


Contemporary Review

Earfold: A New Technique for Correction of the Shape of the Antihelix

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An absent or poorly defined antihelix often plays a central role in the perception of the prominent ear. A wide variety of otoplasty techniques have been described over the last 50 years that aim to reshape, create, or enhance the definition of the antihelix, which can, in turn, help to reduce the prominence of an ear. In addition to conventional suture and cartilage-scoring techniques, a permanent implantable clip system (Earfold[®]) has recently become available that is placed using a minimally invasive approach performed under local anesthesia. In this review, we summarize conventional otoplasty techniques to correct the antihelix and compare these with the Earfold implantable clip system.

Key Words: Prominent ear, otoplasty, external ear cartilage, surgery, plastic.

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INTRODUCTION

Prominent ears are a common developmental anomaly affecting 5% to 10% of the population worldwide.^{1–3} In clinical practice, the presence or absence of prominence is largely a matter of subjective perception. However, to facilitate quantitative assessment for research purposes, ear prominence has previously been defined as a helical–mastoid distance of 20 mm or more.⁴

Regardless of the specific definition of prominence, there is a consensus that ears may be perceived as prominent if the antihelical fold is poorly developed, if the concha is hypertrophied, or the conchoscaphal angle is increased (Fig. 1). Although most patients exhibit one or more of these features to some degree,^{4,5} unfolding of the antihelix contributes to the prominence in

approximately 70% of cases.⁶ Therefore, interventions aimed at reshaping the antihelix are beneficial in the majority of cases of prominent ear. This review provides a broad overview of conventional otoplasty techniques for shaping the antihelix and their safety profiles. A more focused discussion of the Earfold[®] implantable clip system is also included, together with a description of its effectiveness and safety.

TREATMENT OVERVIEW

Selection of the appropriate technique for correction of prominence depends on many factors. These include the specific wishes of the patient, previous surgical intervention, the specific shape of the pinna, the patient's age, the elasticity of the patient's cartilage (i.e., soft, moderate, or firm), and the surgeon's personal experience and expertise. Each of these factors must be considered before selecting a particular technique. Patient requirements are best considered by placing the patient in front of a mirror and asking them how they wish to look after the correction is performed. Differences in the symmetry of the ears and details such as prominence of the earlobes should also be noted at this stage. Previous surgical correction of the pinna may limit the options for remedial surgery, depending on whether there is residual prominence, asymmetry, or iatrogenic deformity, as well as the presence and type of complications from any prior procedure.

The age at which treatment is performed is important. It has been shown that early treatment has a positive impact on psychological well-being and development.^{1,7} Moreover, in the first few weeks of life (up to 6 months), nonsurgical molding or splinting techniques can be effective, while the cartilage remains pliable.^{8,9} However, after 6 months (and certainly after 5 years), the auricular cartilage becomes increasingly rigid and more resistant to

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N.V.K. is the inventor of the Earfold[®] implant used for this investigation. He was formerly the chairman and chief technical officer for the company (Northwood Medical Innovations [NMI] Ltd.) that supplied the Earfold implant. NMI Ltd. has now been acquired by Allergan plc, Dublin, Ireland. M.S. is an employee of Allergan plc and owns stock in that company.

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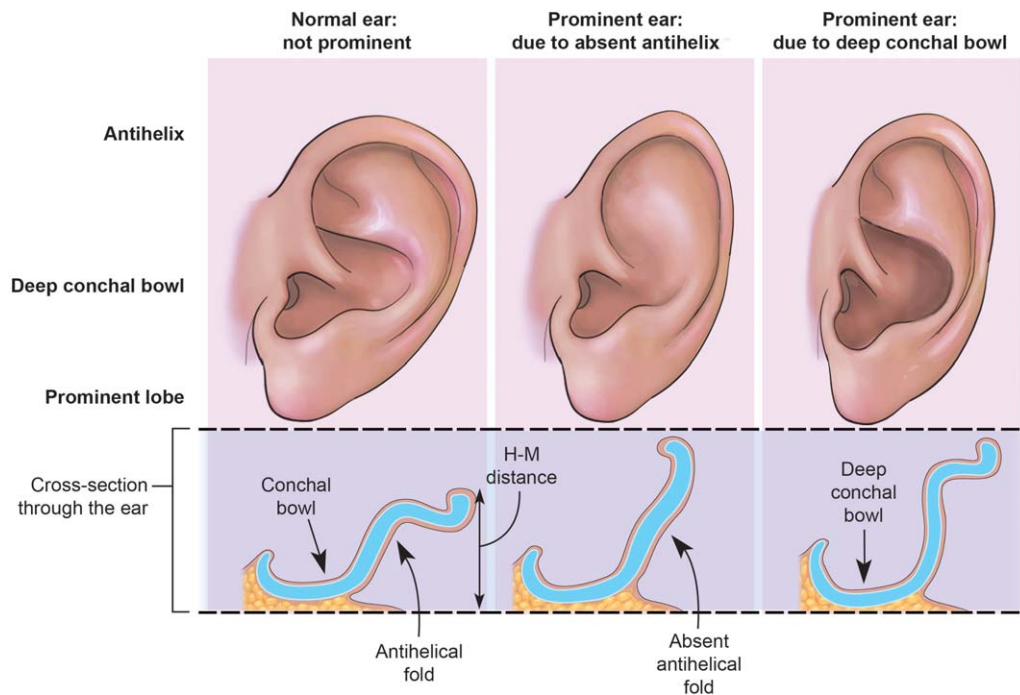


Fig. 1. Causes of prominent ears. The thick blue line indicates the profile of the cartilage seen in cross-section through the middle third of the ear. H-M = helical-mastoid.

molding. For patients more than 6 months of age, for whom cartilage molding is no longer an option, surgical intervention after the age of 5 or 6 years becomes increasingly likely. Some techniques are better or worse than

others or have more or less applicability in pediatric versus adult patients due to age-related differences in cartilage quality. The advantages of any particular surgical intervention must then be weighed against the risks associated

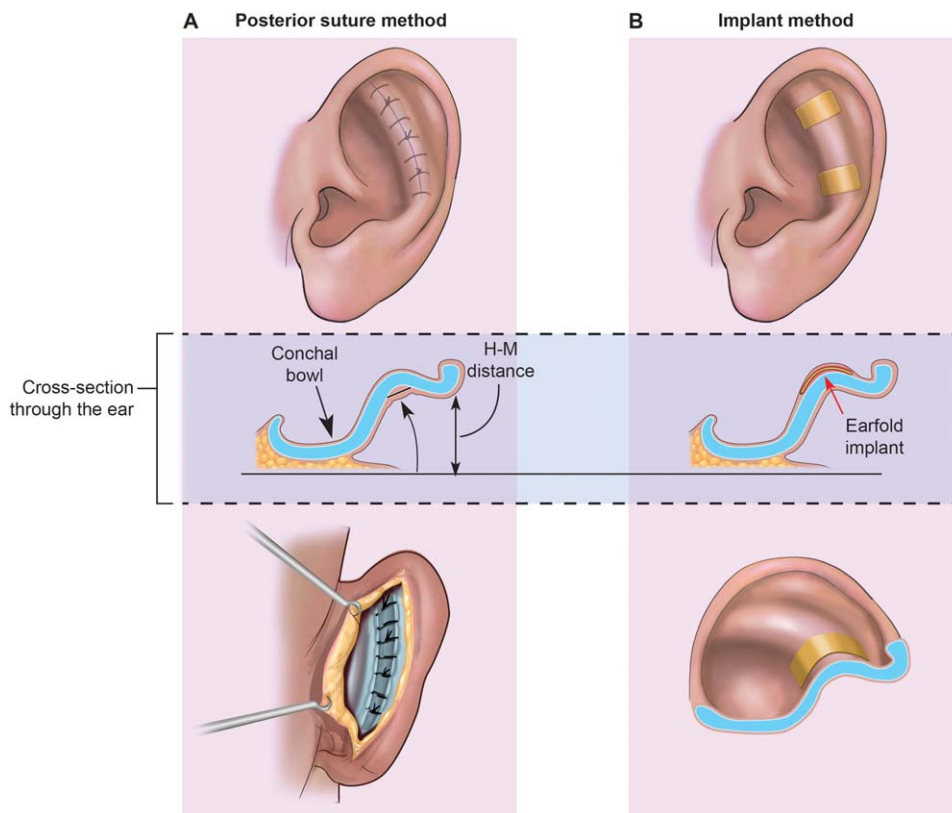


Fig. 2. Cartilage-sparing methods to create an antihelical fold and reduce ear prominence. The posterior suture method (A) places permanent sutures between the upper scapha and fossa triangularis and between the lower scapha and the concha. With the Earfold[®] system (B), a permanent nitinol implant is fixed to the cartilage in the region of the planned antihelix, causing the ear to fold back. The black curved arrow in the center-left illustration indicates the posterior sutures behind the antihelical fold. H-M = helical-mastoid.

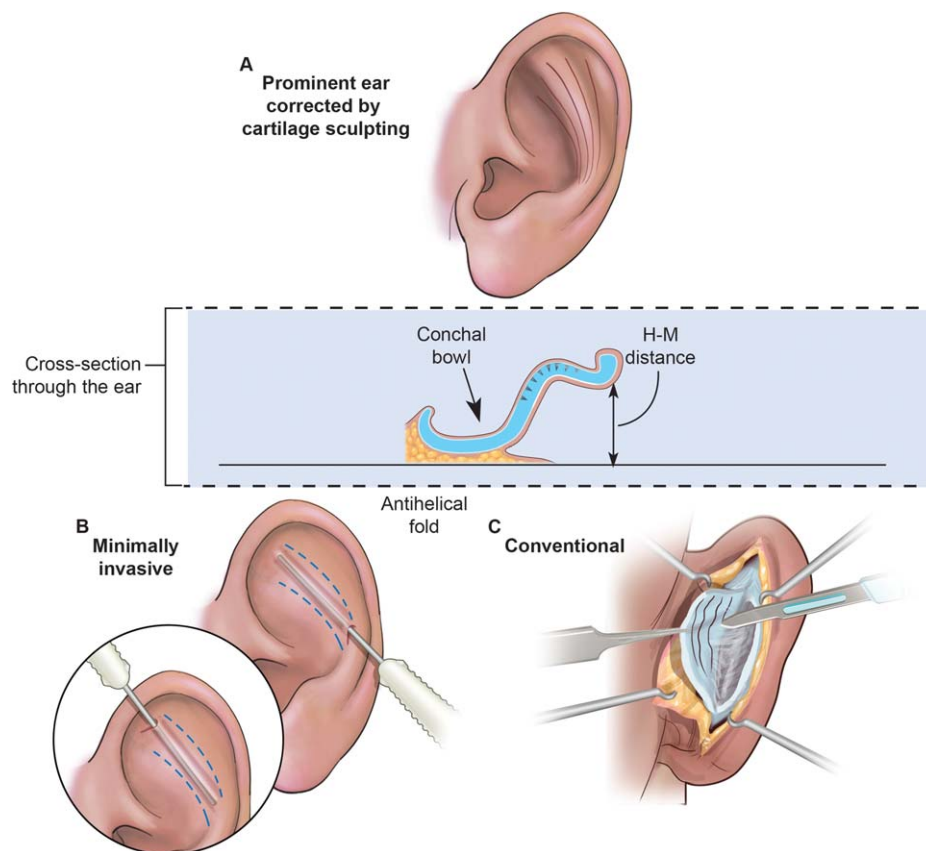


Fig. 3. Cartilage-cutting and sculpting methods to create an antihelical fold and reduce ear prominence. (A) The desired outcome is shown. (B) This can be achieved with minimally invasive approaches (inferior or [inset] superior) involving the insertion of a rasp, bent needle, or ophthalmic knife into the anterior, subcutaneous aspect of the pinna, and abrading or cutting the cartilage in the area of the planned antihelix. This causes the cartilage to bend or curl to the opposite side. (C) The conventional approach to the anterior surface of the cartilage involves a postauricular approach through the cartilage, which is dissected away from the anterior skin and then scored. H-M = helical-mastoid.

with the relative complexity and invasiveness of the surgical technique(s) employed.

TECHNIQUES TO RESHAPE THE ANTIHELIX

Over the past 5 decades, many surgical techniques have been described for treatment of the antihelix.^{1,10} No single technique has emerged as the gold standard, and all have potential advantages and drawbacks. However, all of the techniques described aim to create an aesthetically pleasing, gently curved, antihelical fold. By doing so, they may simultaneously reduce prominence of the ear.

The techniques that have been described can be grouped into those that are cartilage sparing (Fig. 2), those that involve cutting and/or sculpting of the cartilage (Fig. 3), and those that involve a combination of these approaches.^{1,10} Recently, a first-in-class implantable device, Earfold[®], has been added to the list of cartilage-sparing methods available to assist with reshaping the antihelix (Fig. 2).

Conventional Otoplasty Techniques

Conventional cartilage-sparing otoplasty for correction of prominent ears is achieved through the use of horizontal mattress sutures placed posteriorly, to create or enhance the antihelical fold. The best known suture-based technique was first described by Mustarde¹¹ (later modified by Spira¹²), and involves posterior placement of sutures using a nonabsorbable material. The method has

been modified and refined, and the medical literature now describes a wide range of suture techniques to correct prominence of the ear.

From a surgeon's perspective, using posterior sutures to create or enhance the shape of the antihelix has many advantages. It is easy to understand, infinitely adjustable, and suitable for correction of ear prominence for most patients. However, it is generally acknowledged that there are challenges with suture-based techniques. These include difficulties with accurate placement of sutures and the need for more extensive dissection, which can then lead to problems with hematomas or infection (Table I).^{5,10,13-31} The most common complications are recurrence of prominence or problems with asymmetry, both of which may result in a need for reoperation.

Cartilage-cutting/sculpting techniques can also be used to reshape the antihelix. The key observations that underpin all anterior approaches to reshaping of the antihelix were made by Gibson and Davis.³² They noticed that when cartilage is incised on one side it has the tendency to warp to the opposite side. The original observations of Gibson and Davis have since given rise to a large number of modifications, all involving scoring, scratching, scraping, filing, rasping, abrading, or in some way damaging the anterior surface of the cartilage (Table I).³³⁻³⁶ Other, more complex techniques are more akin to cartilage sculpting.^{37,38} As with posterior suture techniques, the most common complications reported are recurrences of the original prominence and the need for

TABLE I.
Complication Rates of Surgical Techniques for Prominent Ears.*

Author and Year	Technique Used	No. of Patients in Study	Hematoma and/or Bleeding (%)	Infection (%)	Skin Necrosis or Skin Problem (%)	Suture or Implant Extrusion (%)	Keloid and Hypertrophic Scars (%)	Recurrence of Prominence (%)	Overall Complication Rate (%)	Reoperation (%) [†]
Tan 1986 ¹³	Posterior suture	45	33.0	15.6	0	15.6	0.0	9.0	N/A [†]	24.0
Adamson et al. 1991 ¹⁴	Posterior suture	119 [‡]	0.8	0	0	9.2	1.6	5.9	17.5	6.6
Messner and Crysdale 1996 ¹⁵	Posterior suture	58	0	1.7	1.7	8.6	1.7	N/A	13.7	3.4
Mandal et al. 2006 ¹⁶	Posterior suture	94	5.3	1.1	4.3	3.2	2.1	8.0	24.0	6.0
Olivier et al. 2009 ¹⁷	Posterior suture	104	1.0	0	0	4.8	3.8	7.7	17.3	2.9
Kang and Kerstein 2016 ¹⁸	Earfold [®]	39	0	5.1	0	12.8	5.1	0	20.5	15.3
Kang et al. 2018 ³¹	Earfold	403	0	1.7	0	3.7	0	0	5.4	4.2
Tan 1986 ¹³	Anterior scoring	101	8.0	0	0	0	2.0	5.0	15.0	9.9
Calder and Naasan 1994 ¹⁹	Anterior scoring	562	2.0	5.2	1.4	0	2.1	8.0	18.7	8.0
Jeffery 1999 ²⁰	Anterior scoring [§]	122	3.3	3.3	1.6	0	0.8	12.3	21.3	3.3
Mandal et al. 2006 ¹⁶	Anterior scoring	68	1.5	1.5	3.6	0.0	1.4	11.0	19.0	8.8
Bhatti and Donovan 2007 ²¹	Anterior scoring	34	5.9	2.9	2.9	0	0	2.9	14.7	0
Horlock et al. 2001 ²²	Posterior suture and fascial flap	51	2.0	0	0	0	0	11.8	13.7	3.9
Bulstrode et al. 2003 ²³	Anterior scoring and posterior sutures	114	0.9	3.5	0	0	1.8	6.2	12.4	1.8
Mandal et al. 2006 ¹⁶	Posterior suture and fascial flap	41	2.4	0	0	2.4	0.0	4.8	9.6	3.6
Scharer et al. 2007 ²⁴	Anterior scoring and posterior suture	75	1.3	1.3	1.3	21.3	2.7	22.7	53.3	14.7
Schlegel-Wagner et al. 2010 ²⁵	Anterior scoring and posterior sutures	301 [‡]	2.5	0	3.8	5.0	2.3	13.3	26.9	NA
Maricevich et al. 2011 ²⁶	Cartilage sculpting and posterior sutures	111	0.9	0	0.9	0	0	0.0	1.8	0.9
de la Fuente and Sordo 2012 ²⁷	Anterior scoring and posterior suture	100	0	0	6.0	0	0	3.0	9.0	3.0
Park and Jeong 2012 ²⁸	Cartilage grafting and posterior sutures	66	0	0	0	0	1.5	1.5	3.0	1.5
Ribeiro and da Silva 2012 ⁵	Anterior scoring, cartilage excision, and posterior sutures	897	0.4	0.3	0	0	0	0	0.7	0.4
Sinha and Richard 2012 ²⁹	Posterior suture and fascial flap	227	0.0	0.4	0.4	2.6	1.3	4.8	9.5	4.8

TABLE I.
(Continued)

Author and Year	Technique Used	No. of Patients in Study	Hematoma and/or Bleeding (%)	Infection (%)	Skin Necrosis or Skin Problem (%)	Suture or Implant Extrusion (%)	Keloid and Hypertrophic Scars (%)	Recurrence of Prominence (%)	Overall Complication Rate (%)	Reoperation (%) ^a
Fioramonti et al. 2014 ¹⁰	Four consecutive techniques: hemitransfixing microincisions, anterior scoring, squeezing, and posterior mattress suture fixation	41	0	0	0	0	0	0	0	0
Sinno et al. 2015 ³⁰	Scaphal reduction and wedge excision of helical rim	84	0.0	0.0	0.0	1.2	0.0	0.0	1.2	0.0

Adapted from Kang and Kerstein,¹⁸ by permission of the American Society for Aesthetic Plastic Surgery, Inc.

^aAll patients who had an adverse event of the type shown in this table, with some patients counted more than once if they experienced more than one complication; reoperation rate (%) is not included in the overall complication rate and excludes cases where reoperation was due to an adverse event already listed; however, patients may be counted more than once in cases where reasons for reoperation were not detailed in the published report and it was not possible to make such an exclusion.

^bDue to limited detail and reporting of multiple complications in individual patients, overall complication rate could not be determined.

^cNumber of ears treated. For Adamson et al. 1991, otoplasty was performed in 62 patients. Denominator for all percentages reported is 119. For Schlegel-Wagner et al. 2010, otoplasty was performed in 222 patients. Denominator for all percentages reported is 301 (ears available for follow-up evaluation).

^dAnterior scoring was the primary procedure in 118 of 122 patients.

NA = data not available.

reoperation (Table I).^{13,16,19–21} With only a few exceptions, the incidence of other complications is generally less than 5%; nevertheless, the extensive dissection required with such techniques increases the risk of skin necrosis and hematoma. However, with cartilage-sculpting techniques, substantial injury to the cartilage also makes it very difficult to revise the outcomes should problems arise.

The limitations of standard otoplasty procedures (suture only or cartilage only) have driven the development of combined techniques using sutures, cartilage sculpting, and/or local fascial flaps to correct the prominent ear.^{5,16,22–29} Each additional step employed increases the surgical complexity and the operative time, but also appears to have the desired effect of reducing the risk of problems associated with single-technique approaches. The overall complication rates for combined procedures in previous reports are highly variable, and are likely to have been heavily influenced by surgeon experience. However, the most common complications reported are still recurrence of the original prominence and the need for reoperation (Table I), although the rates of other complications are generally less than 5%.

Earfold Prominent Ear Correction System—A New Cartilage-Sparing Technique

The aim of cartilage-sparing procedures is to reshape the antihelix while limiting the risk of permanent damage to the cartilage. The recently introduced Earfold implant is a new cartilage-sparing option. The Earfold implant, manufactured by Allergan plc, Dublin, Ireland, is made from nitinol, a nickel-titanium alloy. It is intended for use in patients 7 years of age and older and is currently only available in Europe. The primary function of the Earfold implant is to reshape the antihelical fold without causing major damage to the cartilage (Fig. 2, Fig. 4).¹⁸ Whereas suture-based techniques enhance the shape of the antihelical curve through posterior placement of sutures, the Earfold implant achieves the same objective by anterior placement of a metal implant.

The Earfold system involves three primary components: the Prefold[®] positioner, the permanent Earfold implant, and the Earfold introducer (Fig. 5).¹⁸ The Earfold implant exhibits superelasticity, allowing the implant to behave like a spring that is able to return to its original shape in a predictable manner; all Earfold implants have the same size and shape and exhibit the same degree of tension/stiffness. Successful use of the Earfold implant can only be achieved through careful patient selection and detailed preoperative planning using the Prefold positioner. The Prefold positioner is a nonsterile version of the Earfold implant, which is placed onto the anterior surface of the skin of the ear. Use of Prefold is necessary to determine the optimal position and number of Earfold implants to achieve a particular outcome. Using Prefold, surgeons can also assess whether it is possible to achieve the patient's desired goals. Once patient and surgeon are in agreement, the exact position and orientation of each Prefold positioner is carefully marked. Each Earfold implant is then inserted in this same position to achieve the outcome

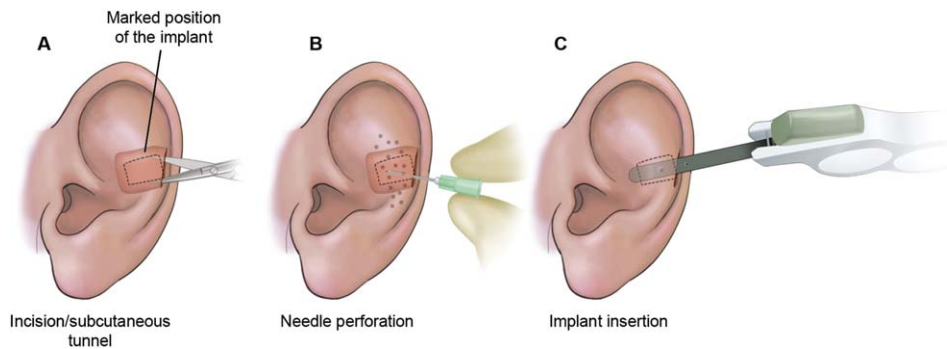


Fig. 4. The Earfold[®] implant insertion procedure. (A) To insert an Earfold implant, a subperichondrial tunnel is created that extends 2 to 5 mm beyond the area marked for the position of the implant. (B) Multiple through-and-through perforations of the cartilage may be necessary to enhance cartilage folding if the cartilage is particularly stiff. (C) Insertion and deployment of the implant using the introducer.

predicted by the Prefold. The third component of the Earfold system is the introducer, which holds the implant in the correct configuration during insertion of the implant.

As reported previously, placement of the Earfold implant is rapid, with operating times ranging from 10 to 20 minutes for a bilateral procedure; exact times vary depending on the number of implants used and the experience of the surgeon.¹⁸ Using a local anesthetic, an incision (8–10 mm long) is made a few millimeters from the proximal edge of the skin markings. A subperichondrial tunnel is then developed that is 2 mm wider and 3 to 4 mm longer than the footprint of the implant (Fig. 4). If the surgeon feels that cartilage weakening is needed to enhance the molding effect of the implant—particularly if the cartilage is inelastic or resistant to deformation—multiple needle perforations of the cartilage can be helpful (Fig. 4).

Once the tunnel has been created, the preloaded introducer is inserted in line with the skin markings. To further ensure correct positioning of the implant, there is a dimple on the dorsum of the introducer that corresponds with the proximal edge of the implant. Once the implant is in the correct position, the operator presses the implant firmly onto the anterior surface of the cartilage to fully engage the tines into the underlying cartilage. This ensures that the implant remains flush with the cartilage while being deployed. Once deployed, the

Earfold implant returns to its preprogrammed shape, folding the ear cartilage in the manner predicted using Prefold. The skin incision is then closed with a single 6-0 Vicryl Rapide (Ethicon, Livingston, United Kingdom) suture and dressed with Steri-Strips (3M, Bracknell, United Kingdom).

Early experience with Earfold in a prospective pilot study has shown that patients who retained their implants through 18 months postimplantation experienced a 34.6% reduction in their helical-mastoid distance.¹⁸ This is an outcome comparable to that using the suture-based standard otoplasty techniques discussed earlier.¹⁵ Importantly, the pilot study showed that implantation with Earfold yielded results that were predictable and stable over at least 18 months, with no recurrences and only a few cases of reoperation due to hypertrophic scarring, infection, or implant extrusion.¹⁸ A typical outcome achieved with Earfold is shown in Fig. 6.

Based on the pilot study, the Earfold implantation procedure is associated with an overall complication rate that is similar to the rates associated with standard otoplasty using combination techniques (Table I).¹⁸ An ongoing, long-term, postmarketing audit has monitored safety outcomes in a series of 403 patients who underwent the procedure in the United Kingdom and Croatia.³¹ The overall complication rate in this series,

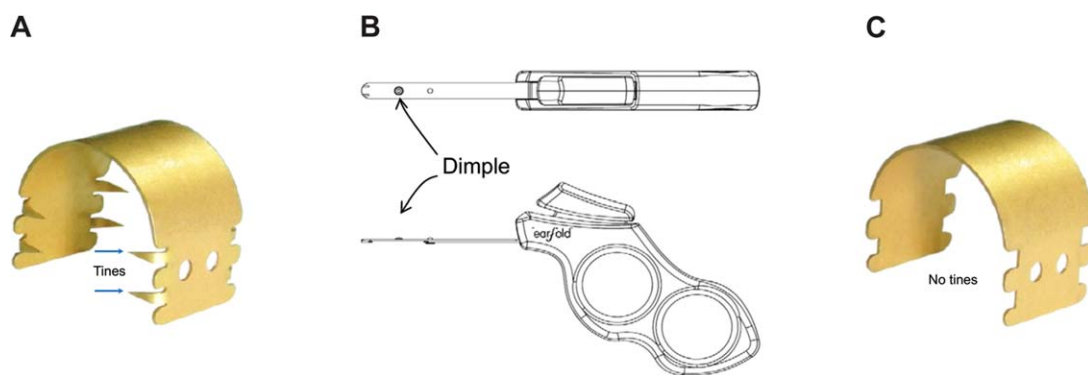


Fig. 5. The Earfold[®] system. The Earfold implant (A) is preloaded into the introducer (B) to hold the implant in a flattened position before insertion. (C) The Prefold positioner is used to determine the number, position, and orientation of the Earfold implants prior to surgery. Adapted from Kang and Kerstein.¹⁸ By permission of the American Society for Aesthetic Plastic Surgery, Inc.

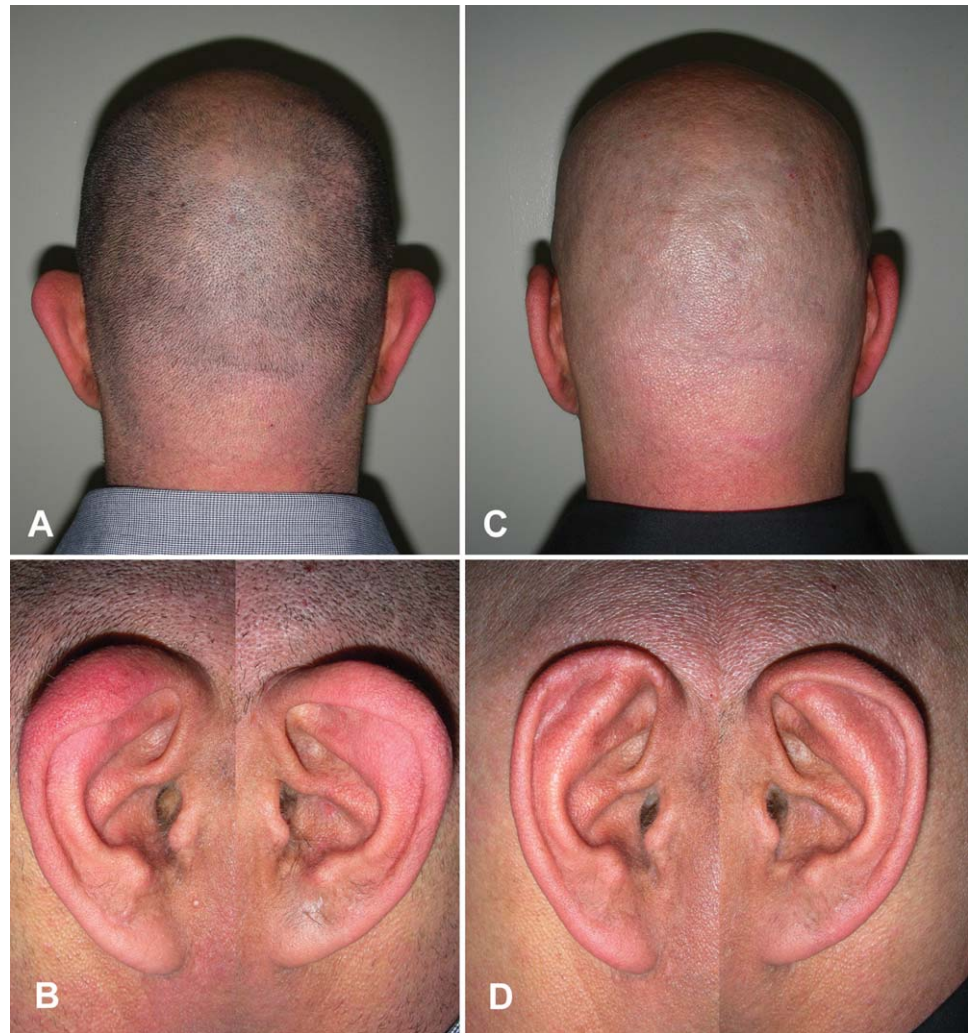


Fig. 6. A 45-year-old male with bilateral prominent ears and slight lop-ear deformity of the right ear, with no prior history of prominent ear correction. (A and B) Preoperative ear prominence. (C and D) Three months after treatment with a single Earfold implant inserted into the upper pole of each ear. Images courtesy of Norbert V. Kang.

including patients who underwent reoperation, is currently 9.7% after up to 34 months of follow-up. Minor postoperative pain, swelling, and bruising may occur after Earfold placement. In most cases, the postoperative pain subsides after 24 to 48 hours, and is adequately managed with simple, nonprescription analgesic medications (e.g., acetaminophen or ibuprofen). Likewise, swelling and bruising usually resolve within 7 days after implantation.

In contrast to standard otoplasty, postoperative care after an Earfold procedure is relatively simple. There is no requirement for a head bandage, and patients can shower immediately after the procedure and return to school or work within a few days. By comparison, our review of standard otoplasty techniques suggests that the typical recovery time is longer, and it may take 2 weeks before patients are able to return to the majority of their normal activities.³⁹

Learnings from the pilot study led to modifications of the Earfold implantation technique. These included ensuring that the implant was flush with the cartilage after deployment, specific attention to the orientation of the implant in relation to the planned antihelix,

selective use of needle perforation of the cartilage, and use of the introducer dimple to assist with correct positioning.³¹ With the updated Earfold implantation procedure, an audit of outcomes in 403 patients showed a lower overall complication rate (9.7%) and lower reoperation rate (4.2%) compared to the rates observed in the pilot study (20.5% and 15.3%, respectively).^{18,31} Overall, postsurgical safety was improved, evidenced by a greater than twofold decrease in infections, implant extrusion, and reoperations.^{18,31}

Preliminary experience using Earfold in combination with a conchal bowl resection has also shown promising results (unpublished clinical experience, N.V.K.) (Fig. 7). The use of Earfold simplifies the correction of any deficiency in the shape or definition of the antihelix because wide dissection to place the posterior sutures becomes unnecessary. Currently, the evidence supporting this approach is anecdotal, retrospective, and based on a small number of cases. A larger, prospective, formal case review would be highly informative for assessing the potential usefulness of Earfold in those cases where both the antihelix and concha require correction.

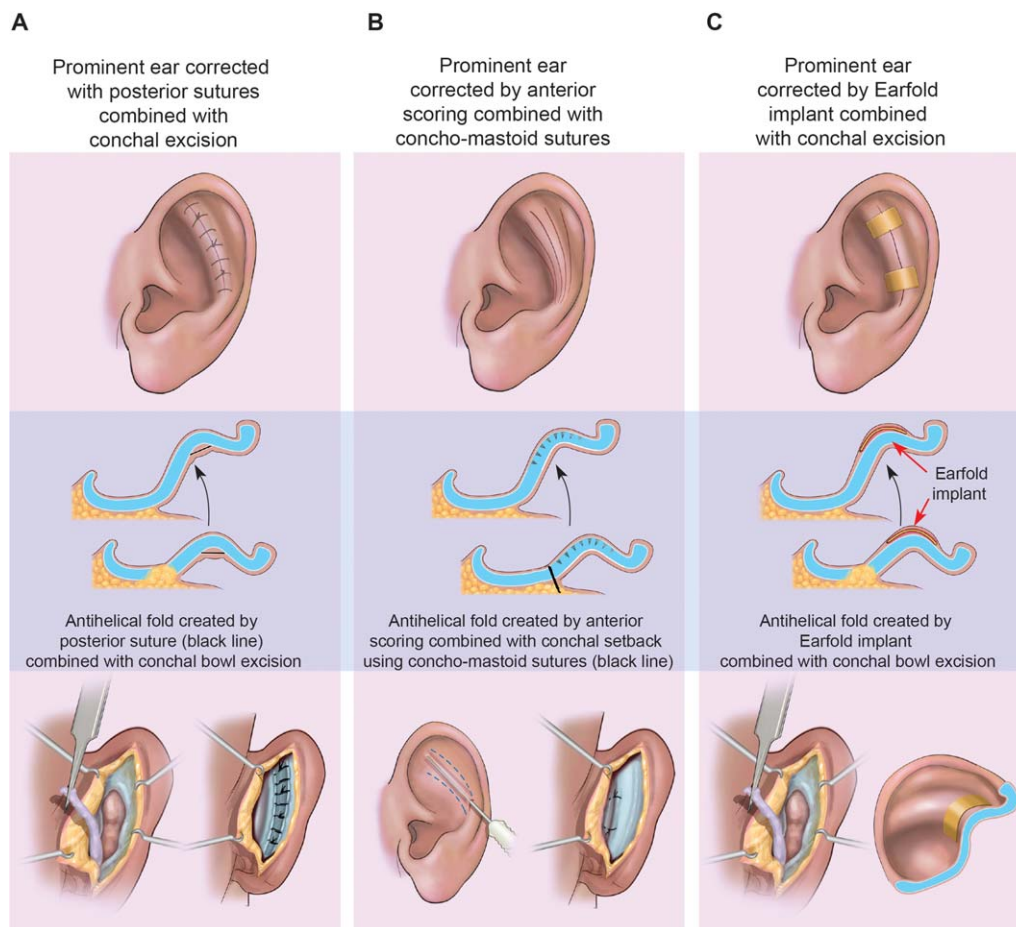


Fig. 7. Combined procedures. Examples of several combination approaches to reducing ear prominence, including (A) conchal cartilage excision and placement of posterior sutures, (B) minimally invasive anterior cartilage scoring paired with posterior concho-mastoid sutures, and (C) the Earfold[®] implant paired with conchal excision. Black curved arrows in the center illustrations indicate the posterior surface of the antihelical fold.

CONCLUSION

Numerous surgical techniques, including cartilage-sparing, cartilage-cutting, and combined procedures, have been described over the past 50 years to correct an absent or poorly formed antihelix and any associated prominence. No single technique has been proven superior, and no consensus has yet evolved as to which technique is best for any given situation. All otoplasty approaches carry a risk of complications such as infection, hematoma, delayed healing or skin necrosis, chronic pain, suture extrusion, and problems with scarring.^{7,16,18,20,25} However, in the hands of an expert surgeon, these risks are likely to be low, and the early and long-term outcomes for both suture-based and cartilage-based procedures are often excellent.

The development of a cartilage-sparing, minimally invasive implant system represents a further option, which patients and surgeons may find preferable to conventional otoplasty because of the predictability of the outcome, lower recurrence rates, faster recovery, and minimally invasive approach. Although it is easily taught to skilled otoplasty surgeons, the Earfold[®] system does have a learning curve. The key skill that

must be acquired for success with Earfold is to select patients who are appropriate for treatment. To do this, the surgeon must first become familiar with how the implant performs and understand the subtle changes in aesthetics accomplished by even small variations in the position and orientation of the Earfold implant. It takes time for a surgeon to fully understand the indications for use of the implant. Fortunately, one of the key advantages of Earfold is its reversibility. If the desired result is not achieved, the implant can be removed and repositioned or removed altogether. Importantly, because Earfold is cartilage sparing, many of the complications that may arise can be resolved by simply removing and/or repositioning the implant. However, as with all otoplasty procedures, Earfold cannot be used to treat all aspects of every case of ear prominence. It is designed to correct cases where a poorly defined or absent antihelix is the main cause for the prominence. For example, it is not intended to address conchal bowl hypertrophy, although future studies are planned to examine the use of the Earfold implant in combination with conventional otoplasty techniques, such as conchal bowl resection.

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