Vocal Fold Injection Augmentation with Novielle Voice Gel

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ABSTRACT

Introduction: Vocal fold augmentation is being undertaken with increasing frequency both in the office and operating room. Preganglionic agents do not wish to incur the expense, time, or risk involved with thyroplasty. Injection medialization has been employed to treat glottal insufficiency secondary to vocal fold paralysis, fixation, atrophy, post-surgical injury, and Parkinson’s disease among others.

There are several implants which have been utilized since 1911 when Brunnin first injected a vocal fold with paraffin. These include fat, gelfoam, collagen, Teflon, Bioplastique, calcium hydroxyapatite, polymethylmethacrylate spheres, polyacrylamide gel and hyaluronic acid.

The newest injectable approved by the FDA for vocal fold injection augmentation is Novielle Voice Gel (Coapt Systems, Palo Alto, CA). This product is a carboxer gel which is thixotropic - a fluid with pseudoplastic properties. This means that the viscosity of the fluid changes depending on the stress placed on the material. As shear stress increases, viscosity decreases – a property which is most valuable when considering vocal fold form and function. It is colorless, non-pyrogenic and latex free.

We sought to evaluate the efficacy and tolerability of Novielle Voice Gel and obtain information regarding longevity of the implant.

Methods and Materials: We prospectively recruited patients injected with this implant beginning from 1 April 2008. Inclusion criteria were age >18yrs, diagnosis of vocal fold paralysis or paresis, presbylarynx or glottal insufficiency and willingness to provide informed consent. Patients underwent voice assessment, stroboscopy, acoustic analysis and completed self assessment tools including the Voice Handicap Index-10 (VHI) at entry and each subsequent follow up visit.

Vocal folds were injected either unilaterally or bilaterally depending on the clinical diagnosis and stroboscopic findings. Injection was either in-office via a transcervical thyrohyoid approach or in the operating room using a transoral microlaryngeal suspension technique.

Patients were reviewed at one month, three months, and 6 months following injection. Stroboscopy was performed with the Kay videostroboscope (Kay Elemetrics, Lincoln Park, New Jersey) or the Edersil videostroboscope (Edersier USA LLC, San Diego, CA). Acoustic analysis was recorded on the Computerized Speech Lab MDVP Advanced programme Model 4150 (Kay Elemetrics, Lincoln Park, New Jersey). Data was collected and analyzed with the matched pairs t-test.

Results: Thirty one patients undergoing 35 injections were enrolled. The mean age of the cohort was 68 years. 61% percent was male. Diagnoses were vocal fold paralysis (58%), vocal fold paresis (13%), presbylarynx (29%). Four patients required repeat injection augmentation (13%) during the follow up period. Vocal folds were injected unilaterally in 52%. Injection was performed in the office in 29 patients (83%) and in the operating room in 6 (17%).

Initial data suggests that vocal fold injection augmentation with Novielle Voice gel is safe and effective. Further follow up data is required to confirm long term safety and durability.

CONCLUSIONS

Initial experience suggests that vocal fold injection augmentation with Novielle Voice gel is safe and effective. Further follow up data is required to confirm long term safety and durability.

REFERENCES