The Effect of Polydioxanone Absorbable Plates in Septorhinoplasty for Stabilizing Caudal Septal Extension Grafts

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IMPORTANCE Caudal septal extension grafts (CSEGs) can be used to alter and secure nasal projection and length. Graft position and thickness play an important role in terms of both function and aesthetics. The limitations of harvesting cartilage from additional sites necessitate development of a more efficient method for securing CSEGs.

OBJECTIVE To assess the efficacy and safety of polydioxanone absorbable plates used in primary and revision septorhinoplasty.

DESIGN, SETTING, AND PARTICIPANTS We investigated all patients who underwent primary or revision septorhinoplasty with the use of absorbable plates to secure CSEGs at a tertiary academic medical center from 2010 to 2014. To standardize and objectify the symptoms of nasal obstruction, a validated quality-of-life instrument called the Nasal Obstruction Symptom Evaluation (NOSE) questionnaire, with 5 questions on a scale of 0 to 4, was implemented preoperatively and postoperatively. Preoperative and multiple successive postoperative measurements of nasal length and projection were taken using 3dMDvultus imaging software.

MAIN OUTCOMES AND MEASURES Change in NOSE questionnaire score, change in nasal length and projection, and complications.

RESULTS There were no absorbable plate–related complications in the 95 included patients. Comparing preoperative and postoperative NOSE questionnaire scores, there was a statistically significant improvement in all 5 categories: mean (SD) change of −1.42 (1.59) in congestion, −1.56 (1.53) in blockage or obstruction, −1.60 (1.54) in breathing through nose, −0.90 (1.54) in trouble sleeping, and −1.28 (1.46) in breathing during exercise (P < .001 for all) in the 50 patients with available data. In the 24 patients with greater than 180 days of follow-up, follow-up ranged from 183 to 717 days, and mean (SD) change in nasal length and projection was 0.64 (2.19) and 0.26 (0.96) mm, respectively, showing no statistically significant change over time (P = .17 and .21, respectively).

CONCLUSIONS AND RELEVANCE In our study population, nasal length and projection maintained position over time when absorbable plates were used to secure CSEGs. Absorbable plates appear safe and effective when used to secure CSEGs and limit the requirement of harvesting additional cartilage. Nasal airway improvement can be obtained when absorbable plates are used to secure CSEGs.

LEVEL OF EVIDENCE 4.
Caudal septal extension grafts (CSEGs) can be used to alter and secure nasal projection and length. The graft position and thickness play an important role in terms of both function and aesthetics. The CSEG is placed end to end to the caudal portion of the native septum to allow for maximal airway patency (Figure 1). Overlapping the CSEG with the existing caudal septum can result in blockage of the nasal airway. The CSEG then requires bilateral supporting struts to secure it to the caudal septum. The material used as struts needs to have sufficient rigidity to support the new CSEG. Autologous cartilage grafts can be used to secure CSEGs; however, rigidity and strength are closely related to the thickness of the material used for struts. To obtain sufficient strength, autologous cartilage grafts are often too thick and bulky, which will contribute to persistent nasal obstruction. Another constraint of this method is the limited amount of cartilage available. If there is not enough cartilage for both the CSEG and the supporting struts from a septoplasty, then auricular or costal cartilage will likely be required. Because of the morbidity associated with harvesting cartilage from an additional site, an effort remains to find alternative methods to address this problem.1-4

Polydioxanone absorbable plates have been Food and Drug Administration approved for use in septorhinoplasty since February of 2010. This material is a fully biodegradable copolymer that is hydrolyzed and eliminated from the body at approximately 6 months. The absorbable plates are rectangular in shape (Figure 2) and are available commercially in 3 standard thicknesses, 0.15 mm (perforated), 0.25 mm (nonperforated), and 0.5 mm (nonperforated).5-9

The goal of this investigation was to assess the efficacy and safety of polydioxanone absorbable plates used in primary and revision septorhinoplasty. From a structural standpoint, we sought to better understand the postoperative changes in nasal length and projection when using absorbable plates to secure CSEGs. We hypothesized that plates can be used as a reliable source for securing CSEGs and that the changes obtained would maintain projection and length over time.

From a functional standpoint, we sought to investigate whether absorbable plates add substantial bulk and lead to airway obstruction. We hypothesized that there would be a significant improvement in the patients’ subjective airway symptoms assessed by means of the Nasal Obstruction Symptom Evaluation (NOSE) questionnaire. Our final hypothesis was that absorbable plates are safe with minimal complications when used to secure CSEGs.

Methods
This study was approved by the Institutional Review Board at the University of Illinois at Chicago and met all standards for human experimentation. Written informed consent was obtained from participants.

Surgical Technique
Caudal septal extension grafts were fashioned on the basis of the need of the patient. The CSEGs were shaped from septal cartilage and then placed end to end with the existing caudal septum. In all cases, a 0.25-mm absorbable polydioxanone plate was used to fixate the CSEG. To maximize fibrous and vascular ingrowth, the plates were perforated with multiple holes using a 16-gauge needle (Figure 3A). Absorbable plates typically measured 5 × 7 × 0.25 mm. It is advisable to use the smallest sized plate possible to achieve adequate fixation. The plates were sutured to the existing caudal septum with 5-0 polydioxanone suture (Figure 3B)
and C). Then the CSEG was positioned against the existing caudal septum and sutured into place with a 5-0 polydioxanone suture (Figure 3D). In many patients, extended spreader grafts were used to stabilize the CSEG superiorly on the dorsal surface (anterior septal angle). The absorbable plates, or another material, are still required to stabilize the CSEG posteriorly and caudally. The goal of this investigation was to define the benefit of using plates, as opposed to cartilage, for securing the posterior and caudal segments of the CSEG. Included are the preoperative and postoperative photographs (Figure 4) of a patient who underwent absorbable plate placement to secure a CSEG.
Study Parameters
The present study included all patients treated at our institution between 2010 to 2014 who underwent primary or revision septorhinoplasty with the use of absorbable plates to secure a CSEG. The decision to use absorbable plates was made intraoperatively by D.M.T. Preoperative and postoperative measurements were taken using 3dMDvultus imaging software to analyze nasal length and projection. Nasal length was measured by selecting 2 points on a 3-dimensional reconstructed image. The first point selected was the nasion, which is the deepest point of the radix area. The second point selected was the nasal tip–defining point. Similarly, nasal projection was measured by selecting 2 points on the 3-dimensional reconstructed image. The subnasale, which is the midline point of the columellar base and upper lip crease, was used for the first point. The tip-defining point was used for the second point. For measurement acquisition, the investigator can zoom into the pixelated screen and be extremely precise. Each region of interest has an X, Y, and Z axis, and the image can be manipulated in 3 dimensions. The mean error associated with the placement of landmark points has been shown to be submillimeter in multiple studies.10-12 To further temper human error, a single investigator (B.P.C.) performed all measurements and 3 measurements were taken for each metric and the mean calculated. For the maintenance of nasal tip projection and nasal length, we were interested in those patients with follow-up times greater than 6 months because the estimated time to complete absorption for the plates is 6 months. A subgroup of patients with follow-up times greater than 6 months was isolated and included in these data.

For nasal length and projection, 3 time points (TPs) were evaluated. Time point 1 refers to the preoperative measurements, TP 2 refers to the first postoperative measurement, and TP 3 refers to the last postoperative measurement. We then investigated nasal length and projection to see whether there was a statistically significant difference between TP 1, TP 2, and TP 3. The goal of this analysis was to determine whether length and projection were lost over time during the postoperative period, mainly between TP 2 and TP 3.

To standardize and objectify the symptoms of nasal obstruction, a validated quality-of-life instrument was implemented called the Nasal Obstruction Symptom Evaluation (NOSE) questionnaire. For the NOSE questionnaires, we compared preoperative scores vs postoperative scores to assess for nasal airway obstruction similar to other published studies.13,14 Unique to our study, the NOSE score results were isolated by question (Q) (Q1, congestion; Q2, blockage or obstruction; Q3, breathing through nose; Q4, trouble sleeping; Q5, breathing during exercise). All patients filled out the NOSE questionnaire preoperatively, as well as at all routine follow-up visits. The standard postoperative follow-up schedule required patients to return once weekly for the first month, every other week for the second month, then once per month thereafter. The preoperative symptoms were compared with the last completed postoperative questionnaires.

Safety and complication data collected included any postoperative complications related to the absorbable plate in the perioperative and postoperative periods (TP 1-3). Postoperative complications were assessed in all patients in whom absorbable plates were used as securing struts. Postoperative complications were defined as infection, exposure or extrusion of the implant, patient-reported discomfort, and/or malpositioning leading to obstruction.

Results
Ninety-five patients (75 female, 20 male) had an absorbable plate used for stabilization of a CSEG. In only 7 of the 95 patients was additional autologous cartilage harvested (6 patients required costal cartilage and 1 patient auricular carti-
Table 1. Nasal Obstruction Symptom Evaluation (NOSE) Questionnaire Comparing Time Point 1 With Time Point 3 for 50 Patients

<table>
<thead>
<tr>
<th>NOSE Question</th>
<th>Change, Mean (SD)</th>
<th>SE</th>
<th>df</th>
<th>t Value</th>
<th>P Valueb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congestion</td>
<td>−1.42 (1.59)</td>
<td>0.23</td>
<td>49</td>
<td>6.31</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Blockage or obstruction</td>
<td>−1.56 (1.53)</td>
<td>0.22</td>
<td>49</td>
<td>7.22</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Breathing through nose</td>
<td>−1.60 (1.54)</td>
<td>0.22</td>
<td>49</td>
<td>7.35</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Trouble sleeping</td>
<td>−0.90 (1.54)</td>
<td>0.22</td>
<td>49</td>
<td>4.13</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Breathing during exercise</td>
<td>−1.28 (1.46)</td>
<td>0.21</td>
<td>49</td>
<td>6.21</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Abbreviation: SE, standard error.
* These data compare preoperative NOSE questionnaires with the last measured postoperative scores.
* Statistical significance with P < .05.

Table 2. The CORR Procedure

<table>
<thead>
<tr>
<th>Variable</th>
<th>Observations, No.</th>
<th>Pearson Correlation Coefficienta</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal length change, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TP 1 to 2</td>
<td>40</td>
<td>−0.07</td>
<td>.66</td>
</tr>
<tr>
<td>TP 2 to 3</td>
<td>39</td>
<td>0.05</td>
<td>.75</td>
</tr>
<tr>
<td>Nasal projection change, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TP 1 to 2</td>
<td>40</td>
<td>−0.02</td>
<td>.88</td>
</tr>
<tr>
<td>TP 2 to 3</td>
<td>39</td>
<td>−0.11</td>
<td>.51</td>
</tr>
</tbody>
</table>

Abbreviation: TP, time point.
* Demonstrates that there was no significant difference between successive postoperative measurements of either nasal length or projection.

Discussion

These results suggest that absorbable plates are a safe and effective material to stabilize autologous grafts. This research helps to validate the long-term safety of using absorbable plates in septorhinoplasty.

In the NOSE trial, Stewart and colleagues15 developed an instrument to measure the subjective sensation of nasal obstruction. This scale now serves as a well-accepted tool to assess postoperative nasal obstruction.13,14 In our study, the results of the NOSE questionnaire demonstrated statistically significant improvement in all 5 categories when absorbable plates were used to secure CSEGs. From a functional standpoint, these results suggest that absorbable plates can be used in septorhinoplasty to secure CSEGs without leading to obstruction. The contribution of the extended spreader graft to stability and airway improvement could not be controlled for because of the small number of patients included in the study. This is a weakness of the article and should be recognized.

We also sought to assess the structural changes in nasal projection and length over time. With the subgroup of patients with follow-up longer than 180 days, we were able to demonstrate that over time with the use of absorbable plates to secure CSEGs, nasal length and projection were maintained.

A CORR procedure was used to establish whether the amount of change for both nasal length and projection was related to the time of measuring throughout the postoperative period. This showed no statistically significant relationship between nasal length and/or projection with time when comparing successive postoperative measurements (Table 2). This allowed us to ensure that there was no follow-up length effect. A paired t test procedure was performed to determine whether the change in nasal length and/or projection was significant from TP 2 to TP 3. For this analysis, we included only the patients who had follow-up longer than 180 days to ensure that we were assessing changes after resorption of the plate and resolution of acute postoperative edema. This analysis showed no statistically significant change over time from TP 2 to TP 3 of either metric, using P < .05 (Table 3). Nasal tip projection was maintained over time (TP 2 to TP 3) with no statistically significant change during postoperative follow-up (eFigure 1 in the Supplement). Nasal length was also maintained over time, and there was no statistically significant change postoperatively (eFigure 2 in the Supplement). Time points 1 and 2 of both measurements were also compared for all patients. For nasal projection, there was a statistically significant difference from TP 1 to TP 2 (Table 3). This finding reflects that most patients underwent a desired increase or decrease in nasal tip projection to achieve the proposed aesthetic outcome.
septal position. The absorbable plates were perforated to encourage fibrous ingrowth into the junction between the CSEG and existing caudal septum. These perforations also allowed vascular ingrowth into the cartilage to minimize the chance of cartilage resorption. It is important to note that the absorbable plates are used only to secure the grafts. It is the autologous graft that contributes to the stabilization of projection, length, and structure over time.

In our experience, implementing absorbable plates for purposes of stabilizing autologous grafts saves the patient the morbidity of additional harvesting sites. The use of absorbable plates to splint CSEGs and/or existing septal cartilage minimized the need for additional autologous cartilage harvest in our patient population.

A relative limitation to this study is the length of patient follow-up. Continued follow-up with even longer-term outcomes would allow greater insight into the structural changes that may occur with the use of these plates.

**Conclusions**

Absorbable plates are safe and effective when used to secure CSEGs. In our study population, nasal length and projection were maintained over time when absorbable plates were used to secure CSEGs. The absorbable plates likely allowed scar tissue to secure the changes obtained during septorhinoplasty and to maintain airway patency.

**REFERENCES**