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Long-term restoration of fecal continence after autologous bio sphincter implantation in a large animal model of passive fecal incontinence

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Background & Aim: Internal Anal Sphincter (IAS) dysfunction can lead to fecal incontinence (FI). The objective of this study was to demonstrate sustained restoration of fecal continence using monomeric recordings in a rabbit model of passive fecal incontinence after implantation of the Bio Sphincter.

Methods: The methodology followed in this study include: (1) New Zealand female white rabbits underwent IAS injury with hemi-circumferential IAS sphincterectomy; (2) Bio Sphincters were engineered using autologous IAS smooth muscle and enteric neural progenitor cells. Rabbits were randomized: Control untreated group and Bio Sphincter treated group. In the treated group, 4 autologous engineered Bio Sphincters were implanted 6-8 weeks following the sphincterectomy surgery; and (3) Anorectal manometry was used to measure resting anal pressure and recto-anal inhibitory reflex (RAIR) at baseline, 6 weeks post sphincterectomy, and at 3 months and 6 months after Bio Sphincter implantation.

Results: In the control untreated group, deterioration in fecal hygiene, decreased resting tone and loss of RAIR were observed post sphincterectomy in all rabbits. Autologous Bio Sphincters were successfully implanted into the donor rabbits without complications. Survival rate was 100%. In the Bio Sphincter treated group, restoration of basal tone (37 ± 3 mmHg, $p<0.05$) and RAIR ($60\pm 4\%$, $p<0.05$) were observed at 3 months was sustained for 6 months following Bio Sphincter implantation.

Conclusions: This study provides proof of concept of safety and efficacy of Bio Sphincters and restoration of IAS integrity and function and fecal continence in a large animal model. A regenerative medicine approach to restore impaired IAS function offers a safe and long-term treatment for passive fecal incontinence.

Biography

Khalil N Bitar, PhD, AGAF, is a Professor of Regenerative Medicine, Gastroenterology, Physiology and Biomedical Engineering. He is the Director of Gastroenterology program at the Wake Forest Institute for Regenerative Medicine. He has published more than 100 papers in high impact journals and has been funded by NIH for more than 30 years. He is a fellow of the American Gastroenterological Association.

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