

Lessons Learned from the Cranial Helmet Experience

O&P Leadership & Its Future
Palm Beach, FL
January 11, 2015

ORTHOMERICA

U.S. Standards of Care

- The standard of care in the U.S. is to provide cranial remolding treatment for deformational plagiocephaly & craniosynostosis
- The majority of insurance companies in the U.S. provide coverage and reimbursement for Cranial Remolding Orthoses (CROs). National insurance companies include:
 - ✓ Aetna
 - ✓ CIGNA
 - ✓ UHC
 - ✓ Major BCBS plans
- Clinical standards of care are more defined in the U.S. than other countries
- Technology - Laser/scanning technologies are more accurate & provide more detailed reports to quantify treatment outcomes.

ORTHOMERICA

U.S. Manufacturing Guidelines

- Cranial orthosis in the United States are regulated by the Food and Drug Administration (FDA) as Class II Devices which require stringent manufacturing & labeling controls.
- FDA requires that Current Good Manufacturing Practices (CGMP) be followed to ensure the design and manufacturing of the device is safe and effective.
- It is evident that with so many clinical issues cited in this study e.g., (fit, skin breakdown, pain, etc.) that there is no similar regulatory oversight in the Netherlands regarding the manufacture of cranial remolding orthoses.

ORTHOMERICA

FDA CGMP Requirements

From the Code of Federal Regulations 21
(21 CFR Part 820):

- Current good manufacturing practices (CGMP) Requirements are set forth in the quality system regulation. The requirements in this part govern the methods used in and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug and Cosmetic Act.
- In order to ensure quality and safety in the marketplace, the FDA has imposed Special Controls for cranial orthosis.
- All manufacturers must receive 510(k) clearance from the FDA before providing cranial orthosis to the U.S. market.

ORTHOMERICA

Industry Response to BMJ Study

- Cranial manufacturers work together to educate physicians, providers and parents about defects of the study
- AOPA responded to NYT editor along with sponsoring Cranial Round Table at AOPA National Assembly that featured manufacturers and leading cranial orthotic specialists
- Social media push by many parties on Facebook and plagiocephaly support groups to educate parents about the flaws of this study
- Key craniofacial specialists such as pediatric plastic surgeons have gone on record citing several weaknesses in the study (AAP Letter to Editor-November 2014)
- Educating insurance companies about flaws of the study as they review medical coverage policies for cranial remolding treatment

ORTHOMERICA

More Studies Needed

- New Clinical Studies to be released with much larger sample sizes further reinforcing effectiveness of cranial remolding treatment
 - Effectiveness of Conservative and Helmet Therapy for Positional Cranial Deformation. Steinberg, Rawlani, Humphries, and Vicari. Plastic and Reconstructive Surgery. Dr. Frank Vicari. Over 4,000 infants evaluated and of these, 1,454 received cranial remolding helmets and achieved 95% correction with helmet therapy.
 - Dr. Stelnicki, South, FL. Completing a study of over 4,000 infants showing similar results.
 - Texas Children's Hospital - Over 1,000 patients
- Randomized Control Trials (RCT)

ORTHOMERICA

Randomized Control Trials (RCT)

- Study will need to use outcome measures that are reproducible and reliable.
- Is a RCT ethically possible in the U.S., where the standard of care is to orthotically treat babies with moderate to severe head shape deformities?
- In what country might a randomized control study be possible?



ORTHOMERICA

Future Randomized Control Trials (RCT)

- The country would need to have qualified practitioners, funding source(s), treatment facilities, parental compliance, proper equipment, oversight and strict protocols.
 - ✓ China?
 - ✓ Sweden?
 - ✓ Brazil?
 - ✓ Mexico?

Question to ask before opting for an RCT...

What's your treatment?



We don't have one, we just heard RCTs were the gold standard.



freshpectrum.com

ORTHOMERICA

Conclusion

- The effectiveness of any cranial orthosis treatment is directly tied to the expertise of the orthotist, quality of the manufactured orthosis and following defined clinical standards of care.
- The issues cited in this study are not reflective of best practices and as a result, the study is flawed by suggesting that orthotic therapy is not effective based upon poor clinical outcomes documented in this study.
- Evidence-based practice should rely on a very broad, diverse base of evidence since science demands replicability and no one study changes existing science.

ORTHOMERICA



THANK YOU!

William Gustavson
Orthomerica Products, Inc.

ORTHOMERICA