orthosis is normally used in conservative therapy [13, 14]. Despite the different design, all orthoses have one thing in common: they “flex and spread” [3, 15]. This situation causes a centralization of the femoral head in the acetabulum and ultimately leads to a physiological (post-)maturing [2, 15, 16]. As a result of the pressure relief, particularly on the anterior acetabular region, a greater potential for osseous and cartilaginous reorganization results [13, 3, 15, 17, 18, 19]. A number of orthoses are used in treating DDH, the therapeutic outcome of which is comparable, if the Graf type dislocation and principle of treatment (abduction and flexion of the hip) are the same. Long term effects on the axial skeleton of an infant have not been studied yet.

In regard to the design however, the orthoses are quite different [13, 5, 19, 20, 21]. There are orthoses with an abdominal or chest strap and splints without intermediate fixation. This becomes noticeable in the force that is transmitted to the infant’s axial skeleton. Published studies with only one sensor [11] already indicate force differences between orthoses. The objective of the study presented here was to technically expand the test series of the prior publication (which found great axial loads) up to three sensors, to determine whether the findings are the same or change significantly. We aimed to remove disruptive factors due to a too small number of sensors.

The following questions are to be clarified in the study:

- Does the different structure of the splints lead to different forces that may have an effect on the infant’s axial skeleton?
- Do the forces, that arise during phases of rest and phases of movement, differ?
- Does body weight or length have an effect on these forces?

2. Methods

2.1. Patient collective

The healthy children relevant to this work were selected directly after birth. After the hip ultrasound and a verified Type I hip on both sides, the examination was conducted with the parents' consent. There was no randomization or blinding. The approval of the Ethics Commission (A 48–2008) of the University Medical Centre Rostock was given at the time of beginning the study.

We included a total of 19 healthy children in these measurements from 3/2013 to 01/2015. The youngest newborn was one-day-old, the oldest a seven-day-old. The average age of the group amounted to 2.63 days at the time of measurement. The average weight of the children was 3495 g (2800 g–4300 g). Gender distribution indicates a girl:boy ratio of 1.125:1. The following was recorded: initials, date of birth, weight, hip type according to Graf [2], day postpartum, sex.

2.2. Orthoses

The difference between the structure of the Tübinger splint (Otto Bock) and the hip flexion abduction orthosis according to Mittelmeier Graf (“Hüft-Beuge-Spreizorthese nach Mittelmeier Graf”, AIDAMED e.K [22].) is that the Superior orthosis has an abdominal strap. Both aids are capable of positioning the child in the recommended sitting-squatting position [5,23].

2.3. Test set-up

The test set-up can be seen in Figures 1 and 2. Three sensors were integrated into the orthoses used, without changing the design or tension of the straps in the process. The objective was to reflect the transmission of force in the closed system (orthosis and child) by attaching a sensor to each individual strap. Each sensor (Figure 3) had a fixed position for all measurements (front left, front right and in the back on each of the shoulder straps, refer to Figure 2), to ensure reproducibility.

The 19 newborns were fitted with the Tübinger splint and the Superior orthosis consecutively. After an adjustment phase, the measurement began for a defined period of respectively 2 min at 50 hz (50 points of measurement per second). The measurements are highlighted according to calm and active phases (leg kicking/stretching). These phases were not documented but subsequently calculated mathematically from the force vectors.

2.4. Measurement and statistical evaluation

The type “KD24s” sensors used are from ME-Meßsysteme, Hennigsdorf, Germany [24]. The sensors can be loaded with up to 100 N with an accuracy of 0.1%. Each sensors weighs 12 g. Data is always collected with the same sensors at their marked and defined positions. A zero offset calibration of the sensors was conducted prior to every measurement. There was no need to change the sensors. The test set-up is shown in Image 1, 2 and 3. We referred to the prior publication regarding the measurement set-up [11].

The measurement data was stored using the Microsoft Windows Software “GSV Multichannel” (© 2001–2007 National Instruments Corporation) as “tdms” and “tdms_index” and distinctly designated according to a defined pattern. After the data was exported to Excel, the statistical evaluation took place with R: a language and environment for statistical computing [25].

2.5. Statistical evaluation

Force was measured for around 2 min. We built an overall force effect by summing up three measurements, from the two front sensors and from

Figure 1. Test set-up showing the Tübinger orthosis with integrated sensors.

the one back sensor. The newborn were calm most of the time. In this time frame, minimal force was measured. When children were stimulated to move, maximal force was measured. To find the time frames of movement respectively rest, we considered measurements with the highest, respectively lowest, force amplitudes in a time frame of 10 s corresponding to 500 measurements (10 s * 50 Hz = 500). To determine time frames of movement (highest force measurements) and rest (lowest force measurements), we calculated standard deviation for force measurements of 5500 time frames (6000 measurements, frame size 500). We chose the time frame with the maximal standard deviation as the time frame with the highest force amplitudes, thus the time frame of movement. This was repeated for minimal standard deviation as the time frame with the lowest force amplitudes, thus the time frame of rest. Since we conducted the experiment for each child, in both hip flexion splints, we determined the following force vectors.

Superior — movement
Superior – rest
Tübinger — movement
Tübinger — rest

Those force vectors were averaged, to get a general force vector.

2.6. Correlation

The general force vector was used to calculate correlations. Those were calculated with the R function cor.test [25, 26]. The Pearson method of correlation calculation was used. Null hypothesis is that the correlation is 0 and therefore, no connection can be found in the data. We calculated p-values for maximal values during phases of rest and movement as well as for all measurements with "Tübinger" splint and "Superior" orthosis. A p-value <0.05 is statistically significant.

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Figure 3. KD24s sensor used in the set-ups shown.

2.7. Linear regression

We performed linear regressions upon the general force vector with the R function lm and calculated linear regression coefficients as well as p-values with different parameters from the data and the weight of the newborns [25, 26]. We chose mean values of all measurements, the maximal value of measurements, while the children were in rest or in movement. We also applied the coefficients to the common linear regression equation $y = ax + b$. Here, y is the force in Newton, x is the weight in grams.

3. Results

In the addition of the forces absorbed by the three sensors used, the newborns developed significant axial (tensile) forces that indicated significant differences based on the orthoses (Figure 4).

3.1. Rest and movement

The mean for the Tübinger splint resulted in an axial force of 15.1 N and for the Superior orthosis in an axial force of 4.09. The values of axial tensile force changed for both orthoses by the incremental factor 2.23 (Tübinger) and 2.63 (Superior) during the movement phases. We

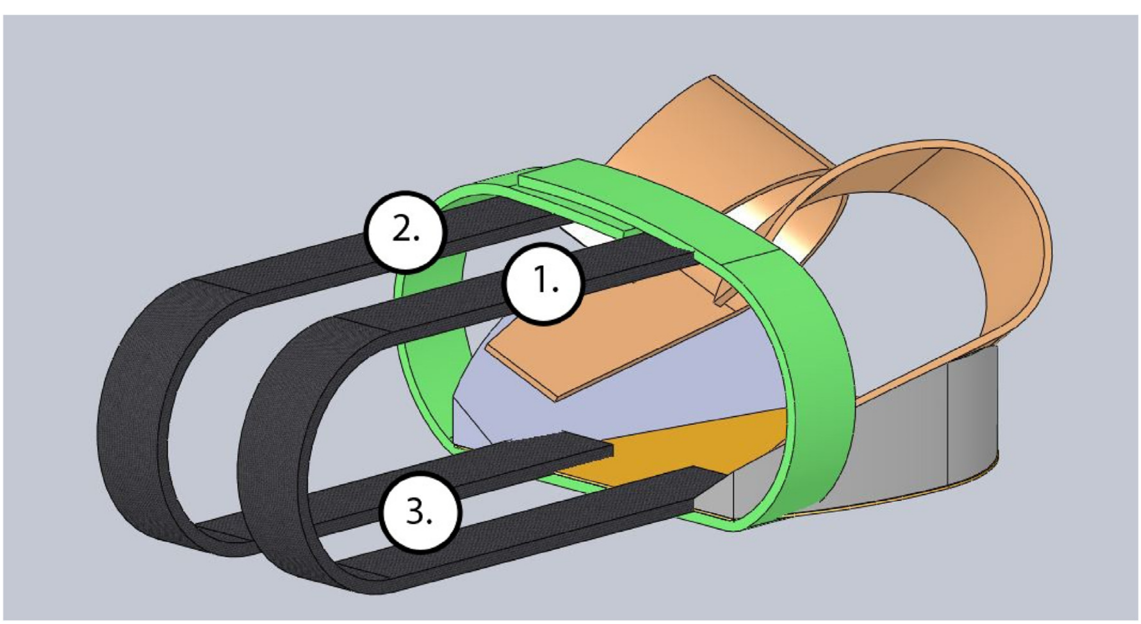

Figure 2. Test set-up model of the Superior orthosis, numbers indicate the position of the sensors. Illustration courtesy of Prof. Dr.-Ing. Volkmar Schwanitz.

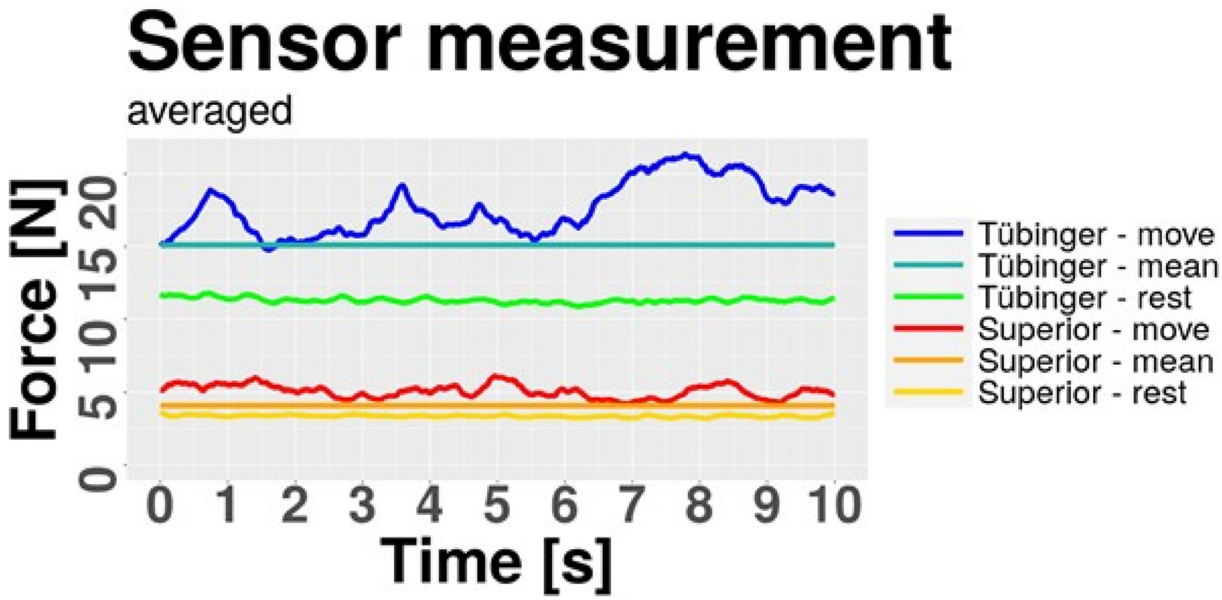

Figure 4. Sensor measurements: Comparison of calculated means, for each time point mean is indicated in blue respectively green (Tübinger splint), red respectively yellow (Superior orthosis) during phases of move-ment respectively rest, mean of overall measurement.

examined the correlation between body weight and the arising axial force because of the in part extreme acting forces. The ratio between acting force and body weight was cumulative with higher body weight.

3.2. Correlation

We calculated correlation coefficients and their p-value for correlations between force and weight or/and length (Table 1). We did not find any significant correlation coefficient for correlations between length and any force parameter for both hip flexion splints. Neither did we find correlations between length and weight and any force parameter for the "Superior" orthosis.

Testing for significant correlation parameters of weight and resulting power the "Tübinger" splint resulted in significant correlation parameters (Table 1).

3.3. Linear regression on averaged sensor measurements for Tübinger

We performed linear regressions for force and weight with averaged sensor measurement for all sensor measurements in newton = n weight of children in gram = w.

Given the results of correlation calculation for the "Superior" orthosis lead to no significant parameters for a linear regression equation (Figure 5), we calculated those regression parameters with the purpose of comparison between "Tübinger" splint and "Superior" orthosis. Here, the regression equations of the "Tübinger" splint are shown (Figure 6).

3.3.1. Mean value for all sensor measurements

The correlation coefficient of 0.48 for the "Tübinger" splint reveals a significant correlation ($p = 0.037$) between weight and averaged force for all sensor measurements. The linear regression equation is as follows $n = 0.01 *w - 15.36$

Table 1. Correlation parameters for Tübinger splint.

	Correlation (weight/power)	p-value
Maximum of all measurements	0.55	0.015
Mean of all measurements	0.48	0.037
Maximum of measurements while resting	0.54	0.017
Maximum of measurements while resting	0.54	0.017
Standard deviation while resting	0.52	0.022
Maximum of measurements while moving	0.46	0.047

3.3.2. Mean values for sensor measurements while resting

The correlation coefficient of 0.54 between weight and averaged force for sensor measurements of the "Tübinger" splint while resting also reveals a significant correlation ($p = 0.017$). The linear regression equation is as follows $n = 0.01*w - 13.89$

3.3.3. mean values for sensor measurements while moving

No significant correlation coefficient was calculated for the "Tübinger" splint while moving ($R = 0.38$, $p = 0.113$) between weight and averaged force sensor measurements. For the purpose of comparison, we calculated regression parameters resulting in the following equation. The linear regression equation is as follows $n = 0.01*w - 9.82$.

4. Discussion

The treatment of developmental dysplasia of the hip at the earliest possible time is indisputable, extensively clinically investigated and classified as proven successful [2, 27]. The orthosis option for treating DDH is manifold [5, 19, 28, 28]. The design of two orthoses used regularly at the Orthopedic Clinic and Polyclinic of the University Medical Centre aroused the authors' interest in expanding an already preexisting analysis of the load transmission via the axial skeleton of the newborn [11].

It can be proven that a higher body weight is also accompanied by greater averaged axial forces. We were only able to verify this for the Tübinger splint, for which, contrary to the Superior orthosis, there were significant findings in the linear regression.

4.1. Results

Both types of orthoses indicate relatively constant values for the axial force during phases of rest and in the mean. The infant's movement caused high amplitudes in the Tübinger splint. This correlated significantly with a high body weight. The differences between phases of rest and movement are significantly greater in the Tübinger splint than in the Superior orthosis. Furthermore, in regard to the Tübinger splint, the statistical evaluation indicates a significant correlation between body

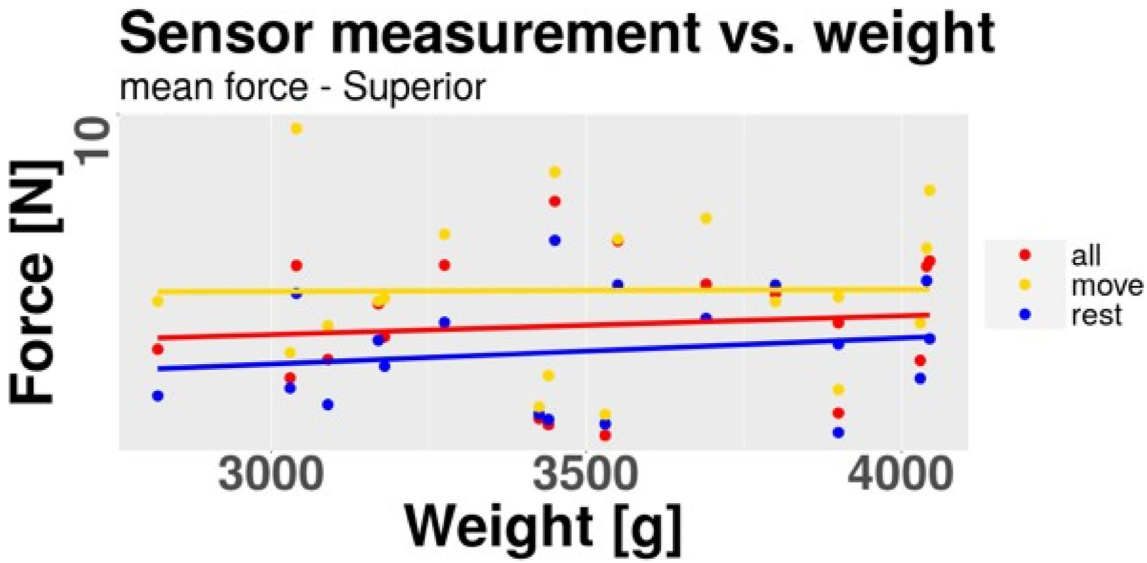

Figure 5. Comparison of linear regression: linear regression parameters for weight in grams (g) and force in newton (N) were calculated; red: all measurements were used for the calculation of regression parameters; yellow: measurements of a phase of movement were used for the calculation of regression parameters; blue: measurements of a phase of rest were used for the calculation of regression parameters; dots — measurements, line — linear regression curve, curves for "Superior" orthosis are not significant.

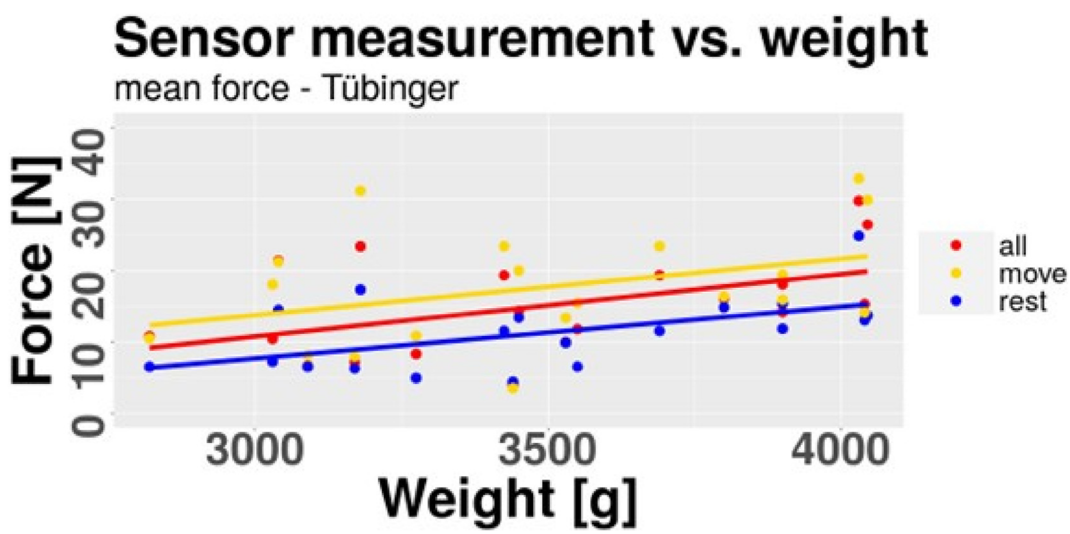

Figure 6. Comparison of linear regression: linear regression parameters for weight in grams(g) and force in newton (N) were calculated; red: all measurements were used for calculation of regression parameters; yellow:measurements of a phase of movement were used for the calculation of regression parameters; blue: measurements of a phase of rest were used for the calculation of regression parameters; dots — measurements, line — linear regression curve, curves for the "Tübinger" splint — all and rest are significant but not for movement.

weight and acting axial force in our measurement system; on the one hand for all values and in particular for movement values. Consequently, heavier infants develop a higher axial load in the Tübinger splint compared to lighter infants. This could represent a substantial problem because infants with higher weights indicate a greater prevalence for DDH [29]. The correlation body weight/axial load could not be shown for the Superior orthosis. The acting forces have a direct effect on the infant's shoulder strap and axial skeleton because of the design of the orthoses. The greater number of sensors compared to the prior publication [11] enables a more accurate recording of the acting axial forces and a better perception of the average strain on the body in the respective orthosis. The positioning of the sensors excellently displays the acting forces on the shoulder strap and axial skeleton however, not the compressive loads in the area of leg supports and the hip joints themselves. The examined orthoses indicate a significant difference in design in the load transmission to the shoulder straps [5, 28], so that a new positioning of the sensors can be discussed for future studies depending on the hypotheses.

4.2. Comparison of findings with national and international literature

Existing literature emphatically proves the necessity of early orthotic treatment of developmental dysplasia of the hip [13, 2, 3, 6, 20, 27, 30, 31]. To date, there is only one study regarding the forces on the axial skeleton caused by splints [11]. The loads may have an effect on an actively and fast-growing and in part, still cartilaginous skeleton. Therefore, a shorter treatment time as a result of an early treatment start could be sought. In this study, the authors can confirm the results of the only prior study to date with a higher accuracy. In this respect, it is only possible to use similar studies on axial compromising of the spinal column after strain [32, 33, 34, 35, 36, 37]. There are comparable studies that prove significant physical strains, which can result in local ischemia of the skin and connective tissue, muscular tension with (shoulder, back) pain and limitations of cardiac and pulmonary function [34, 35, 38, 39]. Functional scoliosis is also described as an effect of the axial load [35, 36].

The global recommendation is that a weight load, for instance caused by a knapsack or even schoolbag, should not exceed a maximum of 10–15% of the child's body weight and 30% in the case of adults [33, 36]. There are initial image based studies in adults, which prove that an axial load led to significant discogenic compression while lying as well as standing [40]. If we examine the aforementioned orthoses merely based on this aspect, considerably higher loads occur regularly in at least one of the two orthoses. It is currently unknown whether and when possible long-term damages occur or occurred.

4.3. Strengths and weaknesses of the study

The duration of the measurements was limited to a defined period of 2 min for the respective orthosis with an "adjustment phase". In this respect, a small glimpse into the wearing time can be imparted at best. A 24 h measurement or long-term measurement with smaller, permanently integrated sensors would most certainly lead to even more accurate findings, to possibly find out why the orthoses initiate different degrees of force. Given there is only one study on this topic to date [11], an adequate comparison with the same objective but, if applicable, different measurement methods is not possible. An infant is virtually always in a horizontal or dorsal position during the first weeks. Insofar, comparisons with school children with upright, standing posture are only suitable as a rough approximation. Furthermore, the physiological form of the spinal column (lordoses, kyphoses) changes with verticalization. The double S-curve does not develop from a kyphotic configuration of the infant's spinal column until full verticalization. Furthermore, this study lacks comparisons to other orthoses, because these two orthoses are the most commonly used ones in Germany and thus are the clinically most relevant ones.

4.4. Outlook

Considering these findings, it seems reasonable to expand the test series to orthoses, which are configured in a similar matter compared to the ones examined. There are no long-term studies in terms of longitudinal monitoring. A retrospective tracking of children who have completed treatment represent an option of making statements regarding possible problems associated with the spinal column. Whether or not affected children, with DDH on one side, achieve similar results is to be clarified in a subsequent study.

5. Conclusions

This study proves that the orthotic design has an influence on the infant's axial load. Moreover, a higher body weight is also accompanied by a higher average degree of axial forces.

Irrespective of this statistical finding, it must be emphasized that in the long-term, both examined orthoses haven proven themselves in the treatment of DDH.

Declarations

Author contribution statement

Mr. Schwanitz von Keitz and Mrs. Fröhlich: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Mrs. Kleimeier and Mr. Kasch: Analyzed and interpreted the data; Wrote the paper.

Mr. Lutter, Mr. Rehberg and Mrs. Osmanski-Zenk: Analyzed and interpreted the data.

Mr. Mittelmeier: Conceived and designed the experiments; Analyzed and interpreted the data.

Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Data availability statement

Data will be made available on request.

Declaration of interest's statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

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