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Cranial Remodeling Devices: Treatment of Deformational Plagiocephaly and Postsurgical Applications

Timothy R. Littlefield

Since the first cranial remodeling devices were introduced in 1979, both their design and availability have continued to evolve. Today, these devices are used to treat deformational plagiocephaly (plagiocephaly, brachycephaly, and dolichocephaly) and are used as adjuncts to surgery for craniosynostosis. In deformational plagiocephaly, the goal is to improve cranial symmetry and return the cranium to a more normal proportion. Postoperatively, these devices are used to provide stabilization and to enhance surgical outcomes. Numerous clinical studies have demonstrated the safety and efficacy of these devices by documenting statistically significant reductions in the cranial vault, skull base, and facial asymmetries as well as improvements in the cephalic index. These studies indicate that cranial remodeling devices play an important role in the treatment of cranial deformations.

For centuries, many cultures have used external "molding" devices to intentionally alter cranial shape into a more desirable configuration. The methods used typically consisted of devices applied to the rapidly growing head of infants during the first several months of life. In Egypt, young nobles would have their head bound to produce a tall, turricephalic head shape that distinguished them as nobility. In North America the Chinook Indians used two flat boards (one across the forehead and one along the occiput) secured with straps to produce a tall, flat forehead. This shape was a symbol of an individual's freedom; only those born free or certain "favorite slaves" were allowed the privilege of flattening the skulls of their children (Fig 1).[1] In South America, many cultures intentionally deformed the skull because they believed that it helped ward off evil spirits, made them more intimidating to enemies, or increased their health and vitality.[1-3]

Dr. Sterling Clarren introduced the first therapeutic device for the treatment of plagiocephaly based on similar principles. In 1979, Clarren hypothesized that "if the pressure of a rapidly growing brain against a flat surface would flatten the skull, then pressure against a concave surface should round it back again." Hence the cranial molding helmet was conceived.[4,5] In the United States, introduction of the cranial molding helmet revolutionized the treatment of plagiocephaly by providing the first nonsurgical alternative for its management. The device has become known as a "passive" molding helmet because it works by providing a symmetrical mold for the head to grow into. Treatment is complete when the "head takes on the shape of the helmet."[4]

In 1986, we began work on a new device that became known as Dynamic Orthotic Cranioplasty[SM] (DOC®; Cranial Technologies, Phoenix, AZ).[6] Rather than waiting for the head to grow into a symmetric mold, this new device immediately applies a corrective force to the prominent areas of the skull while leaving room for growth in the adjacent flattened regions (Fig 2). An inner foam liner is incorporated to allow the band to be adjusted weekly to biweekly, thereby achieving control of the correction. The word "dynamic" (characterized by continuous change, activity, or progress[7]) in the device's name derives from this process of continuously monitoring the patient's progress and then adjusting the corrective forces applied.

Despite the development of the DOC, the use of cranial remodeling devices did not become widespread until after 1992, when the American Academy of Pediatrics (AAP) began to recommend a supine sleeping position for infants in an effort to reduce the incidence of sudden infant death syndrome (SIDS).[8] An unforeseen consequence of this recommendation was an increase in the incidence of deformational

From Cranial Technologies, Inc., Tempe, AZ.
Disclosure: Mr. Littlefield is the Director of Research and Development for Cranial Technologies, Inc. He holds no stock and has no other financial interest in Cranial Technologies, Inc.
Address reprint requests to Timothy R. Littlefield, Director of R&D, Cranial Technologies, Inc., 1395 W. Auto Drive, Tempe, AZ 85284.

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Figure 1 Chinook infant in molding apparatus. (Reprinted with permission from Cranial Technologies, Inc.)

plagiocephaly.[9,10] The condition became so prevalent that a special meeting between craniofacial and pediatric neurosurgeons was convened in 1997 to draft a position statement on its management.[11,12]

The increase in plagiocephaly also prompted the introduction of numerous cranial remodeling devices and increased scrutiny by the U.S. Food and Drug Administration (FDA). In 1998, the FDA classified the "cranial orthosis" as a Class II neurology device.[13-15] This classification confirmed the FDA's concern about the potential adverse consequences of using these devices inappropriately. These devices are unique because they are applied to the rapidly growing infant cranium. They therefore represent an inherently greater risk than most other types of orthotics. They are currently the only orthoses that require FDA clearance. To date, 23 cranial remodeling devices have been approved for the market.

Cranial Remodeling of Deformational Plagiochephaly

Using cranial remodeling bands to treat deformational plagiocephaly has now become a standard of care in the United States.[3-6,9,10,16-22] The process of fabricating a cranial band requires the clinician to first obtain a negative or "cast" impression of the child's head shape. Plaster casting is a time-tested technique by which almost all cranial remodeling devices have been made since the late 1970s. Obtaining a plaster cast begins by pulling a cotton stockinette over the child's head and then casting with quick-setting, low-temperature plaster splints.[6] The casting process takes 7 to 10 minutes. When performed by a skilled clinician, an accurate three-dimensional model of an infant's cranium is obtained. The accuracy of our plaster casting technique was recently confirmed in a study comparing models obtained with casting to those obtained with a new three-dimensional digital imaging system.[23]

Once a negative impression of the child's head is obtained, a positive model is created by filling it with a plaster-based slurry. This positive model represents the infant's initial deformity. The positive model is modified to a symmetric shape with the application of molding material, and the cranial headband is fabricated around this corrected model. When fit to the infant, the device applies a mild holding pressure to the prominences while leaving room for growth in the adjacent flattened regions (Fig 2). The infant is evaluated weekly to biweekly by specially trained medical personnel, who monitor cranial growth and make adjustments to the band to control the correction. Therefore, successful outcomes rely not only on a well-designed device, but also on the training and experience of the medical professionals providing treatment.

By changing the direction and point of application of corrective forces, this approach has been used to successfully treat all forms of positional head deformities, including plagiocephaly, brachycephaly, dolichocephaly and combinations thereof. In plagiocephaly, the corrective forces are applied diagonally across the skull, holding the frontal and occipital prominences while redirecting growth into the flattened regions (Fig 3). In brachycephaly, a lateral holding force is applied, and growth is redirected in the posterior direction to return the head to a more normal cephalic index as well as to round the flattened occiput (Fig 4). Conversely, in scaphocephaly or positional dolichocephaly, an anteroposterior holding force is applied. Growth is redirected in the lateral direction, again returning the head to a more normal cephalic index.

Because corrective pressure is applied immediately at the onset of treatment, changes are often observed within the first week. This immediate application of corrective forces has also extended the effectiveness of these devices well into the second year of life (Fig 5).[24] Average treatment time is 4.5 months, but treatment time is a function of the child's entrance age and the severity of the presenting condition.

The efficacy of dynamic orthotic cranioplasty has been documented in several clinical investigations.[6,14,21,22,25] In the first study, Ripley and coworkers followed 47 infants. Using anthropometric measurements, they documented a reduction in cranial vault, skull base, and upper face asymmetry after treatment.[6] In two additional investigations, Littlefield and coworkers followed 285 infants and documented statistically significant reductions in all three measures of craniofacial asymmetry (Table 1).[14,25] The correction remained stable after patients left treatment. In 2002, Teichgraeber and coworkers reproduced these studies by following 125 infants treated for plagiocephaly with molding helmet therapy (DOC; Cranial Technologies).[21] They also found statistically significant reductions in cranial vault and upper face asymmetry. In 2004, Teichgraeber and coworkers compared treat-

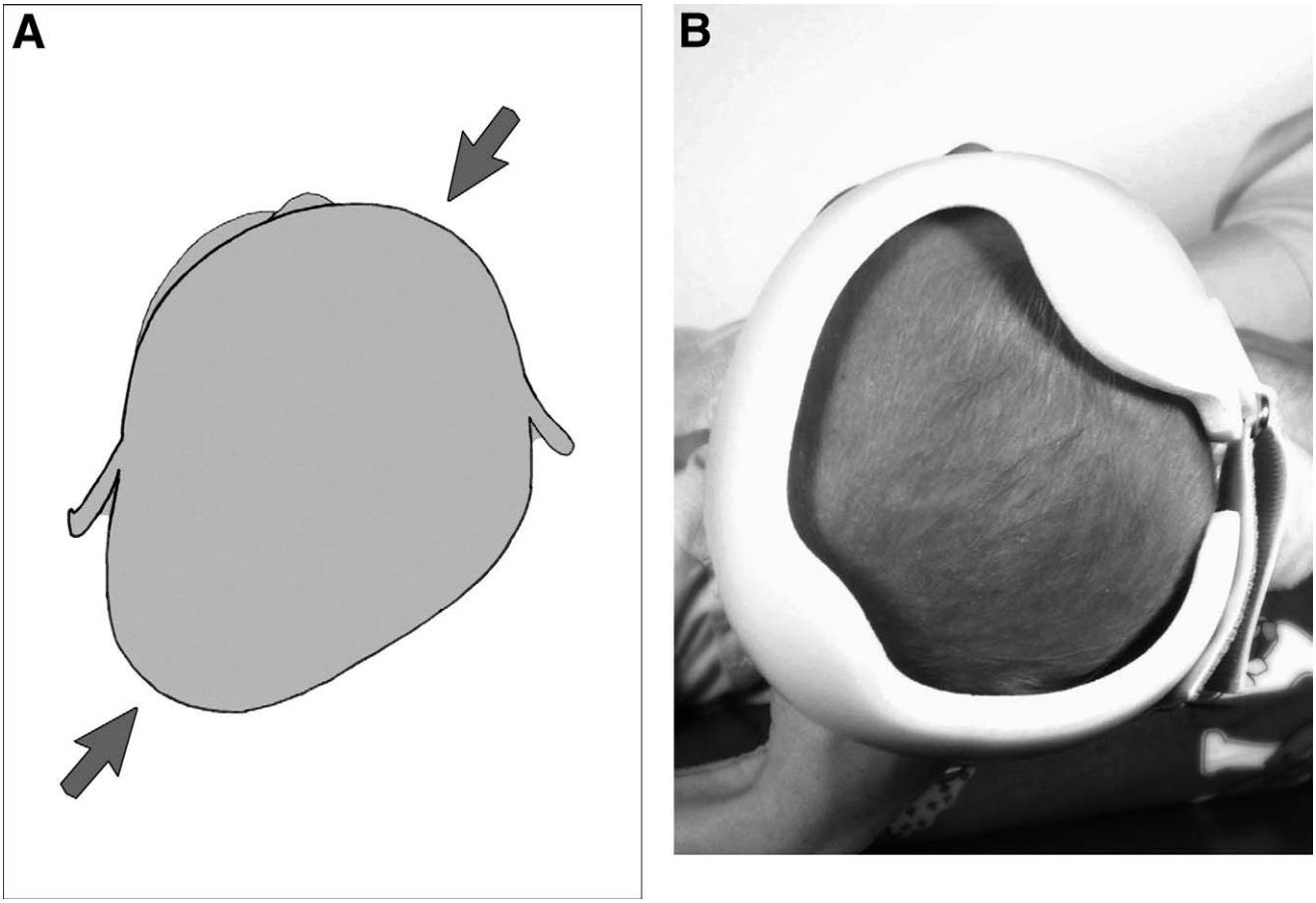

Figure 2 (A) Corrective forces are applied to the anterior and posterior prominences. (B) Vertex eye view of infant in cranial remodeling band (DOC Band; Cranial Technologies, Inc.) demonstrating holding on prominences with room left in the band where growth is desired.

ment outcomes of positional plagiocephaly (n = 292) and positional brachycephaly (n = 64).[22] Molding helmet therapy significantly improved both deformities, but outcomes were more pleasing in the plagiocephalic group.

In 1999, Kelly and coworkers investigated concerns about potential restriction of cranial growth reported in 190 infants (a subset of the previous 285 reported by Littlefield and coworkers[19]) who also had undergone pretreatment and posttreatment circumference measurements.[26] Cranial growth was not restricted. They found a statistically significant reduction in craniofacial asymmetry. More importantly, however, this correction was achieved with concomitant, statistically significant growth of the skull. The study demonstrated that treated infants exhibited normal growth trajectories and plotted appropriately on pediatric growth charts compared against age- and gender-specific norms.

In 1999, Kelly and coworkers also investigated three variables thought to influence treatment outcomes, including entrance age, treatment time, and initial severity.[27] The effects of these three variables on treatment outcome were assessed using three-way analysis of variance. They found that earlier intervention significantly improved outcomes, independent of the severity of the presenting asymmetries. Given that these devices rely on capturing and redirecting symmetrical growth of the head and the relatively rapid growth of the cranium in the first 6 months of life, these findings were not surprising.

Cranial Remodeling in Postsurgical Applications

Cranial remodeling devices have also been used postoperatively to provide stabilization and enhance surgical outcomes. Some of the earliest work in this area was performed at the University of Virginia and was reported by Persing and coworkers in 1986[28] and by Ham and Meyer in 1987.[29] These authors reported the development of "skull molding caps" fabricated with Orthoplast® (Dow-Corning Medical Products, Midland, MI) and used as an adjunct to surgery. No quantitative data were provided, but the use of these devices after surgery consistently improved the "cranial vault form over what could be achieved by operation alone."[28]

In 1995, Joganic and coworkers reported 62 cases treated postoperatively with a cranial remodeling device (DOC; Cranial Technologies).[30] This series included 14 cases of sagittal synostosis, 12 cases of unilateral coronal synostosis, 5 cases of metopic synostosis, 10 cases of multiple suture synostosis,

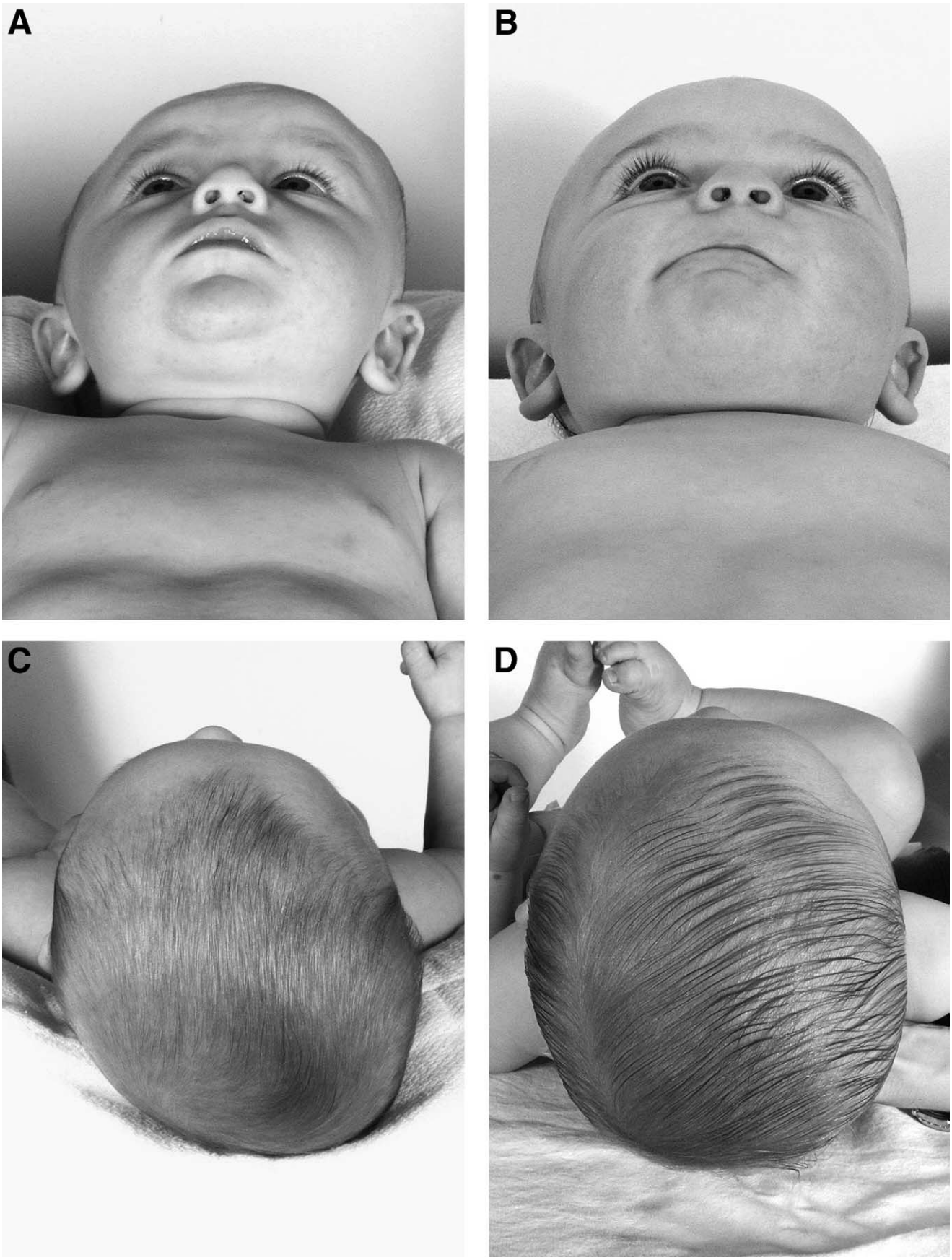

Figure 3 Submental views of a 4.5-month-old boy showing (A) initial asymmetry and (B) correction after 3.5 months in treatment. Vertex view of same infant showing (C) initial cranial asymmetry and (D) improvement on exiting from treatment.

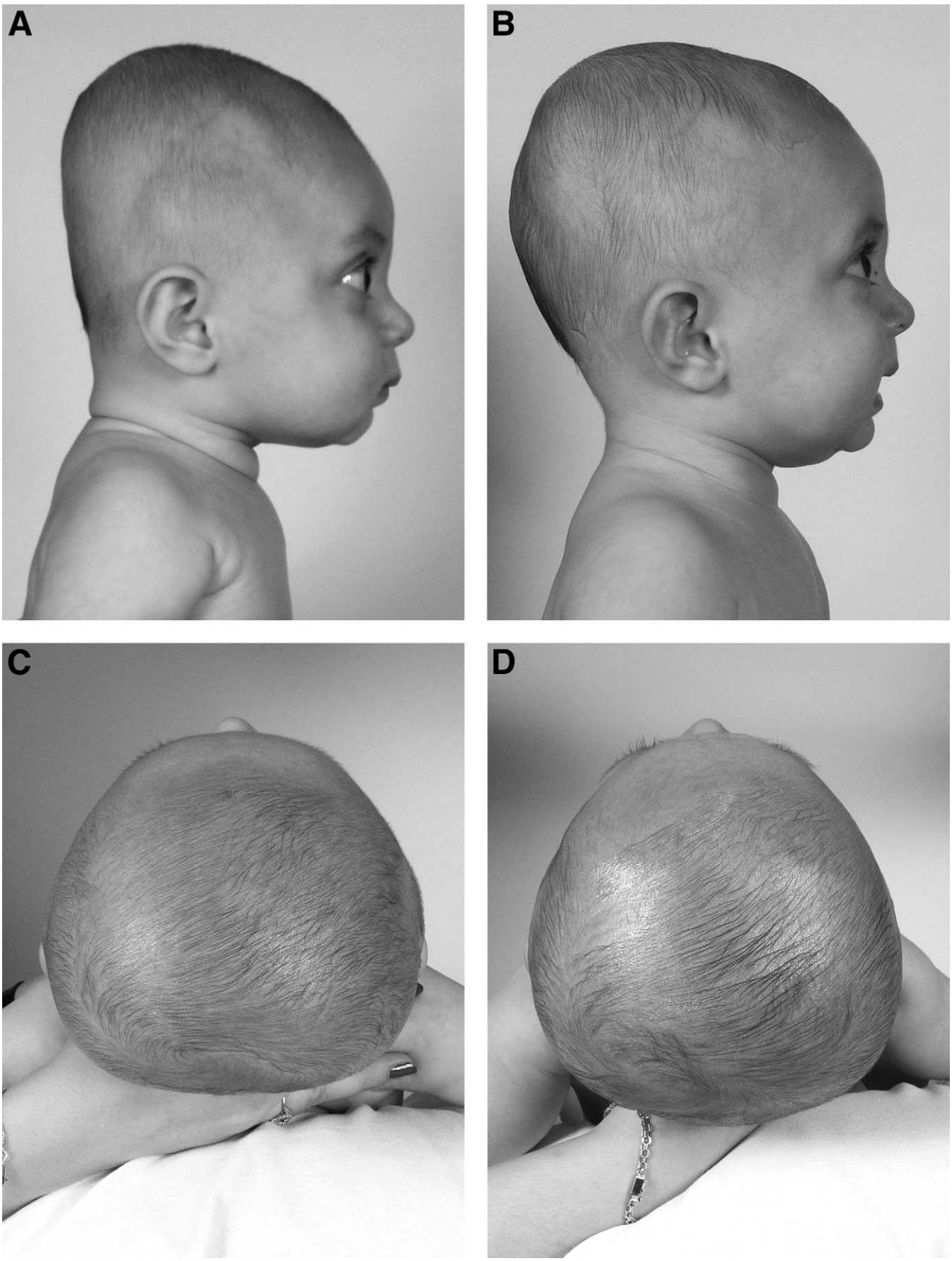

Figure 4 A 6.5-month-old girl with severe brachycephaly treated for 3.25 months. Lateral views at (A) entry and (B) exit. Vertex views at (C) entry and (D) exit. Cranial length increased 14 mm, while cranial breadth was maintained.

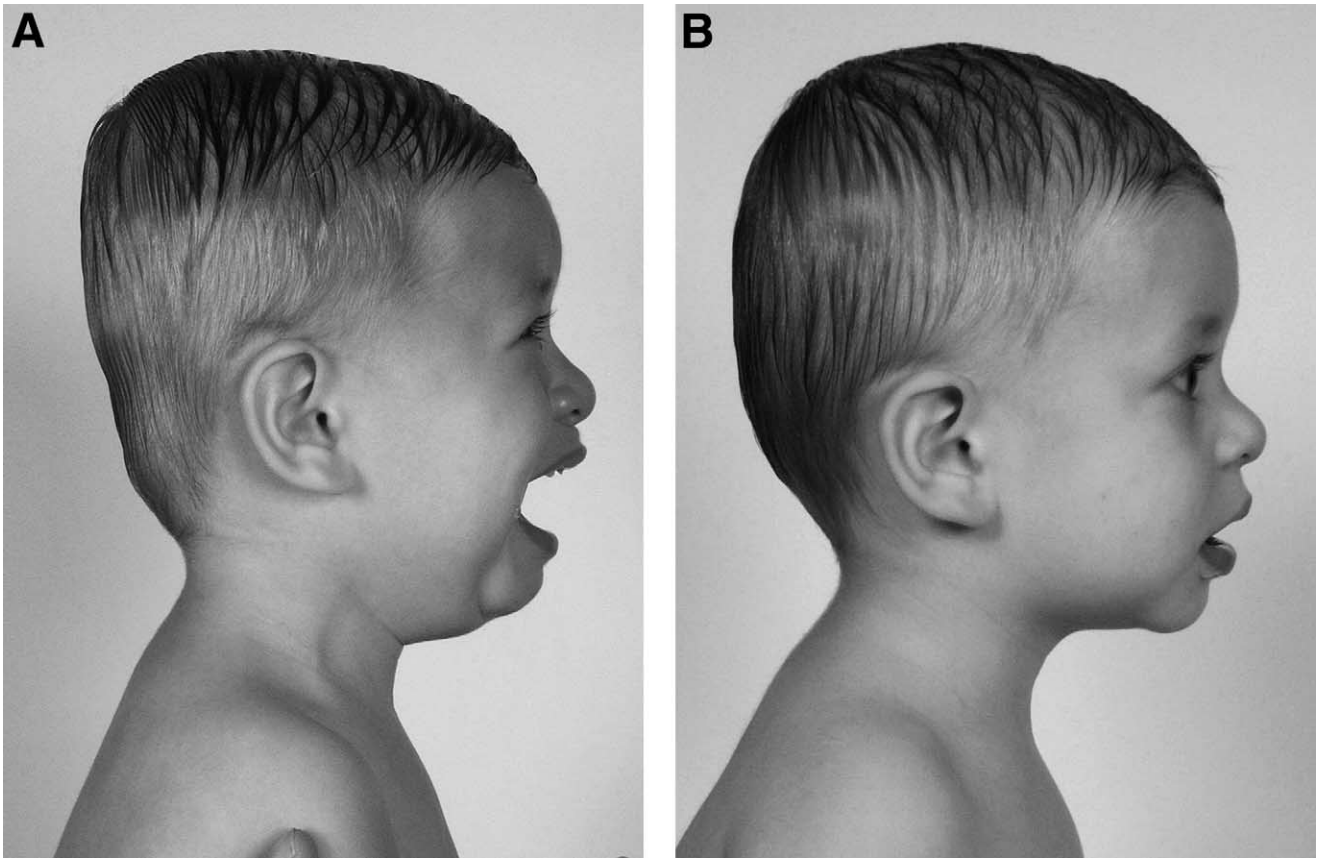

Figure 5 A 19-month-old boy whose mother was reassured the head would round out with normal growth and development. Lateral views at (A) entry and (B) exit. Images demonstrate that correction with cranial remodeling bands can be achieved during the second year of life. Treatment time was 4.5 months.

3 cases of oxycephaly, 9 cases of hydrocephalus, and 2 cases of encephalocele (Fig 6). From this work, Joganic and coworkers concluded that several advantages are associated with using cranial remodeling devices postoperatively and that preoperative planning for the use of these devices would allow surgeons to alter the design pattern of osteotomies to better prepare the skull for operative molding. Furthermore, they noted that "when effectively employed, it was possible in some cases to improve the result of surgery to a degree that a secondary operation was avoided. Occasionally, the objectives of a planned two-stage reconstruction could be accomplished in a single procedure."[30]

In 2002 Seymour-Dempsey and coworkers reported 21 children operated on for sagittal synostosis between 1994 and 2001.[31] Fifteen patients were fit with a cranial remodeling device (DOC; Cranial Technologies) postoperatively, and six were not. Although surgical improvement was seen in both groups, the group that wore a cranial remodeling device postoperatively had better outcomes than the nonhelmeted group. The authors therefore recommended postoperative helmet use as an adjunct to surgery.

For many years, cranial remodeling devices have been applied after both cranial vault remodeling and standard strip craniectomies. Recently, however, interest in a new surgical approach known as endoscopic-assisted strip craniectomy has increased. The advantages of this new technique reportedly include decreased scarring, reduced blood loss, and decreased hospitalization time.[32-35] Unfortunately, this technique does little to correct the stigmatic shape of the skull. Therefore, cranial remodeling devices are used postoperatively to normalize skull shape.

Most of these endoscopic procedures have focused on sagittal synostosis, in which after releasing the fused sagittal suture, additional osteotomies and barrel staving are per-

Table 1 Reduction in Craniofacial Asymmetries

Parameter	Entrance, mm (mean ± SD)	Exit, mm (mean ± SD)	Change, mm (mean ± SD)	*T*	*P* > *T*
CVA	8.2 (3.7)	3.2 (2.9)	5.0 (3.2)	22.0	0.001
SBA	5.8 (2.9)	3.1 (2.1)	2.7 (2.4)	14.9	0.001
OTDA	4.3 (2.2)	2.4 (1.6)	1.9 (1.8)	14.3	0.001

Abbreviations: CVA, cranial vault asymmetry; SBA, skull base asymmetry; OTDA, orbitotragial depth asymmetry; SD, standard deviation.

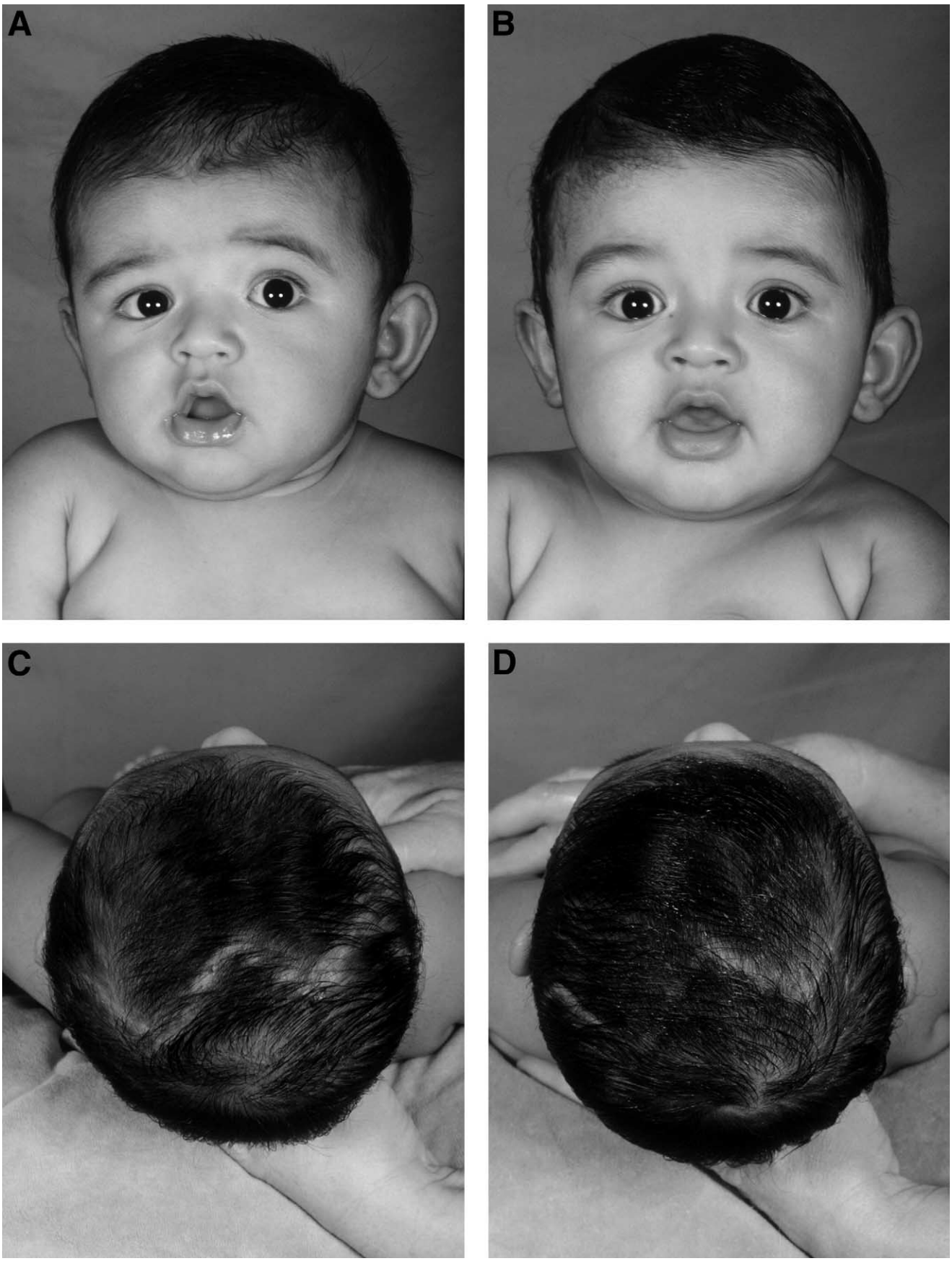

Figure 6 A 4.5-month-old boy after cranial vault remodeling surgery for left coronal synostosis. Front views at (A) entry and (B) after 8 weeks of treatment demonstrate nice correction of facial asymmetry. Vertex views at (C) entry and (D) exit demonstrate correction of left occipital flattening and forehead asymmetry.

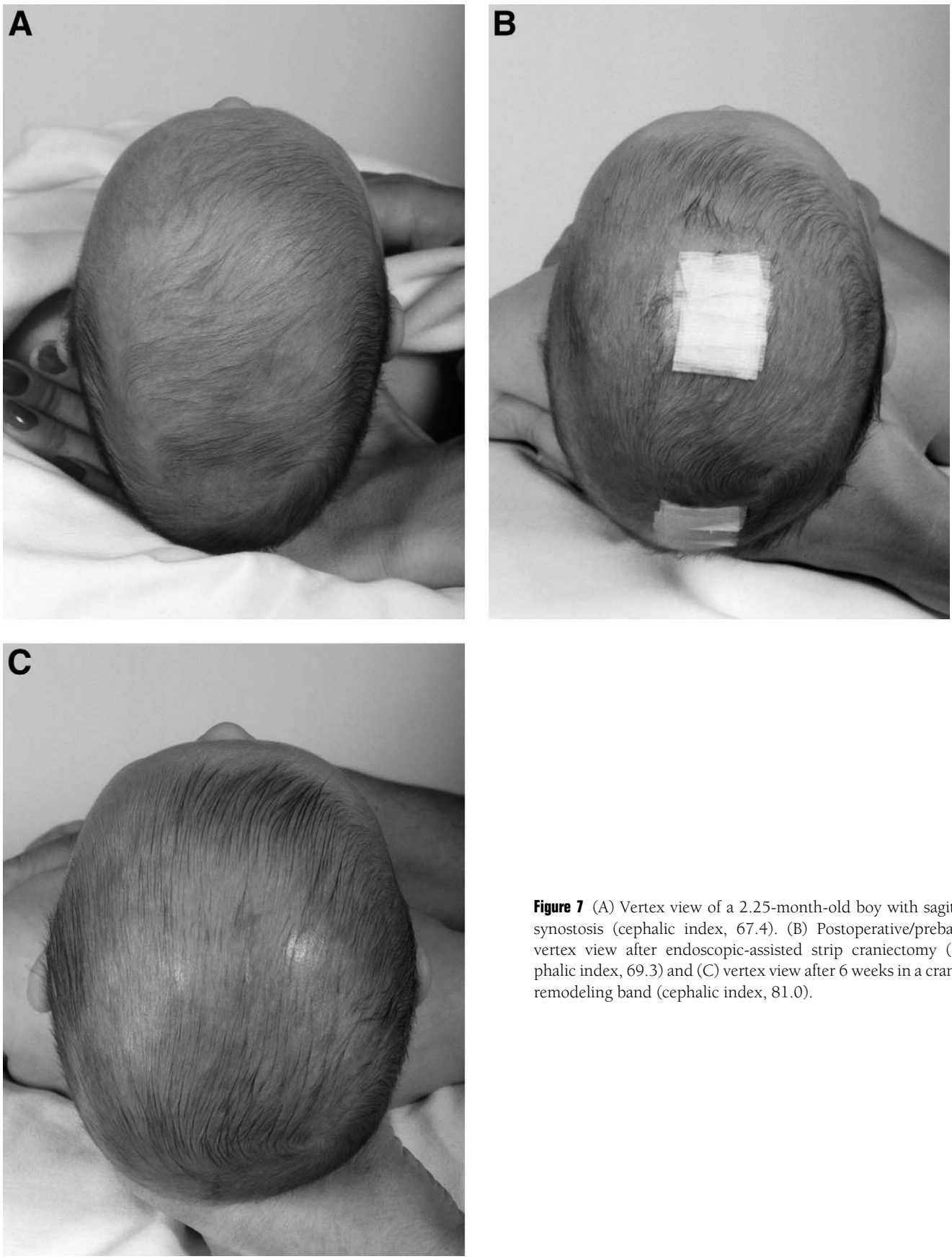

Figure 7 (A) Vertex view of a 2.25-month-old boy with sagittal synostosis (cephalic index, 67.4). (B) Postoperative/preband vertex view after endoscopic-assisted strip craniectomy (cephalic index, 69.3) and (C) vertex view after 6 weeks in a cranial remodeling band (cephalic index, 81.0).

formed to prepare the skull for postoperative remodeling. The cranial remodeling bands encourage the development of a more normal head shape by maintaining cranial length and guiding the remaining growth in the lateral direction.

In 2001, Pomatto and coworkers reported a new treatment protocol and cranial remodeling band designed specifically for use after endoscopic-assisted craniectomy.[36] This device uses a dual-opening design that applies an anteroposterior corrective pressure using medical-grade elastics. A strut over the top of the head maintains height at the sagittal suture. In nine cases, Pomatto and coworkers reported a 16.3% improvement in postoperative cephalic index, from 69.9 to 79.7, as well as improvements in occipital curvature, bitemporal narrowing, and forehead bossing (Fig 7). The mean age at entrance was 3.9 months, and the mean treatment time was 3 months. Longitudinal follow-up to 1 year posttreatment demonstrated that the head had a tendency to return to a more scaphocephalic shape, as was previously reported by Marsh and coworkers,[37] yet head shape still remained significantly improved compared with the postoperative cephalic index. Because of these encouraging results, endoscopic-assisted craniectomy with postoperative banding is now also being used to treat other forms of craniosynostosis, including metopic, unilateral and bilateral coronal, and unilateral lambdoid synostoses.[33-35]

Summary

Cranial remodeling devices have been used to successfully treat deformational plagiocephaly (plagiocephaly, brachycephaly, and dolichocephaly) and as an adjunct to various types of surgery for craniosynostosis. However, it is important to recognize that successful treatment relies not only on the device, but also on the treatment protocols and skill of the medical staff. A product can be excellent, but a deformity can actually be made worse if applied by an individual lacking the necessary training or expertise in fitting and adjusting these devices. Conversely, well-trained medical personnel working with a poorly designed device can also compromise outcomes. To ensure the best possible outcomes, both sides of this equation must be controlled.

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