

# Effects of Implant Stiffness, Shape, and Medialization Depth on the Acoustic Outcomes of Medialization Laryngoplasty

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**Summary: Objective.** Medialization laryngoplasty is commonly used to treat glottic insufficiency. In this study, we investigated the effects of implant stiffness (Young modulus), medialization depth, and implant medial surface shape on acoustic outcomes.

**Study Design.** Basic science study using *ex vivo* laryngeal phonation model.

**Methods.** In an *ex vivo* human larynx phonation model, bilateral medialization laryngoplasties were performed with implants of varying stiffness, medial surface shape (rectangular, divergent, and convergent), and varying depths of medialization. The subglottal pressure, the flow rate, and the outside sound were measured as the implant parameters were varied.

**Results.** Medialization through the use of implants generally improved the harmonic-to-noise ratio (HNR) and the number of harmonics excited in the outside sound spectra. The degree of acoustic improvement depended on the implant insertion depth, stiffness, and to a lesser degree implant shape. Varying implant insertion depth led to large variations in phonation for stiff implants, but had much smaller effects for soft implants.

**Conclusions.** Implants with stiffness comparable to vocal folds provided more consistent improvement in acoustic outcomes across different implant conditions. Further investigations are required to better understand the underlying mechanisms.

**Key Words:** Type 1 thyroplasty–Medialization laryngoplasty.

## INTRODUCTION

In phonation the intrinsic laryngeal muscles control the prephonatory geometry (shape) and stiffness of the vocal folds. With vocal fold paralysis the affected laryngeal muscles are unable to set up the proper glottal posture and stiffness. This often leads to the symptoms of glottic insufficiency such as hoarseness, vocal fatigue, and even aspiration.<sup>1</sup> Surgical procedures have been developed to attempt to return the desired glottal posture for phonation. The earliest surgical intervention for vocal fold paralysis was injection laryngoplasty. However, these efforts were hampered by the unpredictable results, temporary nature of many of the injectibles, and complications with some such as Teflon granulomas.<sup>2</sup> Medialization laryngoplasty procedures such as type 1 thyroplasty and arytenoid adduction were developed to improve on the limitations of injection laryngoplasty.<sup>3–5</sup> In medialization laryngoplasty, a lateral thyroid cartilage window is made at the level of the vocal fold, and an implant is placed in the paraglottic space to move the vocal fold tissue toward the glottic midline with the goal of improving vocal quality and efficiency. Materials used include stiff preformed implants of titanium, calcium hydroxylapatite, or firm silicone.<sup>6–9</sup> Additionally softer materials including hand-

carved silicone and layered Gor-Tex are used.<sup>10–13</sup> The materials used for injection laryngoplasty include firm calcium hydroxylapatite and acellular dermis, and soft collagen and hyaluronic acid, and these also obviously vary in stiffness.<sup>14,15</sup>

In spite of the large variety in the material used for laryngoplasty implants, the common goal remains improvement of voice quality by moving the paralyzed or paretic vocal fold into a more ideal glottal posture for phonation. However, there has been no consensus on the optimal implant shapes, sizes, and materials as the phonatory effects of these parameters have not been discussed or investigated in detail. In particular, because the medial surface of the vocal fold cannot be readily visualized during phonation, its shape due to vocal fold posturing (and thus the target shape laryngoplasty implants intend to achieve) is poorly understood. It is also unknown which medial surface shape leads to optimal voice production. Few studies have focused on the optimal medial surface shape that produces the lowest phonation threshold pressure. Using a surface wave model, Titze<sup>16</sup> proposed that the ideal glottal conformation for phonation with the lowest phonation threshold pressure ( $P_{th}$ ) would be a divergent glottis. However, later experiments using a physical vocal fold model and numerical studies showed that minimum phonation threshold pressure occurs for a slightly convergent or near-rectangular glottis.<sup>17–19</sup> Little has been accomplished in applying these data to human larynx models and surgical rehabilitation of glottic insufficiency. No studies have investigated the effects of implant stiffness on voice production following medialization laryngoplasty surgery. Furthermore, there have been no systematic investigations of how different implant material and shape affect the acoustic outcomes in laryngoplasty surgery.

The goal of this study was to identify implant parameters that critically determine the acoustic outcomes of medialization

Accepted for publication July 9, 2014.

This study was supported by research grant nos. R01 DC011299 and R01 DC011300 from the National Institute on Deafness and Other Communication Disorders, the National Institutes of Health. The authors have no other funding, financial relationships, or conflicts of interest to disclose.

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Journal of Voice, Vol. 29, No. 2, pp. 230-235

0892-1997/\$36.00

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<http://dx.doi.org/10.1016/j.jvoice.2014.07.003>

laryngoplasty. Implants of different stiffness and medial surface shape were designed and inserted to excised human larynges at different insertion depths. Phonation experiments were then performed, and the effects of different implant conditions on the aerodynamic and acoustic outcomes of phonation were investigated. Specifically, the effects on the glottal resistance, the phonation frequency, the phonation threshold pressure, and the harmonic-to-noise ratio (HNR) and the number of harmonics excited in the sound spectra were investigated.

## MATERIALS AND METHODS

Silicone material of varying stiffness was hand-carved into laryngoplasty implants and used in this study (Table 1). For the stiffest silicone material, commercially available Silastic used for type 1 thyroplasty was obtained from the operating room at the University of California, Los Angeles. Two softer silicone implants were made by mixing a two-component liquid polymer solution (Ecoflex 0030; Smooth On, Inc., Easton, PA) with a silicone thinner solution, with a 1:1:0 and 1:1:2 ratio between the two components (components A and B) and the silicone thinner solution. The stiffness of the materials was measured using a validated microindentation system.<sup>20</sup> The Young moduli of the three materials were measured to be 1386 kPa (Silastic, implant 1), 60.6 kPa (silicone with ratio 1:1:0, implant 2), and 11 kPa (silicone with ratio 1:1:2, implant 3).

Adult human larynges were harvested from autopsy less than 48 hours postmortem and quick-frozen at  $-80^{\circ}\text{C}$ . One day before the experiment, the larynx was allowed to thaw overnight at  $-4^{\circ}\text{C}$ , and soaked in isotonic saline the morning of the experiment until completely thawed. The supraglottic structures were removed and one suture was placed between the mucosa of medial aspects of the arytenoids to prevent the vocal folds from completely separating with air flow. Rectangular laryngoplasty windows were then created bilaterally using an otologic drill. The inferior edge of the window was placed parallel to and 2 mm from the inferior border of the thyroid cartilage. The superior edge was placed at the level of the true vocal folds, which were about half-way between the thyroid notch and the inferior border of the thyroid cartilage. The anterior border was placed 5 mm posterolateral to midline, and the posterior edge was 10 mm posterolateral to the anterior edge.

Implants were then carved by the senior laryngologist (D.K.C.) into the shape presented in Figure 1. For each silicone implant material four implants were carved. First, two mirror-image implants with rectangular medial surface were carved (right and left) such that at full implant insertion the medial sur-

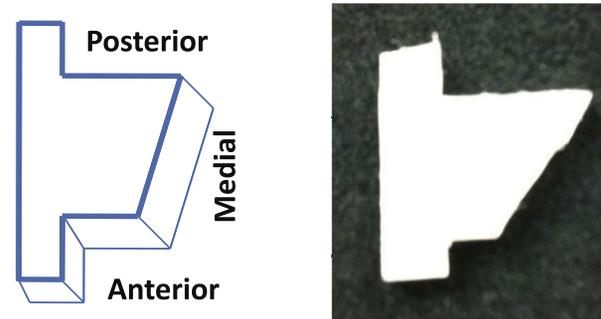


FIGURE 1. Shape of thyroplasty implants carved.

faces of both true vocal folds barely touched at glottal midline. Then two additional implants were carved of the same exact dimensions of the rectangular implants, but the medial surface was then beveled at an angle of  $30^{\circ}$  to create divergent implants. When these implants were switched to the contralateral side and flipped vertically, they became convergent implants of the exact dimensions. This was repeated for each implant material, thus a total of 12 implants were carved for each larynx.

An excised larynx phonation apparatus similar to that previously described was used.<sup>21</sup> Compressed air was passed through an upstream pressure valve and was heated to  $37^{\circ}\text{C}$  and humidified to 100% humidity before discharging into an expansion chamber (inner dimension of  $42 \times 42 \times 48$  cm). Downstream of this chamber was an outflow polyvinyl chloride pipe containing a pressure transducer and a microphone to measure subglottal pressure and acoustic pressure. The larynges were attached to this pipe at tracheal ring 3 with an O-ring with an air-tight seal. A restraining ring was then affixed to the cricoid cartilage of the larynx to prevent movement of the larynx. An external microphone was placed 12 inches from the larynx to record the radiated outside acoustic pressure. A high-speed camera was mounted above the larynx to record vocal fold vibration.

For each implant condition (three stiffness and three medial shapes), a flow-ramp phonation procedure as used in our previous studies was used.<sup>21,22</sup> The flow rate was slowly increased in increments. For each flow rate increase, after a delay of about 1–2 s, the mean flow rate, mean subglottal pressure, the subglottal and outside acoustic pressures were recorded. High-speed video of vocal fold vibration was recorded at the time of phonation onset and at another one to two above-onset subglottic pressures. As a baseline, the larynx was phonated first without any implants in place. Then with each type of implant stiffness and shape, the mirror-image (ie, bilateral divergent, convergent, rectangular) implants were placed bilaterally first at full insertion, then slightly retracted by 2 mm (measured by 2 mm shim and secured with a suture), and then retracted by 4 mm (measured by a 4 mm shim and secured with a suture).

With the aerodynamic data the pressure-flow relationship was examined for each implant condition. With the subglottic acoustic data, acoustic measures such as cepstral peak prominence (CPP), harmonic-to-noise ratio (HNR), H1-H2, and H2-H4 were extracted. To quantify high-order harmonic excitation, the number of harmonics (NumHarm) visible in the sound spectra up to 5 kHz was counted as described by Zhang et al<sup>23</sup>

TABLE 1.  
Implant and Experimental Conditions

Implant No.	I1	I2	I3
Material	Silastic 2	Silicone	Silicone
Young modulus (kPa)	1386	60	11
Larynges	1 (Male, 80 y old), 2 (Male, 59 y old)	1 (Male)	1 (Male), 2 (Male)

and normalized to calculate the harmonic excitation percentage (HEP):

$$\text{HEP} = \frac{\text{NumHarm}}{5000/F_0} \quad (1)$$

where  $F_0$  is the phonation fundamental frequency. Because either no consistent patterns or only small changes were observed regarding the effects of different implant conditions on CPP, H1-H2, and H2-H4, the following discussion on the acoustics focuses on the HNR and HEP.

## RESULTS

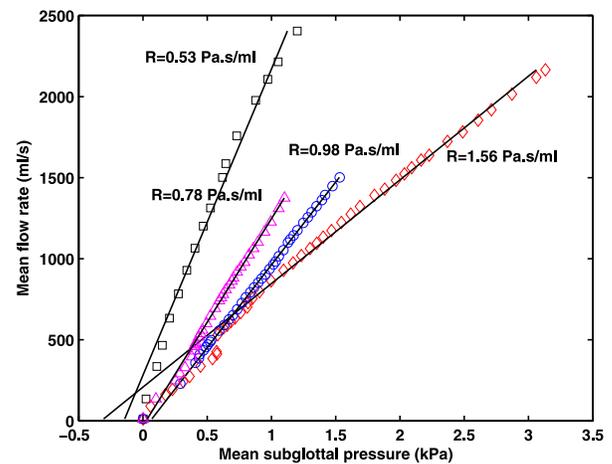
### Effects of medialization depth on pressure-flow relationship

Figure 2 illustrates the pressure-flow relationship changes at various depths of medialization (data presented for implant I1, larynx 1). Compared with the baseline condition without implant, insertion of implant reduced the mean flow rate for a given mean subglottal pressure. In other words, the implants increased the glottal resistance (Figure 3A), thus allowing the vocal folds to better maintain adductory position and glottal closure for a given subglottal pressure.<sup>21</sup> Although the glottal resistance is known to vary with the flow rate, in this study this variation was generally small except for very small flow rates. Thus, in this study, a linear curve fitting of the measured pressure-flow data was performed using data in the upper three quarter of flow rate range, and the glottal resistance was estimated as the slope of the linear curve fitting, as shown in Figure 2.

### Effects of implant stiffness and insertion depth on glottal resistance, phonation onset pressure, and acoustic parameters

Figure 3A shows the glottal resistance for conditions of different implant stiffness and insertion depth in larynx 1. All implants had rectangular medial surface shape. As expected, for the same implants, the glottal resistance decreased with decreasing insertion depth of the implant. The range of variations in glottal resistance across different insertion depths decreased with implant stiffness. The maximum increase in the glottal resistance was obtained with the stiffest implant (implant I1) at full insertion depth, and the minimum glottal resistance was also produced by this implant at minimum insertion depth. In contrast, softer implants (I2 and I3) increased the glottal resistance but the increase did not vary much with insertion depth. In other words, although all implants increased the glottal resistance, the amount of increase in glottal resistance was much less sensitive to the insertion depth for soft implants than for stiff implants. The soft implants were able to provide a modest but more or less uniform increase in glottal resistance across different insertion depths.

The effects of implant stiffness and insertion depth on the phonation threshold pressure ( $P_{th}$ ) and the phonation frequency ( $F_0$ ) are shown in Figure 3A and B, respectively. In general, the  $P_{th}$  and  $F_0$  followed similar trends as the glottal resistance, with their values decreasing with decreasing implant stiffness and insertion depth. Stiffer implants led to larger variations in



**FIGURE 2.** Pressure-flow relationships with thyroplasty implant I1 in an *ex vivo* human larynx. □, baseline condition without implants; ◇, implant at full insertion depth; ○, implant retracted 2 mm from full insertion depth; △, implant retracted 4 mm from full insertion depth. The solid lines represent linear curve fitting of the corresponding pressure-flow data points, from which the glottal resistance for each condition was calculated.

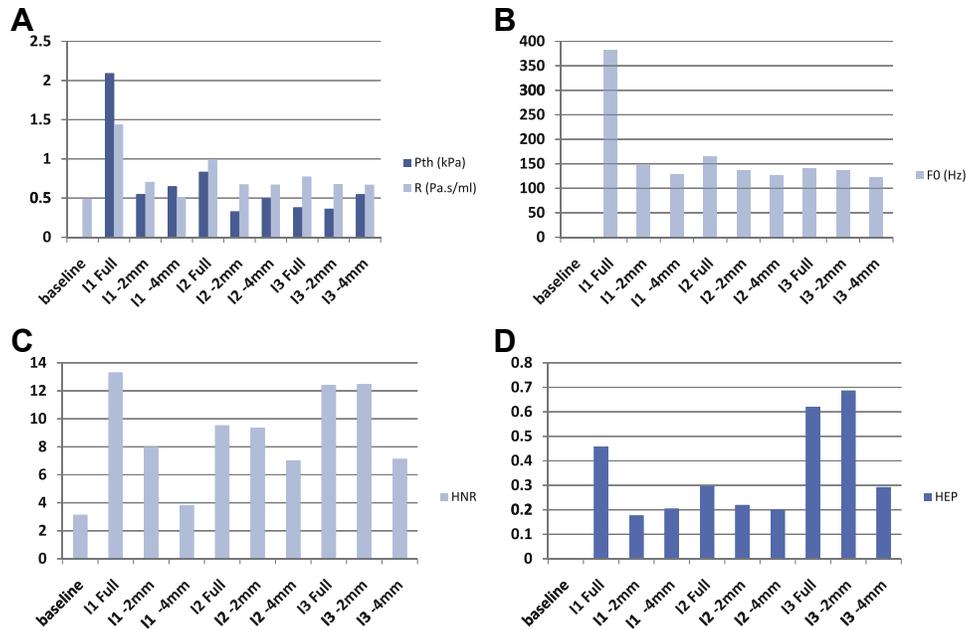
both  $P_{th}$  and  $F_0$  across different implant insertion depths, with the highest values in  $P_{th}$  and  $F_0$  obtained with the stiffest implant I1 at full insertion depth.

The effects of implant stiffness and insertion depth on the two acoustic measures (HNR and HEP) are shown in Figure 3C and D. In general, both the HNR and HEP increased with increasing insertion depth. Stiffer implants generally led to larger variations in HNR across different insertion depths compared with softer implants. For harmonic excitation (HEP), although similar trends regarding the effects of stiffness can be still observed (ie, stiffer implant I1 led to larger range of variation in HEP than for I2), the softest implant I3 led to the strongest harmonic excitation consistently across all three insertion depths. In fact, in this study, the best improvements in both HNR and HEP were obtained with the use of the softest implant I3.

To further quantify the effects of implant stiffness on the range of variations of different aerodynamic and acoustic measures, a test for equality of variances was performed for implants I1 and I2 across all nine conditions (three implant shapes and three insertion depths) for each implant. The stiff implant I1 showed significantly larger variance (across the nine different implant shapes and insertion depths) than the soft implant I2 in  $F_0$  ( $F(8,8) = 24.58$ ,  $P < 0.05$ ),  $P_{th}$  ( $F(8,8) = 4.84$ ,  $P < 0.05$ ), and HNR ( $F(8,8) = 13.21$ ,  $P < 0.05$ ). No significant difference in variance was found in HEP between implants I1 and I2.

### Effects of implant medial shape

Figures 4 and 5 show the aerodynamic and acoustic effects of implant medial shape for implants I1 and I2, respectively. In general, similar observations as previously mentioned can be made on the effects of implant insertion depth on the glottal resistance,  $P_{th}$ ,  $F_0$ , and acoustics, with all variables decreasing with decreasing insertion depth. The softer

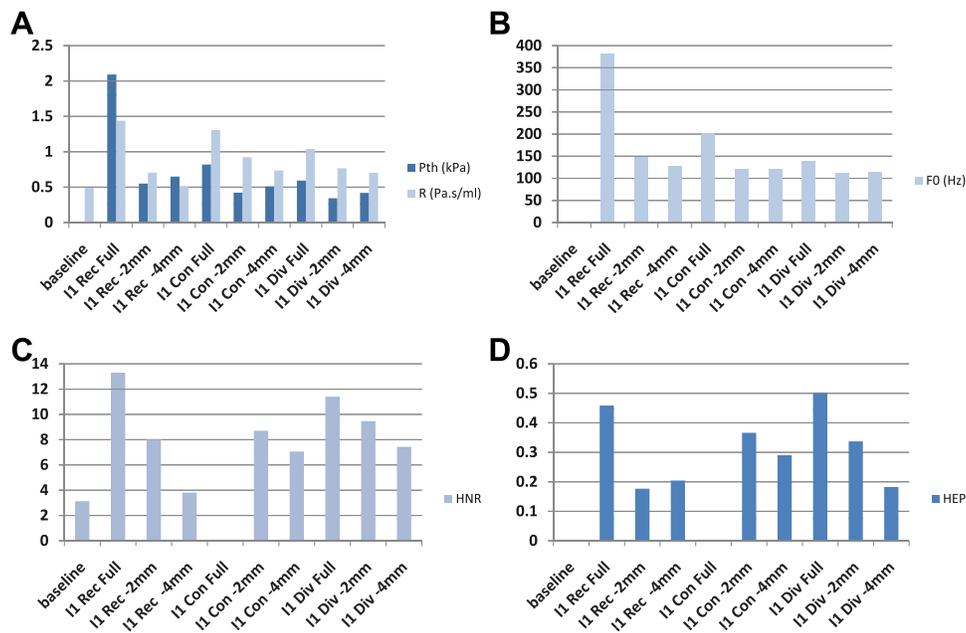


**FIGURE 3.** A. The glottal resistance  $R$  and phonation threshold pressure  $P_{th}$ . B. Phonation frequency  $F_0$ . C. HNR. D. HEP as a function of implant material and insertion depth. All implants had rectangular medial surface shape. Larynx 1.

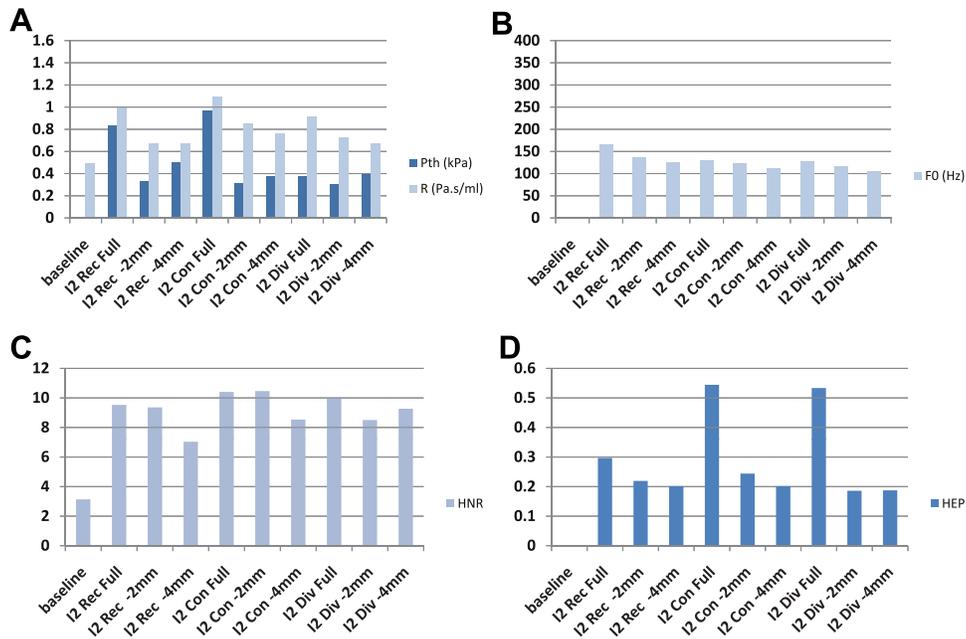
implant I2 produced generally more uniform improvement across different implant shape and insertion depths. There appeared to be some effects of the implant shape. For example, rectangular implants tended to have a larger effect on  $F_0$ , especially for stiffer implant, whereas nonrectangular implants appeared to be more effective in improving HNR and HEP. However, this effect seemed to be much smaller compared with that of the implant insertion depth and stiffness so that it was difficult to conclusively sort out the effects of implant shape.

#### Effects of glottal resistance

The similar trends between the glottal resistance and other aerodynamic and acoustic measures indicate that the glottal resistance may capture the combined effects of implant stiffness and insertion depth. Figure 6 shows the HNR and HEP as a function of the glottal resistance for all conditions of different implant stiffness, shape, and insertion depth. The HNR generally increased with increasing glottal resistance. For the harmonic excitation HEP, it also exhibited an increasing trend with increasing glottal resistance. However, there are two



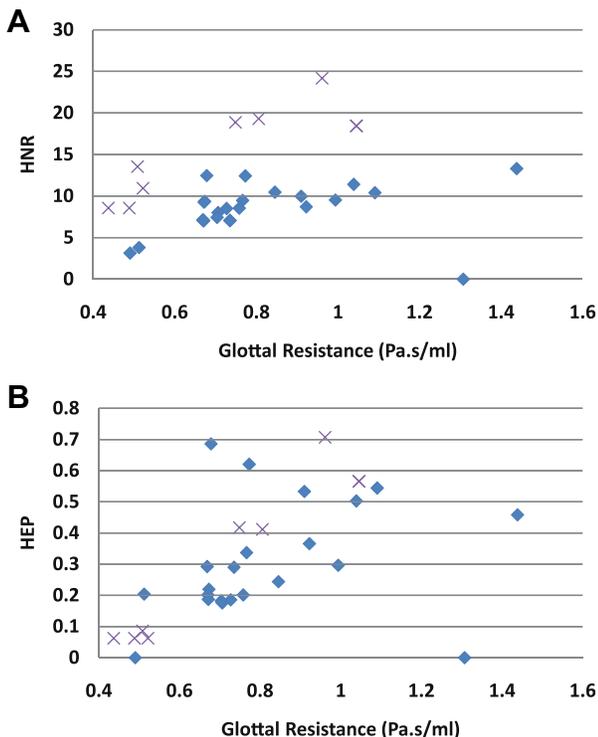
**FIGURE 4.** A. The glottal resistance  $R$  and phonation threshold pressure  $P_{th}$ . B. Phonation frequency  $F_0$ . C. HNR. D. HEP as a function of the implant shape and insertion depth. Implant 1 (I1) was used in all conditions. Rec, rectangular; Con, convergent; Div, divergent implant.



**FIGURE 5.** A. The glottal resistance  $R$  and phonation threshold pressure  $P_{th}$ . B. Phonation frequency  $F_0$ . C. HNR. D. HEP as a function of the implant shape and insertion depth. Implant 2 (I2) was used in all conditions. Rec, rectangular; Con, convergent; Div, divergent implant.

regions of outliers. These two regions corresponded to two conditions of the softest implant I3 (around  $r = 0.7 \text{ Pa}\cdot\text{s/mL}$ ), which had strong harmonic excitation, and one condition with the stiffest implant I1 with a convergent shape at full insertion (around  $r = 1.3 \text{ Pa}\cdot\text{s/mL}$ ), at which vocal fold vibration was pressed and limited to a small anterior region.

Figure 6 also shows the HNR and HEP data as a function of the glottal resistance from larynx 2 ( $\times$  symbols) with implants I1 and I3. Similar observations can be made, with both the HNR and HEP increasing with the glottal resistance and gradually reaching a plateau. It is interesting that both larynges produced optimal HNR and HEP values for glottal resistances around 0.8–1.1.



**FIGURE 6.** A. HNR. B. HEP as a function of the glottal resistance.  $\diamond$ , Larynx 1 with implants 1–3;  $\times$ , Larynx 2 with implants 1 and 3.

**DISCUSSION**

One of the goals of medialization laryngoplasty is medialization of the vocal folds toward the glottal midline. This study showed that, when medialization was achieved (as quantified by the increase in glottal resistance), the use of implants was able to increase both HNR and high-order harmonic excitation, similar to our previous findings.<sup>21</sup> The amount of changes (most likely improvements) depended on implant insertion depth and implant stiffness, and to a lesser degree on implant shape.

An important finding of this study was that, for stiff implants, voice production was very sensitive to the implant insertion depth so that a large variation in acoustic outcomes can be observed depending on the exact implant insertion depth. For example, for the stiffest implant (implant 1) of this study, its full insertion significantly increased both  $F_0$  (increased from 150 Hz to 350 Hz) and  $P_{th}$ . Phonation was also more likely to exhibit nonmodal vibration patterns such as subharmonics and frequency jumps. Such high sensitivity indicates high precision is required in inserting and securing the stiff implants during medialization laryngoplasty surgery, which may not be desirable. In contrast, for soft implants (I2 and I3), the implant insertion depth was much less critical in determining the acoustic outcomes, and the acoustic outcomes are thus relatively easier to control with the use of soft implants. Soft implants

in this study also led to strong high-order harmonic excitation. Although the underlying mechanisms are unclear, it is possible that, with Young modulus comparable to that of the vocal folds, the soft implants can easily mold to the shape of its surrounding tissue so that the specific implant shape and insertion depth did not matter much. Future studies are required to better understand the underlying mechanisms.

This study also showed that a very high glottal resistance suppressed harmonic excitation in the acoustic spectra. High-speed recordings of vocal fold vibration at this condition showed that the vocal folds were pressed tightly against each other so that either no phonation was observed or phonation occurred but with a very small open quotient. This suggests that an optimal range may exist for which optimal improvement in acoustic outcomes, at least measured by HNR and HEP, can be obtained. Beyond this range, either too low (no restraining<sup>21</sup>) or too high (too strong restraining) glottal resistance would lead to reduced number of harmonics excited in the acoustic spectra. Similar optimal range of phonation has been observed before by Nasri et al<sup>24</sup> for vocal efficiency as a function of increasing recurrent laryngeal nerve stimulation in an *in vivo* canine larynx model.

Limitations of our study are that the experiments were performed bilaterally in an *ex vivo* model. Although bilateral implants are sometimes performed for presbylaryngis, the most common indication for medialization laryngoplasty is unilateral vocal fold paralysis or paresis. An *in vivo* physiologic model with contraction of the contralateral vocal fold may be more ideal and more applicable to the common use of the procedure. Future directions of the study include performing similar procedures unilaterally in an *in vivo* animal or human model of vocal fold paralysis to achieve more clinically applicable data.<sup>25</sup>

## CONCLUSIONS

Use of all silicone implants led to increased excitation of high-order harmonics in the acoustic spectra (as measured by HEP) and increased HNR. The amount of changes (most likely improvements) depended on implant insertion depth and implant stiffness, and to a lesser degree on implant shape. The results also showed that voice production with soft implants was much less sensitive to implant insertion depth and generally had strong high-order harmonic excitation in the acoustic spectra. As a result, soft implants were able to produce relatively consistent acoustic improvement across different implant conditions.

## Acknowledgments

The authors are grateful to Dr. Jody Kreiman for assistance on the statistical analysis and Dr. Yue Xuan for assistance with experiments.

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