Comparison of the use of silastic with titanium prefabricated implant in type I thyroplasty

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Abstract
Introduction: Type I thyroplasty is the treatment of choice for unilateral vocal cord palsy with no spontaneous recovery.
Objectives: To compare the use of silastic implant with titanium vocal fold medializing implant (TVFMI®) in type I thyroplasty for unilateral vocal cord palsy with respect to subjective and objective improvement in voice, endoscopic changes in vocal cords, surgical time, and cost effectiveness.
Methodology: This was a prospective study conducted on 40 patients with unilateral vocal cord paralysis who underwent type I thyroplasty with either silastic implant or TVFMI®. Pre-operative and four-week post-operative assessment and statistical comparison were performed by videolaryngoscopy, stroboscopy, perceptual assessment (GRBAS), subjective (voice handicap index) analysis of voice, and computer-assisted acoustic and electroglottographic assessment. The duration of surgery and cost of implant were also recorded.
Results: Although both implants showed improvement in quality of voice following thyroplasty, TVFMI® presents slightly better results in objective voice analysis. The surgery time for TVFMI® insertion was shorter, but the costs were higher.
Conclusion: TVFMI® may be preferred for medialization thyroplasty as it presents better voice results and demands less surgical time; however, it is costlier than silastic implant.

Keywords
Vocal cord paralysis; Voice quality; Cost-efficiency analysis

PALAVRAS-CHAVE
Paralisia das cordas vocais; Qualidade da voz; Análise de custo-benefício

Comparação do uso de implante de Silastic® com titânio pré-fabricado na tireoplastia tipo I

Resumo
Introdução: A tireoplastia tipo I é o tratamento de escolha nas paralisias unilaterais das pregas vocais que não se recuperam espontaneamente.
Objetivos: Comparar o uso de implante de Silastic® com o uso de titânio pré-fabricado TVFMI® (Titanium Vocal Fold Medializing Implant) na tireoplastia tipo I para o tratamento da paralisia unilateral das pregas vocais com relação à melhora subjetiva e objetiva da voz, às alterações endoscópicas nas pregas vocais, ao tempo de cirurgia e à relação custo-benefício.
Método: Trata-se de um estudo prospectivo com 40 pacientes portadores de paralisia unilateral das pregas vocais submetidas à tireoplastia tipo I com implante de silastic® ou TVFMI®. A avaliação e comparação estatística foram realizadas antes e quatro semanas depois da cirurgia por

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meio de videolaringoscopia, estroboscopia, análise perceptiva (escala GRBAS-Grade, Roughness, Breathiness, Asthenia, Strain) e subjetiva (IDV-índice de desvantagem vocal) da voz e avaliação eletroglotográfica e avaliação acústica computadorizada. Também foram observados o tempo de cirurgia e o custo do implante.

Resultados: Embora os dois implantes mostrem melhora na qualidade da voz após a tireoplastia, o TVFMI® teve um resultado ligeiramente melhor na análise objetiva da voz. O TVFMI® levou menos tempo de cirurgia para ser inserido, porém foi mais caro.

Conclusão: O TVFMI® poderá ser preferencial na tireoplastia de medialização, já que possui melhores resultados vocais e leva menos tempo de cirurgia, porém é mais caro que o implante de Silastic®.

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Surgery duration varied according to the type of implant being inserted. In cases where conventional silastic implant was used, average surgery duration was 85.05 min. In cases where TVFMI® was inserted, surgery duration was much shorter, 49.5 minutes.

Each TVFMI® implant cost $330. In cases where TVFMI® was inserted, an additional instrument, the moulding pliers, were required. They were a one-time investment of $215. The cost of the silastic block used in each surgery was $38.

Videolaryngoscopic and stroboscopic assessment demonstrated a reduction in glottic gap at the time of adduction in all cases except for one, with apposition of both vocal cords in the mid-line. There was only one case who underwent medialization with silastic implant and did not achieve complete closure of glottic gap. Mucosal wave pattern was not observed in any of the cases pre-operatively; post-operatively, it was present in 14 and 16 patients undergoing insertion of silastic implant and TVFMI®, respectively.

Table 1 shows the pre-operative and four weeks post-operative mean values of various parameters (VHI, GRBAS, acoustic analysis, and EGG) for patients with silastic implant or TVFMI®. p-values less than 0.05 were considered to be significant (95% confidence interval).

Discussion

Unilateral vocal cord paralysis is generally observed on left side, with the ratio of left to right ranging from 3 to 4:1.2 Unilateral vocal cord paralysis can present as hoarse voice, vocal fatigue, dysphagia, decreased pitch, decreased loudness, and aspiration. The severity of these symptoms depends on the position of the paralysed cord.3 Various techniques have been developed to reduce the glottic gap, such as injection thyroplasty and medialization thyroplasty. Payr described an external medialization technique in 1915. In 1978, Isshiki revolutionized the surgical treatment for unilateral vocal cord paralysis by using silastic implant for medialization of the paralysed cord.4,5 Based on the basic principles given by Isshiki, several modifications have been introduced. Over the years, the shape of silastic implant has been modified, and different materials were used, such as Gore-tex, Vo Com, and titanium, among others. Currently, individually-fitted implants based on computed tomographic (CT) images have been developed for use in medialization thyroplasty.6

As in other studies,2 the present study also observed that most of the cases were of unilateral vocal cord palsy; 25% were due to malignancies of head and neck, followed by surgical trauma, 12%. These are comparable to the documented percentages in other studies; patients with malignancies constitute 25% of the cases with unilateral vocal cord palsy, the same as that of the present study. Non-surgical trauma has been shown to contribute 15% of the cases, which is also similar to the present study. Literature reports inflammatory causes as responsible for 5% of cases; in the present study, this rate was 10%. This was perhaps due to the higher number of chronic infective diseases observed in the Indian study. 8% of patients were of non-surgical trauma in the present study. In 45%, no cause could be identified, and they were labelled as idiopathic; this high percentage could again be due to higher number of infective (viral) pathologies in the present study.

The average surgery duration was 85.05 minutes for silastic implant and 49.5 minutes for TVFMI®. One study reported surgery durations of 65 minutes for silastic implant and 49.5 minutes for TVFMI®.
Table 1 Pre-operative and post-operative mean values of various parameters studied, and comparison of improvement between silastic implants and titanium vocal fold medializing implant (TVFMI®) (n = 40).

<table>
<thead>
<tr>
<th>S. N</th>
<th>Parameter</th>
<th>Pre-operative mean value</th>
<th>Post-operative mean value</th>
<th>p-value</th>
<th>Pre-operative mean value</th>
<th>Post-operative mean value</th>
<th>p-value</th>
<th>Difference between silastic implant / TVFMI®</th>
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<tr>
<td>1</td>
<td>VHI</td>
<td>84.7</td>
<td>23.4</td>
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<td>83.8</td>
<td>23.05</td>
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</tr>
<tr>
<td>2</td>
<td>G</td>
<td>1.75</td>
<td>0.9</td>
<td>0.001</td>
<td>2</td>
<td>0.8</td>
<td>0.000</td>
<td>No statistical difference</td>
</tr>
<tr>
<td>3</td>
<td>R</td>
<td>0.75</td>
<td>0.35</td>
<td>0.072</td>
<td>1</td>
<td>0.2</td>
<td>0.001</td>
<td>No statistical difference</td>
</tr>
<tr>
<td>4</td>
<td>B</td>
<td>0.5</td>
<td>0.05</td>
<td>0.040</td>
<td>0.65</td>
<td>0.15</td>
<td>0.029</td>
<td>No statistical difference</td>
</tr>
<tr>
<td>5</td>
<td>A</td>
<td>0.4</td>
<td>0</td>
<td>0.017</td>
<td>0.75</td>
<td>0</td>
<td>0.001</td>
<td>No statistical difference</td>
</tr>
<tr>
<td>6</td>
<td>S</td>
<td>1.45</td>
<td>0.1</td>
<td>0.000</td>
<td>1.55</td>
<td>0.75</td>
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ACOUSTIC ANALYSIS

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<tr>
<th>7</th>
<th>F0</th>
<th>205.44</th>
<th>207.28</th>
<th>0.840</th>
<th>134.08</th>
<th>160.21</th>
<th>0.001</th>
<th>No statistical difference</th>
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<tr>
<td>8</td>
<td>Shimmer</td>
<td>6.94</td>
<td>3.07</td>
<td>0.002</td>
<td>8.6</td>
<td>2.88</td>
<td>0.000</td>
<td>TVFMI® better</td>
</tr>
<tr>
<td>9</td>
<td>Jitter</td>
<td>1.84</td>
<td>0.49</td>
<td>0.004</td>
<td>2.33</td>
<td>0.377</td>
<td>0.000</td>
<td>Silastic implant better</td>
</tr>
<tr>
<td>10</td>
<td>MPT</td>
<td>2.55</td>
<td>6.45</td>
<td>0.000</td>
<td>2.6</td>
<td>6.85</td>
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<tr>
<td>11</td>
<td>HNR</td>
<td>15.49</td>
<td>22.27</td>
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<td>12.052</td>
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</tr>
<tr>
<td>12</td>
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<td>-4.46</td>
<td>-8.78</td>
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<td>-3.018</td>
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EEG

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<tr>
<th>13</th>
<th>F0</th>
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<tr>
<td>14</td>
<td>Shimmer</td>
<td>8.94</td>
<td>3.23</td>
<td>0.002</td>
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<td>1.76</td>
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<tr>
<td>15</td>
<td>Jitter</td>
<td>1.89</td>
<td>0.61</td>
<td>0.001</td>
<td>2.016</td>
<td>0.48</td>
<td>0.000</td>
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</tr>
<tr>
<td>16</td>
<td>HNR</td>
<td>15.22</td>
<td>24.06</td>
<td>0.010</td>
<td>16.12</td>
<td>29.32</td>
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<tr>
<td>17</td>
<td>NNE</td>
<td>-12.29</td>
<td>-17.16</td>
<td>0.042</td>
<td>-13.63</td>
<td>-25.01</td>
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<td>CQ</td>
<td>67.34</td>
<td>66.08</td>
<td>0.725</td>
<td>70.33</td>
<td>96.67</td>
<td>0.390</td>
<td>No statistical difference</td>
</tr>
<tr>
<td>19</td>
<td>CQP</td>
<td>6.95</td>
<td>6.65</td>
<td>0.915</td>
<td>8.29</td>
<td>4.4</td>
<td>0.168</td>
<td>No statistical difference</td>
</tr>
</tbody>
</table>

and 55 minutes for TVFMI®. Other studies also reported shorter surgery times for TVFMI®. TVFMI® is pre-moulded, so that only its posterior limb needs to be adjusted, and it has been shown to be easier to insert and fix, thus reducing the operative time. The present study used time compared to other studies in cases where silastic implant was inserted, because the silastic implant was moulded at the time of surgery. Keeping the silastic block pre-moulded may reduce the surgical time, as observed in other studies. TVFMI® is costlier than silastic implant and also requires a specialized tool (bending pliers) for insertion.

The improvement in quality of life scales, such as VHI, was observed in various studies. In the present study, a statistically significant post-operative improvement in VHI was observed with both silastic implant and TVFMI®. No statistically significant difference was observed between the improvements in the score of the two implants. Several studies have found the improvement in VHI to be a good indicator of voice improvement.

GRBAS scale showed improvement. Breathiness, asthenia, and strain in voice were reduced, but roughness persisted post-operatively. Improvement in mean roughness score in patients treated with silastic implant was not found to be significant. Overall, the voice grading improved with surgery. Other studies have shown similar improvement in the perceptual scores post-operatively, even though the voice may still be rough and hoarse.

Endoscopic evaluation of vocal cord movement is an important tool. On videolaryngoscopic and stroboscopic examination, the glottic gap was found to be reduced in all but one case who underwent type I thyroplasty with silastic implant. This was a case of idiopathic vocal cord palsy. During intra-operative fibreoptic laryngoscopic assessment, the glottic closure was found to be adequate; however, at follow-up, vocal cord atrophy was observed and the glottic gap reappeared. Mucosal wave pattern was not observed in any of the cases pre-operatively; post-operatively, it was present in 14 and 16 patients undergoing insertion of silastic implant and TVFMI® respectively. Due to better glottic closure, the patients had a better voice quality and could also...
cough more effectively. Glottic gap closure was found to be reduced in 93% to 100% of cases following type I thyroplasty.\(^7\text{,}\text{10}\) Storck et al. observed that TVFMI\(^\circ\) pushes the entire cord medially, and hence gives better results.

In the acoustic analysis and electroglottography, shimmer and jitter were reduced; maximum phonation time increased substantially, allowing patients to speak without voice breaks. HNR and NNE also improved, thus the hoarseness of voice decreased. There was improvement in the contact quotient of the vocal cords, and its perturbation decreased. The overall result was improved voice quality, as observed in several other studies.\(^7\text{–}\text{10}\) Jitter and shimmer percentage have been reported to improve after TVFMI\(^\circ\) insertion from 7.15 to 3.58 and from 27.8 to 13.69, respectively.\(^8\) Other studies have also observed statistically significant improvements in jitter and shimmer.

On objective testing, TVFMI\(^\circ\) presented superior results to silastic implant regarding to the following parameters: shimmer (acoustic and EGG) and F0 (EGG). Considering all the parameters, TVFMI\(^\circ\) was better than silastic implant in only three. Better outcome with TVFMI\(^\circ\) in these objective parameters may have been due to the case who had inadequate glottic closure with silastic implant. In VHI, perceptual rating of voice with GRBAS, and acoustic analysis and electroglottography, the voice improvement was statistically similar with both types of implants. The medialization of vocal cords was adequate in both types of implants, and the glottic gap was adequately reduced in both. Other studies have observed that TVFMI\(^\circ\) presented a better voice outcome and shorter surgical duration.\(^7\text{–}\text{10}\) In the present study, the voice outcomes were similar between TVFMI\(^\circ\) and silastic implant, except for the few abovementioned objective parameters. The case that presented inadequate glottic closure with silastic implant may have been responsible for a slight bias in objective parameters towards TVFMI\(^\circ\).

### Conclusion

This study has demonstrated that, in cases of unilateral vocal cord palsy, there is a subjective improvement following type I thyroplasty using both silastic and TVFMI\(^\circ\) implants (VHI and GRBAS). Videolaryngoscopy and stroboscopy demonstrated a reduction in glottic gap in all cases but one after surgery. TVFMI\(^\circ\) presented slightly better result in objective voice analysis, but the impact of the case with persistent glottic gap after medialization with silastic implant should be taken into consideration. Type I thyroplasty with TVFMI\(^\circ\) is faster, but more expensive.

### Conflicts of interest

The authors declare no conflicts of interest.

### References

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