The science behind the springs

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The Science Behind the Springs: Using Biomechanics and Finite Element Modeling to Predict Outcomes in Spring-Assisted Sagittal Synostosis Surgery

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Abstract: Spring-assisted surgery for the correction of scaphocephaly has gained popularity over the past 2 decades. Our unit utilizes standardized torsional springs with a central helix for spring-assisted surgery. This design allows a high degree of accuracy and reproducibility of the force vectors and force distance curves. In this manuscript, we expand on the biomechanical testing and properties of these springs. Standardization of design has enabled us to study the springs on bench and in vivo and a comprehensive repository of calvarial remodeling and spring dynamics has been acquired and analyzed.

Finite element modeling is a technique utilized to predict the outcomes of spring-assisted surgery. We have found this to be a useful tool, in planning our surgical strategy and improving outcomes. This technique has also contributed significantly to the process of informed consent preoperatively. In this article, we expand on our spring design and dynamics as well as the finite element modeling used to predict and improve outcomes.

In our unit, this practice has led to a significant improvement in patient outcomes and parental satisfaction and we hope to make our techniques available to a wider audience.

Key Words: Biomechanics, finite element modeling, scaphocephaly, spring, spring-assisted surgery

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Surgical treatment for the correction of scaphocephaly caused by the premature fusion of the sagittal suture is undertaken for esthetic 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 remodeling procedures.[1] Regardless of the strategy, the aim of the surgery is to regularize 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 popularized by Joe McCarthy and his team in the 1970s.[2] Initially, external distractors were used to achieve this; subsequently, wire-form distractors were popularized by Lauritzen et al in the late 1990s.[3] David et al published their initial experience in 2004[4] and Davis and Lauritzen[5] 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 standardize the device force/opening behavior. The aim of the standardized 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 modeling and 3D scanning techniques 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. This manuscript discusses an investigational use of a device (GOSH spring) not yet approved by the FDA.

BENCH TESTING OF THE GOSH SPRING

The GOSH spring model is a torsional spring with a central loop that extends into 2 longer arms (Fig. 1) with a slightly out of plane

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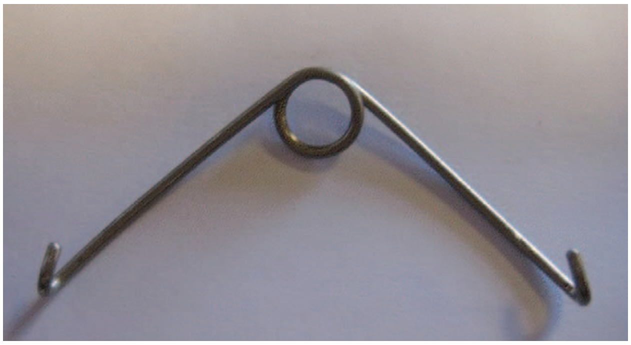

FIGURE 1. Picture of a GOSH spring.

curvature. The central loop (diameter 10 mm) was introduced to the wire form initial shape after a number of iterations to improve accuracy and reproducibility of the mechanical behavior—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 (Fig. 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 standardized models are currently used, which have the same geometry but vary in wire thickness (Fig. 1): model S10—1.0 mm wire thickness, model S12—1.2 mm thickness, and model S14—1.4 mm thickness. Design standardization ensures reproducibility of the force/opening behavior for each spring model.

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

The spring showed an initial linear behavior followed by a highly nonlinear behavior due to the stainless steel deforming plastically and undergoing localized unrecoverable deformations. Due to this, the unloading phase (bold lines in Fig. 2) and the unloading phase (dotted line in Fig. 2) show different behavior: crimping forces are higher than those exerted by the spring once implanted (Fig. 3).

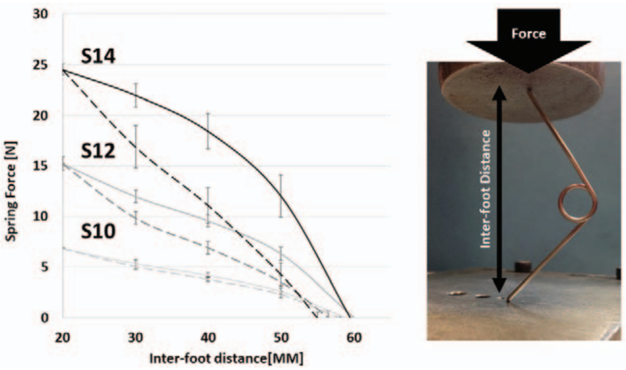

FIGURE 2. Graph showing spring force vs inter-foot distance for the three spring models used in GOSH (left) bold lines show forces during the loading phase while dotted lines show forces during the unloading phase; sample of cranioplasty spring during testing (right).

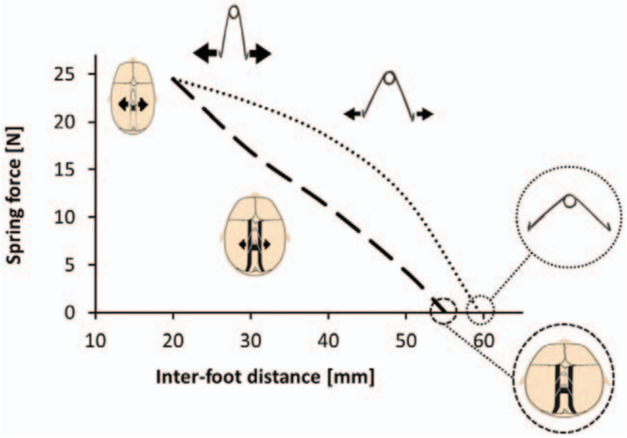

FIGURE 3. The graph shows in detail the stages of spring crimping and the forces exerted in this phase (top), compared to the forces exerted while inserted in the patient calvarium (bottom).

3D ANALYSES OF PRE- AND POSTOPERATIVE 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, noninvasiveness, and portability, thus enabling the acquisition of 3D images of the head surface in theatre and during patient appointments[14,15] (Fig. 4).

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 modeling techniques,[17,18] the construction of population mean shapes has revealed further quantitative and localized descriptive information on the average effects of spring cranioplasty (Fig. 5). Immediately after spring insertion, 2 prominences are evident at the top of the head, indicating localized deformations (Fig. 5-post-op); however, with time, the springs affect larger areas of the skull gradually widen it (Fig. 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 (Fig. 5-removal).

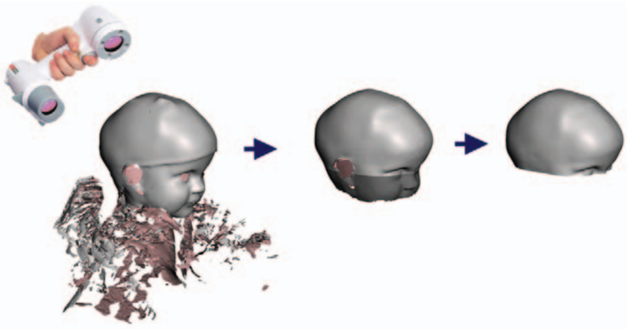

FIGURE 4. Post-processing steps of a 3D scan of a patient with sagittal synostosis.

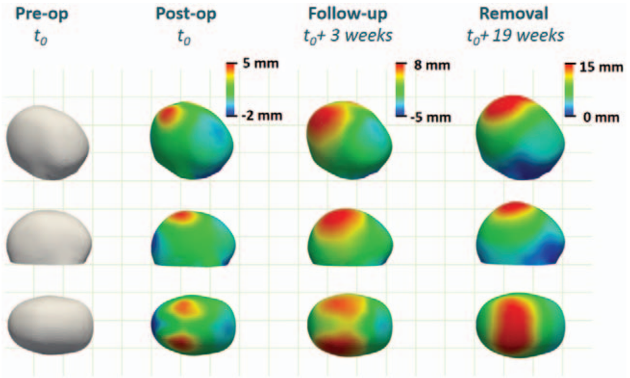

FIGURE 5. Average head shape models immediately before (pre-op, n = 25) and after surgery (post-op, n = 22), in the 3-week follow-up (follow-up, n = 18), and right after spring removal (removal, n = 23). Colour-maps describe shape changes in terms of distance when compared to the pre-operative average model.

Due to the complex dynamic biomechanical remodeling, associations between surgical choices at the time of spring insertion and postoperative 3D head shape features once the springs are removed are difficult to assess. To overcome this limitation, our theatre team started to systematically record surgical parameters such as craniotomy size and spring positioning. Population-based statistical shape modeling was then combined with advanced regression techniques to gain insight into how the choices of these surgical parameters affected post-surgical head shape (Fig. 6).[19] This analysis indicated that spring-assisted cranioplasty was most successful (ie, 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 >2 cm. Overall, population-based 3D statistical shape modeling allowed for quantification and visualization of trends in achieved head shape outcomes depending on each of the selected surgical parameters.

FINITE ELEMENT MODELING

Finite element modeling is a computational method used in engineering to study the behavior of complex structures by calculating approximate solutions for problems with known boundaries. It is applied to a continuous geometry by discretizing 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.

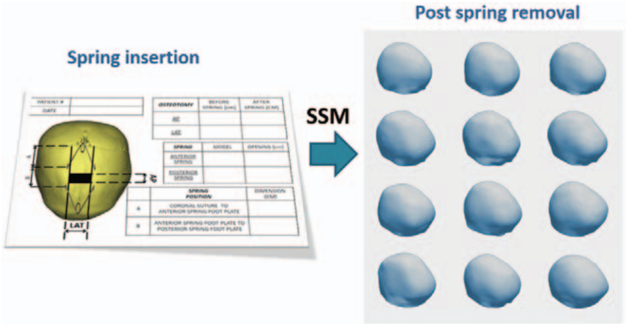

FIGURE 6. SSM and regression techniques were used to find relations between surgical parameters at the time of spring insertion and head shape features several months later when the springs were removed. SSM indicates statistical shape modelling.

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 suboptimal 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 optimize 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 suboptimal esthetic 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 utilized 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[24] evaluated spring forces using finite element models which simulated elastic properties of the skull bone. 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 images acquired for clinical diagnosis were used to reconstruct 3D patient-specific skull models of a population of pediatric patients who underwent spring insertion and expansion. Osteotomies were replicated, following measurements acquired during surgery (Fig. 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 (Fig. 7).

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

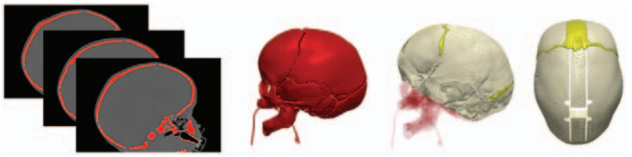

FIGURE 7. Creation of FE model for modeling of spring cranioplasty; segmentation of CT images (left); creation of a 3D skull model (center-left); identification of the region of interest for the modeling (center-right); reproduction of surgical osteotomies (right).

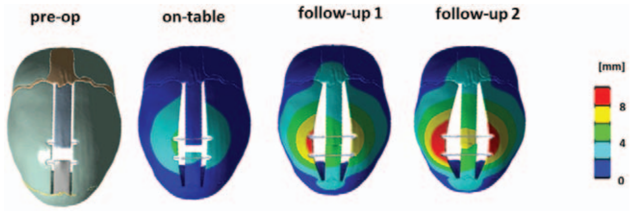

FIGURE 8. FE model of spring cranioplasty model. The pre-op mode retrieved through segmentation is used to calculate the skull shape after spring insertion (on-table) and follow-up 1 and 2.

Validation was performed using noninvasive 3D surface scanning (Fig. 9): by retrieving the postoperative 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 localized prediction error. Postoperative Cranial Index was also predicted within 1.9% ± 1.7%.

The patient-specific model, although requiring further large scale validation, can be used for individual patients to plan the surgery, optimize 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 intraoperatively into the desired U shape. The strength of each spring was measured using a sliding pressure gauge. This process was further standardized in some centers with the use of a custom designed wire bender which created a 1-inch bend diameter.[28] A lack of standardization among 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 standardized torsional spring with the introduction of a helix to improve elastic recoil, using surgical grade stainless steel wire (Fig. 1) and mechanically characterized to assess force/opening behavior, 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, >200 cases have been undertaken in the sagittal synostosis patients utilizing 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 behavior of the springs in the interaction with the sagittal synostosis pediatric 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 optimize outcomes. Using the modeling 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 optimize outcomes in bespoke fashion. Standardization of device and surgical technique enabled the above analyses, which in turn has promoted bespoke outcomes.

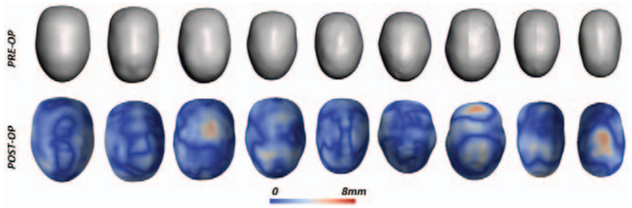

FIGURE 9. Validation of the finite element model in 9 patients. On top row, the pre-op head shape; on the bottom row, the postoperative reshaped head; the colors show the difference between the calculated shape and the on-table 3D scan retrieved during surgery.

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 centers 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 analyze more complex shape changes in pathologies where these springs have been utilized, such as posterior vault expansions in multisutural cases, and treatment of coronal and lambdoid synostoses, with promising results. We are also utilizing clinical data and modeling 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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