Issue date: June 2005

NHS
National Institute for Health and Clinical Excellence

Collagen injection for vocal cord augmentation

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

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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 (see below).

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.

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June 2005

Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG130publicinfo

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

Available from www.nice.org.uk/ip258overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0882. *Information for the public* can be obtained by quoting reference number N0883.

The distribution list for this guidance is available at www.nice.org.uk/IPG130distributionlist

Published by the National Institute for Health and Clinical Excellence, June 2005; ISBN 1-84629-044-9

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N0882 1P 10k Jun 05