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RESEARCH

The novel BioHealx®assisted fistula treatment (BAFT): effective primary fistula healing with continence preservation

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Abstract

Background This is the first in human assessment of the BioHealx® assisted fistula treatment (BAFT) procedure for the primary healing rate of non-branching transsphincteric fistula in ano. The BAFT procedure consists of compression apposition closure of the lumen of the fistula tract from the internal opening across the transsphincteric length of the fistula tract with a bioabsorbable implant (BioHealx device) and distal fistulectomy. This medium-term follow-up study assesses the healing and functional outcome at the last follow-up (12–40 months; average 23.4 months) following this procedure.

Methods The study was a multi-center, prospective, single-arm (non-randomized), non-blinded, clinical study for elective compression closure of non-branching transsphincteric anal fistula of cryptoglandular origin. Participants were recruited from three sites (two hospitals in Budapest, Hungary and one hospital in Szeged, Hungary). The primary outcome was combined fistula and fistulectomy wound healing, and fecal incontinence quality of life scores (FIQL) were a secondary outcome. Fistula healing was assessed independently in cases where the fistulectomy wound had not fully healed.

Results Thirty-two adults, (18–75 years; M- 27 vs F- 5) were included in the study. The 30-day complication rate was 4/32 (12.5%) and was restricted to the fistulectomy wound with no device-related complications. All patients were assessed in person at 12 months, and patients with unhealed fistulectomy wounds were reassessed after 12 months to confirm fistula healing status. The data demonstrated that 27/32 (84.4%) of transsphincteric fistulas were healed with no recurrences. There were 3(9.4%) persistent transsphincteric fistulas and 2 (6.3%) with undocumented fistula healing with healing fistulectomy wound at last follow-up. Assessment of available baseline and last follow-up FIQL scores demonstrated stable or improved scores for 30/31 (96.8%). Surgeon assessment reflected ease of adoption.

Conclusions This first in human assessment of the BAFT procedure for transsphincteric cryptoglandular fistula in ano demonstrated an 84.4% rate of primary healing without recurrence of transsphincteric fistulas with preservation of fecal continence quality of life in 96.8% of patients. Successful compression apposition closure of the fistula tract lumen within the anal sphincter complex delivered the healing rate by primary intention of the fistula tract without any device-related complications or migration. Surgeon mastery of the procedure is straightforward. These outcome data support both a high rate of initial healing and durability of the BAFT procedure for transsphincteric cryptoglandular fistula in ano that are favorable when compared to LIFT, endoanal flap, cutting seton, or fistulotomy/sphincteroplasty surgical options.

Keywords Anal fistula · Transsphincteric fistulas · Bioabsorbable implant · BioHealx · Fecal continence · BAFT procedure

Introduction

Transsphincteric fistula in ano presents a significant clinical challenge for the surgeon, and current treatment options place the patient at risk for both surgical failure, impairment of fecal continence and the potential for increased health care costs [1–3]. The current surgical options for transsphincteric fistula include endoanal advancement flap, ligation of the intersphincteric fistula tract (LIFT), cutting seton

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with distal fistulotomy, or fistulotomy with primary sphincter repair [4–8]. The outcomes for these procedures vary widely across studies with successful healing rates ranging from 55 to 70%; however, incontinence risks are significant and typically range from 10 to 20% for the initial curative procedure [4–8]. However, inclusion of recurrence which results from failed primary healing of the fistula tract within the sphincter complex yields substantially lower healing rates [4–8]. Surgical failure and the requisite repeat procedures risk further impairment of continence when assessed over the entire episode of care, as well as delivering an even lower rate of successful healing compared to the initial attempt [4–8]. Historically, attempts at using various bioabsorbable implants or glues for intralumenal occlusion of the fistula tract have largely failed to provide acceptable levels of fistula healing [9–11]. The predominant reason for failure with current fistula procedures is the inability to consistently deliver healing by primary intention of the fistula from the internal opening across the entire width of the anal sphincter complex. The purpose of this study is to assess first in human experience with the BioHealx Assisted Fistula Treatment (BAFT) for transsphincteric cryptoglandular fistula in ano and to provide medium-term assessment of the durability of primary fistula healing and continence.

Methods

The study was a multi-center, prospective, single arm (non-randomized), clinical pilot study to evaluate the safety and effectiveness of the BioHealx implant and delivery system for the repair of transsphincteric, non-branching anal fistulas with fistula tracts > 2 cm. Patients presenting for primary curative surgery or patients with persistent/recurrent transsphincteric anal fistula were eligible for inclusion. Exclusion criteria included inflammatory bowel disease, hidradenitis suppurativa of the anal region, pilonidal sinus disease, a hemorrhoid involving the fistula site, a lesion treatable by simple anal fistulotomy (i.e., < 30% of external anal sphincter involvement), an active infection or abscess involving the fistula site, a known allergy to PLGA material, or any severe, acute, or uncontrolled perirectal infection involving the fistula that according to the investigator might render the patient unsuitable for the study. Participants were recruited from two clinical sites in Budapest, Hungary, and one site in Szeged Hungary (Site 1: 23 participants, Site 2: 3 participants, Site 3: 7 participants). The first participant was recruited in June 2019 and the final follow-up visit took place in August 2023. Some delays took place during the COVID-19 pandemic due to the closure of the sites for elective surgeries. The study was funded, and devices were provided to the study sites by Signum Surgical Ltd, New Docks, Port of Galway, Co. Galway, Ireland.

Clinical Investigation Protocol (SP001) was reviewed and approved by the Hungarian Competent Authority and Ethics Committee. All participants provided informed consent in writing. Data collected included: age; gender; prior fistula interventions; device-related complications; 30-day procedural complications; baseline, 6-month and 12-month FIQL scores; and assessment of fistula healing and fistulectomy wound healing at ≥ 12 months or last follow-up, whichever was longer. The FIQL scores at baseline were compared to the 12-month interval for each patient. A surgeon usability survey for thee BAFT procedure was also performed. The data that support the findings of this study are available from the Signum Surgical Ltd Chief Medical Officer (Anthony Senagore,MD tony.senagore@signumsurgical.com) or from Signum Surgical Regulatory Affairs group (currently Suzanne O'Rourke; suzanne@signumsurgical.com), upon reasonable request.

The BioHealx implant (Signum Surgical) is a novel, bioabsorbable, helical coil implant made from PURASORB PLGA 8218, a bioabsorbable copolymer of L-lactide and Glycolide, and is 9.1 mm in length with an outer diameter of 5.1 mm. The helical coil implant design facilitates insertion into the tissue surrounding the internal opening and the fistula tract traversing the sphincter complex with the barbs, at the outer perimeter of the implant, function as anti-rewind features to prevent device migration/extrusion once implanted. The geometry of the implant is designed to securely close the intra-sphincteric portion of the fistula by circumferential compression of the surrounding muscle tissue from the internal opening, across the internal sphincter and transsphincteric space with distal anchoring into a substantial portion of the external anal sphincter to allow healing of the tract. The purpose of the BioHealx compression closure process is to provide healing by primary intention of the tract from the internal opening across the width of the sphincter complex. Current surgical options address specific portions of the fistula tract, or in the case of fistulotomy, risk significant sphincter injury in the attempt to provide ultimate closure of the fistula tract within the sphincter complex. The implant (see Fig. 1b) is delivered by means of the BioHealx Anal Fistula Delivery Device ("the delivery device"; see Fig. 1a), which is a single-use device for the controlled delivery of the implant. The process of device implantation into the sphincter complex is demonstrated in Fig. 2a–c.

Postoperative care and wound management were at the discretion of the operating surgeon. Follow-up visits occurred on the day of discharge, 6 weeks, 3 months, 6 months, 12 months, and at variable times after 12 months for patients with unhealed fistulectomy wounds. Evidence of fistula drainage, a non-healed and patent fistula tract, and/or confirmation of fistula patency by flush test were classified as an ineffective treatment. At the 12-month follow-up visit all patients were assessed for status of healing of

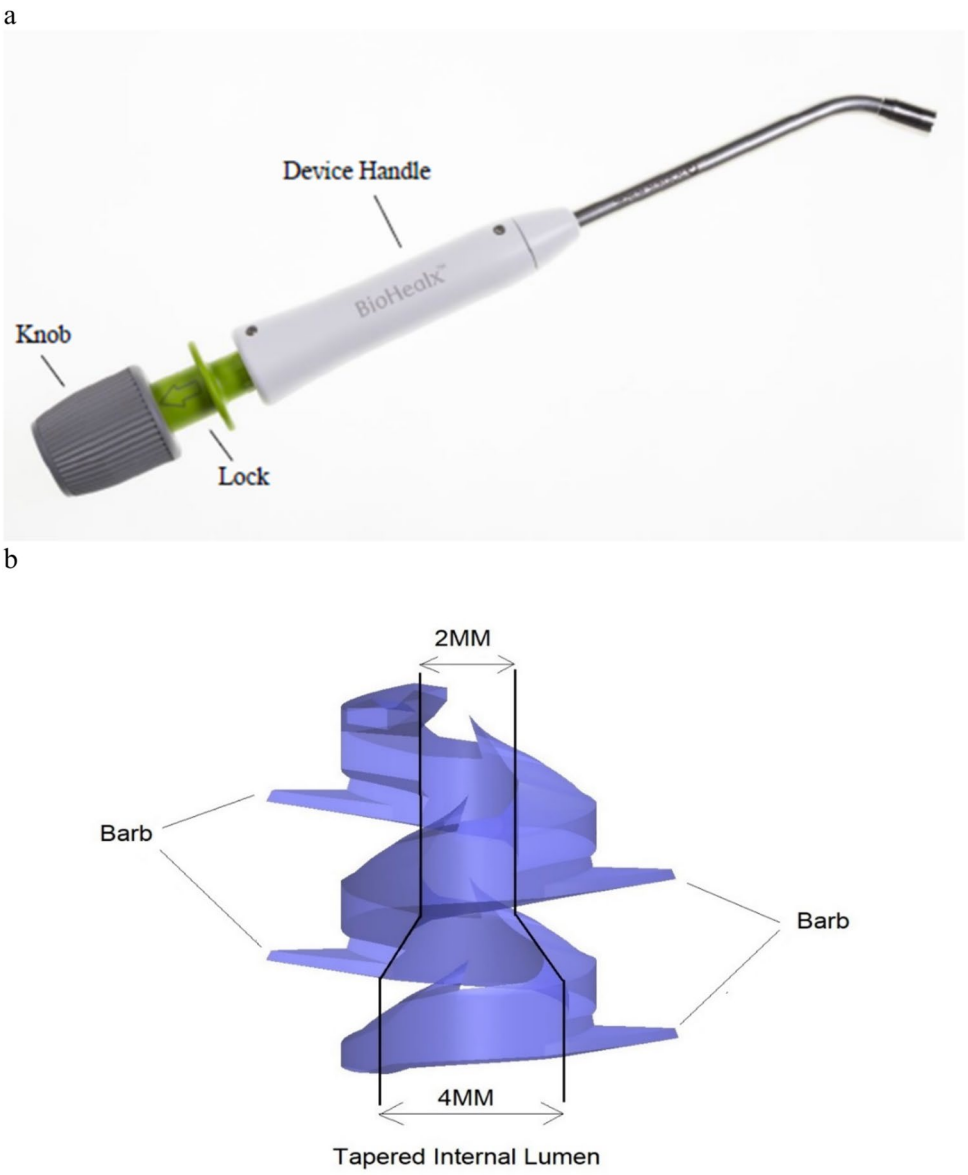

Fig. 1 Demonstrates the Bio-Healx delivery device (**a**) and implant (**b**)

the perianal wound (i.e., persistent external opening, fully healed, or healing fistulectomy wound), and if necessary closure of the internal opening of the fistula was evaluated using a standard flush test. The flush test (using an injection of hydrogen peroxide, betadine, or a mixture hydrogen peroxide and betadine) was performed to evaluate if there was communication between the external opening and the original internal fistula opening. A negative test confirmed healing of the transsphincteric fistula regardless of whether the fistulectomy wound was fully healed. A cohort of 18 patients agreed to follow up (12–40 months; mean 23.4 months) for an in office assessment for continued complete healing of the fistula.

The Rockwood Fecal Incontinence Quality of Life scale (FIQL), a questionnaire designed to evaluate the impact of fecal incontinence on four sub-scales: lifestyle, coping behavior, depression or self-perception, and level of embarrassment. Each aspect is measured on a scale of 1 to 4 (1 = very affected, 4 = not affected). At the post-12-month follow-up, patient satisfaction data were also collected via questionnaire that included 8 questions about the participant's experience [12]. Total score reductions of < 1.5 points were considered stable in terms of fecal continence.

User survey

Each participant in the summative usability/human factors evaluation was asked to complete a user survey on their experience with the BioHealx Anal Fistula Device. The user survey comprised twelve questions, incorporating a Likert scale scoring system, about the user experience with the

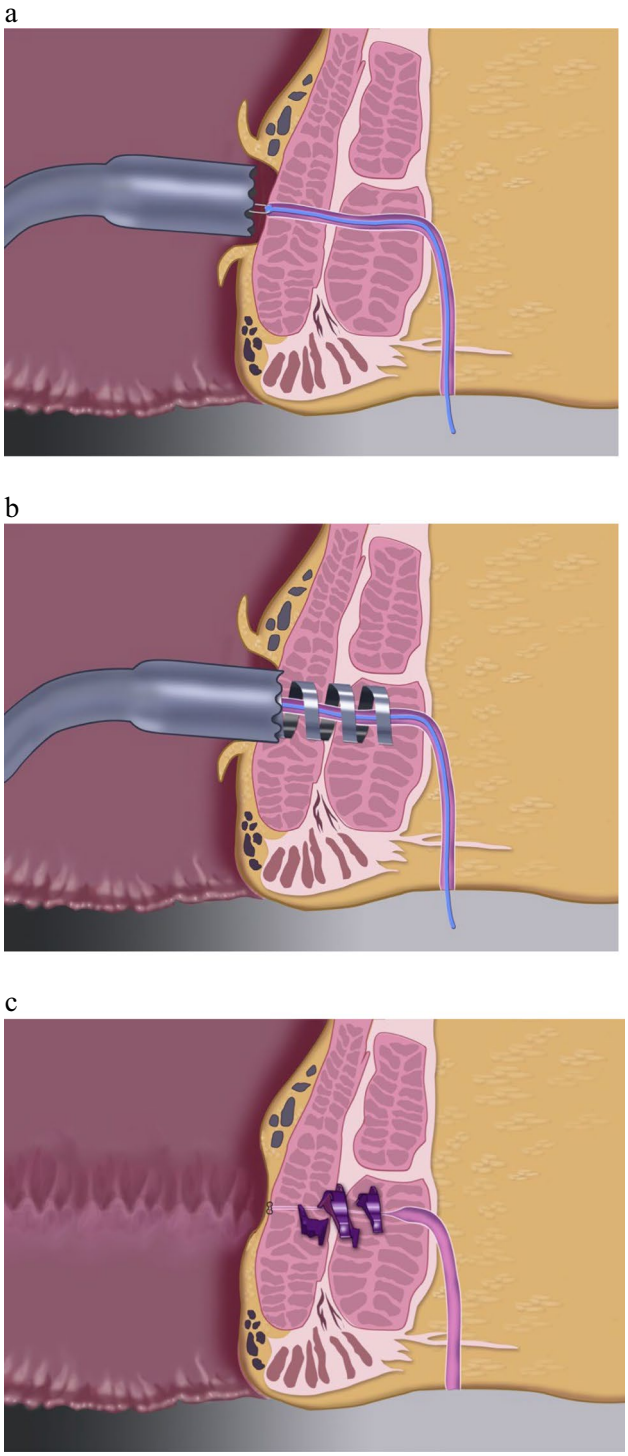

Fig. 2 Demonstrates the process of implantation of the BioHealx device for compression closure of the fistula tract within the sphincter complex: **a** Guidance of the BioHealx insertion device to the surface of exposed internal anal sphincter at the internal fistula opening by the traction suture in the fistula tract; **b** Deployment of the BioHealx within the sphincter complex; and **c**- compression closure of the fistula tract by the BioHealx implant within the sphincter complex and closure of the anodermal wound

training/instructions for use, ease of use of the device and assessed the likelihood of the participant using the device if it was available as an approved treatment option for their patients.

Results

Participants included 32 adults (males = 27, females = 5) with an average age of 49.9 years (SD = 11.6, min = 33, max = 76). The patient demographic data is presented in Table 1. Initially, 33 participants were enrolled in the study; however, one was excluded because it was identified during the implant procedure that there was insufficient tissue to support the implant. The BioHealx implant was removed, and no further data were collected from this participant.

The distribution of prior procedures, with some patients having undergone multiple procedures, is demonstrated in Table 2. The 30 day complication rate was 4/32 (12.5%) and was restricted to the fistulectomy wound, not the device insertion site nor the device itself (1 hemorrhage from fistulectomy requiring surgical hemostasis of the wound; 1 infection (3.1%); 1 drainage; and 1 mild pain). There were

Table 1 Summary of medical history

Medical history	BioHealx study (N = 32)	
	Yes (n/N, %)	No (n/N, %)
Anemia	0/32 (0.0%)	32/32 (100%)
Diabetes	3/32 (9.4%)	20/32 (90.6%)
Congestive heart failure (CHF)	0/32 (0.0%)	31/32 (96.9%)
Hypertension	14/32 (43.8%)	18/32 (56.3%)
Coagulation abnormality	0/32 (0.0%)	32/32 (100%)
COPD	0/32 (0.0%)	32/32 (100%)
Obesity (> 150% of ideal weight)	5/32 (15.6%)	27/32 (84.4%)
Smoker	6/32 (18.8%)	26/32 (81.3%)
Current active abscess or infection	0/32 (0.0%)	32/32 (100%)
Other significant condition	7/32 (21.9%)	25/32 (78.1%)

Table 2 Procedures performed prior to BAFT

Prior Interventions (some had multiple)	N = 32
Non-curative	
Abscess drainage	2 (6.3%)
Abscess management	1 (3.1%)
Seton placement	30 (93.8%)
Exploratory surgery	3 (9.4%)
Failed curative	
Anal fistula repair	2 (6.3%)
Endoanal flap	2 (6.3%)
Laser ablation	3 (9.4%)

Table 3 BAFT Procedure healing outcomes at last follow-up (12–24 months)

Successful healing	27/32 (84.4%)
Fistula healed with or without healed fistulectomy wound	
Unsuccessful healing	2/32 (6.3%)
Unconfirmed fistula healing with unhealed fistulectomy wound	
Persistent transsphincteric fistula	3/32 (9.3%)

no device-related complications at any time interval. Primary fistula healing occurred in 27/32 (84.4%) and no recurrences occurred after documented fistula healing. There were 3/32 (9.4%) persistent transsphincteric fistulas and 2/32 (6.3%) patients with undefined fistula healing with healing fistulectomy wounds who were counted as treatment failures (see Table 3). In the cohort of 18 patients undergoing longer follow-up (12–40 months; mean 23.4 months) the in office assessment confirmed continued for complete healing of the fistula without recurrence.

The comparison of baseline to 12-month FIQL scores demonstrated consistent improvement of scores during the healing process with stable or improved scores for 30/31 (96.8%), a reduction of 2.05 points for 1/31 (3.2%) patients, and one patient who did not have available scores (see Table 4). The patient with the 2.05 point score decreased had an unhealed fistulectomy wound at 6 months and remained in the category of unconfirmed fistula healing and unhealed fistulectomy wound with mucopurulent/feculent drainage at last follow-up.

Evaluation of the procedure and device implantation process was assessed in 94% (16/17) cases where participant surgeons returned the user survey to Signum Surgical (see Table 5). The data suggested a minimal learning curve and a willingness to adopt the procedure as an option for the management of transsphincteric fistula in ano.

Table 4 Comparison of baseline to 12-month fecal incontinence quality of life scores

Patient ID	Baseline	12 month	Score Change
01–001	15.89	15.89	0
01–002	10.87	15.89	5.02
01–005	9.82	12.64	2.82
01–006	13.3	15.68	2.38
01–007	14.07	15.02	0.95
01–008	15.77	15.77	0
01–009	14.97	14.71	0.26
01–010	15.14	15.66	0.52
01–012	13.13	15.44	2.31
01–013	14.51	14.51	1.49
01–014	15.56	15.19	−0.37
01–016	15.77	15.89	0.12
01–018	13.42	16.00	2.58
01–012	16	16.00	0
01–022	15.89	15.40	−0.42
01–023	15.4	15.89	−0.05
01–026	15.89	13.67	2.33
02–001	13.67	15.89	0.11
02–002	15.89	10.23	−0.59
02–003	10.23	14.50	−0.08
02–004	15.77	15.77	0
03–001	15.89	16.00	0.11
03–002	15.81	13.76	−2.05
03–003	10.06	14.97	4.91
03–004	13.55	15.58	2.03
03–005	8.98	15.78	6.8
03–006	13.46	15.68	2.22
03–007	9	10.13	1.13
03–008	11.99	15.89	3.9
03–009	10.79	11.61	0.82

Discussion

The results of this medium-term assessment of the BAFT procedure demonstrated an 84.4% rate of transsphincteric fistula healing without recurrence, with 3 persistent transsphincteric fistulas and 2 cases of undefined fistula healing. Importantly, the results demonstrate a 96.8% rate of preserved or improved FIQL scores at 12 months (one patient with a score decrease of 2.05 points) which exceeds the substantial reduction in continence resulting from most currently used surgical options for transsphincteric fistula [4–8]. It is important to note that the patient with the 2.05 FIQL point drop suffered from a non-healed fistulectomy wound and a persistent fistula, and thus the tool may have had limited granularity to discern fecal incontinence from symptoms related to wound drainage and inflammation. The absence of any device-related complications demonstrates that the BioHealx device effectively delivers the long-sought goal of fistula closure by primary healing of the fistula tract across most of the sphincter complex by use of the bioabsorbable compression device. Experience with prior bioabsorbable devices or glues deployed to occlude the fistula lumen has failed to demonstrate similar healing rates while being associated with significant device failure and/or migration rates of 40–60% [7–9].

The BioHealx device is the first bioabsorbable fistula therapy which provides for compression closure of the sphincteric portion of the fistula tract from the internal opening into the external sphincter muscle by incorporating the peri-fistula muscular tissue. This is in contradistinction to prior strategies of occluding the fistula lumen which have

Table 5 Demonstrates the results of the surgeon usability assessment of the insertion tool and device deployment by the study surgeons

Category	Question in the User Survey Form	User Response
Ease of use	**Q1. Were you able to understand the Instructions for Use?** **a. Yes, that was very easy** **b. Yes, that was easy** **c. Yes, but it was too complicated** **d. Yes, but it was quite difficult** **e. No. Please, explain**	**16/16 users found the Instructions for Use were easy to understand** very easy to understand (14/16 users) easy to understand (2/16)
Device suitability	**Q2. Is the delivery instrument suitable for your anal fistula procedures?** **a. Yes, 80 −100% of cases** **b. Yes, 50–80% of cases** **c. Yes, but less than 50% of cases** **d. No. Please, explain"**	**14/16 users responded that the delivery instrument would be suitable for:** 80–100% of cases (6/16 users) 50–80% of cases (8/16 users) **One user stated that the delivery system would be suitable for < 50% of cases. One user stated that the delivery instrument would be suitable for the low, difficult to treat fistulas**
Informative	**Q3. Did you use the device to deliver an implant?** **a. Yes, demonstration only** **b. Yes, bench (gel) Model** **c. Yes, animal model** **d. Yes, human case** **e. No. Please, explain"**	**16/16 users had delivered the BioHealx implant in (b) the gel model. Of these:** **- 6/16 users have delivered the device in (c) an animal model** **- 3/16 users have delivered the device in (d) human (clinical) cases**
Ease of use	**Q4. If you used the instrument to deliver an implant, was it…** **a. Very easy to use** **b. Easy to use** **c. Too complicated** **d. Quite difficult** **e. Not possible Please, explain"**	**16/16 users were able to use the delivery instrument to deliver the BioHealx implant,** Very easily (9/16 users) or Easily (7/16 users)
Ease of use	**Q5. Were you able to attach the suture?** **a. Yes, that was very easy** **b. Yes, that was easy** **c. Yes, but it was too complicated** **d. Yes, but it was quite difficult** **e. No. Please, explain"**	**16/16 users were able to attach the suture** very easily (9/16 users) easily (6/16 users) **1/16 users responded that while he was able to attach the suture that it was c) too complicated**
Ease of use	**Q6. Were you able to advance the implant and simulate fistula closure?** **a. Yes, very easy** **b. Yes, easily** **c. Yes, but too complicated** **d. Yes, but quite difficult** **e. No. Please, explain"**	**16/16 users were able to advance the implant, simulating fistula closure** very easily (9/16 users) or easy easily (7/16 users)
Ease of use	**Q7. Were you able remove the delivery device after implanting the device?** **a. Yes, very easy** **b. Yes, easily** **c. Yes, too complicated** **d. Yes, but quite difficult** **e. No. Please, explain"**	**16/16 users were able to remove the delivery device after implanting the device** Very easily (11/16) or Easily (5/16)
Informative	**Q8. Was the force to deploy…** **a. Too low** **b. About right** **c. Too high** **d. Other? Please, explain"**	**15/16 users stated that the force to deploy the implant was (b) about right** **A single user stated that the force to deploy the device was (c) too high**
Informative	**Q9. Was the handle of the delivery device…** **a. Too small** **b. About right** **c. Too large** **d. Other? Please, explain**	**16/16 users stated that the delivery device handle was (b) about right**

Table 5 (continued)

Category	Question in the User Survey Form	User Response
Device suitability	**Q10. Would you be likely to use the Signum device …?** **a. More often than any other fistula repair if indicated** **b. About as often as another fistula repair method** **c. Yes, but only in specific cases** **d. No. Please, explain**	**14/16 users would be more likely to use the Signum device** more often than any other repair option about as often as another fistula repair method **1 users indicated that they would use the device only in specific cases; 1 user said that they would (d) currently choose the device in a trial setting**
Informative	**Q11. Did you experience any problems during the usage of the device?** **a. No** **b. Yes, please, explain**	**13/16 users did (a) not experience any problems during the usage of the device** • 1 user had difficulty in retracting the green lock pre-deployment during the initial device training. This user had reported (Q8) that the force to deploy the device was too high • 1 user experienced a device protrusion post implant during their initial implant training (this was prior to human factors evaluation) • 1 user indicated that the 2–0 suture wire can become corrupted (caught) on the helical implant (screw)
Informative	**12. Would the device likely increase risk to the patient?** **a. No** **b. Yes, Please, explain"**	**16/16 users indicated that the device would (a) not increase risk to the patient**

largely failed, while still providing for the resorption of the device over a 3–6-month time frame [14–18]. The BAFT procedure offers several unique benefits compared to competing surgical strategies for fistula treatment. First, it does not require any dissection of the anal sphincter complex or perirectum. Second, it provides a novel secure approach for compression closure of the fistula tract from internal opening across the sphincter complex with final anchoring of the implant within the external anal sphincter to deliver primary healing (i.e., healing by primary intention) of the fistula tract, as well as compression closure of the intersphincteric space. Fistulotomy is the only competing procedure which attempts to heal the entire length of the fistula tract within the sphincter but adds significant risk for sphincter injury. The BAFT mechanism of action is also substantially different than prior attempts to provide fistula healing via occlusion of the fistula lumen with an intra-luminal device with aspirations of tissue integration of the device into the fistula tract which was not ultimately demonstrated in clinical studies. Thirdly, the procedure could be modified to allow for either distal fistulotomy or potentially curettage treatment of the distal fistula tract to further reduce wound healing issues. Finally, the successful primary fistula healing rate is accompanied by virtually no risk to fecal continence because no dissection is required within the sphincter complex and minimal sphincter muscle is incorporated into the closure, thus preserving most of the length of the sphincter complex. BAFT provides single-step closure of the intra-sphincteric closure of the fistula tract without dissection, unlike laser ablation or the VAAFT procedure which still require some additional method of closure of the internal fistula opening resulting in additional combined device costs and risk of surgical dissection with modest outcomes [19, 20]. These attributes are distinct from endoanal flap which requires inclusion of a portion of the internal anal sphincter for flap construction. Similarly, the original LIFT procedure requires significant dissection within the intersphincteric space for identification and management of the fistula tract, or the TROPIS procedure variation where actual division of the internal anal sphincter is performed for exposure of the intersphincteric space [4–9].

Fistula recurrence represents a failure of primary healing of the fistula tract within the sphincter complex with the nonhealed portion of the tract producing delayed infection and restoration of the fistula tract despite the temporary healing of the external opening. Thus the more accurate definition of successful healing with fistula procedures should be healing without recurrence, which can only occur with successful primary healing of the majority of the fistula tract from internal opening thru the external anal sphincter. Using this definition for successful healing the results for the competing operative procedures are: 1) fistulotomy with sphincter repair- 52.7%; 2) LIFT- 60%; and 3) Flap- 50% [13–17].

van Oostendorp et al. reported on short and long term continence after LIFT and identified an 11% incidence of newly induced cases of incontinence and overall a 74% incontinency rate in those patients without subsequent surgery for a recurrence vs 49% incidence in patients reoperated for incontinence at long-term follow-up [18]. Similarly, other current surgical options such as cutting seton or fistulotomy with sphincter repair also risk failed primary healing and damage to both the internal and external anal sphincters with resulting in impairment of incontinence due to both the index and subsequent procedures for failed healing [11, 12,

21, 22]. Lunqvist et al. reported on the economic and total number of procedure burden of managing the entire episode of care for fistula in ano patient with the assessment of 362 patients of who 36% required multiple procedures to cure the fistula (average number of procedures was 4.1) with a total discounted cost of care of €5,561 per patient [1]. The BAFT procedure does introduce an additional hospital cost for the device; however, current facility reimbursement for the treatment of transsphincteric fistula ranges from $5469 to $14,784 based on publicly available data from the open source hospital transparency program mandated by the Centers for Medicare and Medicaid Services (https://hospitalpricingfiles.org/). While a comprehensive economic assessment of the total episode of care for transsphincteric fistula comparing BAFT to alternative procedures has not been performed, there are several attributes that contribute to a better value proposition for both patients and integrated delivery networks for the total episode of care costs for fistula. The total cost of managing surgical failure with multiple procedures is a significant cost to the healthcare system, including both the patient and insurer's costs [1]. Future assessment of these potential benefits of BAFT, based on the impact on the entire episode of care costs compared to current standard of care options is warranted. This should include an assessment of patient centric cost which includes out of pocket expenses due to insurance deductibles and uncovered benefits, as well as the cost impact of managing the permanent impact of incontinence.

The BAFT procedure accurately and securely delivers the BioHealx implant in a fashion which appears superior to device-related failures for attempted intraluminal closure of the fistula tract [12]. Because the BAFT procedure does not involve any dissection of the sphincter complex, the potential exists for consideration of a repeat BAFT procedure after allowing sufficient time for device bioabsorption as rescue therapy of an initial treatment failure. Alternatively, it is possible that the BioHealx device could be used in conjunction with an endoanal flap to provide closure of the intrasphincteric fistula tract depending on the clinical scenario.

Limitations of this pilot study included the small sample size, restriction for fistulectomy to manage the distal portion of the fistula tract, and a lack of direct comparison to another type of curative fistula procedure.

Conclusions

This long-term follow-up study of the BAFT procedure for transsphincteric cryptoglandular fistula in ano demonstrated an 84.4% rate of primary healing without recurrence of transsphincteric fistulas with preservation of fecal continence in 96.8% of patients. Successful compression closure of the fistula tract within the anal sphincter complex and closure of the intersphincteric space was achieved without any device-related complications or migration. These data support both a high rate of initial healing and durability of the BAFT procedure for transsphincteric cryptoglandular fistula in ano that are favorable when compared to LIFT, endoanal flap, cutting seton, or fistulotomy/sphincteroplasty surgical options.

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Author contribution LH, PO, GF, AN, ET, GB, SA, GL- Participated in protocol development, data review and manuscript review. MZ, AS - Participated in protocol development, data review, and manuscript preparation and review.

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Data availability The data that support the findings of this study are available from the Signum Surgical Ltd Chief Medical Officer (Anthony Senagore,MD tony.senagore@signumsurgical.com) or from Signum Surgical Regulatory Affairs group (currently Suzanne O & Rourke; suzanne@signumsurgical.com), upon reasonable request.

Declarations

Participating investigators were compensated for their research efforts.

Competing interest Moshe Zilversmit and Anthony J Senagore are employees of Signum Surgical. The other authors have no competing interests.

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