Applying the guidelines to my treatment algorithm in femoropopliteal disease

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Disclosure

Speaker name:

Prof. Dr. med. Iris Baumgartner

I have the following potential conflicts of interest to report:

- √ Institutional educational & research grants: Abbott, Cook,
- ☐ Boston Scientific, Amgen
- ☐ Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- √ Other(s)
- ☐ I do not have any potential conflict of interest

Vascular Medicine 2017; 22(3), NPI-NP43

Eur Heart J 2018; 39, 763-821

AHA/ACC & ESC 2017

COR	LOE	RECOMMENDATION
IIa	A	Revascularization is a reasonable treatment option for the patient with lifestyle-limiting claudication with an inadequate response to GDMT (13,25,26,190,191).

GDMT Best medical treatment

Eur Heart J 2018; 39, 763-821

ESC 2017

Recommendations on revascularization of femoro-popliteal occlusive lesions[c]

Recommendations	Class[a]	Level[b]
An endovascular-first strategy is recommended in short (i.e. <25 cm) lesions.[302,303]	I	C
Primary stent implantation should be considered in short (i.e. <25 cm) lesions.[304,305]	IIa	A
Drug-eluting balloons may be considered in short (i.e. <25 cm) lesions.[77,306–310]	IIb	A
Drug-eluting stents may be considered for short (i.e. <25 cm) lesions.[302,303,311]	IIb	B
Drug-eluting balloons may be considered for the treatment of in-stent restenosis.[312,313]	IIb	B

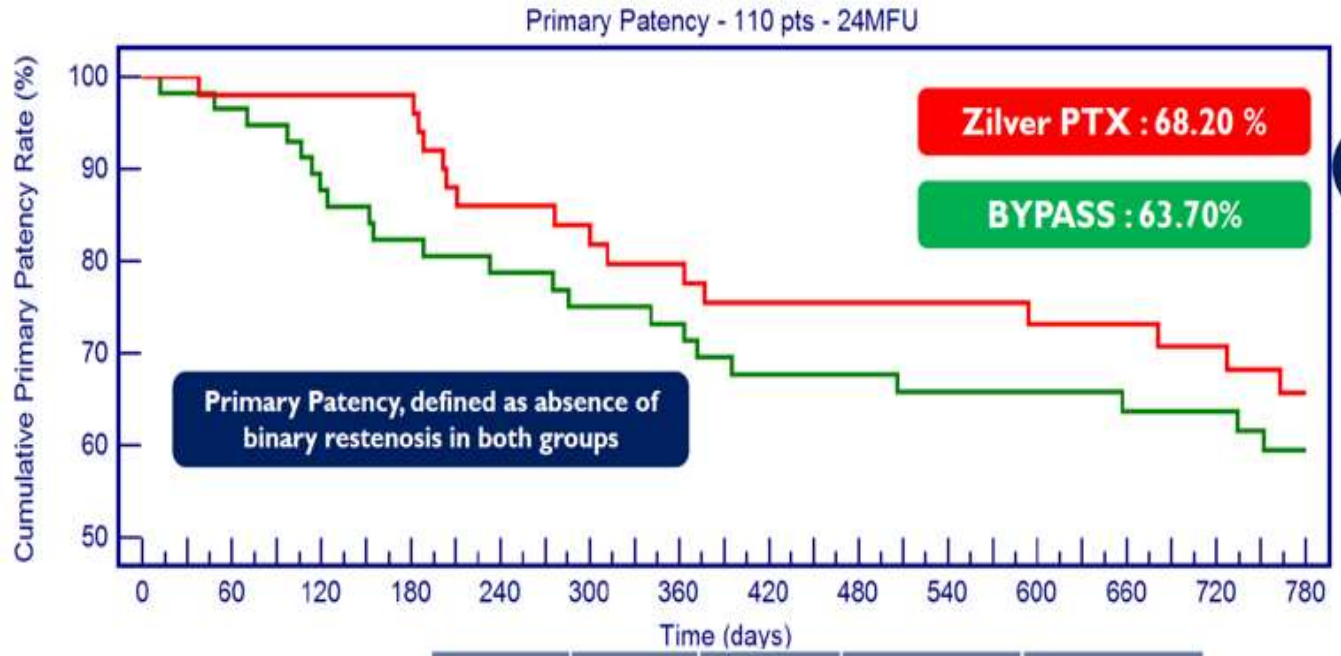
Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

ESC 2017

Zilverpass RCT
Zilver PTX vs. Surgical Bypass *(1:1 random., n=220, 13 sites)*

Bypass vs DES in femoropopliteal artery disease (ZilverPass RCT)

24-MONTH PRIMARY PATENCY (110 / 220 PTS)



		Baseline	30 days	6MFU	12MFU	24MFU
ZILVER PTX	Tar	52	51	49	38	28
	%	100	100	98.00	77.60	68.20
BYPASS	Tar	58	56	46	40	30
	%	100	98.20	82.30	71.40	63.70

Bosiers, LINC 2019

Eur Heart J 2018; 39, 763-821

ESC 2017

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Paclitaxel-Eluting Stents Show Superiority to Balloon Angioplasty and Bare Metal Stents in Femoropopliteal Disease
Twelve-Month Zilver PTX Randomized Study Results

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
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Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

ESC 2017

A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial

Vascular Medicine 2017; 22(3), NPI-NP43

AHA/ACC 2017

8.1.1. Endovascular Revascularization for Claudication. Endovascular techniques to treat claudication include balloon dilation (angioplasty), stents, and atherectomy. These techniques continue to involve and now include covered stents, drug-eluting stents, cutting balloons, and drug-coated balloons. The technique chosen for endovascular treatment is related to lesion characteristics (e.g., anatomic location, lesion length, degree of calcification) and operator experience. Assessment of the appropriateness of specific endovascular techniques for specific lesions for the treatment of claudication is beyond the scope of this document.

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American Heart Association. life is why

Eur Heart J (2019) 40, 87–165

ESC 2017 (Coronary artery disease)

Recommendations on choice of stent and access site

Recommendations	Class[a]	Level[b]
DES are recommended over BMS for any PCI irrespective of: • clinical presentation • lesion type • planned non-cardiac surgery • anticipated duration of DAPT • concomitant anticoagulant therapy.[100,578,579,640]	I	A
Radial access is recommended as the standard approach, unless there are overriding procedural considerations.[172,638,641]	I	A
BRS are currently not recommended for clinical use outside of clinical studies.[642–650]	III	C

BMS = bare-metal stents; BRS = bioresorbable scaffolds; DAPT = dual antiplatelet therapy; DES = drug-eluting stents; PCI = percutaneous coronary intervention.
[a]Class of recommendation.
[b]Level of evidence.

Recommendations on specific lesion subsets

Recommendations	Class[a]	Level[b]
Stent implantation in the main vessel only, followed by provisional balloon angioplasty with or without stenting of the side branch, is recommended for PCI of bifurcation lesions.[654–658]	I	A
Percutaneous revascularization of CTOs should be considered in patients with angina resistant to medical therapy or with a large area of documented ischaemia in the territory of the occluded vessel.[629,659–663]	IIa	B
In true bifurcation lesions of the left main, the double-kissing crush technique may be preferred over provisional T-stenting.[620]	IIb	B

CTO = chronic total occlusion; PCI = percutaneous coronary intervention.
[a]Class of recommendation.
[b]Level of evidence.

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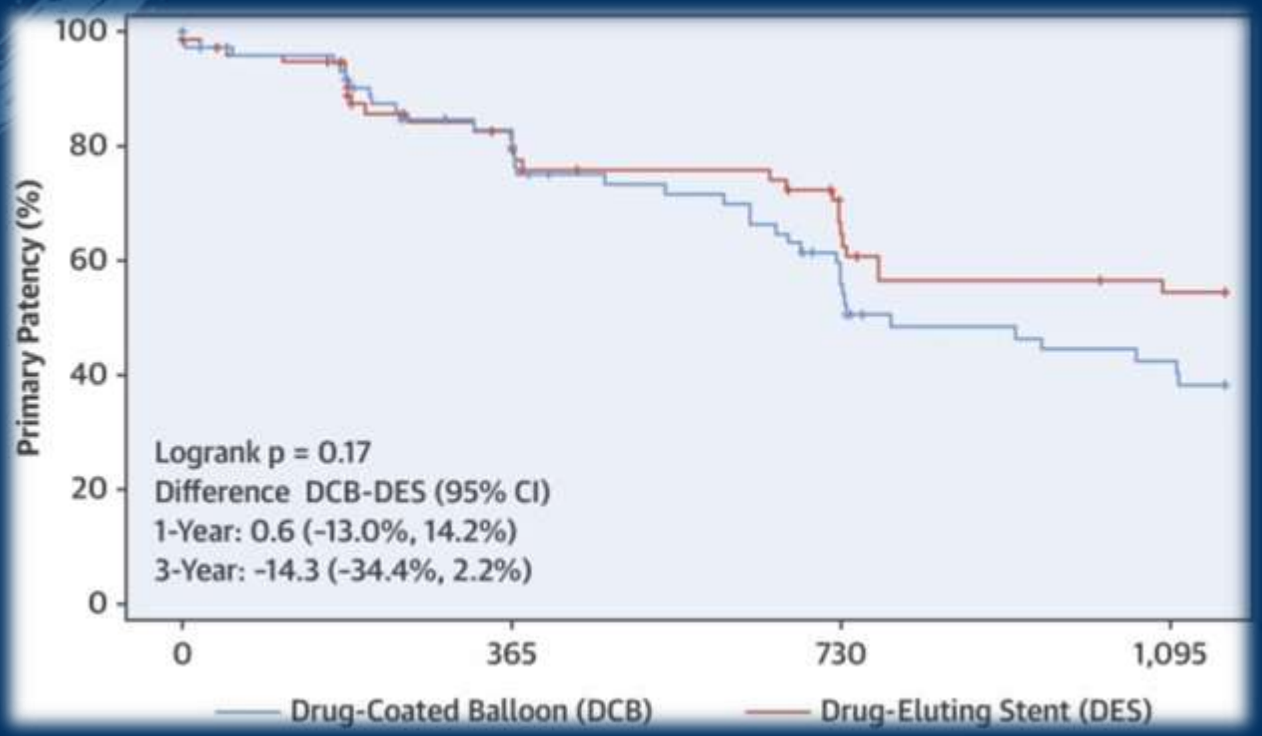
DES vs DCB revascularization in femoropopliteal artery disease (REAL PTX RCT)

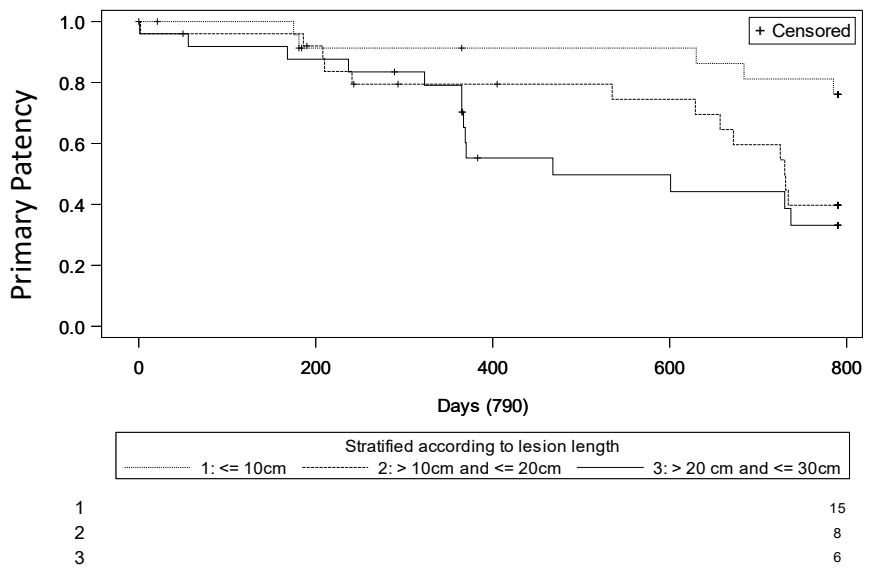
Patency rates @ 12 mo suggest comparable effectiveness and safety of DES versus DCB plus bailout stenting in femoropopliteal interventions; a trend in favor of the DES was observed up to 36 months.



JACC 2019; 73 (6), 667-79

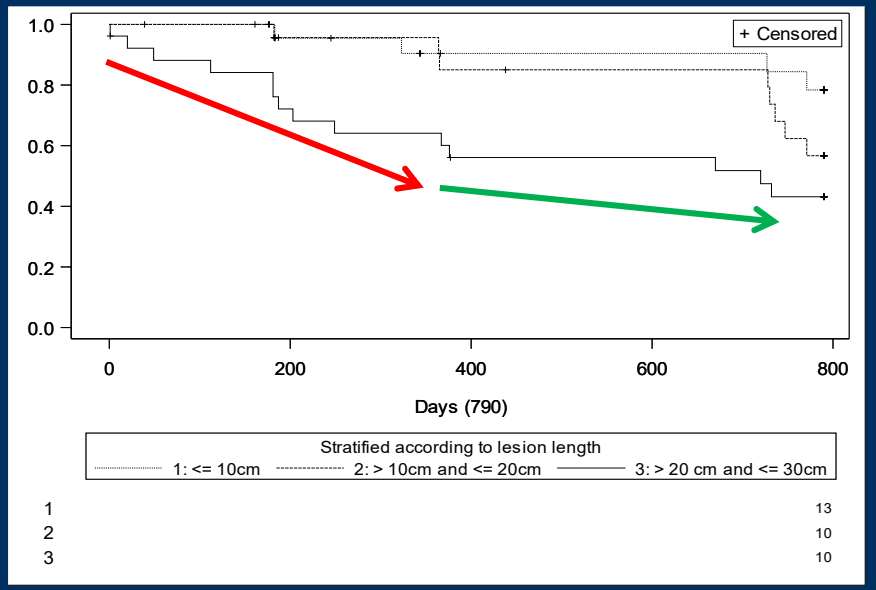
DES vs DCB revascularization in femoropopliteal artery disease (REAL PTX RCT)

Drug Coated Ballon (ITT)



	Stratified (n)	PP @ 24 month (%)
1	≤ 10cm (22)	76.1
2	> 10cm ≤ 20cm (18)	40.0
3	> 20 cm ≤ 30cm (18)	**33.1**

Zilver PTX



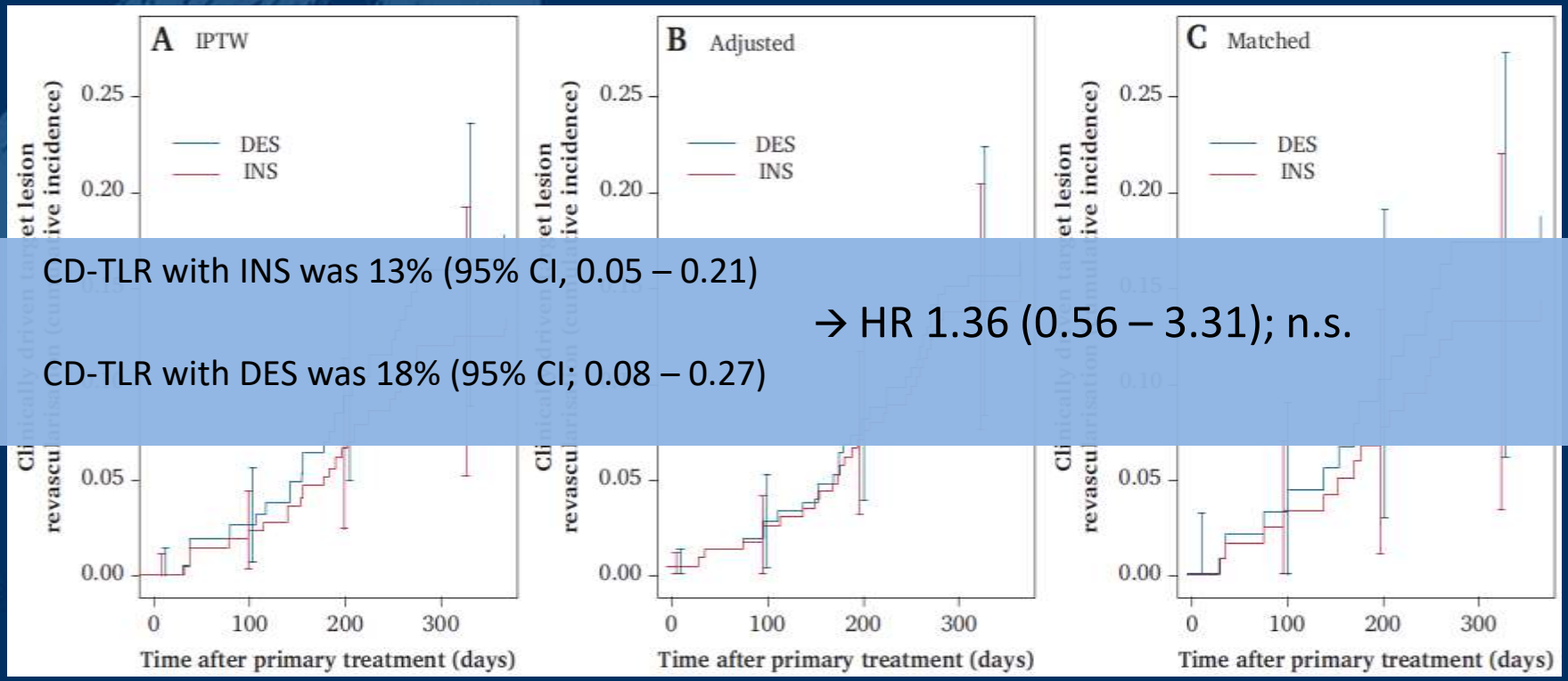
	Stratified (n)	PP @ 24 month (%)
1	≤ 10cm (25)	78.4
2	> 10cm ≤ 20cm (24)	56.7
3	> 20 cm ≤ 30cm (26)	**43.2**

* p was calculated using log rank test

Scheinert LINC 2017

JVES 2019; 58(6), 865-873

Comparison between Supera interwoven Nitinol stent and DES for endovascular treatment of femoropopliteal artery disease



CD-TLR with INS was 13% (95% CI, 0.05 – 0.21)

CD-TLR with DES was 18% (95% CI; 0.08 – 0.27)

→ HR 1.36 (0.56 – 3.31); n.s.

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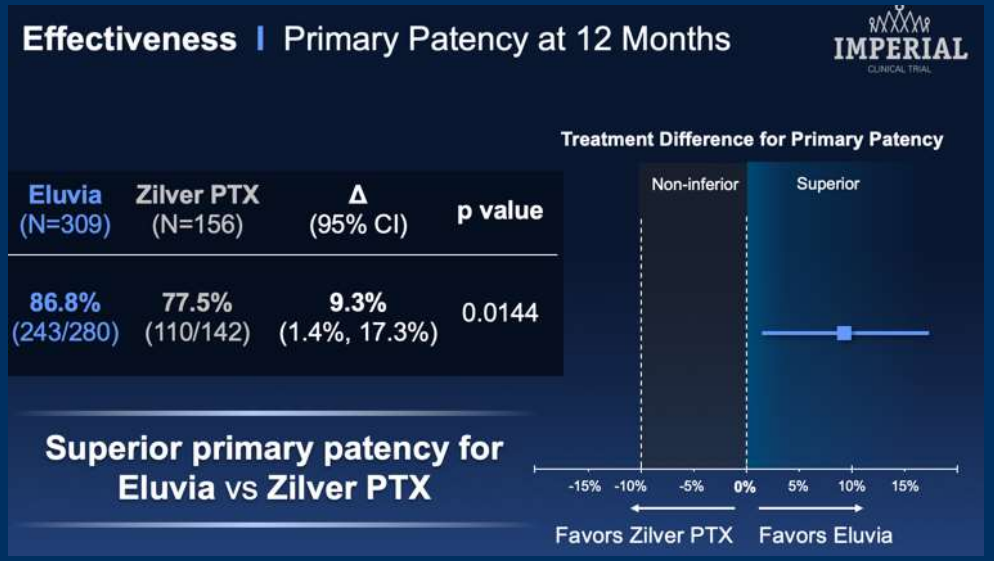
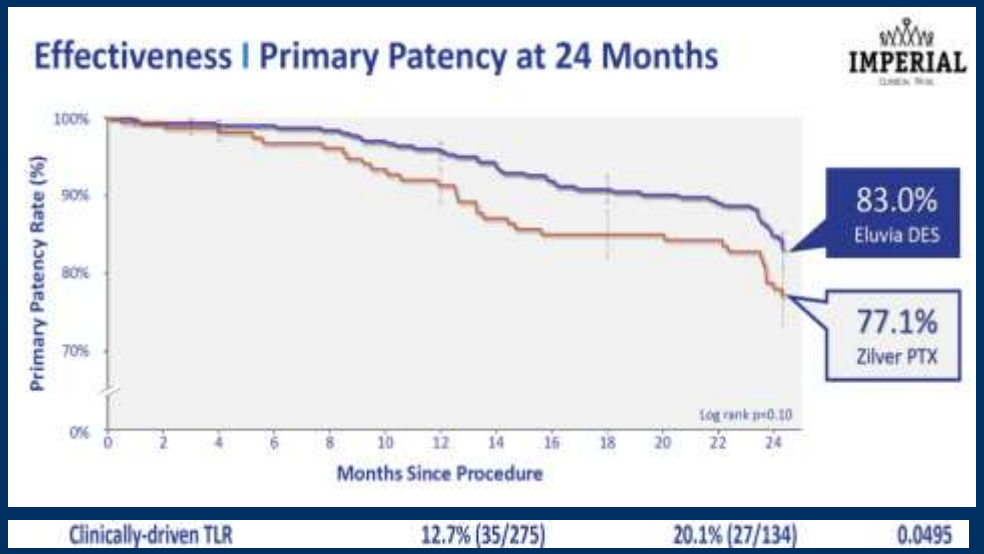
Primary endpoint (DES vs DES)

Eluvia stent non-inferior to Zilver PTX

in terms of primary patency and major adverse events @ 12 mo after treatment of patients for femoropopiteal LEAD





Lancet 2018; 392(10157):1541-1551

Conclusion I

Best interventional training & skill (minimal case load)

Endo preferred, but bypass in selected cases & failed endo treatment

- *respect surgical landing zone; interdisciplinary approach*

POBA vessel prepararion (strongly suggested)

- *DCB considered in short (< 25 cm) lesions with optimal POBA*
- *DES recommended over BMS*
- *DES recommeded with suboptimal POBA irrespective of lesion length*
- *other devices for selected cases (operator experience)*

Conclusion II

I. real world data

II. challenging lesions (subgroups RCT & postmarket)

RCT (evidence B & A)

III. continuously monitor safety

economic constrains

Simplified algorithm by guideline committees

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