

Ear Scaffold

The Problem

An estimated 5% of the UK population (3 million people) are affected by prominent ears. A prominent ear is defined as projecting more than 17mm from the side of the head and is most commonly caused by an absence or reduction of the antihelical fold. While this does not pose any health risk, for those affected it can be a very distressing and demoralising condition.

Currently, standard surgery takes 90 minutes, is performed under general anaesthesia by a highly skilled plastic surgeon and requires a hospital stay. The procedure involves; releasing the skin at the back of the ear and separating the skin from the ear cartilage. The cartilage is then reshaped by hand to create an antihelical fold which is held in place with sutures before the skin is replaced over the cartilage and the incision is closed. Standard surgery is complex with a high risk of complications (up to 60% in inexperienced hands) including infection, skin necrosis, keloid scarring, numbness, ear asymmetry and problems with general anaesthesia.



Before standard surgery (left). The ear is prominent due to a poorly formed antihelical fold highlighted in pink (right)



After standard surgery (left). The antihelical fold has been recreated by inserting sutures into the cartilage

In the UK this procedure is reserved for patients in the greatest distress and therefore only 6,500 corrective procedures are carried out a year, despite 34,000 new births annually with prominent ears. Non-surgical splinting treatments, such as Ear Buddies™ and AuriClam™ exist and have some success in the very young. External splints such as these can cause discomfort, pain and pressure sore. Consequently they can be difficult to wear reducing the chance of success.

The Solution

A small metal strip (the Ear Scaffold) is inserted into the ear between the skin and the cartilage. The strip is made of Nitinol, a biocompatible metal alloy. Once inserted, the super-elastic properties of Nitinol bend the Ear Scaffold into a predetermined shape, applying a force to the ear cartilage which deforms, thereby correcting the prominence. Over time, the ear cartilage moulds itself into the new shape imposed by the Ear Scaffolds which can then be removed after several months. This new approach will revolutionise prominent ear correction turning it into a simple 10 minute outpatients' procedure performed under local anaesthetic.



Ear Scaffolds & applicator

For more information visit: www.earscaffolds.com

Contact us at: info@earscaffolds.com

How does it work?

The Ear Scaffold - a new, 21st Century technology that effectively re-shapes the ear from within.

The scaffolds are paper thin c-shaped strips of Nitinol, a biocompatible memory metal alloy of nickel & titanium that is commonly used in flexible spectacle frames, orthopaedic and coronary implants.

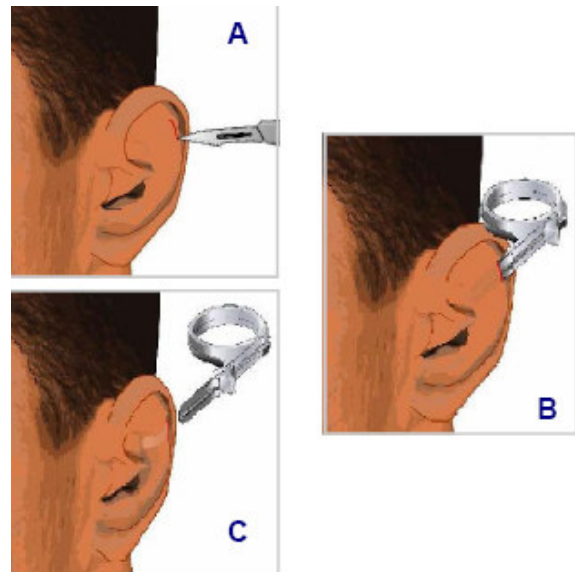
The Ear Scaffold is inserted into the ear between the skin and the cartilage. Once inserted, the scaffolds bend into a predetermined shape, reshaping the ear cartilage and correcting the prominence. The scaffolds are available in a number of different sizes and curvatures. For the first time in cosmetic ear surgery patients (rather than the surgeon) will be able to choose how their ears look. This aspect of total choice allows different scaffolds to be used on each ear, allowing pre-existing asymmetry to be corrected.



Trial versions of the Ear Scaffolds can be placed on the ear **before** insertion **under the skin**. The amount of correction and the exact position of the Ear Scaffolds can be chosen by the patient before treatment is carried out. This ensures that the end result is exactly how the patient wants it to be.

Following the application of a local anaesthetic to the ear, the selected Ear Scaffold is introduced through a small incision in the ear surface (A) and deployed from its applicator between the skin and the ear cartilage (B).

Once in place, the Ear Scaffold is virtually undetectable. The Ear Scaffold adopts its pre-determined curve, bending the ear cartilage to reform its antihelical fold thus reducing the prominence of the ear (C).



The incision is now closed and the scaffold holds the ear in its new position allowing nature's healing process to re-mould the ear cartilage.

While the scaffold is in place the super elasticity of the Nitinol is able to return the ear to its new position even if the ear is briefly bent by an external force.

After 6 months the ear cartilage will hold its new position permanently without the need for the Ear Scaffold and it can be removed through the original incision.

Benefits:

- The procedure is simple and so can be performed under local anaesthetic.
- Treatment can be performed in an outpatient clinic so no stay in hospital is required.
- Pre-selection of scaffolds allows complete patient control over the outcome.
- No need for the Ear Scaffolds to be left in place permanently.
- Post operative complications are reduced to extremely low levels.

Commercialisation and patents:

The device is protected by International Patent Application [Pub No. WO2007/0232964]. Northwood Implants is seeking investment partners to assist in the development of the Ear Scaffold to a CE marked product available for the benefit of patients and the improvement of healthcare.