Introduction

Diabetes mellitus (DM) is a disease that accounts for big debates and efforts by all the involved parties in this clinical process. Among the chronic complications associated with DM we find the ulcers of the lower extremities, with special emphasis those located in the foot, which 15% of patients suffer at some point in the course of their disease. These ulcers can be classified into venous, arterial and neuropathic, according to their etiology; though frequently ulcers are caused by several etiologic factors at the same time can be found. Neuropathy affects sensor motor fibers of the peripheral nervous system, as much as autonomic nervous system fibers. Its prevalence increases with poorly controlled glucose and the diabetes evolution time, affecting up to 50% of the patients with more than 25 years of evolution. With peripheral neuropathy, patients present a progressive decrease in pain sensation, temperature and vibration, and deep and superficial sensitivity.

All these alterations cause a loss of tone to the sole of the foot skin and worsen the foot response to mechanical stress, causing high plantar pressure and ulcer development. Although many studies have proposed a pressure threshold for the development of foot ulceration, as Armstrong et al. pressures higher than 99 N/cm² would cause delay in healing, however, this statement remains controvertial.

Therefore, an insensitive foot, whether ischemic or not, should be considered at high risk of suffering ulcer. The use of pressure relief as etiologic treatment, if properly applied, has shown to produce modifications on the ulcer histology, changing from a chronic inflammatory state to a much more evolutionary condition. This pressure reduction has the basic principle of distribution or transmission of the load over wider areas, so it reduces pressure peaks in certain points. The pressure reduction depends on three factors: 1) the use of an option of spe-
specific treatment for pressure reduction, 2) patient compliance and 3) biomechanics.  

General features of strategies for pressure discharge

The general concept that any used device must meet is that it will have to vary a factor, either numerator or denominator, of the mathematical expression of the pressure. The pressure is expressed as a ratio where the numerator is the force (Newton) and the denominator is the unit of area (cm²); and if the result of the ratio is expected to tend to zero, the force applied should decrease, or increase the support area so that there is a redistribution of pressure. But not only have these two factors influenced on the foot load. There are others, such as the duration and the direction of the forces, which will influence the onset of overload and the risk of appearance of an ulcer. With all that, Guzman, et al. described a series of ideal features, that strategies for pressure reduction should have (table 1).

Alternatives for pressure discharge

There are multiple different strategies for the plantar pressure reduction, many of which are not exclusive of one another, but should be applied in a protocol manner as to achieve favorable results in ulcers cicatrization (figure 1).

Among these strategies we find:
- Laminar cut of keratopathies.
- Silicone orthoses.
- Temporary offloads.
- Custom plantar orthosis.
- Temporary post-operative shoe.
- Total Contact Cast (TCC).
- Removable cast walkers (RCWs).
- Preventive surgery.

Laminar cut of keratopathies

Keratopathies formation is due to a compensation attempt by the skin to counteract the excess of local pressure. A keratinocytes proliferation rate increase produces a decrease of its absorption capacity, which, together with the presence of a rigid or flexible digital deformity, precedes 82.4% of foot ulcers in patients with DM. A patient presenting sensory neuropathy and keratopathy has an 11 times higher risk of developing lesions than a patient without keratopathy, increasing up to 56.8 times if the patient has already suffered a previous lesion to the same location. All these data lead to the development of prevention strategies that will be directed towards the screening and appropriate management of keratopathies.

It is difficult to observe the inflammatory changes that appear on the surrounding areas of the keratopathy. In a study by Nishide et al. on the use of thermography and ultrasonography as screening methods for chronic inflammation of the keratopathies, inflammation was localized by thermography, and subsequently the severity and tissue damage by ultrasound. These authors were able to detect chronic inflammation in 10% of the keratopathies of the group of patients with DM, while in the non-diabetic group they did not find any case. Therefore, using these techniques on high-risk patients can be effective as a screening method for the appearance of foot ulcers.

Regarding the proper keratopathies management, laminar cutting is a simple but effective treatment for pressure reduction. According to the study by Slater et al. in 14 patients with DM, the pressure was reduced by 29% of the initially registered. When this treatment was combined with the use of digital silicone orthoses, the reduction increased to 54%. Therefore it is important for the DM patient to go regularly to the podiatrist for control.

Silicone orthosis

Since the 1950’s, Europe began to use different techniques to compensate, correct or mitigate the digital alterations present on the feet. Silicone is a dual-component polymer belonging to the group of elastomers and is mainly made of silicon. Silicone has features which are particularly suitable for the manufacture of orthoses, including: 1) its temperature resistance (from –80º C to

Table 1. Strategies for pressure reduction on a diabetic foot

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
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<tbody>
<tr>
<td>Provide an effective pressure reduction of the ulcer continuously</td>
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<tr>
<td>Applicable to different types of patients</td>
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<tr>
<td>Do not cause side effects, or if so, that are lesser than the beneficial effect sought</td>
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<td>Easy application</td>
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<tr>
<td>Appropriate cost-effectiveness</td>
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<tr>
<td>Allow for the use of other complementary treatments</td>
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<td>To facilitate patient treatment compliance</td>
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Figure 1. Different alternatives of discharge for treating diabetic foot ulcers
250°C), so it can be sterilized; 2) it is inert, so allergic reactions are almost nonexistent; 3) it is hydrophobic; 4) it is nonstick, and finally, 5) it is fungal and microorganisms resistant.12

Slater et al.11 states that the use of silicone digital orthoses significantly reduces the pressure to such level in DM patients, whether presenting peripheral neuropathy or not. Another study by Sciré et al.9 shows that the use of these treatments presents good tolerance and safety, and the percentage of treatment compliance by patients is quite high. Consequently, this study concludes that the use of silicone digital orthoses can be considered as an effective and safe solution for patients at high risk of ulcers, since it allows a redistribution of the maximum in the forefoot area.

Temporary discharges
The application of these discharges is a promising method for the temporary reduction of plantar pressures in the ulcer area, but there are hardly any studies demonstrating its results. To carry out this treatment, different or a combination of materials may be used, but if we had to highlight one of them for its easy handling, cost and good results, adhesive felt would be the one. This felt comprises polyester and polyethylene, and has a hypoallergenic adhesive layer. It is commercially available in different thicknesses, from 1 to 10 mm. Applying the felt around the ulcer with a design adapted to the size, location and the patient’s biomechanics, performs the offload.

This point is the most important in the discharge execution, because a pattern error may produce treatment failure or worsening of the ulcer. To avoid this, a biomechanical study of plantar pressures prior to the start treatment must be performed, in order to customize the design (figure 2). It would also be advisable to make another measurement of pressures once the offload felt is placed, to check two factors: 1) that there is a selective offload of the ulcer area, and 2) that there is not an overload in another area of the same foot or the collateral, with the consequent risk of a new injury.

In a study by Armstrong et al.13 where they assessed offloads in non-diabetic patients without ulcers, it was found that while there was a pressure reduction on the opening area of the felt, it also appeared an overload and increased shear forces on the periphery, which they called “edge effect”. To minimize this effect, we have to execute offloads that are in contact with the largest possible area of the sole and set it afterwards.5

Another factor that must be considered is the material physical characteristics, since it has very little memory and low yield strength, so it is recommended the change after 3-4 days of treatment.14 Our experience at the Instituto Valenciano del Pie is that the change of material should not be extended more than 48 hours to maintain a continuous offload of the ulcer. This setback could be solved by the combined use of materials such as felt and polyethylene foam, both of 0.6 cm thick, as described by Fleischli et al.15, who managed to reduce pressures by 34 and 48% in the forefoot and first toe, respectively. In a more recent study by Zimny et al.16 these authors obtained a reduction of approximately 10 days in ulcer healing on neuropathic feet through the use of felt. Finally, note that the adhesive material may cause some allergic reaction and the appearance of lesion adjacent excoriations during the change.

Customized plantar orthosis
In this case the offload is customized on to the plantar orthosis, and it allows us to improve the support and make a redistribution of pressures. If until now the design of plantar orthoses for downloading the areas at risk of the diabetic foot has been a craftwork and little scientific, nowadays measurements of pressure inside the shoe are more spread, and so the substantial difference be-

**Figure 2.** Study of plantar pressures by Novel Pedar X® system (Novel GmbH, Munich, Germany), which is made to patients as to evaluate the effectiveness of felt discharge.
tween using and not using a custom plantar orthosis can be observed. In a study of polyurethane plantar orthoses by Kato et al., the authors obtained some measurements of increase of the contact area by 62.7% and pressure reductions of 56.3%. Also Frykberg et al. designed a closed-cell thermoplastic copolymer plantar orthoses with an anterior wedge, which when properly placed back of the metatarsal heads, performed a forefoot pressure download of 48% when used together with a postoperative shoe.

**Temporary post-operative shoe**

The ideal post-operative shoe should protect the foot during recovery from surgery or a lesion. Not only it may be prescribed to accommodate sizeable dressings, but also to obtain plantar pressure downloads by the elimination of part of the gait propulsion phase. There are different variants of flat post-operative shoes in the market: with anterior discharge, posterior discharge, with a rocker outsole, etc. Depending on where the sole modification is presented, we will obtain the sought offload, so that if a forefoot injury appears, we will place an anterior offload shoe, etc. A remarkable point is the patient’s stability and balance assessment before and after the placement of these devices, since often they must be accompanied by the use of other devices such as crutches, walkers, etc. to ensure adequate stability.

In the study by Fleischli et al., anterior download shoes (where the heel area is increased to decrease forefoot forces) have always been the third most effective treatment method, after the TCC (TCC) and the DH pressure relief walker, reducing pressure up to 66% while being cost-effective.

**Total contact cast**

Dr. Paul Brand often used the total contact cast or TCC in the mid 1970’s to offload insensitive foot of Hansen’s disease. For many years this procedure was considered by many experts as the reference treatment for neuropathic ulcer offload in patients with DM. The use of TCC for the diabetic foot ulcers healing has been well documented in literature and has proven to be extremely effective, getting to reduce the forefoot maximum pressure by 87%. This effect can be achieved, among other mechanisms, by limiting ankle motion and redistributing the load along the device, in addition to the guaranteed compliance with treatment because it the patient cannot remove it.

Despite its advantages, TCC has not been widely used because its implementation requires training and must be changed every 7-10 days. The technique consists of applying of a reinforced plaster dressing with fiberglass dressing on the foot-ankle-leg complex, producing its immobilization. If not properly applied, it can cause unwanted effects such as abrasions, burns or iatrogenic ulcers. In addition, joint stiffness may occur, or even ankylosis if the immobilization is prolonged and a deficient night’s sleep for the patient.

Regarding its use on heel ulcers, these are often more problematic due to the difficulty of reducing pressure on the posterior part of the foot. In a study by Armstrong et al., TCC reduced the maximum plantar pressure better the other methods tested (pneumatic Aircast Walker and DH pressure relief walker); however, time of integral pressure on the heel during walk was significantly lower for the DH pressure relief walker than for the TCC or any other method tested.

**Removable cast walkers (RCWs)**

The prefabricated gait splints, generally called removable cast walkers (RCWs) are an alternative to TCC and they maintain the ankle joint in a 90° position, limiting the digital propulsion during gait and reducing pressure on the foot sole. Initially, this product was designed for fracture treatment and has been subsequently used to reduce pressure on plantar ulcers. Currently there are multiple models in the market that differ from one another in small alternatives, such as the use of different types of rocker in the sole, made modular foot orthosis consisting of layers of different rigidity that adapts to the actual location of the ulcer, pneumatic chambers with vacuum gauges to control compression, etc. These devices are easily applied and allow wound inspection and can be used to treat superficial infection ulcers. In addition, as a reusable treatment, the total cost decreases. It also allows patients to perform good personal hygiene and a more comforting rest.

However these same advantages of the RCWs (easy application, reutilization and patient satisfaction) are also, paradoxically, its greatest inconvenience. The possibility of removing the device eliminates the feature of “forced compliance”, which is the best attribute of TCC. Thus, in a study by Armstrong et al. proposed using RCWs and applying a layer of fiberglass so that the patient could not remove the device, calling it “instant TCC” (i-TCC). In another study by Piaggesi et al. they used a RCW that has a plastic cord that can only be removed by a specific cutting tool, making it non-removable by the patient. These studies confirm the efficacy and safety of RCWs and their ability to manage diabetic foot ulcers at the same level as the TCC, while solving the lack of treatment compliance by patients.

**Preventive surgery**

Any treatment plan that we use in these patients is intended to reduce the areas of increased pressure. The arsenal of orthopedic variants described can achieve this. But if these therapies do not obtain a good result, the second alternative may be the preventive surgery. This surgery aims to correct structural deformities and limit joint mobility that are associated with increased plantar pressures and increased risk of foot ulcers. Several prospective controlled studies have shown that surgical procedures such as Achilles tendon lengthening, metatarsophalangeal joint arthroplasty and metatarsal head resection may have some value in healing in DM patients with forefoot area ulcers.
Armstrong et al. concluded that percutaneous lengthening of Achilles tendon in DM patients significantly reduced about by 27% the plantar pressure in the forefoot area. Also Mueller et al., in 2003, compared two groups of DM patients, one treated by TCC plus an Achilles tendon lengthening, and the other treated with a TCC splint. The first group patients healed in 100% of the cases, with a 75% reduction of recurrences at 7 months and a 52% less at 2 years compared to the second group.

However, surgery in these DM patients should be taken with caution as a foot, whether is well perfused or ischemic, must be regarded as at high risk for ulcer. According to Steven Kravitz, Executive Director of the American Professional Wound Care Association, “the decision to perform surgery as a preventive measure should only be taken after a thorough evaluation and a precise diagnosis based in the patient’s medical records, current status, the physical assessment of the risk zone, the analytical and image tests”. Although the surgical procedure can be effective for the ulcer healing, more prospective and controlled studies are needed to define better the role of surgery compared with conservative treatment before its widespread use can be recommended.  

Conclusions
Retrospective and prospective studies have shown that high plantar pressure is a causal factor in the development of plantar ulcers in DM patients, and ulceration is often a precursor to lower extremity amputation. However, there is a gap between evidence-based guidelines and regular practice, as only 41% of ulcers in the U.S. and 34% in Europe were treated using an offload device. The international work group on diabetic foot has developed specific guidelines based on evidence about the use of shoes and offloads for the prevention and healing of diabetic foot ulcers.

The recommendations for the use of discharge in treating of uncomplicated neuropathic plantar ulcers are:
1. Relieve pressure on the ulcers should always be part of the treatment plan.
2. The TCC and non-removable RCW are the interventions of choice, although the clinician should take into account possible adverse effects of these devices.
3. Anterior offload shoes may be used when above the ankle devices are contraindicated or are not tolerated by the patient.
4. Standard shoes should not be used, as other devices are more effective.

We must not forget that the treatment does not end with the ulcer closure, and offloads should be subsequently applied for definitive treatments and of a preventive nature, such as the plantar orthosis and custom shoes.

Declaration of potential conflicts of interest
The authors of this article state that there are no conflicts of interest as regards to this article.

References


