



Title: Systematic review of dynamic graciloplasty for the treatment of faecal incontinence.

Agency: ASERNIP-S, Australian Safety and Efficacy Register of New Interventional Procedures - Surgical

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Aim:

This systematic review aims to assess the safety and efficacy of dynamic graciloplasty compared to colostomy in the treatment of fecal incontinence.

Results:

No high-level evidence or comparative studies were available.

Safety. Mortality rates were around 2% for both graciloplasty and colostomy. Morbidity rates reported for graciloplasty varied widely across studies, with an average of one morbidity reported for each patient. Morbidity rates for colostomy were reported in a single study to be around 50%. There were no data available directly comparing the two surgical procedures.

Efficacy. Dynamic graciloplasty was clearly effective at restoring continence in 42% to 85% of patients, whereas colostomy is, by its design, incapable of restoring continence. Dynamic graciloplasty is associated with a significant risk of reoperation, with rates reported to range between 0.14 per patient up to 1.07 per patient. Reoperation rates for colostomy were reported at 0.13 per patient up to a cumulative risk of 0.17 at 11 years. No data directly compared the two procedures.

Conclusions and Recommendations:

The evidence base for dynamic graciloplasty was found to be inadequate to determine safety in comparison to colostomy, and a controlled clinical trial should be conducted although randomization would probably prove impractical for ethical reasons. Any such trial should also assess quality of life issues between the two procedures. Dynamic graciloplasty was found to be clearly more efficacious than colostomy for restoring continence in around 60% of patients. However, patients must be clearly informed of the high probability of failure of this operation.

Methods:

All original, published studies on dynamic graciloplasty and colostomy were identified by searching Current Contents, EMBASE, MEDLINE and the Cochrane Library from 1991 onward. Only studies of patients diagnosed with intractable fecal incontinence were included for review. English language papers were selected. Acceptable study designs included randomized controlled trials, controlled clinical trials, case series, or case reports.