A Sleeping & Supine Approach to the Management of Infant Headshape Asymmetry: Made Possible by 3D Printing

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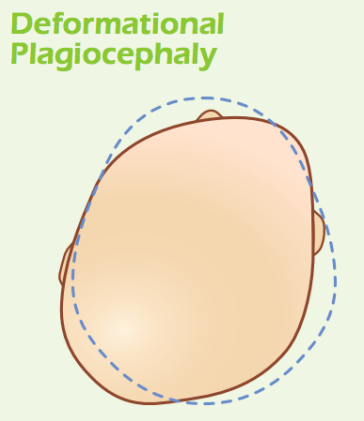
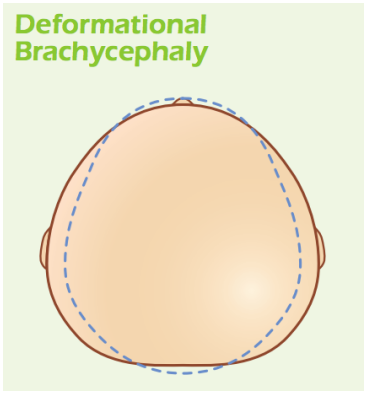
Background

The "Back to Sleep" program of the 1990's dramatically decreased the incidence of sudden infant death syndrome (SIDS), but unfortunately cranial deformations such as asymmetric (plagiocephaly) and symmetric occipital flattening (brachycephaly) have experienced a concomitant 600% increase in incidence.



Severe deformational plagiocephaly (DP) has obvious cosmetic concerns, but may also lead to medical concerns such as impaired temporomandibular joint function, issues with eye alignment and ear canal orientation as well as functional issues like comfortable fitting sports helmets and effective protection from injury or concussion.
Literature reports that 20%-30% of cranial asymmetries will resolve on their own or with therapy, which leaves between 70%-80% that may need some additional help to correct.
Cranial Remodeling Orthoses (CRO) are the most studied, most effective and most widely recognized treatment modality for moderate to severe positional cranial deformation of infants. Traditional CRO treatment has remained largely unchanged over the past 40 years, which makes this an area of orthotic practice with great potential for clinical and technical modernization.
Current practice standards strive to begin CRO treatment between the 5th to 8th month of life but often begin much later. Recent studies have shown that earlier treatment leads to better outcomes in a shortened amount of time.



Traditional CRO treatment options may impair infant gross motor skill development and head control if initiated before 5-6 months of age. These delays can be the result of traditionally bulky (up to 15mm thick on each side of the child's head) and heavy (between 300-350 grams) plastic and foam CRO designs. Furthermore, many families do not proceed with CRO treatment due to concerns of social acceptance, comfort of their baby (rashes, heat, pressure etc.) and that the 23 hour/day wear schedule will be a barrier to cuddling and bonding with their child. These issues may prevent families from seeking treatment for their babies.

What if a CRO could be 70% less weight, and 80% less thick? Could we start treatment much younger, like 10 weeks old? If started at a younger age, with more growth-directing potential and a more malleable skull, could the head shape be remodeled with 12-18 hours/day instead of the traditional 23 hr/day protocol? Parents would love that!
We wanted to explore this concept and since babies this age are supine and sleep a lot we wanted to see if earlier treatment could allow for supine use-only as these are the times when there is the most deformational pressure

on their heads. This would allow them to take the CRO off for daytime, so mom and dad could rub their fuzzy heads and go to the mall without so much attention to them and their cumbersome headgear.

This case study report focuses on using 3D printing technology to provide the required design flexibility to make lighter and thinner CRO's without structural compromise. This would allow us to assess the effectiveness of early treatment of DP while maintaining comfort and not hinder gross motor skill development.
The fused filament fabrication (FFF) style of 3D printing uses thermoformable layers as thin as .1mm and fuses them on top of one another via a computer-guided extruder to build a desired 3-dimensional shape (see figure 1). 3D modelling and FFF have technical design options that are unparalleled when compared to current manufacturing techniques. Case in point: this new 3D printed design reduced the weight of the CRO by up to 250 grams to 1/3 the weight of traditional designs and reduced the thickness up to 12mm per side to about 1/5 that of a traditional CRO with no compromise in structural integrity, comfort or the application of biomechanical forces within the CRO.

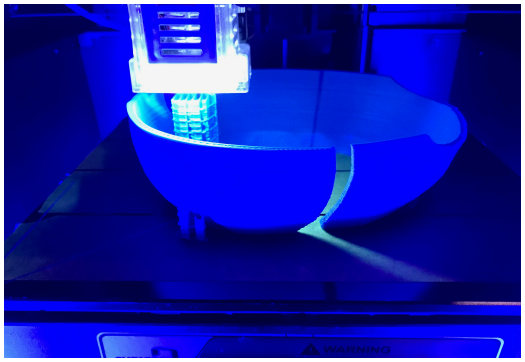


Figure 1: Fused Filament Fabrication of a CRO

3D CRO Design

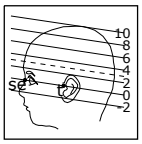
HeadStart Medical, Ltd. is a medical design company based out of Vancouver, BC that used topological optimization techniques to create the 3D printed, biocompatible custom made CRO's used in this case study. The CRO's are printed using hollow-core technology from proprietary plant-based biodegradable plastic. They utilize an innovative quadrant-based design structure with growth-adapting layers of orthopedic and shape-changing foam for containment of select cranial features. In non-contact areas there is strategically-placed ventilation to reduce heat retention and orthosis weight. The sub-occipital region is designed to maximize the cervical spine range of motion required during activities such as tummy-time and for development of gross motor skills such as spinal extension, rolling and crawling.

Case Description and Methods

At time of initial treatment, infants in this case study were between the ages of 13 and 18 weeks. They were referred from their family doctor or pediatrician and presented in our clinic with persistent cranial asymmetry and cranial ratio's (CR) in excess of 95% and / or 30° oblique diagonal differences (ODD) in excess of 10mm. Neck range of motion was within normal ranges in all four cases with no torticollis present.
Families were informed that the CRO's must be worn while baby is supine and for a minimum of 12 hours per day. Average wear time ranged from 12 to 18 hours in this group.
Four infants were treated. 1 female and 3 males. Average time in orthotic treatment was 14.25 weeks.
Infant head-shape was captured via Vorum's Spectra Scanner and assessed via Vorum's Cranial Comparison Utility (figure 2). Orthoses

were then fit within 6 days. Families received regular follow-up and adjustments were made for growth, comfort and to optimize the remodeling effect of their orthosis. At completion of treatment a second topographical 3D scan was performed using the Spectra Scanner and compared via Vorum's Cranial Comparison Utility.
An anonymous independent survey (figures 3, 4 & 5) was distributed via email to the families at completion of treatment for their qualitative input.
All families consented to participating in this case study.

Child's Name: Case 1
Birthdate: 2016-01-01
Practitioner: Jason Goodnough, MSc, CPO(c)
Phone: 778.388.3499
Fax: 604.608.3991
Comments:



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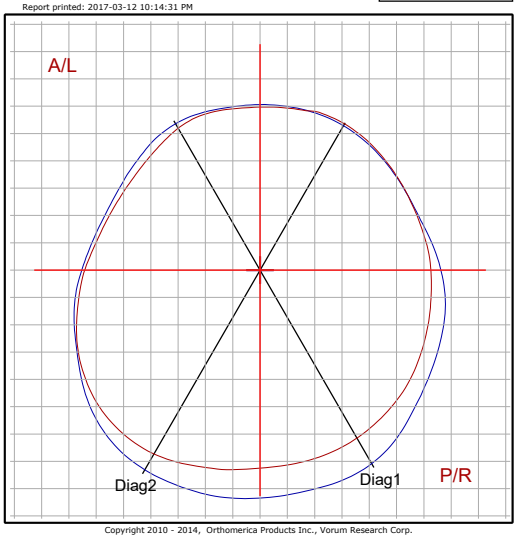

Section (3) Measurements			
Circumference	(mm)	417.1	442.0
Cranial Breadth (M-L)	(mm)	130.0	136.0
Cranial Length (A-P)	(mm)	132.8	144.3
Cephalic Ratio (M-L / A-P)		0.979	0.943
Radial Symmetry Index (RSI)		43.1	17.1
Oblique - Diagonal 1, at -30.0 deg	(mm)	131.0	143.6
Oblique - Diagonal 2, at 30.0 deg	(mm)	139.6	145.5
Cranial Vault Asymmetry	(mm)	8.6	1.9
Cursor Specified - D1	(mm)		
Cursor Specified - D2	(mm)		
Volumes (Level 2 to Level 8)			
Q1 Volume (A/L)	(cc)	104.8	143.5
Q2 Volume (A/R)	(cc)	106.8	144.0
Q3 Volume (P/R)	(cc)	147.9	259.8
Q4 Volume (P/L)	(cc)	174.3	269.1
Anterior Symmetry Ratio		0.981	0.997
Posterior Symmetry Ratio		0.849	0.965
Overall Symmetry Ratio		0.915	0.981
Landmark Based Measurements			
Upper Facial Left (TrL-Se)	(mm)	87.4	92.4
Upper Facial Right (TrR-Se)	(mm)	94.1	97.5
Upper Facial Difference	(mm)	6.7	5.0
Cranial Base Left (TrL-Sn)	(mm)	93.1	99.7
Cranial Base Right (TrR-Sn)	(mm)	105.8	103.9
Cranial Base Difference	(mm)	12.7	4.3
Orbitotragial Depth Left (TrL-ExL)	(mm)	51.5	53.9
Orbitotragial Depth Right (TrR-ExR)	(mm)	62.1	60.1
Orbitotragial Depth Difference	(mm)	10.6	6.2
Anterior Ear Shift	(mm)	18.2	11.8
Cranial Base Width (TrL-TrR)	(mm)	127.5	135.2
Vertex Height (Lev0-Lev10)	(mm)	77.4	100.3
Cranial Vault Asymmetry Index (CVAI)	(mm)	6.1	1.3
M1	(mm)		
M2	(mm)		
M3	(mm)		
M4	(mm)		

Figure 2: 3D Cranial Comparison Report for Case 1

Results and Outcomes

Quantitative Data from 3D Scans

All infants had notable improvement in their cranial symmetry over the course of treatment (Table 1). All infants started treatment with head shapes within North American accepted CRO treatment parameters of over 95% CR and / or over 10mm ODD (ie. greater than 2 standard deviations outside of accepted headshape normative data) and all infants completed their supine treatment program with head shape symmetry within normal ranges and below treatment parameters. These symmetry outcomes are similar to or better than many reported outcomes in literature for traditional CRO treatment. This data is statistically limited due to the small sample size associated with a case study. A larger study is forthcoming.

Table 1: Quantitative 3D Scan Data

	Infant Age at Start of Treatment	Pre-Treatment CR	Pre-Treatment ODD	Immediate Post-Treatment CR	Net Change to CR	Immediate Post-Treatment ODD	Net Change to ODD	Time in CRO
Case 1	13 weeks	98%	9mm	94%	-4%	2mm	-7mm	11 weeks
Case 2	18 weeks	97%	10mm	88%	-9%	5mm	-5mm	16 weeks
Case 3	14 weeks	85%	16mm	85%	0	7mm	-9mm	9 weeks
Case 4	16 weeks	96%	6mm	86%	-8%	2mm	-4mm	21 weeks

Survey

Due to the limited feedback that can be obtained from the patient, qualitative feedback from the families is particularly valuable in these cases.

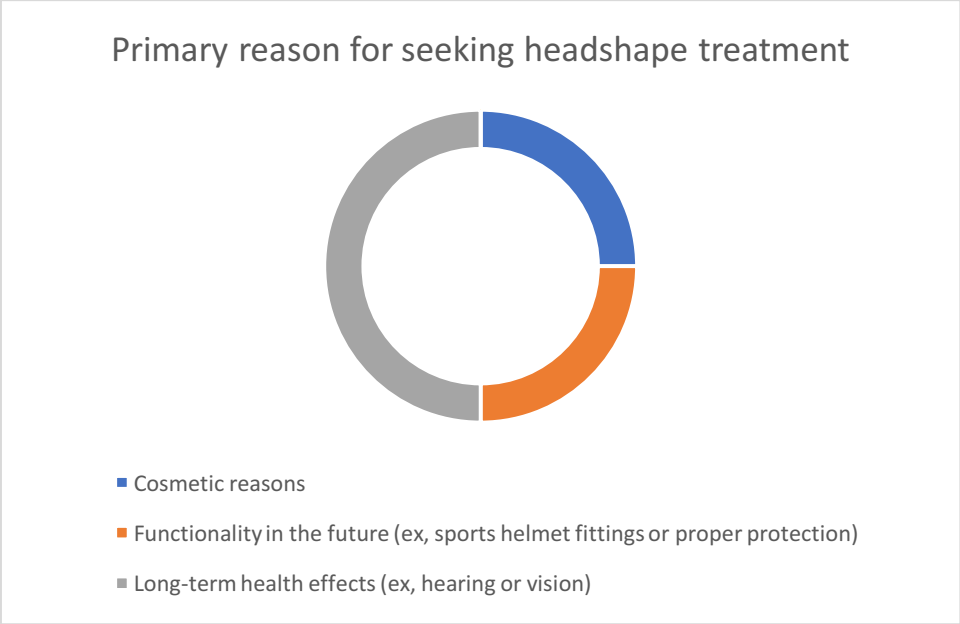

Figure 3: Survey Question 1 Results

Question 1: Most families were primarily concerned with long term health effects of persistent cranial deformation.

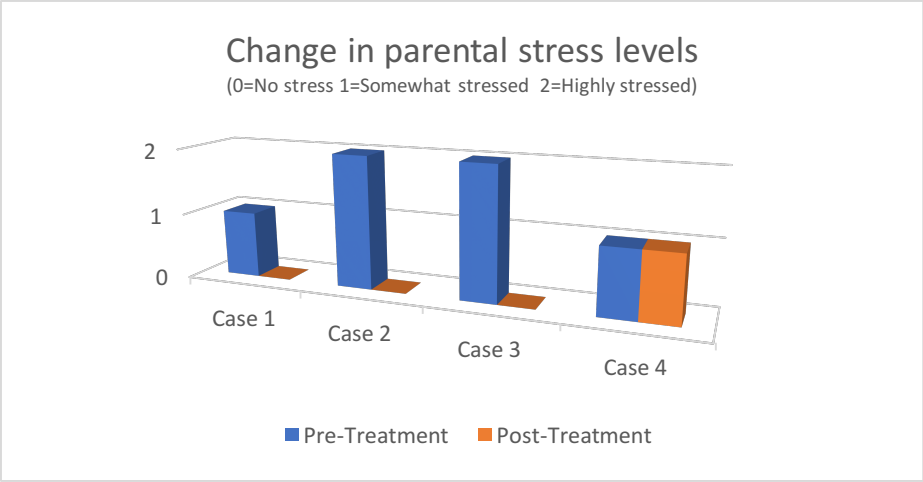

Figure 4: Survey Question 2 Results

Question 2: Families presented initally either somewhat stressed or highly stressed about their childs head shape asymmetry. Upon completion of the 3D printed supine CRO treatment program 3 out of 4 no longer had any stress associated with their childs head shape. One family continued to be somewhat stressed.

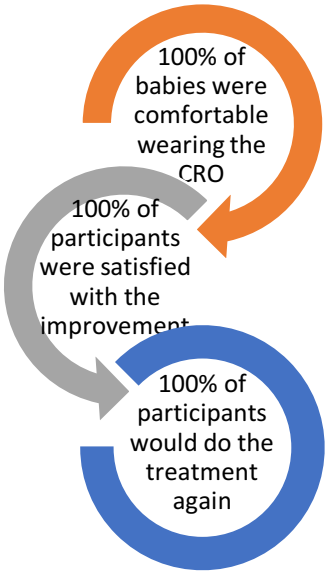

Figure 5: Survey Questions 3, 4 & 5 Results

Question 3: All families stated that their children seemed comfortable in the supine CRO.
Question 4: All families stated that they were satisfied with the head shape improvement they had observed.
Question 5: All families said that if they had to, they would do it again.

Conclusion

Knowledge that current research evidence suggests improved outcomes and reduced treatment times are possible with early intervention was coupled with 3D printing technology to design an innovative treatment program for infants with positional cranial deformation. This new treatment option has been shown to allow this population to access early care without the associated limitations of current CRO technology.
Quantitative 3D data showed excellent head shape symmetry outcomes, while parent compliance, satisfaction and acceptance exceeds previous reports in the literature for this population.

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