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The application of the strip-shaped cymba conchae orthosis in the nonsurgical correction of complex auricular deformity

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[ABSTRACT]

Objective: This study aims to evaluate the efficacy and safety of using a strip-shaped cymba conchae orthosis for the nonsurgical correction of complex auricular deformities.
Methods: Clinical data were collected from 2020 to 2021 for 6 patients who underwent correction using a strip-shaped cymba conchae orthosis. The indications, corrective effects, and complications associated with use of the orthosis were analyzed.
Results: There were four indications for treatment: cryptotia with helix adhesion; cryptotia with grade I microtia; cryptotia with excessive helix thickness; and auricular deformity beyond the treatment time window (≥6 months). Excellent corrective effects were observed in all 6 patients. Complications occurred in one patient, who recovered after symptomatic treatment.
Conclusion: The use of a strip-shaped cymba conchae orthosis alone or combined with a U-shaped helix orthosis presents a feasible approach for correcting complex auricular deformities or deformities beyond the treatment time window in pediatric patients.

1. Introduction

Previous studies have demonstrated a high incidence of congenital auricular deformities, with reported rates ranging from 55.2% to 57.5% (Zhao et al., 2017; Byrd et al., 2010). Auricular deformities encompass structural and morphological abnormalities of the external ear. Auricular structural deformity refers to external ear malformation caused by hypoplasia of the auricular skin and cartilage during early embryogenesis, a condition generally termed microtia. Grade I microtia is primarily characterized by hypoplasia affecting the upper third of the external ear, while the scapha, antihelix, and lower crus of the antihelix retain structural clarity (Guo, 2020). Grade I microtia is amenable to nonsurgical correction. Auricular morphological deformity refers to distortion and malformation of the external ear resulting from aberrant development of the auricular muscles or abnormal external forces, in the absence of evidence of cartilaginous deficiency (Byrd et al., 2010). A diverse range of auricular deformities have been reported, including cryptotia, helix adhesion, excessive helix thickness, protruding ears, cup ear deformity, and others (Zhong et al., 2020). Although approximately 31.5% of mild auricular deformities may resolve spontaneously, many patients still require treatment, such as pediatric cases of complex auricular deformity or deformities beyond the therapeutic time window (≥6 months). Auricular molding is an established nonsurgical approach for the correction of auricular deformities (Leonardi et al., 2012; Ullmann et al., 2002). It is primarily utilized to treat auricular morphological deformities and, to a lesser extent, structural deformities.

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Table 1
Clinical data of 6 pediatric patients with auricular deformity.

Sex	Side	Characteristics of auricular deformity	Corrective method	Age at correction	Corrective duration	Corrective effect	Effect at one year follow-up	Complication
M	unilateral	II grade cryptotia and the helix adhesion	use the strip-shaped cymba conchae orthosis alone	10 days	3 weeks	effective	no rebound	no
F	unilateral	II grade cryptotia and the helix adhesion	use the strip-shaped cymba conchae orthosis alone	1 year	2 months	effective	no rebound	no
F	unilateral	III grade cryptotia and the helix adhesion	use the strip-shaped cymba conchae orthosis alone	3.5 years	4 months	effective	no rebound	no
M	unilateral	III grade cryptotia and I grade microtia	use the strip-shaped cymba conchae orthosis alone	2 months	3 months	effective	no rebound	no
M	unilateral	I grade cryptotia and the excessive helix thickness	use the strip-shaped cymba conchae orthosis alone	4 years	3 months	effective	no rebound	no
M	unilateral	II grade cryptotia beyond the treatment time window	use the strip-shaped cymba conchae in combination with the U-shaped helix orthoses	5 years	6.5 months	effective	no rebound	yes, recovered after symptomatic treatment

Currently, the EarWell nonsurgical correction system is the predominant orthotic device used clinically for the treatment of auricular deformities (Van Wijk et al., 2009; Muraoka et al., 1985; Lindford et al., 2007; Yotsuyanagi et al., 1998; Sorribes and Tos, 2002; Doft et al., 2015). The EarWell orthosis consists of a support structure (base frame and outer cover), three helical components, and a conchal piece. It has the advantage of restoring structural integrity for certain auricular deformities and reconstructing a normal concha-mastoid angle. As a solid orthosis with comprehensive functionality, the EarWell represents an effective and novel approach. The strip-shaped cymba conchae orthosis possesses advantages of adjustable length, light weight, and easy moldability into U and L shapes. Therefore, the strip-shaped cymba conchae orthosis can be used alone or in combination for pediatric patients with complex auricular deformities or deformities beyond the treatment window when helical orthosis alone provides unsatisfactory outcomes. Use of this orthosis aims to improve nonsurgical correction and enable individualized treatment approaches.

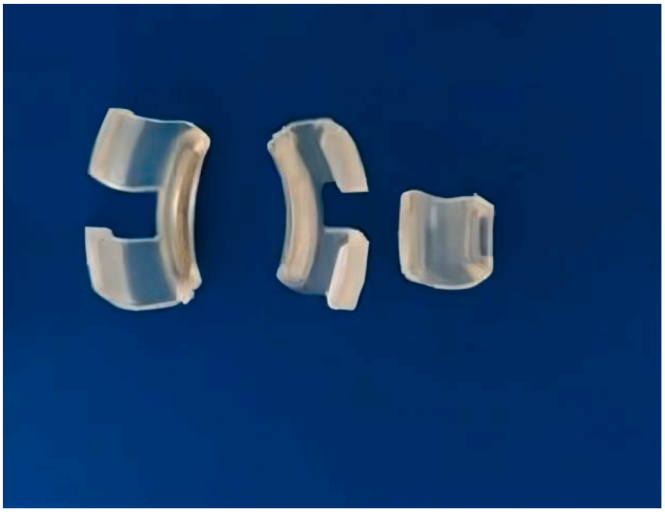

Fig. 1. The U-shaped helix orthosis (large, medium, small, EarWell Correction System).

2. Materials and methods

This study protocol was approved by the Medical Ethics Committee of Henan Provincial People's Hospital (approval no. 2019PHB109-01).

2.1. Inclusion criteria

① Complex auricular deformity is defined as the concurrent presence of at least two types of auricular deformities. ② Or auricular deformity beyond the treatment window is defined as correction at age ≥6 months.

2.2. Clinical data

This retrospective study included 6 pediatric patients with complex auricular deformity or deformity beyond the treatment window who underwent nonsurgical correction at the outpatient clinics of Henan Provincial People's Hospital and Zheng Dong Mihuan Clinic between January 2020 and January 2021. Patients were followed up for one year post-correction. Data collected included sex, side (unilateral/bilateral), characteristics of auricular deformity, corrective method, age at correction, corrective duration, corrective effect, effect at one year follow-up, and complications (Table 1).

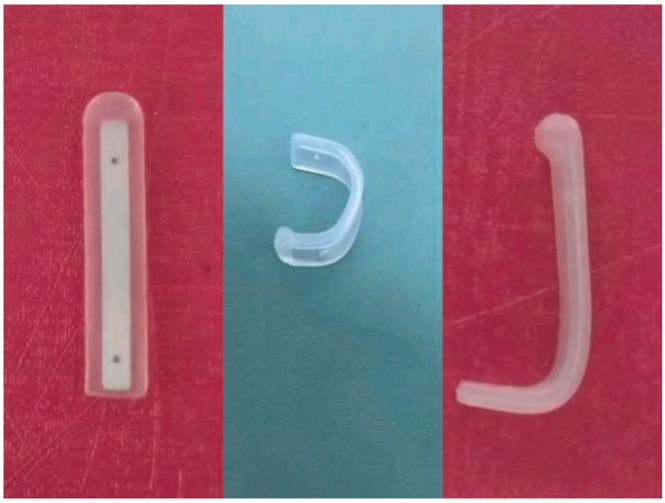

Fig. 2. The strip-shaped cymba conchae orthosis.

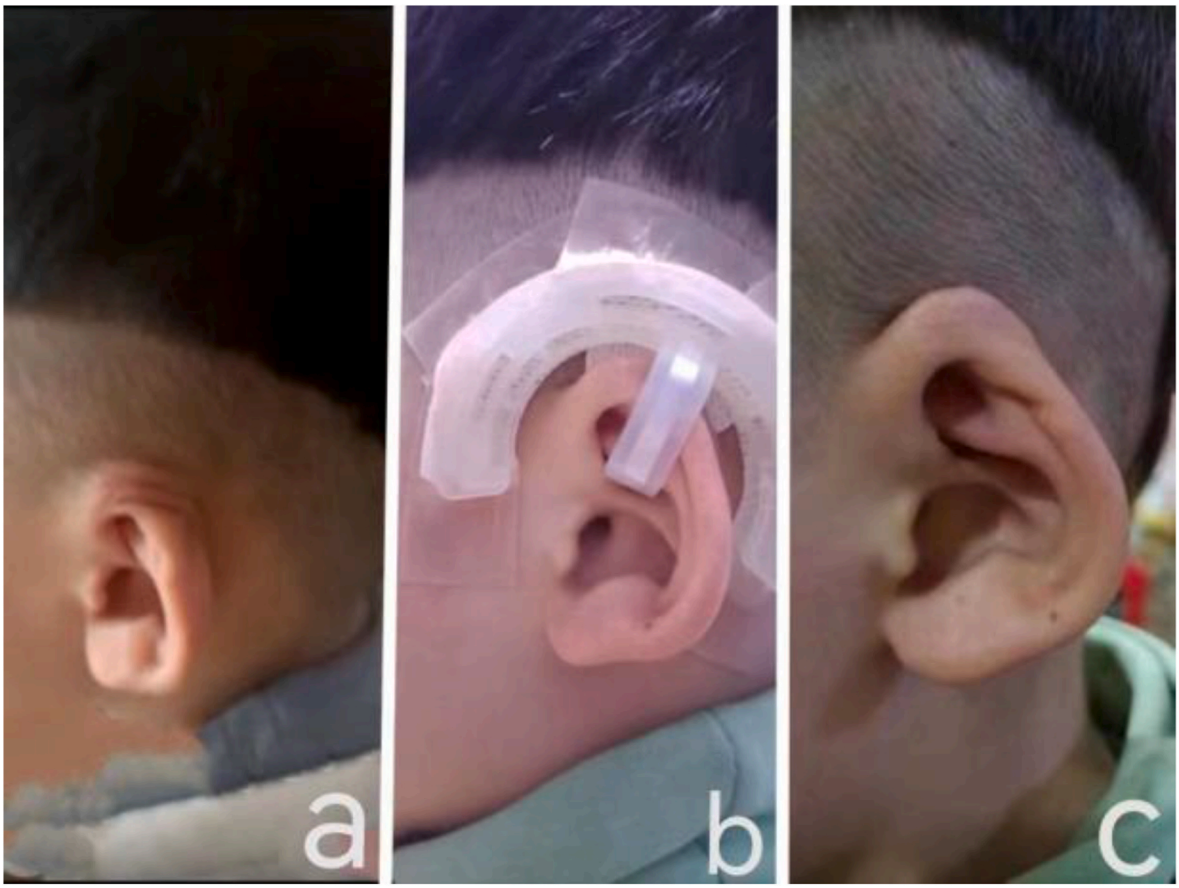

Fig. 3. A female child with cryptotia and the helix adhesion, corrected by using the strip-shaped cymba conchae orthosis alone; (a): Before correction (begin 3.5 years old) (L); (b): In correction (L); (c): After correction (4 months of correction) (L).

2.3. The U-shaped helix orthosis and the strip-shaped cymba conchae orthosis

The EarWell Correction System is fabricated from medical silicone. It includes three sizes of U-shaped helical orthoses - large, medium and small (Fig. 1). One end of the U-shaped orthosis wraps around the helix, while the other end attaches to the base, creating a continuous upward and backward pulling force on the helix (Park, 2009).

The strip-shaped cymba conchae orthoses (Hunan Cihui Medical Technology Co., China) possess the attribute of facile moldability into U and L shapes (Fig. 2). One end of the strip-shaped orthosis encircles the cymba conchae, while the other end affixes to the base, generating a continuous upward and backward pulling force on the cymba conchae.

2.4. Correction methods

The EarWell Correction System was used for nonsurgical correction, which involved three steps: First, hair surrounding the auricle was shaved to facilitate placement of adhesive tape and skin glue. Next, the hidden portion of the auricle was pulled out using mechanical traction. Finally, the orthoses were adhered to the postauricular skin using double-sided adhesive tape.

During the orthosis use, parents should be instructed to examine the skin at the application site daily for any adverse reactions. Care should be taken to avoid risks of skin erythema or erosion potentially caused by prolonged compression. It is also important to maintain dryness and cleanliness of the orthosis application sites.

2.5. Follow-up

Patients were followed up for one year, returning monthly to the hospital in-person or via WeChat video follow-up. Parental participation was maintained throughout the process. Pre- and post-correction photographs were independently assessed by two medical professionals.

2.6. Evaluation criteria of efficacy

① Effective: Auricular shape returns to normal or near-normal form, or improves without achieving normal morphology. ② Ineffective: No improvement in auricular shape. ③ Recurrence: Temporary improvement in auricular shape followed by reversion to original deformed state.

3. Results

3.1. General information

This study included 6 pediatric patients with complex auricular deformity or deformity beyond the treatment window. The age range at correction was 10 days to 5 years, with a mean age of 2.3 years. The correction duration ranged from 3 weeks to 6.5 months (Table 1).

3.2. The indications and contraindications of using the strip-shaped cymba conchae orthosis

There were four indications for using the strip-shaped cymba conchae orthosis: pediatric patients with cryptotia and helix adhesion; cryptotia with grade I microtia; cryptotia with excessive helix thickness;

Fig. 4. A male child with cryptotia and I grade microtia, corrected by using the strip-shaped cymba conchae orthosis alone; (a): Before correction (begin 2 months) (L); (b): In correction (L); (c): After correction (3 months of correction) (L).

and auricular deformity beyond the treatment window (≥6 months).

The strip-shaped cymba conchae orthosis is contraindicated in pediatric patients with cutaneous allergies.

3.3. Corrective effects

All 6 patients achieved successful correction without recurrence. The efficacy rate was 100% (6/6), and the recurrence rate was 0% (0/6). Use of the strip-shaped cymba conchae orthosis demonstrated high efficacy for nonsurgical correction of complex auricular deformities or deformities beyond the treatment window in this pediatric cohort.

3.4. Complications

One patient, corrected at age 5 years, experienced recurrent local skin erythema and mild erosion at the orthosis application site. However, with symptomatic treatment involving orthosis discontinuation and maintenance of dryness and cleanliness of the skin, this patient still attained excellent correction without recurrence at one year follow-up.

4. Discussion

Congenital auricular deformities encompass diverse types, with cryptotia being relatively common. Cryptotia is classified into three grades based on the presence of cartilage adhesion and dyschondroplasia (Zhao et al., 2017): Grade I involves skin deficiency of the auricular upper pole; Grade II has upper pole skin insufficiency with cartilage adhesions; Grade III has upper pole skin deficiency combined with dyschondroplasia. The 2019 Chinese expert consensus on nonsurgical correction of auricular deformities indicates that pediatric patients with cryptotia can still achieve significant treatment effects at 6 months; thus, the therapeutic window for cryptotia can be extended appropriately (Expert, 2019; Daniali et al., 2017). For mild cryptotia, the window for nonsurgical ear molding correction can be prolonged up to 6 years of age (Xu et al., 2023). Given previous findings that correction duration prolongs with increasing age at treatment (Xu et al., 2023), early nonsurgical correction is recommended for pediatric patients with complex auricular deformity or deformity beyond the therapeutic window.

The EarWell system is currently the predominant nonsurgical orthosis utilized clinically for correction of auricular deformities (Van Wijk et al., 2009; Muraoka et al., 1985; Lindford et al., 2007; Yotsuyanagi et al., 1998; Sorribes and Tos, 2002; Doft et al., 2015). The U-shaped helical orthosis alone can meet the needs of nonsurgical correction in some pediatric patients with auricular deformity (Zhao et al., 2017).

The strip-shaped cymba conchae orthosis, with its advantages of adjustable length, light weight, and facile moldability into U and L configurations, can fulfill the needs of individualized nonsurgical correction in some pediatric patients with complex auricular deformities or deformities beyond the therapeutic window. This orthosis can be used alone or in conjunction with the U-shaped helical orthosis when helical orthosis alone provides unsatisfactory outcomes. In this study, we included 6 pediatric patients with complex auricular deformity or deformity beyond the treatment window who underwent correction using the strip-shaped cymba conchae orthosis, either alone or combined with helical orthosis. The indications, treatment effects and complications associated with use of this orthosis were examined.

In this study, three pediatric patients with cryptotia and helix adhesion were treated with the strip-shaped cymba conchae orthosis alone due to very shallow or absent scapha preventing placement of the U-shaped helical orthosis (Fig. 3). All three patients achieved effective

Fig. 5. A male child with cryptotia and the excessive helix thickness, corrected by using the strip-shaped cymba conchae orthosis alone; (a): Before correction (begin 4 years old) (R); (b): In correction (R); (c): After correction (3 months of correction) (R).

correction without recurrence at one year follow-up. One patient with cryptotia and grade I microtia underwent correction using only the strip-shaped cymba conchae orthosis because of absent scapha precluding application of helical orthosis (Fig. 4). Effective correction was attained in this case without recurrence at one year follow-up. One patient with cryptotia and excessive helical thickness was treated with the strip-shaped cymba conchae orthosis alone since the U-shaped helical orthosis slot was too narrow, resulting in skin erosion, and too far from the base for attachment (Fig. 5). Effective correction was achieved without rebound at one year follow-up. One patient with cryptotia beyond the treatment window underwent combined orthosis correction due to high skin and cartilage tension and inadequate force from helical orthosis alone (Fig. 6). The patient developed complications that resolved with symptomatic treatment. Excellent correction was obtained without recurrence at one year follow-up.

There were four indications for using the strip-shaped cymba conchae orthosis: First, in pediatric patients with cryptotia and helix adhesion, the U-shaped helical orthosis tends to slip at the helix. Second, for cryptotia with grade I microtia, characterized by hypoplasia of the auricle upper third (Guo, 2020), the strip-shaped orthosis enables nonsurgical correction. Third, for cryptotia with excessive helical thickness, the U-shaped helical orthosis cannot adequately expose the hidden ear portion. Fourth, for auricular deformity beyond the treatment window (≥6 months), limited space or distance due to auricular growth and development can preclude normal application of the U-shaped helical orthosis.

In this study, all patients achieved excellent correction without recurrence. One patient with auricular deformity beyond the treatment window, corrected at age 5 years, experienced repeated local skin lesions at the orthosis application site resulting in intermittent wear. However, this patient still attained excellent correction without rebound at one year follow-up. Use of the strip-shaped cymba conchae orthosis demonstrated high efficacy and low complication rate for nonsurgical correction of auricular deformity or deformity beyond the therapeutic window in this pediatric cohort.

The strip-shaped cymba conchae orthosis possesses attributes of adjustable length, light weight, and facile moldability into U and L configurations. Therefore, it can be used alone or in conjunction with the U-shaped helical orthosis when helical orthosis alone provides unsatisfactory outcomes. This orthosis demonstrates high efficacy in meeting the needs for individualized nonsurgical correction in pediatric patients with complex auricular deformities or deformities beyond the therapeutic window.

This study had a limited sample size of pediatric patients with complex auricular deformity. Future research should aim to recruit larger numbers of relevant cases to enable more robust evaluation of the long-term efficacy of nonsurgical correction in this population.

5. Conclusion

The strip-shaped cymba conchae orthosis demonstrates excellent corrective efficacy and minimal complications for nonsurgical treatment of pediatric patients with complex auricular deformities or deformities beyond the therapeutic window. Therefore, using the strip-shaped cymba conchae orthosis alone or in conjunction with the U-shaped helical orthosis presents a feasible approach when helical orthosis alone provides unsatisfactory outcomes in this population.

Fig. 6. A male child with cryptotia beyond the time window, corrected by using the strip-shaped cymba conchae in combination with the U-shaped helix orthoses; (a): Before correction (begin 5 years old) (R); (b): In correction (R); (c): After correction (6.5 months of correction) (R).

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Declaration of competing interest

The authors have no conflicts of interest to disclose.

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