



Force measurements during posterior calvarial vault osteodistraction: A novel measurement method[☆]



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ARTICLE INFO

Article history:

Paper received 1 December 2016

Accepted 13 February 2017

Available online 2 March 2017

Keywords:

Posterior calvarial vault osteodistraction

Force measurement

Osteodistraction

Craniosynostosis

Craniosynostosis surgery

ABSTRACT

Posterior calvarial vault osteodistraction (PCVO) has become increasingly popular in the correction of craniosynostosis. When compared to cranioplasty, PCVO offers a shorter, less invasive operation, greater intracranial volume advancement and a lower rate of relapse.

In general, distraction protocols are based primarily on clinical observations rather than systematic research. Faster distraction protocols may reduce complications. However, distraction protocols producing higher forces can increase complications. Thus, we need to understand these forces in order to improve distraction protocols and devices.

We developed a force measurement method that can be used on PCVO devices. Here, we present preliminary data about the forces developed during PCVO. We measured the forces in four bicoronal craniosynostosis patients during PCVO.

We observed a linear-like trend between the force increase and the distraction distance within distraction sessions. We also observed a step-wise force increase between distraction sessions and found that the distraction force relaxed rapidly shortly after the distraction session. The mean maximum pre-distraction force for one distracter was 20.4 N, while the mean maximum end-distraction force for one distracter was 57.6 N. Our data suggests that current treatment protocols might be re-evaluated favouring shorter distraction distances and more frequent distraction sessions.

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1. Introduction

Posterior calvarial vault osteodistraction (PCVO) has become increasingly popular in the correction of craniosynostosis in recent years. Compared to one-stage calvarial vault reconstruction (CVR), PCVO offers a shorter operation time, less blood loss, a lower risk of venous sinus puncture, the potential for greater increases in the intracranial volume (ICV) and a lower rate of relapse (Imai et al., 2002; Steinbacher et al., 2011; Lao and Denny, 2010; Kim et al., 2008). PCVO represents a more physiological treatment when

compared to CVR; since bone segment vascularity remains intact, no dead space is left between the dura and bone segments and no ossification defects remain (Nonaka et al., 2003; Lao and Denny, 2010; Derderian and Seaward, 2012). Furthermore, better soft tissue adaptation is reached via gradual advancement and tension-free incision closure ensuring better wound healing (Steinbacher et al., 2011; Lao and Denny, 2010). In addition, a shorter inpatient stay may reduce total costs (Steinbacher et al., 2011).

Managing intracranial hypertension (ICH) and anatomical anomalies for syndromic craniosynostosis patients requires ICV advancement at an early age (Blount et al., 2007; Nowinski et al., 2012). Early resolution of ICH is imperative for central nervous system (CNS) development (Nonaka et al., 2003; Blount et al., 2007). Traditionally, for aesthetic reasons, fronto-orbital advancement (FOA) has been the primary intervention for syndromic patients. PCVO's popularity is increasing, becoming the primary intervention, because a larger increase in ICV can be achieved and

[☆] Presented at: European Association for Cranio-maxillo Facial Surgery Congress, London, UK, 15 September, 2016.

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ICH is more efficiently resolved when compared to FOA (Steinbacher et al., 2011; Kim et al., 2008; Derderian and Seaward, 2012; White et al., 2008; Derderian et al., 2015). Clinical experience has also shown that PCVO carries a corrective effect for the aesthetic contour of the frontal part the calvarium (White et al., 2008; Derderian and Seaward, 2012).

To simultaneously achieve ICV increase and bone regeneration, a distraction rate between 0.5 and 2 mm per day is commonly used (Steinbacher et al., 2011; Kim et al., 2008; Nonaka et al., 2003; Komuro et al., 2005; Nowinski et al., 2011). The desired distraction rate is achieved in one to three distraction sessions per day depending upon the centre (Lao and Denny, 2010; Komuro et al., 2005; White et al., 2008; Nowinski et al., 2011; Maurice and Gachiani, 2014). Faster distraction rates may reduce complications (Steinbacher et al., 2011; Nowinski et al., 2012). Currently, distraction protocols are primarily based on clinical observations rather than systematic clinical research.

Due to the well-known viscoelastic behaviour of soft tissue, a high distraction rate is likely to increase the resistive tissue forces the distractor needs to overcome in order to realise distraction. This may increase the risk of mechanical failure in the distractor, footplate loosening and conflicting distraction vectors (Nonaka et al., 2003; Imai et al., 2002; Steinbacher et al., 2011; White et al., 2008; Derderian et al., 2015; Nowinski et al., 2012), which are related to the mechanical stress environment around the distractor. However, limited data exist related to the forces formed during PCVO. In order to optimise the distraction protocol and develop better distractors, we must understand how the resistive forces develop during distraction.

This study aimed to develop a method for measuring these forces during PCVO that could be easily introduced into current clinical practices. In addition, we aimed to understand the tissue resistance forces and their development during PCVO.

2. Materials and methods

This measurement method is based on measuring the torque (Nm) required to turn the distractor arm, which translates into distraction via the threaded rod inside the distractor used for PCVO (Arnaud Cranio-orbital Distractor, KLS Martin, Tuttlingen, Germany). By characterising the distractor performance in a laboratory setting, we can establish the torque–force relationship, allowing us to non-invasively derive the force (N) caused by tissue resistance during routine clinical practice. We performed force measurements for PCVO in three syndromic and one nonsyndromic craniosynostosis patients. Two patients underwent surgery at Uppsala University Hospital and two at Helsinki University Hospital. The ethics committees at both hospitals approved the study protocol. In addition, patients' parents granted informed consent prior to

participation. All patients were female, with a mean age of 8.1 months (Table 1). All four patients had a bilateral coronal synostosis. Pre- and post-operative CT evaluation was performed in all four patients.

Experienced craniofacial teams performed all operations at both hospitals. The surgical procedure was performed as described by Nowinski et al. (2011). The calvarium was exposed by bicoronal incision. Osteotomies, a bicoronal osteotomy and a horizontal osteotomy above the torcula, were performed to create a maximal posterior bone segment. Two distractors were placed in the lower parietal position and two distractors were placed in the upper parietal position (Fig. 1) for patients 1, 2 and 4.

For patient 3, in addition to the lateral distractors, only one medial distractor was used, which was placed close to the midline of the calvaria. In all cases, distractors were placed in the parasagittal positions and the vectors were oriented visually parallel to one another (Fig. 1). The devices were attached across the osteotomy using two 4-mm titanium screws per footplate. The distractor arms were guided through the skin through incisions from the anterior part of the scalp (Fig. 1).

A dural puncture occurred in patient 3 at the area of the vertex during the bicoronal craniotomy. The puncture was closed with tissue glue and sutures. The other operations were uneventful.

In total, 20 mm of distraction was planned for each patient with a 48-h latency period. We used a rapid distraction rate of 2.0 mm/

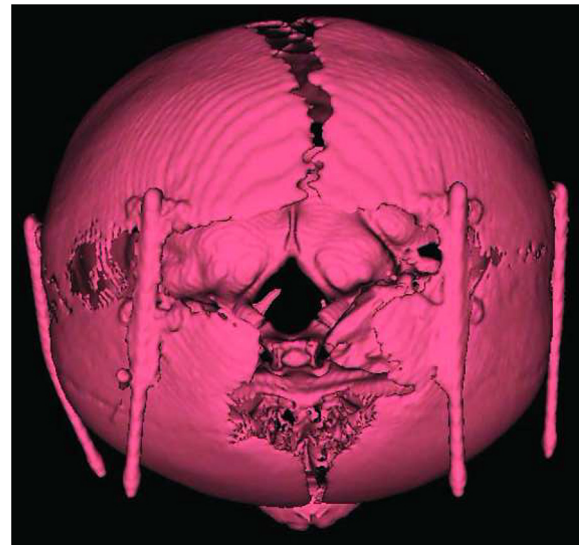


Fig. 1. Post-operative three-dimensional computed tomographic reconstruction for patient 2.

Table 1
Patient characteristics.

	Patient identification number			
	1	2	3	4
Age (months)	7	7	13	5.5
Sex	Female	Female	Female	Female
Diagnosis	Nonsyndromic, bicoronal synostosis	Apert syndrome, bicoronal synostosis	Crouzon syndrome, bicoronal synostosis	Crouzon syndrome, bicoronal synostosis
No. of distractors	4	4	3	4
Distraction rate	1.2 mm/d	2.1 mm/d	1.2 mm/d	2.1 mm/d
Distraction protocol	Once daily (á 1.2 mm)	Twice daily (0.9 mm + 1.2 mm)	Once daily (á 1.2 mm)	Twice daily (0.9 mm + 1.2 mm)
Total distraction (mm)	20	20	~13	20
Measurements/distraction sessions	4/17	18/18	9/9	20/20
Complications	None	None	Dural leakage	None

day in Uppsala through two daily sessions (typically, 1.2 mm in the morning and 0.9 mm in the afternoon) (Nowinski et al., 2011). The planned distraction protocol in Helsinki consisted of 1.2 mm/day during a single daily session. Patients 2, 3 and 4 received inpatient treatment during the entire distraction process. Patient 1 moved to outpatient treatment after the fifth day of distraction, after which the patient's parents performed the distraction at home. Follow-up care was received in an outpatient clinic on distraction days 10 and 17.

The distraction protocol proceeded without complications in patients 1, 2 and 4 (Table 1). Distraction was terminated for patient 3 after the ninth session (achieving a distraction of 11.4 mm) due to repeated dural leakage originating from the intraoperative dural puncture (Table 1). Force measurements were performed when possible; the distraction sessions with the force measurements performed appear in Table 2. In patient 2, the session measurements were performed only until reaching 0.9 mm, although a 1.2-mm distraction was created (as indicated in Table 2), because sensing the tightness of the tissue with the torque screwdriver was significantly more difficult. During these events, the last turn was performed with the screwdriver provided by the distractor manufacturer.

During treatment, the surgeon adjusted the distraction protocol based on his clinical judgement (Table 2). The distractors were removed under general anaesthesia after sufficient consolidation was observed radiologically. The anterior footplates and the distractors were removed through a bicoronal incision. An extra incision was made at the site of the posterior footplates to unscrew the attachments.

2.1. Data collection

The developed measurement system consisted of a high-resolution digital torque screwdriver (HTG2-4, Imada Inc., USA/Japan) connected to a conventional laptop computer for data acquisition (Fig. 2, left panel). The original tip of the distractor screwdriver was attached to the Jacobs chuck of the torque screwdriver. We used Matlab (R2011a, Mathworks Inc., USA) for data acquisition, post-processing and analysis. This allowed us to record torque data at a rate of 36 Hz.

Distraction was performed routinely by a surgeon while the patient was held by a parent (Fig. 2, right panel). Each 1.2- or 0.9-mm distraction event was considered a distraction session. Each full circle rotation (turn) of the distractor arm (corresponding to 0.3 mm of distraction) was performed in three steps (one-third of a full circle marked by the torque screwdriver) followed by hand repositioning to the initial position. This allowed us to increase the measurement resolution and to clearly distinguish artefacts related to changing the hand position during subsequent data processing steps. Each full turn was measured as one dataset without interrupting data logging, and the distractor IDs and order of distraction were recorded.

To capture the relaxation behaviour of the tissue after a distraction session, we made additional torque measurements in patient 4 at 10, 20 and 60 min after distraction between sessions 18 and 19. All four distractor screws were turned minimally and then returned to the starting position to record the torque at each time point.

The surgeons were trained to perform the distraction in a repeatable and steady manner with a table-mounted setup comprising a distractor and a spring to mimic the resistance of the tissue. AR controlled data logging while the surgeon performed the distraction.

2.2. Data processing

We used Matlab to transform the measured torque data into force for every 0.1 mm of distraction (after every distraction step) (Fig. 3). From the raw data, each 0.1 mm of distraction could be separated manually using the Matlab software by noting the drop in the torque caused by hand repositioning at each one-third turn (Fig. 3, step 1).

To reduce the effect of manual data selection and any artefacts related to movements in the surgeons' hands, a 10-point mean was calculated. To calculate this, we used five points from the previous distraction steps and five points from the subsequent distraction steps to represent the value of the torque at each 0.1 mm of distraction (Fig. 3, step 2). The error bars show the standard deviation of these values. Thus, a resolution of 0.1 mm could be achieved.

The calculated torque values were transformed into force values by using a conversion function and the corresponding error values obtained from the distractor characterisation setup, which we plotted against the realised distraction (every 0.1 mm) (Fig. 3, step 3). For each session of distraction, a linear regression fit along with a goodness of fit (GOF) was determined in order to establish the stiffness of the tissue (N/mm). To analyse the development of the tissue resistance force during the distraction treatment and any relaxation behaviour between sessions, the forces at the beginning (pre-distraction force) and end (end-distraction force) of each distraction session were plotted against the distraction sessions (Fig. 3, step 4). The same procedure was repeated for each distractor for each patient.

2.3. Distractor characterisation

The laboratory setup (Fig. 4) allowed us to establish the conversion function from torque (T (Nm)) to force (F (N)) for the distractor using the developed measurement system. Distraction was performed against a spring over a near-frictionless rod by rotating the distractor arm with the torque screwdriver. We used a load cell (MTS Systems Corporation, Minneapolis, MN, USA) to record the force (N) produced by the distractor and recorded the

Table 2
Realised distraction schedule.

Patient ID	Distraction distance (mm)																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1	1.2 ^a	1.2 ^a	1.2	1.2 ^a	1.2	1.2 ^a	1.2 ^a	1.2 ^a	1.2 ^a	1.2	1.2 ^a	1.2 ^a	1.2 ^a	1.2 ^a	1.2 ^a	1.2 ^a	1.2 ^a	1.2 ^a	1.2 ^a	1.2 ^a
2	0.9	0.9	1.2 (0.9)	0.9 (0.6)	0.9	1.2 (0.9)	0.9	1.2	0.9	1.2 (0.9)	0.9	1.2 (0.9)	0.9	1.2 (0.9)	0.9	1.2 (0.9)	1.2			
3	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	0.6 ^b											
4	0.9	1.2	0.9	1.2	1.0	0.9	0.9	0.9	1.2	0.9	0.9	0.9	1.2	1.2	1.2	0.9	0.9	0.9	0.9	0.9

Distraction distance involving force measurements marked in the brackets for patient 2 because additional distraction was performed without measurement.

^a No measurement.

^b Distraction terminated due to dural leakage.



Fig. 2. Measurement set-up. Left: high-resolution digital torque screwdriver connected to a conventional laptop. Right: measurement of torque during distraction.

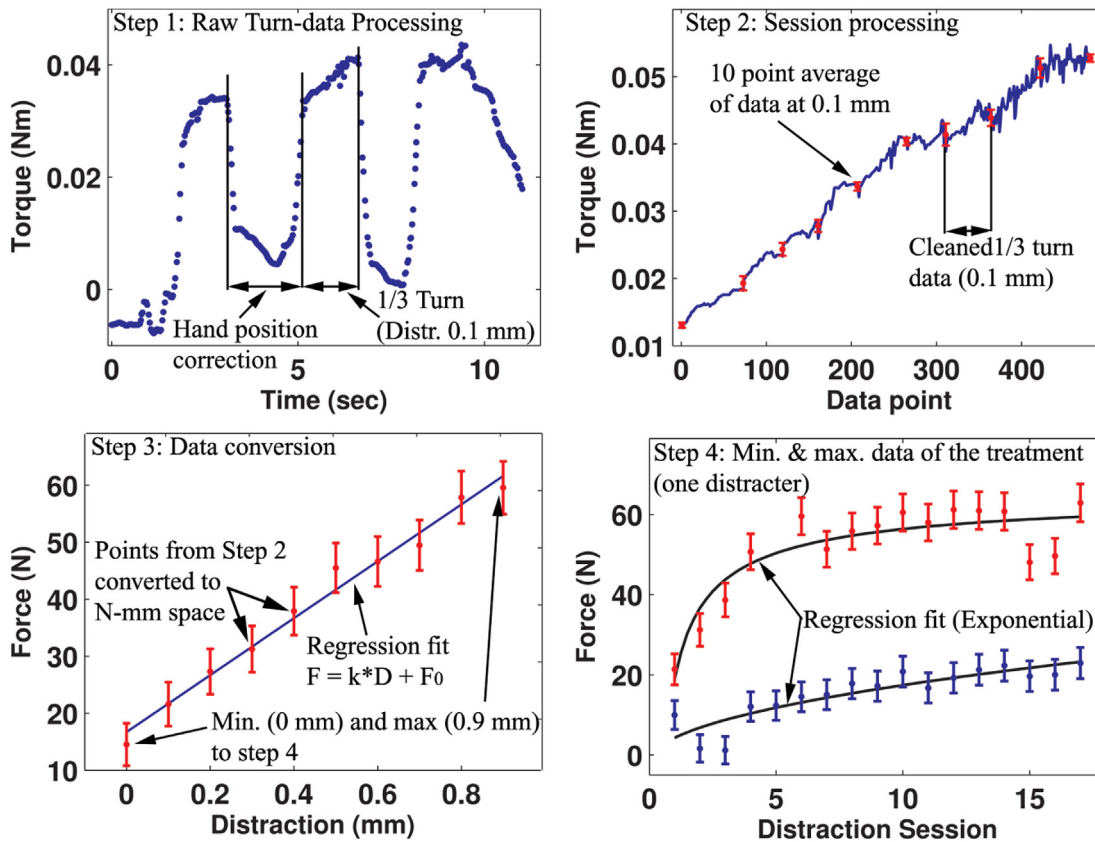


Fig. 3. Clinical data processing. Step 1: The data from the distraction of 0.1 mm (one-third turn) was filtered from the raw data using a computer-assisted system. Step 2: A 10-point mean was calculated, using five points from both sides of the data included, representing the value of the torque at each 0.1 mm of distraction. Step 3: The calculated torque values were transformed into force values by using the conversion function and the corresponding error values obtained from the laboratory calibration data and plotted against the realised distraction (resolution: 0.1 mm). Step 4: Data expressed as a plot of the force at the beginning (pre-distraction force) and end (end-distraction force) of the distraction sessions.

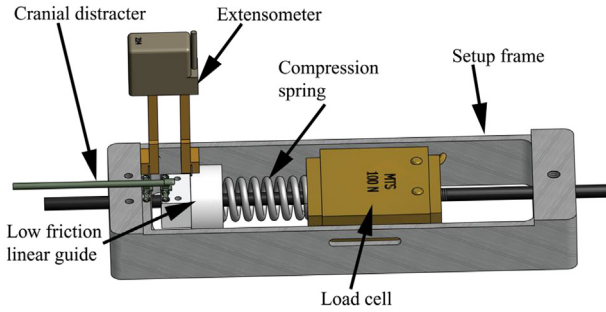


Fig. 4. Laboratory set-up designed to establish the conversion function from torque (T (Nm)) to force (F (N)).

corresponding distraction achieved with an extensometer (MTS Systems Corporation, Minneapolis, MN, USA).

Distraction against the spring was performed at 0–80 N to cover the observed tissue–force range. A spring at a constant of 30 N/mm was chosen for the laboratory setup, since this best represented the observed tissue behaviour. The characterisation cycle was repeated using various starting lengths for the distractor and with different distractors to obtain an accurate measurement method. AR performed the characterisation using the same procedures as those used in the clinical setting.

Both the data from the distractor characterisation and clinical measurements were processed identically. The manual method accurately recognised the distraction from hand repositioning, reaching an acceptable level (Fig. 5, step 1). The linear regression

equation ($F(N) = k * T(Nm) + b$) was fit to the torque–force data obtained from the torque screwdriver and load cell, respectively, using an error equal to 1 standard deviation (SD) (Fig. 5, step 2). The final torque–force conversion function and its error were calculated as the mean of parameters k and b from all characterisation measurements (Fig. 5, step 3). The validity of the conversion function was verified by performing two additional measurements (0–80 N), and the measured force was compared to the values calculated from the torque data using the conversion function (Fig. 5, step 4). The accuracy of the data measurement system was set to ± 3 N.

2.4. Data analysis and statistical methods

The correlation of the relaxation time to force relaxation was determined for patients 2 and 4. We compared the shorter relaxation time (morning–afternoon) and the longer relaxation time (afternoon–morning). We determined statistical significance between the groups using a one-tailed Student t-test.

3. Results

3.1. Force measurements

Table 3 provides the measurement results, including the maximum pre- and end-distraction force, the mean force relaxation percentage between sessions, the spring constant of tissue stiffness (k) and the linear fit of k (mean r^2). The mean maximum pre-distraction force for one distractor was 20.4 N (range

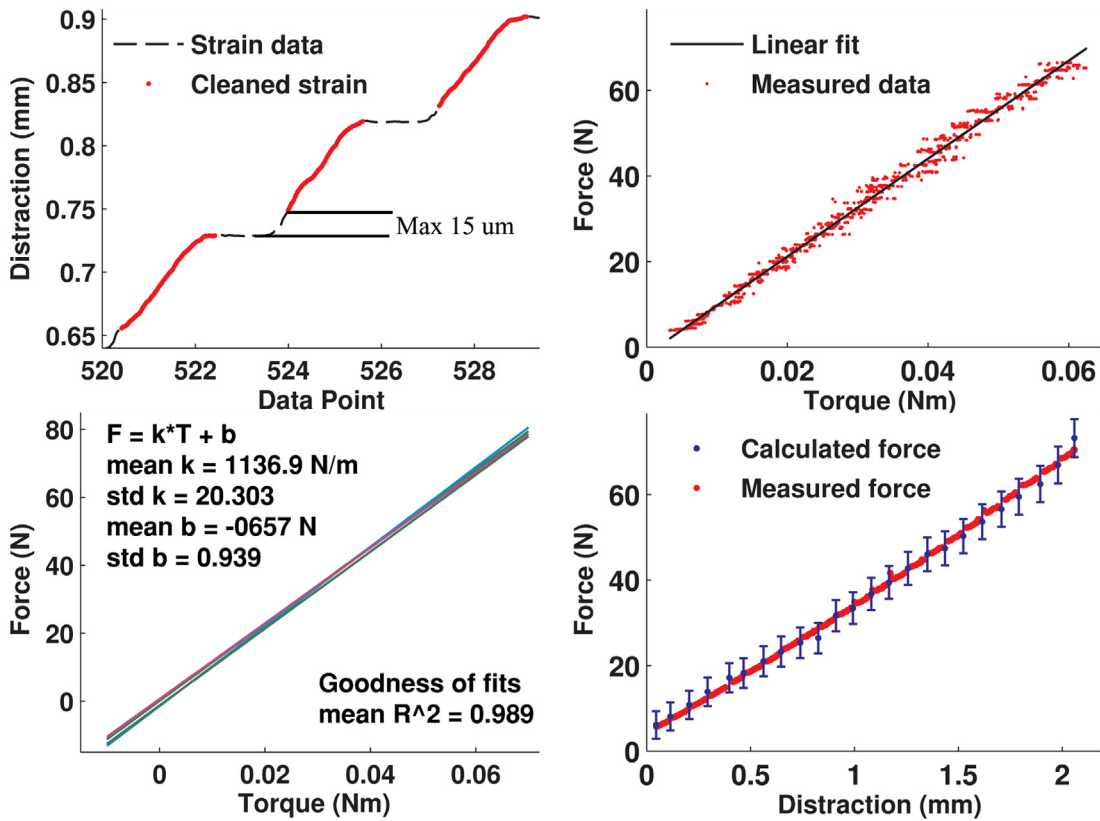


Fig. 5. Calibration of the torque values to the force values. Step 1: Hand re-positioning artefacts were manually cleaned from the dataset. Steps 2 and 3: Linear function ($F(N) = k * T(Nm) + b$) was fit to the torque–force data and the error was determined ($SD \pm 1$). The torque–force conversion function was calculated as the mean of parameters k and b from all nine measurements. Step 4: The validity of the calculated conversion function was verified using two additional measurements (0–80 N), and the measured force was compared to the values calculated using the function.

Table 3
Summary of data from patient measurements.

Patient	Distractor	$F_{\max, 0.9 \text{ mm}}$ (N)	F_0 (N)	$F_{\text{relax. mean}}$ (%)	$F_{\text{relax. SD}}$ (%)	k_{mean} (N/mm)	k_{SD}	R^2_{mean}	R^2_{SD}
1 ^a	Mean	46.5 ± 6.0	8.1 ± 3.2	N/A	N/A	29.2	8.1	0.97	0.02
	1	52.7	12.3	N/A	N/A	36.8	10.4	0.98	0.01
	2	40.9	7.1	N/A	N/A	22.2	4.3	0.95	0.02
	3	41.8	4.7	N/A	N/A	27.2	5.3	0.97	0.01
	4	50.8	8.2	N/A	N/A	30.5	4.9	0.97	0.02
2	Mean	59.7 ± 11.1	23.2 ± 3.0	68.9 %	12.7 %	31.4	9.8	0.96	0.06
	1	53.4	23.1	68.1 %	13.2 %	29.4	5.8	0.95	0.04
	2	65.9	27.0	68.8 %	13.1 %	34.4	7.4	0.97	0.03
	3	72.0	23.0	70.7 %	11.4 %	39.2	8.7	0.97	0.04
	4	47.8	19.7	68.0 %	14.2 %	22.8	9.1	0.94	0.10
3 ^b	Mean	57.3 ± 14.1	13.8 ± 6.3	81.7 %	8.4 %	28.3	7.9	0.95	0.04
	1	65.3	19.3	75.8 %	5.4 %	28.1	5.6	0.94	0.03
	2	41.1	7.0	89.3 %	8.8 %	22.8	5.5	0.93	0.04
	3	65.7	15.3	80.2 %	3.9 %	33.9	8.5	0.97	0.04
4	Mean	66.8 ± 7.1	34.7 ± 2.8	62.2 %	13.7 %	29.5	7.9	0.95	0.05
	1	60.7	32.0	55.2 %	11.5 %	31.7	7.7	0.96	0.03
	2	72.5	37.5	62.8 %	13.8 %	28.5	7.8	0.97	0.02
	3	60.5	32.7	64.5 %	14.1 %	32.5	5.9	0.94	0.04
	4	73.5	36.7	66.4 %	13.4 %	25.4	8.3	0.92	0.09

^a Four measurements during 17 sessions.

^b Only 13 measurement sessions due to complication.

4.7–37.5 N, SD ± 11.2). The mean maximum end-distraction force for one distractor was 57.6 N (range 40.9–73.5 N, ±SD 11.6).

Fig. 6 shows the relationship between the force increase and distraction distance for all distraction sessions for patient 2 and distractor 4. We found that the linear regression model between the achieved distraction and tissue resistance during a single distraction session was a valid estimate (Table 2, mean r^2). In addition, we calculated slope k (N/mm) of the regression model to approximate the tissue stiffness during a single session (Fig. 6). Yet, similar behaviour approximating a linear relationship was observed for all distractors in other patients. An analysis of the regression model residuals, however, did not demonstrate a truly linear relationship.

Fig. 7 illustrates the force evolution over the entire distraction distance for patient 2. In all patients, we observed an increase in the pre- and end-distraction force towards the end of the distraction process as well as substantial relaxation behaviour of the tissue resistance between two consecutive distraction sessions. The mean force relaxation between distraction sessions reached 69.9%

(SD ± 9.9) for all patients. The end-distraction force increased steeply from session to session during the first four to five sessions and, thereafter, exhibited plateau-like behaviour (Fig. 7). The pre-distraction force showed a more moderate and linear-like increase throughout treatment. In patient 3, in whom only three distractors were used, we observed no increase in the pre-distraction force of the only medial distractor.

3.2. Force relaxation measurement

Fig. 8 displays the results of the relaxation measurements for patient 4. We found a total force relaxation of 44.6% over 16 h, of which 65.1% occurred during the first 60 min.

3.3. Relaxation analysis

In patient 2, we found a mean force relaxation of 71.6% after a shorter relaxation time (mean 9 h 7 min, SD ± 48 min) and 73.1%

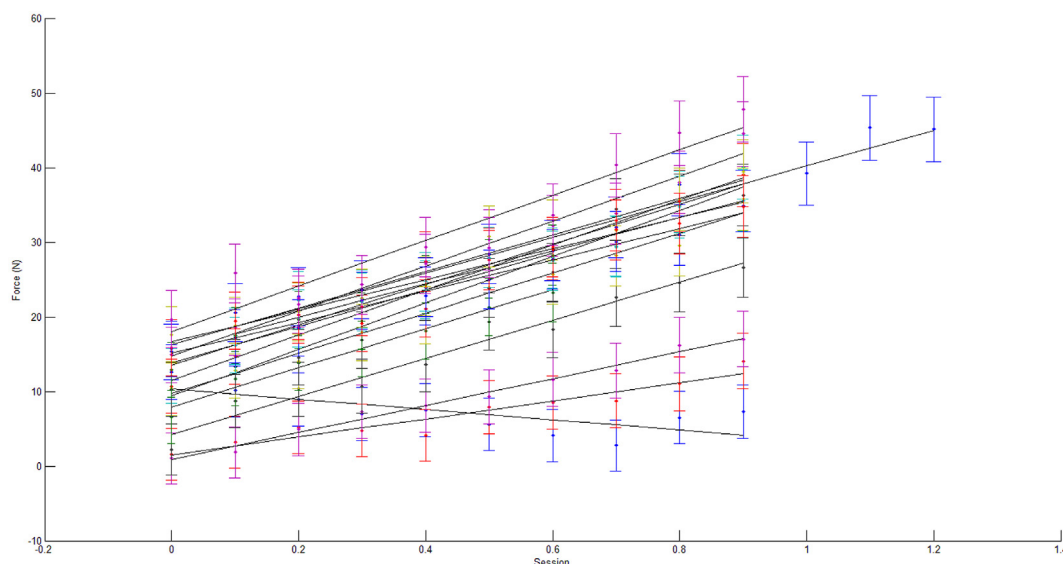


Fig. 6. Relationship between the force increase and distraction across all distraction sessions for patient 2.

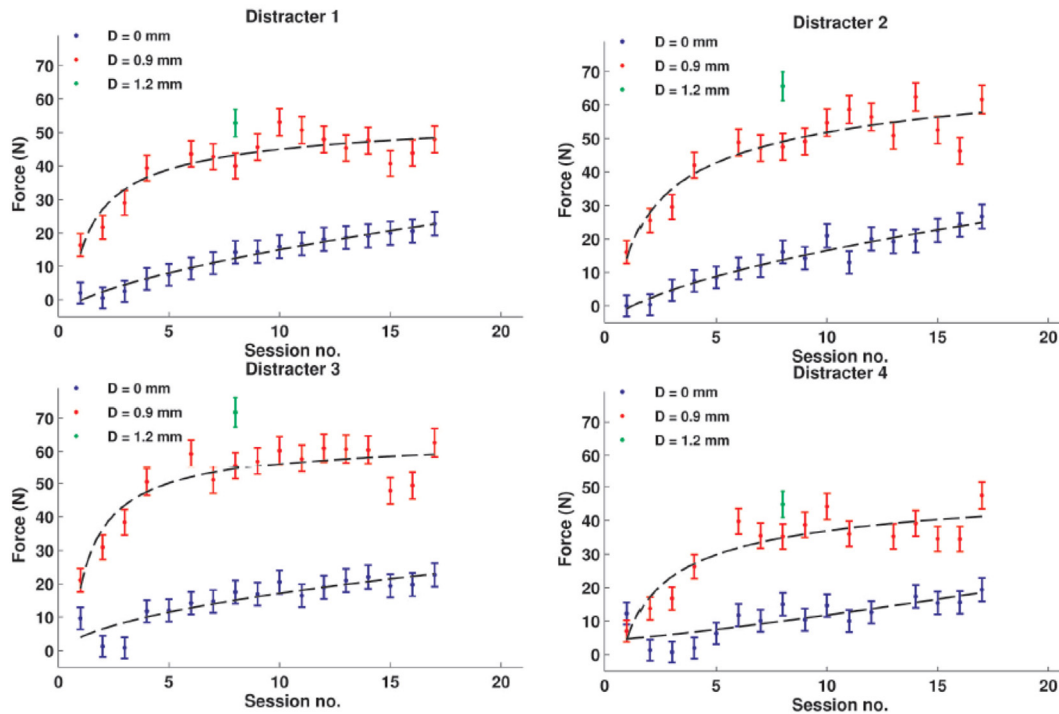


Fig. 7. Force evolution of patient 2 during the distraction process. The force versus session number curve represents the pre- and end-distraction forces.

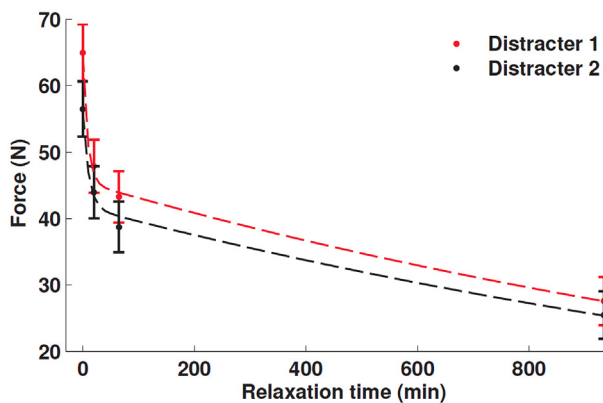


Fig. 8. Results from the relaxation measurements performed in patient 4 between distraction sessions 18 and 19.

after a longer relaxation time (mean 14 h 40 min, SD \pm 1 h 35 min) ($p > 0.40$).

In patient 4, we found a mean force relaxation of 65.1% after a shorter relaxation time (mean 9 h 13 min, SD \pm 28 min) and 69.4% after a longer relaxation time (mean 15 h 2 min, SD \pm 45 min) ($p > 0.23$).

4. Discussion

This study introduces a novel, non-invasive force measurement method that can be used for PCVO in routine clinical practice. The measurement method introduced provides an acceptable accuracy in the clinical setting and does not carry any additional risks to the patient. In addition, we present the preliminary results of tissue resistance forces appearing with this treatment modality. The results of this study reveal a linear-like relationship between the distraction distance and force increase during distraction sessions as well as force relaxation after distraction.

The observed force evolution can be explained by the tissue viscoelastic response to osteodistraction (Waanders et al., 1998). Viscoelasticity refers to how a material reacts in an elastic manner to rapid changes when stressed, whereas viscous manner refers to stress over longer periods of time. We can describe this distraction behaviour using the general spring formula $F = kx$, where spring constant k evolves from session to session as distraction advances (Fig. 6). Our preliminary results suggest that tissue resistance can be approximated with a spring constant $k \sim 30$ N/mm (Table 3). We also found that force relaxation seems to occur relatively quickly after distraction and that a longer relaxation period does not significantly lower the pre-distraction force for the next session. Thus, we hypothesise that distraction performed based on smaller distractions per session and more frequent sessions may reduce the maximum force required to achieve the same total distraction rate. Furthermore, an increased distraction rate could be used without a remarkable force increase simply by shortening the time between sessions. This process could be effectively controlled through the continuous monitoring of forces in routine clinical practice. However, to what extent the distraction rate can be increased without compromising soft tissue compliance remains unclear.

In their study, Meswania et al. (1998) found a linear relationship between the distraction distance and force increase in lower- and upper-limb osteodistraction. In animal and computer models, force measurements performed on human femoral osteodistraction (FOD) and mandibular osteodistraction (MOD) showed a force increase during distraction sessions that relax to a slightly higher value after a session than the previous pre-distraction force (Kessler et al., 2005; Reina-Romo et al., 2010; Gardner et al., 1998; Forriol et al., 1997). While the calvaria and surrounding soft tissue exhibit a unique biomechanical environment (Raul et al., 2008; Coats and Marguilles, 2006), we recorded a similar tissue response to distraction in our study. Thus, we put forth three potential causes for the non-zero pre-distraction force: 1) the distracted bone regenerated responds to distraction in a viscous manner, and further distraction is carried out before the relaxation

process is completed; 2) bone formation progress increases the force needed in the distractor to cause additional lengthening; and 3) non-parallel distraction vectors cause two or more distractors to 'fight' one another. Because bone is substantially stiffer than soft tissue, even a small misalignment of the distractor vectors could significantly increase the distraction force of distractors situated near one another. These preliminary results do not allow us to state, however, how valid these hypotheses are. To do so requires further research.

The maximum forces measured in the human MOD reach 22.2 N (Burstein et al., 2008). Studies using a porcine model showed a maximum force of 76.3 N in intermittent-distraction MOD and 28.3 N in continuous-distraction MOD (Kessler et al., 2005). The resisting force against distraction originates from tissue elongation and the increasing stiffness of the regenerated growing bone (Reina-Romo et al., 2010). The forces measured in this study using PCVO were higher than in MOD potentially due to the larger amount and type of resisting soft tissue (e.g., galea aponeurosis), the wider length of the osteotomy bridged with the regenerated bone and the attachment of the bone to the dura. This may carry implications for the design of distractors intended for PCVO.

Footplate loosening, distractor exposure and breakage are common complications in PCVO (Lao and Denny, 2010; Lee et al., 2008; Steinbacher et al., 2011; Goldstein et al., 2015; Nowinski et al., 2012). The external distractor arms may lead to pin-tract infections and exposure to trauma additionally causing footplate loosening or device breakage (White et al., 2008; Lee et al., 2008; Steinbacher et al., 2011). Based on the force data, optimisation of the mechanical structure of current distractors to minimise their size in critical positions while still maintaining sufficient mechanical strength could reduce distractor-related complications. Furthermore, the development of a fully implantable distractor with sufficient force output could reduce the risk of external distractor arm-related complications and patient discomfort.

The disadvantages of osteodistraction include the necessity of a second operation to remove the distractors (Derderian and Seaward, 2012). To address this issue, resorbable distractors were recently introduced (Maurice and Gachiani, 2014). Using these devices, a second operation is unnecessary, since the distractor can be removed through the wound for the distractor arm (Maurice and Gachiani, 2014). Another benefit lies in the use of resorbable fixation screws or pins that reduce the risk of a fixation-related dura injury (Nowinski et al., 2012). Paediatric calvarium is often too thin for footplate attachment using conventional screws. Thus, PCVO is primarily performed in patients older than 6 months when the bone is thicker (Nonaka et al., 2003; Steinbacher et al., 2011). In some cases, resolving ICH is necessary before the age of 6 months when the osteogenic potential improves. Recently, ultrasound-activated resorbable pins were introduced, enabling fixation on a thin bone since tapping is not required (Eckelt et al., 2007; Savolainen et al., 2015). Attaching the footplate using pins would be beneficial for PCVO patients with thin calvarium. The lower strength of the pins represents a limiting factor in some cranio-maxillofacial applications, and, given the relatively high forces, this is likely to have an impact on PCVO as well (Tominaga et al., 2006). The recorded force values may aid in estimating the number of resorbable pins needed to establish a sufficiently stable fixation for PCVO.

Many clinics typically use only two lateral distractors in PCVO, while we primarily used four. We chose four distractors because they provide more stability and the forces may be distributed across all four distractors causing less load during distraction. However, non-parallel distractor vectors could partially outweigh the latter benefit. Given the softness of the paediatric cranial bone, the transfer of distraction from the distractors to the entire bone

gap may be more complex than in a mature rigid bone and may partially explain the rapid drop of the forces during relaxation. The bone immediately surrounding the distractor footplates could primarily deform elastically under the distraction force and only later translate across the entire bone segment as the soft tissues relax. These issues should be clarified when evaluating the optimum number of distractors in PCVO.

This study has several limitations. The threaded rod of the distractor's lengthening mechanism was open to the host tissue, which may have enabled tissue ingrowth, thus causing some of the increase in the pre-distraction force and tissue stiffness from session to session. Human factors in the measurement process, such as the rapid movement of the patient, varying speed of rotation by the surgeon and hand shaking were likely to cause measurement errors. The effects, however, could be diminished through data processing. In addition, this study featured a small patient group, allowing only limited analyses. Proper statistical analysis was not possible due to the small patient sample and the non-independent nature of the distractors in one patient. Finally, some variance existed in the measurement procedures related to the development of the measurement method. Therefore, these results should be considered as preliminary.

5. Conclusion

To conclude, we developed a novel, non-invasive force measurement method that can be used for PCVO in routine clinical practice. The tissue exhibits a spring-like behaviour during distraction and rapid force relaxation after distraction. We propose that treatment rely on smaller distractions per session along with more frequent sessions. This protocol could reduce the maximum force required to achieve the same distraction rate. Thus, the success rate of PCVO may improve.

Sources of support in the form of grants

No financial support was received for this study.

Declaration of interests

No conflicts of interest.

Acknowledgements

We thank Synoste for providing technical support for this study.

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