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SUBCAPSULAR RELOCATION FOR SACRAL NEUROMODULATION PULSE GENERATOR IMPLANT REVISION

Hypothesis / aims of study
We describe our technique and experience with subcapsular placement of the Interstim [Medtronic, Minneapolis, Minnesota] pulse generator in cases of revision for implant site pain.

Study design, materials and methods
Case series. Surgical technique: Under conscious sedation and local anesthesia, the old implantation scar is excised or an incision through the old scar above the IPG is performed. The capsule is opened and the IPG and neuroelectrode are completely exteriorized and freed from all tissue attachments. The pocket is generously irrigated and the floor of the capsule is incised. The new pocket is created beneath the capsule and is vigorously irrigated. The floor of the original pocket now serves as the roof for the new one – and the IPG and neuroelectrode are relocated to this deep pocket. A layered closure is performed [The capsulotomy is closed over the IPG and the old pocket is obliterated using interrupted sutures incorporating the walls and floor of the capsule]. A drain is not required. Impedence testing is performed. The skin is closed with a running subcuticular suture. An elastic bandage is applied for 3 days to try to prevent possible seroma, hematoma, or IPG migration.

Results
During the last 4 years (2005-2008) we have evaluated and treated 7 patients complaining of pain at the gluteal implant site without associated infection. Review of the operative reports revealed that all devices were placed at least 2cm from the skin surface. Mean BMI was 28 [range 23-41]. IPG site discomfort was due to atrophy of the subcutaneous fat in 4 patients (one patient had lost 60lbs after having the IPG placed) and rotational movement of the IPG in the other 3 [Pain was reproduced with rotational movement of the IPG on exam]. Two patients opted for complete explantation due to loss of response. The remaining 5 patients elected to have revisions in which we utilized the technique described. Due to the small size of the series, validated measures of pain were deferred [All patients had significant enough discomfort that they would have otherwise undergone explantation]. All patients after revision are pain-free and have had uneventful follow-up ranging between 6 months to 3 years

Interpretation of results
Although this is a small series, all patients who underwent a revision utilizing the technique described are pain – free. Utilizing the capsule in the revision, presumably improves defects in skin microcirculation, but also creates additional cushion superior to the pulse generator, helping to counteract the vertical mechanical forces of the pulse generator

Concluding message
Despite the number of patients presenting with soft-tissue complications related to IPG placement, there is little published regarding the technique for IPG revision and revisions performed for device-related pain are reported to be not always successful. A successful revision is probably not simply a matter of “placing it deeper”.
IPG related pain is multi-factorial. The specific use of the capsule in an IPG revision may help overcome the vertical forces exerted by the device and resist infection. The subcapsular relocation technique does not harm surrounding healthy tissue nor use up another implantation site. The technique is also repeatable.

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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**