Clubfoot (talipes equinovarus) is a common congenital deformity that may be treated by the Ponseti method. In this method, the treating physician manipulates the clubfoot by applying manual pressure on the medial side of the first metatarsal (FM) with counter pressure on the lateral side of the talar neck (TN). This causes the forefoot to align with the talus while the calcaneus is manipulated into its proper position in the subtalar joint. The newly imposed position stretches and remodels the tissues of the clubfoot and is maintained for a week with a plaster cast. Most cases of clubfoot are corrected, sometimes with the addition of a percutaneous Achilles tenotomy, after five or six changes of cast. After the period of casting, an abduction brace needs to be worn for several years to prevent relapse. It is suggested that in serial casting, most of the correction is obtained by the manipulation. It is hypothesized that the plaster does not produce the correction but maintains the improved orientation of the foot, which is gained by the manipulation. The mechanical behaviour of clubfoot tissues can be characterized as visco-elastic. Thus, their behaviour is partly elastic, in which deformation is recovered after removal of the load, and partly plastic, in which deformation is permanent. Initially, the tissues resist correction, acting as a spring pressing on the cast. When the cast is removed after a week, the foot does not return to its original position unless the tissues are stretched and remodelled during the period of casting.
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not immediately return to its original position. It appears that the tissues adapt to the applied force over time. The decreasing stress in response to an initial stretch is known as stress-relaxation and the rate at which the force decreases is the rate of adaptation. It can be characterized by a half-life time $t_{1/2}$, which is the time required for the force to decrease to half of its original value.

Quantifying the Ponseti method objectively would allow a better understanding of the corrective processes. Force sensors may be used to measure the corrective forces. We hypothesized that the force that the clubfoot exerts on the plaster cast will decrease with time, as a result of the adaptation of the tissues in the clubfoot to the position imposed by the plaster cast. The aim of this study was to test this hypothesis, to determine the forces exerted by the foot on the cast with the passage of time and to calculate the half-life time in a clubfoot undergoing correction using the Ponseti method.

**Patients and Methods**

This was an exploratory observational study performed at the University Medical Centre of Groningen (UMCG) in the Netherlands. The ethical evaluation committee of the UMCG reviewed the study in accordance with the declaration of Helsinki, and found that it did not meet the criteria as stated by the Medical Research Involving Human Subjects Act (WMO), and therefore did not require ethical approval (document number M16.196266).

Ten children with an idiopathic clubfoot, who were all aged less than three months and who had not undergone any previous treatment, were included in the study after obtaining informed written consent from their parents. Their mean age was seven days (2 to 30); there were nine boys and one girl. In those with bilateral clubfoot, the foot with the highest Pirani and Diméglio scores was included.

Figure 1a shows a custom-made force sensor, based on inductive sensing, that was specifically developed for the study. The output signal of the sensor is LHR_DATA, a 28-bit digital value proportional to the resonance frequency, which is a measure of the applied force. The design of the sensor and its performance, as summarized in Table I, have been previously described. A digital DS1825 thermometer (Maxim Integrated, San Jose, California) was included to allow removal of the temperature-induced signal error.

Table I. The characteristics of the force sensor; for more details, see Giesberts et al.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions ($\varnothing \times$ thickness), mm</td>
<td>10 × 2.3</td>
</tr>
<tr>
<td>Resolution, N</td>
<td>0.15 × 10⁻³</td>
</tr>
<tr>
<td>Accuracy, %</td>
<td>3.4</td>
</tr>
<tr>
<td>Sample rate, Hz</td>
<td>18</td>
</tr>
<tr>
<td>Drift, % / log$_{10}$(hr)</td>
<td>&lt; 2.1</td>
</tr>
<tr>
<td>Hysteresis, %</td>
<td>6.0</td>
</tr>
<tr>
<td>Temperature sensitivity, N / °C</td>
<td>-0.1</td>
</tr>
</tbody>
</table>

An acquisition unit equipped with a small battery and microSD card was used to store the measurements of both the force sensors and the thermometer locally (Fig. 1b).

Before use, the sensors were calibrated using ten weights of 100 g each. Both the Pirani and Diméglio scores were recorded to assess the severity of the deformity and the progress of treatment. Successful correction was defined as a Pirani score of ≤ 1.0 after treatment.

Before manipulation of the foot, the physician carefully placed a force sensor on both the first metatarsal and the talar neck using a Cutinova Hydro dressing (Smith & Nephew, Hull,
length can be modelled using equation (1).

\[ F(t) = (F_0 - F_\infty) \cdot 2^{-t/t_{1/2}} + F_\infty \]  

(1)

In this equation, \( F(t) \) is the (resistive) force at time \( t \), and \( F_0 \) and \( F_\infty \) are the starting \( (t = 0) \) and end force after a long time \( (\infty) \), respectively. The parameter \( t_{1/2} \) is the half-life time. The equation means that the force decays from \( F_0 \) to \( F_\infty \). The lower the \( t_{1/2} \), the faster the force decays. \( t_{1/2} \) represents the time after which the force has dropped from \( F_0 \) to half of the final value \( F_\infty \). Figure 3 illustrates how the force decays to 95% after 4.3 half-life times.

Each set of retrieved data consisted of the time, force, and temperature of one week. All data were processed using Matlab version R2017b (Mathworks Inc., Natick, Massachusetts). Erroneous data points, that is LHR_DATA = 2^\( n \) - 1, or \( T = 85^\circ C \), were removed from the data sets.\(^{12,13} \)

The data were corrected for temperature changes and filtered to reduce the influence of noise caused by movements of the child. The first four hours of continuous force sensor data were processed using a moving standard deviation filter (stdfilt) with a window of ten seconds to identify and remove spikes. Next, the data were low-pass filtered (cut-off frequency 1/60 Hz) and resampled to have one data point per ten seconds. Each ten-second period in the data was filtered using the same standard deviation filter and the median was taken over the filtered data (Fig. 2). The force sensor data (LHR_DATA) were then converted to a force value \( (F(t)) \) using the calibration data. The start of each measurement \( (t_0) \) was defined as the exact moment the physician released the foot, when casting was finished.

Each data set was then fit to equation (1) using Matlab 2017b’s fit function, which generates values and 95% confidence intervals (CIs) for \( F_0, F_\infty, \) and \( t_{1/2} \). The restrictions (bounds) which were used for the fit function were 0.001·ln(2) < \( t_{1/2} < 1000\cdot\ln(2) \) hrs and \( F_\infty < F_0 \). Data sets for which \( t_{1/2} \) could not be calculated (R^2 < 0.50) were excluded from further analysis.

**Statistical analysis.** The values for \( F_0, F_\infty, \) and \( t_{1/2} \) were tested for normality using Lilliefors’ test and presented as median (interquartile range [IQR]). Statistical significance was defined as p < 0.05.

**Results**

The characteristics of the children are shown in Table II. All the clubfeet were treated successfully. Complications in the form of pressure marks on the skin were encountered in four children after a cast was removed. In one child, this was after the
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Table II. The characteristics of the children

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children, n</td>
<td>10</td>
</tr>
<tr>
<td>Mean age, days (range)</td>
<td>7 (2 to 30)</td>
</tr>
<tr>
<td>Boys:girls, n</td>
<td>9:1</td>
</tr>
<tr>
<td>Bilateral, n</td>
<td>6</td>
</tr>
<tr>
<td>Mean pre-treatment Pirani score (so)</td>
<td>4.3 (0.7)</td>
</tr>
<tr>
<td>Mean pre-treatment Diméglio score (so)</td>
<td>14.0 (1.6)</td>
</tr>
</tbody>
</table>

first cast; in the others, it was at a later stage (the third or fourth cast). Further measurements were cancelled in two of these four children but the data that had been obtained were included in the analysis. Technical malfunctioning occurred in ten measurements (insufficient battery power in eight, one disconnected force sensor, and one disconnected thermometer). In total, 29 successful measurements were performed on ten clubfeet.

The results of a typical measurement are shown in Figure 4. For five data sets (three for the first metatarsal, and one for both the first metatarsal and the talar neck), the goodness of fit was too small ($R^2 < 0.50$) to determine a relationship between the force and the time elapsed, and were excluded from further analysis. In total, 25 data sets for the force on the first metatarsal and 28 for the force on the talar neck were analyzed. The values for $t_{1/2}$, $F_0$, and $F_\infty$ are shown in Table III.

Discussion

Previous authors have estimated the forces and torque on the clubfoot. Ours is the first report of force measurements in many children over several weeks of treatment each. This allowed the change of the force applied using the Ponseti method to be graphically visualized. There was a clear decrease in force in all measurements, with almost all data showing a typical stress-relaxation curve, supporting the hypothesis of a decrease of force over time. The adaptation may have taken place in the foot, in the cast, or both. However, the creep behaviour of cast materials is too limited for this effect, indicating that the tissues in the clubfoot adapt to the position imposed by the cast.

The study has limitations. Since the sensors are attached to the skin with tape, each measurement has an unknown baseline force acting on it. The exact location of the sensor is also
unknown since both the skin and the padding can move in relation to the cartilaginous structures below. This makes the absolute values that are registered by the sensors unreliable as can be seen in the unlikely negative values for \( F_{x} \). However, this does not affect the calculation of the half-life time \( t_{1/2} \), since this is only determined by the shape of the curve and not its absolute value.

The small sample size did not allow for statistical analysis of differences within the group, such as laterality or gender.

Although a clear decrease in force was observed, it does not necessarily say anything about the internal structures in a clubfoot. No imaging techniques were used to allow correlation between the measured force and physical changes within the foot. Although a mechanical equilibrium was reached within several hours during every period of measurement, this does not imply that a biological equilibrium is reached during the same time span.

**Stress-relaxation.** As shown in Figure 3, after 4.3 times the half-life time \( 4.3 t_{1/2} \), which under these circumstances corresponds to less than two hours), the corrective force has been reduced by 95% with respect to its final value \( (F_{x}) \). The forces do not change much after the first period; the tissues are in a stable position.

MRI studies comparing the appearances of the tarsal bones before and about ten minutes after casting show immediate changes in the shape of the cartilage anlagen of the tarsal bones.\(^5,17\,18\) Stress-relaxation is said to occur within 15 to 20 minutes after the application of a cast,\(^19,20\) but therapists are warned that “this phenomenon cannot be repeated many times in rapid succession, because once the relaxation has occurred, the tissue length is maintained by the elastic restraints within the tissue components”\(^,20,21\). Our observation that the clubfoot reaches a mechanical equilibrium within two hours suggests that most of the correction is complete long before the end of one week and the treatment could be accelerated drastically. However, the biological processes that may influence the speed of correction are not yet fully understood. Decreasing the duration of casting has been proposed before\(^,5,17,18\) and performed in studies in which the intervals between cast changes was altered from weekly to every 3 weeks\(^22,23\) and even to three times a week.\(^24\) The studies all report a reduced time of treatment without adverse effects.\(^25\) More research is needed to find the optimal interval between cast changes. Our findings suggest that if there is a limit to the reduction in the interval between cast changes, it is more likely to be related to biological rather than mechanical factors.

In conclusion, in the treatment of clubfoot using the Ponseti method, the foot is manipulated and held in place with a plaster cast. The applied forces rapidly decrease and reach an equilibrium within hours of casting, suggesting that the tissues of the clubfoot adapt and stresses within the foot reduce within a very short time. The rapid reduction of force between the foot and the cast suggests that the duration of treatment could be reduced significantly. More research is required to determine the optimal time interval between cast changes.

**Take home message**
- Stress on soft tissue is relaxed to a low level within hours after the application of the plaster cast.
- From a force-level point of view, there is room to shorten the time interval between consecutive castings.

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**References**


Author contributions:
R. B. Giesberts: Conceived and designed the experiments, Performed the experiments, Analyzed the data, Wrote the manuscript.
E. E. G. Hekman: Critically edited and reviewed the test protocol, the data interpretation, and the manuscript.
G. J. Verkerke: Critically edited and reviewed the test protocol, the data interpretation, and the manuscript.
P. G. M. Maathuis: Performed the experiments, Critically edited and reviewed the test protocol, the data interpretation, and the manuscript.

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