SPRING ASSISTED CRANIOPLASTY: A PATIENT SPECIFIC COMPUTATIONAL MODEL

Alessandro Borghi PhD, Naiara Rodriguez-Florez PhD, Will Rodgers MRCS, Gregory James MRCS (Eng), Richard Hayward FRCS (Eng) PhD, David Dunaway FRCS (Plast), Owase Jeelani FRCS (NeuroSurg), Silvia Schievano PhD.

Corresponding author
Dr Alessandro Borghi
UCL Great Ormond Street Institute of Child Health
30 Guilford Street
London WC1N 1EH
Tel: +44 (0) 207 9052733
Fax: +44 (0) 207 4046181
e-mail: a.borghi@ucl.ac.uk

KEYWORDS: craniosynostosis, spring cranioplasty, finite element modeling

Total word count: 3902 words (excluding references).

ABSTRACT [199 words]

Implantation of spring-like distractors in the treatment of sagittal craniosynostosis is a novel technique that has proven functionally and aesthetically effective in correcting skull deformities; however, final shape outcomes remain moderately unpredictable due to an incomplete understanding of the skull-distractor interaction.

The aim of this study was to create a patient specific computational model of spring assisted cranioplasty (SAC) that can help predict the individual overall final head shape. Pre-operative computed tomography images of a SAC patient were processed to extract a 3D model of the infant skull anatomy and simulate spring implantation. The distractors were modeled based on mechanical experimental data. Viscoelastic bone properties from the literature were tuned using the specific patient procedural information recorded during surgery and from x-ray measurements at follow-up. The model accurately captured spring expansion on-table (within 9% of the measured values), as well as at first and second follow-ups (within 8% of the measured values). Comparison between immediate post-operative 3D head scanning and numerical results for this patient proved that the model could successfully predict the final overall head shape.

This preliminary work showed the potential application of computational modeling to study SAC, to support pre-operative planning and guide novel distractor design.

INTRODUCTION

Craniosynostosis is a rare disease affecting 1 in 1,700 live births consisting in premature fusion (ossification) of one or more cranial sutures during infancy [1]. The most common presentation is sagittal craniosynostosis, which occurs when the sagittal suture fuses, causing scaphocephaly – a craniofacial deformity described by long narrow heads (Figure 1) – and in some cases, raised intracranial pressure with functional problems [2–4].

Treatment options for craniosynostosis include extensive surgical procedures such as total cranial vault remodeling [5] and strip craniectomy [6], or less invasive endoscopic approaches [7]. In 1998, a new technique for treating scaphocephaly was first reported by Lauritzen et al. with the use of spring devices [8]. In his procedure, bony cuts were performed to free the fused suture and metallic springs were placed on the osteotomy borders to widen the skull over a few weeks gradually remolding it.

Since then, clinical studies have shown no difference in efficacy and safety of SAC compared to traditional surgical techniques [9], but have reported considerably lower blood loss, transfusion requirement and overall hospital cost in the case of SAC [10]. The main clinical criticism of SAC is the lack of long-term morphological outcome data and the need for a second operation to remove the springs and, therefore, for a second general anesthesia. A technical limitation of current devices is the lack of control on spring action, available for other types of distractors [11], which can in some patients result in suboptimal outcomes such as under-correction and coronal or lambdoid ridging [12]. The main reasons for these are still unclear, potentially depending on many different factors, such as severity of the disease, patient age and relative bone formation, spring positioning on the skull and choice of spring model, with no consensus yet achieved [8,12].

Patient specific computational modeling, able to replicate each individual characteristics and take into account many different external factors, represents an ideal tool to study this complex problem, provide quantitative assessment of surgical outcomes and potentially help planning the procedure.

Different approaches are described in the literature that attempt to create patient-specific models of the skull for virtual surgical 3D simulation and planning, mostly focusing on adult cases, and with each method designed and developed for a different application. The starting point common to all approaches is the post-processing of pre-operative CT imaging datasets as this accurately provides the anatomy of each specific individual. The methods then differ in terms of modelling of the bone and soft tissue properties, with structures mostly treated as rigid bodies – 3D translations and rotations are rigidly prescribed – to simulate craniofacial reshaping achieved by means of external rigid distractors [13,14]. Recent developments in the field have addressed soft tissue displacement as an effect of rigid translation on underlying tissues using thin plate spline interpolation [15,16]; however the accuracy of such methods, which ignore tissue extensibility and compressibility and only ensures continuity of displacement, is still debated [17,18]. Latest attempts to include the physical behavior of soft and hard tissue through FE modelling of the skull have proven to provide better results [19–22] than previous approaches, with one study also focusing on sagittal SAC [23] with the aim of predicting the expansion force in a cohort of scaphocephalic patients treated with springs: the model was able to capture the on-table spring performance with expansion forces within 10% of the on-table measurements. The region of interest was however limited to the calvarial strip relative to the osteotomy border and, therefore, the model was unable to predict the final skull shape over time.

In this work, a computational model of spring cranioplasty was built which included infant specific anatomy and material properties purposely tuned using spring opening information from a SAC patient. Serial 3D surface imaging of the patient head was used to validate the computational results, thus demonstrating feasibility and the potential of such methodology.

METHODS

SAC procedure

In 2008, SAC was introduced at Great Ormond Street Hospital for Children (GOSH), London, UK, with a different distractor design (Figure 2a) [24] compared to that proposed by Lauritzen [8,25] and a standardized surgical procedure in order to ensure result reproducibility [26]. Three different spring models (S10, S12 and S14) are available with same geometry, but different wire size (1.0, 1.2 and 1.4 mm respectively) hence varying stiffness (0.17, 0.39 and 0.68 N/mm respectively, Figure 2b) [26]. At GOSH, SAC is used for correction of scaphocephaly in sagittal craniosynostosis, in children from 3 to 8 months of age. During the procedure, an incision is made on the patient scalp perpendicular to the sagittal suture. A square craniectomy is performed, approximately halfway along the fused sagittal suture, and two parasagittal osteotomies are made at a distance LAT from each other and parallel to the midline, starting from the craniectomy site and extending to the coronal sutures anteriorly and the lambdoid sutures posteriorly (Figure 3). Two pairs of grooves are created on the osteotomy lines at a distance A and P from the coronal suture (Figure 3) for the insertion of the anterior and posterior spring. Spring strength selection is made on-table according to clinical assessment of the calvarial bone quality and desired expansion. Measurement of LAT, A, P, spring models and on-table opening of the springs are recorded before closure of the wound. After surgery, patients are followed up with x-rays at day 1 (FU1) and after three weeks (FU2), before spring removal is carried out approximately 3-6 months from insertion.

Patient selection and image analysis

A 5.5 month old boy treated with SAC (S10 anteriorly and S12 posteriorly) at GOSH in 2014 was retrospectively selected for this study as he had pre-operative computed tomography (CT) images (age at scan = 4.4 months). CT data were post-processed (ScanIP, Synopsis, Mountain

View, CA, USA) to create a patient specific geometrical 3D model of the skull: a combination of grey level thresholding and morphological operations was performed to isolate the hard tissue (the skull) from the soft tissues (fontanelle, coronal sutures and lambdoid suture, Figure 3). The geometry was cut with a horizontal plane above the orbits, and slightly scaled to adjust for the growth of the patient between the time of the CT scan and the time of the operation (= 1.1 months) using dimensions from a pre-operative 3D surface scan acquired at the time of surgery (more information below). Bony cuts were replicated in the model (ScanIP, Simpleware, Exeter UK) to simulate the surgical procedure (Figure 3) including the grooves corresponding to the spring insertion sites, according to the measurements and information recorded for this patient in theatre (LAT = 2.0cm, A = 3.4cm P = 5.3 cm).

Opening of the springs was measured from the x-ray images at follow-ups (FU1 = 1 day and FU2 =22 days) after calibration [27].

Finite element model

The 3D reconstructed model, including skull, anterior fontanelle, coronal suture, lambdoid suture, was meshed using hexahedral elements (ScanIP) and imported into ANSYS mechanical (Canonsburg, Pennsylvania, US) for simulation. Boundary conditions were applied to avoid rigid displacements, but allow free expansion of the head base on the cutting plane: all nodes at the cutting plane were constrained in the vertical direction but free to move in the in-plane direction, with one node at the back fully constrained to avoid rigid displacements.

The action of the springs on the patient head was simulated by two linear spring connections applied to the grooves, with behavior defined by the linear fitting of the unloading portion of the force-opening curve derived from experimental tests of each device model (Figure 2b) and considering the spring initial crimping (LAT = 20mm) from the theatre notes.

Hard and soft tissue elastic material properties were retrieved from literature: for the bone, Young's modulus E and Poisson ratio ν were respectively 421 MPa and 0.22 [28]; for coronal and lambdoid sutures and anterior fontanelle, values were E = 16 MPa and ν = 0.49 [29].

The viscoelasticity [23,30] of both bone and soft tissues were modeled through the Prony shear and bulk relaxation relationship (equation 1)

$$\frac{G(t)}{G_0} = \alpha_\infty + \sum_i \alpha_i e^{-\frac{t}{\tau_i}} \quad [1]$$

where α_∞ and α_i are the relative moduli, τ_i are the time constants (considered equal for shear and bulk relaxation), G(t) is the instantaneous shear modulus and G_0 is the shear modulus at the beginning of the relaxation (t=0). The constants relative to the bone were retrieved from the literature assuming a relaxation behavior equivalent to that of cancellous bone [31,32]. The viscoelastic properties of sutures and fontanelle were assumed similar to that of meninges and retrieved from literature [33].

To account for the difference in bone source and age, a scaling constant was used to adapt the parameters of the model (equation 2):

$\alpha_i' = \Gamma \cdot \alpha_i$, [2]   with Γ tuned as explained below.

Simulations of spring expansion were run for a total of 5 days (432,000 s), as preliminary tests showed that no difference was present in the Finite Element (FE) results between 5 days and the time of the second follow-up. Therefore, t = 432,000 s was assumed to represent the configuration at the time of second follow-up (T_{FU2}), whilst t = 0 s corresponded to the time of spring insertion (T_0), t = 1 s to the time at which the spring had expanded on-table after release (T_1), and t = 86,400 s (= 1 day) to the time of first follow-up scan (T_{FU1}).

Spring opening OP(t) at T_1, T_{FU1} and T_{FU2} from the computational model was compared with the values retrieved by direct measurement in theatre, and from x-rays at FU1 and FU2. The sum of root mean square errors (Σ_{RMS}) between measured and computed OP was calculated (equation 3):

$$\Sigma_{RMS}(\Gamma) = \sqrt{\sum_{i=1}^{2}\left(\sum_{j=1}^{3}\left(OP_i^{FE}(T_j,\Gamma) - OP_i^{M}(T_j,\Gamma)\right)^2\right)} \quad [3]$$

where i refers to the anterior or posterior spring, while j refers to the time point (T_1, T_{FU1} and T_{FU2}), OP^{FE} is the value retrieved from the numerical simulation, while OP^{M} is the value measured in theatre or from x-ray. A set of simulations were run with varying Γ from 1 to 1.1 in order to minimize Σ_{RMS}. Maximum principal stresses on the patient bone were plotted to assess the effect of the springs over time (Figure 5b).

3D head scan for validation

A 3D surface head scan was available for this patient before ($SCAN_{PRE}$) and after spring insertion ($SCAN_{POST}$), acquired with a structured light 3D handheld scanner (M4D Scanner, Rodin4D, Pessac, France) in the operative theatre (Figure 4a). The scans were post-processed [34] to extract the surfaces of interest which were registered with each other using the portions of the head not affected by the surgery. $SCAN_{PRE}$ was used to compensate for the patient growth between the time of CT scanning and the time of operation by comparison of the scalp reconstructed from CT with the surface scan. In addition, $SCAN_{PRE}$ allowed registration of the FE model with $SCAN_{POST}$ handheld scan surface for comparison of the final head shape. $SCAN_{POST}$ was used to validate the results of the FE simulation of spring insertion: as the outer scalp was not included in the FE simulation, the shape of the patient head after SAC (FE_{POST})

was retrieved from the model by offsetting the outer surface of the expanded skull by a constant value calculated from the pre-operative CT images (figure 4b – 4c, 3.02 mm±0.95mm), followed by patching on the area of the osteotomy to assure scalp surface continuity (Figure 4d). Since $SCAN_{POST}$ was acquired after skin closure, which occurred about 20 minutes after spring insertion, FE_{POST} was selected as the deformed configuration of the FE model at t = 1200 s. To assess the quality of the results, the nearest distance color map between $SCAN_{POST}$ and FE_{POST} was calculated (Robin Cloud, Robin 3D, 2006). A histogram was used to visualize the distribution in distance difference between the $SCAN_{POST}$ and FE_{POST}.

RESULTS

The anterior and posterior spring opening measured on the operative table just after insertion was 30 and 35 mm respectively (Figure 5a, Table 1). From the x-ray measurements, at FU1, the springs further widened to 43.6 mm (anterior) and 48.2 mm (posterior), and to a final value of 48.2 mm and 50 mm at FU2 (Table 1).

Three sets of simulations were run with $\Gamma =$ 1.0, 1.05 and 1.1 until the minimum Σ_{RMS} was identified for $\Gamma = 1.054$. The FE simulation with this value of Γ provided the opening curves plotted in Figure 5a: the largest difference between OP_{FE} and OP_{M} was recorded for the anterior spring (8.9%, Table 1) at implantation. Looking at the time dependent opening for the two springs, the greatest difference was at the time of second FU for the anterior spring (7.1%,, Table 1). Table 1 reports a comparison of the simulated and measured values for the anterior and posterior spring openings

Figures 5b shows the stress map resulting from the FE simulation of spring expansion immediately after insertion (t = FU1, left) and at t = FU2 respectively: the maps show how the skull accommodates spring expansion, with high stresses localized mainly on the skull parietal bone. The stress relaxation of a representative point in the parietal bone is shown in Figure 5b (right).

The shape of the scalp obtained by offsetting the outer surface of the FE skull was compared with the 3D surface scan performed in theatre after the surgical procedure (Figure 6). $SCAN_{POST}$ was compared to FE_{POST} showing differences mostly within ±2mm (Figure 6a), with some areas of larger discrepancy at the cutting plane. Figure 6b shows a histogram of the point distance between $SCAN_{POST}$ and FE_{POST}: 82.8% of the surface points fall within 0 and

2mm. Figure 7 shows the comparison of a few cross-sections in the coronal (a to d) and sagittal (1 to 3) planes, showing good agreement between the two shapes.

DISCUSSION

In this study, a computational modeling approach was devised to simulate spring assisted cranioplasty (SAC) in infants affected by sagittal craniosynostosis. A patient specific anatomical 3D model including skull bones and sutures was created by processing the pre-operative CT images of an infant who underwent SAC at our Centre, whilst the patient-specific viscoelastic mechanical response to spring implantation was derived by tuning the bone material properties to mimic the actual spring opening measurements. The finite element (FE) scalp shape obtained after spring insertion showed a good agreement with the actual patient skin surface captured in theatre. Difficulties in FE modelling of SAC are mainly due to the paucity of information on the mechanical properties of the pediatric skull. Data, with large discrepancies between ages and skull bone locations [35,36], are lacking especially in terms of viscoelastic properties [31]. To overcome this, in our study, we have retrospectively used the clinical results of a patient who underwent SAC to tune the patient specific material model. After 3D reconstruction of the infant anatomy from pre-operative CT images, the surgery was replicated by applying realistic boundary conditions to mimic spring behavior, retrieved from mechanical testing of spring samples, and using intra-procedural measurements such as position and size of surgical osteotomies, and spring models and their position in the patient calvarium. The bone/soft tissue model was initialized using literature values and the model parameter was tuned by minimizing the difference between the computational and measured spring opening values at the available time points.

Albeit simple, the material model adopted for bone and sutures was able to capture the opening of the springs both at the time of the insertion (elastic properties) and during follow-up (viscoelastic behavior), as proved by the comparison between the simulated results and the measured spring dimensions at the time of insertion, first and second follow-ups (Table 1, figure 6b), with maximum differences below 9%. Comparison between 3D scanning of the patient head after spring insertion and simulated head shape after numerical spring expansion also provided good agreement, with distance between the two surfaces mostly within ± 2 mm, considered a clinically acceptable error.

The model relies on the assumption that bone and sutures responds in a viscoelastic fashion to the spring loads and most of the acute remodeling of the skull (within the first three weeks) is predominantly due to the mechanical adaptation of the bone to the skull to the spring force. A recent publication from our group, where spring opening was retrieved for 60 patients from implantation to removal, showed how the spring behavior closely follows an exponential rise, typical of viscoelastic materials [37]. A similar behavior was observed in animals [38]. Springs are currently used mainly on patients younger than 6 months [9,10,12,39–41] when the skull is more pliable and more viscoelastic [36,42] hence it is reasonable to assume that such material property governs the cranial adaptation during SAC.

For the present work, only the viscous aspect of the model was tuned: data relative to pediatric cranial bone material tensile properties are available in the literature [36,42,43] whilst there is lack of information on the viscoelasticity of paediatric calvarial bone. When the simulation was performed using literature values, an acceptable agreement between simulated and measured values was achieved (Table 1, Figure 5a): the viscoelastic material tuning improved this agreement by only changing the extent of relaxation by 5.4%. In this work, a simplified approach was used to patient specific model tuning (only the extent of relaxation was tuned, by means of the parameter Γ) due to the limited amount of information available (spring opening at 3 time points, retrieved on-table and from planar x-ray). The comparison between model and spring opening information suggests though that kinematics should also be tuned. Future development of the current methodology will address this problem using optimization techniques such parameter optimization by means of design of experiments [44] or inverse finite element modeling, which was in the past successfully coupled with elastography to determine in-vivo mechanical properties in cardiovascular applications [45,46]

The FE modelling process described in this study could be repeated for a group of sagittal SAC patients, in order to build a population specific mechanical property model that would allow for prospective studies, as an additional tool to support the selection of suitable patients for sagittal SAC, and to test and compare different osteotomy approaches and spring models / positioning in order to optimize the treatment for each individual patient. The current main obstacle towards this final goal is the highly limited availability of pre-operative CT scans, usually not required for sagittal craniosynostosis assessment at our Centre, as in the past few years, this investigation was deemed avoidable in order to minimise the risks of radiation exposure in the patients. Thanks to the latest advancements in CT systems, which have allowed a dramatic reduction in the ionizing radiation doses [47,48], CT investigations are now more frequently requested for the clinical assessment of sagittal craniosynostosis. Recent studies have shown that magnetic resonance imaging (MRI) techniques [49] have the potential of reducing the radiation exposure while providing high image contrast between bone and other tissues. The methodology presented hereby could be applied to any tomographic image set, regardless of the technique used. Furthermore, the present methodology could be extended to the prediction of the outcome of other spring assisted procedures, such as posterior-vault expansion [12] and correction of metopic [50] and lambdoid [51] synostosis.

One of the inherent limitations of this model is the impossibility of capturing head growth, which occurs very rapidly for children of this age: however since the time of FU2 is only 22 days after the spring implantation, change in head size was considered negligible. Furthermore, a recent work from our group [24] showed that patient treated with springs to treat scaphocephaly undergo minimal head shape change between the time of FU2 and the time of removal, as proved by a negligible variation in cranial index (ratio between the maximum and the maximum length of the head). Therefore, although our model cannot capture calvarial growth, it will predict the overall change in appearance of the patient head, which is the main target of this type of procedures. .

In order to capture the mechanical behavior of a series of patients, the model may need to be further enhanced for example by including the skin layer and complex contact conditions between the scalp and the skull. In this initial study the skin thickness (3.02±0.95mm) was considered adequately homogeneous to assume that the variation in skull shape would be sufficient to describe the change in outer skin shape. A similar assumption was performed by Zhang et al. [23] which limited the area of analysis to the calvarial bone strip adjacent to the parasagittal osteotomy.

CONCLUSION

In this work, a first attempt of creating a patient specific model for spring assisted cranioplasty was performed, that modelled not only the infant specific geometry, but also accounting for the patient-specific skull material properties. The results from this preliminary study are encouraging, showing the potential of the model to capture spring expansion on-table and at follow-up together with the overall head shape change due to spring implantation. Future work will aim at extending the number of patients modeled using this framework to further tune and refine the material properties to a sagittal craniosynostosis specific cohort, thus allowing prospective use in future cases. The validated tool could help surgical planning of scaphocephaly correction thus improving control and predictability in comparison to more invasive surgical approaches (such as total calvarial remodeling and extended strip craniectomy). Finally, the modelling framework could be extended to study spring assisted posterior vault expansion and could be used to design new devices to aid craniofacial surgeries and the treatment of craniosynostosis.

The results from this preliminary study are encouraging, showing the potential of the model to capture spring expansion on-table and at follow-up together with the overall head shape change due to spring implantation.

ACKNOWLEDGEMENTS AND FUNDING

The work has been funded by Great Ormond Street Hospital for Children Charity (grant number 12SG15).

This report incorporates independent research from the National Institute for Health Research Biomedical Research Centre Funding Scheme. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

ETHICAL APPROVAL

Ethical approval was obtained for the use of patient image data for research purposes (UK REC 15/ LO/0386 - Research Ethics Committee approval - study n.14DS25) .

CONFLICTS OF INTEREST

None declared.

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FIGURES

Figure 1: Skull shape in sagittal craniosynostis (scaphocephaly, left) compared to normal (normocephaly, right). The fusion of the sagittal suture is visible in the skull affected by scaphocephaly.

Figure 2: a) Cranioplasty spring used at GOSH b) Unloading curves for the two spring models used in the patient in this study (S10, S12).

Figure 3: 3D reconstruction of the patient skull from pre-operative CT scan and after simulation of the surgical cuts (the indicated dimensions are retrieved during surgery). The springs are overlaid on the figure to show their positioning in relation to the coronal suture (A for the anterior spring, P for the posterior spring). The dimension of the parasagittal osteotomy width LAT is indicated. b) Three quarter view of the model: the dotted line shows the area constrained in the vertical direction.

Figure 4: a) 3D scan of the patient head surface acquired during surgery ($\text{SCAN}_{\text{POST}}$). The area used for comparison with the computational results is highlighted in green. b) Color-maps showing soft tissue thickness (calculated as distance between the outer surface of the skin and the outer surface of the skull c) Histogram showing the distribution of soft tissue thickness. d) Post-implantation FE model of the patient skull (t = FU2) with the addition of a layer – created by offsetting the skull outer surface – to represent the patient scalp (FE_{POST}).

Figure 5: a) Spring opening over time as predicted by the FE model compared to the measured results (on table and from x-ray images). b) Maximum principal stress distribution on the skull immediately after spring implantation (T=1 s, left) and at the time of second follow-up (T=FU2, middle); maximum principal stress for a representative point (indicated with a star) in the parietal bone displaying the stress relaxation over time (right).

Figure 6: a) Color-maps showing surface difference between FE_{POST} and $SCAN_{POST.}$ b) Histogram showing the distribution of the distance difference between FE_{POST} and $SCAN_{POST}$.

Figure 7: Cross-sections showing a comparison between the shapes of FEPOST (blue) and SCANPOST (red). Vertical cross sections (1-3) and horizontal cross sections (a-d).

TABLES

		FE [mm] (literature values)	FE [mm] (after tuning)	Measurement [mm]
Anterior Spring	T=1s	33.7	33.7	31
	FU1	42.9	44.7	43.6
	FU2	42.9	44.7	48.2
Posterior Spring	T=1s	34.4	34.4	35
	FU1	46.8	49.3	48.2
	FU2	46.9	49.3	50

Table 1: Spring opening comparison between simulation and direct measurements.