# “The Science Behind the Springs”- using Biomechanics and Finite Element Modelling to Predict Outcomes in Spring Assisted Sagittal Synostosis Surgery

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## Introduction

Surgical treatment for the correction of scaphocephaly caused by the premature fusion of the sagittal suture is undertaken for aesthetic and functional indications[1] . Multiple strategies are employed ranging from strip craniectomies with or without the use of helmets, the use of distractors, to open vault procedures which range from pi-plasties to total calvarial remodelling procedures[1]. Regardless of the strategy, the aim of the surgery is to regularise the shape of the head and where possible increase the intracranial volume. All surgical techniques carry with them a degree of morbidity and mortality.

The concept of distraction osteogenesis in craniofacial surgery was popularised by Joe MacCarthy and his team in the 1970s[2]. Initially, external distractors were used to achieve this; subsequently, wire-form distractors were popularised by Claes Lauritzen and his team in the late 1990s[3]. Lisa David and her team published their initial experience in 2004[4] and Charles Davis[5] and his team added to the literature with further animal work. Multiple teams globally have since published their experience with the use of wire forms in Craniofacial surgery[6]. A common feature in these studies is the bespoke nature of the wire-forms used, typically made in the operating theatre by bending stainless steel wire. The bespoke approach does allow greater flexibility for the treatment paradigm, but reduces the possibility of standardization and accuracy of prediction of distraction responses, limiting reproducibility.

In 2007, our Unit at Great Ormond Street Hospital for Children (GOSH), London, UK along with a team of engineers from an external company, the *Active Spring Company (TascUK)*, set out to design a wire-form that would standardise the device force/opening behaviour. The aim of the standardised wire-form design was to allow techniques and results to be shared across Units, and cumulative and comparative analyses to be undertaken[7–13]. Furthermore, the reproducible design would afford us the opportunity to leverage computational modelling and 3D scanning techniques in order to accurately predict the changes in the head scape that the surgery would achieve. The benefits of being able to predict the results of the procedure to a high degree of accuracy before the surgery has actually taken place, cannot be overstated. This has been a severe limitation across the spectrum of craniofacial surgery thus far, especially in the communication with prospective patient parents and families, currently based on sharing results from similar operations in other patients or sketching what the final outcome is expected to be, an artist's rendering during consultation.

In the following paragraphs, we will review the basic science research carried out at GOSH on spring assisted sagittal synostosis surgery, combining engineering and computational methodologies with the clinical data available from patients who underwent implantation at GOSH in the past 12 years.

**Bench testing of the GOSH Spring**

The GOSH spring model is a torsional spring with a central loop that extends into two longer arms (Figure 1) with a slightly out of plane curvature. The central loop (diameter 10mm) was introduced to the wire form initial shape after a number of iterations in order to improve accuracy and reproducibility of the mechanical behaviour – this resulted in a change of terminology from wire formed to spring device. The distance between the tips ("inter-foot distance") is 60 mm at rest and before implantation (Figure 1). Each arm terminates with a footplate that is used to anchor the spring to the bone cuts performed during the surgery. The springs are produced by means of conventional wire winding techniques from stainless steel wire (*TascUK*). Three standardised models are currently used, which have the same geometry but vary in wire thickness (Figure 1): model S10 – 1.0mm wire thickness, model S12 – 1.2mm thickness, and model S14 – 1.4mm thickness. Design standardization ensures reproducibility of the force/opening behaviour for each spring model.

Figure 1: picture of a GOSH spring

Spring mechanical testing was performed in the manufacturing company to characterize the mechanical behaviour: two samples for each model were mounted on a compression machine (Basic Force Gauge, Mecmesin©, Figure 2) and tested in compression. Each spring was crimped from an opening of 60mm (resting conditions) to an opening of 20mm (equivalent to the crimped size at the time of implant) and back to 60mm; vertical spring forces were recorded (Figure 2) and averaged. Force vs opening curves were plotted during both loading and unloading phase (Figure 2).

The spring showed an initial linear behaviour followed by a highly nonlinear behaviour due to the stainless steel deforming plastically and undergoing localised unrecoverable deformations. Due to this, the unloading phase (bold lines in Figure 2) and the unloading phase (dotted line in

Figure 2) show different behaviour: crimping forces are higher than those exerted by the spring once implanted (Figure 3).

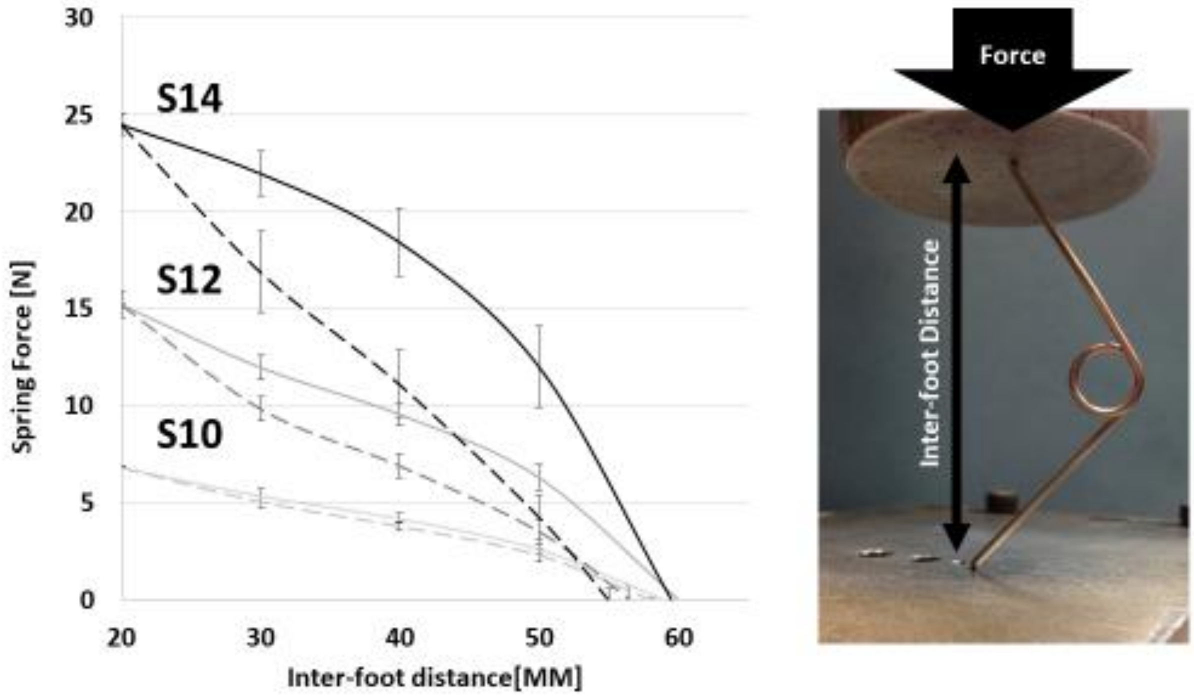


Figure 2: Graph showing spring force vs inter-foot distance for the three spring models used in GOSH (left) bold lines show forces during the loading phase while dotted lines show forces during the unloading phase; sample of cranioplasty spring during testing (right).

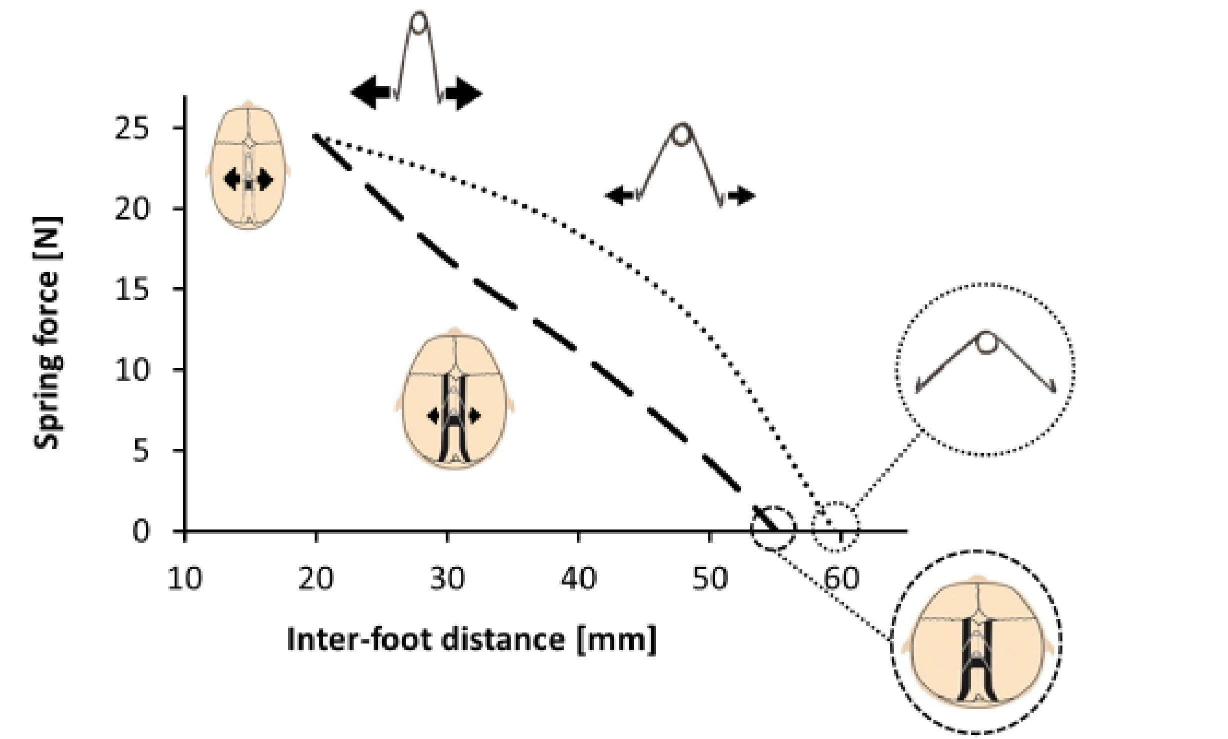


Figure 3: The graph shows in detail the stages of spring crimping and the forces exerted in this phase (top), compared to the forces exerted while inserted in the patient calvarium (bottom).

### 3D analyses of pre and post operative head shapes

Three-dimensional (3D) imaging is an important tool for diagnostics, surgical planning and evaluation of surgical outcomes in craniofacial procedures. In particular, 3D handheld scanning has shown great potential due to its radiation-free nature, non-invasiveness and portability, thus enabling the acquisition of 3D images of the head surface in theatre and during patient appointments [14,15] (Figure 4).

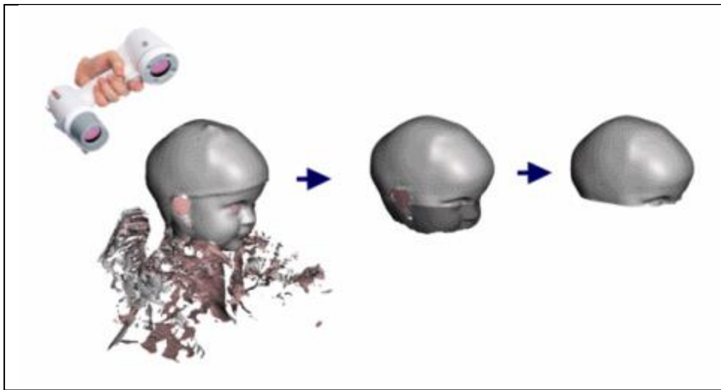

Figure 4: post-processing steps of a 3D scan of a patient with sagittal synostosis

Our team has proven that 3D handheld scanning can be used to objectively evaluate 3D shape outcomes after spring-assisted cranioplasty [16]. Images of patient head shapes at different time points ( immediately before and after spring insertion, at 3-week follow-up and after spring removal) have allowed us to capture not only the changes in cephalic index, the conventional measure to assess head shape, but also other local features that are important in sagittal synostosis, such as frontal bossing or occipital prominence. Moreover, when combined with statistical shape modelling techniques [17,18], the construction of population mean shapes has revealed further quantitative and localised descriptive information on the average effects of spring cranioplasty (Figure 5). Immediately after spring insertion, two prominences are evident at the top of the head, indicating localised deformations (Figure 5-post-op); however, with time, the springs affect larger areas of the skull gradually widen it (Figure 5-follow-up); at the time of spring removal, on average, springs have led to widening of the skull, while also increasing height and reducing frontal bossing (Figure 5-removal).

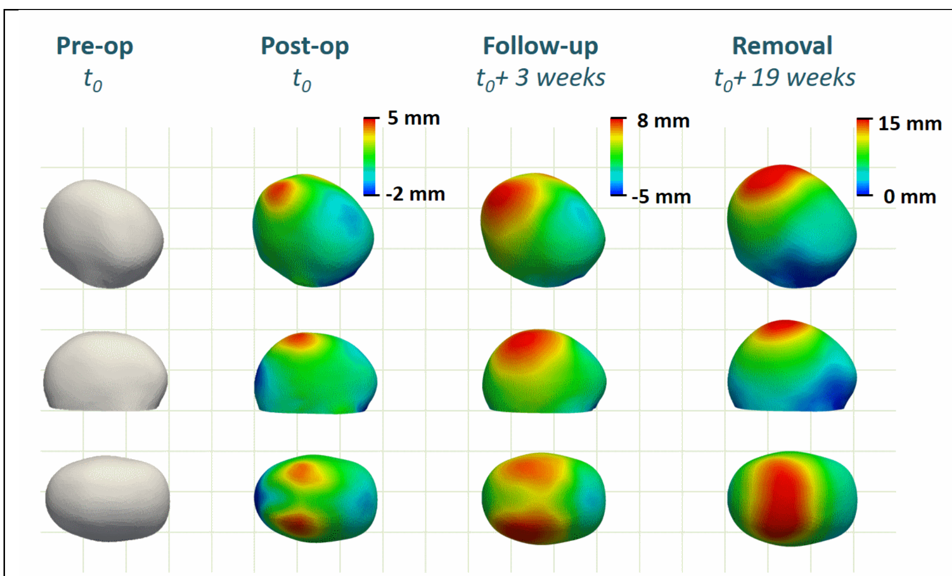

Figure 5: Average head shape models immediately before (pre-op, n=25) and after surgery (post-op, n=22), in the three-week follow-up (follow-up, n=18), and right after spring removal (removal, n=23). Colour-maps describe shape changes in terms of distance when compared to the pre-operative average model.

Due to the complex dynamic biomechanical remodelling, associations between surgical choices at the time of spring insertion and post-operative 3D head shape features once the springs are removed are difficult to assess. In order to overcome this limitation, our theatre team started to systematically record surgical parameters such as craniotomy size and spring positioning. Population-based statistical shape modelling was then combined with advanced regression techniques to gain insight into how the choices of these surgical parameters affected post-surgical head shape (Figure 6)[19]. This analysis indicated that spring-assisted cranioplasty was most successful (i.e. maximum overall bi-parietal widening was achieved) when the anterior–posterior craniotomy length was complete, from coronal to lambdoid sutures, the width of parasagittal osteotomies was narrow, the anterior spring was positioned some distance away from the coronal suture and the separation between both springs was large. So for a typical case, we would recommend the distance from the coronal suture to the anterior spring should be over 5 cm and the distance between the springs over 2cm. Overall, population-based 3D statistical shape modelling allowed for quantification and visualisation of trends in achieved head shape outcomes depending on each of the selected surgical parameters.

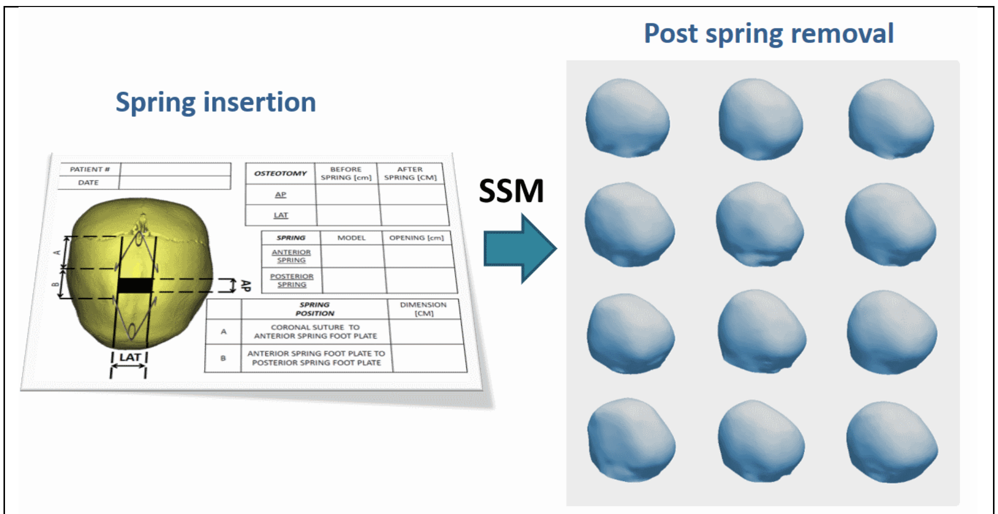


Figure 6: Statistical Shape Modelling (SSM) and regression techniques were used to find relations between surgical parameters at the time of spring insertion and head shape features several months later when the springs were removed.

## Finite element modelling

Finite element modelling is a computational method used in engineering to study the behaviour of complex structures by calculating approximate solutions for problems with known boundaries. It is applied to a continuous geometry by discretising it into smaller elements and solving for each element a set of equations which describe physical quantities such as displacement or deformation for given conditions in the system[20]. The obtained information from a finite element model can be used to calculate further variables which may be the true interests in the problem such as stress or strain.

Computational models have the advantage of allowing control on different variables independently, simulating different settings and scenarios together in the same model. They may allow to understand the effects of different factors that may cause sub-optimal surgical outcome. Moreover, computational models can simulate patient-specific procedures, which may also reveal patient-specific problems. Finally, when fully validated on large scale, computational simulations have the potential to become a surgical planning tool in future, to optimise patient treatment and predict outcomes. Therefore, in the context of spring assisted sagittal synostosis surgery, finite element analyses can therefore be used to simulate the effect of springs on the skull and to measure stresses and strains generated by the spring forces in the patient affected from sagittal synostosis, important parameters that cannot be measured in vivo.

Problems such as sub-optimal aesthetic outcome or unpredictable final shape that may exist due to rapid growth of the skull at early ages, changes in the bone and suture properties, and the limited deformation vectors provided by the springs[21,22] can be studied using finite element models. These analyses have already been utilised to simulate and predict outcome of surgery using patient-specific models with the aim of enhancing our understanding of skull correction in spring assisted cranioplasty[23]. Simulation of spring assisted cranioplasty in sagittal synostosis has been reported by few groups working on biomechanics of craniosynostosis. For instance, Zhang et al. evaluated spring forces using finite element models which simulated elastic properties of the skull bone[24]. They combined biomechanical and statistical learning to create a surgical planning tool which can estimate the optimal spring force preoperatively.

Our group has created a patient specific computational model able to simulate spring assisted cranioplasty and predict the individual overall final head shape[25]. Such model was improved by identifying a set of population specific material parameters, relevant for the sagittal synostosis group of patients, that can be employed as a predictive model[26]. In these studies, preoperative computed tomography (CT) images acquired for clinical diagnosis were used to reconstruct3D patient specific skull models of a population of paediatric patients who underwent spring insertion and expansion. Osteotomies were replicated, following measurements acquired during surgery (Figure 7). The model is then imported into a finite element solver, where spring like conditions are used to mimic the forces exerted by device opening (Figure 7).

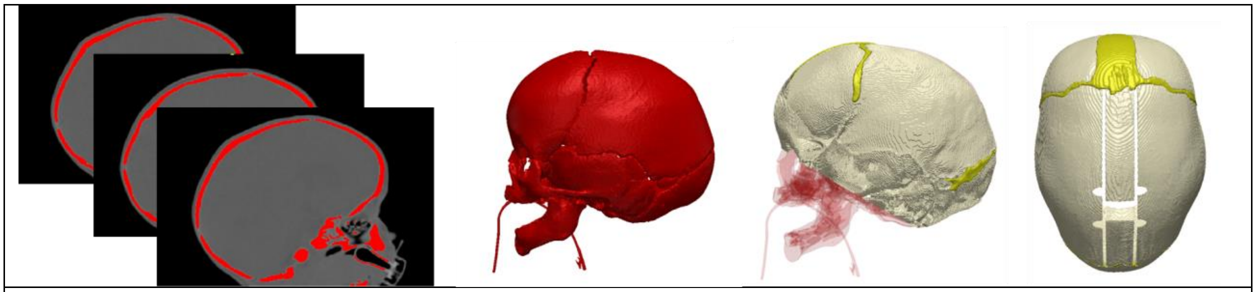

Figure 7: Creation of FE model for modelling of spring cranioplasty; segmentation of CT images (left); creation of a 3D skull model (centre-left); identification of the region of interest for the modelling (centre-right); reproduction of surgical osteotomies (right).

Since the skull remodels over time [27], a viscoelastic behaviour was adopted as the material model for the skull in order to mimic the adaptation of the paediatric calvarium to the spring distraction forces (Figure 8). The material parameters were iteratively tuned to best fit the results of the overall population.

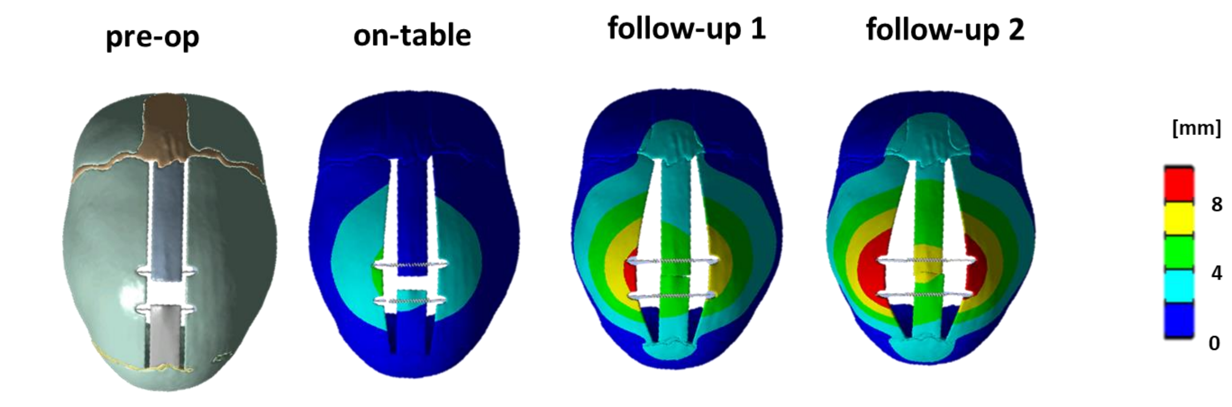


Figure 8: FE model of spring cranioplasty model. The pre-op mode retrieved through segmentation is used to calculate the skull shape after spring insertion (on-table) and follow up 1 and 2.

Validation was performed using non-invasive 3D surface scanning (Figure 9): by retrieving the post-operative shape of the patient head right after the procedure of insertion, when the patient is still on the table, it is possible to compare the actual surgical outcome with the simulated postoperative shape and validate the method. Figure 9 shows a comparison between the preoperative head shape and postoperative head shape of 9 patients: the colourmap on the post-op shape shows localised prediction error. Postoperative CI was also predicted within 1.9%±1.7%.

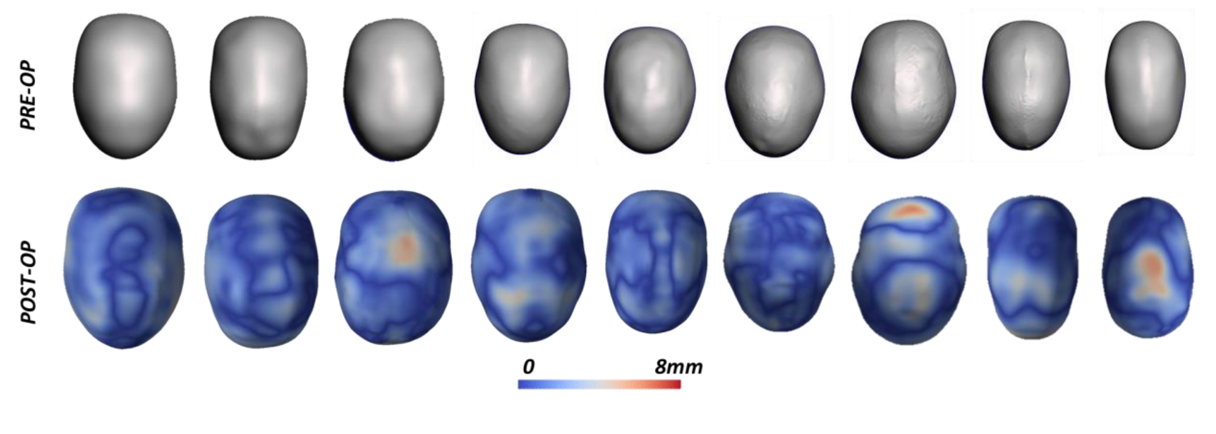


Figure 9: Validation of the finite element model in 9 patients. On top row, the pre-op head shape; on the bottom row, the postoperative reshaped head; the colours show the difference between the calculated shape and the on-table 3D scan retrieved during surgery.

The patient specific model although requiring further large scale validation, can be used for individual patients to plan the surgery, optimise osteotomies, spring positioning and size, and therefore predicting shape outcomes.

**Discussion**

Spring design in craniofacial surgery remains an evolving process. Initially, wire-forms started being manufactured using stainless steel wire[28], bent intra-operatively into the desired U shape. The strength of each spring was measured using a sliding pressure gauge. This process was further standardised in some centres with the use of a custom designed wire bender which created a 1 inch bend diameter[28]. A lack of standardisation amongst these earlier studies makes translation and comparative analyses across Units more difficult. The earlier studies do not comment on the spring biomechanics and report a force at insertion in the range of 5 to 12 N[28],[27] This is the force intrinsic to the wire-form when crimped for insertion. There is no information about the rate of force dissipation over time during the spring opening, in vivo.

To address this issue, our Unit designed a standardised torsional spring with the introduction of a helix to improve elastic recoil, using surgical grade stainless steel wire (Fig 1) and mechanically characterised to assess force / opening behaviour, as described above. During surgery, the distance between the tips is measured in vivo and is then used to calculate the force at implantation. X-rays are then taken at regular intervals and, using a mathematical formula to account for X-ray scatter and out of plane projection, the tip distance and, in turn, the force exerted by the spring is monitor over time. Since 2008, over 200 cases have been undertaken in the sagittal synostosis patients utilising these springs (the first 100 series is reported in[29], and a large repository of clinical data (intra-operative spring opening measurements and x-rays) has been acquired enabling us to understand the behaviour of the springs in the interaction with the sagittal synostosis paediatric calvarium over time, and the dynamic of force dissipation in vivo: the force at implantation are 11.4 ± 4.3 N for the anterior spring and 11.8 ± 4.1 N for the posterior spring, and it takes 10 days from day of surgery for the springs to fully open[27]. From this, followed the development of accurate finite element and statistical shape models as described above. This, in turn, has enabled the operating team to further refine the surgical parameters such as the position and length of craniotomies, and the positions and force of springs used to optimise outcomes. Using the modelling paradigm developed, we are now able to predict with a high degree of accuracy the shape change outcome in surgery for scaphocephaly. This has been a significant breakthrough in not only facilitating informed consent for the families whose children we treat with this pathology, but also being able to 'play with' the surgical variables preoperatively to optimise outcomes in bespoke fashion. Standardization of device and surgical technique enabled the above analyses, which in turn has promoted bespoke outcomes.

Once this was achieved, the next step was to be able to share our springs and experience more widely with a global audience; for this purpose we linked up with an industrial partner (KLS Martin, Tuttlingen, Germany). The GOSH springs as well as an adapted set of instruments are now available as CE marked products and are undergoing post launch clinical validation at present across several centres in Europe. We anticipate these will be available more widely in the coming months.

Our Unit is currently using the above tools and models to analyse more complex shape changes in pathologies where these springs have been utilised, such as posterior vault expansions in multi-sutural cases, and treatment of coronal and lambdoid synostoses, with promising results. We are also utilising clinical data and modelling techniques to design bespoke distractor systems. We hope to present this work in the near future to further push the evolution of spring design in craniofacial surgery.

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