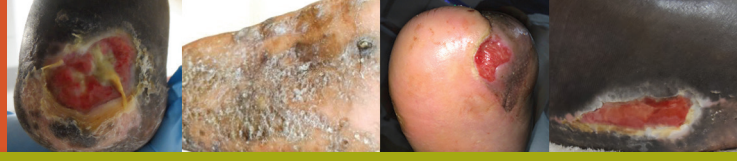
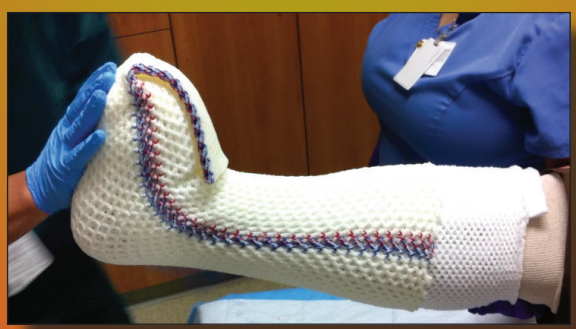


Review of the DFU Off-loading Consensus of 2014

Here is a review of the best evidence for this method of wound healing.

BY LEE C. ROGERS, DPM AND ROBERT SNYDER, DPM



Goals and Objectives

After completing this CME, the reader will:

1) Will learn the methods of off-loading with the best evidence.

2) Will be able to describe how off-loading fits into the wound healing algorithm.

3) Will understand the evidence/practice gap in off-loading and how to combat this.

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*Following this article, an answer sheet and full set of instructions are provided (pg. 112).—**Editor***

The purpose of this article is to review the contribution of off-loading to wound healing, the various methods of off-loading, and the eight consensus statements by the 2014 Consensus Panel on Offloading the Diabetic Foot Ulcer. While offloading is such a central part of wound healing in those with diabetic foot ulcers, there hasn't been firm guidance on which off-loading methods are best in which circumstances until now.

But let's start with a case study. A 54-year-old Hispanic male with Type 2 diabetes presents with an ulcer on the right foot. The ulceration is a breakdown of a split-thickness skin graft site used

Continued on page 106

DFU Off-loading (from page 105)

to cover a transmetatarsal amputation (Figure 1). Vascular studies revealed sufficient perfusion for healing and there was no underlying osteomyelitis. The patient has had the ulcer for eight months, with no improvement after several bioengineered tissue applications, and the referring physician is perplexed. We'll return to this case at the end.

Off-loading can generally be divided into two categories: external (bracing) and internal (surgical). External offloading for DFUs is most commonly performed and includes total contact casting (TCC), removable cast walkers (RCW) or controlled ankle motion (CAM) boots, Charcot restraint orthotic walkers (CROW), off-loading prescriptive footwear or inserts, wedge shoes, or shoe modifications. Internal off-loading includes Keller arthroplasty for distal hallux ulcers, Tendo-Achilles lengthening for plantar forefoot and midfoot ulcers, exostectomies to remove direct pressure, and Charcot foot reconstruction, among other surgeries.

Pressure times repetitive cycles of stress (steps) equals ulceration.

TABLE 1:
The Panel Members of the Consensus on Off-loading the Diabetic Foot Ulcer

Robert J. Snyder, DPM, MSc	Barry University School of Podiatric Medicine, Miami Shores, FL
Robert G. Frykberg, DPM, MPH	Carl T. Hayden Veteran Affairs Medical Center, Phoenix, AZ
Lee C. Rogers, DPM	Amputation Prevention Center, Los Angeles, CA
Andrew J. Applewhite, MD	Comprehensive Wound Center at Baylor University, Dallas, TX
Desmond Bell, DPM	Save a Leg, Save a Life Foundation, Jacksonville, FL
Gregory Bohn, MD	Trinity Center for Wound Healing and HBO, Bettendorf, IA
Caroline E. Fife, MD	Intellicure, Inc., The Woodlands, TX
Jeffrey Jensen, DPM	Barry University School of Podiatric Medicine, Miami Shores, FL
James Wilcox, RN	Healogics, Jacksonville, FL

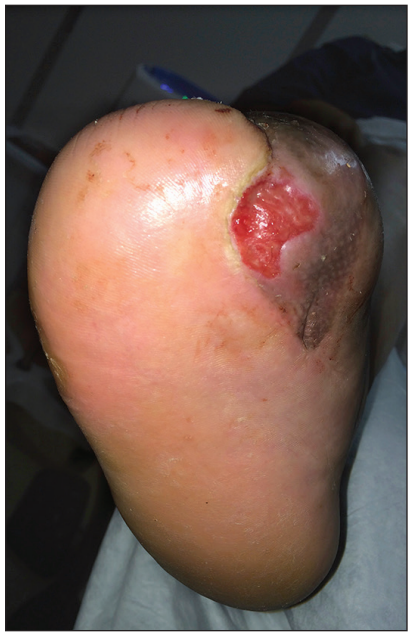

Figure 1: The Stairway to an Amputation describes the natural history of how a person with diabetes requires an amputation.

Adjunctive off-loading can also be helpful. This includes bed rest, wheelchairs, crutches, rolling knee walkers, and vehicle handicapped placards to reduce steps-per-day. However, caution must be used because some of these adjunctive methods have their own complications. Chronic bed rest can lead to pressure ulcers in those with impaired skin quality. Many homes and vehicles are not wheelchair appropriate. People with diabetes and neuropathy are frequently obese, and they may not tolerate crutches. Rolling knee walkers are well tolerated and easy to use for most patients, but care must be taken to avoid falls.

The three most important initial considerations for a diabetic foot ulcer are vascular, infection, and pressure.

Off-loading isn't only about direct pressure; shearing forces play a role as well. Shearing occurs during normal walking, especially with an abductory twist in the gait. It can also occur when transferring patients by dragging the heels or sacrum.

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DFU Off-loading *(from page 106)*

Pressure is one component of ulcergenesis; the number of times pressure is placed on the area is the other component. This is easier understood by the concept that pressure times repetitive cycles of stress (steps) equals ulceration. While not proposed for patients with active DFUs, David Armstrong has advocated prescribing activity as a measure of off-loading. Pedometers, smart phones, in-shoe pressure sensors, among other wearable technologies, can be easily monitored, and clinicians can prescribe a threshold of steps-per-day for patients at risk for ulceration.

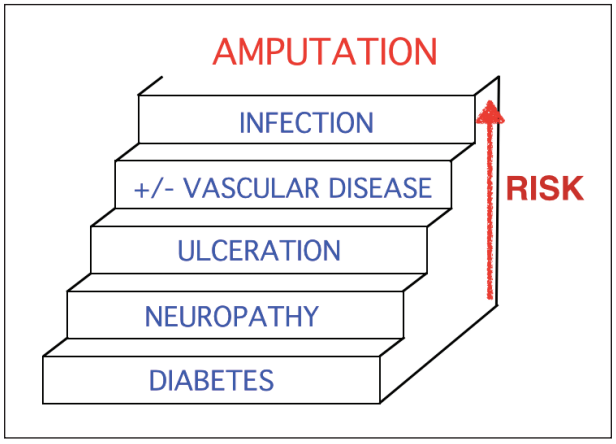

Figure 2: A TCC-EZ® depicted with description of the benefits from Rogers LC. Off-loading thediabetic foot ulcer. Current Dialogues in Wound Healing 2015;1:11-12.

The toe-brachial index is the best test to rule out vascular disease in a person with diabetes.

In 2013, a consensus panel of diabetic foot ulcer (DFU) experts was convened in Philadelphia, PA to address the matter of off-loading. The panel members are listed in Table 1. The panel's task was to review the literature for studies on diabetic foot ulcer off-loading and, based on this evidence, create consensus statements for publication. The panel used the GRADE method (Table 2) to grade each consensus statement.[1]

Approximately 90 articles were selected for review, but using the Wound Healing Society's categorization of level of evidence, that number was reduced to 64 articles to be included in the consensus guidelines evidence tables, with three additional publications known to panel members which were not found in the literature searches.

The panel reached consensus on the following statements which were published in 2014 in the *Journal of the American Podiatric Medical Association*.[2] The strength and quality of each recommendation is indicated as either (Moderate/Strong) or (High/Strong).

Vascular Management, Infection Management and Prevention, and Pressure Relief Are Essential to DFU Healing (High/Strong)

The panel emphasized that off-loading is an inseparable part of the wound-healing process. Since 85% of lower extremity amputations begin with a wound, healing is a major component to limb salvage. Understanding the pathway to amputation is important in preventing one. The major steps leading to an amputation, or the natural history to a diabetic ampu-

Continued on page 108

TABLE 2:

The GRADE Recommendations for Evidence in the Literature

Grade	Quality of Evidence	Definition
A	High	Further research is unlikely to change the confidence —high quality studies, consistent results
B	Moderate	Further research is likely to have an important impact on the confidence —high quality studies with limitations
C	Low	Further research is very likely to have an impact on our confidence —One or more studies with severe limitations
D	Very Low	Estimate of effect is uncertain —Expert opinion only

DFU Off-loading (from page 107)

tation, are visible in Figure 2.[3]

Off-loading is essential, but not the only component to the healing algorithm. The acronym VIP (vascular, infection, pressure) is helpful to remember the first and most important components of DFU healing.[4] Perfusion must be checked in every diabetic foot ulcer, and corrected if impaired. Only palpating the pedal pulses is not sufficient to determine adequate perfusion in those with diabetes.[5]

Certainly, the absence of a palpable pedal pulse is a good indicator of poor perfusion, but the presence of pedal pulses cannot rule out vascular impairment. The ankle-brachial index (ABI) is notoriously problematic in those with diabetes. Due to calcification of the vessels, it renders them less compressible and leads to falsely elevated or falsely normal results. Toe-brachial indices are less susceptible to the effects of diabetes, but the skin perfusion pressure (SPP) is a useful tool (unaffected by diabetes), which can help predict wound healing and level of amputation healing.

Infection is a clinical diagnosis based on the presence of erythema, purulence, odor, warmth, or systemic signs. A culture will only confirm that the correct antibiotic has been used, and should not be taken in uninfected lesions as a matter of protocol. Due to immunopathy associated with diabetes, white blood cell counts are only elevated in about half of individuals with a moderate or severe infection. Infection in a diabetic foot ulcer is, in most cases, an emergency. Soft tissue infections spread rapidly, follow paths of least resistance (like tendons through tunnels), and may be limb- or life-threatening. The management of a diabetic foot infection (DFI) takes precedent over most other factors, including revascularization. In an infected dysvascular foot, manage the infection first, even surgically, if indicated. It is important to know your institution's antibiogram since many institutions are reporting more than 50% of the Staphylococcus aureus isolates are methicillin-resistant. That should be taken into account when choosing an empiric regimen.

Figure 3: A 54-year-old male patient with a plantar diabetic foot ulcer at the transmetatarsal amputation site.

Advanced therapeutics should be used as first-line therapy.

Adequate Off-loading Increases the Likelihood of DFU Healing (Moderate/Strong)

After reviewing all the evidence, the panel concluded that there is no doubt that proper off-loading increases the likelihood that a DFU will heal. Off-loading reduces both direct pressure and the strain rate on the skin. Off-loading can be internal (surgical) or external (bracing/orthotics). External devices include total contact casts, removable cast walkers, Charcot restraint orthotic walkers, patellar tendon-bearing braces, and prescriptive footwear, among other methods with less evidence. Assistive devices, such as wheelchairs, crutches, bed rest, and rolling knee walkers, are also effective at reducing plantar pressure by reducing cycles of repetitive stress.

For Guidance on Off-loading the Charcot Foot, the Panel Endorses the Charcot Foot in Diabetes Consensus Report Published in 2011 (Low/Strong)

In 2011, a task force of 18 Charcot foot experts who met at the La Salpetriere Hospital in Paris co-published the results of their consensus generating meeting in *Diabetes Care* and the *Journal of the American Podiatric Medical Association*.[6] The task force was sanctioned by the American Diabetes Association and

A Keller arthroplasty would be best for a distal hallux ulcer with hallux limitus.

Continued on page 109

DFU Off-loading (from page 108)

the American Podiatric Medical Association. The off-loading consensus panel endorsed the document. It can be found at http://care.diabetesjournals.org/content/34/9/2123.

off-loading and healing diabetic foot wounds, it isn't used as often as it should be. One study of 108,000 patient visits to wound centers revealed that only 6% of patients with DFUs received a TCC.[8] Another study of 895 clinics found that in only 1.7% of clinics, TCC was used more than 50% of the time for DFUs, and 45% of clinics reported using no off-loading.[9]

A total contact cast enforces compliance since it can't be removed by the patient.

full. In summary, off-loading is the most effective treatment for early Charcot foot and can prevent a devastating deformity like the rocker-bottom foot.

TCC Is the Preferred Method for Off-loading Plantar DFUs Because It Has Most Consistently Demonstrated the Best Healing Outcomes and Is a Cost-Effective Treatment (Moderate/Strong)

The panel's review of the literature found that the total contact cast (TCC) is the most effective method to reduce plantar pressure. The TCC works by a variety of mechanisms (Figure 3).[7]

1) Due to the conical shape of the lower leg, weight is transferred to the tibia.

2) Plantar pressure is reduced.

3) Ankle motion is eliminated, reducing push off and forefoot and midfoot pressure.

4) The stride length is shortened, limiting the contact time of the foot on the ground.

5) The cast causes the patient to take fewer steps per day. The TCC has the added benefit of being non-removable. This ensures compliance with off-loading and it prevents manipulation of the dressing or wound environment.

There Currently Exists a "Gap" Between the Evidence Supporting the Efficacy of DFU Off-loading and What Is Performed in Clinical Practice (Moderate/Strong)

Unfortunately, even though the TCC has the strongest evidence for

The panel found that there were several barriers to using TCC including clinician-related, organization-related, and patient-related barriers. Clinicians may have a lack of training, misunderstanding that the TCC would make the wound worse, and concern about the time of application and the reimbursement. Organizations are concerned with the need to change the patient flow algorithm, the time of application, the cost of supplies, and liability.

It is most important to manage infection first in a diabetic foot ulcer.

Patients may feel claustrophobic, have transportation issues, have to interrupt driving if the TCC is on the right foot, be reluctant to comply with the therapy, or they may have fear of injury with the cast saw.

The Likelihood of DFU Healing Is Increased with Off-Loading Adherence (Moderate/Strong)

It almost goes without saying that following the doctor's orders will improve the wound-healing outcome. But the prescription of wound off-loading can't just be given on one visit; it must be reinforced visit after visit to be effective. When patients see an actual improvement in the wound, either visually or graphically, it helps to support the treatment plan, including off-loading, and maximizes compliance.

Advanced Therapeutics Are Unlikely to Succeed in Improving the Wound-Healing Outcomes Unless Effective Off-Loading Is Obtained (Moderate/Strong)

Many advanced products are available for wound-healing, including skin substitutes, dermal stretchers, advanced debridement options, and surgical techniques to close wounds. However, these advanced therapies are unlikely to succeed unless the wound is adequately offloaded. Additionally, many treatment algorithms advise using standard therapy, which includes good off-loading, prior to using advanced therapy.[10]

The Panel Supports the Development of a Per-Visit Off-Loading Quality Measure to Address the Gap Between Evidence of Off-loading and Its Current Use in Clinical Practice (Low/Strong)

As there is an increased use of registries for wound healing outcomes tracking, the panel recommends using off-loading as a quality measure for healthcare tracking. Tools for evidence-based care are being developed, and the addition of an off-loading measure would help the community to better understand its role in wound healing.

Conclusion

The role of off-loading can't be ignored in healing diabetic foot ulcers. Pressure, combined with neuropathy, led to the development of the wound, and pressure has to be removed in order to heal the wound and keep it healed. There are various forms of off-loading, from total to

Continued on page 110

DFU Off-loading (from page 109)

partial, but the total contact cast has been considered by experts to be the gold standard in off-loading the DFU. The difficulty with the term "gold standard" is that it implies that it is the widely used treatment. However, the TCC is seldom used despite its excellent evidence in healing DFUs more completely and more cost-effectively. So, while it may be the best method in off-loading, it will only become the true gold standard if more of us adopt it in our practice.

In closing, let's revisit our 54-year-old male with the ulcer on the TMA graft site. He had adequate perfusion, no infection, and advanced care. But, as we're sure you've ascertained by now, he wasn't properly offloaded. He was started on a total contact cast (Figure 4) and within four weeks, he was completely healed (Figure 5). Off-loading is something so simple and basic, but frequently overlooked. Let's do our parts to ensure that our practices include the standard of care—off-loading with total contact casts. **PM**

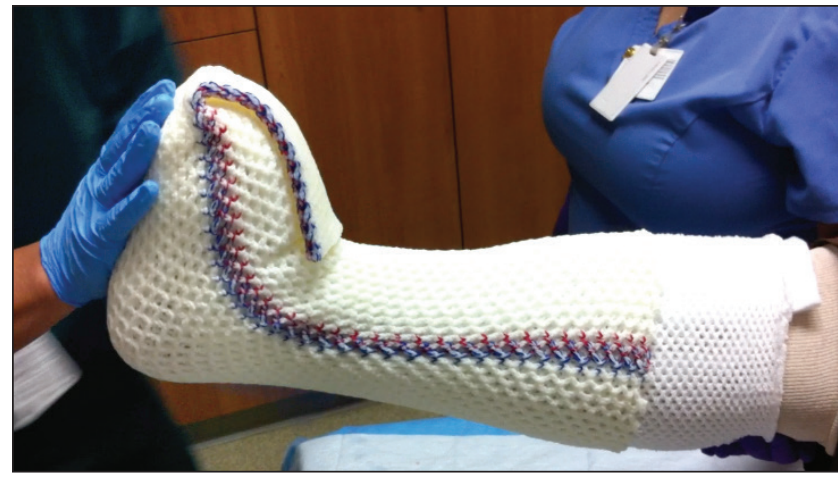

Figure 4: A TCC-EZ® applied to the foot and leg to relieve the pressure at the wound site.

A total contact cast has the best evidence and is the most cost-effective method to treat a diabetic foot ulcer.

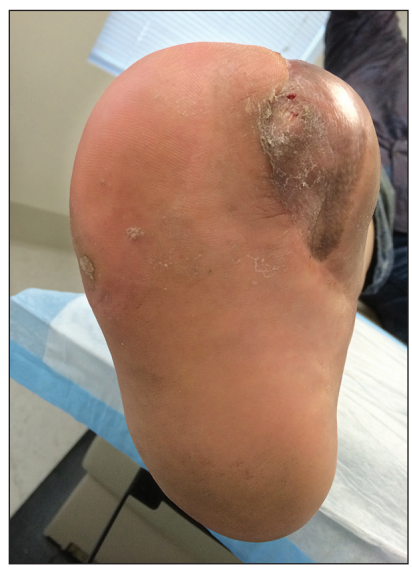

Figure 5: The foot healed at 4 weeks after treatment with a TCC.

Off-loading isn't only about direct pressure; shearing forces play a role as well.

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Dr. Rogers is Director of the Amputation Prevention Center at Sherman Oaks Hospital in Los Angeles, CA.

Dr. Snyder is Director of the Barry University Paul & Margaret Brand Research Center in Miami Shores, FL.

SEE ANSWER SHEET ON PAGE 113.

1) Which of the following is NOT considered external off-loading?
- A) Total contact cast
- B) Removable cast walker
- C) Tendo-Achilles lengthening
- D) Charcot restraint orthotic walker

2) Which of the following would be a complication of chronic bed rest as a method of off-loading?
- A) Pulmonary edema
- B) Pressure ulcers
- C) Leg cramps
- D) Restless leg syndrome

3) Which of the following combines with pressure to create an ulcer?
- A) Cycles of repetitive stress
- B) Poor skin quality
- C) Infection
- D) Equinus

4) Which of the following describe the three most important initial considerations for a diabetic foot ulcer?
- A) Vascular, Debridement, Skin closure
- B) Pressure, Debridement, Infection
- C) Vascular, Infection, Pressure
- D) Pressure, Infection, Skin closure

5) Which of the following would be the best test to rule out vascular disease in a person with diabetes?
- A) Ankle-brachial index
- B) Palpate pedal pulses
- C) Capillary refill time
- D) Toe-brachial index

6) Which of the following statements about a diabetic foot infection is TRUE?
- A) It should be diagnosed with a culture.
- B) The white blood cell count will be elevated.
- C) It is a clinical diagnosis.
- D) Vascular disease should be managed first.

7) Which of the following about off-loading the diabetic foot ulcer is TRUE?
- A) It increases the likelihood of healing.
- B) It is contraindicated in those with vascular disease.
- C) Bed rest is preferable to the total contact cast.
- D) There are no potential complications with off-loading.

8) Which of the following best describes the most effective treatment advocated for early Charcot foot?
- A) Off-loading
- B) Bisphosphonates
- C) Surgery
- D) Ice

9) Which of the following are mechanisms by which the total contact cast (TCC) helps to off-load the foot?
- A) It immobilizes the ankle, reducing push-off.
- B) It transfers weight to the tibia.
- C) It reduces number of steps-per-day.
- D) All of the above.

10) Which of the following describe the evidence-practice gap with total contact cast use?
- A) The evidence for TCC is strong, but it is not used frequently in practice.
- B) The evidence for TCC is weak, and it is not used frequently in practice.
- C) The evidence for TCC is strong, and it is used frequently in practice.
- D) The evidence for TCC is weak, and it is used frequently in practice.

11) Which of the following are sources of barriers to using a total contact cast?
- A) Clinician barriers
- B) Organizational barriers
- C) Patient barriers
- D) All of the above

12) Which of the following is NOT a patient barrier to using a total contact cast?
- A) Claustrophobia
- B) Interference with driving
- C) It uses up too much staff time
- D) Afraid of injury with the cast saw

13) Which of the following is TRUE about wound healing and off-loading?
- A) Adhering to off-loading recommendations makes wound healing more likely.
- B) Off-loading is only a minor part of the wound-healing plan.
- C) A total contact cast should be used as a last resort.
- D) Most clinics do a good job with off-loading.

14) Which of the following best describes the use of advanced therapeutics with off-loading?
- A) Bioengineered tissue is designed to work without off-loading.
- B) Early and effective off-loading may reduce the need for advanced therapeutics.
- C) Advanced therapeutics should be used as first-line therapy.
- D) Off-loading can destroy a graft placed on a wound.

Continued on page 112

Continuing Medical Education

CME EXAMINATION

15) Which of the following internal off-loading options would be best for a distal hallux ulcer with hallux limitus?
- A) Keller arthroplasty
- B) Tendo-Achilles lengthening
- C) Exostectomy
- D) Tibialis anterior tendon transfer

16) Which of the following is TRUE about the total contact cast?
- A) It increases forefoot pressure.
- B) It cannot be used for midfoot ulcers.
- C) It increases the number of steps-per-day.
- D) It enforces compliance since it can't be removed by the patient.

17) Which of the following is most important to manage first in a diabetic foot ulcer?
- A) Vascular disease
- B) Infection
- C) Excessive pressure
- D) Edema

18) Which of the following assistive devices would be most difficult to use with neuropathy and obesity?
- A) Wheel chair
- B) Rolling knee walker
- C) Crutches
- D) Bed rest

19) In addition to direct pressure, which of the following other types of pressures is involved in the causation of a diabetic foot ulcer?
- A) Shearing pressure
- B) Atmospheric pressure
- C) Hydrostatic pressure
- D) Blood pressure

20) Which of the following best describes the use of a total contact cast in off-loading the diabetic foot ulcer?
- A) It has the best evidence and is the most cost-effective method
- B) It should be reserved for severe cases.
- C) The barriers to use can't be overcome.
- D) It is difficult to ensure compliance.

SEE ANSWER SHEET ON PAGE 113.

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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 $2.50 will be charged to your credit card.)

_____ I am not enrolled. Enclosed is my credit card information. Please charge my credit card $25.00 for each exam submitted. (plus $2.50 for each exam if submitting by fax or phone).

_____ I am not enrolled and I wish to enroll for 10 courses at $195.00 (thus saving me $55 over the cost of 10 individual exam fees). I understand there will be an additional fee of $2.50 for any exam I wish to submit via fax or phone.

ENROLLMENT FORM & ANSWER SHEET *(continued)*

EXAM #5/15
Review of the DFU Off-loading Consensus of 2014 (Rogers and Snyder)

Circle:

1.	A	B	C	D	11.	A	B	C	D
2.	A	B	C	D	12.	A	B	C	D
3.	A	B	C	D	13.	A	B	C	D
4.	A	B	C	D	14.	A	B	C	D
5.	A	B	C	D	15.	A	B	C	D
6.	A	B	C	D	16.	A	B	C	D
7.	A	B	C	D	17.	A	B	C	D
8.	A	B	C	D	18.	A	B	C	D
9.	A	B	C	D	19.	A	B	C	D
10.	A	B	C	D	20.	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

How long did it take you to complete this lesson?

_____hour _____minutes

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

Please list :

_____

_____

_____

_____

_____