



New Modalities Treatment for Anal Fistula

By

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Disclosure

- I have nothing to disclose

Objectives

- Background
- Therapeutic goals
- Patients' perspective
- Therapeutic options
- Fistula plug
- Fistula Laser Closure (FiLaC)
- Platelets Rich-Plasma (PRP)
- Conclusions

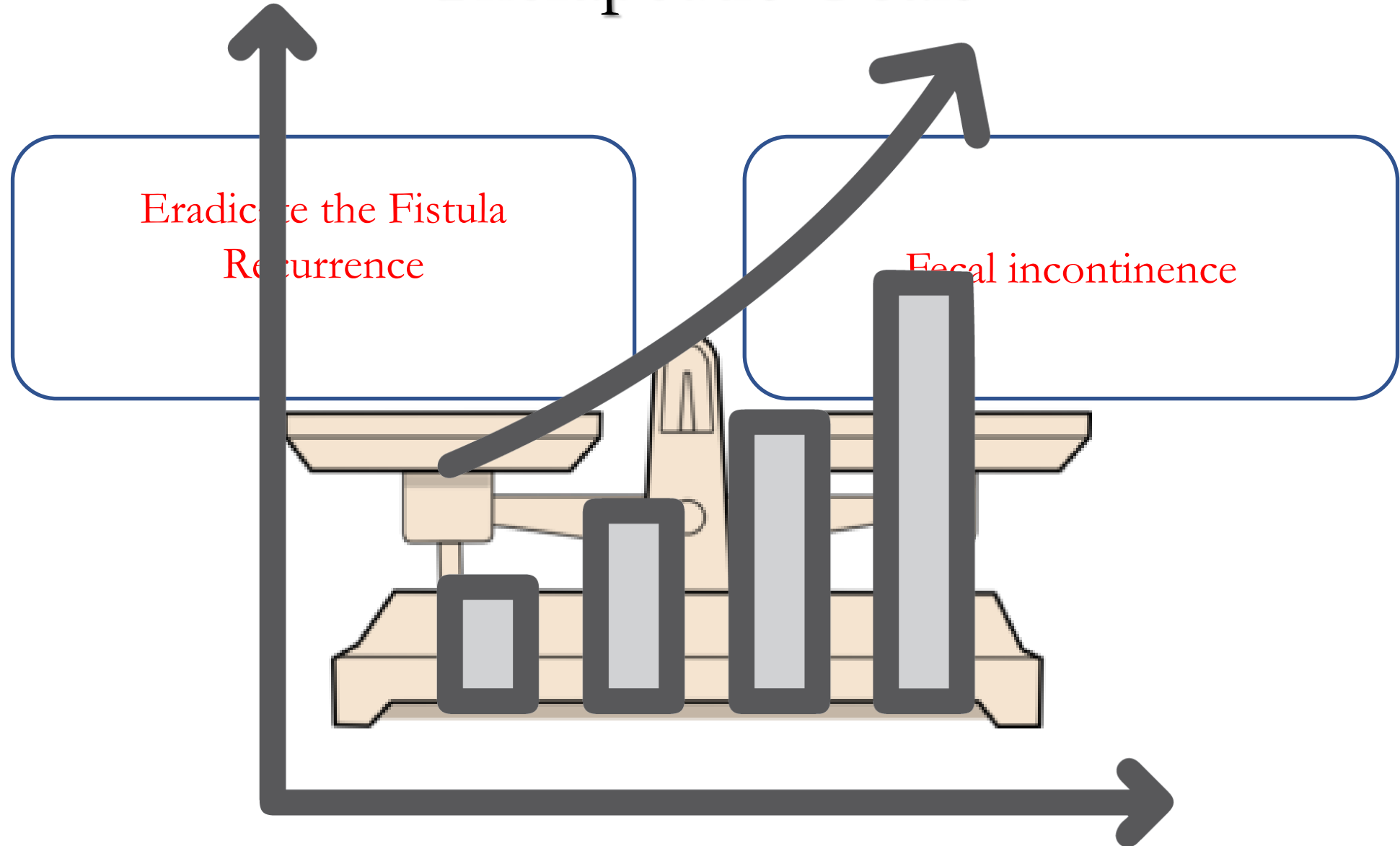
Background

- Anal fistula is one of the commonest conditions seen by anorectal surgeons.
- The prevalence is 6/100,000 - 12/100,000 population in women and men.
- It presents with recurrent abscesses or a draining fistula with various severity.
- Interventions could broadly divide into; cutting and sphincter-saving procedures.
- Recurrence is a common and potentially devastating outcome (3 - 57%).
- It adversely affects the surgeon-patient relationship and patients' quality of life.

Therapeutic Goals

- Define the anatomy of the fistula,
- Drain any associated sepsis,
- Eradicate the fistula track,
- Prevent recurrence,
- Preserve continence and sphincter's integrity.

Therapeutic Goals

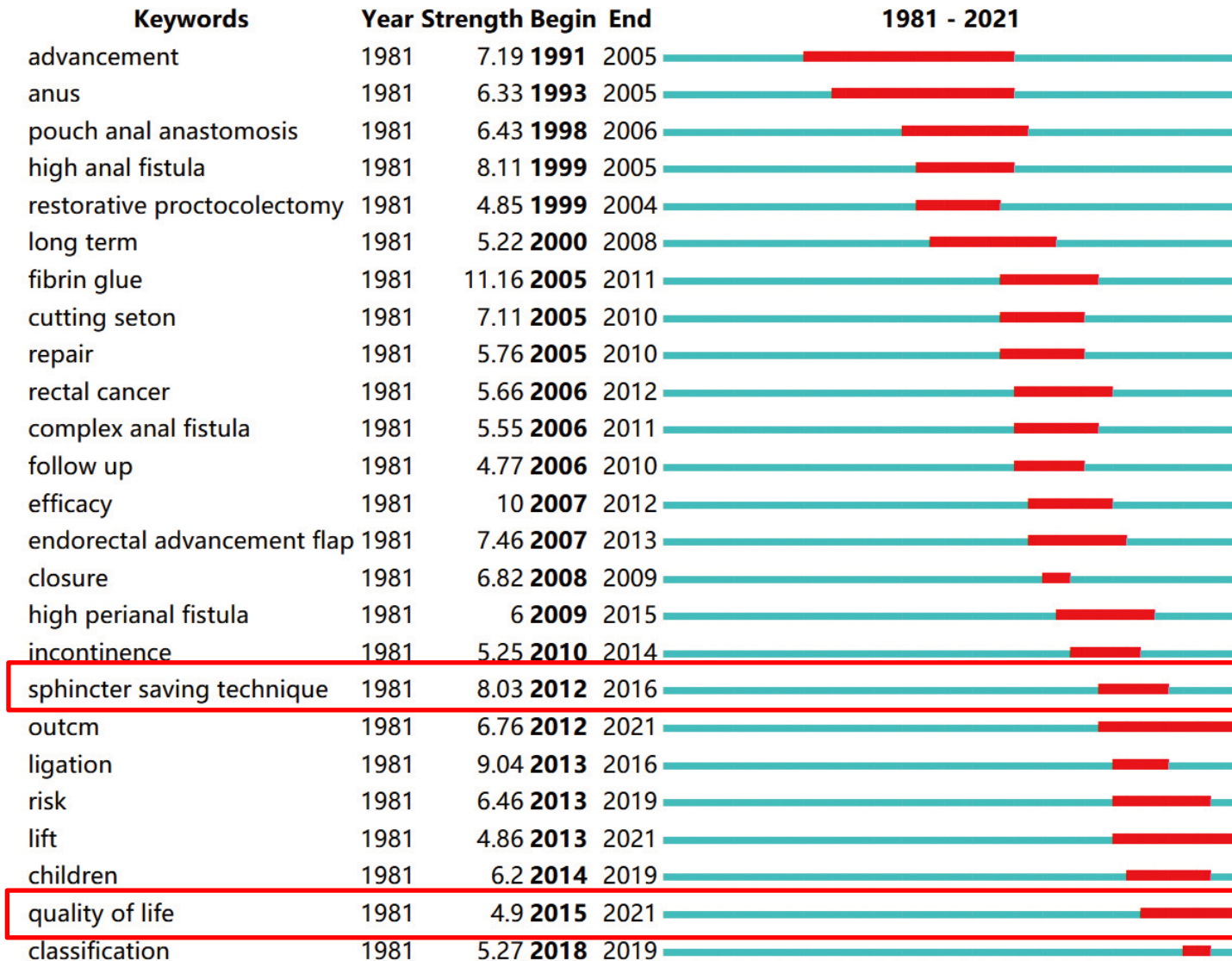


Patients' Perspective



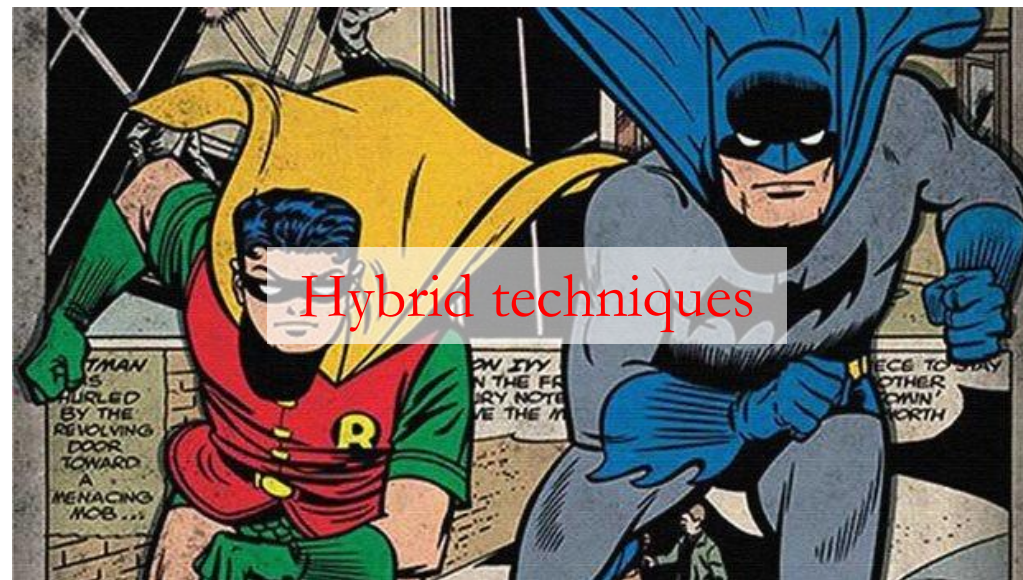
- High healing rate,
- Preservation of continence,
- Fast recovery,
- Minimal surgical trauma.

Trend in FIA Research



Therapeutic Options

- Drainage of the intersphincteric space,
- Cutting,
- Filling,
- Ligation,
- Seton,
- Internal opening closure,
- Regenerative therapy,
- Device-related technology.



Filling Techniques “Biomaterials”

- Fibrin glue
- Anal fistula plug
- Collagen paste

Biomaterials

- It has been proposed that an infill material that bridges the gap and promotes healing.
- The ideal material: allows full host tissue incorporation & neovascularization, withstanding premature degradation & bacterial colonization.
- Over the last 30 years many studies evaluated the role of biological infill materials.

Fistula Plug

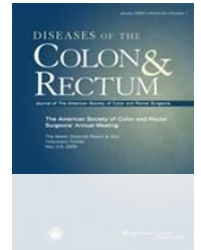
- A bioabsorbable xenograft, made of lyophilized porcine intestinal submucosa.
- It has inherent resistance to infection, produces no foreign body or giant cell reaction.

Biologically derived materials	Synthetic
Xenogeneic grafts (Surgisis® & Permacol®)	GORE BIO-A® fistula plug

Pilot



2006



15 patients

Follow-up 13.8 ± 3.1 weeks

Efficacy of Anal Fistula Plug vs. Fibrin
Glue in Closure of Anorectal Fistulas

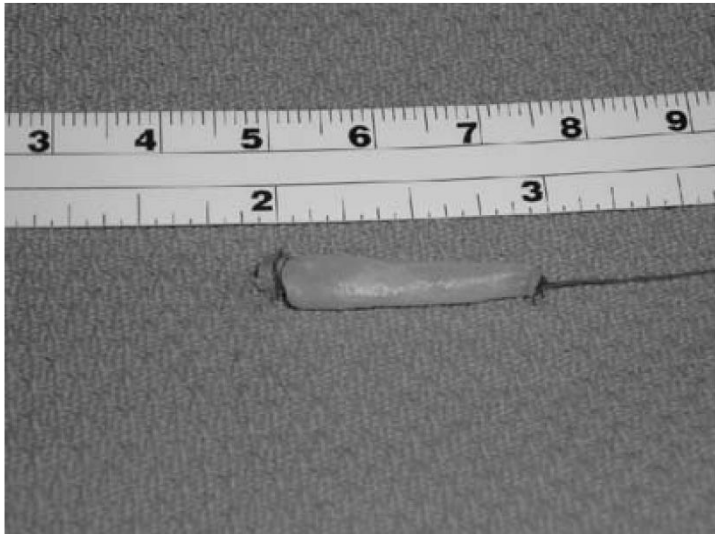
2 patients (13%) had persistent drainage and/or a patent secondary opening

Median time to failure was 4 weeks

Eric K. Johnson, M.D., Janette U. Gaw, M.D., David N. Armstrong, M.D., F.R.C.S.

Georgia Colon & Rectal Surgical Clinic, Atlanta, Georgia

Idea



Fistula Plug

CURRENT STATUS

No of studies 20 **2012**
No of patients 530
Healing 54.3% (20-86%)
Plug extrusion 8.7%



A Systematic Review of the Anal Fistula Plug for Patients with Crohn's and Non-Crohn's Related Fistula-in-Ano

FI J. M. O'Riordan, M.D. • I. Datta, M.D. • C. Johnston, M.Sc. • N. N. Baxter, Ph.D.
 Department of Surgery and The Keenan Research Centre, Li Ka Shing Knowledge Institute, St Michael's Hospital, University of Toronto, Toronto, Ontario, Canada

No (report on 196 only)

Systematic review **No of studies** 2018 **6** doi:10.1111/codi.13208

Delayed absorption of a bioabsorbable plug (GORE® BIO-ABS) for the treatment of fistula-in-ano: a systematic review
Healing 15.8-72.7%
Plug extrusion 8.5% (187)

S. K. Narang*, C. Jones†, N. N. Alam*, I. R. Daniels* and N. J. Smart*
 *Exeter Surgical Health Services Research Unit (HeSRU), Royal Devon and Exeter Hospital, Exeter, Devon, UK and †University of Exeter Medical School, Exeter, Devon, UK

Received 20 April 2015; accepted 10 September 2015; Accepted Article online 6 November 2015

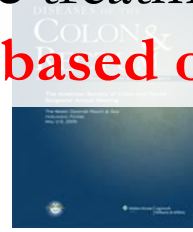
FI 5.8% (report on 187 only)



Guidelines

CLINICAL PRACTICE GUIDELINES The anal fistula plug is relatively **ineffective** treatments for fistula-in-ano. **Grade of recommendation: strong recommendation based on moderate-quality evidence, 1B.**

The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anorectal Abscess, Fistula-in-Ano, and Rectovaginal Fistula



Wolfgang B. Gaertner, M.D., M.Sc.¹ • Pamela L. Burgess, M.D.²
Jennifer S. Davids, M.D.³ • Amy L. Lightner, M.D.⁴ • Benjamin D. Shogan, M.D.⁵
Mark Y. Sun, M.D.¹ • Scott R. Steele, M.D., M.B.A.⁴ • Ian M. Paquette, M.D.⁶
Daniel L. Feingold, M.D.⁷

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DOI: 10.1111/codi.16741

Fistula plug can be **considered** in the management of anal fistula.

Low-level evidence. [Downgraded by GDG, expert opinion]

and treatment of cryptoglandular anal fistula



Lillian Reza¹ | Kevin Gottgens² | Jos Kleijnen³ | Stephanie Breukink⁴ |
Peter C. Ambe⁵ | Felix Aigner⁶ | Erman Aytac⁷ | Gabriele Bislenghi⁸ |
Andreas Nordholm-Carstensen⁹ | Hossam Elfeki¹⁰ | Gaetano Gallo¹¹ | Ugo Grossi¹² |
Baris Gulcu¹³ | Nusrat Iqbal¹⁴ | Rosa Jimenez-Rodriguez¹⁵ | Sezai Leventoglu¹⁶ |
Giorgio Lisi¹⁷ | Francesco Litta¹⁸ | Philip Lung¹⁹ | Monica Millan²⁰ | Ersin Ozturk²¹ |
Charlene Sackitey²² | Mostafa Shalaby²³ | Jasper Stijns²⁴ | Phil Tozer²⁵ |
David Zimmerman²⁶

Device-related Technology

- Video-Assisted Anal Fistula Treatment (VAAFT)
- Fistula Laser Closure (FiLaC)

Laser History

- Over the past 4 decades, laser has been advocated in of benign proctological diseases.
- In 1981, Slutzki used CO2 laser for coring-out fitulous tracks.
- In 2011, Willham introduced FiLaC as a novel sphincter-preserving technique.

Pilot Study

Tech Coloproctol (2011) 15:445–449

2011

Table 1 Summary of all patients treated by the new procedure

Patient	Fistula type	Flap type	Healing	Follow up/months	Incontinence
1	2	Advancement	Yes	6	N
2	2	Advancement	Yes	8	N
3	1	Mucosa	Yes	8	N
4	3	Advancement	Yes	9	Soling
5	2	Advancement	Yes	9	N
6	3	Anodermal	Yes	11	N
7	4	Advancement	Yes	11	N
8	4	Mucosa	No	11	N
9	2	Advancement	Yes	4	N
10	2	Anodermal	No	3	N
11	3	Anodermal	Yes	2	N

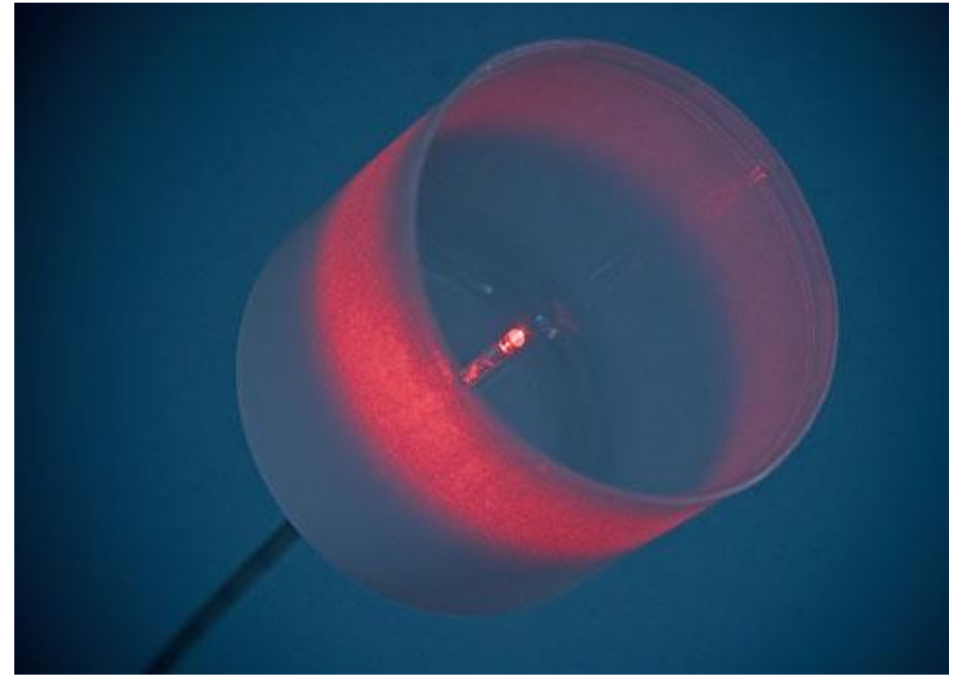
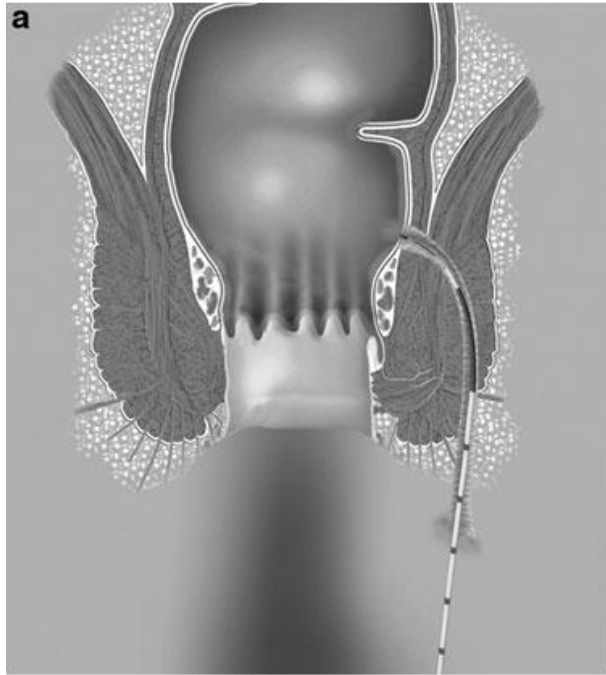
Received: 6 October 2010 / Accepted: 11 July 2011 / Published online: 10 August 2011
 © Springer-Verlag 2011

11

81.8%

Median 7.4

Mechanism



Pilot

Table 1 Patient and fistula characteristics of patients undergoing the FiLaC™ procedure.

Number of patients	35
Gender (M:F)	20:15
Age (years)	48 (27–76)
Type of fistula	
Intersphincteric	8 (23)
Low trans-sphincteric	8 (23)
Mid	12 (34)
High	6 (17)
Suprasphincteric	1 (3)
Multiple fistulous tracks	3
Previous fistula surgery	25
Previous draining (loose) seton	16
Operative time (min)	20 (6–35)

Values are given as *n*, *n* (%) or median (range).

F, female; M, male.

2013

Table 3 Results of the FiLaC™ procedure at a median follow up of 20 (range, 3–36) months.

Results	<i>n</i> (%)
Cured	25 (71.4)
Failed	8 (22.8)
Recurrence	2 (5.8)

aser fibre and a diagram showing its
nal orifice.

Outcomes

Table 3 Types of fistula and technical aspects of the procedure

Study	Clinical type of fistula	Previous surgery			Pathological types		FiLaC device	Watt/ wave length	Probe withdrawal speed	Additional surgical steps	Conflict of interest	p, median	Methodological quality
		Intersphincteric	Trans-sphincteric	Supra/extra	Recurrent cases (%)	Seton (%)							
Ozturk [13]	10	40	0	Were excluded	NA	50	Not included	Biolitec	15 watt/1470 nm	1 cm /6 s	None	The first 20 laser probes used in this study were provided by Biolitec	5
Giamundo [11]	7	36	2/0	35 (77.78)	24 (53)	43	2	Biolitec	12 watt/1470 nm	1 mm /s	None	P. Giamundo is 'surgical trainer' for Biolitec	5
Quaresmini [16]	Not included	82	Not included	33	> 50% of all patients	82	Not included	Not specified	NA/1470 nm	Not specified	None	There is no conflict of interest for the remaining authors	6
Wilhelm [10]	8	90	13/6	16 (13.67)	99 (84.6)	104	13	Biolitec	13 watt/1470 nm	1 cm/3 s	Excision of internal and external opening + closure of the I.O. by MSAF or mucosal flap or anodermal flap or suture closure	Arne Wilhelm has received traveling grants and speaker honoraria from Biolitec and THD Spa	5
Donmez [14]	14	7	5/1	Not specified	5 (18.5)	Not specified		Biolitec	13 watt/1470 nm	1 cm/3 s	None	No conflict of interest	6
Terzi [12]	56+7 superficial fistula	29	11	53 (51.45)	19 (18.45)	103	Not included	Biolitec	12 watt/ 1470 nm	1 mm/s	None	No conflict of interest	7
Lauretta [15]	Not included	30	Not included	22 (73.33)	26 (86.67)	Not specified		EUFOTON	12 watt/ 1470 nm	1 mm/s	None	No conflict of interest	6

Transsphincteric & supra/extrasphincteric fistulas 77.5%
 Recurrent fistulas 35%

I.O internal opening, MSAF mucosal and submucosal advancement flap

Outcomes (continued)

Table 4 Outcomes of the FiLaC

Study	Non-healing	Recurrence	Failure rate	Management of failure	Healing assessment and definitions	Primary healing rate	Secondary	Overall
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Table 5 Perioperative findings and complication

Study	Operative time median (range) minutes	Hospital stay days	Pain control	Complications after primary FiLaC		Incontinence
				Number (%)	Type	
Ozturk [13]	NA	1–2	No patients required opiates	0	-	0
Giamundo [11]	20 (6–35)	Day surgery	Analgesics if needed	11 (24.44)	Eight temporary pain and anismus, three bleeding	0
Quaresimini [16]	18 (9–32)	NA	Analgesic	6 (7.32)	Two pain and four abscess	NA
Wilhelm [10]	NA	1–2	NA	4 (3.42)	Three minor soiling, one late abscess	Minor soiling
Donmez [14]	18.37 (5.27) ^a	1–2	No patients required opioid drugs	0	-	0
Terzi [12]	NA	Day-case surgery	Analgesics if needed	0	-	0
Lauretta [15]	18.3 (7.9) ^a	Day-case surgery	Analgesics	4 (13.33)	Two fever, one bleeding, one severe pain	0
NA not available						
^a Mean (standard deviation)						
					4%	1%
Non, one VAAFT, one loose seton and eight patients are still waiting for surgery				33%		
recurrence					67%	
Success was defined as the absence of any discharge and closure of the external opening for at least for 6 months						70%

Outcomes (continued)

Table 2 Characteristics of the included studies

Study	Country	Year	Study design	Time period	Median follow-up	No. of pfCD participants	Healed	Primary healing rate	Recurrence
Giamundo [9]	Italy	2015	Retrospective	Jul 2010–May 2014	30 (6–46) months	2	2	100%	N.A
Wilhelm [5]	Germany	2017	Retrospective	Oct 2009–Jul 2014	25.4 (6–60) months	13	9	69%	N.A
De Hous [10]	Belgium	2019	Retrospective	Nov 2016–Dec 2018	9 (4–26) months	2	2	100%	0
Alam [13]	France	2020	Retrospective	Mar 2016–Nov 2018	7.1 (2–22.5) months	20	11	55%	N.A
Wolicki [11]	Germany	2020	Retrospective	Jan 2011–Dec 2017	41.99 (4–87) months	2	1	50%	N.A
Nordholm-Carstensen [12]	Denmark	2021	Retrospective	Mar 2017–Jul 2019	19 (12–26) months	11	6	55%	0
<i>pfCD</i> perianal fistulizing Crohn's disease, N.A. not available									
						6	50	68%	

Long-term Results

Table 4 Univariate analysis of potential predictive factors (175 patients)

Factor	Success (<i>n</i> = 117)	Failure (<i>n</i> = 58)	<i>p</i>
Sex (<i>n</i> , %)			0.86 ^a

Table 3 Re

Table 2 Postoperative morbidity

Bleeding (requiring surgical hemostasis) (<i>n</i> , %)			1 (0.6)
Pain (requiring pain relief medications for 1 week) (<i>n</i> , %)			4 (2.3)
Perianal abscess (<i>n</i> , %)			2 (1.1)
Urinary retention (<i>n</i> , %)			4 (2.3)
Soiling (<i>n</i> , %)			6 (3.4)
	No (33)	17 (51.5)	16 (48.5)
			17 (10%)

Limitations

FiLaC

- Significant cost implication
- Limitations of laser probe in suprasphincteric fistulas, extensions, abscess cavities
- No internal opening closure
- Blind technique

Limitations (continued)

Studies reporting FiLaC

- Retrospective nature,
- No RCT,
- Single-centre,
- Heterogeneous study populations.
- **This limits the external validity and reproducibility of the results.**

Guidelines

CLINICAL PRACTICE GUIDELINES
The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anorectal Abscess, Fistula-in-Ano, and Rectovaginal Fistula

Minimally invasive approaches to treat fistula-in-ano that use endoscopic or laser closure techniques have **reasonable short-term** healing rates but **unknown long-term** fistula healing and recurrence rates. **Grade of recommendation: weak recommendation based on low-quality evidence, 2C.**

Wolfgang B. Gaertner, M.D., M.Sc.¹ • Pamela L. Burgess, M.D.²
Jennifer S. Davids, M.D.³ • Amy L. Lightner, M.D.⁴ • Benjamin D. Shogan, M.D.⁵
Mark Y. Sun, M.D.¹ • Scott R. Steele, M.D., M.B.A.⁴ • Ian M. Paquette, M.D.⁶
Daniel L. Feingold, M.D.⁷

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LAFIT can be **considered** in patients with a **high anal fistula**. **Very low-level evidence.**

Repeated LAFIT can be **considered** in patients following primary failure from the first attempt. However, repeat procedures should be undertaken with **caution** as the **cumulative** effect of LAFIT on the sphincter complex is unknown. **Very low-level evidence. [GDG expert opinion]**

Charlene Sackitey²² | Mostafa Shalaby²³ | Jasper Stijns²⁴ | Phil Tozer²⁵ | David Zimmerman²⁶

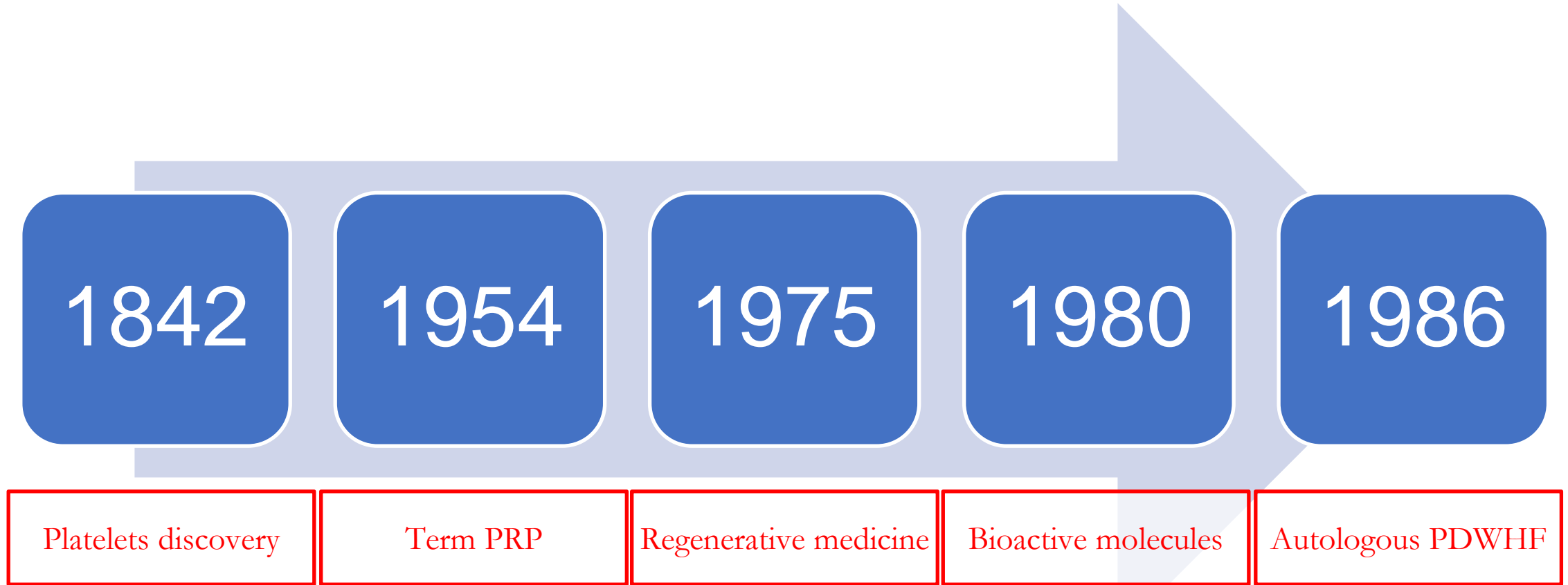
Regenerative Therapy

- Mesenchymal stem cells (MSCs)
- Platelets-rich plasma (PRP)

PRP

- PRP is rich in proteins and growth factors, which have various roles in tissue repair.
- PRP has tissue-like anti-inflammatory and regenerative properties.
- Automated microprocessor-controlled kits has improved PRP production by rapidly generating standardized levels of polymerized.

History



Pilot

Original article

doi:10.1111/j.1463-1318.2009.01991.x

2009

Autologous platelet-derived growth factors (platelet-rich plasma) as an adjunct to mucosal advancement flap in high cryptoglandular perianal fistulae: a pilot study

PRP & mucosal advancement flap
10 patients
1 recurrence (10%)
No FI

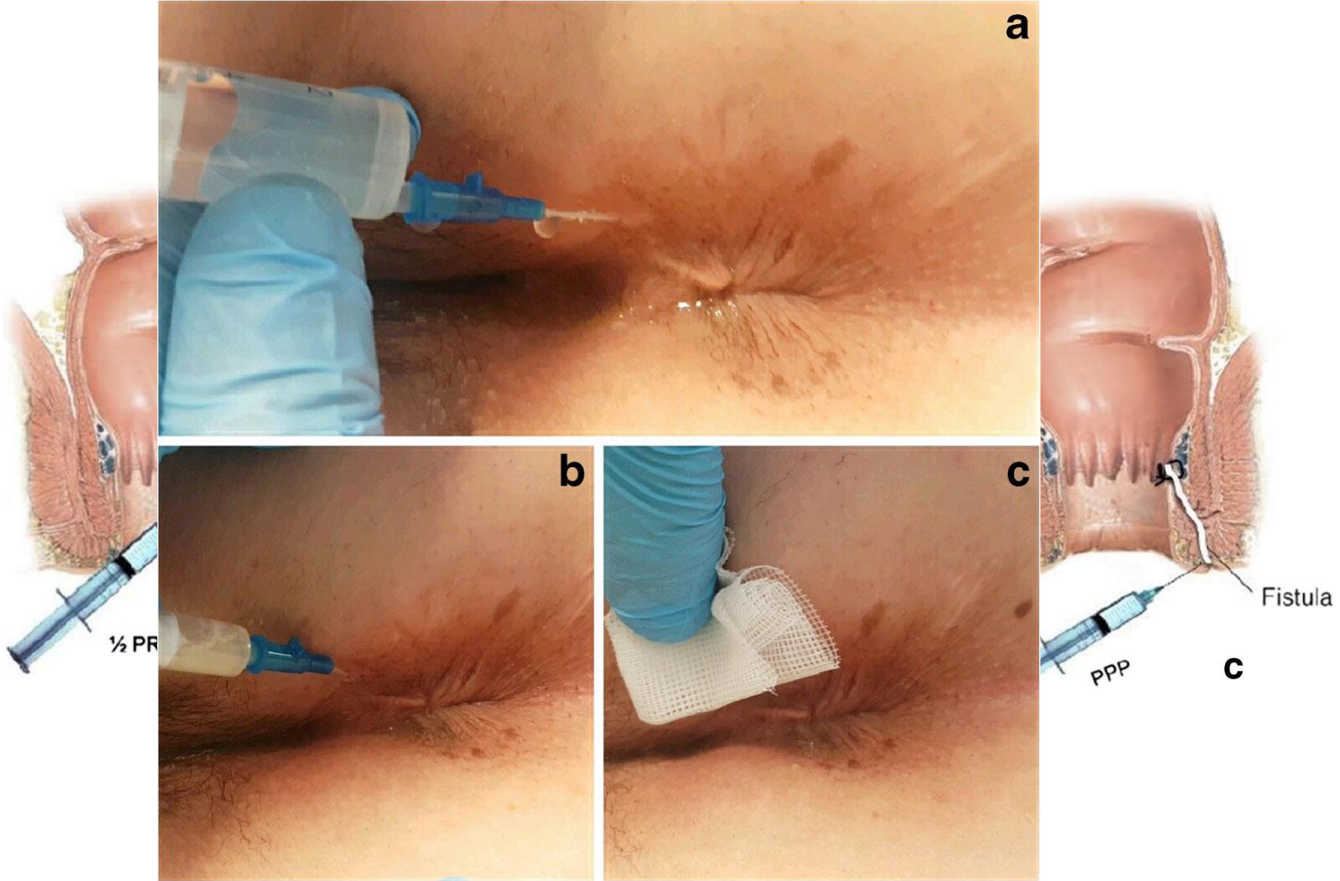
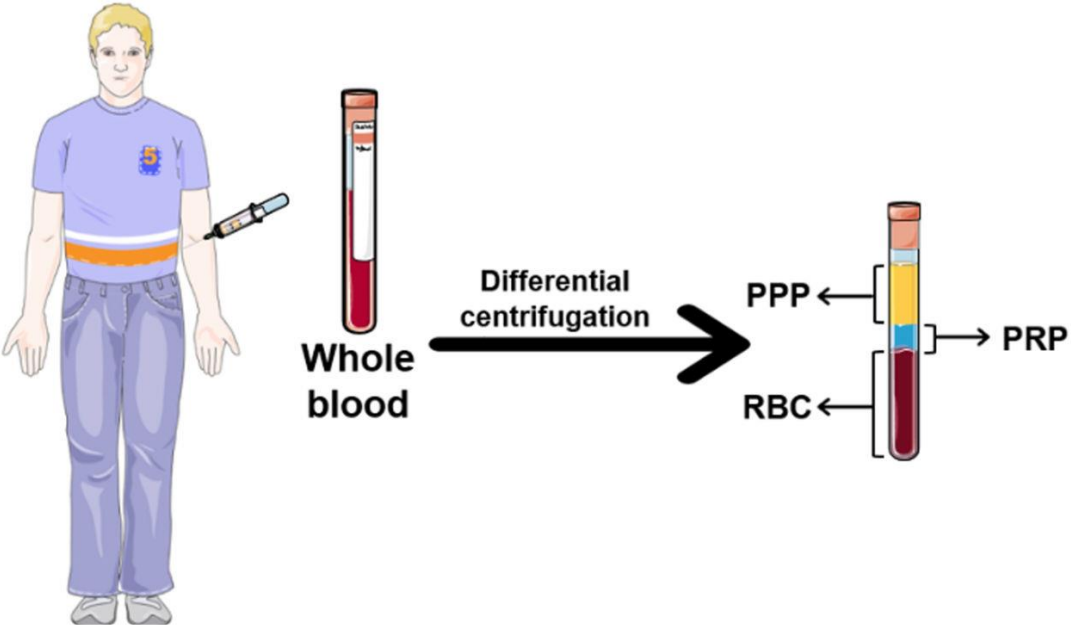
S. J. van der Hagen, C. G. Baeten, P. B. Soeter and W. G. van Gemert

Department of Surgery, Refaja Hospital Stadskanaal, University Hospital Maastricht, The Netherlands

Received 16 February 2009; accepted 19 May 2009; Accepted Article online 3 July 2009



PRP preparation



Santos et al., (2018). Tissue Eng Part B Rev; Lara et al., (2019) & Portilla et al., (2020). J Gastrointest Surg

PRP solo in FIA

J Gastrointest Surg (2015) 19:360–368
DOI 10.1007/s11605-014-2698-7

ORIGINAL ARTICLE



2015



Platelet-Rich Fibrin Sealant & internal opening closure of Complex Perianal
Fistulas: A Multicentre Study 60 patients

Success 68.3% (median follow-up 24 months)

F. J. Pérez Lara · A. Moreno Serrano · J. Oleck · Moreno · S. Hernández Carbona ·
M. Ferrer Márquez · J. Romero Pérez · A. del Real Moreno · H. Olaya Muñoz

Local infection in 2 patients (abscess & cellulitis)

No FI

Received: 4 August 2014 / Accepted: 5 November 2014 / Published online: 25 November 2014
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Table 1 Basic information of included studies

Author	Year	Research design	Therapeutic method	Type of anal fistula	Number of patients	Number of cured cases	Number of complete cured cases	Number of recurrences	Number of adverse events		
van der Hagen et al. [11]	2011	Prospective, observational	PRP+MAF	High perianal cryptoglandular fistulae	10	9	N	1	0		
Göttgens et al. [14]	2014	Retrospective	PRP+MAF	High cryptoglandular perianal fistulas	25	23	23	4	0		
Göttgens et al. [15]	2015	Prospective, pilot	PRP+MAF	Crohn's disease-related high perianal fistulas	10	7	N	1	1		
Moreno-Serrano et al. [16]	2016	Prospective, open-label, descriptive	PRP	Complex perianal fistula or perianal fistula	21	13	N	4	2		
de la Portilla et al. [17]	2017	Prospective, phase II clinical trial	PRP	Transsphincteric fistula-in-ano	36	16	12	N	7		
de la Portilla et al. [18]	2020	Phase II single-center	PRP	Crohn's fistula	21	15	7	N	5		
Cwaliński et al. [19]	2021	Preliminary, prospective, randomized	PRP vs PRP+NPWT	Recurrent cryptoglandular anal fistulas	8 vs 10	4 vs 7	N	3 vs 5	N		
Madbouly et al. [20]	2021	Prospective randomized	PRP+LIFT vs LIFT	High transsphincteric fistula	49 vs 49	42 vs 32	38 vs 29	4 vs 3	3 vs 0		
Schouten et al. [21]	2021	Prospective cohort	SVF+PRP	Transsphincteric cryptoglandular fistulas	45	38	33	1	0		
Mortagy et al. [22]	2021	Prospective randomly comparative	PRP vs LIFT	High transsphincteric perianal fistula	9 vs 9	6 vs 7	N	3 vs 2	3 vs 3		
Hermann et al. [23]	2021	Retrospective	PRP vs PDP	High anal fistulas of cryptoglandular origin	25 vs 25	16 vs 9	16 vs 9	3 vs 2	N		
Hermann et al. [24]	2022	Prospective, randomized	PRP vs MAF	High transsphincteric anal fistulas	49 vs 47	35 vs 27	35 vs N	0 vs 0	0 vs 2		
Cwaliński et al. [25]	2022	Randomized controlled prospective	MAF or oversewing+ PRP vs MAF or oversewing	Active anal fistula	20 vs 22	16 vs 10	16 vs 10	2 vs 2	0 vs 0		
Niknami et al. [26]	2022	Descriptive-prospective	PRP	High transsphincteric fistula	24	16	N	8	0		
					14						514

International
<https://doi.org/>

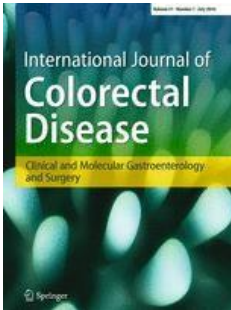
REVIEW

Platele
 review

Yajie Wang

Accepted: 5 M
 © The Author

2023



Outcomes (continued)

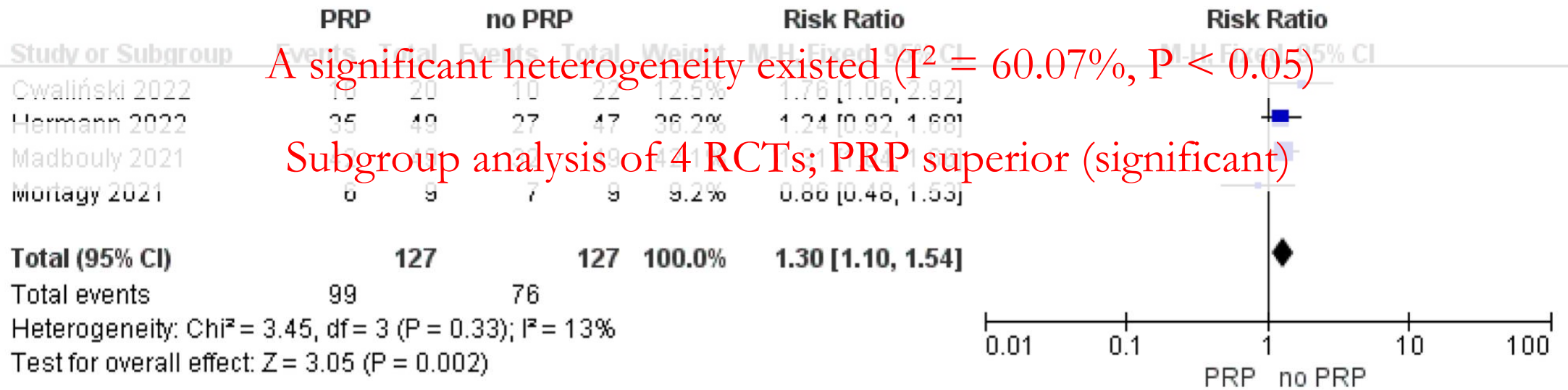


Fig. 5 Randomized controlled trial meta-analysis of PRP for anal fistula

Patient selection

Avoid in

- Platelet dysfunction disorders,
- Hemoglobin <10 g/dL,
- Hematological or bone malignancies,
- Hyperglycemia can all affect the final fibrin clot formation,
- Those on NSAIDs, corticosteroids, and aspirin (suboptimal results).
- Tobacco users (poor response; vasoconstriction & affects final fibrin clot).

Fistula selection

- Non-candidate for fistulotomy (complex fistulas)
- Single tract
- No collection

Benefits

- Outpatient clinic; cost reduction (outpatient basis) 98%
- Repeated application

Limitations

Studies reporting PRP

- Several classifications have been proposed, with no consensus classification.
- There are many variation products of PRP.
- Comparison elaborates on preparation and hardware factors.
- **This limits the external validity and reproducibility of the results.**

Guidelines

CLINICAL PRACTICE GUIDELINES

2022



The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anorectal Abscess, Fistula-in-Ano, and Rectovaginal Fistula

Wolfgang B. Gaertner, M.D., M.Sc.¹ • Pamela L. Burgess, M.D.²
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Daniel L. Feingold, M.D.⁷

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No recommendations can be made for the use of PRP alone in the management of anal fistula. **Very low-level evidence. [GDG expert opinion]**

PRP can be **considered** in the management of anal fistula as an add-on treatment to LIFT. **Very low-level evidence [Downgraded by GDG, expert opinion].**

Peter C. Ambe⁵ | Felix Aigner⁶ | Erman Aytac⁷ | Gabriele Dislenghi⁸ |
Andreas Nordholm-Carstensen⁹ | Hossam Elfeki¹⁰ | Gaetano Gallo¹¹ | Ugo Grossi¹² |
Baris Gulcu¹³ | Nusrat Iqbal¹⁴ | Rosa Jimenez-Rodriguez¹⁵ | Sezai Leventoglu¹⁶ |
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Charlene Sackitey²² | Mostafa Shalaby²³ | Jasper Stijns²⁴ | Phil Tozer²⁵ |
David Zimmerman²⁶

Debate

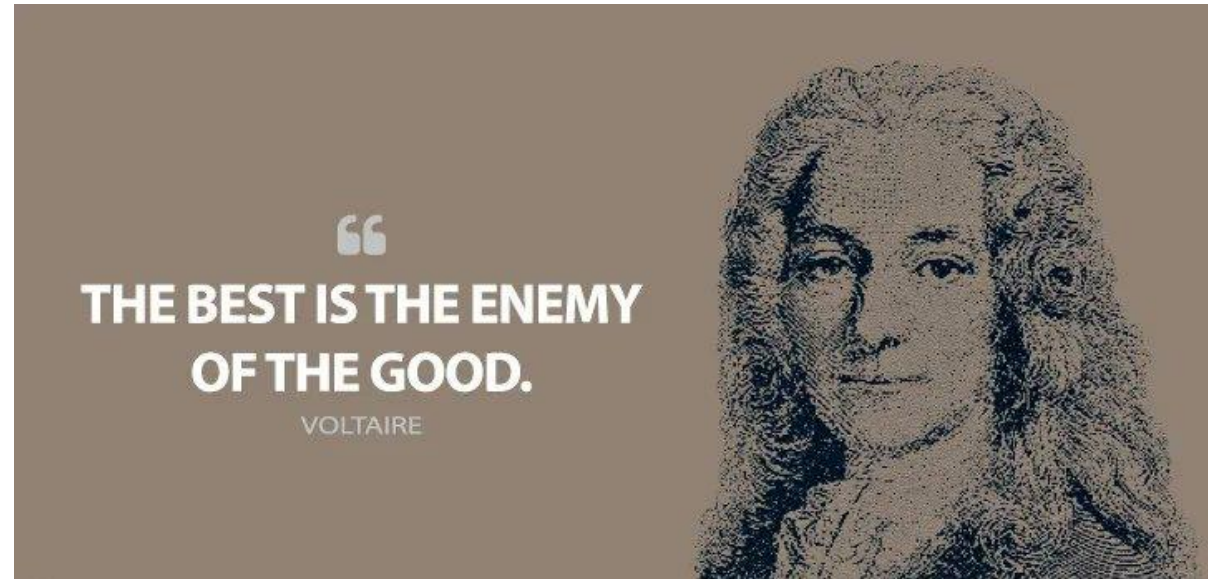
- When hybrid results are reported, the question arises whether the healing rates obtained are due to the surgical closure techniques (flap or other) or due to the use of newly introduced technique.



Conclusions

- There is **no one gold** standard technique that can treat all types of FIA.
- Fistula cure and continence preservation are the overriding **goals** of the treatment.
- Failure rates should be **discussed**, and patients should be aware of their alternatives.
- A given treatment must be **individualized** according to patient's situation.
- **Standardization** of the technique with full documentation

Best?



Prof. Mohamed Farid 1952-2024



THANK YOU
ANY QUESTIONS