

Research Article**Amit Jain's Offloading System for Diabetic Foot Wounds: A Better and Superior Alternative to Felted Foam***Amit Kumar C Jain**

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Corresponding author: Dr Amit Kumar C Jain**ABSTRACT:**

Offloading is an essential treatment modality that is key in preventing and healing of ulcers in the foot of diabetes patients. Various different offloading modalities exist with each having their own advantage and disadvantage. What is essential in clinical practice is which one is the best that can be applied with ease and which can facilitate in ulcer healing. Felted foam is one of the common offloading modality used in the west by the clinical practitioner. It is however not available in many Asian and African countries. The author proposes a new offloading technique that can be considered an alternative to felted foam with superior characteristics which works on concept of deflective offloading and can be easily made and used all over the world.

Keywords: Offloading, felted foam, Amit Jain's technique,**INTRODUCTION**

Foot wounds are one of the most common complications seen in patients with diabetes [1, 2]. Foot ulceration in diabetes is an important precursor to amputation [3]. Peripheral neuropathy represents the most important risk factor for the first time foot ulceration, predisposing the foot to acute or chronic injury [4]. Mechanical trauma is a key factor for causing foot ulceration [5]. Foot ulcers in fact are caused by an imbalance between excessive pressure at the plantar aspect and cycles of repetitive stress resulting from daily ambulation [6]. Redistribution of the plantar pressure, which is commonly referred to as "offloading" has shown to result in faster healing of uncomplicated neuropathic foot ulcers [5]. Thus pressure offloading is central to achieve a good wound healing thereby minimizing the risk of amputation [4].

CURRENTLY AVAILABLE PRESSURE OFFLOADING DEVICES/METHODS

Offloading is now recommended as a primary therapy for prevention and management of ulcers [5]. The pressure offloading may be achieved by a variety of means [4]. The various available methods are bed rest, crutches, wheel chair. Walkers, half shoes, therapeutic shoes, healing sandals, total contact casts(TCC), removable case walkers, felted foam, samadhan system , etc [4, 6, 7]. Each of these devices has been used in different regions with an aim of achieving wound healing in diabetic foot wounds. However, the evidence of effectiveness of some of these offloading modalities is limited [5].

SHIFTING TOTAL CONTACT CASTING FROM GOLD STANDARD TO LAST RESORT

Total contact cast offloading has been considered for years by many to be a gold standard for ulcer offloading [5, 6, 8, 9]. TCC has been effective in offloading diabetic foot with

reduction in peak pressure at forefoot up to 87% [10]. TCC has been frequently reported as effective in treating plantar diabetic foot with healing ranging from 72% to 100% in times ranging from 1 month to several weeks [9]. TCC has been used in offloading diabetic foot ulcers since 1960 [8].

However, there are many problems with total contact cast. It is time consuming to apply, require expertise. It can cause skin ulcers, impacts patients lifestyle, is expensive and it cannot be used in infected wounds, causes postural instability [8, 9, 10]. Wu et al showed that only 2% used TCC in their practice [6]. Today there are various offloading methods that can be used especially for forefoot ulcers before using TCC. Hence instead of considering it as a gold standard, the author believes that it should be considered as a last resort, especially when the ulcer fails to heal with other offloading modalities.

ACCOMODATIVE PADDING

Various materials have been used to temporarily offload the wound in the foot [2]. These can be applied around the wound. The best known accommodative padding is felted foam[2]. They are also known as deflective padding whose aim is to deflect the pressure from the ulcer site [4]. Various other materials have also been used to offload the wound. They include foam mattress, roller gauge, sponges, hospital wastes like gloves, rolled handkerchiefs, etc.

Samadhan system is one such system that utilizes cylindrical mattress foam of density 40 and it is adhered to foot using elastocrepe bandaging [7, 11]. Subsequently, other materials were also used like roller gauge, waste gloves, rolled up pads, etc to offload the ulcer. Most of these were attempted to mimics the concept of deflective padding like felted foam.

FELTED FOAM

Felted foam padding are often been used in diabetic foot centre's for offloading wounds especially at forefoot [4]. The

technique involves adhering a felt or felted foam to the sole of the foot, with an aperture [U shaped or circular] cut into the material which corresponds to the location of ulcer [13]. The aperture was cut 5 mm larger than wound with all edges beveled [4]. Felted foam is found to be effective in offloading ulcer though was found to be lower than TCC. It however had advantages over TCC like allowing patient activity, could be used in infection, allowed frequent dressing change, etc [4].

One concerned with accommodative felt dressing was edge effect [2]. Although measures were not made on diabetic with wounds, one needs to be cautious of it [2]. Another issue with felted foam is that its pressure relief properties last only up to 3 days after which it is ineffective [14].

AMIT JAIN OFFLOADING SYSTEM/ TECHNIQUE

The author developed a new technique [one can also call it a device or a system] that could be considered a better alternative to felted foam for a variety of reasons. One is a bottoming of the felted foam. It also cannot be utilized in patients with friable skin or dermatological disorders [15]. Also, it is not available in many developing and underdeveloped countries where it needs to be imported from the west. Further, it is likely to be ineffective in obese patients where it can be completely be compressed by patients body weight

The author thus devised a new technique of offloading that addresses the above issues. It utilizes viscoelastic materials like EVA and Microcellular rubber in creating an offloading device. This offloading can be used in ulcers, postoperative wounds and also to protect the scars from breakdown at plantar area.

STEPS OF MAKING AMIT JAIN'S OFFLOADING SYSTEM

- 1] Cut a square/ rectangular piece of 3 mm microcellular rubber sheet of appropriate size required for offloading
- 2] Cut an equivalent size [Figure 1] of 4mm of ethyl vinyl acetate viscoelastic elastomer [EVA]. One can also use two pieces of 2mm.



Figure 1 showing the Ethyl vinyl acetate(brown) and microcellular rubber (black) cut in 2 small rectangular pieces of equal size.

- 3] Stick both of these pieces with rubber adhesive [Figure 2 and 3].



Figure 2 showing application of rubber adhesive to both EVA and Microcellular rubber piece.



Figure 3 showing joining of both these pieces

- 4] Apply 2 to 3 small pieces of adhesive elasto crepe adhesive bandage to EVA. This is to adhere to the skin of the plantar aspect of the foot. Elasto crepe bandage is frequently used in surgical patients and is easily available [Figure 4].



Figure 4 showing application of 2 small pieces of adhesive elasto crepe adhesive bandages to the EVA side of the offloading device. This is used to adhere this device to the skin or dressing. One can use more small pieces of bandage if needed. It is ready to be used.

- 5] Then place this device at the sole of the foot [Figure 5]



Figure 5 showing the application of Amit Jain's offloading device. One can apply over the dressing or before the dressing on the skin.

6] An aperture can be created to accommodate the ulcer just like the one uses in felted foam technique. Alternatively, those who don't want to create an aperture can place the device proximal to the ulcer in forefoot or distal in hindfoot ulcer.

7] Apply a large piece of elastocrepe adhesive bandage over it to secure it firmly [Figure 6].



Figure 6 showing the firm securing of the Amit Jain's offloading device with elasto crepe adhesive bandage.

8] One can do a small dressing over the wound then used this device or one can apply this device and then do the dressing based on surgeon's preference and status of the wound.

One can reuse this device by separating it from elasto crepe adhesive bandage [dynaplast] and applying a new dynaplast. Alternatively, it can be wrapped in roller gauge before applying the adhesive bandage. Later it is easy to separate from it and reuses it. The author doesn't advocate the reuse in exudating wounds.

WHERE EVIDENCE MEET EVIDENCE

The author devised this new offloading method based on previous evidences. Felted foam has well known evidence in reducing plantar pressure and healing ulcers. Deschamps et al [16] found in his study that peak pressure reduction occurred

by 50% in forefoot with felt. Felted foam gained clinical interest to offload as it can be easily customized to the morphology of an anatomical area. Immediate pressure reduction with this tiny dressing has been between 30 to 60% [16]. Various size of felted foam has been used in literature ranging from 5 mm to 10 mm thickness [4, 13]. Curran et al [13] found in their study that 7 mm felt padding produces greater reduction in pressure than 5mm felt padding. They also found that peak pressure decreased even at the edge of the cutout. Another study [17] also supported that apertures can be very effective for decreasing localized pressure under metatarsal head.

Viscoelastic materials came into widespread use as insoles in footwear because of their pressure reduction properties [18, 19]. The commonly used viscoelastic materials are microcellular rubber, plastazotes, ethyl vinyl acetate, poron, silicon rubber, etc [17, 18, 19, 20, 21].

Microcellular rubber (MCR) of shore hardness of around 15⁰ shores A is known to prevent high pressure points and known to avoid plantar ulcers in anesthetic feet [20]. The cushioning property of MCR reduces force which in turn reduces pressure over the plantar surface [21]. MCR stretches in all directions and has a ability to spring back to its original shape when pressure is released while walking [20, 22]. MCR is a specially processed rubber material with 15 chemicals where air bubbles are introduced into the rubber creating millions of microcells containing air, resembling fat filled cells of sole of the foot [23]. The MCR withstands friction while walking and still maintain its thickness, elastic recoiling and it will not tear easily [23]. 3mm and 10 mm MCR are available in various South East Asian countries.

Various different viscoelastic materials have different properties. But from clinical point of view, these materials have a ability to redistribute the force beneath foot, thereby reducing pressure in the area of the foot [19]. Viscoelastic materials like polyurethane, EVA, polyethylene, etc have good shock absorbing properties. They are soft and light. But there is a tendency to bottom at moderate loads unless a considerable thickness is used, but more thickness is seldom practical [24]. These however bottom out over months of usage unlike felt which bottom out within 3 days.

RATIONALE FOR USING AMIT JAIN'S OFFLOADING DEVICE/SYSTEM

With knowing the concept of deflective padding, the advantages and disadvantages of felted foam is well known. Since 7mm felted foam [13] is good enough to reduce greater pressure reduction compared to 5mm, the author combined a 3 mm microcellular rubber along with 4 mm of EVA which is commonly available all over the world. In a study by Hissink et al, 8mm thick felted foam was used and they found that 91% of their ulcers healed in a mean time of 34 days [25]. EVA is available in 2mm, 5 mm and 10 mm thickness and is better used as insoles in shoes of Shore 15⁰ on an average [ranging from 12 to 20⁰ shore]. One can also combine 3mm MCR and 5mm EVA to produce 8 mm thick Amit Jain's offloading device.

Combining 3 mm MCR and 4mm EVA produces 7 mm thickness that can be used to replicate 7mm Felted foam [Figure 7 and 8].



Figure 7 showing how felted foam is normally used



Figure 8 showing the Amit Jain's offloading device in similar way like felted foam. Here both MCR and EVA are black in colour.

EVA, which is the first layer, provides a smooth, light weighted, soft, effective cushioning and shock absorption properties. It however can completely get compressed in 2mm or 5mm thickness when used alone in patients with overweight. Further there is delay in complete reformation recovery after compression is reversed. So if patient stands for prolong period and sufficient period or if patient is overweight, there can be chances of EVA or other materials like polyurethane and polyethylene in losing its purpose. This is an undesirable property referred to as "compression set" [19]. In such scenario, the second layer of 3 mm MCR comes to its rescue. High pressure or prolonged pressure can produce a greater indent in 2mm or 5mm thick EVA or other materials which is to be avoided in presence of ulcer/ wounds. The underneath 3 mm MCR undergoes minimal distortion, stretches effectively in all direction and resumes to its shape immediately [22], withstanding the friction and maintaining its thickness without allowing the ulcer to touch the ground or the underneath hard surface.

Thus this new Amit Jain's offloading system or technique, which is a combination of viscoelastic material is lightweighted, can be shaped in rectangular or square shape with or without aperture in similar concept of felted foam. It is durable with shock attenuation capabilities and has good physical and mechanical properties with well defined and controllable thickness with measurable hardness. This thus forms an excellent material for offloading with deflective

padding concept.

The Amit Jain's offloading system/ device is capable of distributing inevitable forces and provides an excellent pressure relieving device for ulcer healing. This offloading technique is safe, physiological, scientifically characterized with optimized composition and excellent pressure mitigation capability.

DISPLACING THE EXISTING MATERIALS

With the above known characteristic of Amit Jain's offloading system that is scientifically rationale, the currently used materials like rolled up pads, roller guage, hospital wastes like gloves, foam mattress, rubber tyres, etc used by different people for offloading shall be henceforth displaced. Although these materials were used with an aim of offloading diabetic foot ulcers at an economic and rural set up where earlier good materials were not available for offloading, the current era requires scientifically characterized and acceptable material with a rationale use of the concept (deflective padding) and the viscoelastic materials are now easily available.

VARIATIONS OF AMIT JAIN'S OFFLOADING DEVICE / TECHNIQUES

The author currently used Micro cellular rubber and Ethyl vinyl acetate as they are easily available and affordable in many countries and they come in different color.



Figure 9 showing the combination of polyurethane with microcellular rubber.

"Any other viscoelastic/ elastic materials like polyurethane, polyethylene, etc used in isolation or in combination [Figure 9] in thickness of acceptable range like felted foams should be considered to be a variation of Amit Jain's offloading system/ technique [AMIT JAIN'S LAW]". These would serve to be a better alternative to felted foam in offloading diabetic foot wounds.

ADVANTAGES OF AMIT JAIN OFFLOADING SYSTEM

- 1] Simple
- 2] Easy to prepare and applied
- 3] cost effective world wide
- 4] Can be accommodated in therapeutic foot wear [Figure 10]



Figure 10 showing the easy accommodation of the Amit Jain's offloading device along with dressing in the footwear.

- 5] Compliance can be considered to be partially forced as patient cannot remove it till he removes the dressing
- 6] It can be used in infected wounds or highly exudating wounds
- 7] Patient is mobile and can also do day to day activity [but should be restricted]
- 8] Most importantly this offloading system has defined properties and characteristics unlike any other materials
- 9] Based on concept of deflective padding like felted foam, this offloading system is scientifically rationale
- 10] It can be used in non diabetic foot wounds or for protecting sutures/ scars.

CONCLUSION

Felted foam is most commonly used offloading method in clinical practice in some of the western countries with proven scientific evidence. It however bottoms out and loses its property within 3 days/ much earlier. It also doesn't have elastic properties, shock attenuation capabilities and gives way to higher pressure especially in overweight/obese patients. Other materials that are used to offload like roller guage, foam mattress, hospital waste like gloves etc have no defined properties. They have no defined thickness, compressing properties or measurable hardness with elastic recoiling. They are scientifically unacceptable material in today's era of evidence based practice and indeed a few of this material could serve as a foreign body in the foot.

Amit Jain's offloading device/ system is a new offloading technique that uses scientifically acceptable material with defined properties and that utilizes the concept of deflective padding which is also a known scientifically proven method of offloading where felted foam is used. The Amit Jain's law clearly states that "Any viscoelastic/ elastic materials like polyurethane, polyethylene, EVA, etc used in isolation or in combination in thickness of acceptable range like felted foams should be considered to be a variation of Amit Jain's offloading system/ technique". This offloading system can be considered to be a better and a superior alternative to felted foam.

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