Continuing Medical Education

Taking the Pressure Off: An Update

Here are the latest concepts in off-loading DFUs.

BY WINDY COLE, DPM

Objectives

After completing this CME, the reader will:

1) Understand the pathophysiology responsible for the development of diabetic foot ulcers

2) Have reviewed the scientific rationale and supporting evidence for off-loading

3) Have been introduced to proper off-loading techniques

4) Be able to evaluate emerging off-loading devices to increase patient outcomes

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Introduction

Diabetes mellitus (DM) is a major public health concern in the U.S., with diabetic foot ulcer care totaling $9-13 billion in direct yearly medical costs.[1] Diabetics have a 25% lifetime incidence of foot ulcers with a 28-51% five year recurrence rate.[1] One study has estimated that the world prevalence will be 382 million by 2030,[2] while the World Health Organization has estimated a prevalence of 366 million diabetics by this date.[3] Up to 50% of those with diabetes will develop complications related to the disease.[4,5] Diabetic foot ulcers (DFUs)are among the most common preventable complications in patients with diabetes.

Medical care in the U.S. to treat diabetic foot ulcers totals $9-13 billion in direct yearly costs.

Foot ulcers can develop due to a series of pathological changes related to elevated blood glucose levels at both cellular and tissue levels. Diabetes mellitus is a metabolic disease characterized by impaired metabolism resulting in higher than normal glucose levels in the body. This condition occurs due either to cells failing to produce insulin or lacking the response to insulin, or both. Vascular and/or neurological impairment affects oxygen perfusion, leading to poorer healing responses to localized

trauma such as pressure.[6,7] It has been well-established that increased blood glucose levels attribute to damage of neurons, causing a decrease in the ability of nerve fibers to transmit adequate signals, resulting in neuropathy.[8]

Sensory Neuropathy

Sensory neuropathy results when there is a loss of the body's protective response mechanisms to pain resulting in the lack of detection of minor trauma such as blisters or abrasions.[9,10] Motor neuropathy detrimentally affects patient balance and spatial awareness, which can have a negative impact on gait and ambulation. Foot structure abnormalities, decreased muscle volume, and strength in the foot and ankle can also lead to friction or pressure-related lesions such as callus or corns.[11] Skin becomes dry and thin as a result of autonomic neuropathy and therefore is more susceptible to damage or breakdown.

Furthermore, microvascular dysfunction contributes to reduced tissue perfusion causing reduction in oxygenation of the tissues, which may result in an increased vulnerability to mechanical stress.[10-12] Changes resulting in the pathophysiology described are major contributors to the development of a diabetic ulcer and subsequent wound healing failure (Figure 1).

Sensory neuropathy causes a loss of the body's protective response to pain, resulting in the lack of detection of minor trauma such as blisters or abrasions.

Figure 1: Example of a typical plantar DFU

As detailed, the etiology of diabetic foot ulcers usually is multifactorial.[14-16] Although infection is not commonly an etiology in diabetic foot ulcers, it is a common occurrence because these wounds typically contain areas of necrosis and increased bioburden, and are

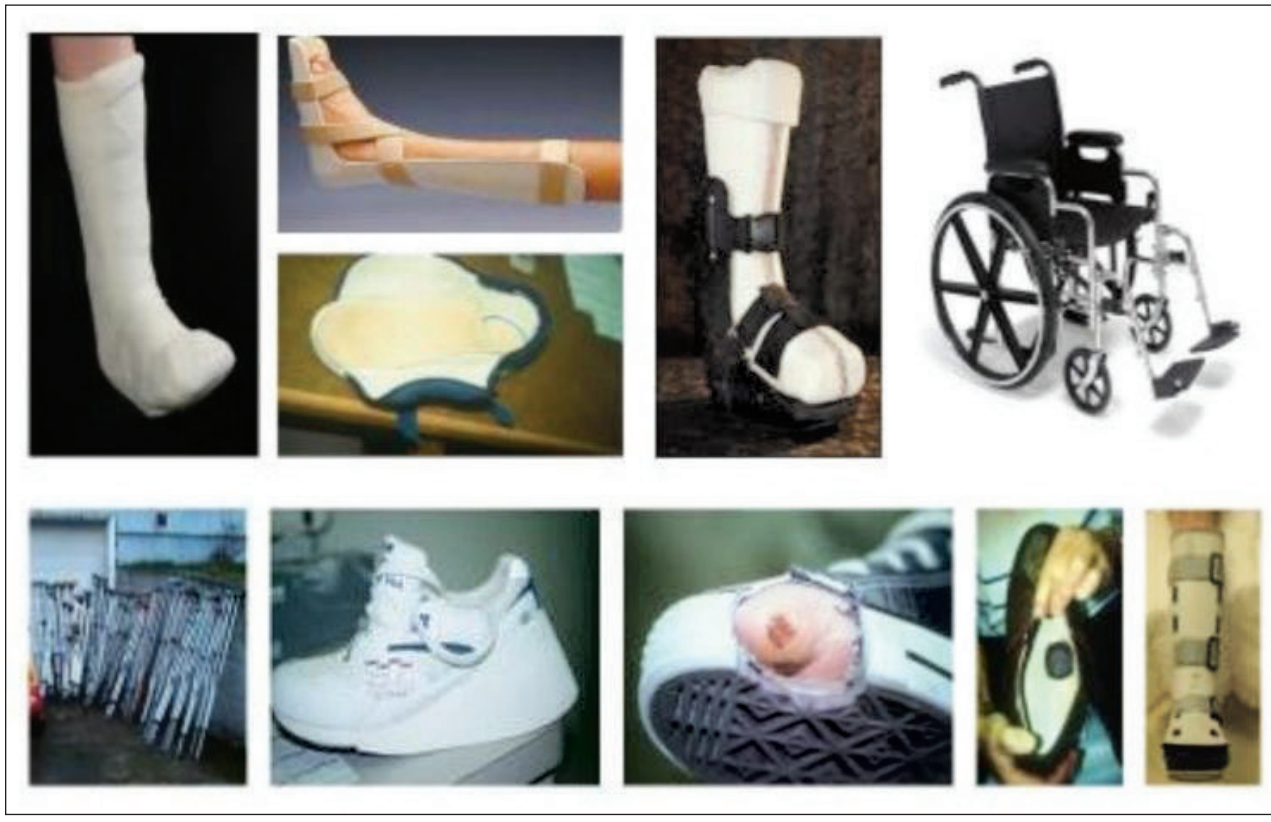

Figure 2: Examples of commonly-used off-loading devices

prone to bacterial contamination due to the immunocompromised state of the patient.[14-16] These risk factors for foot ulcers are also predisposing components leading to amputations. 85% of all amputations are a direct result of diabetic foot ulcers.[5]

Interventions that can help increase wound closure in this patient population would therefore not only be cost-effective, but prevent potential long-term sequelae and maintain patient quality of life. Therapeutic options used to treat chronic diabetic ulcers include adequate wound bed preparation with appropriate debridement and application of specialized dressings to provide the wound with a moist environment. In the treatment of diabetic foot ulcers, pressure reduction is commonly referred to as off-loading. None of these therapeutic options will succeed without sufficient DFU off-loading in order to decrease the development of pressure necrosis.

Pressure Reduction

Plantar foot ulcers are a direct result of increased pressure to the foot in the presence of neuropathy. Elimination of repetitive stresses and decrease in plantar pressures must be achieved in order to have any success in wound healing. Generally, throughout the gait cycle, plantar pressures are greatest in the forefoot and lessen in the hindfoot and medial arch. Common methods to offload the foot include bed rest, wheelchair, crutch-assisted gait, total contact casts, felted foam, half shoes, therapeutic shoes, and removable cast walkers. The most effective off-loading is achieved when forces are spread over a wide area of contact. There are a variety of commercially available off-loading devices available on the market (Figure 2).

Generally, throughout the gait cycle, plantar pressures are greatest in the forefoot.

Unfortunately, the effectiveness of these devices varies significantly. Armstrong, et al.[17] performed comparison mean peak pressure measurements in the area of the plantar metatarsal heads among several types of devices commonly used for off-loading (Figure 3).

Among the studied foot gear, the highest peak plantar pressures were found in those wearing canvas oxfords, 44.7N/cm2. Diabetic extra depth shoes performed only slightly better at 39.5N/cm2. Total contact cast exhibited the least significant measurement of plantar pressures at 7.0 N/cm2. Simply applying a dressing to the wound and allowing the patient to ambulate in a surgical shoe or diabetic shoe will not provide the decrease in pressure distribution needed for wound healing to occur. Pressure reduction is the cornerstone of plantar diabetic foot ulcer treatment.

In the study conducted by Armstrong, et al., the highest peak plantar pressures were found in patients wearing canvas oxfords.

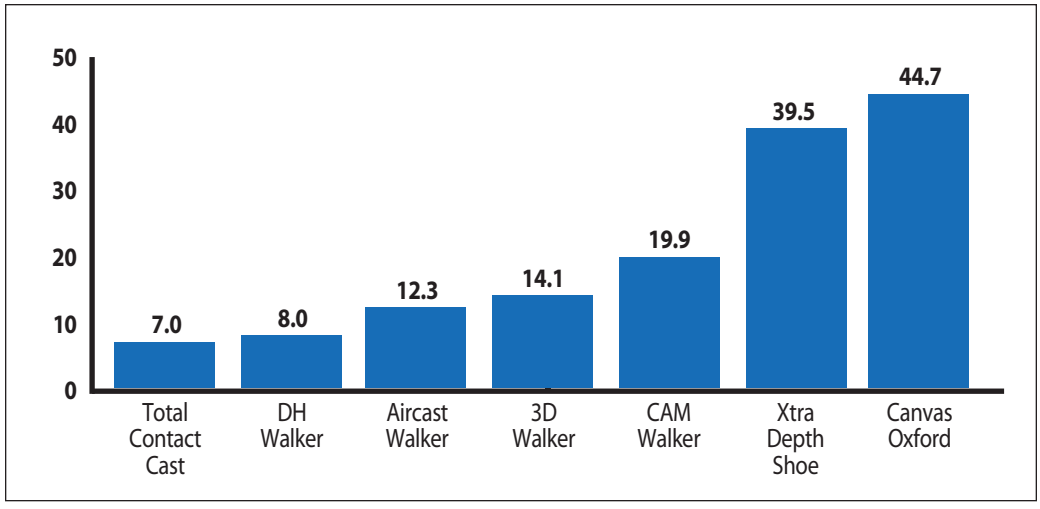

Figure 3: Off-Loading Devices Pressure Reduction

Total Contact Cast (TCC)

Total Contact Casts (TCC) are widely thought of as the gold standard in off-loading. TCCs are a very effective means of allowing for ambulation while uniformly distributing pressures over the entire plantar surface of the foot. There are several types of TCCs commercially available in the United States (Figure 4).

Birke, et al. reported that TCCs reduced pressure at the plantar metatarsal heads in six patients studied by up to 84 percent.[18] Numerous randomized controlled trials have been performed validating the TCC's efficacy to off-load. Plaster casts used to treat neuropathic wounds were first used by Milroy Paul, but later popularized in the U.S. by Dr. Paul Brand.[19]

TCCs not only reduce plantar pressures, they also eliminate ankle joint motion. When properly applied, a TCC will keep the ankle joint at neutral. Plan-

tarflexion is prohibited and therefore force is reduced in the forefoot and midfoot. TCCs also transfer weight to the lower leg. Due to the conical shape of the tibial segment of the lower extremity, there will be a transfer of weight to the hard cast. This will result in the removal of pressure from the plantar foot.

Patients wearing TCCs have a shortened stride length and decrease contact on the floor. When the ankle joint motion is eliminated, the lower extremity cannot move through all normal phases of gait. Heel strike and propulsion are minimized. The foot has less contact with the ground and there are fewer ground reactive forces present. TCCs are cumbersome and cause the patient to take fewer steps a day. Repetitive stresses are then also reduced.

Lastly, TCCs mold to the leg, helping to decrease edema. Perhaps the single most important attribute of this off-loading technique is forced patient compliance. Patients cannot easily remove the device on their own. TCCs are contraindicated in patients who have signs of osteomyelitis or acute wound infection. Adequate perfusion must be present in the lower extremity. Most manufacturer recommendations require an ABI of >0.7. Weekly cast changes are the standard of care; therefore, patients should be compliant with appointments. Any allergy to the casting kit materials would also be a contraindication for use.

In 2014, a consensus article was released by Snyder, et al.[20] examining optimal off-loading in the treatment of diabetic foot ulcers. The group concluded that total contact casting is the preferred method for off-loading diabetic plantar foot ulcers. One of the reasons cited in the review is that TCCs have most consistently demonstrated the best healing outcomes and cost-effective treatment.

Figure 4: Types of Total Contact Casts

TCCs are contraindicated in patients who have signs of osteomyelitis or acute wound infection or an ABI of <0.7

The average cost of treatment for patients getting a TCC is $11,946 vs. $22,494 without a TCC. The likelihood of ulcer healing is increased with off-loading adherence. The group even went as far as saying advanced therapeutics are unlikely to succeed in improving wound healing outcomes unless effective off-loading is obtained.

Figure 5: VACOcast diabetic boot with locking mechanism

The Gap: Evidence vs. Practice

In 2019 the International Working Group on the Diabetic Foot released the most recent version of practical guidelines for diabetic ulcer care. In this document, it is noted that off-loading is the cornerstone in treatment of diabetic foot ulcers caused by increased biomechanical stresses. They too recommend a non-removable, knee-high off-loading device in the treatment of neuropathic plantar ulcers.[21] But a retrospective analysis of the U.S. Wound Registry found that only 2.2% of the 221,192 plantar ulcers registered were off-loaded.[22] Of those that did receive off-loading, 36.8% were simply placed in a surgical shoe.[22] It was also noted that there were significantly more amputations in this group than in those patients treated with TCCs.[22]

So what's the deal? Why are clinicians slow to adopt TCCs in their practice? The most common excuses are that it is ex-

pensive, messy, takes too much time, or there is too great a risk for complications. The truth is that cast kits are available for as little as $75 and can have very positive reimbursement. Medicare reimbursements for TCC application have been showing an incremental increase in the last few years.

The use of fiberglass casting materials have significantly cut down on application and dry time with virtually no mess involved. On average, it takes an experienced clinician 15 minutes to apply. The overall complication rate associated with TCCs is 0.25% with the most common complication being superficial ulcers. A 2005 safety study by Guyton concluded that a frequently changed total contact cast is a safe modality for off-loading and immobilizing the neuropathic foot, even with a constant rate of minor reversible complications.[23]

Viable Alternatives to TCC

Originally designed for the treatment of fractures and sprains, a prefabricated removable cast walker may be useful in off-loading diabetic foot ulcers. In a study performed by Fleischli, et al.,[24] it was concluded that the Ossur DH Off-loading walker reduced plantar pressures by 79% to 80% in the study cohort. Removable cast walkers do have several tangible advantages over total contact casts. A removal walker allows clinicians, patients, and care-givers access to the wound to perform more frequent dressing changes. This is especially important in cases of wound infection or excessive exudate. Patients may also remove the cast walkers to sleep.

One of the most frequent complaints made by patients wearing TCCs is that they are difficult to sleep in. Some patients have sustained minor injuries to the contralateral extremity with the cast during the night. TCCs are not waterproof, making showering more difficult. When patients are placed in a cast boot they may remove the device in order to shower.

These advantages found in the use of removable cast boots may also be pitfalls. The lack of forced compliance found with removable cast walkers is a causative factor for delayed healing in patients utilizing this form of off-loading. In a study by Armstrong,[25] et al., 63 patients with superficial non-infected wounds were placed in different off-loading devices. The subjects were randomly assigned to wear a half shoe, TCC, or removable cast walker (RCW).

Wound healing in each subset was tracked over the course of 12 weeks. The results of the study are as follows: 89.5% of subjects wearing TCC, 58.32% of subjects wearing half shoes, and 65.0% of subjects wearing RCWs healed within the 12-week period. The median time to heal was 4.8 weeks in the TCC group, 7.2 weeks in the RCW group, and 8.7 weeks in the half shoe group. Although there seems to be similar decreases in plantar pressures in both TCCs and RCWs, the overall efficacy is increased in patients who use TCCs. The most likely reason is the forced compliance of the device.

According to the latest guidelines released by the International Working Group on the Diabetic Foot it is recommend that a non-removable, knee-high off-loading device be used in the treatment DFUs.

The Best of Both Worlds

For clinicians still on the fence about utilizing TCCs in their practices due to concerns over application time or cost, there may be other options. A randomized controlled trial was conducted of 41 patients treated with either a TCC or a RCW rendered irremovable by circumferentially wrapping a layer of fiberglass cast material around it ("instant TCC"). The results of this comparison study suggested that the "instant TCC" may be as efficacious as the standard TCC in healing and may be associated with no more or possibly fewer complications, takes less time to place/remove, and is associated with lower costs.[26]

More recently, OPED, the manufacturers of the VACOcast Diabetic boot (Figure 5) has developed what perhaps could be the best of both worlds. This cast boot device has a locking mechanism for forced compliance similar to TCCs. The VACOcast lining is composed of a bead-filled vacuum insert that molds to the foot like plaster or fiberglass. This allows for optimal pressure distribution.

A published expanded case series evaluated the VACOcast Diabetic boot in 20 patients treated by a community podiatry service in the UK. The cohort studied consisted of 17 male and 3 female patients with an age range of 41-80 years. Of the patients enrolled, 19 were type 2 diabetics. There were no device-related injuries reported during this case series. The device was highly rated by patients for comfort, safety, stability, and ability to ambulate. Additional studies are needed to evaluate the efficacy and determine rates of wound healing compared to the known standard set by the TCC.[26]

An additional study was performed to analyze the results of the VACOcast boot in the treatment of DFUs in a real-world setting. A retrospective review of records of patients with DFUs treated with a VACOcast from 2011 to 2017 was performed. Eighty-three episodes of ulcerations in 42 subjects were identified, of which 48 (57.8%) healed in a median duration of 17.5 (95% confidence interval = 15-33) weeks with the use of the VACOcast and 35 (42.2%) discontinued its use. This data added to the growing research showing that alternatives to TCC such as the VACOcast are preferred by many patients and seem to be as equally effective as other removable cast walkers but with the added feature of being able to lock the device.[27]

Conclusion

Pressure reduction is crucial for the healing of plantar diabetic foot

ulcers. The TCC has long been considered the gold-standard off-loading device by researchers and consensus bureaus alike. There is a wealth of research that confirms the effectiveness of TCCs in off-loading plantar diabetic wounds. With all that we know about TCC therapy, there still remains a gap in clinical use. It has been reported that fewer than 2% of wound clinics in the U.S. utilize TCCs for off-loading of diabetic foot ulcers. Perhaps it is due to the fact that TCC application does have an associated learning curve.

With all that we know about TCC therapy, there still remains a gap in clinical use.

There is a cost associated with cast materials, but it is lowered when pre-packaged kits are purchased. Medicare does have positive reimbursement for TCC application for wound care centers and medical offices. Dry time involved could be another reason for the slow adoption of TCC therapy. Fiberglass cast materials have accelerated dry time over older plaster materials. Patients are restricted in mobility and activities of daily living may be impaired; therefore, they may be less likely to consent to TCC use.

Limited access to the wound in order to assess healing progress or perform dressing changes can also be a disadvantage to TCCs. In comparison, removable cast walkers are just that…removable. They do allow access to the wound for more frequent evaluations and bandage changes, but patients may not use them as directed. The lack of forced compliance remains the top reason healing rates for RCWs are less than seen in TCCs.

RCW devices may not be reimbursed in certain settings. It is imperative that clinicians understand the need to decrease pressure, shear, and repetitive injury stresses on the foot as the cornerstone of proper diabetic foot ulcer care. No modality is perfect. Based on the evidence, clinicians should perform a thorough cost/benefit analysis, clinic workflow evaluation, and reimbursement estimate along with the above-mentioned information in order to determine the best solution to off-loading to allow for the best outcome for each individual patient. **PM**

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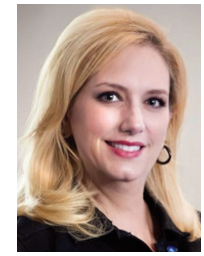

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1) Which is a true statement regarding diabetic wound statistics?

A) Diabetics have a 15% lifetime incidence of foot ulcers with a 28-51% five-year recurrence rate.

B) Up to 30% of those with diabetes will develop complications related to the disease.

C) Medical care in the U.S. to treat diabetic foot ulcers totals $9-13 billion in direct yearly costs.

D) One study has estimated that the world prevalence will be 100 million by 2030.

2) All of these statements are true except:

A) Diabetes mellitus is a metabolic disease of impaired metabolism resulting in high glucose levels in the body.

B) In patients with diabetes, cells fail to produce insulin or lack the response to insulin, or both.

C) Increased blood glucose levels cause neuron damage, thus resulting in neuropathy.

D) Diabetics do not have decreased healing responses to localized trauma or wounds.

3) Neuropathy negatively affects the diabetic foot in what way?

A) Sensory neuropathy causes a loss of the body's protective response to pain, resulting in the lack of detection of minor trauma such as blisters or abrasions.

B) Motor neuropathy has no impact on the diabetic foot.

C) Skin becomes dry and thin as a result of autonomic neuropathy, but does not contribute to tissue damage or breakdown.

D) No changes occur in the microvascular system.

4) Therapeutic options used to treat chronic diabetic ulcers include the following, EXCEPT:

A) Adequate wound bed preparation with appropriate debridement.

B) Application of specialized dressings to provide the wound with a moist environment.

C) Off-label use of expensive adjunctive therapies.

D) Proper off-loading resulting in pressure reduction on the wound.

5) Generally, throughout the gait cycle, plantar pressures are greatest in what part of the foot?

A) The toes

B) The medial arch

C) The heel

D) The forefoot

6) In the study conducted by Armstrong, et al., the highest peak plantar pressures were found in patients wearing

A) TCCs

B) RCWs

C) AFOs

D) Canvas oxfords

7) All are ways total contact casts reduce plantar pressures except:

A) Eliminate ankle joint motion

B) Shorten stride length and decrease foot contact on the floor

C) Minimize heel strike and propulsion during gait

D) Enable the patient to remove the device in order to shower

8) TCCs are contraindicated in patients who have:

A) Signs of osteomyelitis or acute wound infection

continued on next page

B) An ABI of < 0.7
C) Both a and b
D) None of the above

9) What statement is true of the latest guidelines released by the International Working Group on the Diabetic Foot?
A) Diabetic foot ulcers do not need off-loading
B) It is recommend that a non-removable, knee-high off-loading device be used in the treatment of DFUs
C) Removable cast walkers are the treatment of choice for DFUs
D) Wound healing in diabetics is not accelerated with off-loading

10) Which of the following statements are true regarding TCC therapy?
A) Total contact cast kits are available for as little as $75 and can have very positive reimbursement
B) On average, it takes an experienced clinician 15 minutes to apply a TCC
C) The overall complication rate associated with TCCs is 0.25%
D) All of the above

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State License(s)_____ Is this a new address? Yes_____ No_____

Check one: _____ I am currently enrolled. (If faxing or phoning in your answer form please note that $2.95 will be charged to your credit card.)

_____ I am not enrolled. Enclosed is my credit card information. Please charge my credit card $35.00 for each exam submitted. (plus $2.95 for each exam if submitting by fax or phone).

_____ I am not enrolled and I wish to enroll for 10 courses at $299.00 (thus saving me $51 over the cost of 10 individual exam fees). I understand there will be an additional fee of $2.95 for any exam I wish to submit via fax or phone.

Over, please

ENROLLMENT FORM & ANSWER SHEET *(continued)*

EXAM #4/26
Taking the Pressure Off: An Update
(Cole)

Circle:

1.	A	B	C	D	6.	A	B	C	D
2.	A	B	C	D	7.	A	B	C	D
3.	A	B	C	D	8.	A	B	C	D
4.	A	B	C	D	9.	A	B	C	D
5.	A	B	C	D	10.	A	B	C	D

Medical Education Lesson Evaluation

Strongly agree [5]	Agree [4]	Neutral [3]	Disagree [2]	Strongly disagree [1]

1) This CME lesson was helpful to my practice ____

2) The educational objectives were accomplished ____

3) I will apply the knowledge I learned from this lesson ____

4) I will makes changes in my practice behavior based on this lesson ____

5) This lesson presented quality information with adequate current references ____

6) What overall grade would you assign this lesson?

A B C D

7) This activity was balanced and free of commercial bias.

Yes _____ No _____

8) What overall grade would you assign to the overall management of this activity?

A B C D

This CME has been certified by a psychometrician as taking a minimum of 1.5 hours to complete.

What topics would you like to see in future CME lessons? Please list :

_____

_____

_____

_____

_____

_____