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Modification of a Braided Support Catheter into a Rapid Exchange System for Navigation of a Distal Protection Device through Significant Vascular Tortuosity

DALE DING[1], ROBERT M. STARKE[1], CHRISTOPHER R. DURST[2], AVERY J. EVANS[2]

[1] Department of Neurological Surgery, [2] Department of Radiology, University of Virginia; Charlottesville, VA, United States

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Summary

Cerebral embolic protection devices (EPD) reduce the rate of periprocedural thromboembolic complications and are currently used in all carotid artery stenting (CAS) procedures. However, tortuous vascular anatomy of the internal carotid artery (ICA) may prevent navigation of distal EPDs, thereby leading to inadequate cerebral protection.

We present a case in which significant tortuosity of the ICA distal to the stenotic lesion precluded navigation of currently available distal EPDs.

During a CAS procedure, significant vascular tortuosity of the distal cervical ICA was noted which prevented navigation of currently available distal EPDs due to catheter kinking. In order to overcome this anatomic barrier, a novel rapid exchange catheter system (RECS) was created using a modified DAC 038 braided catheter through which a distal EPD and microguidewire were placed. This newly devised RECS allowed navigation of the distal EPD past the tortuous ICA bend and successful completion of the CAS procedure without periprocedural complications.

We demonstrate that modification of currently available devices can, in select cases, effectively address cases of significant vascular tortuosity which limit the use of conventional distal EPDs.

Introduction

Carotid stenosis due to thromboembolic atherosclerotic disease of the internal carotid artery (ICA) is one of the leading causes of ischemic stroke [1]. Recently, the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) reported equivalent outcomes of carotid endarterectomy (CEA) compared to carotid artery stenting (CAS) for the treatment of symptomatic carotid stenosis [2]. Cerebral embolic protection devices (EPD) have been shown to decrease periprocedural thromboembolic complications and improve overall outcomes following CAS by distal shielding of embolic plaque debris [3-5]. Therefore, EPDs have been readily incorporated into major clinical trials evaluating the efficacy and safety of CAS, such as CREST and the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) study, and their usage is currently part of standard CAS practice [2,3]. However, tortuous vascular anatomy of the ICA's cervical and proximal petrous segments may preclude navigation of a distal EPD thereby leading to inadequate cerebral protection and potentially abandonment of the CAS procedure. We present a novel rapid exchange catheter system which was devised in response to a CAS case in which significant vascular tortuosity did not allow navigation of currently available distal EPDs.

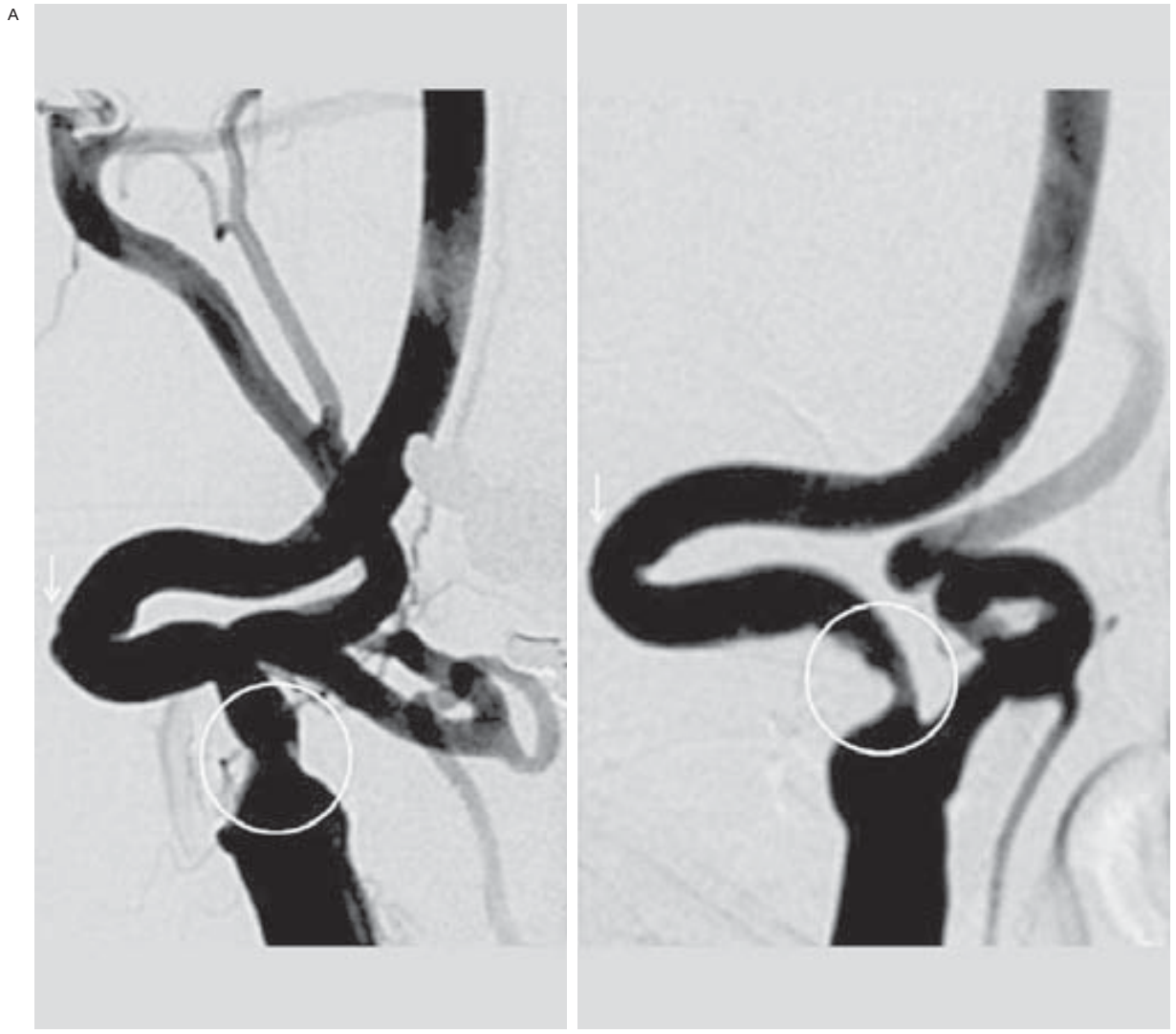

Figure 1 Angiography, right common carotid artery injection, demonstrates 73% stenosis of the proximal ICA measuring 3 mm in length (circle) as visualized on AP (A) and lateral (B) projections. The severe inferiorly oriented bend of the distal cervical ICA (arrow) precluded initial attempts to pass the Spider and Angioguard distal protection devices past this tortuous portion of the ICA.

Technical Note

Case Presentation

An 80-year-old woman presented one month ago to an outside institution with transient ischemic attacks (TIA). She was diagnosed by Doppler ultrasonography with severe, 80-99%, stenosis of the right cervical internal carotid artery (ICA). The patient was scheduled for a CEA at the outside institution, but she presented to our center for a second opinion regarding the possibility of CAS. At the time of presentation to our clinic, the patient continued to be symptomatic with intermittent TIAs. The patient's neurological examination was normal without focal deficits. After discussing the risks and benefits of CEA, CAS, and observation, the patient elected to undergo CAS.

Endovascular Procedure

The patient was premedicated with aspirin 325 mg daily and clopidogrel 75 mg daily for one week. On the day of the procedure, the patient's aspirin and P2Y assays demonstrated effective platelet inhibition at 418 aspirin reaction units (ARU, therapeutic level <551 ARU)

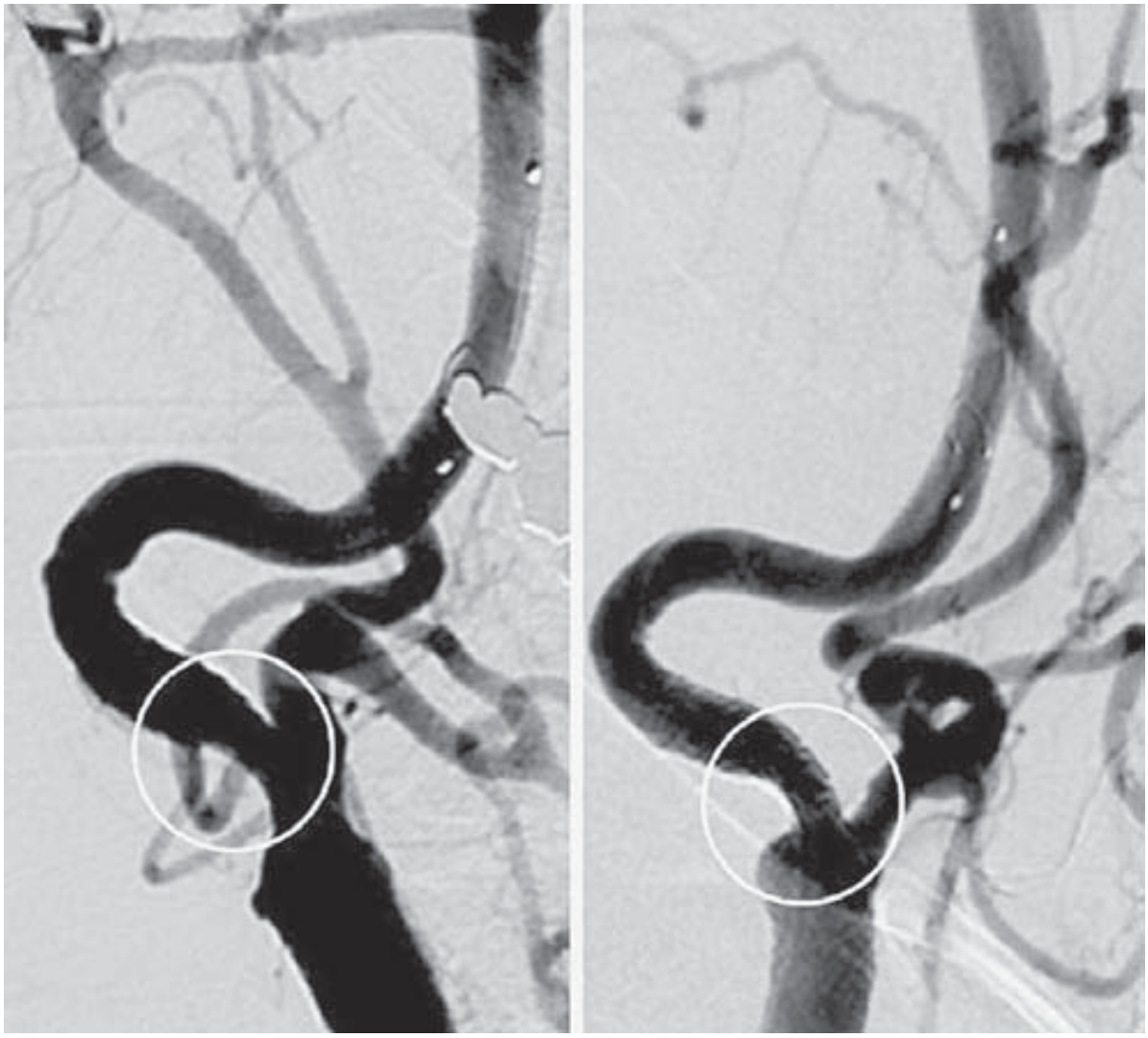

Figure 2 Post-treatment angiography, AP (A) and lateral (B) projections, demonstrates significantly improved luminal diameter of the proximal internal carotid artery (circle) compared to pre-treatment imaging as well as the appropriate position of the 8×30 mm Precise stent.

and 171 P2Y12 reaction units (PRU, therapeutic level <208 PRU), respectively. A 6 French Envoy catheter (Depuy, Warsaw, IN, USA) was navigated into the right common carotid artery (CCA). Diagnostic angiography of the right CCA demonstrated 73% stenosis of the proximal ICA, 3 mm in length, with a severe inferior bend in the ICA just distal to the cervical segment (Figure 1). The carotid bifurcation and ECA were widely patent, and the contour and caliber of the CCA were normal. A Transend microguidewire (Boston Scientific, Natick, MA, USA) was placed through an Angioguard distal protection device (Cordis Corporation, Miami Lakes, FL, USA) to bypass the stenotic lesion in the ICA. However, the Angioguard device could not be navigated past the tortuous bend in the ICA. A second attempt to pass through the tortuous ICA segment with a Spider distal protection device (ev3, Irvine, CA, USA) was also unsuccessful. The navigation of both EPDs past the tortuous ICA bend was prohibited due to kinking of their delivery catheters.

In order to overcome the limitations imposed by the vascular tortuosity of the distal cervical ICA, a novel rapid exchange catheter system (RECS) was created to provide addi-

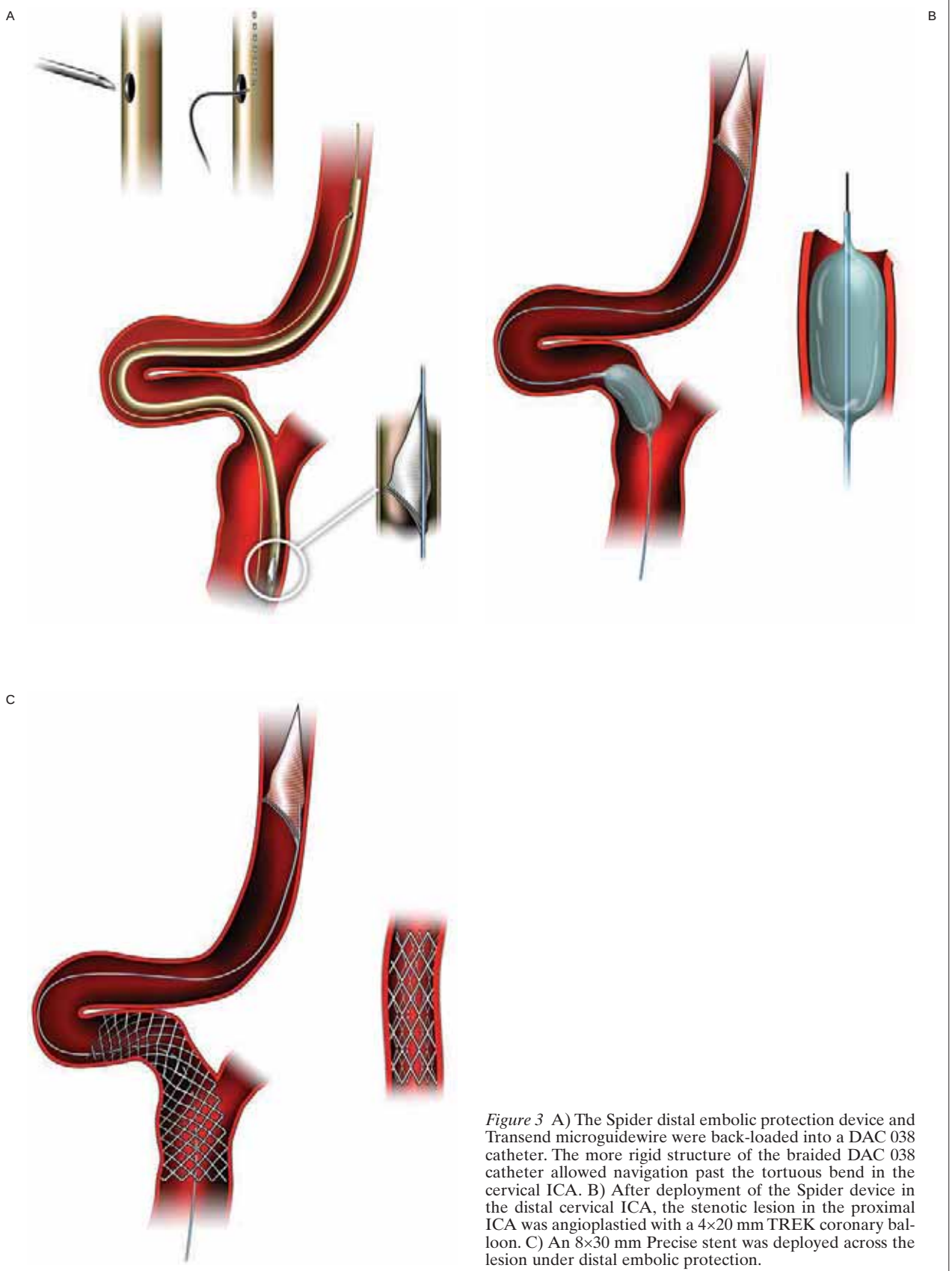

Figure 3 A) The Spider distal embolic protection device and Transend microguidewire were back-loaded into a DAC 038 catheter. The more rigid structure of the braided DAC 038 catheter allowed navigation past the tortuous bend in the cervical ICA. B) After deployment of the Spider device in the distal cervical ICA, the stenotic lesion in the proximal ICA was angioplastied with a 4×20 mm TREK coronary balloon. C) An 8×30 mm Precise stent was deployed across the lesion under distal embolic protection.

tional support for the EPD. A braided DAC 038 catheter (Concentric Medical, Fremont, CA, USA) was converted into a RECS by introducing two small bores, the sizes of which were pre-planned based on the dimensions of the Spider device, with a 19-gauge needle. The Spider device and Transend guidewire were back-loaded into the DAC 038 catheter which was able to be navigated past the tortuous bend in the ICA. The Spider device could then be safely deployed in the cervical ICA allowing subsequent completion of the stenting procedure. Following deployment of the Spider device, a 4×20 mm TREK coronary balloon (Abbott Vascular, Abbott Park, IL, USA) was used to angioplasty the ICA at the level of the stenosis prior to deploying an 8×30 mm Precise stent (Cordis Corporation, Miami Lakes, FL, USA) across the lesion. Post-stent angiography performed through the Envoy catheter in the right CCA showed significant improvement in the diameter of the proximal ICA lumen with an appropriately positioned stent spanning from the distal CCA to the proximal cervical ICA (Figures 2 and 3).

Post-Procedural Course

Post-procedural carotid Doppler ultrasonography demonstrated minimal to mild residual stenosis of the right ICA measuring 0-39% with appropriate stent patency. The patient's post-procedural course was uneventful, and she remained neurologically intact at follow-up one month after CAS. The patient was maintained on aspirin 325 mg daily indefinitely and on clopidogrel 75 mg daily for two months.

Discussion

CAS has been found to be an efficacious and durable treatment alternative to CEA for patients with carotid stenosis who are deemed high risk for surgery or who prefer to be treated by an endovascular approach [2,3]. However, the results from CREST are not applicable to the management of this case, since patient age of at least 80 years and severe tortuosity of the extracranial ICA were exclusion criteria for CREST [2]. Although CEA was initially offered to the patient, she refused surgical intervention and would only agree to treatment with CAS. Given the high rate of recurrent cerebral ischemic events in patients with symptomatic carotid stenosis, we elected to proceed with CAS, despite the patient- and lesion-specific characteristics which predisposed the patient to a relatively increased risk of periprocedural stroke compared to CEA.

The use of EPDs has been shown to significantly increase the safety of CAS procedures [4,5]. Based on the consistently superior outcomes of protected compared to unprotected CAS, these procedures are no longer performed without an EPD. Therefore, the inability to navigate an EPD past significant vascular tortuosity, such as in our case, will result in inadequate protection or potential abortion of the CAS procedure due the significantly increased risk of periprocedural stroke associated with unprotected CAS. The novel RECS, comprising a Spider distal EPD and Transend guidewire within a modified DAC 038 catheter, devised by the senior author (AJE) allowed successful navigation of the EPD past the significant vascular tortuosity of the cervical ICA distal to the stenotic lesion. This novel technique is not limited to CAS procedures, but may be readily applied to any endovascular intervention in which challenging proximal vascular anatomy is encountered. In contrast to the buddy wire technique, in which a second guidewire is placed within a microcatheter to increase its rigidity or within a vessel to decrease its tortuosity, our approach allows easier tracking of an EPD within a larger diameter braided support catheter without the additional risk of vessel injury introduced by a second wire [6]. Continued research and development of newer generation distal EPDs may allow neurointerventionalists to overcome the limitations of currently available devices. Meanwhile, currently available devices may be modified to provide distal protection during CAS.

Conclusions

Due to their proven ability to significantly reduce the risk of periprocedural complications, cerebral EPDs have become an integral part of CAS procedures. Although uncommon, the presence of significant vascular tortuosity of the ICA distal to the stenotic lesion prevents the navigation and deployment of distal EPDs. When the utilization of an EPD is prohibited, the CAS procedure may be associated with an unacceptably high complication rate. We pre-

sent the creation of a novel RECS through a larger diameter braided support catheter which allowed the successful navigation and deployment of a distal EPD during a CAS procedure.

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Dale Ding, MD
Department of Neurological Surgery
University of Virginia
P.O. Box 800212
Charlottesville, VA 22908, United States
Tel.: 1-434-924-2203
Fax: 1-434-243-6726
E-mail: dmd7q@hscmail.mcc.virginia.edu