Transitional Off-Loading—Part 2

Here's an evidence-based approach to pressure redistribution in the diabetic foot.

Objectives

After participating in the educational activity, the participant should be better able to:

1) Relate diabetic foot problems to the need for using off-loading devices

2) Distinguish between the various types of dressings and off-loading devices used for diabetic foot wounds.

3) Apply the "transitional approach" to off-loading the diabetic foot.

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*Following this article, an answer sheet and full set of instructions are provided (p. 206).—**Editor***

By James McGuire, DPM

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Transitional Approach

In order to ensure that clinicians are using the most appropriate off-loading device for each phase of wound healing and to prevent a rapid recurrence of the wound after closure, the author has developed a "transitional approach" to applying each of the off-loading devices based on its demonstrated ability to off-load the foot and heal open wounds. An open wound, regardless of the

An open wound, regardless of the depth, is a serious risk for the patient with diabetes.

Continued on page 200

Off-Loading...

depth, is a serious risk for the patient with diabetes. It is essential that clinicians' educational efforts focus on that and ensure that patients understand the gravity of the situation they face.

Without a proper understanding of the mechanism of wounding and the consequences of infection, patients with diabetes can too easily resist the clinician's attempt to place them in what they consider a bulky and cumbersome device. Once they understand the concept of off-loading and embrace the need to restrict loading and decrease both the pace and the amount of ambulation, patients are more likely to accept the restrictions of non-removable devices and the need to constantly protect the delicate tissues of the regenerating wound bed.

Regardless of the depth of the wound, devices that force adherence and restrict forward motion of the ankle should be used in the early stages of treatment when the wound is open. Most of the problems the author has seen in the clinic occur when shallow wounds are treated less aggressively and are off-loaded with surgical shoes or depth footwear. Most clinicians are compassionate individuals who want their patients to get better.

Regardless of the depth of the wound, devices that force adherence and restrict forward motion of the ankle should be used in the early stages of treatment when the wound is open.

At the same time, they feel bad about putting their patients in non-removable devices or devices that are very visible or particularly restrictive. They actually listen to and concede to their patients' concerns, and proceed with a shoe or surgical shoe and allow the patients to remove it for daily bathing and sleeping. Clinicians know that patients will not be adherent and will inevitably remove the device, walk barefoot in the shower, and use standard footwear when they go out in public. Consequently, clinicians may go against their better judgment and use less tissue protection than the patient needs in favor of a lesser device that is "better than nothing" and that the patient will actually use.

After years of treating patients with diabetic foot ulcers, the author firmly believes that clinicians need to accept the fact that this is not helping patients and they need to "hold the line" and use devices that aggressively protect the tissues they are trying to heal. The only proven devices for consistently healing diabetic foot ulcers with several studies to support them are the TCC and the iTCC.

Once the wound is closed, the patient can transition to a shoe-based total contact device, such as the modified Carville healing sandal or surgical shoe with a total contact molded insert.

Despite this evidence, these devices are rarely used by most clinics in America. According to a study by Wu, et al.,[33] the TCC is actively used by only 1.7% of centers for treatment of the majority of their plantar diabetic foot ulcers. In that same study, Wu, et al[33] found that RCWs were used by only 15.2% of the centers in the treatment of most of the wounds treated. In most centers, shoe modifications were the most commonly used off-loading devices, despite data that suggest they were not the most effective means of off-loading.[53]

Given the poor acceptance of the TCC as a primary therapy by most clinicians despite the evidence to the contrary, this author believes that clinicians should use a non-RCW as the standard first-line therapy. After 2 to 4 weeks, or at least 50% closure of the wound, allow the device to be removed for bathing and dressing changes, using advanced wound dressings to enhance wound closure. This is a more widely accepted device and a significant step up from shoes or surgical shoes.

iTCC

Armstrong, et al.[54] first used the term instant total contact cast, or iTCC, in 2002. They followed that with a study in 2005, where they directly compared removable and non-removable walkers.[46] They were able to demonstrate complete and earlier healing at 12 weeks in 82.6% of patients in the iTCC group, compared with 51.9% of patients who were free to remove the device if they chose. Katz, et al.[47] compared the nonremovable walker with the TCC and showed that the two devices were statistically equivalent in terms of healing rates, but the iTCC took less time to apply and remove and was more cost-effective.

Once the wound is closed, the patient can transition to a shoe-based total contact device, such as the modified Carville healing sandal or surgical shoe with a total contact molded insert. The patient also could use a commercial off-loading shoe with a similar conforming or total contact molded insole to protect and mature the skin for the first 3 to 4 weeks after wound closure. Rapid return to standard footwear, regardless of the patient's insistence, is fraught with problems and, in this author's clinical experience, accounts for a large portion of the recurrences noted in the literature asso-

Continued on page 201

ciated with diabetic foot wounds.

After the wound has closed and the epithelial tissues thicken to the point where they are able to withstand the shear and pressure forces produced during ambulation, the patient can be transitioned to a final or permanent off-loading device. These devices include depth or custom-molded shoes or total contact insoles in standard footwear. Patients who exhibit marked deformity associated with a Charcot foot may need to be placed in a CROW, or a rocker-soled shoe with a total contact molded innersole attached to a double upright brace and a patellar tendon-bearing attachment to protect the foot and avoid risky reconstructive surgery.

Figure 1: Pre-ulcerative Footwear

Total Contact Concept

When completely healed, the foot should always be protected with a heat or cast-molded, in-shoe, total contact foot orthosis designed to off-load areas of high pressure. Ulcers form in areas of high pressure on the neuropathic foot.[55] Too often, practitioners settle for returning the patient to his/her pre-ulcerative footwear with no modifications (Figure 1). They also accept prescription footwear with no attempt to contour the insoles just because it comes from a certified footwear provider. Simple, flat-cushioned insoles are not enough to adequately off-load the neuropathic foot and redistribute pressure across the plantar surface.

Allowing patients to leave the office with devices that do not fill the arch and accommodate for areas of bony prominence is less than standard of care for patients. This author has also witnessed too many patients with flat soles that do not have a built-in or added rocker to the base. The inclusion or addition of a rocker sole to a shoe further reduces midfoot and forefoot pressures that even contoured insoles cannot do.[56]

To be considered total contact, the position, length, and height of the arch of the device must match that of the beneficiary's uncompensated arch to achieve the clinical benefits.

The concept of using a total contact molded innersole to improve pressure distribution and increase the effectiveness of any off-loading device has been used for many years and was pioneered by doctors Joseph Kahn[57] in the 1930s and Paul Brand,[58] the father of modern off-loading. Many insoles produced for the patient with diabetes are not custom molded to either the foot (heat molded) or a positive cast of the patient.

Most shoe fitters or pedorthists today rarely mold the multi-laminate insoles that come with the shoes to achieve a true total contact foot bed. This is usually done because of time and/or financial constraints. Most patients end up walking around and dynamically molding the insole over time—a technique discouraged by the Medicare Therapeutic Shoe Bill that clearly states: "For the inserts to be covered under the Medicare Program, it must be multi-density and molded directly to the foot or the model of the foot, to the degree necessary to achieve total contact of the beneficiary's foot."

A molded total contact insole increases foot-bed contact area and spreads pressure out across the entire surface of the foot.

To be considered total contact, the position, length, and height of the arch of the device must match that of the beneficiary's uncompensated arch to achieve the clinical benefits.[59]

Molded Total Contact Insoles

A molded total contact insole increases foot-bed contact area and spreads pressure out across the entire surface of the foot. Multi-laminate insoles can be heat molded or conform over time by a process referred to as dynamic molding, but by themselves, they do not have an inherent ability to off-load. Without contouring, they are simple cushioning devices at best.

Commercial off-loading devices have been designed with

Continued on page 202

Off-Loading...

memory foams that automatically mold to the foot or insoles with removable hexagonal or diamond-shaped segments that can be selectively removed to off-load specific areas of the foot. A hexagonal plug insole system and a memory foam insole are among available products.

A diabetic walking boot offers the ability to remove segments of the memory foam composite insole to selectively off-load problem areas of the foot. Thin soles that are not thick enough to fill the arch of the foot may be able to cushion areas on the plantar surface but cannot transfer forces away from high-pressure areas effectively.

In the author's experience, it is important that devices have sufficient depth of their foam materials to provide for true total contact of the insoles.

Devices that do not control the motion of the ankle and are based on a modified shoe platform, such as commercial off-loading shoes, depth shoes, or even a modified surgical shoe with a molded insert, have been unable to consistently approach the TCC's effectiveness with regard to percentage of wounds healed at 12 weeks and should not be used to heal open wounds. TCCs or removable walkers have a fixed ankle and a rigid rocker sole. Because they are able to prevent forward motion of the tibia during midstance and propulsion, they can significantly reduce forefoot and midfoot loading.

Any open foot wound that is not overtly infected should be treated with an iTCC or non-removable device until at least 50% wound closure has been obtained.

These devices have been able to consistently demonstrate healing rates of 80% to 90%. In a Cochrane[60] review in 2000 when the various off-loading devices were assessed, limited randomized clinical trial (RCT) evidence for the effectiveness of the TCC and the iTCC was found, but no solid evidence existed for using shoes as a treatment for open wounds.

Shoes had some limited evidence to support their use in the prevention or recurrence of ulcers.

No patient should go longer than a week between inspections to prevent complications from infection, mechanical irritation, or wound maceration.

Specialized Dressing Techniques

Two specialized dressing techniques, felted foam and the football dressing, are both non-removable off-loading treatments that have reported favorable results in several limited clinical studies. These dressings require some specialized training in application and usage and are not commonly used in a majority of wound clinics. However, in one randomize clinical trial (RCT), felted foam was not found to be any better than the half-shoe in its ability to heal wounds.

Another RCT found that felt padding applied directly to the skin or indirectly on an insole made no difference to the healing ability of the techniques.[61,62]

Treatment Considerations

After reviewing the data, and after 25 years of experience with managing diabetic foot wounds, this author concludes that applying a transitional approach to the use of off-loading devices has the best chance of producing a healed wound within the least amount of time. Strict adherence to a predetermined protocol is necessary to provide the patient with the most appropriate off-loading device at the correct phase of the healing process. It also relieves the clinician of the temptation to deviate from the prescription in the face of unrelenting pressure from the patient to return to standard footwear ahead of schedule.

Any open foot wound that is not overtly infected should be treated with an iTCC or non-removable device until at least 50% wound closure has been obtained. This should happen within the first 2 to 4 weeks of initiating treatment and will give the wound a great start before the clinician allows the patient to remove the device and use advanced wound products to further enhance the healing process. The clinician needs to sharp-debride the wound to remove slough and fibrin, clean the wound of excess bioload, and reduce hyperkeratotic overgrowth at the wound edges. Wounds should then be covered with a dressing that can remain in contact with the wound bed for seven days and control both drainage and wound bioload. Silver, cadexomer iodine, or methylene blue dressings should work well. Barrier creams or films should be used when the wound is draining so much that maceration may occur between dressing changes.

Patient visits should be weekly, or biweekly if the drainage is high and the risk of infection is great. No patient should go longer than a week between inspections to prevent complications from infection, mechanical irritation, or wound maceration. The almost miniscule expense of changing a cable tie with each visit makes removal and reapplication of the iTCC very cost-effective as compared with the TCC.

Strict monitoring of the

Continued on page 203

progress of these patients will produce the best results. Not only does it give the practitioner regular access to the wound, but it also allows the clinician to continually reinforce the reason for the forced adherence and show the patient by measurements and photographs the progress s/he is making.

Once the wound has shown it is responding to the treatments, it may be possible to allow patients to have access to the wound themselves to use advanced dressings, such as oxidized regenerated cellulose, collagens, growth factors, grafts, or wound-stimulating therapies such as noncontact ultrasound. It also allows patients to bathe and sleep with the device removed to help reduce some of the anxiety or claustrophobia that develops with non-removable devices.

Anytime a device is removable, however, it increases the possibility that the patient will walk without it. Most patients who are placed in shoe-based devices or removable walkers "cheat" and remove the devices to ambulate, placing their wound healing at risk. It is imperative that they see good results quickly and that they embrace the concept of adherence to the off-loading protocol established.

The use of the iTCC as the first-line therapy has the best chance of ensuring adherence, while gaining patient cooperation based on its perceived benefit.

Once the wound is closed, the patient should be transitioned to one of the shoe-based platforms, such as the modified Carville healing sandal, or a commercially produced off-loading shoe with a custom-molded total contact or segmentally adjustable innersole.

Most surgeons who do plantar foot surgery ask patients to remain non-weight bearing for three weeks before sutures are removed and they begin stressing the wound.

Depth shoes with molded inserts should not be used at this stage because they allow a much more normal gait and encourage the patient to increase both the amount and the pace of his/her ambulation. The surgical shoe or the commercially produced wound care shoe has a rigid, slightly rockered base and significantly reduces the pace of ambulation and the tendency to push off with the forefoot during gait (apropulsive).

Before patients return to any of the devices where the ankle is free to move, it is essential that the wound be fully epithelialized and that they are actively cooperating with the treatments. Once there is a layer of epithelium over the wound, it has to have several weeks to thicken and mature before it is able to withstand the stresses of ambulation. Most surgeons who do plantar foot surgery ask patients to remain non-weight bearing for three weeks before sutures are removed and they begin stressing the wound.

It seems reasonable to allow the epithelium to mature for a similar period; thus, this author avoids transitioning into standard footwear for at least 3 weeks after the wound first closes. There is little evidence to help clinicians decide when to return a patient to a prescription or modified shoe. One study has shown the mean turnover time of the entire epidermis to be 39 days or approximately five weeks.

Selected patients, such as those with unstable Charcot arthropathy or failed reconstructive surgery, will require the use of rigid immobilization for many months until the foot attains a stable plantigrade posture.

This author has used these data to decide on the protocol to be followed. The 5-week period would roughly correspond to a recommended 3 weeks in a step-down or transition device after the iTCC, followed by two weeks of monitored off-loading in the patient's new or prescription footwear before the clinician allows the patient to go for several weeks without supervision.[63]

Selected patients, such as those with unstable Charcot arthropathy or failed reconstructive surgery, will require the use of rigid immobilization for many months until the foot attains a stable plantigrade posture. Some patients may need the device permanently. For most patients, the standard RCW with a custom-molded total contact foot bed is able to provide the stability needed.[64]

For those patients with foot deformities so severe that standard walkers with custom-molded foot beds are not adequate to accommodate the foot, practitioners may wish to prescribe a CROW. The CROW is very expensive compared with the RCW and should be considered only for a patient with an extremely unstable foot who is trying to avoid amputation and desires to wear a permanent device instead.[65] The adjustable nature of the RCW and its lower cost make it a much better choice for all but the most unstable patients.

Summary

Patients with diabetic foot ulcers need to be regarded as lifelong

Continued on page 204

Off-Loading...

patients. Regular follow-up care and the use of protective footwear remain essential preventative measures.[66] It is extremely important to maintain off-loading therapy permanently after any wound has healed. Patients will always be tempted to return to the footwear worn prior to the development of their ulcer. They must be informed that returning to their former footwear before will likely lead to a return of the ulcer at the same site, which has already been weakened and is now more susceptible to ulceration. Once the practitioner has succeeded in closing a foot wound and has maintained closure for several weeks, patients need to have access to reliable preventive foot care on a regular bimonthly basis to prevent reulceration.[67]

Regular foot care and observation of the diabetic foot will give the patient long periods of, if not complete, freedom from wounds.

The transitional approach to off-loading gives the practitioner an evidence-based approach to off-loading the diabetic ulcer. When a foot ulcer heals as anticipated, there should be an orderly progression from one off-loading device to another. If a patient has a setback, the clinician should simply revert back to the more aggressive off-loading technique until the wound heals, then move ahead with a less restrictive device. Once the foot has healed, constant vigilance is necessary to prevent recurrence of the wound. Regular foot care and observation of the diabetic foot will give the patient long periods of, if not complete, freedom from wounds.

After reading this article, the practitioner should be better able to apply the available off-loading devices to ensure that each patient is receiving the appropriate amount of off-loading. They also should be able to modify existing protocols to better reflect the available data on off-loading devices and monitor the effectiveness of products prescribed or provided for their patients by practitioners or device manufacturers. ■

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EXAMINATION

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See answer sheet on page 207.

1) A stepwise approach to the application of off-loading devices to address the specific needs of the diabetic plantar wound is referred to as
   A) Pressure redistribution approach
   B) Classic off-loading approach
   C) Transitional offloading approach
   D) Selective off-loading approach

2) The greatest impediment to the application of a proper off-loading device is:
   A) Patient resistance
   B) Cost and insurance issues
   C) The depth of the wound
   D) The location of the wound

3) The most important off-loading concepts to apply to improve outcomes early in the treatment when the wound is open are:
   A) An inability to remove the device between visits and a fixed ankle design
   B) A multilayer cushion insole
   C) A dynamic molded contact orthosis
   D) Daily access to the wound

4) The concept of using a non-removable cast walker or instant total contact cast is attributed to:
   A) Peter Cavanaugh
   B) Paul Brand
   C) David Armstrong
   D) Larry Lavery

5) According to a study by Wu et al. what percent of clinicians regularly employ the total contact cast TCC as part of their off-loading regiment?
   A) 1.7%
   B) 5.9%
   C) 10.2%
   D) 22%

6) The most commonly used off-loading device is/are:
   A) A wedge surgical shoe
   B) The felted foam dressing
   C) Shoe modifications
   D) The removable cast walker

7) Which device has been shown to be statistically equivalent in terms of healing rates to the TCC?
   A) The Carville healing sandal
   B) The Removable cast walker
   C) The iTCC
   D) The football dressing

8) Rapid return to standard footwear accounts for a large portion of the recurrences noted in the literature associated with diabetic foot wounds. It is therefore important to maintain the patient in an off-loading shoe with a conforming or total contact molded insole to protect and mature the skin for how many weeks after the wound has finally closed?
   A) 1-2 weeks
   B) 3-4 weeks
   C) 6-8
   D) Once a callus begins to form at the healed site it is OK to return to regular footwear

9) The concept of the total contact molded innersole to aid in off-loading the diabetic foot was developed by:
   A) Paul Brand
   B) Joseph Kahn
   C) David Armstrong
   D) A & B are correct

10) The thing most pedorthic suppliers don't do when they provide shoes under the shoe bill is:
   A) Use a multilaminate innersole
   B) Choose the proper size shoe
   C) Mold the innersole to be truly total contact
   D) Make sure there is adequate room to allow for the innersole

11) Whenever you have a device with a fixed ankle it is essential that you add which of the following additional modifications to allow for a smooth normal gait and assure maximum off-loading of the forefoot?
   A) An insole with removable segments to unload areas of high pressure
   B) A total contact molded innersole
   C) A heel roller or SACH heel
   D) A rocker sole

12) At what point in the healing cycle do you transition to a shoe-based platform off-loading device such as a Carville healing sandal or commercial diabetic wound healing shoe?
   A) It should be your initial off-loading choice
   B) When the wound is shallow and has begun to epithelialize
   C) When the wound has closed but is not yet mature enough to take the stresses of normal walking
   D) 3-4 weeks after wound closure

13) Which of the following modifications should be part of the patient's final off-loading footwear?
   A) A total contact molded innersole
   B) A rigid rocker sole
   C) A high toe box with adequate internal room for a molded innersole
   D) All of the above

14) Patients with severe unstable Charcot arthropathy who can not have reconstructive surgery should be maintained and protected with:
   A) A Charcot Restraint Orthopedic Walker or CROW
   B) A depth shoe with a molded innersole, double upright brace attachment, patellar tendon bearing (PTB) shell and a rigid rocker sole
   C) A high top depth shoe with a semi rigid reinforced total contact innersole, roller heel, and rocker sole
   D) A&B are correct

Continued on page 206

Continuing Medical Education

EXAMINATION

(cont'd)

15) Using a removable cast walker is almost totally based on:
- A) The size and depth of the wound
- B) The presence of infection
- C) The need for advanced wound products
- D) Demonstrated patient compliance

16) In a recent Cochrane review which of the following offloading devices had randomized control trial evidence to support its use in healing diabetic foot ulcers?
- A) The TCC
- B) The iTCC
- C) The Felted Foam technique
- D) A&B

17) Devices with a fixed ankle and a rigid rocker are able to significantly reduce compressive and shear forces during which phase of gait?
- A) Heel strike
- B) Midstance
- C) Propulsion
- D) Double support

18) According to a study by Wu et al. what percentage of clinics utilize the removable cast walker RCW as their primary off-loading device?
- A) 5%
- B) 10%
- C) 15%
- D) 25%

19) A large proportion of the recurrences seen in diabetic foot wounds are due to:
- A) Inadequate off-loading choices
- B) Non-conforming poorly molded innersoles
- C) Lack of patient compliance
- D) All of the above

20) According to CMS which of the following are essential components necessary for an insole to be covered under the shoe bill?
- A) The insoles must be multidensity
- B) It must be molded directly to the foot or a model of the foot
- C) The length, width, and height of the device must match the uncompensated contour of the plantar surface of the foot
- D) All are essential components

See answer sheet on page 207.

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There is **no charge** for the mail-in service if you have already enrolled in the annual exam CPME program, and we receive this exam during your current enrollment period. If you are not enrolled, please send $20.00 per exam, or $139 to cover all 10 exams (thus saving $61* over the cost of 10 individual exam fees).

Facsimile Grading

To receive your CPME certificate, complete all information and fax 24 hours a day to 1-631-563-1907. Your CPME certificate will be dated and mailed within 48 hours. This service is available for $2.50 per exam if you are currently enrolled in the annual 10-exam CPME program (and this exam falls within your enrollment period), and can be charged to your Visa, MasterCard, or American Express.

If you are *not* enrolled in the annual 10-exam CPME program, the fee is $20 per exam.

Phone-In Grading

You may also complete your exam by using the toll-free service. Call 1-800-232-4422 from 10 a.m. to 5 p.m. EST, Monday through Friday. Your CPME certificate will be dated the same day you call and mailed within 48 hours. There is a $2.50 charge for this service if you are currently enrolled in the annual 10-exam CPME program (and this exam falls within your enrollment period), and this fee can be charged to your Visa, Mastercard, American Express, or Discover. If you are not currently enrolled, the fee is $20 per exam. When you call, please have ready:

1. Program number (Month and Year)
2. The answers to the test
3. Your social security number
4. Credit card information

In the event you require additional CPME information, please contact PMS, Inc., at **1-631-563-1604**.

ENROLLMENT FORM & ANSWER SHEET

Please print clearly...Certificate will be issued from information below.

Name _____ Soc. Sec. #_____
Please Print: FIRST MI LAST

Address_____

City_____State_____Zip_____

Charge to: _____Visa _____ MasterCard _____ American Express

Card #_____Exp. Date_____

Note: Credit card is the only method of payment. Checks are no longer accepted.

Signature_____Soc. Sec.#_____Daytime Phone_____

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 $20.00 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 $139.00 (thus saving me $61 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.

Over, please

ENROLLMENT FORM & ANSWER SHEET (cont'd)

EXAM #9/10
Transitional Off-Loading—Part 2
(McGuire)

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

LESSON EVALUATION

Please indicate the date you completed this exam

_____

How much time did it take you to complete the lesson?

_____ hours _____minutes

How well did this lesson achieve its educational objectives?

_____Very well _____Well

_____Somewhat _____Not at all

What overall grade would you assign this lesson?

A B C D

Degree_____

Additional comments and suggestions for future exams:

_____

_____

_____

_____

_____

_____