Microtia is a rare congenital birth defect in which the outer ear, or auricle, of a baby’s ear is deformed, minimally present or wholly missing. It often affects only one ear and is often accompanied by hearing loss due to abnormalities of the ear canal or middle ear.

Microtia is classified into four grades:

1. **Grade I**: Minimal or no deformity
2. **Grade II**: Partial deformity with some hearing loss
3. **Grade III**: Severe deformity with significant hearing loss
4. **Grade IV**: Complete absence of the ear canal, middle ear, and inner ear

In the U.S. alone, approximately 1,500 babies are born with microtia per year.¹,²,³

**Prevalence**
- Boys are more likely than girls to be affected, by 20-40%⁴,⁵
- Hispanic, Asian, Pacific Islander and Native American populations are 2-3 times more likely to experience microtia as non-Hispanic whites⁴

**Patient Impact**
Microtia is not life-threatening but children may experience damage to their self-image. Aside from the physical effects, microtia can also impact children in the following ways:

- **Teasing, bullying and ridicule from other children**⁶
- **Long-term mental health problems, including poor self-esteem, depression, anxiety, hostility, and aggression**⁷
- **Mood disorders that persist into adulthood, with negative self-esteem and body image**⁷

Given this emotional burden on a developing child, the ideal time to perform a surgical intervention is when the child is under 5 years of age and before elementary school where bullying is likely to occur.
CURRENT STANDARDS OF CARE

There are two primary standards of care for surgical reconstruction of microtia, however these techniques may have limitations. Current methods are difficult to perform and few surgeons have the training and experience to obtain consistently good aesthetic outcomes.

<table>
<thead>
<tr>
<th>RIB CARTILAGE EAR RECONSTRUCTION</th>
<th>ARTIFICIAL IMPLANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>A more than 60-year-old procedure that uses costal (rib) cartilage surgically removed from the patient and fashioned into the shape of an ear.</td>
<td>A more than 30-year-old procedure that uses prefabricated alloplastic, synthetic implant constructed from porous polyethylene (PPE)</td>
</tr>
<tr>
<td>Benefits:</td>
<td>Benefits:</td>
</tr>
<tr>
<td>• The cartilage used to create the ear-shaped implant comes from the patient and avoids body rejection</td>
<td>• Long-lasting ear implant</td>
</tr>
<tr>
<td>• Long-lasting ear implant</td>
<td>• Single, out-patient surgery</td>
</tr>
<tr>
<td></td>
<td>• Patient can be 4-6 years old</td>
</tr>
<tr>
<td>Potential Challenges:</td>
<td>Potential Challenges:</td>
</tr>
<tr>
<td>• Obtaining enough rib cartilage to create an artificial ear requires “harvesting” of a substantial amount of cartilage from at least three ribs</td>
<td>• Most successful procedure requires the use of a large skin flap taken from the scalp which requires significant surgical skill and may produce alopecia</td>
</tr>
<tr>
<td>• At least two separate hours-long procedures</td>
<td>• The stiff, non-biologic implant early on can lead to infection, hematoma, implant exposure, pain and stiffness</td>
</tr>
<tr>
<td>• May result in chest deformity</td>
<td>• At later timepoints, implant fracture, pigment changes and implant position changes may be seen</td>
</tr>
<tr>
<td>• Patient generally must be at least 10 years old</td>
<td>• Current implants are rigid, do not feel like human ears, and can cause discomfort during sleep or underneath a helmet</td>
</tr>
<tr>
<td>• Current implants are rigid, do not feel like human ears, and can cause discomfort during sleep or underneath a helmet</td>
<td>• Alloplastic implants can shatter if the child suffers a head impact and can become exposed if the skin covering splits</td>
</tr>
</tbody>
</table>

HOPE ON THE HORIZON

Striking innovations in reconstructive surgery may offer a new and better option for those born with microtia. Biotechnology is evolving towards 3D-bioprinting for customized implants grown from living cells.

3DBio Therapeutics is pioneering an end-to-end surgical solution using the patient's own cells and integrated biotech manufacturing system. Its first-of-a-kind investigational ear implant, AuriNovo™, received orphan drug and rare pediatric disease designations from the US Food and Drug Administration (FDA) for treatment of microtia. The FDA has accepted the Company's investigational new drug (IND) application and allowed a Phase 1/2a clinical trial to evaluate the safety and preliminary efficacy of using AuriNovo™. AuriNovo™ has not received FDA approval. The implant is made of the patient’s own ear cells and is designed to look and feel like the natural ear. It is expected that this reconstructive procedure will be able to be completed in one operation through an out-patient procedure, a major benefit to patients.

For further information on 3DBio Therapeutics and AuriNovo™, please visit 3DBioCorp.com.