AUDIOLOGYONLINE & oticon MEDICAL

INNOVATIONS IN
MICROTIA ATRESIA TREATMENT

Sheryl Lewin, MD

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MICROTIA ATRESIA TREATMENT

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SURGERY

ARCHITECTURE

TO EARS

CREATE

CREATIVITY

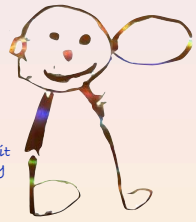
MEDICINE

LEWIN EAR
RECONSTRUCTION

MICROTIA

MICROTIA

- Microtia means “little ear”



Self-portrait
by Manny
Age 4

MICROTIA

- Microtia means “little ear”
- 1 in 6,000 to 12,000 babies

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- boys > girls

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- right > left

MICROTIA

- Microtia means “little ear”
- 1 in 6,000 to 12,000 babies
- boys > girls
- right > left
- Bilateral microtia:7-22%

MICROTIA

Syndromic/other anomalies are seen in 20-60%

Oculo-Auriculo-Vertebral Syndrome (OAVS)

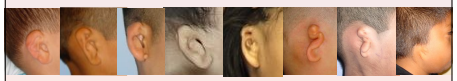
Treacher Collins

MICROTIA

Higher Prevalence in

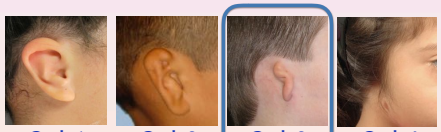
- Asians
- Hispanics
- Native Americans

Microtia occurs as a spectrum



partial ear — no ear

Grades of Microtia*



Grade 1	Grade 2	Grade 3	Grade 4
Small but almost normal	Some recognizable anatomy	Small rudiment of soft tissue	No external ear and no ear canal

*Marx Classification (1926)

Cause of Microtia

Genetic vs. Environment

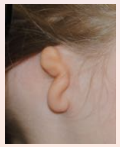
Cause of Microtia

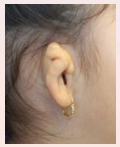
NOTHING A MOTHER DID DURING PREGNANCY CAUSED THE BABY'S MICROTIA

AURAL ATRESIA

AURAL ATRESIA

Failure of the ear canal to open


Complete Atresia


Aural Stenosis

AURAL ATRESIA

- 1 in 10,000 to 20,000 babies
- 70% unilateral, 30% bilateral
- boys > girls
- right > left

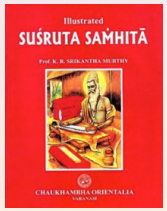
Treatment Options for Atresia

- Bone Anchored Hearing Systems
- Middle Ear Implants
- Atresia Repair

The Evolution of Ear Reconstruction

Creating an ear is widely accepted as one of the most challenging operations performed in all of plastic surgery

6th Century BCE



Susruta Samhita
First description of ear surgery.
A cheek flap was suggested for repairing the earlobe.

16th Century

Tagliacozzi
Used tissue from behind the ear to repair traumatic ear deformities

1920

Sir Harold Gillies
"Father of Plastic Surgery"
Microtia reconstructions
using cadaver rib cartilage and
maternal rib cartilage (resorbed)

1959

Dr. Radford Tanzer
Father of Cartilage Ear Surgery
Used the patients own rib cartilage.
Excellent results with a 6 stage technique - the basis of today's cartilage ear reconstructions

1966

Dr. Thomas Cronin
Ear reconstructions using a silicone framework.
Initial results were good.
Plagued by infection and extrusion.

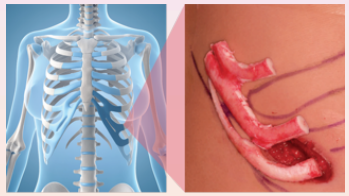
1970's to present

Rib Cartilage technique is the GOLD STANDARD

Same basic procedure,
but condensed into fewer stages

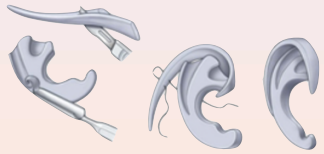
Attempts to minimize the negatives
(scars, pain, poor outcome)

Rib Cartilage Ear Reconstruction



3 ribs are removed from the chest
Standard of care for > 60 years
Safe and durable

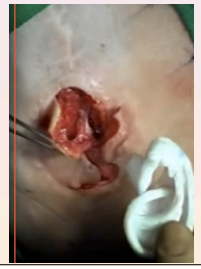
Rib Cartilage Ear Reconstruction



Rib Cartilage Ear Reconstruction

- **Inpatient** hospitalization
- **Multiple surgeries** (up to 4)
- The rib removal is **painful**
- **Surgery must be delayed** until the child is old enough to have enough rib cartilage to form an adult size ear (10 years)
- Requires a lot of experience to get consistent results

Rib Cartilage Ear Reconstruction



* Photo courtesy of
Dr. Leila Kasrai

Rib Cartilage Ear Reconstruction

After suction is placed, The skin pocket tightens and the form of the ear framework is seen

* Photo courtesy of **Dr. Leila Kasrai**

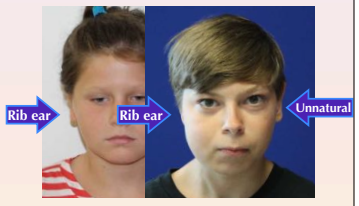
Rib Cartilage Ear Reconstruction

Dr. Brent | Dr. Nagata | Dr. Firmin | Dr. Park | Natural Ear

Rib Cartilage Ear Reconstruction

Dr. Brent | Dr. Nagata | Dr. Firmin | Dr. Park | Natural Ear

Rib Cartilage Ear Reconstruction



Poor Projection Often have to pin back the normal ear

Rib Cartilage Ear Reconstruction

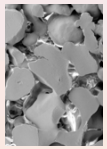
My Conclusion

The Rib Cartilage technique **cannot** achieve the delicacy and 3-dimensional complexity of a natural ear.

Porous Implant Ear Reconstruction (PIER)

Implant-Based Technology

High Density Porous Polyethylene



- First developed 1970's
- First used clinically in the 1980's
- Light weight (50% air due to "pores")
- Least reactive material (FDA)

Implant-Based Technology

High Density Porous Polyethylene

More than 400,000 Surgeries over 35+ years

1982

1st porous polyethylene ear surgery performed by Dr. Berghaus in Germany

* Photos courtesy of Dr. Alexander Berghaus

1996

Medpor Implant

2 piece porous polyethylene implant

Today's Medpor implant is nearly identical

The two pieces are melted together with heat

Porous Ear Implant

PORES = TISSUE INTEGRATION

designed to allow the body's tissue to grow into the implant

- Can be very thin, yet still strong
- Biocompatible
- 2015: Su-Por
- Not flexible
- **Must be covered 100% with the body's own tissues**

How is PIER surgery performed?

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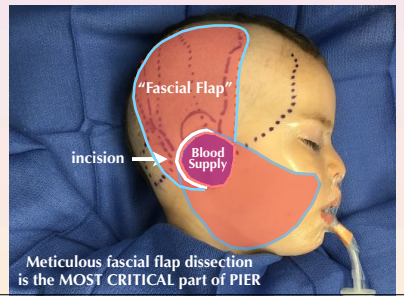
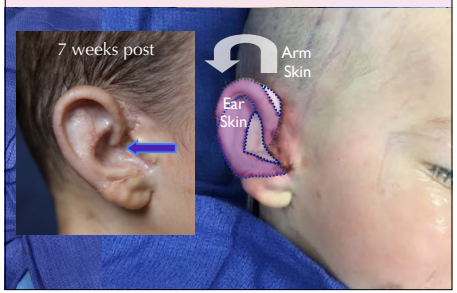


How is PIER surgery performed?



PIER vs. Rib Cartilage

Outpatient

Inpatient

PIER vs. Rib Cartilage

Outpatient

Inpatient

One stage

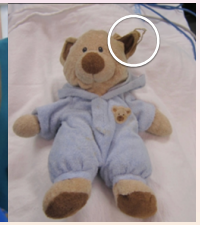
Multiple stages

PIER	vs.	Rib Cartilage
Outpatient		Inpatient
One stage		Multiple stages
Minimal pain		Rib dissection is painful

PIER	vs.	Rib Cartilage
Outpatient		Inpatient
One stage		Multiple stages
Minimal pain		Rib dissection is painful
Can be done early (4 yrs)		**Must be delayed (7-10 yrs)**

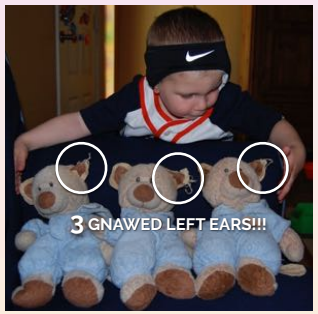
Trey (3 yrs)

Trey (3 yrs)

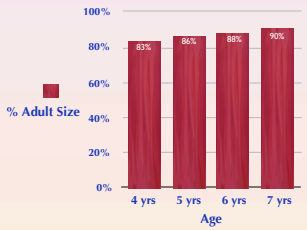


Bunny Bear

Coincidence, right?



Ear growth from 4 to 7 years old



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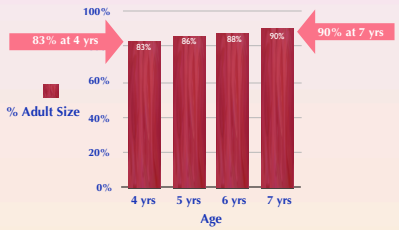


Advantages of early surgery

- Less anxiety
- Experience less pain
- Earlier increase in confidence and self esteem
- Less memory of the process
- Less exposure to teasing & bullying
- Completed ear(s) before kindergarten

Post-op Result

Before | After

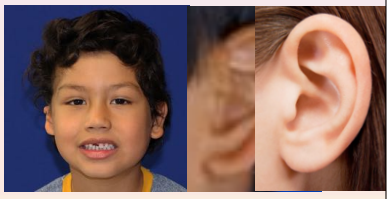
Before | After

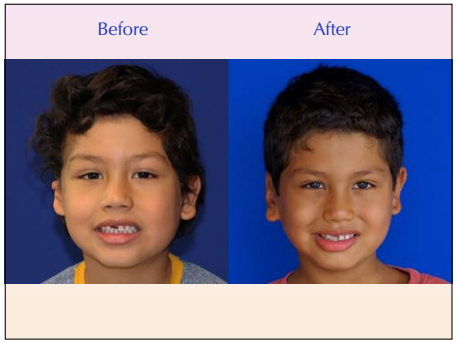
Before After

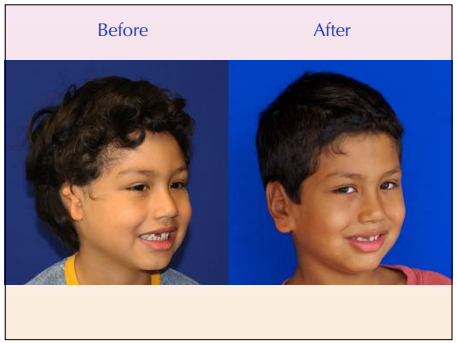
After

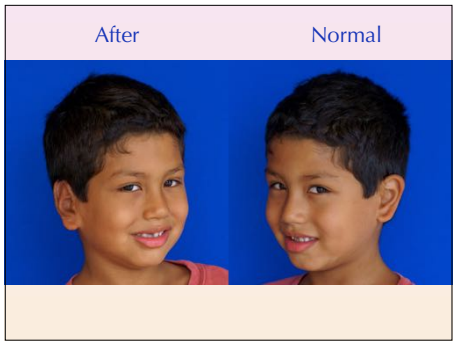
Just like eyes and noses,
everyone's ears are unique

Before



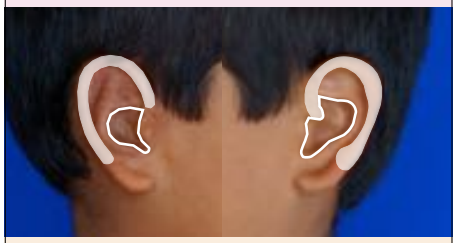

Before
After


Before
After


After
Normal


After
Normal

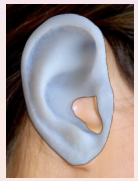
After Normal



Since everyone's ears are unique, wouldn't it be ideal to make an ear by replicating a patient's natural ear?

2018

3D Lewin Ear Implant

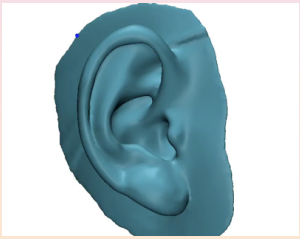


Rib Cartilage Ear Reconstruction

Porous Implant Ear Reconstruction (PIER)

3D Lewin Ear Implant

3D Lewin Ear Implant



3D Lewin Ear Implant

Creates a “perfect” match to a patient’s natural ear from every angle.

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Creates a “perfect” match to a patient’s natural ear from every angle.

3D Lewin Ear Implant

The results with the 3D Lewin Ear are so much better
I no longer use the old technique

3D Lewin Ear Implants

- Manufactured by Su-Por

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- First surgeon to offer a 3D ear implant

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- Bilateral patients…still get a 3D ear implant

3D Lewin Ear Implants

- Manufactured by Su-Por
- First surgeon to offer a 3D ear implant
- 1-piece implant, much stronger and more stable
- Creates a “perfect” match
- Bilateral patients…still get a 3D ear implant

- Over 70 3D implants in the past year

3D Printing vs. 3D scanning

3D Scanning is the process of visually capturing a 3 dimensional object

3D Printing the action or process of making a physical object from a three-dimensional digital model, typically by laying down many thin layers of a material

3D vs Medpor

2 piece implants can fracture

Medpor

3D vs Medpor

This was a critical problem to solve, because a fractured implant **REQUIRES SURGERY** to remove and replace the implant

Before Surgery

A 3D scan of the **natural LEFT ear** is used to make...

...a 3D printed model of an adult-sized **RIGHT ear**

3D Lewin Ear Implant

Before

After

3.5 months post-op

3D Lewin Ear Implant

Before After

3.5 months post-op

3D Lewin Ear Implant

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3D Lewin Ear Implant

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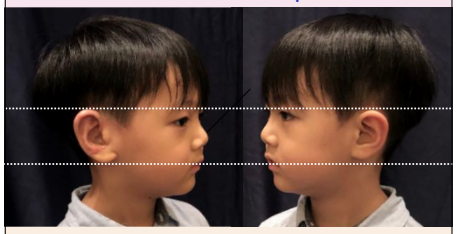
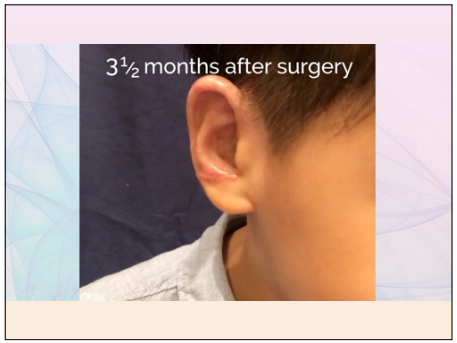
3D Lewin Ear Implant



3.5 months post-op



3D Lewin Ear Implant

Before After

3D Lewin Ear Implant

Before After

Grade 3 Microtia

3D Lewin Ear Implant

Before After

Grade 3 Microtia

3D Lewin Ear Implant

3D Lewin Ear Implant

Before After

3D Lewin Ear Implant

Before After

3D Lewin Ear Implant

Before After

3D Lewin Ear Implant

Grade 3 Microtia

Risks of PIER

- Fracture
- Exposure
- Infection
- Nerve injury to eyebrow
- Failure of PIER

Fracture

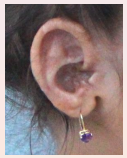
Fracture

With the **3D Lewin Ear Implants**, there is essentially **no risk of fracture**.

Exposure

Implant exposed

Surgery



After healing

In the past, an exposure has always required surgery.

New breakthrough!!

IMPLANT INFECTION

Infection can usually be treated with antibiotics only

10 days after surgery

After 1 week of medicine

10 months later

COMPLICATIONS: Porous Implant Ear Reconstruction

395 consecutive* patients from Jan 1, 2013 to Dec 31, 2018
*All patients with previous ear surgery were excluded

Dr. Sheryl Lewin Complication Rates in the past 6 years

Complication	ALL PIER	Lewin
Exposure (Hole)	7.8%	4%
Fracture	2.9%	0%
Infection	2%	2%
Bleeding	1%	2%
Nerve Injury	1%	0%
Vascular Injury	0	0%

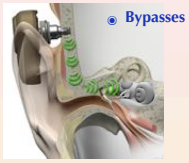
AURAL ATRESIA

Bone Anchored Hearing System (BAHS / BAHA)

- Converts sound into vibrations creating a DRIVING FORCE

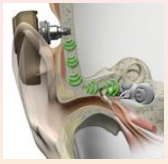
Processor → implant → bone → cochlea

- **Bypasses** the canal and middle ear



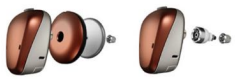
Bone Anchored Hearing System (BAHS / BAHA)

- Excellent sound conduction
- Allows for better sound localization



Bone Anchored Hearing System (BAHS / BAHA)

Cochlear Baha 5



Attract Connect

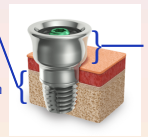
Oticon Medical

Ponto 3 Super Power Ponto 4

Bone Anchored Hearing System

Single Stage

- Adequate bone thickness. (5 yrs)



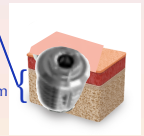
≥ 3mm

Increase abutment size as child grows

Bone Anchored Hearing System

Two Stage

- bone too thin or too soft

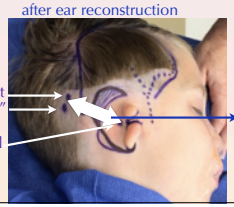


< 3mm

- Leave covered for 3-6 months
- Add abutment under local anesthesia

Bone Anchored Hearing System (BAHS / BAHA)

- Positioning is critical!
- Do BAHS at the same time or after ear reconstruction



Implant placement "sleeper"

Location of canal

50-55mm

Bone Anchored Hearing System (BAHS / BAHA)

- Positioning is critical!
- Do BAHS at the same time or after ear reconstruction

Implant & Sleeper placed under scalp without any scar

Bone Anchored Hearing System Risks

- Bleeding
- Infection
- Healing issues
- CSF leak
- Poor osseointegration

Atresia Repair Surgery

Atresia Repair Surgery

*Only 50% of children with atresia are considered "good" candidates for surgery

Atresia Repair is UNPREDICTABLE

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- Even with the best surgeon in the world, hearing improvement cannot be predicted

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- I have had 2 patients in the past year who have LOST THEIR EAR IMPLANT from complications of the canal

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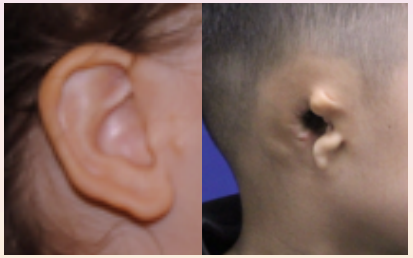
- Long term data hasn't proven the hearing gains will last
- Life-long care is required to clean the canal
- Most of the world has abandoned this surgery
- I have had 2 patients in the past year who have LOST THEIR EAR IMPLANT from complications of the canal
- I have had several patients have to get their canals closed

Normal Ear Atresia Repair



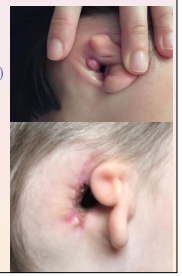
Atresia Repair Surgery

Normal Ear | Lewin Ear Implant

Atresia Repair Surgery

Risks of Atresia Repair

- Infection
- Eardrum separation
- Closing of the canal (stenosis)
- Hearing nerve injury
- Facial nerve injury
- **Hearing loss over time**
- Bone exposure
- Keloid
- Failure (requires reversing the surgery)



Atresia Options: RISK vs REWARD

ATRESIA REPAIR =

HIGH RISK / UNPREDICTABLE REWARD

UPSIDE: Doesn't require a visible device
Particularly significant in bilateral patients

DOWNSIDE: Hearing gain may be minimal or temporary
May still require BAHS/BAHA
Poor aesthetic appearance

Atresia Options: RISK vs REWARD

Bone Anchored Hearing System

LOW RISK / HIGH REWARD

UPSIDE: "Normal" hearing
Minor surgery (minimal risks)
Processors getting smaller

DOWNSIDE: Visible device
Infections

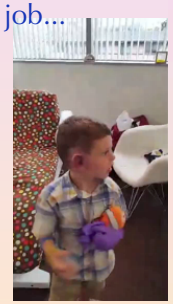
A 3D Hearing Ear in One Surgery …with no scars!

A 3D Hearing Ear in One Surgery …with no scars!

LAMAC
Los Angeles Microtia Atresia conference
2020
August 1-2, 2020

Why I love my job...

First Look...




THANK
YOU