Standards for Anal Sphincter Replacement

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PURPOSE: Anal sphincter replacement offers a new treatment option for patients with severe refractory fecal incontinence or for those who require abdominoperineal resection for localized malignancy. The purpose of this study was to review the current status of anal sphincter replacement, formulate a consensus statement regarding its current use, and outline suggestions for future development. METHODS: Four areas of interests were selected: indications for sphincter replacement, continence scoring and quality of life, choice of therapy, and dissemination of new technology. A questionnaire regarding these issues was developed and circulated to working party members; its results served as the basis for this consensus document. RESULTS: Both electrically stimulated skeletal muscle neosphincter and artificial anal sphincter are options for patients with end-stage fecal incontinence. Electrically stimulated skeletal muscle neosphincter is also appropriate for reconstruction after surgical excision of the anorectum in selected cases. Avoidance of complications requires strict attention to sterile technique, prophylactic antibiotics, and deep venous thrombus prophylaxis. A standardized scoring system is proposed that evaluates both continence and evacuation. Quality of life is a critical endpoint for assessing sphincter replacement, and use of The American Society of Colon and Rectal Surgeons incontinence-specific quality-of-life instrument is recommended. As the efficacy of sphincter replacement becomes proven, dissemination of the technique should occur in a controlled manner to ensure adequate surgeon training, minimization of complications, and optimization of results. CONCLUSIONS: Sphincter replacement by electrically stimulated skeletal muscle neosphincter and artificial anal sphincter provide a continent option for patients with end-stage fecal incontinence and those requiring abdominoperineal resection. The guidelines offered in this document are intended to facilitate the controlled and safe development and acceptance of these new techniques.

[Key words: Fecal incontinence; Sphincter replacement; Neosphincter; Artificial anal sphincter]


Resurrection and restoration of continence are two consistent themes throughout the history of colon and rectal surgery. Traditional approaches range from sphincter-sparing cancer surgery to various operations designed to repair sphincter injuries and improve function in neuropathic sphincters. In the past decade an improved understanding of skeletal muscle and pelvic floor physiology and the development of implantable leads, pulse generators, and artificial sphincters have provided new opportunities for sphincter replacement. However, independent development of these techniques by various centers of expertise has produced a literature marred by varying operative indications, assessment of results, and definitions of success. Furthermore, novel technology brings with it critical issues regarding its dissemination: how to provide training with new techniques? How to minimize the "learning curve" of new opera-
tions and procedures? How to appropriately limit their spread to qualified individuals and centers?

The working party on anal sphincter replacement was assembled to address these important issues and suggest appropriate standards for anal sphincter replacement. Because no randomly assigned, controlled trials exist in this nascent field, evidence considered was based on the relatively small number of published reports on the subject and the individual experience of the working party members. Accordingly, the conclusions of the working party should be viewed as what they are: a starting point toward standardization of investigation and reporting that is hoped to facilitate the safest and most expedient assessment of several lines of novel and exciting technology.

MATERIALS AND METHODS

Working party members were selected for their expertise in the various areas of electrically stimulated skeletal muscle neosphincter, artificial anal sphincter, sacral nerve stimulation, and assessment of fecal incontinence severity and quality of life. Four areas of special interest were selected: continence scoring and quality-of-life evaluation, indications for sphincter replacement, choice of therapy, and dissemination of new technology. The questionnaire was developed by consensus of the working party chairman (RDM) and four subchairmen (CGMIB, JC, HRR, and NSW), and it was circulated to the remaining members of the working party. Results of the questionnaire serve as the basis of the initial working party report, which was recirculated for comments and approval by members.

SURGICAL OPTIONS

The surgical options for anal sphincter replacement in clinical use are stimulated muscle wrap, artificial anal sphincter, and to a lesser extent, although not a sphincter replacement sensu strictu, sacral nerve stimulation.

Stimulated Muscle Wrap

Muscle wrap without stimulation has been used for many years mainly by use of the gracilis and to a lesser extent the gluteus maximus muscles. The gracilis muscle is especially well suited for transposition around the anal canal because of a very constant innervation from the obturator nerve and vascular supply from the profunda femoris vessels, which enter the muscle through one neurovascular bundle proximally, allowing mobilization of the muscle without endangering its vitality or function. Published studies on nonelectrostimulated graciloplasty have, however, shown very inconsistent results. One problem with unstimulated muscle wraps is the need for the patient to maintain constant muscle contraction on the basis of voluntary effort. A second problem is that the majority of fibers in the gracilis muscle are fatigue-prone type 2 fibers, which allow the muscle to sustain contraction for only a limited time. The addition of chronic, low-frequency electrical stimulation of the nerve or muscle close to the entry of the nerve results in conversion of the fatigue-prone fibers to fatigue-resistant fibers (type 1). Once converted, the muscle may be continuously stimulated, resulting in prolonged closure of the anal canal.

What has been said about the gracilis muscle is also true for the gluteus maximus, except that the nerve and vascular supply is much more variable, which means that the effect of electrical stimulation is far less reliable and, even under optimal conditions, will require stimulation with considerably higher voltage and consequently shorter battery life. As a result, the electrically stimulated gracilis muscle wrap has gained wider acceptance. The technique involves mobilization of the muscle through one long or two or three lesser incisions on the medial aspect of the thigh. The neurovascular bundle is isolated and the muscle is transposed around the anal canal through two small, usually lateral, perianal incisions. Finally, the tendon is fixed either to the ischial tuberosity or the skin after a 360° or 540° wrap. The stimulating electrodes are placed in the muscle close to the entry of the nerve, which is the method most widely used, or a single electrode is placed directly on the nerve after freeing this structure from the vessels. The stimulator is implanted in a subcutaneous pocket in the abdominal wall and is connected to the stimulating electrode by subcutaneously placed leads. The procedure may be performed in two stages with transposition of the muscle as the initial stage followed six to eight weeks later by implantation of the stimulating electrode.

Artificial Anal Sphincter

The artificial anal sphincter in clinical use has been adapted from the artificial urinary sphincter. It consists of a cuff that is placed around the anal canal, a