Clinical Study on the Treatment of Congenital Auricle Malformation with Ear Mold Corrector

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Abstract: OBJECTIVE To investigation the efficacy of ear molding in the treatment of congenital auricular deformation. METHODS 30 in fants(40 ears)who from the head and neck surgery of October 2020 to June 2021, the head and neck surgery of children's hospital in kunming city was treated was treated were treated with ear molding devices(EarWell Infant Ear Correction System). Doctors and parents were surveyed 1 months after treatment. RESULTS All cases were treated successfully without severe complications. 36 ears(90%) were rated as very satisfied or satisfied by doctors and parents. CONCLUSION Ear molding is a noninvasive treatment, and effectively corrects congenital auricular deformation.

1. Introduction

The ear is one of the important senses of the human body, and its exquisite structure of concave convex gyration forms its important aesthetic basis. Foreign scholars divide neonatal ear malformations into structural malformations and morphological malformations [1]. The structure of the ear is the hypoplasia of ear skin and cartilage caused by abnormal embryonic development. The morphological malformation of the ear is the abnormal appearance of auricle caused by external force on the normal structure, while the development of ear skin and cartilage is normal. For the structural malformation of the ear, the unified clinical treatment standard is that auricle reconstruction and plastic surgery must be performed to correct it [2]. For children with morphological changes of auricle, they can be treated by surgical intervention or earwell ear mold corrector. In this paper, a new and noninvasive method for the treatment of auricle deformity is obtained by observing the curative effect of earwell ear mold corrector on children with auricle deformity.

2. Clinical Data and Methods

Clinical data: the subjects were 32 newborns with unilateral or bilateral congenital external auricle malformation (40 ears in total) who were treated in the Department of Otolaryngology, head and neck of Kunming children's Hospital from October 2020 to June 2021. The children involved in this study were diagnosed by our doctors as having different types of congenital external auricular
malformations, but they should be excluded \[1\] The diagnosis of auricle deformity requires surgical treatment, \(\odot\) Premature birth, \(\odot\) Children older than 3 months, \(\odot\) Children with systemic diseases. There were 23 males and 7 females, with an average age of 52.5 ± 28.4 days.

Treatment process: Clinically, the appropriate type of orthosis is usually selected and worn correctly according to the size and age of children's auricles. Ear well ear mold orthosis consists of four parts: base, outer cover, retractor and ear cavity orthosis (Fig. 1). The base is close to the skin through the bottom adhesive tape, fixed behind the ear and provides support to correct the shape of abnormal earrings, especially the opposite earrings. Retractor and ear cavity orthosis should be placed according to the deformation of children in order to achieve the orthopedic effect. Pay attention not to overlap with the base protrusion to avoid excessive pressure. The retractor is placed on the deformed ear wheel to provide continuous external force, so that the ear wheel can regain the normal bending radian and reshape the boat like fossa. The ear nail cavity orthosis is used to correct the abnormal protrusion of the ear nail cavity. It is installed into the ear nail cavity according to the external auditory meatus and the depth of the ear nail cavity. The outer cover is accurately aligned with the base, and the outer cover provides continuous pressure from the outside for the retractor and the ear nail cavity orthosis, so as to achieve the orthopedic effect. Finally, fix the surface of the outer cover with medical tape (Fig. 2). The treatment time lasts for more than 2 weeks according to the deformity, but it needs to be revisited every week during the wearing period. Adjust the position of the appliance according to the improvement of auricle deformity. After the auricle correction has achieved satisfactory results, continue to wear it for 1 week and then remove it to end the treatment. If the correction effect is not satisfactory and there is no improvement for 3 consecutive weeks, the treatment shall be ended. During wearing, it is necessary to ensure that the orthosis is continuously fixed in the correct position. In case of complications such as skin rupture, the orthosis shall be removed temporarily, reinstalled after the rupture is healed, and the treatment time shall be extended appropriately. Comparison of auricle photos before and after treatment. One month after treatment, the orthopedic effect was evaluated by doctors and parents. The evaluation grade is divided into: very satisfied: the abnormal auricle has been greatly corrected, which is highly consistent with the healthy ear; Satisfaction: the abnormal auricle has been corrected, basically reaching the appearance of normal auricle structure, which is slightly different from the healthy ear; Basically satisfied: the abnormal auricle was partially improved, but failed to return to the normal auricle structure; Ineffective: the correction effect of abnormal auricle is not obvious, or even improved. The complications during the treatment were recorded.
3. Result

32 cases (40 ears) were successfully treated, including 9 ears of wind or cup-shaped ears, 5 ears of vertical ears, 11 ears of constriction, 1 ear of Stahl's ears, 6 ears of concealed ears and 8 ears of compound malformation; The treatment time was 55.8 ± 21.4 days; The morphology of all affected ears was improved to varying degrees (Fig. 3 and 4). One month after operation, doctors and parents jointly evaluated: 20 ears were very satisfied, 16 ears were satisfied, 4 ears were basically satisfied, and 0 ear was ineffective; Very satisfied and satisfied as effective, the total effective rate is
90%. In all 40 ears, the skin was broken and the orthosis was removed. Only one child rebounded after successful correction. However, after re correction, there was no rebound after observation for 2 months.

![Images of ear surgery before and after orthotic wear](image)

**Fig.3 Changes of Auricle after Wearing the Mold for 5 Weeks**

**Fig.4 Changes of Auricle after Wearing the Mold for 4 Weeks**

4. **Conclusion**

The ear is one of the important senses of the human body, and its exquisite structure of concave convex gyration forms its important aesthetic basis. Although its status is not as important as eyes and nose, severe auricle deformity will affect children's appearance and hearing, and even cause psychological problems [3]. It is reported that the incidence of neonatal auricle malformation is 43.36% [4], less than 55.2% of similar reports abroad [5]. The occurrence of congenital auricle malformation is not a single process, but the result of multiple factors [6]. Genetic factors, environmental factors and genetic and environmental factors are important factors leading to auricle deformity. The development period of auricle cartilage scaffold is from 5 to 9 weeks of embryo. The
abnormal development during this period can lead to the defects of auricle cartilage and soft tissue structure, and then lead to the deformity of auricle structure, such as children's deformity; After 9 weeks of embryo, the auricle cartilage and soft tissue structure basically completely appear, but its structure is relatively thin and fragile. When subjected to external force, it is very prone to degeneration, such as improper physical external force compression in utero or postpartum, including birth canal extrusion, fetal position, incorrect sleeping position, etc, can cause deformation of auricle support \[7\]. Among them, the earrings and opposite earrings are the most common abnormal parts. According to Byrd et al. \[1\], neonatal auricle malformations are divided into the following 9 types: windy ear, vertical ear, cup ear, Stahl's ear, ring retracted ear, hidden ear, transverse protruding ear wheel angle, ear wheel malformation and compound malformation. In this experiment, the proportion of compound malformations of draught ear, cup ear and retracted ear is relatively large. The changes of auricle structure can only be corrected through surgical treatment \[2\]. At this stage, the auricle reconstruction mainly includes autologous costal cartilage auricle reconstruction and double-layer fascia covered Medpor ear stent auricle reconstruction, However, the operators of these operations need to meet certain conditions, and will cause certain trauma to children. There are some unpredictable complications after operation. For children with auricle morphological changes, they have 30% self correction ability within two weeks after birth, but for children who cannot self correct, they can be intervened through non-surgical treatment in the early stage. Compared with school-age surgery, early intervention saves cost, reduces the incidence of complications and avoids the pain of invasive treatment \[8\].

Non operative treatment to correct congenital ear malformation was first proposed by Japanese scholars Matsuo et al. \[9\] and kurozumi et al. \[10\] in the 1980s. At this stage, ear mold correction is recommended to start wearing 5-7 days after birth. The wearing time depends on the morning and evening of starting wearing ear mold. Some studies believe that treatment should be carried out as soon as possible after birth. It is generally believed that it can be used within 1 week after birth, which can reduce the shaping period from 6-8 weeks to less than 2 weeks \[11\]. Because maternal estrogen remains in the neonatal blood circulation, estrogen can maintain the high plasticity of neonatal auricle by increasing the concentration of hyaluronic acid in cartilage. Estrogen decreases rapidly 72 hours after birth, so the plasticity of ear will be greatly reduced. Therefore, the ear mold should be worn before the decrease of estrogen, and the treatment can be completed within 1 week \[11\]. After more than 3 weeks of treatment, it is not easy to achieve normal ear morphology and requires a long treatment duration \[12\]. At present, there is no unified standard for the treatment duration of earwell ear mold orthotics. At present, most experts adjust the treatment time according to the orthopedic effect during the follow-up. The age of the children in this experiment is 52.5 ± 28.4 days, and the treatment days are 55.8 ± 21.4 days, which are higher than those reported abroad, and the effective rate of satisfactory and very satisfactory treatment is 90%, which is lower than 96% of doft \[11\]. The reason may be due to the older age of children than abroad. The best treatment time for newborns with hard cartilage is missed. Secondly, considering the reasons, the sample size of this study is small, which may cause some errors.

Auricle deformity needs early intervention. As a non-invasive treatment method, earwell ear mold corrector has a significant effect on the treatment of neonatal auricle deformity. All types of auricle deformity including hidden ear are indications, which is expected to be popularized as the first-line treatment of most neonatal auricle deformity.

References

[2] Zhu Jing jing , Shi Run jie, Jiang Chen yan, et al One stage auricle reconstruction with porous HDPE stent for