Reviewer’s report

Title: Experience with a new prosthetic anal sphincter in three coloproctological centres.

Version: 4 Date: 12 May 2013

Reviewer: Donato Francesco Altomare

Reviewer’s report:

This study deals with an old problem for the management of severe fecal incontinence using artificial prosthesis.

The experience with the new anal device reported by the Authors is useful to convince the readers (even if there is evidence enough) that this is not the right way to manage these patients.

There are some points, which should be corrected or modified:

Background:
Please move the description of the device in the material and methods section

Methods
The major concern of this paper is the choice of a completely unknown incontinence scoring system impossible to find in the literature. I am not aware of any other study on fecal incontinence where it has been applied. Has this score been prospectively and statistically validated? Looking at the table 1 it seems that for example those how have only occasional incontinence to solid (total score 33) fall into the complete continent group (!)

Did the 3 Centers use the same manometric equipment or this evaluation was centralized?

Results: please move the patients demographic data in the Material and Methods section in the results section only the results of your work

Inclusion of patients with 1 month follow-up (your range 1-58) could underestimate the complication rate which in your experience occur in 90% of the cases in the first year

The score of incontinence improved significantly (from 2.6 to 14.3) but remained well far from the normal (36). This mean that these patients remained with major incontinence symptoms. This point is of crucial importance to take the decision for a prosthetic implant like this. The patients should be made aware in their informed consent, that their continence will only partially improve and that 50% of them will experience complication with high risk of device removal.

Another major point of concern is the lack of information about the quality of life changes in these patients. Since this is a functional disorder, the improvement in QoL is the major endpoint.
Further information about the cost of the device should be included in the paper.

References:
Please keep the correct numerical sequence of the reference in the text (they start with 7), the Lancet paper on “scott sphincter” must be quoted. Not sure that ref 2 deals with obstetric trauma.

The English language needs revision for several spelling mistakes in the text and tables.

**Level of interest:** An article whose findings are important to those with closely related research interests.

**Quality of written English:** Needs some language corrections before being published.

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

'I declare that I have no competing interests.