Polydioxanone Absorbable Plate for Cartilaginous Grafting in Endonasal Rhinoplasty
A Randomized Clinical Trial

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**IMPORTANCE** The caudal septal extension (CSE) graft maneuver commonly is used to adjust the nasal tip projection. It can, however, be difficult to stabilize and straighten the CSE graft, especially when the procedure is performed through an endonasal approach. Because the stabilization and correct positioning of the CSE graft are vital for achievement of the desired outcome, new approaches must be found that facilitate the technical ease of this procedure.

**OBJECTIVE** To assess the safety and efficacy of the polydioxanone (PDS) absorbable plate in CSE graft procedures performed via an endonasal approach.

**DESIGN, SETTING, AND PARTICIPANTS** In an open-label, 2-arm parallel trial, 30 patients who requested a surgical nasal correction and required a CSE graft performed via an endonasal approach were randomized into 2 groups of 15 patients each. All patients underwent endonasal rhinoplasty at a single center from February 17, 2011, to December 26, 2013. Depending on their treatment group, patients received a CSE graft with or without a PDS plate. Data were collected and evaluated from November 24, 2010, to January 19, 2015, when final follow-up occurred. Data were analyzed based on an evaluable population.

**INTERVENTIONS** Endonasal rhinoplasty with or without the use of a PDS plate.

**MAIN OUTCOMES AND MEASURES** Technical difficulty assessed using a visual analog scale (range, 0-100; higher scores indicate increased difficulty of use), surgeon and blinded evaluator satisfaction with the graft assessed using a 4-point categorical scale (1 indicates highly satisfied; 4, unsatisfied), change in nasal tip projection, and complications at 30, 60, 180, and 365 days after surgery.

**RESULTS** Twenty-seven patients (13 in the PDS group and 14 in the non-PDS group) completed their 6-month postoperative visit, and 19 patients (10 in the PDS group and 9 in the non-PDS group) completed the entire study (12 months). The mean (SD; range) surgeon-assessed visual analog scale score for ease of use was 46 (13; 25-64) mm for the 15 patients in the non-PDS treatment group and 17 (10; 7-48) mm for the 15 patients in the PDS group (P < .001). The surgeon's satisfaction with the graft did not differ significantly between the PDS and the non-PDS groups (P = .34), and the nontreating blinded evaluator’s assessment of standardized photographs taken at the time of the graft placement and at postoperative days 30, 60, 180, and 365 did not establish any significant differences between the 2 groups (P > .99). Postoperative change in the nasal tip projection at 365 postoperative days compared with 30 postoperative days was significantly lower in the PDS group compared with the non-PDS group (−0.31% vs −6.5%; P = .04), thus increasing the long-term stability of the graft in the PDS group. A single incident of infection was observed in each group along with no episodes of rejection or extrusion.

**CONCLUSIONS AND RELEVANCE** In this study, use of a PDS plate in CSE graft procedures was associated with less technical difficulty than CSE graft procedures without use of a PDS plate and with reduced long-term variations in the nasal tip projection after the graft placement.

**LEVEL OF EVIDENCE** 1.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT01225250

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Nasal reshaping or rhinoplasty is the second most frequently performed cosmetic surgical procedure in the United States, with 217,000 procedures conducted in 2014. According to the American Academy of Facial Plastic and Reconstructive Surgery, it was the most commonly performed cosmetic surgery in 2013 and the surgical procedure performed most often among women and men younger than 35 years. The objective of rhinoplasty is to create an aesthetically pleasing and natural-looking nose with a normal respiratory function. Depending on the specific needs, different methods are used to accomplish these goals. A common practice, however, is the use of cartilaginous grafts. Because these grafts often provide the structural framework, the appropriate and precise placement of the grafts is vital for achievement of the desired and long-lasting results.

The caudal septal extension (CSE) graft is used in many cases for properly positioning the nasal tip and adjusting the alar-columellar relationship and the nasolabial angle. The CSE graft is a relatively straight fragment of cartilage that is sutured to the medial crural footplates as an extension to the native septum. Since the graft provides the physical support for the nasal tip, proper positioning and stability are critical for obtaining and maintaining an optimal nasal tip projection. To attain a stable fixation, the CSE graft generally is sutured to overlap the caudal septum by at least 4 mm. Although this end-to-side method of affixing the graft to the septum provides stability and allows for integration, it can lead to partial blockage of the nasal airway because the overlapping site of the graft can protrude into the naris. Therefore, in many cases, suturing the CSE graft to the native septum in an end-to-end manner can provide better results.

It is, however, technically challenging to perform this maneuver in endonasal rhinoplasty owing to the limited space and visibility. The surgeon can circumvent this difficulty by taking advantage of a scaffolding agent to facilitate and reinforce the fixation and straighten the CSE graft. In that way, the graft can be more easily and firmly sutured to the caudal septum in an end-to-end manner, and the scaffolding agent can provide further structural support during the healing process.

Polydioxanone (PDS) is a type of resorbable aliphatic polyester that can provide a structural platform in nasal cartilage reconstruction procedures. Polydioxanone is available in multiple film thicknesses and can be trimmed to the desired size and shape. Polydioxanone has been used successfully in the repair of bony deficiencies and in septal reconstruction procedures. Studies examining the properties of PDS in bone repair have demonstrated that PDS is fully resorbed and does not interfere with the healing process. These properties reduce the risk for potential long-term complications.

Thus, using a PDS plate as a scaffolding agent in CSE graft procedures can reduce the technical difficulty of this process and allow for more predictable long-term results. To test this hypothesis, we compared the efficacy and technical ease of the CSE graft procedure performed with or without the use of a PDS plate via an endonasal approach. Thirty patients who requested a surgical nasal correction and required a CSE graft were randomized into 2 groups and underwent the procedure with or without use of a PDS plate. Ease of use was determined by the surgeon with a visual analog scale (VAS). Furthermore, the duration of the grafting process was also recorded. Efficacy was determined by a live assessment of surgeon’s satisfaction with the graft, a blinded 4-point satisfaction scale, and the Goode ratio of tip projection. Safety was determined by the rate of infection, rejection, and extrusion of the graft.

Methods

Patient Selection

We enrolled and treated a total of 30 patients who requested a surgical nasal correction and required a CSE graft performed via an endonasal approach from February 17, 2011, to December 26, 2013. Data were collected and evaluated from November 24, 2010, to January 19, 2015, when final follow-up occurred. This study was approved by Independent Investigational Review Board, Inc, and the patients provided written informed consent. The full study protocol can be found in Supplement 1.

Demographic characteristics of the patients are described in the eTable in Supplement 2. Patients were randomized into 2 groups in a 1:1 ratio (PDS vs non-PDS groups) (Figure). At enrollment, each patient was assigned a unique 2-digit identification number. Randomization was performed through the following process: a randomization schedule linked unique, sequential treatment assignment numbers to treatment codes (PDS or non-PDS). When the patients were enrolled and allotted a study identification number, they were assigned the lowest available treatment assignment number, which randomly allocated them to the PDS or non-PDS group.

All patients underwent endonasal rhinoplasty but, depending on their treatment assignment, received a CSE graft with or without a PDS plate. Twenty-seven patients (13 in the PDS group and 14 in the non-PDS group) completed their 6-month postoperative visit, and 19 patients (10 in the PDS group and 9 in the non-PDS group) completed the entire study (12 months). All 30 patients, regardless of their treatment group, underwent the same preoperative and postoperative assessments. Twenty-nine patients required a secondary rhinoplasty. Therefore, inferences in regard to any variations in the use of PDS plates in a primary compared with a revision rhinoplasty could not be drawn in this study.

PDS Plate

Polydioxanone plates are a type of biodegradable aliphatic polyester manufactured by the polymerization of mono-meric p-dioxanone to form poly(p-dioxanone). The PDS plates are available in different film thicknesses, can be trimmed to the desired size and shape, and are supplied in
sterile, individually wrapped pouches (Ethicon, Inc). The 0.50-mm PDS plate was used for the first 6 patients. Based on experience and evolving knowledge, the decision was made to use the 0.25-mm plate for the remaining 9 patients. The 0.25-mm plate provides as much support as the thicker plate but is easier to mold and manage and, most importantly, presents less foreign body to the patient.

Surgical Technique
All surgical procedures were performed by a single surgeon (S.H.D.) at the Chicago Center for Facial Plastic Surgery. The normal operating protocol for endonasal rhinoplasty in patients requiring a CSE graft was executed for all 30 patients. Caudal septal grafts were harvested from the posterior inferior quadrangular cartilaginous septum and carved to the appropriate size based on each patient’s needs. In the non-PDS group, the graft was attached directly to the end of the caudal septum with multiple 5-0 PDS sutures in a mattress fashion while maintaining an end-to-end relationship. Multiple sutures were required to achieve a stable union. In the PDS group, the graft was first fixated to the PDS foil with multiple 5-0 PDS sutures. Care was taken to leave a lip of the PDS plate, measuring approximately 2 to 3 mm, extending beyond the graft boundaries, and the remainder of the plate was discarded (eFigure 1 in Supplement 2). The graft was held in situ with its end aligned with the end of the septum. The lip of the overlapping PDS plate was then sutured easily to the caudal septum. The end of the septum on which the PDS plate overlapped was contingent on each patient’s needs. Thus, a stable end-to-end positioning of the graft and the caudal septum was achieved with a scaffolding PDS plate spanning the union. After fixation, regardless of whether a PDS plate was used, the medial crural footplates were secured onto the caudal septal graft in a tongue-in-groove fashion. A double-prong skin hook was used to hold the tip in position while it was fixated with a 4-0 catgut suture on a Keith needle. All wounds were then meticulously closed with 5-0 fast absorbing catgut to ensure that no exposure of the PDS plate occurred (eFigure 2 in Supplement 2).

Assessment Criteria
Technical ease of use was determined by the surgeon using a VAS score recorded within 1 hour of graft placement. The VAS consisted of a 100-mm scale, with higher scores indicating an increase in the difficulty of use.

Follow-up visits occurred at 30, 60, 180, and 365 days after the procedure. Patients were followed up to assess any treatment-related adverse events. Photographs were obtained preoperatively and at each subsequent follow-up visit for each patient. To account for potential variability, we used a protocol to standardize all the variables for photography.

The surgeon’s satisfaction at the time of the graft placement and at postoperative days 30, 60, 180, and 365 was determined using a 4-point categorical satisfaction scale in which 1 indicated highly satisfied, with an optimal cosmetic result; 2, very satisfied, with obvious improvement in appearance compared with the initial condition but not completely optimal; 3, satisfied, with marked improvement in appearance from the initial condition; and 4, unsatisfied, with an appearance essentially the same as or worse than the original condition. A nontreating blinded evaluator assessed the patients’ grafts with the 4-point categorical satisfaction scale, as described above, using standardized photographs taken preoperatively and at postoperative days 30, 60, 180, and 365. The evaluating physician was aware of the purpose of the study and the type of the graft but unaware of the treatment group status or the specific grafting site.
Nasal tip projection was determined using the Goode method as described in Powell and Humphreys.\(^a\) The Goode ratio defines tip projection as the ratio of the distance between the nasal tip and the alar line (ie, the perpendicular line to the Frankfort plane that runs from the alar base to the cheek) to the distance between the nasal tip and the nasion. To determine the Goode ratio of tip projection, the corresponding measurements were recorded from the standardized photographs taken preoperatively and at postoperative days 7, 30, 60, 180, and 365 using Adobe Photoshop software (Adobe Systems, Inc).

Intraoperative duration of the grafting procedure was measured by an assistant using a stopwatch to record the time to harvest, shape, and satisfactorily secure the graft. Safety was determined by the rate of infection, rejection, and extrusion of the graft at 7, 30, 60, 180, and 365 days after the graft placement.

**Statistical Analysis**

Data analysis was based on the evaluable population. Arithmetic means and SDs are reported unless otherwise indicated. Statistical significance was determined for all the variables assessed in this study using a 2-tailed t test for continuous variables and a χ² test for categorical variables. We compared the PDS with the non-PDS groups at each follow-up visit. \(P < .05\) was considered statistically significant.

**Results**

**Technical Difficulty of the CSE Graft Procedure**

To establish whether the use of a PDS plate lessens the technical difficulty of the CSE graft maneuver, we compared the ease of use between the PDS and non-PDS groups. Technical ease of use was determined by the surgeon using a VAS, which consisted of a 100-mm scale with higher scores indicating an increase in the difficulty of use. The mean (SD; range) VAS score for ease of use was 46 (13; 25-64) mm for the non-PDS treatment group \(n = 15\). In the PDS treatment group \(n = 15\), however, the mean VAS score for ease of use was reduced to 17 (10; 7-48) mm. Thus, the use of a PDS plate reduced the technical difficulty of the CSE graft procedure by 29.4% \(P < .001\).

**Length of the CSE Graft Procedure**

To determine whether the use of a PDS plate alters the length of the surgical procedure, duration of the grafting procedure was measured by an assistant using a stopwatch to record the time to harvest, shape, and secure the graft satisfactorily. The mean (SD) duration of the grafting procedure was 9.5 (3.0) minutes in the non-PDS group and 10.1 (3.7) minutes in the PDS group. Therefore, use of a PDS plate does not alter the duration of the grafting procedure significantly \(P = .66\).

**Long-term Variations in the Nasal Tip Projection After a CSE Graft Procedure**

We used 3 methods to compare the efficacy of the PDS plate in the CSE graft procedure. A live assessment of the surgeon’s satisfaction with the graft was established using the 4-point categorical satisfaction scale at the time of the graft placement and at postoperative days 30, 60, 180, and 365. The surgeon’s satisfaction with the graft did not differ significantly between the PDS and non-PDS groups \(P = .34\) (Table 1). A
The safety of the CSE graft procedure in endonasal rhinoplasty was examined by determining the rates of infection, rejection, and extrusion of the graft at 7, 30, 60, 180, and 365 days after the graft placement. One difficult grafting procedure is among the most common indications for an open rhinoplasty. Plastic surgery has been experiencing a movement toward less invasive approaches that would allow for the preservation of the natural anatomy and, theoretically, a quicker recovery time.

### Table 3. Goode Ratio of Tip Projection

<table>
<thead>
<tr>
<th>Time of Measurement by Treatment Group</th>
<th>Goode Ratioa</th>
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<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
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<tr>
<td></td>
<td>Range</td>
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<tr>
<td><strong>Non-PDS</strong></td>
<td></td>
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<tr>
<td>At graft placement (n = 12)</td>
<td>0.57 (0.05)</td>
</tr>
<tr>
<td>POD 7 (n = 11)</td>
<td>0.57 (0.04)</td>
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<tr>
<td>POD 30 (n = 11)</td>
<td>0.58 (0.05)</td>
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<tr>
<td>POD 60 (n = 9)</td>
<td>0.58 (0.04)</td>
</tr>
<tr>
<td>POD 180 (n = 8)</td>
<td>0.57 (0.03)</td>
</tr>
<tr>
<td>POD 365 (n = 7)</td>
<td>0.55 (0.05)</td>
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<tr>
<td><strong>PDS</strong></td>
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<tr>
<td>POD 7 (n = 11)</td>
<td>0.58 (0.03)</td>
</tr>
<tr>
<td>POD 30 (n = 11)</td>
<td>0.55 (0.06)</td>
</tr>
<tr>
<td>POD 60 (n = 10)</td>
<td>0.54 (0.06)</td>
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<tr>
<td>POD 180 (n = 10)</td>
<td>0.54 (0.05)</td>
</tr>
<tr>
<td>POD 365 (n = 8)</td>
<td>0.55 (0.06)</td>
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Abbreviations: PDS, polydioxanone; POD, postoperative day.

* Defined as the ratio of the distance between the nasal tip and the alar line to the distance between the nasal tip and the nasion.

Nasal tip projection was measured with the Goode ratio, which is the ratio of the distance between the nasal tip and the alar root to the distance between the nasal tip and the nasion. An optimal tip projection is considered to have a Goode ratio ranging from 0.55 to 0.60. Goode ratios were determined using measurements recorded from the standardized preoperative photographs and those obtained at postoperative days 30, 60, 180, and 365. No significant differences in the Goode ratios between the PDS and the non-PDS groups were observed at any of the assessment points in this study (P = .46) (Table 3).

Changes in the tip projection at postoperative days 7, 30, 60, 180, and 365 are displayed in eFigure 3 in Supplement 2. Although we found no differences in the absolute values of the Goode ratios between the 2 groups, the change in the Goode ratio at postoperative day 365 compared with postoperative day 30 was significantly lower in the PDS group compared with the non-PDS group (P = .04) (Table 4). Therefore, use of a PDS plate increases the long-term stability of the nasal tip projection in endonasal rhinoplasty requiring a CSE graft.

### Table 4. Changes in the Goode Ratio of Tip Projection by Postoperative Assessment

<table>
<thead>
<tr>
<th>Time of Measurement by Treatment Group</th>
<th>Change in Goode Ratioa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
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<tr>
<td></td>
<td>Range</td>
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<tr>
<td><strong>Non-PDS</strong></td>
<td></td>
</tr>
<tr>
<td>POD 60</td>
<td>−0.09 (0.04)</td>
</tr>
<tr>
<td>POD 180</td>
<td>−0.99 (0.04)</td>
</tr>
<tr>
<td>POD 365</td>
<td>−6.50 (0.06)</td>
</tr>
<tr>
<td><strong>PDS</strong></td>
<td></td>
</tr>
<tr>
<td>POD 60</td>
<td>−1.30 (0.08)</td>
</tr>
<tr>
<td>POD 180</td>
<td>0.31 (0.04)</td>
</tr>
<tr>
<td>POD 365</td>
<td>−0.31 (0.04)b</td>
</tr>
</tbody>
</table>

Abbreviations: PDS, polydioxanone; POD, postoperative day.

* Defined as the ratio of the distance between the nasal tip and the alar line to the distance between the nasal tip and the nasion. Changes are compared with the POD 30 assessment.

b P < .05 compared with POD 30.

### Discussion

The CSE graft is used to adjust and support the nasal tip. Because of limited space and visibility, the graft is technically challenging to fixate and position properly via an endonasal approach. Considering the fundamental impact of the CSE graft in setting the nasal tip projection, we need new approaches that would alleviate this difficulty and allow for a more predictable surgical procedure, which would subsequently lead to a more predictable surgical outcome.

In this study, we examined the ease of use, efficacy, and safety of the PDS plate in CSE graft procedures performed via an endonasal approach. First, we established that using a PDS plate significantly lessens the technical difficulty of this maneuver. The ease of use, however, was determined by a single surgeon using a VAS. The ease of a technique is a subjective variable, and the VAS is a widely accepted method to quantify such variables in part to make comparisons. Studies with a larger number of surgeons should be performed to establish the full strength of this statement. Further limitations of this study were a small sample size and the large percentage of patients who were lost to follow-up.

A difficult grafting procedure is among the most common indications for an open rhinoplasty. Plastic surgery has been experiencing a movement toward less invasive approaches that would allow for the preservation of the natural anatomy and, theoretically, a quicker recovery time.
that would, in turn, lead to improved patient satisfaction.\textsuperscript{20} Therefore, new and improved methods, such as use of the PDS plate, that allow for the execution of difficult techniques through the less invasive endonasal approach are increasingly gaining importance.

Next, we compared the efficacy of performing the CSE graft procedure with or without use of a PDS plate. Although the use of a PDS plate did not significantly alter the surgeon’s or the blinded evaluator’s satisfaction with the graft, use of the plate significantly reduced the change in the Goode ratio of tip projection in the first 12 months after the graft placement. Reduction in the Goode ratio indicates a drop in the nasal tip projection, which can generally result from instability in the caudal septum cartilage after the procedure. Therefore, our results suggest that use of a PDS plate reduces long-term variations in the nasal tip projection after a CSE graft procedure. This finding is probably due to the physical support that the PDS plate provides during the healing process while new cartilage is being generated to integrate fully and to sustain the graft properly.

One patient in the PDS group had a culture-positive methicillin-resistant \textit{S aureus} infection, which was resolved successfully after a course of antibiotic treatment that covered \textit{S aureus}. The PDS plate was never exposed. Unlike infections associated with the alloplastic grafts, the infection could be treated successfully without sequelae and the need to remove the PDS implant. In addition, the patients in the PDS group did not display an increased rate of infection because we also observed 1 incident of infection in the non-PDS group, which was also successfully resolved after a course of antibiotic treatment. To avoid possible postoperative complications, we recommend ensuring that the graft is completely enveloped by mucosa or skin during the procedure.

The PDS plate is fully biodegradable.\textsuperscript{9} Therefore, use of the plate avoids the long-term complications that can result from permanent alloplastic implants. The resorbance rate depends on the thickness of the plate and ranges from 8 to 25 weeks.\textsuperscript{16} Furthermore, the relationship between the flexural stiffness of the PDS plate and its thickness has been shown to be nonlinear.\textsuperscript{21} A cartilage-PDS composite with a 0.50-mm PDS plate was only 1.7 times stiffer than a composite with a 0.15-mm plate.\textsuperscript{23} Thus, the small increase in the flexural stiffness of thicker PDS plates may not justify the potential complications resulting from using more of the alloplastic scaffold. Our observations also indicate that using the smallest piece of the 0.25-mm plate provides results comparable to those obtained using the thicker 0.50-mm plate but with less foreign body material and potentially better delivery of nutrients to the graft site because less of the PDS material is used. Moreover, in our experience, handling and positioning the thinner 0.25-mm plate is easier.

Other investigators\textsuperscript{16} have noted benefits of using thinner plates. Saddling of the dorsum has been observed in septal reconstructions with PDS plates. A retrospective study by Tweedie et al\textsuperscript{16} found that 4 of 26 patients (15\%) who underwent external septal reconstructions with unperforated PDS plates experienced moderate saddling of the dorsum. Therefore, the investigators suggested that a perforated PDS plate may provide better results in septorhinoplasty.

Since the PDS plate can be trimmed to the desired size and shape, we suggest using the minimum amount needed to suture the graft-PDS composite to the medial crural footplates of the native septum and then using a tongue-in-groove maneuver to set the tip projection. The PDS plate resorbs in about 6 months.\textsuperscript{10} Furthermore, our results indicate that using a PDS plate reduces long-term (>6 months) variations in the nasal tip projection. This observation suggests that the nasal tip fixates into place before the complete resorbance of the PDS plate and is properly maintained even after the PDS plate is biodegraded.

The CSE graft is commonly used in rhinoplasty to set the nasal tip projection and rotation. However, the maneuver can be technically difficult to execute in an endonasal approach, especially for the novice surgeon. A PDS plate used as a temporary scaffold allows for the end-to-end placement of the CSE graft to be technically easier and may also lead to better predictability of the long-term tip projection. The PDS plate can be particularly helpful when there is a paucity of septal cartilage available for harvesting or when the only donor nasal cartilage available is thin, weak, or fractured. The PDS plate may allow for the reliable fixation and the avoidance of harvesting additional cartilage from other sources, such as the ear or the rib, hence reducing morbidity and surgical time.

Conclusions

Our findings suggest that a 0.25-mm PDS plate used as a scaffold allows for greater ease of the CSE graft placement in endonasal surgery compared with the traditional techniques. Use of the PDS plate also results in long-term reliability in the nasal tip projection without an increase in morbidity.
REFERENCES


