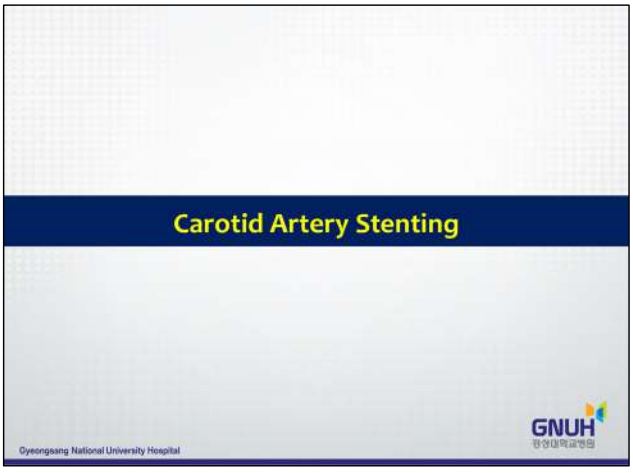
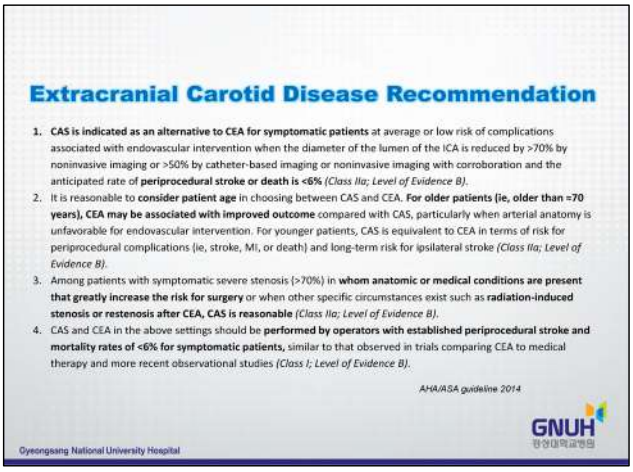
경동맥 및 두개내혈관 협착에 대한 스텐트 설치술

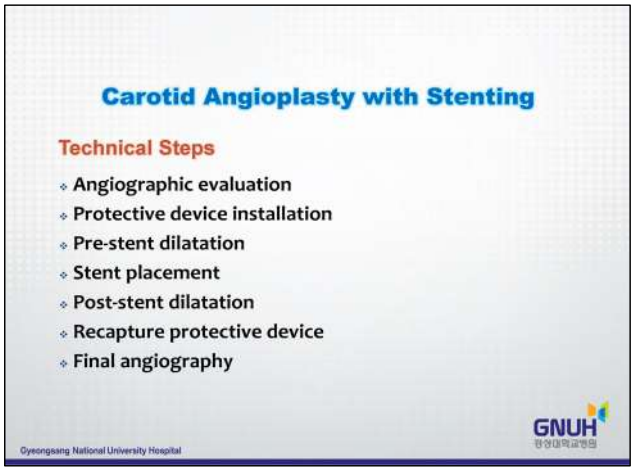
김 창 헌
경상의대

Stenting for carotid stenosis and intracranial stenosis

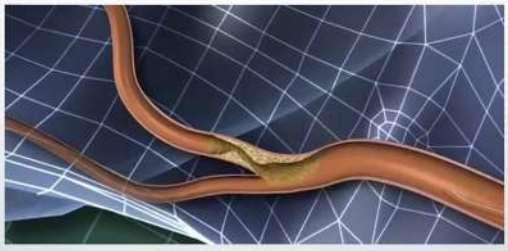
Chang Hun Kim
Department of Neurology, Gyeongsang National University Hospital







Carotid Angioplasty with Stenting



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Balloon Type

- Over the wire (OTW)
- Rapid exchange (RX), Monorail
- Perfusion
- Fixed wire
- Cutting balloon
- ...

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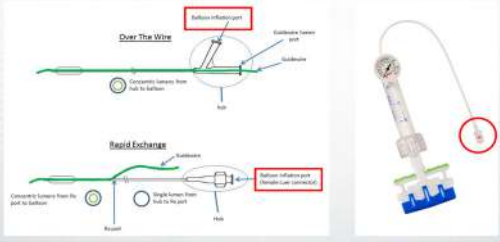
Balloon Type (Over the wire vs. Rapid exchange)



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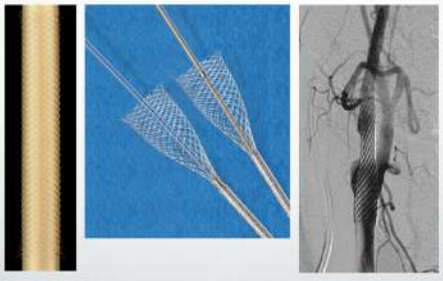
Stent for CAS (Closed cell, wire-braided)



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Stent for CAS – open cell, nitinol slotted tube

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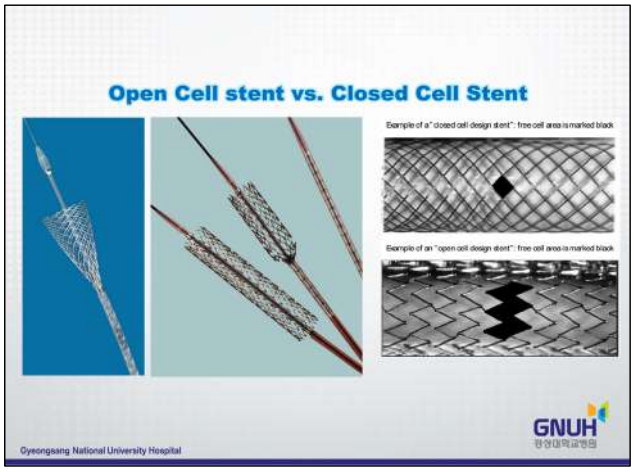
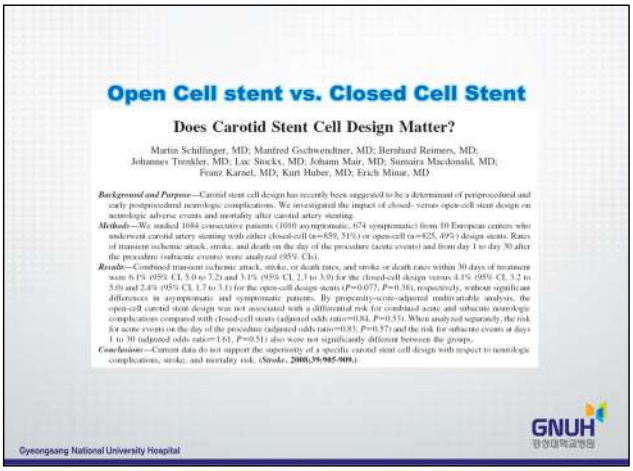
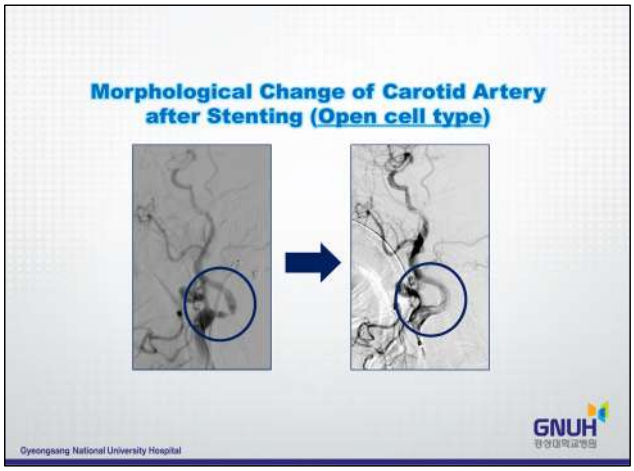
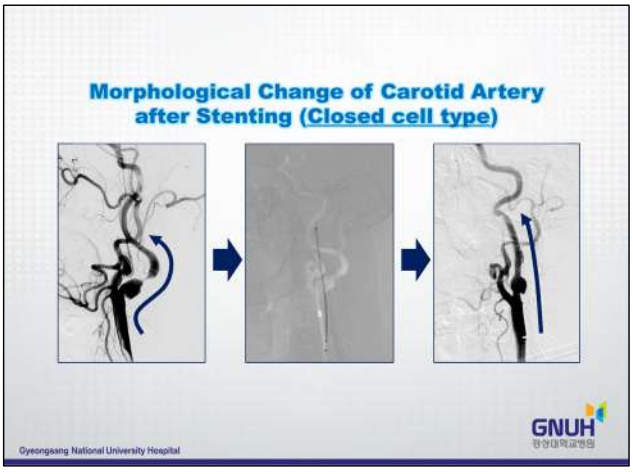
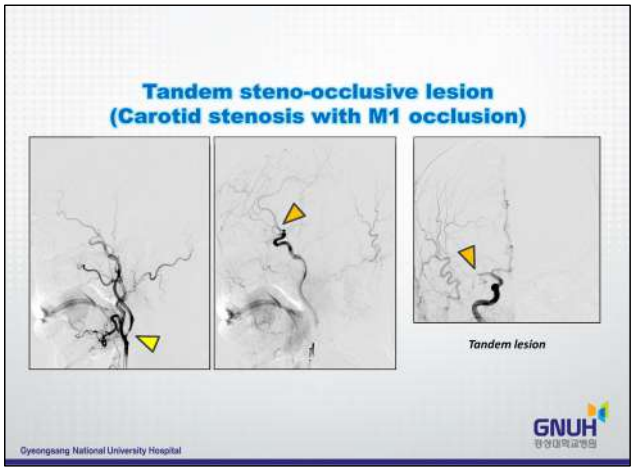
Acculink™ (Open cell)
Gyeongsang National University Hospital
GNUH

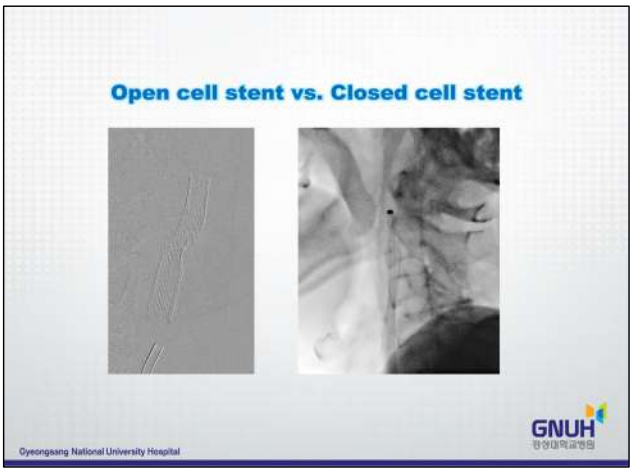

Open Cell stent vs. Closed Cell Stent
Example of a "closed cell design stent": free cell area is marked black
Example of an "open cell design stent": free cell area is marked black
Gyeongsang National University Hospital
GNUH

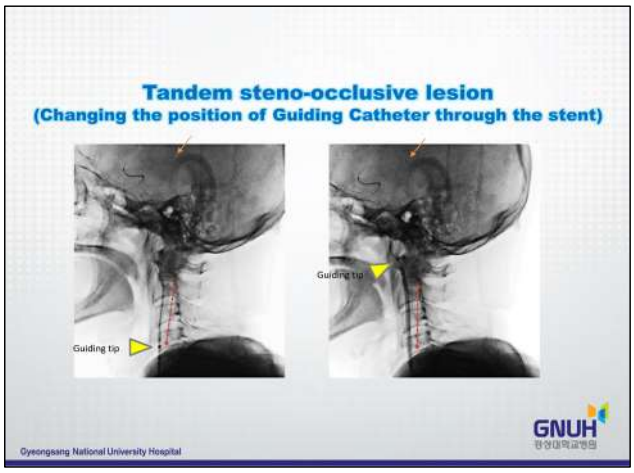

Open Cell stent vs. Closed Cell Stent
Does Carotid Stent Cell Design Matter?
Gyeongsang National University Hospital
GNUH


Morphological Change of Carotid Artery after Stenting (Open cell type)
Gyeongsang National University Hospital
GNUH


Morphological Change of Carotid Artery after Stenting (Closed cell type)
Gyeongsang National University Hospital
GNUH


Tandem steno-occlusive lesion (Carotid stenosis with M1 occlusion)
Tandem lesion
Gyeongsang National University Hospital
GNUH


Open cell stent vs. Closed cell stent
Gyeongsang National University Hospital
GNUH


Tandem steno-occlusive lesion
(Changing the position of Guiding Catheter through the stent)
Guiding tip
Guiding tip
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Deployment of Stent
a)
c)
b)
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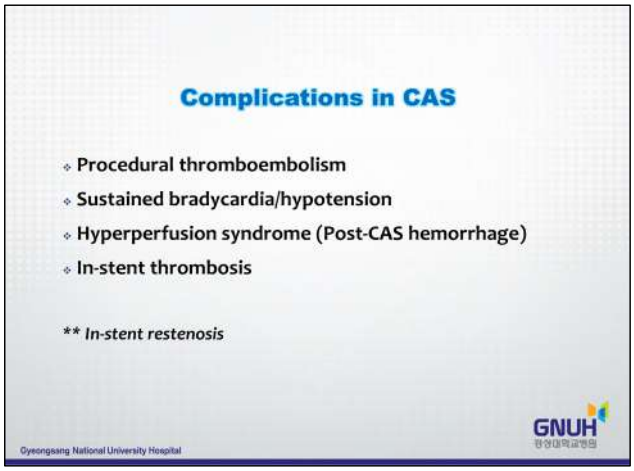
Complications in CAS
Procedural thromboembolism
Sustained bradycardia/hypotension
Hyperperfusion syndrome (Post-CAS hemorrhage)
In-stent thrombosis
** In-stent restenosis
Gyeongsang National University Hospital
GNUH


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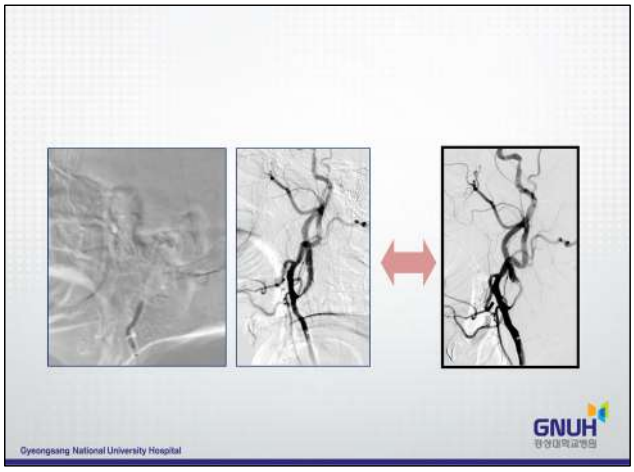
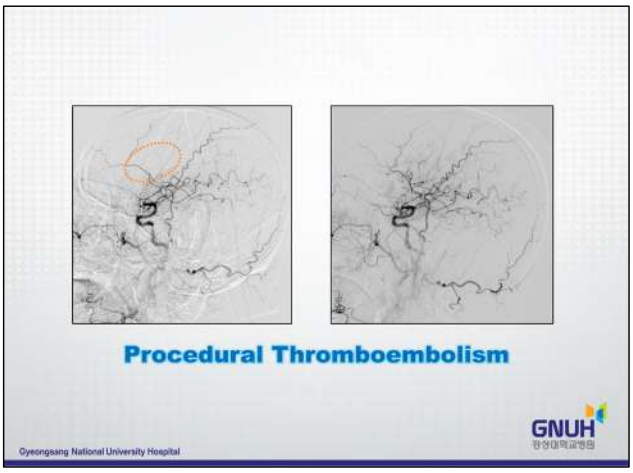
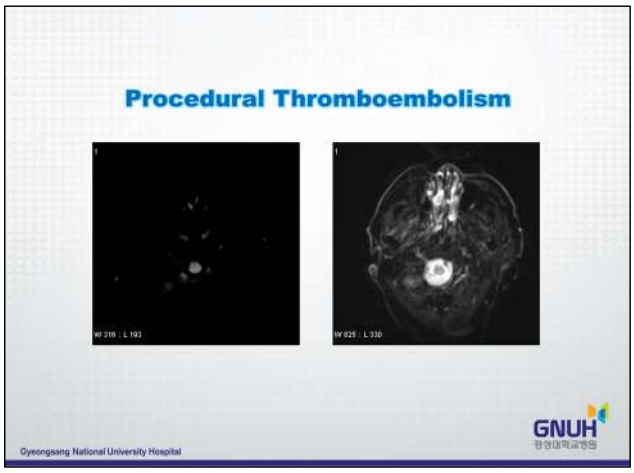
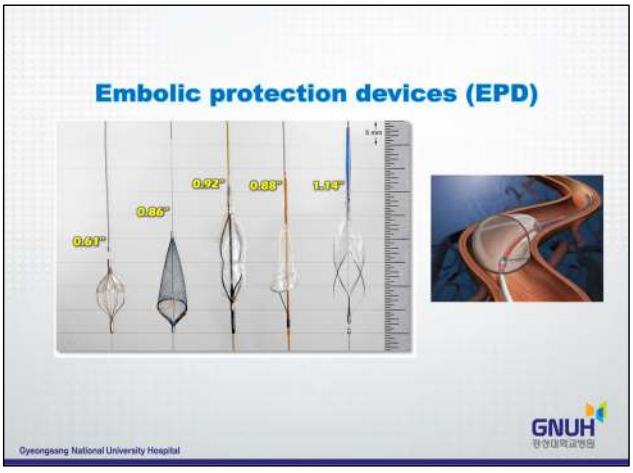
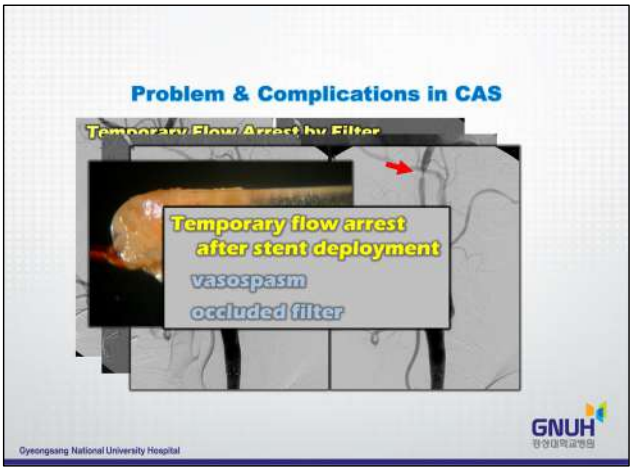

Gyeongsang National University Hospital
GNUH


Procedural Thromboembolism
Gyeongsang National University Hospital
GNUH

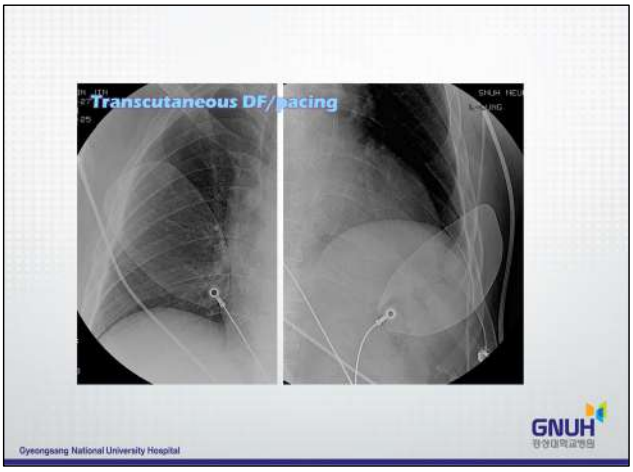

Procedural Thromboembolism
Gyeongsang National University Hospital
GNUH

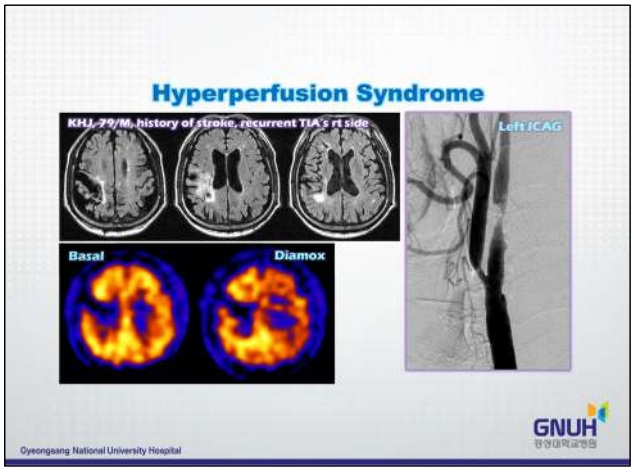

Embolic protection devices (EPD)
0.61"
0.86"
0.92"
0.88"
1.14"
Gyeongsang National University Hospital
GNUH

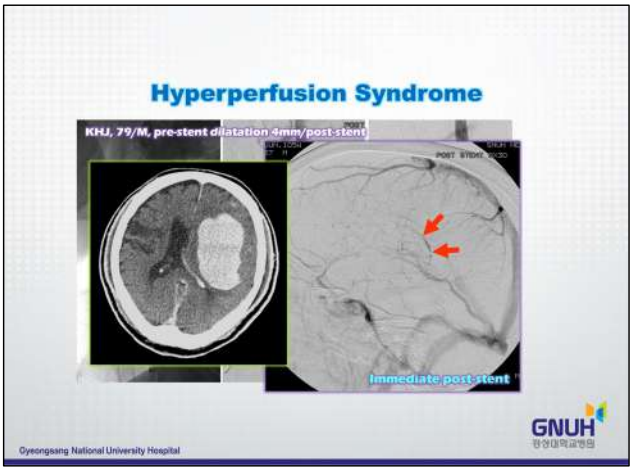

Embolic protection devices (EPD)
AngioGuard
FilterWire
Emboshield
SpiderFx
Gyeongsang National University Hospital
GNUH

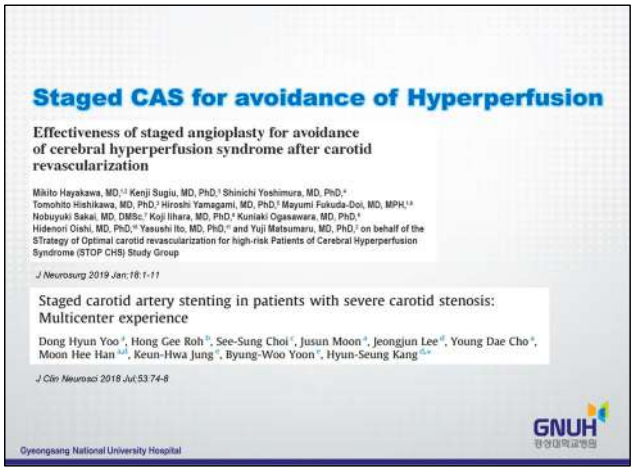

Problem & Complications in CAS
Temporary flow arrest after stent deployment
vasospasm
occluded filter
Gyeongsang National University Hospital
GNUH


MoMA (Proximal Protection Device)
Proximal Occlusion
Gyeongsang National University Hospital
GNUH

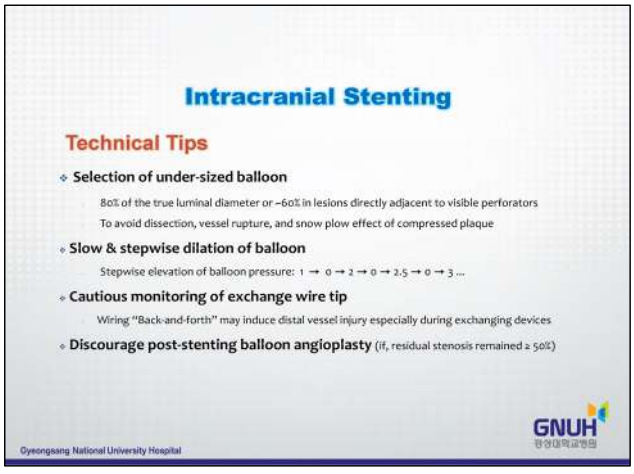

Transcutaneous DF/pacing
Gyeongsang National University Hospital


Hyperperfusion Syndrome
KHJ, 79/M, history of stroke, recurrent TIA's rt side
Left ICAG
Basal
Diamox
Gyeongsang National University Hospital


Hyperperfusion Syndrome
KHJ, 79/M, pre-stent dilatation 4mm/post-stent
Immediate post-stent
Gyeongsang National University Hospital


Staged CAS for avoidance of Hyperperfusion
Effectiveness of staged angioplasty for avoidance of cerebral hyperperfusion syndrome after carotid revascularization
Mikito Hayakawa, MD,[1,2] Kenji Sugiu, MD, PhD,[1] Shinichi Yoshimura, MD, PhD,[3] Tomohito Hishikawa, MD, PhD,[1] Hiroshi Yamagami, MD, PhD,[3] Mayumi Fukuda-Doi, MD, MPH,[1,3] Nobuyuki Sakai, MD, DMSc,[1] Koji Iihara, MD, PhD,[3] Kuniaki Ogasawara, MD, PhD,[1] Hidenori Oishi, MD, PhD,[4] Yasushi Ito, MD, PhD,[1] and Yuji Matsumaru, MD, PhD,[1] on behalf of the STrategy of Optimal carotid revascularization for high-risk Patients of Cerebral Hyperperfusion Syndrome (STOP CHS) Study Group
J Neurosurg 2019 Jan;18:1-11
Staged carotid artery stenting in patients with severe carotid stenosis: Multicenter experience
Dong Hyun Yoo[a], Hong Gee Roh[b], See-Sung Choi[c], Jusun Moon[a], Jeongjun Lee[d], Young Dae Cho[a], Moon Hee Han[a,1], Keun-Hwa Jung[a], Byung-Woo Yoon[e], Hyun-Seung Kang[f,*]
J Clin Neurosci 2018 Jul;53:74-8
Gyeongsang National University Hospital


Intracranial stenting
Gyeongsang National University Hospital


Intracranial Stenting
Technical Tips
Selection of under-sized balloon
80% of the true luminal diameter or ~60% in lesions directly adjacent to visible perforators
To avoid dissection, vessel rupture, and snow plow effect of compressed plaque
Slow & stepwise dilation of balloon
Stepwise elevation of balloon pressure: 1 → 0 → 2 → 0 → 2.5 → 0 → 3 ...
Cautious monitoring of exchange wire tip
Wiring "Back-and-forth" may induce distal vessel injury especially during exchanging devices
Discourage post-stenting balloon angioplasty (if, residual stenosis remained ≥ 50%)
Gyeongsang National University Hospital

SAMMPRIS

- Trial for the comparison of the risk of stroke or death between **intensive medical therapy alone** and **intracranial angioplasty and stenting** in patients with symptomatic intracranial stenosis
- Inclusion criteria
  1. 70-99% stenosis of intracranial artery
  2. TIA or non-disabling stroke within 30 days
  3. mRS ≤ 3
  4. 30 ≤ Age ≤ 80
- Primary endpoints
  1. Any stroke or death within 30 days or
  2. Ischemic stroke in the qualifying territory between day 31 and the end of the follow-up period

N Engl J Med 2011;365(11):993-1003

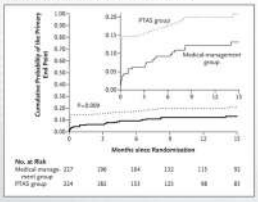
Gyeongsang National University Hospital

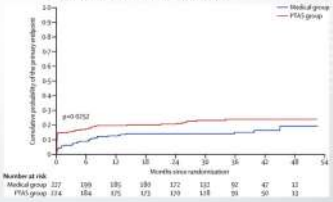
30-day rate of primary endpoint

1. PTAS group = 14.7%
2. Medical management group = 5.8%

Primary endpoint rate during 32.4 months

1. PTAS group = 23%
2. Medical management group = 15%





N Engl J Med 2011;365(11):993-1003

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Intracranial Atherosclerosis Recommendation

1. For patients with stroke or TIA attributable to severe stenosis (70%–99%) of a major intracranial artery, **stenting with the Wingspan stent system is not recommended as an initial treatment**, even for patients who were taking an antithrombotic agent at the time of the stroke or TIA (Class III; Level of Evidence B).
2. For patients with stroke or TIA attributable to severe stenosis (70%–99%) of a major intracranial artery, **the usefulness of angioplasty alone or placement of stents other than the Wingspan stent is unknown and is considered investigational** (Class IIb; Level of Evidence C).
3. For patients with severe stenosis (70%–99%) of a major intracranial artery and recurrent TIA or stroke after institution of aspirin and clopidogrel therapy, achievement of systolic BP <140 mm Hg, and high-intensity statin therapy, **the usefulness of angioplasty alone or placement of a Wingspan stent or other stents is unknown and is considered investigational** (Class IIb; Level of Evidence C).
4. For patients with severe stenosis (70%–99%) of a major intracranial artery and actively progressing symptoms after institution of aspirin and clopidogrel therapy, **the usefulness of angioplasty alone or placement of a Wingspan stent or other stents is unknown and is considered investigational** (Class IIb; Level of Evidence C).

AHA/ASA guideline 2014

Gyeongsang National University Hospital

WEAVE TRIAL

- Wingspan Stent System Postmarket Surveillance trial (on label use in 152 patients)
  : Periprocedural safety of the Wingspan Stent for the treatment of symptomatic ICAS
- **Enrollment criteria**
  1. ≥ 70% of Stenosis degree
  2. Two stroke events in the vascular territory of the stenotic intracranial artery (refractory)
  3. Stented with Wingspan ≥ 8 days after their last stroke (dual anti-PLT med. before stent > 7 days)
- Mean Wingspan case experience for interventionists in the WEAVE trial = 37 stents
  ↔ Median number of cases with Wingspan in SAMMPRIS trial = 10 stents

Stroke 2019;50:889-94

Gyeongsang National University Hospital

Primary End Point Results

	Primary Analysis Trial / On Label
Enrolled	N=152
Subjects without stroke or death within 72 h	97.4% (148/152)
Subjects with death within 72 h	1.3% (2/152)
Subjects with stroke (without death) within 72 h	1.3% (2/152)
Total percentage of patients with stroke or death within 72 h	2.6% (4/152)

Comparison of Multicenter Trials

Trial	Percent Stenosis	Qualifying Event Stroke	Refractory to Medical Therapy	Median Time to Stent, d	Periprocedural Event Rate
HDE trial[1]	50%–99%	95%	100%	22	4.5%
NIH registry[2]	50%–99%	59%	Not reported	10	6.2%
US registry[3]	50%–99%	61%	75%	Not reported	6.2%
SAMMPRIS[4]	70%–99%	63%	64%	7	14.7%
WEAVE trial	70%–99%	100%	100%	22	2.6%

HDE indicates Humanitarian Device Exemption; NIH, National Institutes of Health; SAMMPRIS, Stenting and Aggressive Medical Management for the Prevention of Recurrent Stroke in Intracranial Stenosis; and WEAVE, Wingspan Stent System Post Market Surveillance.

Stroke 2019;50:889-94

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WOVEN Trial

Background

Industry Funded (Stryker) Post Market Surveillance Trial
- FDA mandated trial evaluating peri-procedural stroke and death rate of Wingspan Stent System when used on-label
- On-label use only in 152 patients with 70% or greater stenosis from intracranial atherosclerosis, with two strokes, failed medical therapy, treated greater than 7 days post-stroke
- Peri-procedural event rate 2.6%
- ClinicalTrials.gov **NCT02034058**
- ***Stroke*** 2019 Apr;50(4):889-894. doi: 10.1161/STROKEAHA.118.023996

WOVEN TRIAL
Wingspan One-Year Vascular Events and Neurologic Outcomes

Physician initiated, not funded by industry
- Delayed stroke and death rate of patients treated on-label in the WEAVE Trial at one-year follow up
- 15 participating centers nationally
- Clinical and imaging follow up of 129 patients
- ClinicalTrials.gov **NCT04221984**

J Neurointerv Surg 2020 Jun

Gyeongsang National University Hospital

WOVEN Trial

WOVEN TRIAL
Wingspan One-Year Vascular Events and Neurologic Outcomes

Clinical Outcomes at one year
- Stroke in vascular territory of stented artery
- Neurologic Death

Delayed Imaging Outcomes
- Assessment of re-stenosis incidence and degree
- Symptomatic or asymptomatic stenosis
- Management of re-stenosis, retreatment

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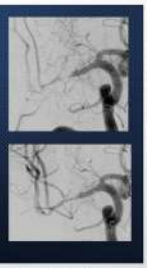
WOVEN Trial

WOVEN TRIAL
Wingspan One-Year Vascular Events and Neurologic Outcomes

Re-stenosis management

- 7 patients symptomatic
  - 3 patients managed medically
  - 3 patients with repeat angioplasty and stent
  - 1 patient with angioplasty alone
- 11 patients asymptomatic
  - 7 patients managed medically
  - 2 patients with repeat angioplasty and stent
  - 2 patient with angioplasty alone



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WOVEN Trial

WOVEN TRIAL
Wingspan One-Year Vascular Events and Neurologic Outcomes

WOVEN Trial Primary Endpoints beyond 30 days

Stroke in vascular territory of stent	7 pts
- Minor stroke (change ≤ 3 NIHSS points)	6 pts
- Major stroke (change > 3 NIHSS points)	1 pt
Non-traumatic cerebral hemorrhage	0 pts
Neurologic death	0 pts

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WOVEN Trial

WOVEN TRIAL
Wingspan One-Year Vascular Events and Neurologic Outcomes

Conclusions

The WOVEN Trial demonstrated an 8.5% one-year stroke and death rate in 129 patients stented on-label with the Wingspan stent, inclusive of the 4 patients who had peri-procedural events.

The re-stenosis rate was 16.8% in this cohort, and 7/18 of these patients (38.9%) were symptomatic. This was the primary cause of delayed stroke within the first year post-stenting

The WOVEN 1-12 month event rate was similar to the stenting arm of SAMMPRIS. However, since the peri-procedural complication rate was very low (2.6%), the WOVEN study total 1-year stroke and death rate (8.5%) trended lower than aggressive medical therapy alone in SAMMPRIS at 1-year (12.2%).

This data strongly supports further randomized clinical trials for ICAD between stenting and medical therapy for the high-risk patients (with hemodynamic compromise) treated in an on-label fashion

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