Earfold Implantable Clip System for Correction of Prominent Ears: Analysis of Safety in 403 Patients

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Background: The Earfold system, a new treatment for the correction of prominent ears, consists of 3 components: the Earfold implant, the Earfold introducer, and the Prefold positioner.

Methods: This is an interim report based on an ongoing analysis of safety in a series of patients treated for prominent ears with the Earfold implant between February 2013 and September 2014. Safety was assessed based on adverse event reports and the need for implant revision; follow-up is ongoing.

Results: Seven surgeons used 1,200 Earfold implants to treat 403 patients (ages, 7–70 years; 63% male); the time since the initial implant procedure now ranges from 30 to 48 months. To date, 145 patients (36%) have returned for a follow-up visit (mean, 7.7 months [range, 1–34 months]). Adverse events requiring intervention have affected 39 of 403 (9.7%) patients; these include implant revisions (n = 17 [4.2%], most often due to implant visibility), skin erosion over the implant (n = 15 [3.7%]), and infection (n = 7 [1.7%]). Bleeding, recurrence of prominence, hematoma, deformity, or adverse scarring did not occur.

Conclusions: This interim analysis has shown that Earfold prominent ear correction system is associated with relatively few adverse events that require intervention; a small number of patients experienced infection, implant extrusion, or implant visibility that required revision. Most adverse events were related to either patient selection or technical errors at implantation. It is expected that with continued use of Earfold by surgeons experienced in otoplasty, the adverse event incidence will decrease. (Plast Reconstr Surg Glob Open 2018;6:e1623; doi: 10.1097/GOX.0000000000001623; Published online 12 January 2018.)

INTRODUCTION

A pilot study (EF-2011-01) of the Earfold implant (Allergan plc, Dublin, Ireland) introduced the concept of prominent ear correction using a permanent metal im-
plant made of nitinol (nickel-titanium alloy). The Earfold implant is used to create an anthelix (where this is absent) or to enhance the shape of a poorly formed anthelix. The effect is similar to that of a posterior horizontal mattress suture, except that the Earfold implant is placed in an anterior subcutaneous position. The implant is not designed to address a deep conchal bowl but can be used to address this cause of prominence in carefully selected cases.

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ventional suture-based otoplasty techniques. Further analysis of the outcomes led us to make changes to our technique for insertion of the implant and to the design of the Earfold introducer. To investigate the possibility that these changes might result in an improvement in the overall complication rate once the implant was put into routine use, we have performed an interim safety analysis describing the adverse events and complication rates in a series of 403 consecutive patients with prominent ears treated by 6 surgeons in the United Kingdom and 1 surgeon in Croatia.

METHODS

Implant Characteristics

The Earfold prominent ear correction system consists of 3 components: the Earfold implant, the Earfold introducer, and the Prefold positioner. The positioner is used during preoperative assessment to determine the number, position, and orientation of the Earfold implants needed to achieve the correction of prominence the patient desires (Fig. 1). There is only 1 size of the implant and it has a specific shape that is designed to grip and fold the cartilage in a predictable manner once deployed. Moreover, the implant is manufactured with a preset tension. Therefore, unlike sutures, it cannot be adjusted once deployed. To ensure that the outcome is the one desired by both the patient and the surgeon, it is critical to carry out a careful preoperative assessment using the Prefold positioners. Prefold has the same size, shape, and tension as the Earfold implant and can therefore be used to predict the likely outcome of treatment. If a satisfactory correction cannot be obtained preoperatively using Prefold alone, then it is likely that the patient is not an appropriate candidate for treatment with the Earfold system alone. The patient should then be advised to consider an alternative method for correction of prominent ears, or a combination of methods (eg, Earfold with conchal reduction).

Surgeon Training

Surgeons were trained by observing the principal author perform preoperative assessments using the Prefold positioner, then assisting him in treating 1 or 2 patients using the implant. The principal author then observed the trainees using the Prefold positioner for preoperative assessment and supervised their treatment of 1 to 2 patients with the Earfold positioner before they proceeded to treat patients independently in their own clinics.

Patients

All consecutive male or female patients ≥ 7 years of age attending a participating author’s clinic who received treatment for prominent ears with Earfold implants between February 2013 and September 2014 were included in this case series. Most had ear prominence due to unfolding of the anthelix. This series also included patients with a deep conchal bowl (> 16 mm) as well as patients who had treatment using a combination of Earfold implants and conchal bowl reduction. Patients treated with the Earfold system combined with conchal reduction were seen exclusively by the principal author. Patients with a serious concurrent illness that might affect the blood supply to the skin (eg, diabetes or peripheral vascular disease) were advised of a potential increase in the risk of skin erosions but still underwent treatment, as these conditions are not specific contraindications to treatment with Earfold implants. Patients were excluded from treatment with the Earfold system if it proved impossible to obtain a satisfactory correction during preoperative assessment using Prefold positioners. Patients were also excluded if they had a concurrent infection, had a current malignancy, were taking anticoagulants, were undergoing active psychiatric or psychological treatment, or were pregnant. Because this was a case-review audit of outcomes, a review by a Research Ethics Committee was not required—as determined by the U.K. National Health Service’s Health Research Authority. Patients whose images have been used in this article provided their written consent.

Method of Earfold Implant Insertion

Insertion of each Earfold implant took approximately 5 minutes (2 minutes for needle perforation and 3 minutes for implant insertion); all implant procedures were performed under local anesthesia (see video, Supplemental Digital Content 1, which displays how the Earfold implant is inserted, http://links.lww.com/PRSGO/A639). The

Fig. 1. Earfold implant, 24-carat-gold-plated to decrease visibility (A). Earfold introducer; dimple on dorsum assists with implant positioning (B). Prefold positioner, used preoperatively to determine number and position of implants needed for correction (C). Source for Figures 1A and 1C: Reprinted from Kang NV, Kerstein RL. Treatment of prominent ears with an implantable clip system: a pilot study. Aesthet Surg J. 2016;36:NP100-NP116, by permission of The American Society for Aesthetic Plastic Surgery, Inc.
basic technique to insert the Earfold implant has been described previously¹ and was applied here, but with the following modifications to the Earfold introducer and the insertion technique: To reduce the risk of a “Spock-ear” deformity, the apex of the new anthelix to be formed was marked preoperatively as a gentle C-shaped curve. The implant was then placed at 90 degrees to this line, thereby ensuring that the anthelix was never too vertical—the main cause of a Spock-ear deformity. To enhance the molding effect of the implant, a 21-gauge (green-hubbed) needle was used to create 10 to 20 full-thickness perforations of the cartilage under the planned footprint of the implant and along the planned position for the new (or enhanced) anthelical fold (Fig. 2). The needle was inserted obliquely through the incision(s) created to insert the implant and did not need to be bent at the tip to reach all parts of the ear to be treated. Needle perforation had the effect of slightly weakening the cartilage and reducing its elasticity, thereby allowing the cartilage to conform more closely to the shape of the implant. Needle perforation was not needed in every case and was not critical to the safe deployment of Earfold implants. However, it was considered in cases where the ear cartilage was especially thick or resistant to deformation when using Prefold during the preoperative assessment.

Surgeons were advised to ensure that the implant/introducer was carefully aligned with the skin markings to avoid misplacing the implant. To further ensure correct alignment of the implant in relation to the planned position of the new or enhanced anthelical fold, a dimple was created on the dorsum of the introducer. The dimple was palpable through the skin and indicated the position of the middle of the implant. Surgeons were advised to use the proximal tines as a further guide by ensuring that the tines coincided with the proximal edge of the planned (marked) position for the implant. Finally, following implant deployment, surgeons were asked to check whether any edges of the implant were palpable, particularly at the apex of the implant. If any edges were excessively palpable, the implant was removed and redeployed, since these edges become visible when the soft-tissue swelling subsides. Moreover, palpable edges are unsightly, increase the risk of skin erosion, and constitute a technical failure since the implant should be flush with the cartilage after deployment.

The technique for removal of the implant has been described previously.¹ Implants were removed if: (1) the implant was palpable intraoperatively at the time of initial insertion; (2) a postoperative complication arose; (3) the patient was dissatisfied with the outcome and/or requested repositioning of the implant; or (4) the patient requested conversion to standard otoplasty.

All patients were asked to return for a final follow-up visit at 2 to 3 months after treatment and were also encouraged to return at any time if they had concerns about the outcome of their treatment.

SAFETY ASSESSMENT

Adverse events and the need for implant revision were recorded in the case notes. Before and after photographs were also used to record outcomes but were not obtained systematically. Adverse events were reported as a percentage of the total cohort under review (ie, 403 patients) and not as a percentage of the patients who returned for review. This method of reporting was based on the reasonable assumption that patients will return for review if they experience an adverse event and, likewise, that those patients who do not return for review have not experienced an adverse event and are most likely satisfied with their outcomes. Although this may mean that we have underestimated the overall rate of adverse events, it has been our experience that patients undergoing an aesthetic procedure tend to be more critical of a poor outcome than patients undergoing surgery for purely functional reasons.

RESULTS

Patients

Between February 2013 and September 2014, 403 patients received treatment with Earfold implants. Details of the patients treated are summarized in Table 1. To date, a
Table 1. Summary of Patient Demographic and Treatment Characteristics (N = 403; 766 Ears)

| Characteristics                          | Value                      |
|------------------------------------------|----------------------------|
| Age                                      |                            |
| Mean age (y) (range)                     | 35 (7–70)                  |
| No. patients < 15 years old             | 25                         |
| Gender (%)                               |                            |
| Male                                     | 63                         |
| Female                                   | 37                         |
| Follow-up                                |                            |
| Patients returning for follow-up, n (%)  | 145 (36)                   |
| Postoperative time (mo), mean (range)    | 7.7 (1–34)                 |
| Treatment, n                             |                            |
| Earfold only                             | 397                        |
| Earfold and conchal reduction            | 6                          |
| Number of implants*                      |                            |
| Total                                    | 1,200                      |
| Mean per patient (range)                 | 3 (1–3)                    |
| Condition                                |                            |
| Unilateral prominence, % of patients    | 10                         |
| Conchal bowl > 16 mm, n                 | 36                         |

*Forty-five percent of patients had 1 implant in each ear. Five patients had 5 implants to treat bilateral prominence (eg, 3 implants in one ear and 2 in the other).

A total of 145 patients (36%) have returned for a follow-up visit (average follow-up, 7.7 months; range, 1–34 months). Monitoring of the full 403-patient cohort will continue to > 5 years, with time since the initial implant procedure now ranging from 30 to 48 months.

**Typical Outcomes**

A typical outcome from treatment with the Earfold implant is shown at 5 months following insertion (Fig. 3). The Earfold implant can also be used for revision after standard otoplasty (Fig. 4).

**Adverse Events**

The most commonly reported adverse events were acute postoperative pain, swelling, and bruising of the ears. In all patients, these resolved by week 2 posttreatment with no additional intervention or medication. Most patients were able to return to work or school within 1 week.

**Adverse Events Requiring Treatment**

Adverse events that required additional intervention or treatment affected 59 patients (9.7%) (Table 2). Each patient experienced 1 adverse event related to 1 implant. These events included revision of the implant’s position (17 patients [4.2%]; 1.4% of implants), erosion of skin over the implant (15 patients [3.7%]; 1.3% of implants), and infection (7 patients [1.7%]; 0.6% of implants). There were no recorded episodes of bleeding, hematoma, adverse scarring, recurrence of ear prominence, or asymmetry at final follow-up. Moreover, no patient experienced a deformity as a result of Earfold implantation.

**Conversion to Standard Otoplasty or Implant Removal**

Five patients who experienced no adverse events (1.2%) elected to have all their implants removed at intervals varying from 3 to 34 months after treatment. Three of these patients (1 child and 2 adults) then requested conversion to standard otoplasty, and the other 2 (both adults) declined any further treatment. The reasons given for requesting complete treatment were (1) concerns over the visibility of the implant (2 cases); (2) dissatisfaction with the outcome of treatment (2 cases); and (3) change of mind. Four of these patients had conchal bowl depths of > 16 mm.

**Implant Repositioning**

The most common adverse event was a request to reposition the implant (17 patients [4.2%]; 1.4% of implants), usually due to excessive visibility of the implant under the skin (15 patients; an example is shown in Fig. 5). However, 1 implant was also repositioned to address residual asymmetry and another to address overcorrection of the prominence. All cases were the result of technical errors at the time of implantation, comprising either a failure to ensure that the implant was flush with the cartilage when deployed or a failure to ensure correct alignment of the implant with the skin markings. All patients requesting revision underwent successful implant removal, repositioning, and redeployment. In all 17 cases, repositioning was carried out within the first 3 months after the initial treatment. Repositioning was especially straightforward when performed within 3 months of the original procedure—before the scar tissue had matured.

**Implant Erosion/Extrusion**

Erosion of the skin over the implant affected 15 patients (3.7%; 1.3% of implants); in each case, a single implant was involved (ie, 15 implants) (Fig. 6). The most common factors associated with erosion were concurrent or history of heavy smoking (5 of 15 cases) and previous standard otoplasty involving degloving of the anterior skin (4 of 15 cases). Most erosions occurred through the anterior skin, commonly at the upper pole where the skin of the ear is thinnest. One patient had erosion of the implant through the posterior skin. The only way in which this could have occurred is for the implant to have migrated through the cartilage. We speculate that this was the result of needle perforation beyond the extent that is necessary, resulting in cartilage morcellization. Patients affected by skin erosion were advised to have their implants removed immediately and to allow their ears to heal for 2 to 3 months before considering reimplantation. Patients were also strongly advised to stop smoking before considering any further surgery. Thirteen of the implants removed because of erosion were subsequently reimplanted with a successful final outcome. The remaining 2 patients declined to have the affected implants replaced and I requested conversion to standard otoplasty.

**Infection**

A total of 7 patients (1.7%; 0.6% of implants) experienced an implant-related infection (Fig. 7). Five of the 7 patients with implants that became infected were successfully treated with a short course of oral antibiotics, and the implants were left in place. However, 2 patients required implant removal because of infection. In both patients, the infections resolved after implant removal. After 2 to 3
months, both patients underwent successful reimplantation with no further complications.

**Helical-Mastoid Distance**

To assess the durability of the results, pre- and postoperative helical-mastoid distances were measured in a subset of patients treated by the principal author (n = 121). The preoperative mean helical-mastoid distance was 27 mm per ear. Immediately after treatment, the mean helical-mastoid distance was 18 mm per ear (reduction from baseline, −9 mm, −34%). At the final follow-up visit, the mean decrease in helical-mastoid distance from baseline was −9.5 mm (−35%), indicating a stable reduction in ear prominence.

**DISCUSSION**

In this series of patients treated with Earfold implants, the overall risk of adverse events requiring treatment was relatively low (9.7%), and all adverse events were resolved with simple interventions. Importantly, patients who requested complete removal of their implants (for whatever reason) were able to convert to standard otoplasty without difficulty if desired. The absence of cases of recurrence of prominence or residual asymmetry after 30 to 48 months of follow-up compares favorably to results with conventional otoplasty techniques where revision can be common.5,7,8 Especially with suture-based techniques. For example, knots may loosen and sutures may break or cheese-wire through the cartilage. These problems are largely overcome with the Earfold implant because the implant is fatigue resistant and does not loosen or shift position, once in place for >4 weeks. In a subset of patients, measurement of the helical-mastoid distances at the final postoperative visit confirmed that the corrections achieved at the time of insertion were stable over time. We acknowledge that interpretation of this finding is limited, since the helical-mastoid distance was only measured in patients treated by the principal author. However, this concurs with the findings of our pilot study after 18 months of follow-up.5

The overall rate of adverse events needing intervention (9.7%) was comparable with or less than that observed with other techniques for prominent ear correction (Table 2).5,7,8 Rates of infection (1.7%) and erosion (3.7%) were comparable with the rates observed with convention-
Fig. 4. A 12-year-old girl experienced recurrence of left ear prominence following 2 previous otoplasty procedures. The initial procedures used a combined approach of Mustardé sutures and a posterior fascial flap (repeated for the second procedure). The left ear prominence was successfully corrected using a single Earfold implant with no complications. At the 3-month postoperative visit, her ears appeared symmetrical. Preoperative (A, C): recurrence of left ear prominence. Assessment with Prefold positioner (D). Three months postprocedure (B, E; 1 implant).

Table 2. Adverse Events Requiring Treatment or Intervention: Comparison Across Surgical Techniques

| Procedures                                                                 | Patients (n) | Hematoma and/or Bleeding (%) | Infection (%) | Skin Necrosis or Other Problem (%) | Suture or Implant Erosion/Extrusion (%) | Hypertrophic or Keloid Scar (%) | Recurrence (%) | Revision (%) | Overall Adverse Events (%) |
|----------------------------------------------------------------------------|--------------|-----------------------------|--------------|-----------------------------------|----------------------------------------|-------------------------------|----------------|-------------|-----------------------------|
| Earfold, current series                                                   | 403          | 0.0                         | 1.7          | 0.0                               | 3.7                                    | 0.0                           | 0.0            | 4.2          | 9.7                         |
| Earfold, original series; Kang and Kerstein1                             | 39           | 0.0                         | 5.1          | 0.0                               | 12.8                                   | 5.1                           | 0.0            | 15.4         | 20.5                        |
| Comparison techniques                                                     |              |                             |              |                                   |                                        |                               |                |             |                             |
| Anterior cartilage scoring; Mandal et al.7                                | 68           | 1.5                         | 1.5          | 3.5                               | 0.0                                    | 1.5                           | 11.0           | 8.8          | 27.8                        |
| Posterior suture; Mandal et al.7                                           | 94           | 5.3                         | 1.1          | 4.3                               | 2.1                                    | 2.1                           | 8.0            | 6.0          | 28.9                        |
| Posterior suture + fascial flap; Sinha and Richard6                       | 227          | 0.0                         | 0.4          | 0.4                               | 2.6                                    | 1.3*                          | 4.8            | 4.8          | 14.3                        |
| Scaphal reduction and wedge excision of helical rim; Sinno et al.9         | 84           | 0.0                         | 0.0          | 0.0                               | 1.2                                    | 0.0                           | 0.0            | 0.0          | 1.2                         |

Values shown are percentages of patients.

Source: Adapted from Kang NV, Kerstein RL. Treatment of prominent ears with an implantable clip system: a pilot study. Aesthet Surg J. 2016;36:NP100-NP116,1 by permission of The American Society for Aesthetic Plastic Surgery, Inc.

* n = 3 cases with keloids.
It was also notable that skin erosions occurred mainly in patients who were heavy smokers or who had undergone a previous otoplasty procedure involving the anterior skin. Therefore, improvements in the rate of this adverse event could be achieved by asking patients to stop smoking before treatment and through careful attention to technique in revision cases. Complications such as bleeding, wound dehiscence, and hematoma did not occur in the present series, which concurs with our experience in the pilot study. In contrast to the pilot study, there were no cases of hypertrophic scarring in this series. We speculate that the absence of problems with scarring might be due to differences in the behavior of the anterior skin compared with the posterior skin. Importantly, when complications did occur, remedial action was generally simple, and all cases were successfully resolved.

The most common adverse event was the need to reposition the implant [17 patients (4.2%)]. In most cases, this followed patient or surgeon concerns about the visibility of the implant (15 patients). Repositioning was advised because excessively visible implants are at greater risk of eroding the skin, whereas incorrectly positioned implants may fail to achieve the degree of correction agreed upon during preoperative assessment. To reduce the risk of visible or palpable implants, users of the Earfold system are advised to practice implant deployment using dummy silicone ears, which are provided by the manufacturer for this purpose. Intraoperatively, surgeons are advised that if the implant can be felt or seen easily through the skin then it should be removed and a new implant should be redeployed that is flush with the cartilage.

Advantages and Limitations of the Earfold Implant

Because implantation of the Earfold implant is quick, it is feasible to treat all or most patients (even children as young as 7 years of age) under local anesthesia. Typically, operating times range from 5 to 20 minutes—depending on the number of implants inserted. This compares favorably with American Society for Aesthetic Plastic Surgery data indicating that a standard otoplasty procedure takes an average of 2 to 3 hours. Similarly, removal of Earfold implants is quick, although we acknowledge that it is faster and easier to remove an extruding suture than an implant if a problem arises. Finally, training in the use of the Earfold system is simple, without the need for the very long learning curve associated with standard otoplasty surgery.

The Earfold system is not a replacement for conventional otoplasty and is only intended for use by surgeons already experienced with standard otoplasty. Surgeons should be mindful that Earfold is simply a tool for achieving a particular objective—to enhance a preexisting antihelical fold or to create one where this did not previously exist. Specifically, Earfold is not designed to address prominence related to a deep conchal bowl and using Earfold alone to treat patients with a deep conchal bowl can sometimes be problematic. Our data underline some of the difficulties encountered when trying to use the Earfold system alone to treat prominence associated with a deep conchal bowl, since 4 of the 5 patients who requested removal of all of their implants had a conchal bowl depth of > 16 mm. Nevertheless, there were also 32 patients in this series who had conchal bowl depths of > 16 mm who appear to have had satisfactory outcomes when using Earfold alone. It is possible to use the Earfold system to achieve some reduc-
tion in the conchal bowl depth by rolling part of the lateral wall of the concha into the new anthelix. Indeed, some patients prefer to compromise on the degree of reduction in conchal bowl depth achieved using Earfold because of the faster postoperative recovery compared with standard conchal reduction surgery. However, based on the first author’s experience, patients with a conchal bowl depth of >16 mm for whom preoperative assessment with Prefold positioners has confirmed that reduction of their conchal bowl depth is inadequate for their aesthetic needs, should not be treated with Earfold alone. Instead, they should either consider treatment with Earfold combined with conchal reduction or proceed to standard otoplasty.

These clinical considerations emphasize the need for careful preoperative assessment with Prefold positioners to determine whether a patient is suitable for treatment with Earfold implants alone or whether the patient may benefit from other methods of correction or from a combined approach (eg, using Earfold combined with conchal reduction). It is also the preoperative assessment that makes it possible to determine how best to position the implant(s) to accommodate the wide variety of ear shapes and cartilage stiffness that may be encountered. Although the implant is manufactured with a preset shape and tension, the final shape adopted by the implant, once deployed, is not the same in every ear or in every position within the same ear. Instead, the final shape of the implant depends on the complex interplay between the stiffness of the implant and the stiffness of the cartilage at each specific position in the ear. These patient-specific effects can be predetermined through trial and error before surgery is attempted through the careful use of Prefold positioners. The positioners are highly predictive of the final outcome because they are identical to the Earfold implant in terms of shape, size, and tension. Therefore, once the surgeon and the patient have agreed upon a final position for the implants (using Prefold), there is no need for any further adjustment once the Earfold implants have been deployed in the ear because the shape created by Earfold will have been anticipated preoperatively through the use of Prefold. Finally, it is worth noting that the anthelical fold produced by Earfold implants can sometimes appear more tubular (Fig. 4) than that achieved using suture-based techniques. However, in practice, we have had no requests for revision for this reason.

Study Limitations
This was an interim safety analysis of 403 patients who were treated with the Earfold system, and only 36% of the patients returned for a final postoperative visit, with a mean of 7.7 months of follow-up. Although it is reasonable to assume that patients who did not return did not encounter an adverse event, we cannot be certain that the outcome in such patients has been entirely satisfactory. Moreover, with the relatively short average follow-up time, the ability to assess patients for late complications, such as recurrence, secondary deformity, or possible device failure or shift in position, was limited. To obtain full information regarding long-term safety of the Earfold implant, we plan to extend safety monitoring for the entire cohort to >5 years. Furthermore, pre- and postoperative photographs were not obtained systematically; the photographs shown in this article are intended for illustrative purposes only. Finally, the data collected relate to 7 surgeons with varying levels of experience with the Earfold system. Although this may have had an effect on the number of adverse events for each surgeon, analysis of the individual adverse event rates (data not shown) does not support this view. The adverse event rate for the principal author, who has performed the most cases, is currently higher than the overall rate, although this may reflect the larger number of difficult cases he has performed (especially in patients with a deep conchal bowl).

CONCLUSIONS
The Earfold prominent ear correction system is a new treatment option for the correction of prominent ears in

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Fig. 6. Implant erosion/extrusion: 59-year-old female; right ear skin erosion over implant at 6 weeks; heavy smoker (30–40 cigarettes/d), history of failed standard otoplasty. The patient declined implant replacement.
cases where prominence is primarily related to a poorly defined or absent anthelical fold. It is intended for use by surgeons who are already comfortable with standard otoplasty techniques. This interim analysis of 403 patients indicates that the safety of the Earfold implant is generally acceptable, with relatively few adverse events that required intervention. Continued follow-up of this patient cohort to > 5 years will help to provide long-term safety information.

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