Potential of New-Generation Double-Layer Micromesh Stent for Carotid Artery Stenting in Patients with Unstable Plaque: A Preliminary Result Using OFDI Analysis

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BACKGROUND: **One disadvantage of carotid artery stenting (CAS) is a high incidence of distal embolism (DE) during or after the procedure. Patients with unstable plaque are considered at high risk for DE and plaque protrusion (PP) after stent placement, which can cause postprocedural ischemic complications. This study was conducted to compare the rate and size of PP between the CASPER stent, a new-generation double-layer micromesh stent, and conventional stents as assessed by optical frequency domain imaging (OFDI), and also to evaluate the efficacy of CAS with the CASPER stent in cases with unstable plaque.**

METHODS: **The study group comprised 46 consecutive patients with unstable plaque, identified on magnetic resonance imaging, undergoing CAS with OFDI image acquisition. Cross-sectional OFDI images within the stented segments were evaluated at 0.125-mm intervals, and the rate and size of PP were compared between the CASPER stent and conventional stents.**

RESULTS: **The CASPER stent was used in 9 patients. No procedural complications occurred. On OFDI analysis, the presence of PP was apparently lower in CASPER stent group compared with the conventional stent group (44% vs. 88%; $P = 0.022$). In addition, mean PP area was significantly smaller in the CASPER stent group (mean PP area, 0.013 ± 0.034 mm^2 vs. 0.057 ± 0.09 mm^2; $P = 0.006$).**

CONCLUSIONS: **On OFDI evaluation after CAS, the degree of PP was significantly smaller in the CASPER stent group compared with the conventional stent group. This result provides new insight into the use of CAS to treat carotid artery stenosis with unstable plaque.**

INTRODUCTION

Carotid artery stenosis is an important cause of ischemic stroke. Carotid artery stenting (CAS) has recently emerged as an alternative to carotid endarterectomy for treating carotid artery stenosis.[1] A disadvantage of CAS is the high incidence of distal embolism occurring during or after CAS, even with improvements in neuroprotection devices. We and other investigators have reported that unstable plaque with a large lipid-rich necrotic core with intraplaque hemorrhage are at high risk for distal embolism.[2-6]

Recently, plaque protrusion (PP) after stent placement has been suggested as one of the major causes of postprocedural ischemic complications, especially in cases with unstable plaque.[7-10] Use of the CASPER stent (Terumo, Tokyo, Japan), a double-layer micromesh low-profile closed-cell stent with an higher mesh density and smaller pore size compared with conventional stents, is expected to reduce the risk of PP through the stent struts and distal embolism.[11,12] This stent is just starting to be used in clinical field in European countries and reports of clinical experiences have

Key words
- Carotid artery stenosis
- Carotid artery stenting
- Magnetic resonance imaging
- Micromesh stent
- Optical frequency domain imaging
- Plaque protrusion

Abbreviations and Acronyms
CAS: carotid artery stenting
IPH: intraplaque hemorrhage
LRNC: lipid-rich necrotic core
MRI: magnetic resonance imaging
OCT: optical coherence tomography
OFDI: optical frequency domain imaging
PP: plaque protrusion
ROI: region of interest
SIR: signal intensity ratio

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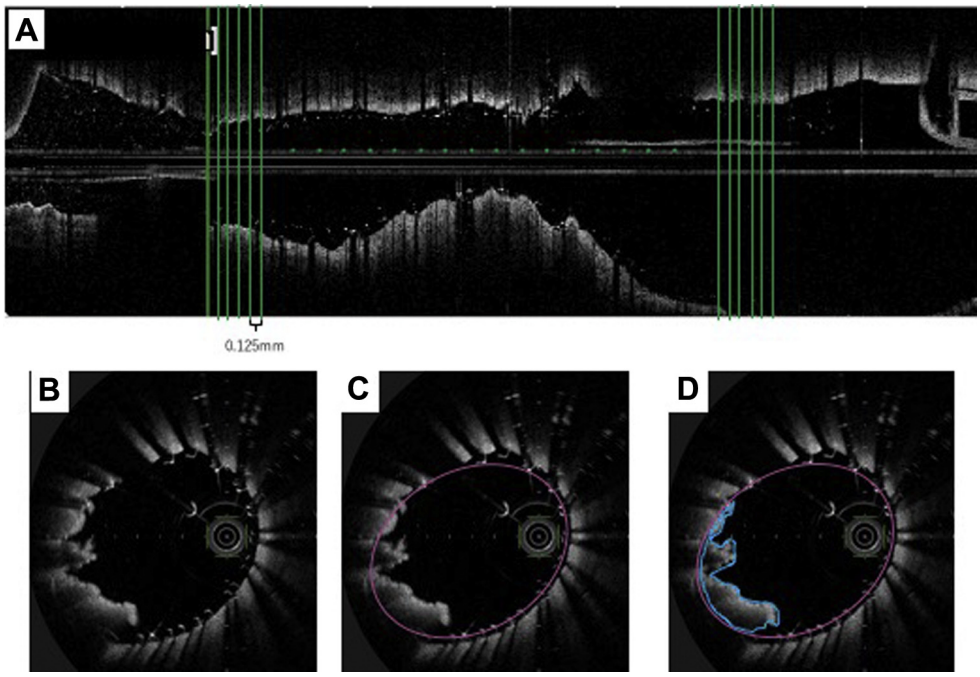

Figure 1. Example of cross-sectional area assessment. (**A**) Long-axis image of optical frequency domain imaging (OFDI) for the analysis of plaque protrusion (PP) between the struts. Cross-sectional OFDI images within the stented segments were evaluated at 0.125-mm intervals. (**B**) OFDI image. (**C**) Semiautomated stent area detection (*pink circle*). (**D**) Manual contour detection of PP (*blue area*).

been published. However, the effectiveness of the CASPER stent in reducing PP has not yet been reported.

Among available intravascular imaging modalities, optical coherence tomography (OCT) provides high-resolution images of carotid arteries.[13-15] The recently developed optical frequency domain imaging (OFDI) technique provides faster image acquisition speed, greater penetration depth, and higher-quality image resolution compared with the conventional time-domain OCT.[16-19]

The purpose of this study was to compare the rate and extent of PP between the CASPER stent and conventional stents as detected by OFDI, and to evaluate the efficacy of CAS performed with the CASPER stent for cases of unstable plaque.

METHODS

Subjects

Between October 2013 and June 2016, a total of 59 consecutive patients were scheduled for CAS because of carotid artery stenosis ≥50% in symptomatic patients and ≥80% in asymptomatic patients, as recommended by the criteria of the North American Symptomatic Carotid Endarterectomy Trial collaborators.[20] Forty-six patients with unstable plaque detected on magnetic resonance imaging (MRI), defined as plaque with a signal intensity ratio (SIR) of ≥1.25 using previously published criteria were included in the study.[2,3,21] Cardiovascular risk factors were evaluated in all patients. Hypertension was defined as systolic blood pressure ≥140 mm Hg, diastolic blood pressure ≥90 mm Hg, or previous use of antihypertensive medication. Hyperlipidemia was defined as serum low-density lipoprotein cholesterol ≥140 mg/dL or previous use of antihyperlipidemia medication. Diabetes mellitus was defined as a hemoglobin A1C level ≥6.5% or the previous use of medications for diabetes mellitus. The CASPER stent was introduced for use in February 2015.

The study protocol was approved by the Institutional Review Board of Hyogo College of Medicine (identification no. 1859), and informed written consent was provided by each patient,.

MRI Evaluation of Carotid Plaques

Double-inversion recovery 2D turbo spin-echo black blood T1-weighted MRI images were acquired on a 3-T MRI scanner (Intera Achieva; Philips Medical Systems, Best, The Netherlands) using a head neck array coil with the following parameters: axial plane; interleaved acquisition with cardiac gating; repetition time, 1 × the R-R interval (i.e., duration of the interval from the center of the subsequent R wave on electrocardiography); echo time, 20 ms; echo-train length, 5; flip angle, 90°; bandwidth, 108.6 kHz; field of view, 16 × 16 cm; matrix, 272 × 265; slice thickness, 3 mm; slice gap, 0 mm; voxel size, 0.59 × 0.6 × 3.0 mm^3. Black blood inversion delay was automatically determined using the Bloch equation, taking the R-R interval and blood T1 value into account. As SPIR fat-saturation pulse was added to reduce the signal from subcutaneous and facial fat. The total scanning time was