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ANAL FISTULA REPAIR: TREATMENT WITH DERMAL MATRIX PLUG

Rosanna Curinga, Andrea Legnaro, Michele Longo, Francesco Pietrangeli, Luigi Losacco

Coloproctology Unit, Rovigo Hospital, Rovigo, Italy

Background This study was designed to evaluate the outcomes of a matrix plug for the correction of anal fistula repair. The three-dimensional structure ensures the stability of the device, the sharp edges of the wedge make an intimate contact and provide the incorporation into the host tissue with lower inflammatory responses. **Methods** The study was conducted at the Unit of Coloproctology, Rovigo Hospital, from January 2014 to September 2017. Patients who underwent anal fistula repair with acellular dermal matrix plug (Pressfit®). Only patients with complex anal fistula were enrolled in the study. Patients were previously treated with a loose seton to promote drainage of the fistula. After removal of the seton and curettage, the larger part of the plug was inserted and sutured at the internal opening that was then closed with a small mucosal flap. The truncated pyramid frustum created an intimate contact to promote tissue regeneration. **Results** There were 21 patients, nine males and 12 females, with a median age of 53 years (range 29–80 years) Mean operative time was 30 min. No major complications, active sepsis or mortality were observed. Fourteen (67%) fistulas were successfully treated at a mean follow up of 21 months (range 1–46 months). Mean time for recurrence was 3–4 months. In seven patients fistula recurred and was treated with redo plug insertion (n = 2), or fistulectomy (n = 5). No patient experienced any change in continence. **Conclusions** Treatment of complex anal fistula with acellular dermal matrix plug is safe, simple and has low risk of morbidity. A longer follow-up period and a larger sample size remain to be explored.

Keywords Anal fistula Plug, perianal abscess, incontinence

Conflict of interest The authors declare that they have no conflict of interest.

VAAFT: SAFETY AND SHORT-TERM RESULTS IN CRYPTOGLANDULAR AND IBD-ASSOCIATED FISTULAS

Guerci Claudio¹, Bondurri Andrea¹, Angiolini Maria Rachele¹, Danelli Piergiorgio¹

¹Surgery Unit, Department of Biomedical and Clinical Sciences, Luigi Sacco University Hospital, Milan, Italy

Background Video-assisted anal fistula treatment (VAAFT) is a sphincter-preserving technique for the treatment of anal fistulas. The aim of this study was to demonstrate its safety and to assess the safety and short-term results of VAAFT in idiopathic anal fistulas as well as in fistulas associated with inflammatory bowel disease (IBD). **Methods** The study was conducted on patients with complex anal fistulas who underwent VAAFT at our institution between April 2017 and May 2018. Continence was assessed with the Wexner Continence Scale. According to Parks' classification, one patient with quiescent Ulcerative colitis had an intersphincteric fistula, 3 patients had a low transsphincteric fistula, and seven patients had a high trans-sphincteric fistula (2 of them had biologic-drug-treated Crohn's disease). Four of these patients had recurrent fistulas. Evaluation was scheduled 2, 4 and 8 weeks postoperatively. Failure was defined as non closure of both orifices, within 4 weeks postoperatively. Recurrence was defined as reopening of a previously healed fistula or formation of abscess. **Results** There were 11 patients (8 men and 3 women). A Clavien-Dindo grade I complication occurred in 2 patients; no disturbance of continence was reported. After 8 weeks, the overall success rate was 63.6% (7/11), whilst 3/3 IBD patients achieved primary healing. Failure occurred in 3 patients with low transsphincteric fistulas (100%) vs. no patients with high transsphincteric fistulas ($p = 0.0083$). Recurrence occurred in one patient after 8 weeks. High transsphincteric fistulas seem to have a better outcome than low transsphincteric fistulas 8 weeks after surgery ($p = 0.0333$). Sex, age, history of recurrence did not correlate with success, failure or recurrence. **Conclusions** VAAFT is a safe technique for both idiopathic and IBD-associated fistulas. It seems to have promising short-term healing rates, which appear to be related to fistula anatomy.

Conflict of interest The authors declare that they have no conflict of interest.

FISTULOTOMY AND PRIMARY SPHINCTEROLASTY (FIPS), A RELIABLE OPTION TO TREAT CRYPTOGLANDULAR ANAL FISTULAS

Litta Francesco, Parello Angelo, De Simone Veronica, Grossi Ugo, Orefice Raffaele, Ratto Carlo

Proctology Unit, University Hospital “A. Gemelli”, IRCCS, Catholic University, Rome Italy

Background Fistulotomy and primary sphincteroplasty (FIPS) has attracted much interest in recent years. The aim of this retrospective study was to evaluate the safety and long-term efficacy of this technique, and to identify potential predictive factors of healing, postoperative incontinence and patient satisfaction. **Methods** The study was conducted on patients with cryptoglandular anal fistulas who underwent FIPS at our institution between June 2006 and May 2017. All patients were evaluated by standardized telephone interview. Main outcome measures evaluated were: fistula healing, continence status (by Cleveland Clinic fecal incontinence score [CCFIS] and post-defecation soiling assessment), morbidity rate, and patient satisfaction (visual analogue scale (VAS)). **Results** Two hundred and three patients (139 males; mean age: 48.7 years, range: 18–85 years) were included in the study. Fistulas were intersphincteric in 58 patients (28.6%), and transsphincteric in 145 (71.4%, 60 low, 85 middle-high). In 17 patients (8.4%) fistula was recurrent. In 103 patients (50.7%) fistulas were complex. A loose draining seton was placed in 46 patients (22.7%) prior to definitive surgery. At a mean follow-up time of 55.9 ± 30.9 months (range 12–143 months), the healing rate was 92.6% (188 patients; 92.0% in simple, and 93.2% in complex fistulas). Three patients (1.4%) developed sphincter dehiscence requiring re-sphincteroplasty. Twenty-six patients (12.8%) complained of “de novo” fecal incontinence, mainly consisting of post-defecation soiling (20 patients, 9.8%); however, CCFIS did not significantly change (preoperative 0.04; at follow-up 0.49). None of the potential predictive factors of healing was statistically significant. Patients with complex fistula were at higher risk of continence disturbances ($p = 0.050$). The mean VAS patient satisfaction score was 9.3 ± 1.6 . The only factor associated with a lower satisfaction rate was the postoperative onset of incontinence ($p = 0.0001$). **Conclusions** FIPS should be considered a valid therapeutic option for selected anal fistulas, giving a good success rate, and providing high patient’ satisfaction. However, a risk of minor postoperative fecal incontinence should be considered and discussed with patients. **Conflict of interest** The authors declare that they have no conflict of interest.

FISTULA IN ANO TREATMENT WITH PERMACOL COLLAGEN PASTE: A REVIEW OF THE LITERATURE

Francesca Da Pozzo

Department of General and Pelvic Suregry, Policlinico Abano Terme Hospital, Abano Terme, Italy

Background Treating anal fistula is challenging due to the need to both preserve anal continence and heal the fistula tract To achieve this goal, especially in complex anorectal fistula where fistulotomy is not an option, use of Permacol Collagen Paste (an injectable acellular

cross-linked porcine dermal collagen matrix) has recently been introduced. The Aim of this study was to review the outcomes of Permacol Collagen paste in anorectal fistula treatment. **Methods** We performed a systematic review of the literature on Pub Med focusing on Permacol Paste use in anorectal fistula treatment. The primary endpoint was the evaluation of fistula healing. Faecal continence, mean operative time, complications and patient satisfaction were secondary end-points. **Results** We found 2 single-center observational studies and 1 multicenter prospective study (the MASERATY 100 study). One study on an experimental porcine model was excluded. A total of 121 patients underwent surgery using Permacol Paste. Ninety-six patients completed 12 months of follow-up. Healing was observed in 50.8% of patients at 12 months. Major (perianal abscess) and minor (external opening with secretions) complications were recorded in 4.4% of and 22% of patients. No patient experienced severe pain. No modification of continence status was found. Regardless of treatment outcome, 73% of patients were satisfied or very satisfied with the procedure. **Conclusions** Permacol Collagen Paste reduces the risk of early extrusion and recurrence. In the era of sphincter saving fistula anal treatment this is a safe and feasible procedure with good results and minimal adverse side effects.

Conflict of interest The authors declare that they have no conflict of interest.

LOCAL TREATMENT OF ANOVAGINAL, RECTOVAGINAL, RECTOURETHRAL AND POUCHVAGINAL FISTULAS USING GRACILIS MUSCLE TRANSPOSITION: LONG TERM FOLLOW-UP DATA

A. Fuerst, G. Liebig-Hoerl, S. Korsun

¹Department of Surgery, Caritas Clinic St. Josef, Regensburg, Germany

Background Recurrent and multi-recurrent fistula combined with perineal defects are a challenging problem in colorectal surgery. The aim of the present study was to evaluate the role of gracilis muscle transposition (GMT) for the treatment of recurrent anorectal fistulas. **Methods** A retrospective study was performed on patients were followed up regarding success rate, complications, additional procedures and stoma closure rate between 2000 and 2015. **Results** In a negatively selected cohort of 72 patients after multiple surgical attempts, successful fistula closure was found in 65% and 67% of patients with or without inflammatory bowel disease (IBD) respectively. Additional surgical procedures were performed in some patients following GMT.

| | Fistulas and IBD | Fistulas without IBD |
|-------------------------------|-------------------|----------------------|
| n | 32 (30 CD / 2 CU) | 40 |
| Primary closure rate | 59% (19/32) | 45% (18/40) |
| Secondary closure rate | 65% (21/32) | 67% (27/40) |
| Gracilis transposition | | |
| with stoma protection | 97% (31/32) | 98% (39/40) |
| Stoma closure rate | 67% (21/31) | 61% (24/39) |
| Secondary stoma rate | | |
| after fistula recurrence | 13% (4/31) | 3% (1/40) |
| Stoma closure rate | | |
| after additional intervention | 25% (1/4) | 100% (1/1) |
| Longterm stoma-free patients | 58% (18/31) | 59% (23/39) |

Conclusions GMT provided a high success rate in the treatment of recurrent and complex anorectal fistulas. Filling up perineal defects and the support of the anal sphincter are additional advantages of GMT.

Conflict of interest the authors declare that they have no conflict of interest.

THE ROLE OF THE IMMUNE SYSTEM IN THE PATHOPHYSIOLOGY OF ANAL FISTULA

Afshin Heydari¹, Gabriele Semprebon², Lorena Losi³

¹Dr. Afshin Heydari, Proctologist, Private Clinics Consultant;

²Dr. Gabriele Semprebon, Biologist; ³Prof. Lorena Losi, Pathologist, Department of Life Sciences, Unit of Pathology, University of Modena and Reggio Emilia, Modena, Italy

Background New technical approaches involving biosynthetic tools have been introduced in the treatment of anal fistula, using the reparative ability of organism and based on the participation of the immune system. The aim of this study was to investigate the role of the immune system in the pathogenesis of anal fistula through serological, histopathological and immunohistochemical features. **Methods** Eleven patients with anal fistula undergoing Video Assisted Anal Fistula Treatment (VAAFT) at our institution were studied to search for serological and histological inflammatory markers. **Results** Only in 1 case was there increased levels of C-reactive protein and protein kinase. No changes of the leukocyte formula were found. In 9 cases the histological examination revealed the presence of granulation tissue characterized by high lymphocytic infiltrate. Immunohistochemistry showed a greater quantity of CD3+ lymphocytes compared to CD20+, with a predominant CD4+ component and macrophages. **Conclusions** The quantitatively significant presence of CD4+, T helper lymphocytes, compared to CD8+, T cytotoxic lymphocytes, leads us to think that the disease may be maintained by the presence of bacterial or other antigens.

Conflict of interest The authors declare that they have no conflict of interest.

TREATMENT OF CRYPTOGLANDULAR COMPLEX ANAL FISTULAS USING A NEW FISTULA PLUG: LONG-TERM RESULTS

Litta Francesco, Parello Angelo, De Simone Veronica, Grossi Ugo, Orefice Raffaele, Ratto Carlo

Proctology Unit, University Hospital “A. Gemelli”, IRCCS, Catholic University, Rome, Italy

Background Treatment of complex anal fistulas of cryptoglandular origin is still debated. The aim of the present study was to evaluate the safety and effectiveness of a new anal fistula plug in long-term follow-up (FU). **Methods** A prospective study was performed on patients with cryptoglandular anal fistula treated at our institution from February 2015 to August 2017. The CuraSeal AF™ Plug device is made of a disk of silicone, and 6 cylindrical collagen matrices. The collagen matrices provide a scaffold during the natural healing process, while the silicone disk provides sealing of the internal opening and is expelled from the anus when the resorbable sutures degrade. All patients were evaluated by clinical and physical examination, and three-dimensional endoanal ultrasound (3D -EAUS) at baseline and, then, at 2 weeks, 1, 2, 3 and 6, 12 months. In the most recent period of the study patients were evaluated also by a pelvic magnetic resonance imaging (MRI) (24 patients), at the baseline and at the 6 and 12 months FU visits. **Results** Thirty-eight patients (20 males, mean age 55.1 years) were enrolled, and 34 patients treated by insertion of the “CuraSeal AF™ Plug”. Thirty-two patients had high transphincteric fistulas and 2 had extrasphincteric fistulas. Neither intranor postoperative complications occurred. The mean length of FU was 17.0 months (range 9–39 months). The healing rate was 61.8% (21/34 patients), as confirmed by clinical evaluation, 3D-EAUS and pelvic MRI at the last FU visit. Failures were related to: persistence of serum discharge (11 patients), persistence of inflammation (one patient), device expulsion (one patient). One case of recurrence after initial healing occurred 10 months after the operation. No patient experienced any change of continence. **Conclusions** The implantation of CuraSeal AF™ Plug is easy, and morbidity appears to be very low. The healing rate seems promising and the risk of postoperative continence impairment is virtually absent. A longer FU and larger population study are needed to confirm these results.

Conflict of interest The authors declare that they have no conflict of interest.

ANAL FISTULA SURGERY IN AN OUTPATIENT SETTING

Costantino Magnani, Alessandra Margiotta, Elio Jovina

Department of General Surgery - Day Surgery Santa Maria della Scaletta Hospital Imola, and Castel San Pietro Terme Hospital, Bologna, Italy

Background The aim of this study was to present our experience of treating anal fistula in an outpatient setting. **Methods** Between May 2015 and April 2018, a retrospective study was performed on patients with transphincteric fistulas operated on at the Castel San Pietro Terme Hospital, in a day surgery setting. Later these patients were regularly evaluated at day 7 and day 15, after 1 month, and finally after 1 year. After these checks we did telephone interviews. Postoperative complications, non-healing, recurrence and the rate of

hospital admission were recorded. **Results** There were 58 patients (43 M, 15 F) (62 surgical procedures). Median age was 49 (range 21–79) years. Forty-two patients had complex anal fistulas, and 16 had low transphincteric fistulas; in 55 patients the fistulas were of cryptoglandular origin, in 2 cases associated with Crohn's disease and in 1 case with ulcerative colitis. Forty-two fistulas were posterior and 16 anterior 34 patients had a loose seton at the time of the surgical procedure. The interventions consisted of: fistulotomy (n = 32), video-assisted anal fistula treatment (VAAFT) (n = 21), fistula-tract laser closure (FILA) (n = 5), fistulectomy (n = 1), fistulotomy with primary sphincteroplasty (n = 1), plug (Pressfit) (n = 1), loose seton (n = 1). Fifty-six patients were sent home the evening of surgery while 2 patients required hospitalization. Median length of follow-up was 22 (range 4–36) months. Panniculitis as a complications of VAAFT was found in 2 patients. Two patients had temporary gas incontinence. Failure to heal or recurrence after surgery developed in 7 patients (12%). Considering the re-interventions healing occurred in 94.8%. **Conclusions** With the new minimally invasive surgical procedures, anal fistulas, especially the complex ones, can be treated safely and effectively in an outpatient setting.

Conflict of interest The authors declare that they have no conflict of interest.

DESTROY TO REBUILD: FISTULECTOMY, SPHINCTEROPLASTY AND ANOPLASTY FOR LOW TRANSSPHINCTERIC PERIANAL FISTULA

D. Mascagni, P. Mascagni, D. Pironi, L. Fralleone, C. Eberspacher

III Clinica Chirurgica, "La Sapienza" University, Rome, Italy

Background Treatments of perianal fistula must eradicate the pathology while preserving sphincter function. Despite the surge of no-cutting techniques, fistulectomy with lay open is still the gold standard for treatment of all fistulas. Arguments against fistulectomy for treatment of low trans-sphincteric anal fistula are the long healing time and the possibility of continence impairment. If it is true that with for low intersphincteric fistulas risk of impaired continence, soiling and anal deformity is minimal, it is not for low transsphincteric fistulas. For the latter, after total fistulectomy and abscess removal we "rebuilt" with sphincteroplasty and anoplasty, closing residual cavity. We compare our experience with this procedure to traditional fistulectomy with lay open. **Methods** We retrospectively studied patients with low transsphincteric fistula (< 30% sphincters involvement) treated at our institution between 2011 and 2017. Patients underwent fistulectomy/lay open (Group A) or FISTulectomy, Sphincteroplasty, Anoplasty (FISA/Group B). Primary end-points were postoperative (PO) soiling rate, major incontinence. Secondary end-points were: operative time, healing time, PO anal deformity (0: no deformity, – 1: light, – 2: medium, – 3: severe), wound dehiscence, recurrence rate. **Results** We treated a total of 59 patients, 25 with fistulectomy/lay open (Group A) and 34 with FISA (Group B). Soiling occurred in 13/25 (52%) patients (Group A) and in 5/34 (14.7%) (Group B); in Group A there was an episode of major incontinence. Comparing fistulectomy/lay open with FISA: mean operative time was 30 min (Group A) vs 41 min (FISA); mean healing time 49 days (Group A) vs 25 days (FISA); mean PO anal deformity – 1.8 (Group A) vs – 0.5 (FISA). After a 24 months follow-up there were no recurrences in either group. **Conclusions** Our results with FISA, combining advantages of classical fistulectomy with benefits of reconstruction

showed that the technique preserved sphincter function, and was associated with faster healing time and minimal anal deformity.

Conflict of interest The authors declare that they have no conflict of interest.

SURGICAL TREATMENT OF RECTOVAGINAL FISTULA IN CROHN'S DISEASE: A TERTIARY CENTER EXPERIENCE

Giovanni Milito¹, Giorgio Lisi¹, Michela Campanelli²

¹Department of Surgery, Clinica Valle Giulia, Rome, Italy;

²Department of Surgery, University Hospital of Modena, Modena, Italy

Background Rectovaginal fistula (RVF) is a disastrous complication of Crohn's disease (CD) that is exceedingly difficult to treat. It is a disabling condition that negatively impacts a women's quality of life. Current treatment algorithms range from observation to medical management to the need for surgical intervention. A wide variety of success rates have been reported for all management options. The choice of surgical repair methods depends on various fistula and patient characteristics. Published success rates vary with initial success being around 50% rising to 80% with repeated surgery. Several surgical and sphincter sparing approaches have been described for the management of rectovaginal fistula, aimed at minimizing recurrence and preserving continence. **Methods** A retrospective study of all patients undergoing RVF repair between 2008 and 2014 was performed in our tertiary centre at the University Hospital of Tor Vergata, Rome, Italy. All the patients had CD, underwent surgery for a RVF performed by the same senior surgeon and were prospectively evaluated. Four different surgical approaches were used: drainage and seton, rectal advancement Flap (RAF), vaginal advancement flap (VAF), transperineal approach using porcine dermal matrix (PDM), and Martius flap (MF). Duration of follow-up was 18 months. **Results** A total of 43 patients were evaluated. The median age was 43 years (range 21–53 years). The median time to "complete healing" was 6 months (range 2–11 months). None of the patients was lost to follow-up. The failure rate was 19% in contrast with the healing rate that was 81%. No demographic nor disease-related factors were found to influence healing. **Conclusions** The results of this study support the dogma "there are no absolute rules to treat Crohn's fistula". There is no gold standard technique yet. However it is mandatory to minimize recurrence with a sphincter saving technique. Randomized trials are needed to find a standard surgical approach.

Conflict of interest The authors declare that they have no conflict of interest.

THE PREVALENCE OF HIDRADENITIS SUPPURATIVA IN PATIENTS WITH PERIANAL FISTULA

C. B. H. Molenaar¹, V. C. Scholten², C. B. Ardon²,
H. H. van der Zee²

¹Department of Surgery, Proctos Clinic, Bilthoven, the Netherlands;

²Department of Dermatology, Erasmus Medical Centre, Rotterdam, the Netherlands

Background Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease of the hair follicle characterized by recurring nodules, sinuses, fistulas and scarring. The name ‘Hidradenitis suppurativa’ suggests involvement of the sweat glands. However, several studies have discarded this finding and found involvement of the hair follicle in the apocrine gland. HS is typically located at the intertriginous regions of the body. When HS is present in the perianal region, perianal fistulas (PF) can develop. The prevalence of HS in PF patients is higher compared to the prevalence of HS in the general population. The aim of this observational study was to determine whether there is an association between HS and PF. **Methods** During 10 weeks all data about patient and fistula characteristics were prospectively collected in patients receiving treatment for PF in a specialized proctological centre in the Netherlands. The validated question for HS proposed by Vinding et al. was used to identify HS in PF patients. The relation between the complexity of the fistula was also studied. Data were analysed by means of Chi square test/Fisher’s exact test and Mann–Whitney *U* test. **Results** In 8 of 132 (6.1%) PF patients HS was observed. Four of the 8 HS patients had previously not been diagnosed with HS (50%). The mean age and mean age of onset of HS were higher in patients with complex PF. **Conclusions** Our study demonstrated that HS is under diagnosed in PF patients. However, further research is needed to establish a detailed association between HS and PF and the clinical implications.

Conflict of interest The authors declare that they have no conflict of interest.

A SINGLE-CENTER EXPERIENCE ON THE MORTALITY RATE IN PATIENTS WITH FOURNIER’S GANGRENE

Ozgen Isik, Murat Sen, Ersin Ozturk, Tuncay Yilmazlar

Department of Surgery, Uludag University School of Medicine, Bursa Turkey

Background Fournier’s gangrene (FG) is a progressive and mortal necrotizing fasciitis of perineal, perianal, and genital region requiring emergency surgery. The aim of this study was to investigate whether the experience of the treating center affected the mortality rate of FG. **Methods** Patients who underwent emergency surgery for FG at our department between 1996 and 2017 were included. The first 120 patients (66.7%) treated between 1996 and 2012 were the historical patients group while the 60 patients (33.3%) treated between 2012 and 2017 were the new patients group. Patient demographics, Uludag Fournier’s Gangrene Severity Index (UFGSI) scores, and perioperative outcomes were documented. Mortality rates of the two groups were compared. **Results** In total, 180 patients (68.9% males) with a median age of 58 (22–88) years were included. 53.3% of all patients had diabetes. Disease originating in the anorectal region (57.2%) was

the most common factor in the etiology. Mean debridement count was 3.3 ± 2.3 , and a diverting stoma was necessary in 38 patients (21.2%). Split thickness skin graft or flap reconstruction was required for wound closure in 64 (35.7%) patients. The overall mortality rate was 21.1%. There were older patients (mean age 60.7 vs. 56.6 years, $p = 0.04$) with higher UFGSI scores (12.5 vs. 9.6, $p = 0.0064$) in the new patients group compared to the historical patients group while the mortality rates in the 2 groups were comparable (20.8% vs. 21.6%, $p = 0.89$). **Conclusions** Despite of the developing medical experience and technology, FG is still associated with a high risk of mortality. However, having comparable mortality rates while treating older and more severely ill FG patients during the past 5 years when compared to the previously treated historical patient group may be associated with the experience of our department.

Conflict of interest The authors declare that there is no conflict of interest.

CONTEMPORARY SURGICAL PRACTICE IN THE MANAGEMENT OF ANAL FISTULA WITH A FOCUS ON SPHINCTER-SPARING REPAIR: RESULTS FROM AN INTERNATIONAL SURVEY

Carlo Ratto¹, Ugo Grossi¹, Phil Tozer²,
David Zimmerman³, Angelo Parello¹, Francesco Litta¹,
Veronica De Simone¹, Gian Luca Di Tanna⁴,
Yasuko Maeda⁵

¹Proctology Unit, University Hospital “A. Gemelli”, IRCCS, Catholic University, Rome, Italy; ²Fistula Research Unit, St Mark’s Hospital and Academic Institute, London, United Kingdom; ³Department of Surgery, ETZ (Elisabeth-TweeSteden Hospital), Tilburg, The Netherlands; ⁴Riskcenter - Institut de Recerca en Economia Aplicada (IREA), Department of Econometrics, Statistics and Applied Economics, Universitat de Barcelona, Spain

Background The aim of the present study was to explore sphincter-sparing repair (SSR) procedures in the management of anal fistula with a focus on technical variations among surgeons. **Methods** A 74-question electronic survey was sent to European Society of Coloproctology (ESCP) and American Society of Colon and Rectal Surgeons (ASCRS) members in March 2018. SSR included endorectal advancement flap (ERAF), ligation of the intersphincteric fistula tract (LIFT), plugs, glue, fistula laser closure (FiLaC), video-assisted anal fistula treatment (VAAFT), and over-the-scope clip (OTSC). **Results** Thirteen percent ($n = 510$) of those e-mailed answered the survey. Overall, 492 were surgeons and contributed to the results. Respondents were mostly men (82%), colorectal surgeons (84%) at consultant level (84%), ≥ 40 years of age (64%), practicing in academic (53%) or teaching (30%) hospitals, from the USA (36%) and Europe (34%). About 80% consider fistulotomy as gold-standard treatment only for simple fistulas. Overall, 79, 71, 26, 14, 10, 8, and 5% of invited surgeons had experience with ERAF, LIFT, plugs, glue, FiLaC, VAAFT, and OTSC, respectively, with significant technical variations (e.g. management of internal orifice and fistula tract). Among these, only 1–4% were confident in performing the most novel SSR in patients with Crohn’s disease. Declared rates of recurrence with these techniques varied consistently. **Conclusions** Profound technical variations exist in SSR of anal fistula, making it difficult to reproduce and compare treatment outcomes among centres.

Conflict of interest The authors declare that they have no conflict of interest.

THE FUTURE OF IMAGING IN COMPLEX PERIANAL FISTULA: 3D IMAGES, ANIMATIONS, FISTULA APP, 3D PRINTED MODELS; AND AUGMENTED REALITY

Kapil Sahnan^{1,2}, Samuel O. Adegbola^{1,2}, Philip J. Tozer^{1,2}, Arun Gupta^{1,2}, Janindra Warusavitarne^{1,2}, Omar D. Faiz^{1,2}, Ailsa L. Hart^{1,2}, Robin K. S. Phillips^{1,2}, Phillip F. C. Lung^{1,2}

¹Robin Phillips' Fistula Research Unit, St Mark's Hospital, London, UK; ²Department of Surgery and Cancer, Imperial College London, UK

Background Perianal fistulas are a topic that is hard to understand let alone teach. The key to understanding the treatment options and the likely success, is deciphering the exact morphology of the tract(s) and the amount of sphincter involved. Our aim was to explore alternative platforms to better understand complex perianal fistulas through three-dimensional (3D) imaging and reconstruction. **Methods** Digital imaging and communications in medicine images of spectral attenuated inversion recovery magnetic resonance imaging (SPAIR MRI) sequences were imported onto validated open-source segmentation software. A specialist consultant gastrointestinal radiologist performed segmentation of the fistula, internal and external sphincter. Segmented files were exported as STereoLithography files. Images and animations were created in collaboration with Touch Surgery™. Cura (Ultimaker Cura 3.0.4) was used to prepare the files for printing on an Ultimaker 3 Extended 3D printer. **Results** 3D models of the fistula tract and sphincter complex were created from several patients with complex perianal Crohn's fistula. A combination of static images, short animations were created. In addition, the reconstructions were uploaded onto an app to allow for manipulation of the images and also removal of the surrounding structures. Three examples of 3D printed models demonstrating complex perianal fistula were created. The anatomical components were displayed in different colours: Red: Fistula Tract; Green: External Anal Sphincter and Levator Plate; Blue: Internal Anal Sphincter and Rectum. Two animations were also created, including an MRI fistulography of a transsphincteric fistula tract with a cephalad extension in the intersphincteric space. An augmented reality platform was used to demonstrate the use of the 3D reconstructions in theatre. **Conclusions** MRI is the reference standard for assessment of perianal fistula, defining anatomy and guiding surgery. However, communication of findings between radiologist and surgeon remains challenging. 3D reconstructions of complex perianal fistula are feasible with the potential to improve surgical planning, communication with patients and augment training.

Conflict of interest KS has received honoraria from Takeda for sitting on an advisory boards and for speaking at a symposia.

COMPARISON OF PERMACOL™ COLLAGEN PASTE INJECTION AND RECTAL ADVANCEMENT FLAP FOR THE TREATMENT OF COMPLEX CRYPTOGLANDULAR ANAL FISTULAS. A PROSPECTIVE, OBSERVATIONAL, COHORT STUDY WITH A 2-YEAR FOLLOW-UP

Michele Schiano di Visconte¹, Gabriele Bellio¹

¹Colorectal and Pelvic Floor Diseases Center, Department of General Surgery, "S. Maria dei Battuti" Hospital, Conegliano (TV), Italy

Background Rectal advancement flap is the standard surgical treatment for complex cryptoglandular anal fistulas, while Permacol™ collagen paste is considered an innovative treatment option for anorectal fistulas. The aim of this study was to compare the clinical outcomes of patients with complex cryptoglandular fistulas treated by endorectal advancement flap versus Permacol™ paste. **Methods** Forty-two consecutive patients with complex cryptoglandular anal fistulas were enrolled in this prospective, double-arm, observational, cohort study. Twenty-one patients were treated with the rectal advancement flap (RAF group), while 21 were treated with Permacol™ paste injection (PP group). Clinical outcomes were assessed in terms of healing rate, faecal continence, postoperative pain, and patient satisfaction. **Results** The median pain scores 1 week postoperatively were 5 (range 3–6) in the RAF group, and 4 (range 3–7) in the PP group ($p = 0.101$). At 4 weeks postoperatively, the PP group experienced less pain than the RAF group (1 (range 1–4) vs. 2 (range 1–4); $p = 0.004$). Four patients (19%) in the RAF group and one (4%) in the PP group experienced fecal incontinence. Three patients (14%) in the RAF group and 5 (24%) in the PP group had continence disorders postoperatively. The 2-year disease-free survival was 57% in the RAF group and 52% in the PP group ($p = 0.910$). The median satisfaction scores were 4 (range 1–10) in the RAF group and 7 (range 2–10) in the PP group ($p = 0.269$). **Conclusions** The RAF and Permacol™ paste produce similar long-term healing, but Permacol™ potentially results in superior clinical outcomes.

Conflict of interest The authors declare that they have no conflict of interest.

PERMACOL™ COLLAGEN PASTE INJECTION FOR TREATMENT OF COMPLEX CRYPTOGLANDULAR ANAL FISTULAS: AN RETROSPECTIVE COHORT STUDY

Michele Schiano di Visconte¹, Andrea Braini², Luana Moras³, Tommaso Cipolat Mis³, Luigi Bruscianno⁴, Ludovico Docimo⁴, Gabriele Bellio¹

¹Colorectal and Pelvic Floor Diseases Center, Department of General Surgery, “S. Maria dei Battuti” Hospital, Conegliano (TV), Italy; ²Department of General Surgery, “Santa Maria Degli Angeli” Hospital, Pordenone, Italy; ³Department of General Surgery, Azienda Sanitaria Universitaria Integrata di Trieste, Italy; ⁴Department of Medical, Surgical, Neurologic, Metabolic and Aging Sciences, XI Division of General and Obesity Surgery, Second University of Naples, Naples, Italy

Background Permacol™ paste injection is a novel treatment approach for complex cryptoglandular anal fistulas. This study was performed to evaluate the long-term clinical outcomes of treatment with Permacol™ paste for complex cryptoglandular fistulas. **Methods** Patients with primary or recurrent complex cryptoglandular anal fistulas treated with Permacol™ paste from 2014 to 2016 were retrospectively analysed. **Results** Forty-six patients (median age, 41.3 years; 21 females) underwent Permacol™ paste injection. Twenty patients (43%) had previously undergone failed fistula surgery. The patients had experienced anal fistula-related symptoms for a median of 10 weeks (range 3–50 weeks). All patients had a draining seton in situ for a median of 10 weeks (range 4–46 weeks). The median follow-up time was 24 months (range 1–25 months). At the 1-month follow-up, 2 patients had paste extrusion and 2 had anal abscesses. The mean preoperative continence grading scale score was 1.10 ± 1.40 , and that at 3-months postoperatively was 1.13 ± 1.39 ($p = 0.322$). There was a significant difference in the preoperative and the 1- and 3-month postoperative pain scores ($p < 0.001$). At the 24-month follow-up, the healing rate was 50% ($n = 23$). Nineteen patients (41%) with a recurrent fistula after failed Permacol™ paste injection required additional surgical procedures. The satisfaction rate at the 2-year follow-up was 65%. **Conclusions** Permacol™ paste injection is minimally invasive and technically easy to perform. It can be considered as the initial treatment option for complex cryptoglandular anal fistulas in patients with fecal continence disorders.

Conflict of interest The authors declare that they have no conflict of interest.

FiLaC™ LONG-TERM OUTCOMES: A SYSTEMATIC REVIEW

Konstantinos Stergios^{1,2,3}, Maximos Frountzas², Ioannis Thivaivos³, Vasilios Pergialiotis^{2,3}

¹Watford General Hospital, Watford, UK; ²National and Kapodistrian University of Athens, Athens, Greece; ³Iaso General Hospital, Athens, Greece

Background Anal fistulas were described more than 2500 years ago but optimal treatment of them remains a challenge. Over the last few years, the use of laser for the treatment of the fistulas has been adopted with enthusiasm. The aim of the present study was to analyze the latest data reported in literature and to identify the long-term

results of fistula laser closure (FiLaC™). **Results** In our systematic review we included 5 studies, published between 2014 and 2018, on total of 342 patients treated with FiLaC. The fistulas were classified according to Park's classification. The median follow-up period was 42.86 months and the median success rate was 70.4%. Terzi et al. observed after a median follow up period of 28.3 months that complete healing was evident in 40% of patients and that stratification of the severity of fistula based on the Park classification did not result in significant differences in terms of fistula healing. Wilhelm et al. followed-up their patients at 6 weeks, 3 and 6 months and at 1 year and reported that primary healing rates reached 64%, while secondary healing rates at the end of the study reached 88% of the population. Donmez et al. observed that the success rate reached 88.9%. Giarmundo et al. reported that the technique cured 71% of cases, failed in 24.4 of cases and 2 cases had a recurrence. Ozturk et al. reported high success rates that reached 82% of cases. **Conclusions** To date the long-term results of FiLaC are not completely known. The results of this systematic review regarding the long-term outcomes are encouraging, although large randomized controlled trials and meta-analyses would offer more robust evidence.

Conflict of interest The authors declare that they have no conflict of interest.

LESS IS MORE FOR DIABETIC PATIENTS WITH ANAL FISTULA: A REVIEW OF THE LITERATURE

Konstantinos Stergios^{1,2,3}, Maximos Frountzas², Ioannis Thivaivos³, Vasilios Pergialiotis^{2,3}

¹Watford General Hospital, Watford, UK;

²National and Kapodistrian University of Athens, Greece;

³Iaso General Hospital, Athens, Greece

Background Diabetes mellitus (DM) is a worldwide health issue. In particular, over the last few years very important studies have been published regarding the impaired healing process in diabetic patients. DM is a confirmed risk factor for developing perianal sepsis and anal fistula and there is recent evidence of increased risk of DM following perianal sepsis. The aim of this study was to review the latest data reported in the literature on the susceptibility of diabetic individuals to anal fistula. **Methods** We analyzed data from studies regarding the biomolecular basis of the healing process in diabetics, their higher rate of presenting perianal abscesses, consequent formation of fistulas! and their higher complications rate. There are kinetic and functional differences in diabetic healing monocyte/macrophages. Davis et al. demonstrated that the diabetic wounds exhibit a chronic inflammatory predisposition and increased local hypoxic conditions with impaired cellular responses to hypoxia. Wong showed that the neutrophil defense mechanism of extruding decondensed chromatin, termed NETosis, mediates delayed wound healing in diabetes. Menegazzo also reported that high glucose and hyperglycemia increase the release of NETs and circulating markers of NETosis, respectively. Their results provide a link among neutrophils, inflammation and tissue damage in diabetes. **Results** It is evident, from the analyzed studies that patients with diabetes mellitus present impaired healing potential, higher incidence of perianal abscesses and fistulas and higher rate of postoperative complications, in confront with their non-diabetic counterparts. **Conclusions** We believe that there is strong evidence to support the impaired healing potential and the susceptibility to infections in diabetic patients. In particular, over the last few years very important studies have been published regarding

the impaired healing process in diabetic patients. We prefer and recommend, when possible, minimally invasive techniques such as fistula laser closure (FiLaC) and video-assisted anal fistula treatment (VAAFT) for the treatment of anal fistulas in these patients.

Conflict of interest the authors declare that they have no conflict of interest.

AUTOLOGOUS, MICRO-FRAGMENTED AND MINIMALLY MANIPULATED ADIPOSE TISSUE AS AN INNOVATIVE APPROACH FOR THE TREATMENT OF COMPLEX ANAL FISTULAS: A PROSPECTIVE OBSERVATIONAL STUDY

A. Sturiale*, B. Fabiani*, C. Menconi*, I. Giani*, G. Toniolo*, G. Naldini*

*Proctological and Perineal Surgical Unit, Cisanello University Hospital, Pisa, Italy

Background The aim of the present study was to evaluate the healing rate of complex anal fistula treated with the association of advancement flap and autologous, micro-fragmented and minimally manipulated adipose tissue injection. **Methods** A prospective observational study was conducted on patients with complex anal fistula treated with advancement flap and autologous, micro-fragmented and minimally manipulated adipose tissue injection between May 2015 and December 2017 at our institution. Twenty-five patients out of 30 expected according to the power analysis, were enrolled. **Inclusion criteria** complex anal fistula confirmed by pelvic magnetic resonance imaging or 3D 360° transanal ultrasound, fistula already drained with a seton from 4 to 6 weeks, first sphincter-saving procedure. **Exclusion criteria** multiple fistula tracts, abscess, inflammatory bowel disease, human immunodeficiency virus, or hepatitis B or C infection, rectovaginal fistula, therapy with anticoagulants, steroids or immunomodulators, previous pelvic radiotherapy, personal history of neoplasia within 5 years from the diagnosis, pregnancy, uncontrolled diabetes, coagulopathy or connective diseases. **Technique** The harvested fat from the lateral abdominal wall was processed in the processing kit (Lipogems®). After curettage of the fistula tract, the internal opening was closed through 3/0 polkydioxanone stiches with mucosal flap above it and a subsequent injection of the processed adipose tissue around the fistula tract and internal opening. Follow-up was scheduled at 7 days, and 1, 3, 6, and 12 months after surgery. Fistula healing was defined as the closure of internal and external openings without any discharge. **Results** Twenty-five patients underwent the procedure. The mean operative time was 55 min. Mean follow-up was 9 months. The recurrence rate was 20%. Overall only 1 case of abscess and 4 cases of persistent discharge without closure of the internal and external openings were observed. **Conclusions** Autologous, micro-fragmented and minimally manipulated adipose tissue injection appears to be a safe, feasible and effective procedure to promote complex anal fistula healing. Preliminary results of this novel technique are very promising, although a larger number of patients is required to draw any conclusions about long-term results compared with the other sphincter-saving procedures.

Conflict of interest The authors declare that they have no conflict of interest.

MANAGEMENT OF PERSISTENT RECTOVAGINAL FISTULA BY TWO-STAGE ADIPOSE-DERIVED STEM CELL TRANSPLANTATION

Marcin Piejko^{1,2}, Michał Romaniszyn¹, Julia Borowczyk-Michałowska², Justyna Drukata², Piotr Wałęga^{1,†}

¹3rd Department of General Surgery Medical College Jagiellonian University, Krakow, Poland; ²Cell Bank, Department of Cell Biology, Faculty of Biochemistry, Biochemistry, Biophysics and Biotechnology, Jagiellonian University, Krakow, Poland

Background The risk of recurrence after surgical treatment of a recurrent anal fistula is up to 50%. It is known that aggressive surgical treatment is associated with an elevated risk of anal sphincter damage and leads to fecal incontinence. Several studies have been designed to elaborate minimally invasive treatment of rectovaginal and anal fistulas. The properties of adipose-derived stem cells (ASC) significantly enhance natural healing potency. In the present study we assess our experience in persistent rectovaginal fistula by two-stage cell therapy. **Methods** Three patients with rectovaginal fistula were enrolled in our pilot study. In 2 cases, fistulas persisted after graciloplasty and colostomy. ASC were isolated from adipose tissue, cultured up to $10 \pm 2 \times 10^6$ cells and injected into the fistula wall. Physical examination and anoscopy were performed at 1, 4, 8, 12 weeks, 6 and 12 months after implantation. **Results** Up to 8 weeks after ASC implantation, symptoms were relieved. At 8 weeks, communication between the vaginal and rectal openings were closed, whilst 2 patients underwent restoration of intestinal continuity at 12–16 weeks. Up to 36 months after ASC implantation no recurrences and adverse events were observed. **Conclusions** ASC injection was successfully performed in 3 patients with persistent rectovaginal fistula after failed surgical treatment. These encouraging results need confirmation with further studies to evaluate the clinical efficacy and cost-effectiveness of this therapy.

Conflict of interest The authors declare that they have no conflict of interest.

LASER ABLATION OF FISTULA TRACT (LAFT): LONG-TERM OUTCOMES

Ersin Öztürk¹, Özgen Isik², Baris Gulcu¹

Medicana Hospital¹ and Department of Surgery, Uludağ Univ. School of Medicine², Bursa, Turkey

Background Laser ablation of fistula tract (LAFT) has become popular for the treatment of fistula in-ano since we published our initial experience [1]. However, there are concerns about LAFT such as its true success rate, whether the healing is due to curettage or the laser itself or what type of fistulas are good candidates for LAFT. The aim of this study was to determine the answers to the current concerns regarding LAFT. **Methods** Patient charts of 100 patients with fistula-in-ano who underwent LAFT at our institution were retrospectively reviewed. The short- and long-term outcomes were analyzed. **Results** Patients were operated on using radial emitting laser probes of 4 different makes. The first 50 patients had been enrolled in our initial trial. Later the rest of the patients were selected based on the initial experience from that study. Selection criteria for LAFT were as

follows: (1) LAFT was avoided for patients who were candidates for simple fistulotomy, (2) A drainage seton was applied prior to LAFT for patients who had perianal abscess or sepsis with perianal fistula, (3) LAFT was avoided for patients with inflammatory bowel disease particularly Crohn's disease, (4) Patients with intrasphincteric fistula tracts shorter than 2 cm did not undergo LAFT (5) Patients with posterior intersphincteric fistula originating from chronic anal fissure were also poor candidates for LAFT. The total number of patients who underwent surgery for perianal fistula was 663 during the study period (the last 5 years). LAFT was only used in 100 patients (15%). There were no short-term complications. The initial success rate was 82% in our initial trial. This decreased to 61% after a median follow up time of 48 (6–56) months. The overall success rate was 60%. A

particular laser tip had a higher failure rate (50%) than the others. When the patients were divided into 2 groups as the first 50 (the first study population) and second 50, and the patients who were treated with that weaker laser tip were excluded the success rate increased up to 71% in the second 50-patient group. **Conclusions** LAFT is a good method to treat fistula-in-ano in highly selected patients. The healing effect is due to energy transfer by laser not curettage.

Conflict of interest The authors declare that they have no conflict of interest.

Reference

1. Ozturk E, Gülcü B (2014) Laser ablation of fistula tract: a sphincter-preserving method for treating fistula-in-ano. *Dis Colon Rectum*. 57:360–364