

APPARATUS AND METHOD FOR INJECTING A VISCOUS MATERIAL INTO THE TISSUE OF A PATIENT

TECHNICAL FIELD

The present invention relates generally to medical devices and procedures, and relates more specifically to an apparatus and method for injecting a viscous material into the tissues of a patient. In particular, the invention relates to an apparatus and method for injecting a viscous material such as collagen into the periurethral tissues of a patient as a treatment for urinary incontinence.

BACKGROUND OF THE INVENTION

It is known to treat urinary incontinence by injecting a viscous biocompatible material such as collagen transcystoscopically into the patient's periurethral tissues. The collagen is injected into the submucosal tissues of the urethra and/or bladder neck, and into the tissues adjacent to the urethra. The injection of the collagen creates increased tissue bulk, thereby exerting a coaptive pressure against the urethra. After injection the suspended collagen forms a soft, cohesive network of fibers, and over time the collagen takes on the appearance of normal host tissue.

The collagen can be implanted into the patient either periurethrally or transurethrally. According to the periurethral injection procedure, a needle is advanced through the perineum parallel to the urethra until the needle tip is located in the desired area for injection. Location of the needle tip is verified cystoscopically by observing the movement of adjacent tissue during gentle movement of the needle. When the needle tip is properly positioned, collagen is injected submucosally until tissue bulking closes the lumen across the midline of the urethral opening. The needle is then withdrawn from the initial injection site, and the procedure is repeated at a location directly across the urethra from the initial injection site. Collagen is injected until urethral closure is observed through the cystoscope, or until a maximum of 30 cc of collagen has been injected.

According to the transurethral procedure, a cystoscope is introduced into the patient's urethra. A catheter having a needle at its forward end is advanced through the working channel of the cystoscope to the desired area for injection. The needle is then advanced into the urethral wall, and collagen is injected submucosally until tissue bulking closes the lumen across the midline of the urethral opening. The needle is then withdrawn from the initial injection site and advanced into other locations on the urethral wall as needed. Material is injected at these other locations until urethral coaptation is observed through the cystoscope, or until the maximum of 30 cc of collagen has been injected.

Occasional problems arise in both the periurethral and transurethral injection procedures. On certain occasions it may require injection of an unexpectedly high volume of collagen to attain coaptation. On other occasions, even where coaptation of the urethra is achieved during the procedure, it has been found that on certain occasions within twenty-four to forty-eight hours after the procedure coaptation is not maintained. Additional injections of collagen may then be required to augment the initial injections to reattain coaptation. Such addi-

tional injections result in increased patient discomfort, cost, and patient morbidity.

Thus there is a need for an improved apparatus and method for injecting collagen or other suitable viscous biocompatible material into the periurethral tissues as a treatment for urinary incontinence.

There is a further need for an improved apparatus and method for periurethral and transurethral injection of collagen or other suitable viscous biocompatible material which affords coaptation while minimizing the volume of collagen which must be injected.

There is a still further need for an improved apparatus and method for periurethral and transurethral injection of collagen or other suitable viscous biocompatible material which maintains coaptation of the urethra once achieved.

SUMMARY OF THE INVENTION

As will be seen, the present invention overcomes these and other problems associated with prior art apparatus and procedures for treating urinary incontinence by injecting viscous biocompatible material into the periurethral tissues. Stated generally, the present invention provides an improved apparatus and method for injecting collagen or other suitable viscous biocompatible material into the periurethral tissues to increase tissue bulk and thereby exert an occlusive pressure against the urethra. The improved method and apparatus not only attains coaptation of the urethra but significantly enhances the prospects for continued coaptation twenty-four to forty-eight hours after the procedure.

Stated more specifically, it has been found that a significant factor in the loss of urethral coaptation in the period immediately following the injection procedure is the backflow of the injected material through the injection tract.

The viscous injected material does not readily diffuse into the tissues but instead causes the tissues to expand and form a pocket. Although the tissue relaxes over time, the initial resiliency of the tissues can exert enough pressure to force the viscous material to extrude back out through the needle tract. It has been found that a sufficient amount of the viscous injected material can leak back out through the needle tract to require an inordinately high volume of material to attain coaptation. Further, even where coaptation is initially attained, it has been found that on occasion a sufficient amount of the viscous injected material can leak back out through the needle tract to compromise coaptation. In addition, the force of the back flow can cause the needle tract to remain open, thereby delaying the healing process.

The present invention overcomes this problem by providing an apparatus and method which utilizes a non-coring needle, instead of the coring needle conventionally used. The non-coring needle creates a tract which immediately seals and resists backflow of the viscous material. The non-coring needle further allows the tissue to heal more quickly and to retain the injected material in the desired location.

However, the use of a non-coring needle presents further difficulties. Since the orifice of a non-coring needle is essentially on the side of the needle, the viscous material will be injected substantially transversely to the axis of the needle. While lateral injection of the material is not a problem with conventional injectable substances which are readily diffused into the tissues, it poses a significant difficulty when injecting viscous