

PLAGH **VEITH SYMPOSIUM**
Connecting The Vascular Community

Update On The WeFlow Devices For Juxtarenal AAA, TAAA And Arch Repairs: A New Inner Branch And Outer Branch



Wei Guo, MD
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On behalf of investigators



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Disclosure

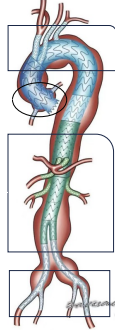
Speaker name: Wei Guo

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest



China solution
Total endovascular aortic repair



EndoBetal

GUARANTEE Study
ClinicalTrials.gov
NCT02054985

GREAT Study
ClinicalTrials.gov
NCT05179977

GUEST Study
ClinicalTrials.gov
NCT04769992

GIANT Study
ClinicalTrials.gov
NCT04769992

GRAFT Study
ClinicalTrials.gov
NCT05754541

EndoSeal
ClinicalTrials.gov
NCT00652328

EndoPatch
ClinicalTrials.gov
NCT04745039

G-Branch

WeFlow-JAAA

G-iliac study
ClinicalTrials.gov
NCT05489605

G-iliac

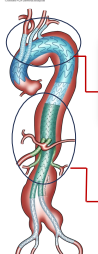
WeFlow-Tbranch

WeFlow-Bbranch

WeFlow-Tribranch

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A New Inner Branch And Outer Branch Devices



WeFlow-Tbranch


WeFlow-Bbranch

WeFlow-Tribranch

G-Branch

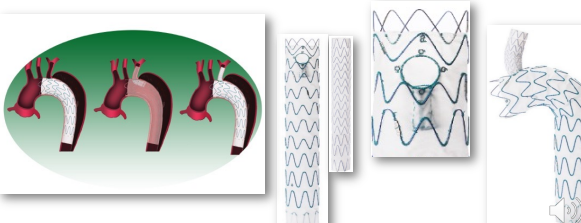
WeFlow-JAAA

-GUEST Study: NCT04765605
-GIANT Study: NCT04769992
-GRAFT Study: NCT05754541
-GUARANTEE Study: NCT05054985
-GREAT Study: NCT05179977



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WeFlow-Tbranch™
One single Inner Branched, Modular Stent Graft



WeFlow-Tbranch™ : GUEST Study
 Quo's sUbcLavian artery reconStruction: the prospective, multiple center study of WeFlow-Tbranch™ stent graft system (GUEST Study). Clinical trial registry number: NCT04765605

Type I Arch

Type II Arch

Type III Arch

WeFlow-Tbranch™ : GUEST Study
 Quo's sUbcLavian artery reconStruction: the prospective, multiple center study of WeFlow-Tbranch™ stent graft system (GUEST Study). Clinical trial registry number: NCT04765605

Research purpose:
 -To evaluate the safety and effectiveness of left subclavian artery reconstruction by WeFlow-Tbranch device in Stanford B dissection

Study Design:
 -Test instrument: single embedded branch stent graft system
 -Research type: Class III implant device registration research
 -Research design: single arm, multi center
 -Number of centers: 20 centers
 -Sample size: The total sample size is 120 cases (96 effective cases, considering the drop rate of 20%)

120 patients have been enrolled, the baseline information

Baseline characteristics and Medical History	Numerical Value (n=120)
Age	56.93±10.61Y (30-80)
Gender (male)	84.17% (101)
Smoking history	43.33% (52)
History of alcohol intake	38.33% (46)
Hypertension	92.50% (111)
Coronary Heart Disease History	5.00% (6)
Distance from the proximal entry tear to the LCCA	26.58±6.90 mm

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Primary safety endpoint:
 Freedom from MAE within 30 days after surgery: 95%

Primary effectiveness endpoint:
 Immediate technical success rate: 99.17% (119/120)
 107 patients completed 2-year follow-up

Primary safety endpoint events		Primary Effectiveness Endpoint events	
	n=120		
Rate of all-cause mortality (%)	0.83% (1)	Rate of immediate technical success, n=120	99.17% (119/120)
Ischemic stroke	2.50% (3)*	The Clinical Success Rate	12 Months 24 Months
Respiratory failure*	1.67% (2)	Displacement of the branch stent graft	0% 0%
Myocardial infarction	0 % (0)	CTA	
Paraplegia	0.83 % (1)	Type I and III endoleak	4.55% (5/110) 2.30% (2/87)
Renal failure	0 % (0)	Branch stent occlusion	0.91% (1/110) 2.30% (2/87)
Liver failure	0 % (0)	Secondary Intervention	4.17% (5/120) 5.61% (6/107)
Intestinal necrosis	0 % (0)		
Amputation	0 % (0)		
Total	5.00%		

*1 patient suffered from respiratory failure accompanied by ischemic stroke.

WeFlow-Bibranch™
 Two Inner Branched, Modular Stent Graft

WeFlow-Tribranch™
 Three Inner Branched , Modular Stent Graft

WeFlow-Tribranch™
 Results of First In Man Study

Baseline characteristics:		Primary Endpoints:	
Baseline characteristics	N=17	MAE within 30 days	N=17
Age	70.00 ± 10.12 (50~83)Y	All-cause Death	3/17 *
Male	76.47% (13)	Stroke	1/17
Hypertension	88.24% (15)	Respiratory failure	1/17*
Coronary Heart Disease History	11.76% (2)	Pericardial tamponade	0
Diabetes	17.65% (3)	Dissection or aneurysm rupture	0
Cerebral Infarction History	23.53% (4)	Paraplegia	1/17
Arch aneurysms	82.35% (14)	Stent occlusion	0
Dissection	17.65% (3)	Stent fracture	0
		Stent displacement	0
		Type I/III endoleak requiring treatment	0
		Thrombosis or rupture of the approach vessel	0
		Conversion to open surgery	0

G-Branch™
Mixed multibranch stent graft for TAAA and complex AAA

G-Branch endograft Two preloading guidewires Semi-release design Delivery system

WeFlow-JAAA™: off-the-shelf

- 1 Scallop+1 Fenestration+2 embedded branches
- Scallop for reservation of Celiac trunk artery
- Fenestration for reconstruction of SMA
- Proximal main body diameter: 20-36mm
- Sealing ring for improving sealing efficiency
- Two embedded branches for reconstruction of renal arteries with 7mm diameter and 15mm in length.

WeFlow-JAAA™: GREAT Study

Guo's visceral arteries reconstruction-2: the prospective, multiple center study about the safety and efficacy of WeFlow-JAAA™ stent graft system for juxtarenal AAA. ClinicalTrials.gov identifier: NCT05179967 (GREAT Study)

Purpose:
To evaluate the safety and effectiveness of WeFlow-JAAA in the treatment of LAAA.

Design:
- Experimental design: prospective, single arm, multi-center
- Sample size: Total sample size was 100

Indication

- The length between aneurysm and SMA: ≥4mm
- The landing zone angulation: $\alpha < 60^\circ$

Baseline Characteristics	N=115
Age	68.34 ± 7.74
Gender (male)	109(94.78%)
BMI Index	25.26 ± 3.00
Smoking	99 (86.09%)
Hypertension	89 (77.39%)
Coronary Heart Disease History	55 (47.83%)
Cerebral Infarction History	30(26.09%)
Iliac Aneurysm	22 (19.13%)
Maximum Diameter of Abdominal Aortic Aneurysm (mm)	63.22 ± 12.25

WeFlow-JAAA™: GREAT Study

Guo's visceral arteries reconstruction-2: the prospective, multiple center study about the safety and efficacy of WeFlow-JAAA™ stent graft system for juxtarenal AAA. ClinicalTrials.gov identifier: NCT05179967 (GREAT Study)

Primary Safety Endpoint: 30 Day MAE (N=115)	Efficacy Endpoint Events
All-cause Death: 0.87% (1) *	Immediate Technical Success ^a , n=115: 99.13% (114/115)
Mycardial Infarction: 0% (0)	Average Procedure Time, n=115: 139.70 ± 78.91 min
Renal Failure: 0% (0)	The Clinical Success Rate ^a : 6 Months: 0% (0/91) 12 Months: 0% (0/78)
Respiratory Failure: 0% (0)	Stent Migration (%): 0% (0/91) 0% (0/78)
Ischemic Stroke: 2.61% (3) *	Type I or III Endoleak (%): * 1.79% (2/113) 0% (0/91) 0% (0/78)
Bowel Ischemia: 0% (0)	Aneurysm Size Increase (%): 0% (0/113) 0% (0/91) 0% (0/78)
Severe Ischemia Necrosis of Lower Limbs: 0% (0)	Target vessel patency (%): 99.41% (136/138) 99.26% (270/272) 99.14% (231/233)
Paraplegia: 0% (0)	Secondary Intervention (%): 1.74%(2/115) 3.81% (4/105) 5.62%(5/89)

* 1 patient died of sudden cardiac arrest on postoperative day 17, which is an aneurysm related.
** 2 patients experienced stroke during the postoperative period.

Summary

- WeFlow-Tbranch is committed to the reconstruction of the LSA, and initial results from 1-year follow-up demonstrated its safety and efficacy.
- WeFlow-Bibranch is dedicated to the reconstruction of the IA and LCCA, which needs to be combined with the LCCA-LSA bypass.
- WeFlow-Tribranch is dedicated to complete endovascular replacement of the aortic arch totally.
- G-Branch is dedicated to the reconstruction of the four branches of TAAA/PAAA.
- WeFlow-JAAA is dedicated to the reconstruction of the renal artery and SMA to address the endovascular treatment of JAAA.
- A larger number of cases and a longer follow-up period will provide more evidence for each product

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