

## Bioplastique™ injection laryngoplasty: voice performance outcome

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### Abstract

**Aim:** To compare voice performance following Bioplastique™ injection with that following Isshiki thyroplasty.

**Measures:** A 12 item, self-reported voice performance questionnaire was completed and observer-rated perceptual voice analysis scores were also measured, before and after Bioplastique injection, for 14 patients. Results were compared with our previously reported outcomes for 28 thyroplasty patients.

**Results:** Only 14 of 30 patients had complete datasets. For these patients, the mean pre-operative voice performance questionnaire score improved significantly, from 40.3 to 18.9 ( $p = 0.002$ , Wilcoxon test). All perceptual analysis parameters showed significant improvement. These results compare favourably with the thyroplasty cohort (mean voice performance questionnaire score: pre-operative 35; post-operative 18;  $p < 0.001$ ). One Bioplastique patient developed contralateral paresis, requiring partial removal of the material 18 months later. Two thyroplasty patients experienced complications and three required revision.

**Conclusions:** Both Bioplastique injection and Isshiki thyroplasty resulted in a significant improvement in both subjective and perceptual voice performance. Our data suggest that the effect size of the two interventions is approximately similar (in nonrandomised cohorts of surviving patients). As in many similar studies, the incomplete follow-up data reflect severe comorbidity. Bioplastique injection is a quicker procedure associated with fewer complications, and thus appears superior to framework surgery in patients with limited life expectancy.

**Key words:** Bioplastique™; Vocal Cord Palsy; Isshiki Thyroplasty; Voice Performance Questionnaire

### Introduction

Unilateral vocal fold palsy results in a weak, breathy voice. It arises from damage to the recurrent laryngeal nerve, resulting in a permanently abducted vocal fold on the affected side. The damage may be due to surgery (e.g. thyroidectomy or oesophagectomy) but most commonly is due to a malignant process (e.g. lung carcinoma). Therefore, the majority of patients have a terminal condition and a short life expectancy. Treatment options aim to medialise the affected vocal fold, and the techniques available include injection laryngoplasty, Isshiki type one thyroplasty, arytenoid adduction and speech therapy.

In the 1950s, Arnold popularised the practice of biological tissue injection, using cartilage and bone dust.<sup>1</sup> Lack of stable, well tolerated, injectable materials has led to the Isshiki type one thyroplasty<sup>2</sup> becoming the 'gold standard' procedure for vocal fold medialisation, against which other treatments are compared.

Bioplastique™ (Uroplasty, Geleen, Netherlands) is a mixture of low molecular weight polyvinylpyrrolidone and solid polymer particles, which has been available in Europe since the 1990s. There are only a handful of reports of Bioplastique being used in vocal fold medialisation.<sup>3,4</sup> No notable side effects have been published to date, either for voice surgery or for other indications such as cosmetic or vesicoureteric surgery.

The purpose of this study was to retrospectively assess the impact of Bioplastique injection for vocal fold palsy on subjective and objective voice performance, and then to compare these results with our previously published data for Isshiki thyroplasty.<sup>5</sup>

### Methods

Patients who had been treated for unilateral vocal fold palsy with Bioplastique injection laryngoplasty, between January 2003 and August 2005, were

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included in this retrospective study. The Bioplastique injection initially involved an in-patient stay, but more recently had been performed as a day case.

At a pre-operative and a post-operative outpatient clinic appointment, a voice recording was taken and a voice performance questionnaire was completed by the patient. The voice performance questionnaire was a validated, 12 item, 60 point questionnaire designed to score the patient's own perception of their voice.<sup>6</sup> It used an answer format whereby the patient selects the statement which best answers the question. Each answer is then awarded a score between one and five, and these are summed to produce a total score out of 60. The higher the severity of the voice disorder, the higher the score. One expert judge then listened to the pre- and post-operative voice recordings of the patients and rated them for grade, roughness, breathiness, asthenia and strain.

All injections were performed by the same surgeon (Figure 1). The injection was directed just lateral to the conus elasticus, avoiding creation of a subglottic shelf and extrusion into the lamina propria, as the former can cause post-operative dyspnoea and the

latter may interrupt the very mucosal wave the treatment aims to preserve. Typically, three puncture sites were used.

Data were analysed using the Wilcoxon matched pairs signed rank tests, and a  $p$  value of  $<0.05$  was considered significant. The results were then compared with our previously reported outcomes for 28 thyroplasty patients, obtained in 2000.<sup>5</sup> Non-parametric tests were used to allow comparability with the statistical methods employed in our previous report.

## Results

Twenty-seven patients underwent Bioplastique injection over a two year period. Fourteen of these had sufficiently adequate pre- and post-operative data to be included in the study. There were eight women and six men, aged between 52 and 79 years. The vocal fold palsy was due to lung cancer (six patients), surgery (three patients) and other causes (five patients). Thirteen patients are not reported here as they did not have voice performance questionnaire scores or voice recordings from both before and after the operation. Those patients with limited pre-operative data available did however demonstrate comparable diagnoses and initial voice scores to those included in the study. The limited data available also demonstrated improvement following the injection. Two patients recorded low post-operative voice performance questionnaire scores (17 and 22), and for one patient an improvement was recorded in the clinic notes.

### *Voice performance questionnaire score*

All of the 11 patients with complete voice performance questionnaire data available had a better post-operative than pre-operative score, with the median voice performance questionnaire score improving by 26. The remaining two patients with no voice performance questionnaire data available showed an improved voice in terms of grade, roughness, breathiness, asthenia and strain. The thyroplasty cohort demonstrated similar results, with a median score improvement of 17 (Table I).

### *Voice grade, roughness, breathiness, asthenia and strain*

There was an improvement in all parts of the above scoring system for both Bioplastique injection and thyroplasty patients, with the most notable increases being in grade and breathiness of the voice (Table I).

### *Complications*

*Bioplastique.* There were no complications for patients in the Bioplastique cohort. However, there were two complications in patients who received the injection but had insufficient data to be included in the study. There was one instance of over-injection, in the first patient injected. This was due to what, in hindsight, was inappropriate use of a second vial. Some injected material was later required to be removed (via a lateral cordotomy)

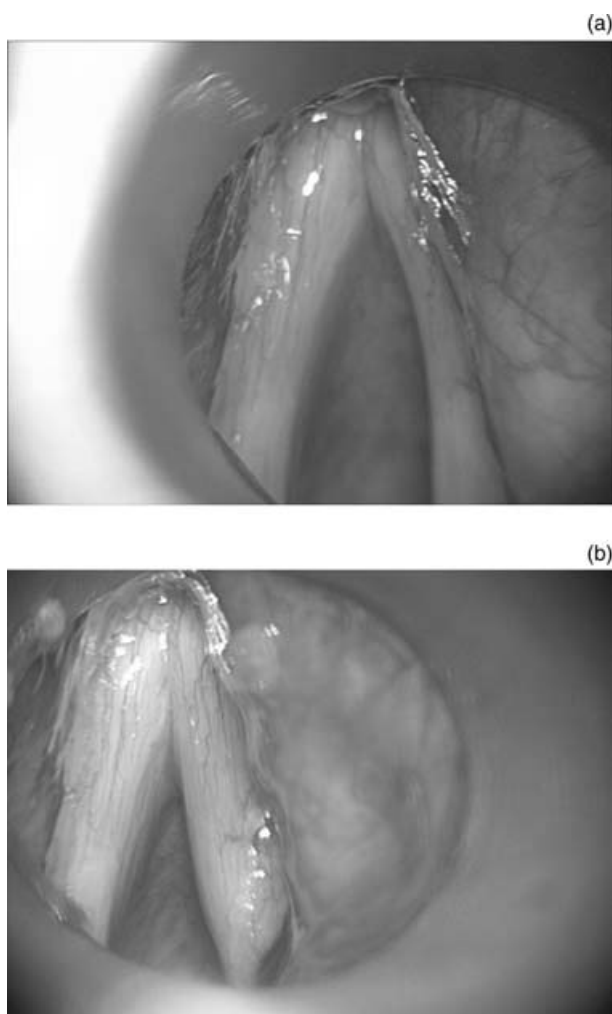


FIG. 1

(a) Pre-injection, intra-operative view of paralysed right vocal fold. (b) Appearance following Bioplastique™ injection.

TABLE I

BIOPLASTIQUE™ INJECTION LARYNGOPLASTY VS ISSHIKI TYPE 1 THYROPLASTY FOR UNILATERAL VOCAL FOLD PALSY: OUTCOMES

|  | Bioplastique injection laryngoplasty |                |            | Isshiki type 1 thyroplasty |                  |            |
|--|--------------------------------------|----------------|------------|----------------------------|------------------|------------|
|  | Pre-op score                         | Post-op score  | <i>p</i> * | Pre-op score               | Post-op score    | <i>p</i> * |
| <i>Subjective outcome measure</i> <sup>†</sup><br>( <i>n</i> = 11) |                                      |                |            |                            |                  |            |
| Voice performance questionnaire                                    | 43 (34.1–46.5)                       | 17 (14.8–23.0) | 0.002      | 35.0 (32.0–42.0)           | 18.0 (15.0–20.0) | <0.001     |
| <i>Perceptual analysis</i> <sup>‡</sup> ( <i>n</i> = 13)           |                                      |                |            |                            |                  |            |
| Grade  | 2.0 (1.9–2.7)                        | 1.0 (0.6–1.2)  | 0.0001     | 3.4 (3.0–4.0)              | 1.4 (1.0–2.8)    | <0.0001    |
| Roughness  | 1.0 (0.7–1.7)                        | 0.0 (0.0–0.6)  | 0.013      | 2.0 (1.0–3.0)              | 1.0 (0.4–1.0)    | 0.0027     |
| Breathiness  | 2.0 (1.9–2.7)                        | 1.0 (0.4–1.2)  | 0.001      | 2.8 (2.0–3.6)              | 1.0 (0.2–2.0)    | 0.0003     |
| Aesthesia  | 2.0 (1.3–2.3)                        | 1.0 (0.3–1.1)  | 0.001      | 0.0 (0.0–1.0)              | 0.0 (0.0–0.6)    | 0.85       |
| Strain   | 1.0 (0.5–1.5)                        | 1.0 (0.0–0.6)  | 0.014      | 1.9 (1.0–2.2)              | 0.6 (0.0–1.0)    | 0.0001     |

\*Paired Wilcoxon test. †Median (96.5% confidence interval). ‡Median (97.3% confidence interval). Pre-op = pre-operative; post-op = post-operative

when the patient's breast cancer also caused a contralateral paresis. We now advise use of only one vial of Bioplastique at a single sitting. One other patient had a short episode of laryngospasm on the day of discharge, which resolved with steroid therapy, extending the patient's hospital stay by one additional night.

**Thyroplasty.** In the thyroplasty cohort, two patients experienced post-operative complications. One patient developed a self-limiting stridor, and one developed an aspiration pneumonia. Three underwent revision of the procedure after several months due to poor initial results, with acceptable subsequent outcome.

## Discussion

In the present study, Bioplastique injection laryngoplasty resulted in significant improvement in voice outcome, with the average voice performance questionnaire score improving from 40.3 to 18.9 ( $p = 0.002$ ), an effect size of more than two. Bioplastique injection laryngoplasty also resulted in voice improvement in terms of the grade, roughness, breathiness, asthenia and strain scoring system, most markedly in grade and breathiness. Bioplastique had a lower complication rate than thyroplasty, with one Bioplastique patient requiring removal of the polymer, as compared with two thyroplasty patients experiencing complications, including three revisions. Therefore, Bioplastique was shown to improve not only observer-rated but also self-reported voice scores. The voice performance questionnaire is very well validated, brief and internally consistent.<sup>6,7</sup> It examines both the physical symptoms and the socio-economic impact of the disorder.

These results are in accordance with those of Alves *et al.*, who assessed the effect of Bioplastique injection on quality of life in a group of 16 terminally ill patients.<sup>4</sup> In this study, Bioplastique injection was again found significantly to improve both subjective and objective scores. Most importantly, these authors found that Bioplastique injection improved the quality of life of their patients, as measured by the Short Form General Health Survey questionnaire

(SF-36).<sup>4</sup> Vocal fold paralysis has been shown to affect quality of life in patients more than any other voice problem.<sup>8</sup> Duruisseau *et al.*<sup>9</sup> assessed a series of 19 cases of unilateral vocal fold paralysis, and found that 95 per cent of patients had a satisfactory outcome from an injection procedure, which was also noted to reduce the incidence of swallowing disorders. These changes were stable over time, the average follow up of their patients being 25 months. Furthermore, follow-up computed tomography scans on 10 patients showed that there was no diffusion of the implant into the paraglottic space or the subglottis.<sup>9</sup>

- **Unilateral vocal fold palsy results in a weak, breathy voice and commonly occurs in patients with significant co-morbidity**
- **Bioplastique™ injection laryngoplasty is a quick and effective method of treating vocal fold palsy, improving both subjective and objective voice outcome measures**
- **Bioplastique injection laryngoplasty has a similar voice performance outcome to Isshiki thyroplasty**

Materials for injection laryngoplasty should have a number of characteristics in order to be effective. They should be easily injectable, biocompatible and resistant to absorption. Bioplastique injection causes minimal local reaction, with no evidence of distant migration, as the injection creates an encapsulated, fibrous sheath.<sup>10,11</sup> Duruisseau *et al.* also reported that, during videostroboscopic examination, Bioplastique injection did little or nothing to alter the structure of the mucosa of Reinke's space, suggesting that there was no detrimental effect on the mucosa of the vocal fold,<sup>9</sup> a property thought to be confined to Isshiki thyroplasty.<sup>12</sup>

Teflon<sup>®</sup> injection laryngoplasty lost popularity due to local tissue inflammatory reaction and long term granuloma formation.<sup>13</sup> Autologous fat injection was also found to be reabsorbed and therefore not permanent.<sup>14</sup> Bioplastique is not reabsorbed,

and therefore it should be reserved for those patients in whom no improvement in vocal fold function is expected.

Tolerance of the injection seems to be good. It was not investigated directly in the present study; however, Hirano *et al.* reported that silicone injection laryngoplasty was well accepted, even by those who initially refused injection laryngoplasty.<sup>15</sup>

**Conclusion**

Bioplastique injection is an effective procedure for the management of unilateral vocal fold paralysis. It produces significant improvement in both patient-reported outcomes and perceptual analyses. By comparing with our previously published data regarding Isshiki type one thyroplasty, we found that Bioplastique injection had a comparably good outcome and was associated with fewer side effects and less need for revision procedures. Due to these encouraging results, the senior author now uses Bioplastique injection as a first line treatment. We recommend that Bioplastique injection be considered in all patients with vocal fold paralysis as a safe, quick and very effective method of improving voice quality.

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