Reference

Willenborg, Hannelore[1]; Seniow, Pauline[2]; Daentzer, Dorothea[1]

3D-printed helmet therapy in infants with positional cranial deformity: effectiveness and parents' satisfaction

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Products

MyCRO Band

Major Findings

With **MyCRO Band** in three different cranial deformities:

→ Significantly decreased cranial deformity after treatment

- **Plagiocephaly (PC)** – Cranial vault symmetry index (CVAI) decreased from 10.0 ± 2.5% to 3.9 ± 1.7% (Δ –6.1%; $p < 0.0001$)
- **Brachycephaly (BC)** – Cranial index (CI) decreased from 101.9 ± 3.5% to 94.3 ± 2.7% (Δ –7.6%; $p < 0.0001$)
- **Combination of PC and BC** - both indices decreased significantly during treatment (Δ –4.8% for CVAI; Δ –6.3% for CI; both $p < 0.0001$)

→ Severity of head deformation decreased by at least 1 level for

- 100% of Plagiocephaly (PC) infants
- 82.3% of Brachycephaly (BC) infants
- 75.7% of infants with combination PC/BC

→ Significantly higher success rate when diagnosis is PC and when deformity is severe at baseline

Multivariate analysis: $p < 0.0001$ (for factor, diagnosis); $p < 0.0001$ (for factor, initial severity)

→ 88% of parents were very satisfied or satisfied with the treatment

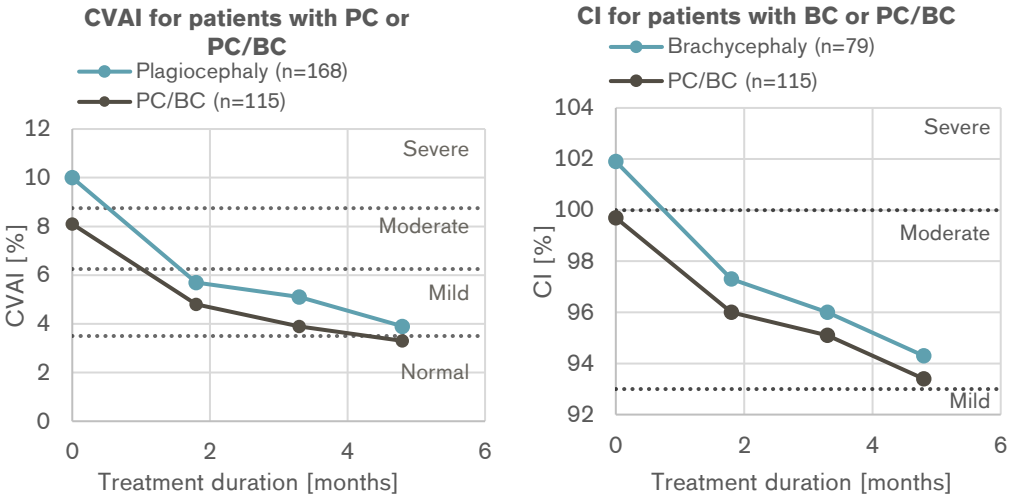


Figure 1: Evolution of cranial deformity indices (Cranial Vault asymmetry (CVAI) for Plagiocephaly (PC) and Cranial Index (CI) for Brachycephaly (BC) over the treatment duration in months. Legend: dotted lines indicate range of the severity of head deformity for the respective indices – for CVAI, normal severity CVAI < 3,5%, mild 3,5 ≥ CVAI < 6,25%, moderate 6,25% ≥ CVAI ≤ 8,75% and severe CVAI > 8,75%; for CI, normal severity CI < 85%, mild 85% ≥ CI <93%, moderate 93%≥ CI ≤100% and severe CI >100.

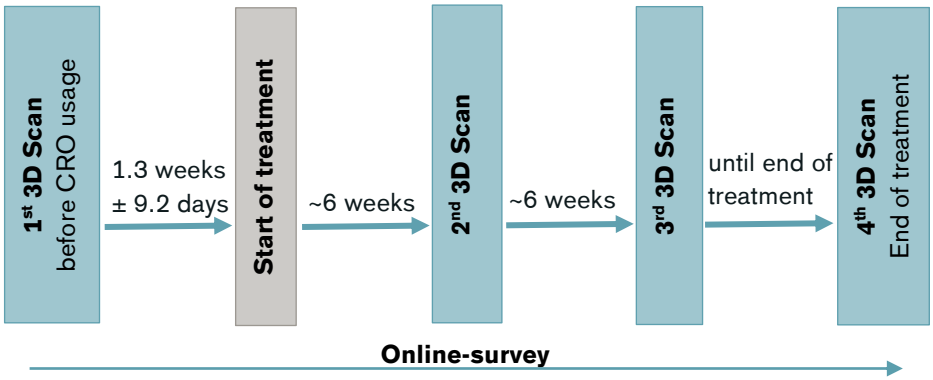
Population

Subjects:	409 infants (80 female, 233 male, 96 missing data) 362 evaluable patients with 3D head scans Parents' survey: n = 313 (96 surveys not completed)
Mean age at treatment start:	6.6 ± 1.7 month
Diagnosis (only from PP patients n=362)	Plagiocephaly (PC): n = 168 Brachycephaly (BC): n = 79 Both deformities (PC/BC): n = 115
Severity of head deformity:	Mild: n = 15 Moderate: n = 117 Severe: n = 277
Associated medical problems:	Torticollis: n = 184 Postural syndrome: n = 13 Other: n = 34

Study Design

Mixed design that combined retrospective and prospective elements

- retrospective clinical data collection (filled in by orthotists)
- prospective online survey (completed by parents)



Measurements:
- evolution of head shape indices
- evolution of head circumference (measured on 3 measuring planes of the 3D scan)

Online- survey:
- satisfaction (QUEST 2.0 [1])
- collection of demographic data
- description of treatment course
- compliance
- tolerance
- involved health care professionals

Primary outcomes were changes in cranial deformity indices (CVAI, CI) measured at several time points (before treatment, 6 and 12 weeks into treatment and at the end). Secondary outcomes included head circumference growth and parental satisfaction (using the QUEST 2.0 questionnaire [1]).

Results

Functions and Activities						Participation	Environment
Biomechanics – Static Measurement	Biomechanics – Gait analysis	X-Rays	EMG	Functional tests	Clinical effects	Satisfaction	Health Economics

Category	Outcomes	Results for MyCRO Band				Sig.[a]
Clinical Effects -Description of treatment (baseline vs. end of treatment)	Treatment duration [days]	**Mild deformity**	**Moderate deformity**	**Severe deformity**	**All**	n.a.
		103.8	119.5	144.1	135.6 ± 44.3	
	Number of appointments	Mean: 6.1 ± 1.9				n.a.
	Delivery of CRO[b] + scan appointments	**Delivery of CRO**	**1st 3D scan after delivery**	**2nd 3D scan after delivery**	**3rd 3D scan after delivery**	n.a.
		1.3 weeks ± 9.2 days	7.7 weeks later	14.4 weeks later	20.7 weeks later	
	Compliance	95% of patients wearing CRO every day 84% of patients wearing CRO more than 22h/day				n.a.
	Physiotherapy	67% of patients underwent physiotherapy during the CRO wearing period				n.a.
	Number of CROs used for treatment	**1**	**2**	**3 to 4**		n.a.
		85.0%	13.4%	1.2%		
Clinical effects - Treatment effectiveness	Evolution of cranial deformity indices [%]	**CVAI** (Cranial Vault Asymmetry Index)				
			1st 3D scan	**2nd 3D scan**	**3rd 3D scan**	**4th 3D scan**
		PC (n=168)	10.0±2.5	5.7±2.3[c]	5.1±1.8[c]	3.9±1.7 ++
		PC/BC (n=115)	8.1±2.9[c]	4.8±2.1[c]	3.9±1.9[c]	3.3±1.8[c] ++
		[c] standard deviation extracted from graphs in publication				
		CI (Cranial Index)				
			1st 3D scan	**2nd 3D scan**	**3rd 3D scan**	**4th 3D scan**
		BC (n=79)	101.9±3.5	97.3±3.3[c]	96.0±3.1[c]	94.3±2.7 ++
		PC/BC (n=115)	99.7±3.7[c]	96.0±3.3[c]	95.1±3.4[c]	93.4±2.9[c] +
		[c] standard deviation extracted from graphs in publication				
	Cranial deformity at end of treatment	In 92.3% of PC patients head shape was normal or only mildly deformed at the end of therapy and none remained in severe class				n.a.

Category	Outcomes	Results for MyCRO Band		Sig.[a]
		In 75.9% of BC patients cranial deformity was moderate at the end of treatment and remained severe in only 2.5% of cases		n.a.
		In 69.6% of PC/BC patients, cranial deformity was moderate at the end of treatment and remained severe in only 2.6% of cases		n.a.
	Factors significantly associated with treatment success	Significant higher success rate if… - helmet usage was initiated before age of 6 month - the deformity was severe - helmet use was associated with physiotherapy - helmet was worn for at least 130 days - the diagnosis was PC		n.a.
		Therapy effectiveness was associated - significantly with deformity type and initial severity - almost significantly with age at treatment start		++ +
	Age for successful treatment	Significantly lower mean starting age in patients with successful treatment (6.4 ± 1.5 months vs 8.4 ± 2.6 months)		++
	Side Effects	Most common side effects - Skin redness (81.1%) - CRO stability issues (60.4%) - Excessive sweating when wearing the CRO (78.5%) Treatment interrupted in 23.3% patients for at least 3 days and discontinued in 17.6%, mainly caused by fever and illness and hot weather.		n.a.
	Head circumference [mm]	**Baseline**	**End of treatment**	n.a.
		440 ± 15	459 ± 14.5	
Satisfaction	Overall satisfaction	88% of parents are either very satisfied or satisfied with treatment		n.a.
	Satisfaction QUEST 2.0 (range 1 (not satisfied) to 5 very satisfied))	Global satisfaction score: 4.5 ± 0.5 - Subscores for satisfaction with the device technology: 4.4 ± 0.5 - Subscores for satisfaction with the services provided by the orthotist: 4.7 ± 0.6		n.a.
	most important satisfaction criteria (cited by parents)	- CRO effectiveness (61.9% of answers) - comfort (40.8%) - weight (25.9%)		n.a.

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.) significance set at $p<0.05$; trends set at $0.1>p>0.05$

[b] CRO- Cranial Remoulding Orthosis

[c] standard deviation extracted from graphs in publication

Author's Conclusion

"The study results confirm that orthotic treatment of positional cranial deformities with the 3D-printed MyCRO Band helmet is effective and safe for children with moderate or severe PC, BC or combined skull deformity. The correction of the deformity appears even more effective if the treatment is initiated before the age of 6 months." (Willenborg et al., 2025)

Author's Affiliation

[1] Department of Orthopedics, Hannover Medical School, DIAKOVERE Annastift gGmbH, Germany

[2] Department of Cranial orthotics, Ottobock Care, O&P clinic, Toulouse, France

Author's References

[1] Demers L, Weiss-Lambrou R, Ska B. Item analysis of the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST). Assist Technol 2000;12:96–105. doi:https://doi.org/10.1080/10400435. 2000.10132015.