Initial Clinical Study of the New CGuard™ MicroNet® covered Carotid Stent: "One Size Fits All"

In-vitro testing and initial Clinical Results

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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)

X I do not have any potential conflict of interest

Background

One of the main difficulties with carotid artery stenting is optimal sizing

- Diameter differences between the common carotid artery (CCA) and the internal carotid artery (ICA)
- Fluoro measurements often give significant diameter errors due to projection differences

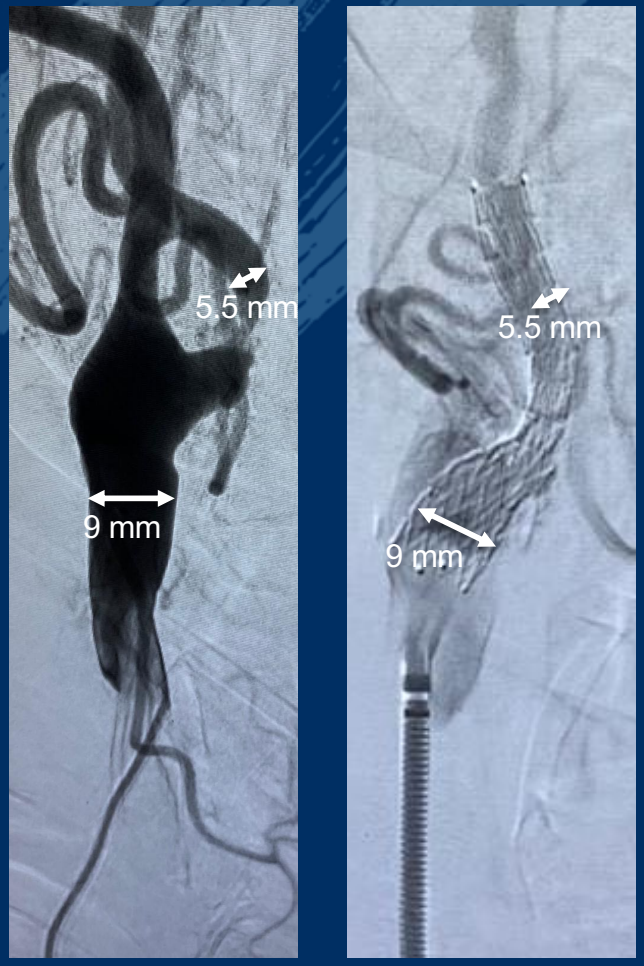
Appropriate sizing is fundamental for optimal stent results

- A gap in the contact between the endothelium and the stent may prolong the endothelialisation period, hence undersized stents may lead to complications
- Excessive radial force may stimulate intimal proliferation, whilst oversized stents may promote restenosis

Background

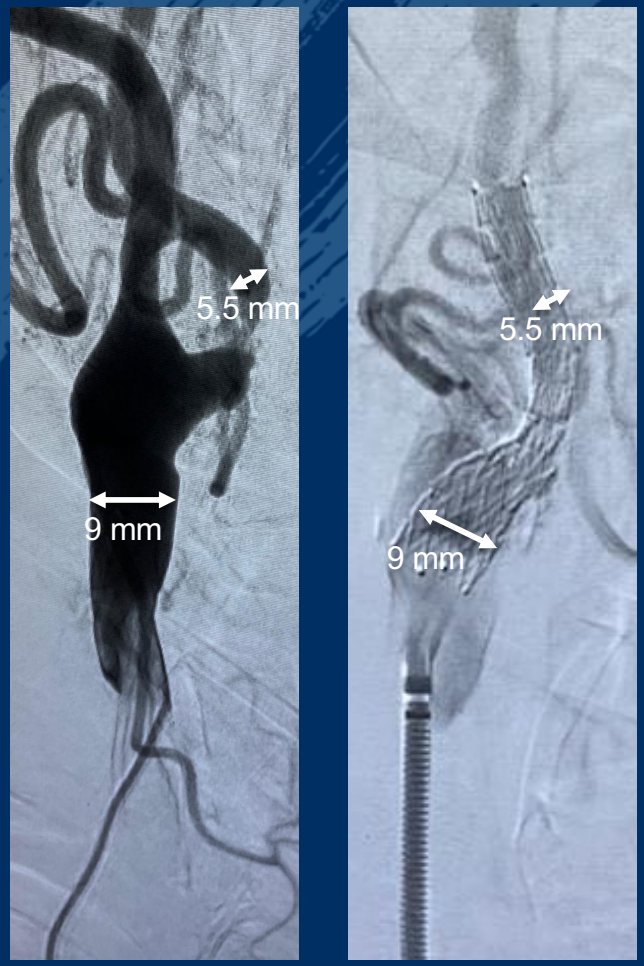
Is there a “one size fits all“ ?

Background



The **10 mm CGuard™ EPS MicroNet®** covered stent with **SmartFit™** technology is characterized by its ability to conform to different diameters with an almost equivalent radial force between 5.5 mm to 9.0 mm expansion diameters

Study Aim

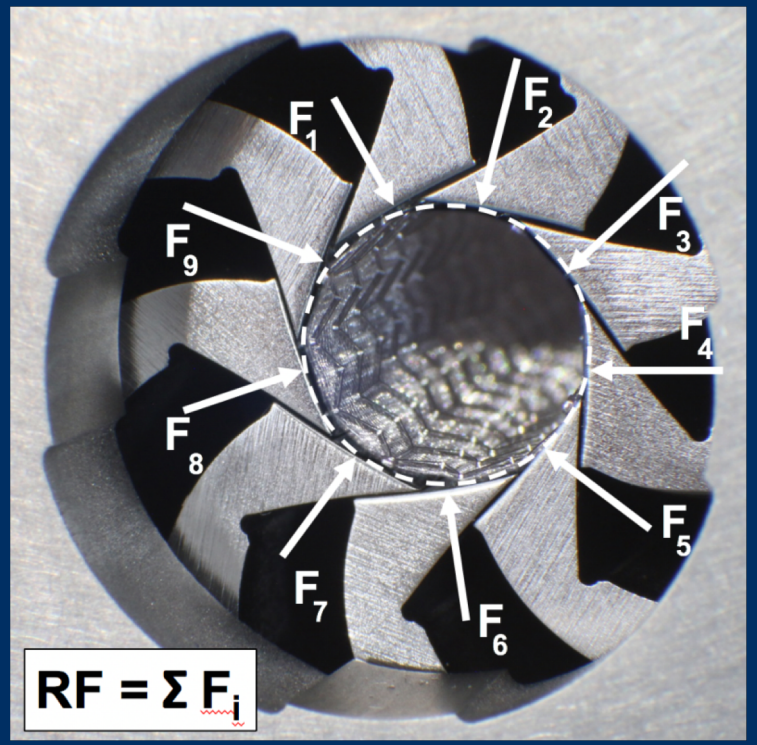


To evaluate the mechanical properties and initial clinical results of the CGuard™ EPS MicroNet® covered stent (InspireMD, Inc) designed for:

- Constant radial force at different diameters
- The new ability to self-adjust to different vessel diameters

In vitro Materials and Methods

- Radial force was determined with a segmented head radial force test device
  (Blockwise Engineering LCC, Tempe, Arizona, USA)
- CGUARD EPS with SmartFit - 10x 40 mm
  (InspireMD Inc, Tel Aviv Israel)
- Radial force was constantly measured while decreasing the diameter of the test device from 10 mm to 5 mm
- Radial resistive force values of CGuard were normalized to device length.

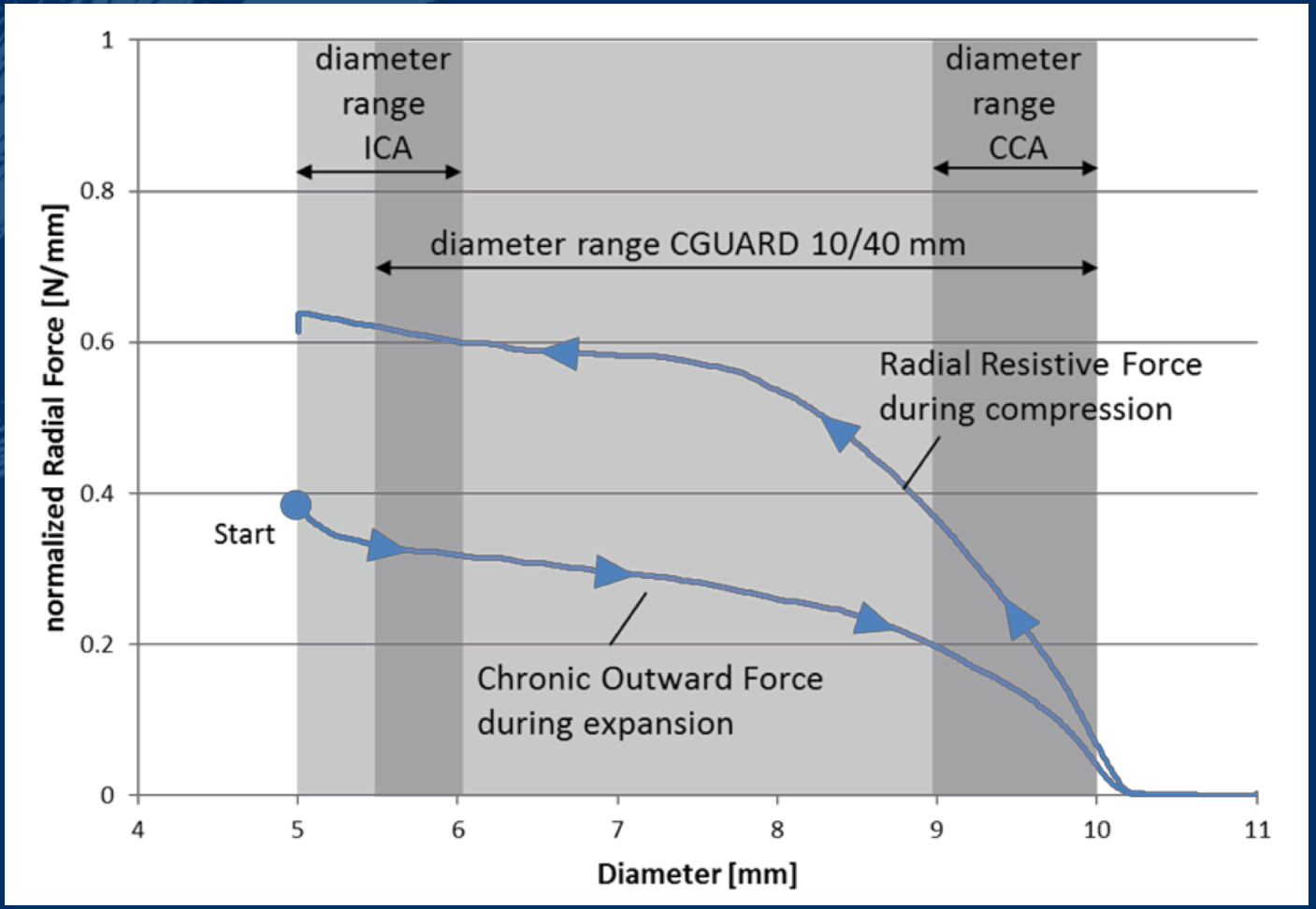


In Vitro Results

Chronic outward force during expansion of CGUARD Stent

Diameter [mm]	Chronic outward force , normalized to stent length [N/mm]	Percentage of max force [%]
5.5	0.330	100
6	0.318	96
6.5	0.307	93
7	0.297	90
7.5	0.282	85
8	0.259	78
8.5	0.237	72
9	0.195	59

In vitro Results



The chronic outward force, normalized by stent length, indicates a near-equivalent radial force between the minimal radial force at 9.0 mm (0.195 N/mm) and the maximal radial force at 5.5 mm (0.330 N/mm)

Initial Clincal Evaluation

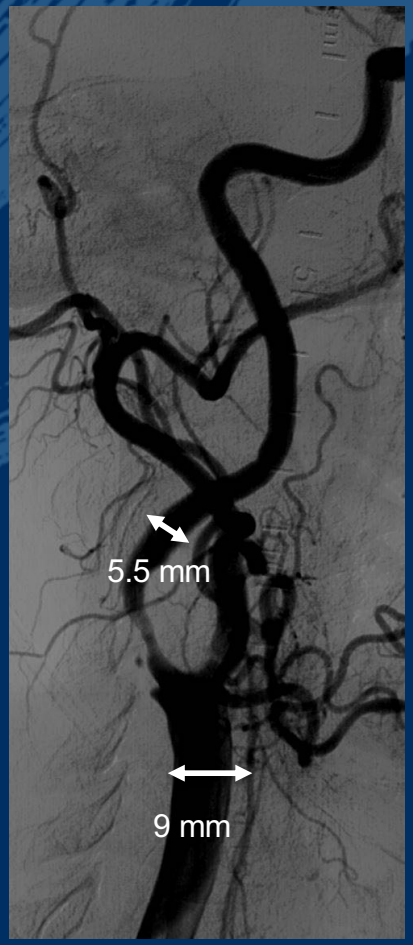
Patient Population

(n=30)

Age, mean	72.1 ± 7.7
Gender, m/f	26m / 4f
Risc factors	
Art. Hypertension	80.0 %
Diabetes mellitus	43.3 %
Hyperlipidemia	56.7 %
Smoking	63.3 %
Rankin Scale	1.4 ± 0.7
Mean Stenosis %	86.3 ± 6.4
Lesion length, mm	18.7 ± 4.4
CCA Diameter, mm	8.4 ± 0.6
ICA Diameter, mm	5.8 ± 0.6
Stents, n	
10/40 mm	25
10/30 mm	5

Clinical Case 1

69 year old male patient with a symptomatic high-grade stenosis of the right internal carotid artery



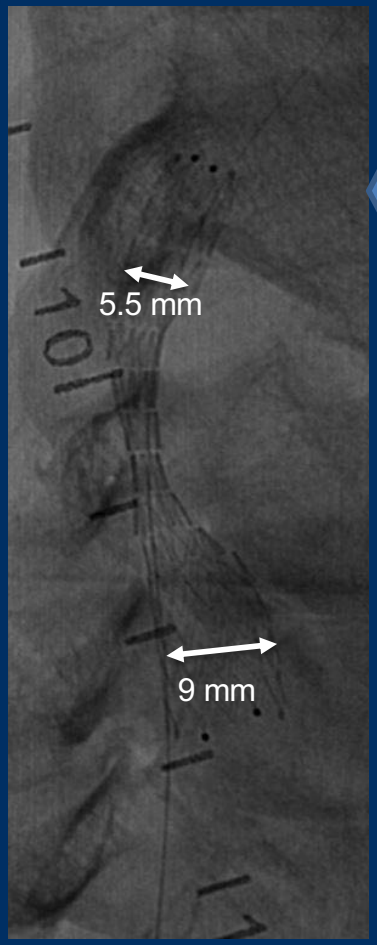
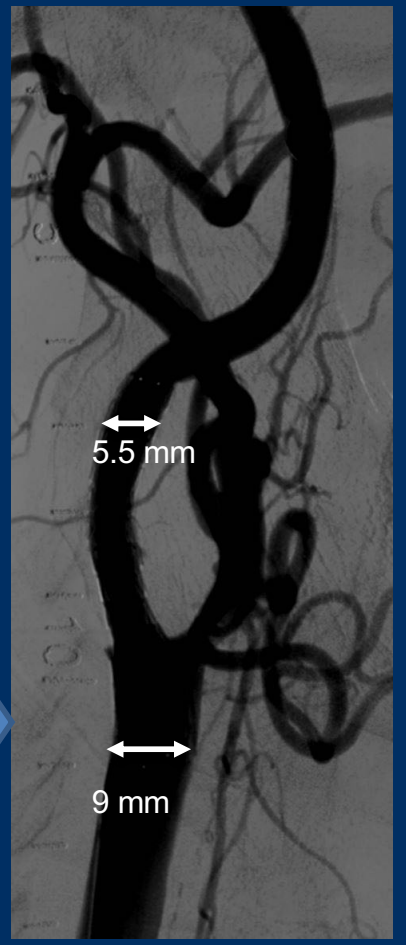


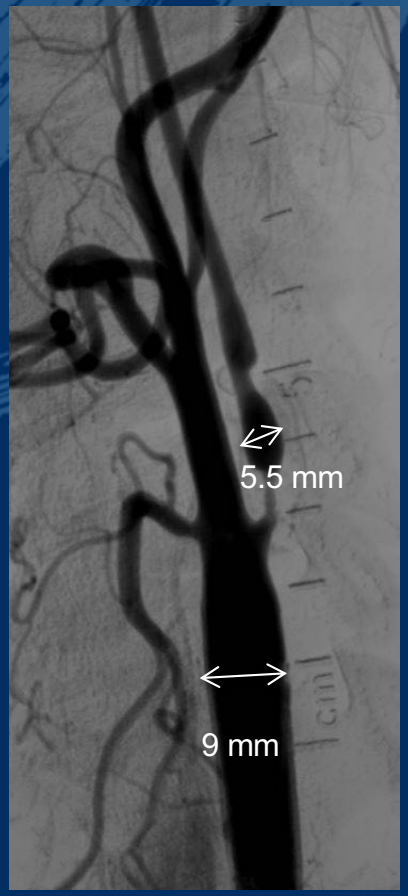
Image after primary implantation of a 10x40 mm CGuard without pre-dilatation.

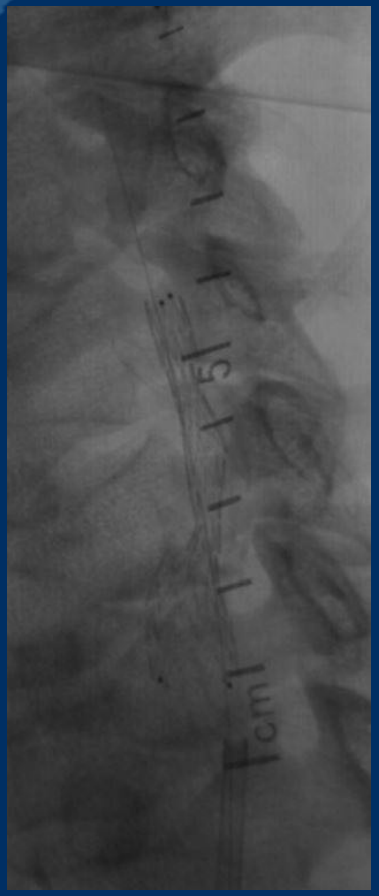
Final result after angioplasty with a 5/30 mm balloon showing a perfect wall adjustment.



Clinical Case 2

59 year old male patient with a symptomatic high-grade stenosis of the right internal carotid artery





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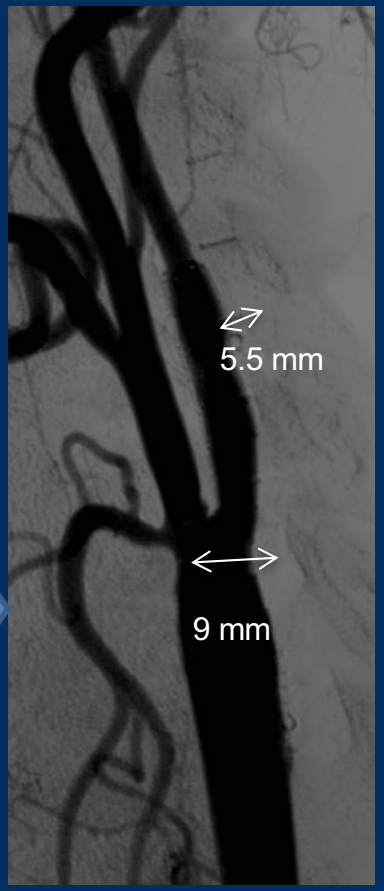

Clinical Results

- 30 consecutive patients were treated and all have completed 6 months FU
- Median procedural time was 37.4±8.7 min
- Median diamter changes in CCA and ICA diameters was 2.6 mm
- 100 % technical success without peri-procedural complications
- No major of minor strokes at 6 months

Clinical Results

- Modified Rankin Scale of the symptomatic patients improved from 1.4 ± 0.7 prior to intervention to 0 post procedure
- DUS indicated all stents and all ECA were fully patent
- peak systolic velocity (PSV) was 75.8±9.1 after 30d
- DWI-MRI from 10 of 30 patients after 30 days and 6 months detected no new ipsilateral lesions

Conclusions

- Through in vitro bench tests, the new “One Size Fits All” CGuard EPS, demonstrated near flat chronic outward radial force in the range of 5.5 to 9.0 mm diameter.
- In this consecutive series of routine CAS patients, the new “One Size Fits All” CGuard EPS demonstrated it can be safely implanted
- The “One Size Fits All”, with the SmartFit technology, adapts well to carotid artery changes in diameter
- The six month clinical and DW-MRI results in this initial cohort of patients treated with the “One Size Fits All” CGuard Eps with SmartFit technology demonstrated prevention of embolic events