

# Collagen injection for vocal cord augmentation

Interventional procedures guidance

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[nice.org.uk/guidance/ipg130](https://www.nice.org.uk/guidance/ipg130)

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

## 1 Guidance

- 1.1 Current evidence on collagen injection for vocal cord augmentation suggests that there are no major safety concerns and that it is efficacious in patients requiring short-term symptom relief. However, evidence on long-term efficacy is lacking.

- 1.2 Patients should be fully informed of the uncertainty about the procedure's long-term efficacy, and of the alternative treatment options. Use of the Institute's [information for the public](#) is recommended.

## 2 The procedure

### 2.1 *Indications*

- 2.1.1 Glottic insufficiency, which may be secondary to vocal fold (cord) scarring, atrophy or paralysis, is a condition that leaves patients with phonatory compromise in both voice intensity and frequency. Vocal fold paresis (where the nerves that control the muscles acting on the vocal fold fail) may be idiopathic or have an iatrogenic cause; one or both of the vocal folds may be affected.
- 2.1.2 Conservative management by voice therapy may be beneficial if the muscle groups affected by vocal fold paresis can be developed through vocal exercise. Surgical approaches can be used to reposition or reshape the vocal fold and they may involve implanting a physical device. Autogenous fat, Teflon, silicone or collagen can be injected to improve vocal fold function. Of these, autogenous fat is generally well tolerated. Teflon and silicone, however, may (rarely) produce complications because of sensitivity reactions to the materials used.

### 2.2 *Outline of the procedure*

- 2.2.1 The collagen is injected either transorally or transcutaneously from below the vocal fold using a laryngeal needle. The exact placement of collagen varies depending on the pathology of the condition. The procedure can be carried out with local anaesthesia, and may not require admission. A variety of collagen products have been used in research studies, such as biochemically cross-linked products and purified bovine collagen. Patients who are selected for therapy commonly undergo a skin sensitivity test. Antibiotic prophylaxis may be given.

### 2.3 *Efficacy*

- 2.3.1 In a case series of 45 patients with glottic insufficiency for whom other forms of treatment were considered unsuitable, collagen injection improved the maximum voice intensity by a mean of 2.91 dB ( $p < 0.026$ ) at 12 months after

the procedure. However, the mean change in normal voice intensity was not statistically significant.

- 2.3.2 In 27 patients with vocal fold paralysis or glottic insufficiency following laryngeal surgery, voice intensity and phonation time were found to have improved significantly following collagen injection. All 27 patients reported an improvement in at least one subjective voice assessment parameter up to 16 weeks after the collagen injection.
- 2.3.3 In one case series of 18 patients with electromyographically confirmed vocal fold paralysis, 93% (13/14) of patients who were injected with purified bovine collagen showed good improvement in dysphonia score compared with baseline at 6.5 months after treatment. In the same study, an improvement was found in maximum phonation time (8.6 seconds compared with 5.7 seconds at baseline). In a longer-term follow-up of patients in this study, 83% (5/6) of patients maintained good results in terms of subjective voice assessment at 3 years. In the four patients available for objective voice assessment at 3 years, maximum phonation time had improved further (12.2 seconds compared with 4.2 seconds at baseline). For more details, refer to the Sources of evidence.
- 2.3.4 The Specialist Advisors noted that injected collagen may be absorbed over time and may require replacement in the long term.

## 2.4 *Safety*

- 2.4.1 In a case series of 27 patients treated with collagen injection, one patient had an immediate short-term decrease in voice quality, which was associated with excessive injection, and one patient had transient vocal fold oedema.
- 2.4.2 Two case series with a total of 63 patients reported no serious adverse events up to 12 months following the procedure. In six patients followed-up for 3 years, there were no complications such as seroma, granuloma formation or migration of injected collagen. For more details, refer to the Sources of evidence.
- 2.4.3 The Specialist Advisors noted that transmission of variant Creutzfeldt–Jakob disease and allergic reactions are theoretical safety concerns with the use of bovine collagen.

## 2.5 *Other comments*

- 2.5.1 It was noted that collagen was just one of a variety of agents used for vocal cord augmentation, and that these may have different risk and benefit profiles.
- 2.5.2 Surgery may be preferable for patients who require long-term improvement in phonation.
- 2.5.3 The evidence is limited, but it was considered sufficient to support use of the procedure as palliative treatment in patients with limited life-expectancy.

Andrew Dillon  
Chief Executive  
June 2005

## 3 Further information

### *Sources of evidence*

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of collagen injection for vocal cord augmentation', December 2004.

### *Information for patients*

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

## 4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

## Changes since publication

24 January 2012: minor maintenance.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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## *Endorsing organisation*

This guidance has been endorsed by Healthcare Improvement Scotland.