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TESI DI LAUREA

DISTAL METATARSAL OSTEOTOMIES (DMOS) FOR DIABETIC FOOT

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RIASSUNTO

Presupposti dello studio. Si stima che nel 2021 il 10,5% della popolazione mondiale adulta fra i 20 e i 79 anni soffra di diabete di tipo 1 o tipo 2 e che la sua prevalenza sia destinate a crescere di oltre il 45% nei prossimi venticique anni. Fra questi, circa il 15% sviluppa, nel corso della vita, complicanze agli arti inferiori e in particolare al piede, fino allo sviluppo di ulcere plantari, la cui patogenesi è strettamente correlata a neuropatia periferica, alterazioni microvascolari e alterata pressione plantare, tipiche dei pazienti diabetici. Si stima, infatti, che circa la metà dei ricoveri effettuati a causa delle complicanze del diabete sia legato al piede diabetic e che l'ulcera plantare cronica sia la prima causa di amputazione non traumatica degli arti inferiori. La terapia standard per l'ulcera plantare è conservativa, tuttavia, quando questa fallisce, si può facilmente arrivare all'amputazione. In questo contesto l'osteotomia distale miniinvasiva dei metatarsi (DMMO) si propone come alternativa terapeutica in caso di fallimento dei trattamenti conservativi, al fine di ristabilire una più equilibrata pressione plantare favorendo la guarigione dell'ulcera e evitandone la recidiva o impedendo la progressione di lesioni preulcerative.

Scopo dello studio. Il presente studio prospettico si prefigge principalmente di analizzare i risultati clinico-funzionali, radiografici, chirurgici ed il grado di soddisfazione soggettivo a medio-lungo termine dei pazienti con diagnosi di metatarsalgia su base biomeccanica associato o meno ad alluce valgo trattati presso la Clinica Ortopedica e Traumatologica di Padova mediante tecnica mini-invasiva (MIS). Mentre, lo scopo secondario è quello di valutare la reale efficacia di questa chirurgia percutanea, confrontando i risultati ottenuti con quelli presente in letteratura.

Materiali e metodi Sono stati presi in considerazione i pazienti operati tra il Gennaio 2010 e Dicembre 2019 inserendoli progressivamente secondo precisi criteri d'inclusione ed esclusione. Sono anche stati raccolti i dati relativi alle loro caratteristiche (genere, età, lato dominante, comorbilità, classe anestesiologica ASA, abitudine al fumo), al tipo di lesione preulcerativa/ulcerativa (lato affetto,

dimensioni, presenza/assenza di ischemia e/o infezioni, classificazione UTDWCS, tempi di guarigione) ed al trattamento eseguito (numero di metatarsali incisi, complicanze presente). Radiograficamente, tutti i pazienti sono stati osservati prima e dopo l'intervento chirurgico per valutare i tempi di guarigione delle osteotomie e il possibile ripristino della formula di Maestro. I risultati a medio-lungo termine sono stati valutati con le seguenti scale: EFAS, 17-FFI, MOXFQ, SF-36 e la VAS per soddisfaczione.

Risultati Nel periodo considerato, sono stati eseguiti 62 interventi chirurgici su un totale di 60 pazienti: 32 (53,3%) maschi e 28 (47,7%) femmine di cui 2 operati bilateralmente. Entrambi i lati sono stati ugualmente interessati e non c'è correlazione con la lateralità dominante del soggetto. L'età media al momento dell'intervento era di 66,10±9,42 anni (range 40-80 anni) con un BMI medio pari a 27,87±4,01kg/m2 (il 33,3% della popolazione aveva un BMI > 30 kg/m2) ed un'abitudine al fumo in 19 (31,67%) pazienti. L'ulcera plantare era presente in 22 (35,48%) dei piedi operati, delle quali 4 di grado II e le restanti 18 di grado III. Nei restanti 40 (64,52%) piedi operati era presente una lesione preulcerativa. Il follow-up medio è stato di 48,73±11,62 mesi con range da 29 a 76 mesi. Il tempo medio di guarigione era pari a 8,46±4,19 settimane (range, 4-17), è stata inoltre evidenziata una relazione diretta fra il tempo di guarigione e il diametro dell'ulcera. Sono state registrate 37 (60%) complicanze in 36 pazienti ma di queste solo in 1 (2,7%) caso si è verificata una complicanza maggiore. I valori ottenuti dall'analisi delle diverse scale hanno dato risultati clinici statisticamente significativi con le seguenti differenze tra i score medi pre-operatorio e all'ultimo follow-up: □ score EFAS pre-operatorio e post-operatorio pari a 7,56 punti (p<0,0001); □ fra la 17-FFI post-operatorio e pre-operatorio è uguale a 24,38±17,91 punti (p<0.0001); □ fra lo score MOXFQ-Pain post e pre-operatori è uguale a 31,42±20,34 punti (p<0.0001); □ fra lo score MOXFQ-Walking post e pre-operatori ha dato un valore di 32,67±16,75 punti (p<0.0001) e in fine la □ fra lo score MOXFQ-Social post e pre-operatori è uguale a 6,42±8,87 punti (p<0.0001). La scala VAS di soddisfazione soggettiva a dato una media pari a 9,03±1,22. I criteri di Maestro mostrano come la formula

metatarsale sia mediamente variata all'ultimo follow-up, tuttavia questa variazione è solo leggermente significativa e non correla ad un migliore outcome del paziente.

Conclusione I risultati dell'approccio percutanea DMMO al trattamento delle lesioni ulcerative o preulcerative nel paziente diabetico, associato o meno ad alluce valgo sono promettenti. Il basso tasso di complicanze e la non evidenza di possibili fattori influenti sull'efficacia della DMMO, conferma l'indicazione della tecnica a tutti pazienti con questo quadro clinico.

ABSTRACT

Background. It is estimated that in 2021, 10.5% of the adult population aged between 20 and 79 years worldwide will suffer from type 1 or type 2 diabetes and that its prevalence is set to increase by more than 45 % over the next twenty-five years. Among them, about 15% develop, during their lives, complications in the lower limbs and in particular in the foot, up to the development of plantar ulcers, the pathogenesis of which is closely related to peripheral neuropathy, microvascular alterations and altered plantar pressure, typical of diabetic patients. In fact, it is estimated that about half of all hospitalisations due to the complications of diabetes are related to the diabetic foot and that chronic plantar ulcer is the leading cause of non-traumatic lower limb amputation. The standard therapy for plantar ulcers is conservative, however, when this fails, it can easily lead to amputation. In this context, minimally invasive distal osteotomy of the metatarsals (DMO) is proposed as a therapeutic alternative in case of failure of conservative treatments, in order to re-establish a more balanced plantar pressure by promoting ulcer healing and preventing ulcer recurrence or preventing the progression of pre-ulcerative lesions.

Purpose of the study. This prospective study aims mainly to analyse the clinical and functional, radiological, surgical results and degree of subjective satisfaction in the medium to long-term of patients diagnosed with metatarsalgia biomechanics in association or not with hallux valgus treated at the orthopaedic clinic and trauma Padua using minimally invasive technique (MIS). While, the secondary purpose is

to evaluate the effectiveness of this percutaneous surgery, comparing the results obtained with those available in the literature.

Materials and methods. They were taken into account patients operated on between January 2014 and December 2019 by inserting them progressively according to specific inclusion and exclusion criteria. data on their characteristics were also collected (gender, age, dominant hand, comorbidity, anesthetic ASA class, smoking), the type of preulcerative/ulcerative lesion (affected side, size, presence/absence of ischemia and/or infection, UTDWCS classification, time to heal) and to treatment performed (number of engraved metatarsals, complications present). Radiographically, all the patients were observed before and after surgery to assess the time to healing of the osteotomies and the possible recovery of the metatarsal formula. The average to long-term results were evaluated with the following scales: EFAS, 17-FFI, MOXFQ, SF-36 and VAS for satisfaction.

Results During the period, they were performed 62 surgeries on a total of 60 patients: 32 (53,3%) males and 28 (47,7%) females of which 2 bilaterally. Both sides were equally affected and no correlation with the laterality of the subject was reported. The average age was 66,10±9,42 years (40-80 years) range with an average BMI of 27,87±4,01 kg / m2 (33,3% of the population had a BMI> 30 kg / m2) and habit of smoking was reported in 19 (31,67%) patients. Plantar ulcer was present in 22 (35,48%) of the operated feet, among these ulcers, 4 were grade II and 18 grade III. In the remain 40 (64,52%) feet preulcerative lesions were observed. The mean follow-up was 48,73±11,62 months with a range from 29 to 76 months. The average healing time was equal to 8,46±4,19 (range, 4-17) weeks; correlation between healing time and diameter of ulcers was notified. 37 (60%) complications were recorded in 36 patients but in only 1 (2,7%) case it was a major complication. The values obtained from the analysis of different scales gave statistically significant clinical results with the following differences between the pre-operative average score and the last follow-up: score pre-operative EFAS and post-operative totaled 7,57±4,22 points (p <0.0001); between the 17-FFI post-operative and pre-operative it is equal to 24,38±17,91 points (p <0.0001); between the score MOXFQ-Pain post and pre-operative is equal to 31,42±20,34 points (p <0.0001); between the score MOXFQ Walking post-and pre-operative gave a value of 32,67±16,75 points (p <0.0001) and in the end the between the score MOXFQ Social post-and pre-operative is equal to 6,42±8,87 points (p <0.0001). The VAS scale of subjective satisfaction to give an average of 9,03±1,22. The Maestro criteria show that the metatarsal formula is changed at the last follow-up, however, this difference is only slightly significant and is not related to a better outcome of the patient.

Conclusion. The results of percutaneous DMMO surgery in the treatment of preulcerative/ulcerative lesions in diabetic patients in association or not with hallux valgus are promising. The low complication rate and no evidence of possible influential factors on the effectiveness DMMO, confirms the indication of the technique to all patients with this clinical picture.

INTRODUCTION

Diabetes

According to International Diabetes Federation (IDF), diabetes mellitus, more simply called diabetes, is a serious, long-term (or "chronic") condition that occurs when raised levels of blood glucose occur because the body cannot produce any or enough of the hormone insulin or cannot effectively use the insulin it produces [1].

Type 1 diabetes is caused by an autoimmune process in which the body's immune system attacks the insulin-producing beta-cells of the pancreas. As a result, the body produces very little or no insulin. The causes of this destructive process are not fully understood but a likely explanation is that the combination of genetic susceptibility (conferred by a large number of genes) and an environmental trigger such as a viral infection, initiate the autoimmune reaction. The condition can develop at any age, although type 1 diabetes occurs most frequently in children and young adults. Type 1 diabetes is one of the most common chronic diseases in childhood.

The typical symptoms of type 1 diabetes include excessive thirst (polydipsia), frequent urination (polyuria), lack of energy or fatigue, constant hunger, weight loss, blurred vision and diabetic ketoacidosis (DKA) [1]. However, the classic clinical picture of polydipsia, polyuria and weight loss may not be present and the diagnosis delayed or even missed entirely until the first hospital admission for DKA, sometimes with fatal results [1].

Type 2 diabetes is the most common type of diabetes, accounting for over 90% of all diabetes worldwide. In type 2 diabetes, hyperglycaemia is the result, initially, of the inability of the body's cells to respond fully to insulin, a condition termed insulin resistance. With the onset of insulin resistance, the hormone is less effective and, in due course, prompts an increase in insulin production. Over time, inadequate production of insulin can develop as a result of failure of the pancreatic beta cells to keep up with demand.

Type 2 diabetes may have symptoms similar to those of type 1 diabetes but, in general, symptoms are much less dramatic, and the condition may be completely symptomless. Also, the exact time of the onset of type 2 diabetes is usually impossible to determine. As a result, there is often a long pre-diagnostic period and as many as one-third to one-half of people with type 2 diabetes in the population may be undiagnosed. If the diagnosis is delayed for a prolonged time, complications such as visual impairment, poorly-healing lower-limb ulcers, heart disease or stroke may lead to the diagnosis [2].

Type 2 diabetes is also seen in older children and is increasing in some countries as childhood overweight and obesity become more common.

Epidemiology [1]

In the 10th edition of the IDF Diabetes Atlas [1], the prevalence of diabetes is estimated for the year 2021 and projected to the years 2030 and 2045. The diabetes estimates are for adults aged 20–79 years, and include both type 1 and type 2 diabetes, as well as diagnosed and undiagnosed diabetes. An estimated 537 million adults aged 20–79 years worldwide (10.5% of all adults in this age group) have diabetes. Projections made to 2046 shows how diabetic populations could increase by 46% reaching 642,7 million of people in 2030 and 783,2 million of people in 2045 (Figure 1).

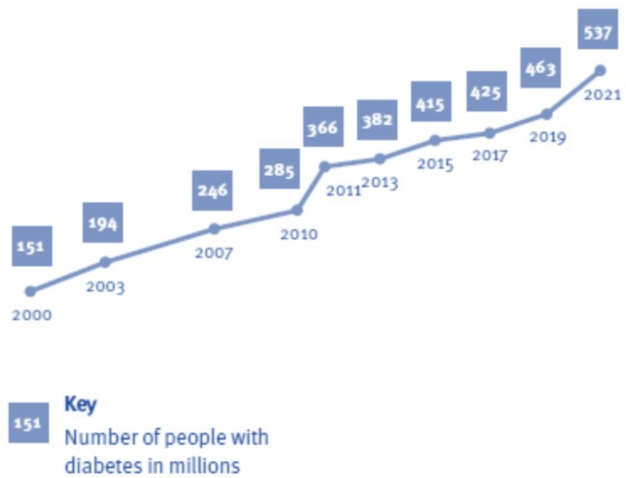

Figure 1: Estimates of the global prevalence of diabetes in the 20-79 years age group (millions) [1]

In Europe the diabetes prevalence is about 9.2% and the estimated number of people with diabetes is 61 million; the projections made by IDF preview a 13% increase of these data by 2045.

Prevalence of diabetes rises by the age: among adults aged 75–79 years diabetes prevalence is in fact estimated to be 24.0% in 2021 and predicted to rise to 24.7% in 2045. The aging of the world's population will produce an increasing proportion of those with diabetes being over the age of 60 years. The estimated prevalence of diabetes in women aged 20–79 years is slightly lower than in men.

The previously data report an increasing trend in prevalence of diabetes, however, this increment does not always mean that the risk of developing diabetes is rising. Prevalence can increase simply because people with diabetes receive better medical care and live longer. Therefore, it is also important to look at incidence: the rate at which new cases of diabetes are occurring. Unfortunately, while incidence has been the standard reporting metric for type 1 diabetes, the number of published studies reporting the incidence of type 2 diabetes is relatively small.

In 2021, almost one-in-two (44.7%; 239.7 million) adults living with diabetes (20–79 years old) were found to be unaware of their status. It is fundamental for people with diabetes to be diagnosed as early as possible to prevent or delay complications, avoid a premature death and improve quality of life. A serious concern is that people with diabetes diagnosed later, rather than earlier, are likely to use more healthcare services due to greater likelihood of diabetes complications.

Economic impact [1]

Diabetes imposes a substantial economic burden on countries, health systems, people with diabetes, and their families.

The increase in global health expenditure due to diabetes has been considerable, growing from USD 232 billion in 2007 to USD 966 billion in 2021 for adults aged 20–79 years. This represents a 316% increase over 15 years. The direct costs of diabetes are expected to continue to grow. IDF estimates that total diabetes-related health expenditure will reach USD 1.03 trillion by 2030 and USD 1.05 trillion by 2045.

Diabetes related mortality [1]

Diabetes is a major driver of mortality worldwide, though its impact varies by region. Excluding the mortality risks associated with the COVID-19 pandemic, approximately 6.7 million adults between the age of 20–79 are estimated to have died as a result of diabetes or its complications in 2021. This corresponds to 12.2%

of global deaths from all causes in this age group. Approximately one-third (32.6%) of all deaths from diabetes occur in people of working age (under the age of 60). This corresponds to 11.8% of total global deaths in people under 60.

Diabetic Foot

Diabetic Foot (DF) is one of the major complications of diabetes, affecting 15% of diabetic patients during their lives and it is associated to peripheral neuropathy and vascular disease [3], [4].

According to van Netten et al. [5], diabetic foot can be defined as infection, ulceration, or destruction of tissues of the foot of a person with currently or previously diagnosed diabetes mellitus, usually accompanied by neuropathy and/or PAD in the lower extremity.

DF is described by a decrease in pain and temperature sensation first and later by a decrease in vibratory sensitivity and superficial touch. As a result, DF patients may not be able to feel painful mechanical, chemical or thermal stimuli in normal situations [6].

In diabetes, in fact, elevated glycaemic levels increase the risk of microvascular and macrovascular complications. These increase the risk of further complications such as retinopathy, cardiovascular disease, and nephropathy, in addition to peripheral neuropathy, which can cause foot ulcerations and other complications as Charcot osteoarthropathy that may lead to lower limb amputations; compared to non-diabetics the need for major amputation is about 30 to 40 times higher in patients with diabetes mellitus type 2 [4]. DF complications have a prevalence of up to 25% and are the main reason for hospitalization and amputation in people with diabetes [7]. From 20% to 40% of the resources in diabetes pathology are used for foot problems [7].

Diabetes morbidity rates are staggeringly high and the 5-year mortality rate, after a lower extremity amputation, is estimated at 39%-68% [4] and is only second to lung cancer [8].

It is easily understandable how diabetic foot is a major medical, social, and economic problem worldwide. However, the reported frequency of ulceration and amputation varies considerably. This may be due to differences in diagnostic criteria as well as regionally specific social, economic, and health-related factors. In most developed countries, the annual incidence of foot ulceration amongst people with diabetes is about 2%. In these countries, diabetes is the most common cause of non-traumatic amputation; approximately 1% of people with diabetes suffer a lower-limb amputation [9].

Primary risk factors for the development of DF are peripheral neuropathy and peripheral artery disease.

Diabetic Peripheral Neuropathy (DPN)

DPN could be defined as the presence of symptoms or signs of nerve dysfunction in a person with (a history of) diabetes mellitus after exclusion of other causes [5].

Peripheral neuropathy may manifest as an inability to detect temperature changes, vibration, proprioception, pressure, and, most seriously, pain. Some patients have

a form of painful sensory neuropathy that includes symptoms, such as burning and tingling, known as paraesthesia [10].

The clinical presentation of DPN can be quite variable. Patients can present with “positive” or “negative” symptoms. Positive symptoms are those that patients complain of (subjective findings), including paraesthesia (tingling, hyperesthesia, burning, allodynia or formication). Negative symptoms are usually unveiled by clinical examination (objective findings). They could consist of numbness, dead/asleep feeling, or muscle weakness in the lower limbs.

About 50% of patients with diabetes mellitus develop symptomatic peripheral neuropathy within 25 years of disease onset. Patient age, disease duration and quality of diabetes control are strong predictors, whereas etiology has no influence. Signs of autonomic neuropathy can be found in 20% of cases, again in strong correlation with age and disease duration as well as microangiopathy. Peripheral neuropathy is accompanied by autonomic neuropathy in 30% to 50% of cases [4].

The majority of patients with neuropathy present with some particular symptom and/or sign of DPN which should be recognized and paid attention to. Up to 50% of patients may experience symptoms, most frequently a burning pain, electrical or stabbing sensations, paraesthesia, hyperesthesia, and a deep aching pain. Neuropathic pain is typically worse at night and at rest as it advances, and the symptoms are most commonly experienced in the feet and lower limbs, although in some cases the hands may also be affected. However, as up to half of the patients may be asymptomatic, a diagnosis may only be made on examination or, in some cases, when the patient presents with a painless foot ulcer or foot infection. When neuropathy initially presents, clinicians need to start paying attention and become vigilant in initiating preventative treatment. [9]

Chronic sensorimotor polyneuropathy afflicts sensory, motor and autonomic nerves of the peripheral nervous system. It is the sensory peripheral neuropathy that leads to the loss of the “gift of pain”, this is the feedback from our feet telling us when to rest, stay off our feet, and change our footwear to protect from tissue damage, injury and high peak pressure areas that may lead to tissue breakdown.

The progressive nature of neuropathy, leading to loss of protective sensation in the feet, makes the feet vulnerable to injuries and ulceration. Small afferent nerve fibers conduct the sensations of pain and temperature while large nerve fibers conduct touch, vibration and sense of joint position. Affliction of motor nerve fibers leads to the atrophy of small muscles in the feet (intrinsic muscles) leading to foot deformities and reduced motor function. Frequently, this targets the intrinsic musculature of the foot resulting in joint instability. As innervation decreases, muscle wasting is observed. Over time, these imbalances lead to flexible deformities that become progressively more rigid. Rigid deformities are subject to greater pressure and predispose patients to ulcer formation.

Autonomic neuropathy is perhaps the most overlooked in the diabetic limb. Autonomic nerve involvement impairs the impaired vasoregulation and may result

in changes to the texture and turgor of the skin, causing the dryness and fissuring [9], [10]. The dryness predominantly effects the plantar foot. Dysregulation of local perspiration may contribute to increased moisture and increase the risk of fungal infections. With increased stiffness within the skin, areas of friction are less accommodating and hyperkeratotic lesions may develop. Untreated, these lesions may progress with respect to thickness and induration and exert increased pressure on deep tissues resulting in ulceration.

Peripheral Artery Disease (PAD)

According to the definition given by Mr. van Netten, PAD is an obstructive atherosclerotic vascular disease with clinical symptoms, signs, or abnormalities on noninvasive or invasive vascular assessment, resulting in disturbed or impaired circulation in one or more extremities [5].

Disease consequences of the compromised vascular system in diabetes can be among the most devastating complications. Hyperglycemia and associated changes in glucose metabolism produces endothelial injury, hyperlipidemia, increased platelet viscosity and activity; and with time the development of atherosclerosis. Among people with diabetes, all blood vessels regardless of size and function are affected [9], and the distribution of lower extremity atherosclerotic disease in diabetics differs from non-diabetics, and preferentially involves the infra-geniculate leg arteries (posterior and anterior tibial arteries) with less common involvement of the femoropopliteal arterial segment (superficial femoral, popliteal), and often sparing of the aortoiliac artery segment [11]. Both macrovascular and microvascular diseases are believed to contribute to the consequences of peripheral vascular disease, resulting in the inability of the dysvascular or ischemic limb to heal itself properly [9].

Small injuries may progress to larger wounds because of reduced healing capacity. Delivery of systemic antibiotics can be compromised, leaving infections uncontrolled to the affected foot.

The 1999-2000 National Health and Nutrition Examination Survey (NHANES) found that the prevalence of peripheral arterial disease was 4.5% (95% CI 3.4–5.6) in the general population but increased to 9.5% (95% CI 5.5–13.4) in people with diabetes. Other reports have shown higher prevalence of PAD with 12.5% of people with normal glucose tolerance compared to 20.6% of those with diabetes or glucose intolerance [12].

In one large population-based study, over half of people with diabetes were found to have absent pedal pulses, a common sign of impaired vascular function. Another study conducted by Selmin et al. found that in patients with nonpalpable pulses, the relative risk of ulceration was 4.72 (95% CI 3.28, 6.78), compared to a normal exam with all four pulses palpable [12]. Ankle-brachial index, despite recognized limitations in the diabetes population, has also been used in diabetes screening. In patients with an ankle-brachial index <0.90, their relative risk has been reported to be 1.25 (95% CI) for developing an ulcer, compared to people with diabetes with a normal ankle-brachial index [10], [13].

The relationship between abnormal glucose metabolism and lower extremity atherosclerotic lesions is closely related [14], [15]. Diabetes combined with PAD is not only a risk factor for diabetic foot disease, but also a major cause of amputation. Patients with PAD had much higher rates of cardiovascular events with a prevalence of cardiovascular events as high as 21.14% up to a year after the diagnosis of PAD. This was similar to those without diabetes who had suffered a cardiovascular event [16].

Clinical manifestations vary across a wide spectrum from asymptomatic to gangrene of the lower extremity.

Most of these patients are unaware that they have PAD and do not seek treatment. Furthermore, some clinicians do not examine and assess their patients with PAD and miss the diagnosis altogether, resulting in high rates of morbidity and mortality [17].

Chronic Plantar Diabetic Foot Ulcers (CPDFUs)

Chronic Plantar Diabetic Foot Ulcers are a common complication among diabetic patients, with a reported annual incidence of 2% to 6% [18], [19]. Those at the level of the metatarsal heads are common and represent 22% of all foot ulcers [20]. As previously said, development of CPDFUs is frequently related with four major risks factors caused by diabetics:

1. peripheral neuropathy, which lead to insensate foot;
2. vascular disease;
3. elevated local pressure under the metatarsal heads due to a plantar flexion deformity of one or more of the metatarsal bones, and also to hyperextension of the proximal phalanx when claw toe deformity is present [21];
4. more intense stress-relaxation phenomena due to the tendency of plantar tissue in diabetic patients to be stiffer than the one in healthy subjects.

These factors lead to hypertrophic callus formation and increased risk for local ulcers [22] (Figures 2).

Figure 2: A 54-year-old diabetic man, presenting hypertrophic callus formations at the level of the 5th MH and distal phalanx of the big toe in his right foot (A), masking plantar DFUs (B).

It has been estimated that approximately 25% of hospitalizations are directly related to foot problems [23], which are responsible for nearly 50% of the hospital bed days caused by diabetes [24], while the lifetime risk of developing diabetic foot ulcers (DFUs) is estimated around 19–34% [25]. The rate of infection of this lesion is higher of 50%, and approximately 15% to 20% of them lead to some level of amputation [26], [27] (Figure 3). Furthermore, CPDFU development is associated with 5% mortality during the first year and 42% mortality within 5 years [28]. That explains why managing DFU and his consequences is an important goal to reach.

The goal of ulcer treatment is to achieve rapid wound closure to prevent serious downstream consequence such as amputation and reduced quality of life.

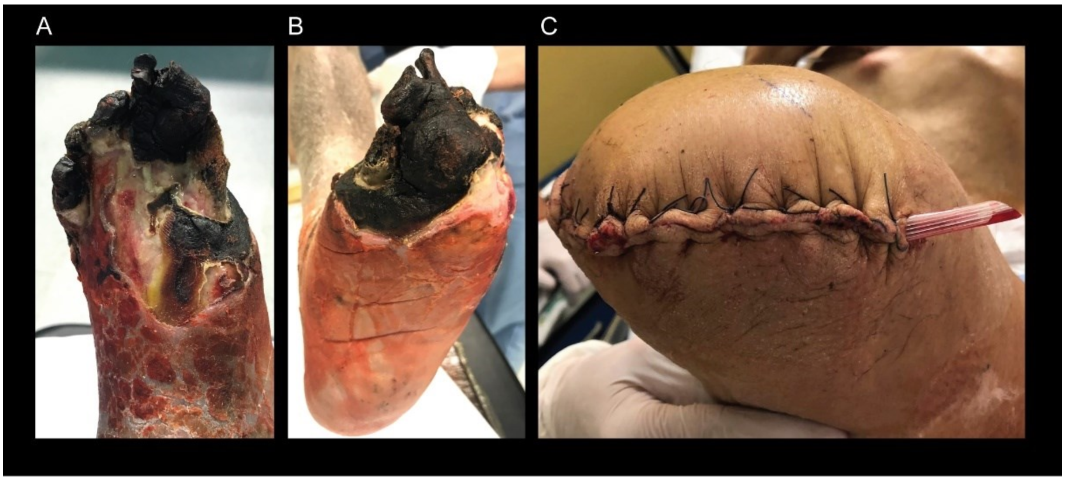

Figure 3: Dry gangrene and osteomyelitis of the left foot in a 76-year-old diabetic man with severe peripheral arterial disease and previous CPDFUs becoming infected (A-B) and leading to a mid-thigh amputation (C).

Treatment should occur in a stepwise approach. The first and most urgent step is to treat any infection that is present. If present, arterial insufficiency needs to be managed. As a team, diabetologists, orthopaedics and vascular surgeons significantly improve clinical outcomes. The vascular surgeon can perform a variety of procedures, from angioplasty to open bypass to restore blood flow to the foot.

During the years several classifications for DFU were developed, but the most commonly used is the Wagner Scale [29]. University of Texas Diabetic Wound Classification System (UTDWCS) is also frequently cited in literature. The Wagner Scale divided foot lesions into six grades according to the depth of the skin lesion and the presence or absence of infection or gangrene [30]: grade 0 lesion includes intact skin whit evidence of healed lesions or bone deformity that can lead to an open wound; grade 1 describes a superficial ulcer that does not penetrate to deeper layers, bone deformity may be present and bone metatarsal head prominence frequently underlies the ulcers; in grade 2 deep ulcer to tendon, bone, or joint capsule is present; grade 3 is used for a deep ulcer with abscess or osteomyelitis; grade 4 describes presence of gangrene of some portion of the toe, toes and/or forefoot; in grade 5 gangrene involves the whole-foot [30]. This classification has different limitations: first of all, infection is included in only one of the six ulcer grades, and vascular disease, considered only in their most sever signs (forefoot and whole-foot gangrene) is only included in the last two classification grades. In addition, he system does not allow classification of superficial wounds that are infected or dysvascular [31].

UTDWCS uses a system of wound grade and stage to categorize wounds by severity (Table 1). Wounds are graded by depth and each grade has four stages that consider the presence/absence of ischemia and/or infection. Grade 0 represents a pre- or postulcerative site; grade I ulcers are superficial wounds through the epidermis or epidermis and dermis, but do not penetrate to tendon, capsule, or bone; grade II wounds penetrate to tendon or capsule; grade III wounds penetrate to bone or into a joint [31]. For what concern the stage, stage A is for a non-ischemic clean wounds, stage B describes a non-ischemic infected wounds, ischemic wounds are stage C, and infected ischemic wounds are described as stage D [31]. The criteria for each of the stages are based on clinical and laboratory data. Clean ulcers are defined as wounds without local or systemic signs of infection. Wounds with frank purulence and/or two or more of the following local signs may be classified as "infected". Lesions that fall into grade 0 may not be classically classified as "wounds", but the system is important to identify sites "at risk" for frank ulceration, and to monitor newly healed wounds [31].

A metanalysis conducted in 2001 by Oyibo et al. [32] shows how UTDWCS, which combines grade and stage, is more descriptive and shows a greater association with increased risk of amputation and prediction of ulcer healing when compared with the Wagner system. Therefore, for groups rather than individual patients, the UTDWCS, which is simple and easy to use, is a better predictor of clinical outcome. That is why UTDWCS was used in this study.

Table 1 Lavery LA, Armstrong DG, Harkless LB. Classification of diabetic foot wounds. Ostomy Wound Manage. 1997 Mar;43(2):44-8, 50, 52-3. PubMed PMID: 9136997

University of Texas Diabetic Wound Classifications System				
Stage	Grade			
	0	I	II	III
A	Pre- or post-ulcerative lesion completely epithelialized	Superficial wound not involving tendon, capsule or bone	Wound penetrating to tendon or capsule	Wound penetrating to bon or joint
B	Infection	Infection	Infection	Infection
C	Ischemia	Ischemia	Ischemia	Ischemia
D	Infection and ischemia	Infection and ischemia	Infection and ischemia	Infection and ischemia

The mainstay of therapy for DFU is offloading of pressure. This is done with bedrest, a wheel chair, crutches, or modalities that can keep the patient weightbearing, such as a total contact cast (TCC), a removable cast walker, or a variety of other devices [9]. However, many other modalities, such as felt or foam padding or wedged shoes have been tried but failed to off-load the foot adequately. TCC is an alternative but not equivalent for offloading the diabetic foot, but few clinicians use it because it is time consuming and can cause more complications. A trained clinician or cast technician is required to apply a TCC. Another more recent concept is to use a removable cast walker rendered irremovable to enforce compliance. This is referred to as an instant total contact cast (iTCC) [33]. This can be done through the use of plastic cable ties, duct tape or fiberglass.

However, the recurrence rate of DFU is 40% following the first year after care and starting full weight-bearing, and 65% within 5 years [22].
That is why, in case of failure of conservative management, minimally invasive surgery as DMOs in treatment of recalcitrant ulcers has become a successful new therapeutic strategy, also because of its lesser complication rates than traditional operative methods.

Distal Metatarsal Osteotomies (DMOs)

During the last thirty years, Distal Metatarsal Osteotomies (DMOs) showed satisfactory short- to medium-term clinical and radiographic outcomes in treatment of Chronic Plantar Diabetic Foot Ulcers (CPDFUs) and metatarsalgia according to literature, that suggest that DMOs, performed at a different level of the distal metatarsal bones, with very few contraindications and low incidence of complications, are an effective surgical treatment option for achieving rapid healing of CPDFUs and preventing their recurrence after balancing the pressures in diabetic forefeet.

DMO is a minimally invasive surgical technique, performed without internal fixation, whose purpose to favour the reduction of bone-induced pressure promoting a reduction of metatarsalgia and/or the healing of CPDFU and restoring the metatarsal parabola of the forefoot [34].

In case of concomitant Hallux Valgus (HV), DMOs can be performed in association with other surgical techniques like Reverdin-Isham osteotomy or Endolog technique, according to the grade of HV.

Different techniques for minimally invasive and percutaneous distal metatarsal osteotomies were proposed since 1986, but all of them share the same main purpose and essential features.

All DMOs proposed by different authors over the years were performed in a minimally invasive way using portals smaller than 3cm open on the dorsal side of the foot at the level of the lesser distal metatarsal bones, all authors performed osteotomies in oblique slide shape and osteosynthesis material were never used if not temporary (K-wires).

DMOs always have two main goals: favouring the reduction of bone-induced pressure on the CPDFUs to consequently promote their healing and restoring the metatarsal parabola of the forefoot, preventing metatarsalgia and recurrent transfer skin lesions and possible future wound and bone infection.

Historical note

The very first to describe a metatarsal neck osteotomy of metatarsal bones was Mr. Wray [35] in 1986 whom osteotomized obliquely, starting proximally on the dorsum but proceeding distally and plantar-ward at an angle of 45° (Figure 4A) and in 1990, Tillo et al. [36] proposed four different types of DMOs: osteoclasis of the MH, V-osteotomy, shortening colectomy and oblique slide osteotomy (Figure 4B). Almost three decades later, in 2016, Tamir et al. [37] performed a perpendicular or short oblique osteotomy at the neck or diaphysis of the metatarsal bone (Figure 4C). In 2018 Biz et al. [38] described a distal metatarsal diaphyseal osteotomy with an angle of approximately 45° with respect to the long axis of the lesser MB, as Mr. Wray before, but performed in a dorsal-distal to proximal-plantar direction (Figure 4D). Similarly, Tamir et al. [39] treated in 2020 another series of patients using a DMO perpendicular to the first MB distal metaphysis (Figure 4E) and in the same year Chiu et al. [40] moved the site of ostectomy proximal to the metatarsal neck at the purpose to preserve metatarsophalangeal joint (MTPJ) function (Figure 4F). In 2021, finally, Tamir et al. [41] proposed a minimally invasive floating distal metatarsal oblique osteotomy (Figure 4G).

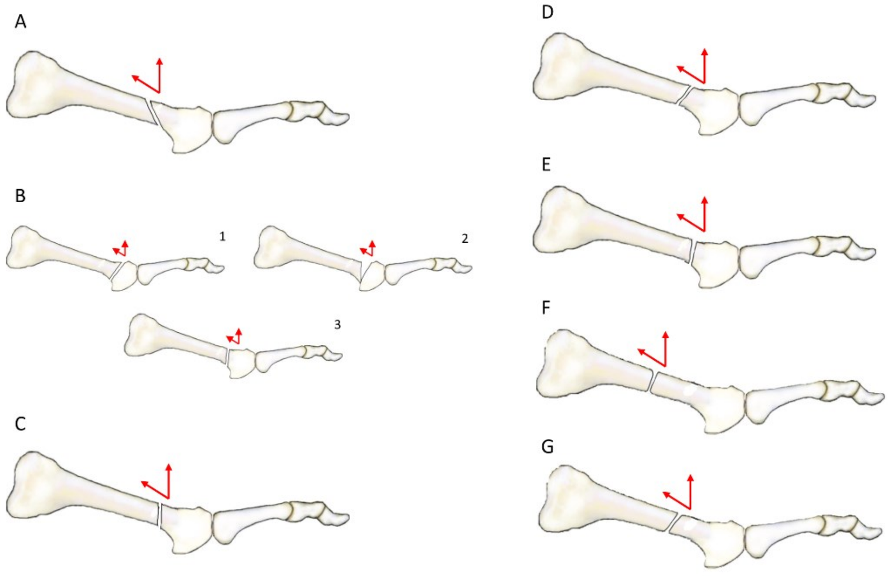

Figure 4:Different shapes of DMOs (A-G) proposed by several authors from 1986 to 2021.

Indications and contraindications

In addition to the general indications shared with metatarsal head resection, arthroplasty resection and bunionette correction [42], DMOs are indicated when all other conservative treatment for CPDFU failed after at least 6 weeks, further, due to minimally invasive approach, DMOs are recommended also in situations where there is poor local soft tissue or previous amputations of toes and/or MBs with scarring [34]. Being a diaphyseal osteotomy, the presence of significant arthritis and stiffness in the associated MTPJ and the consequent association of reported increased risk of non-union in not a contraindication for DMO [43].

In patients whom present ulcers with chronic infection or ulcers penetrating deep structures, or osteomyelitis of the metatarsal bones or the phalanges, or even ankle brachial index below 0.5 and flat pulse volume recording at the ankle level DMO should be perform with caution and just in selected cases [34], discussing the case with vascular surgeon if needed.

On the contrary, the few absolute contraindications of these procedures are severe ischemia and gangrene, insufficient vascular perfusion and extensive soft tissue infection presenting as cellulitis of the foot or toe [34].

Planning

During the clinical preoperative evaluation, which includes a complete clinical history of the patients and their characteristics, the general aspects of diabetic foot and related ulcers are stressed. In particular, control of blood sugar, affected side, site of plantar lesion, depth and size of the ulcer and clinical signs of infection and dorsal dislocation of the proximal phalanx must be evaluated [34]. CPDFUs are routinely graded using the University of Texas Diabetic Wound Classification System [31], while the ulcer's diameter and the major axes of the wounds can be determined manually using a transparent sheet, as originally described by Coughlin [44], or more simply by a ruler.

The number of DMOs needed in each forefoot to preserve or create the harmony of metatarsal parabola and to avoid future skin lesion until ulceration is planned according to how much the metatarsal formula is altered, following the Maestro criteria [45] which define the characteristics of an harmonious forefoot considering the length of each metatarsal tip to lateral sesamoid (SM4) , allowing M1-M2 index calculation (first metatarsal tip/SM4–second metatarsal tip/SM4) and three criteria to check on the lesser metatarsal distal parabola: criterion 1 = second metatarsal tip/SM4–third metatarsal tip/SM4 or M2-M3; criterion 2 = M3-M4; criterion 3 = M4-M5. That explain why these criteria (M1M2 index, Maestro 1, Maestro 2, Maestro 3) must be evaluated on the preoperative weightbearing X-rays (Figure 5). However, even if Maestro criteria are fundamental in the preoperative planning, current literature shows no predictive value in clinical outcomes of DMOs [46]. It is important to highlight that DMO should be carried out only on the metatarsal head causing the plantar lesion unless this shortening would make the neighbouring metatarsal bone too long, resulting in a disharmonious morphotype with a high risk of a transfer plantar lesion. The adjacent MB must be also shortened in this case.

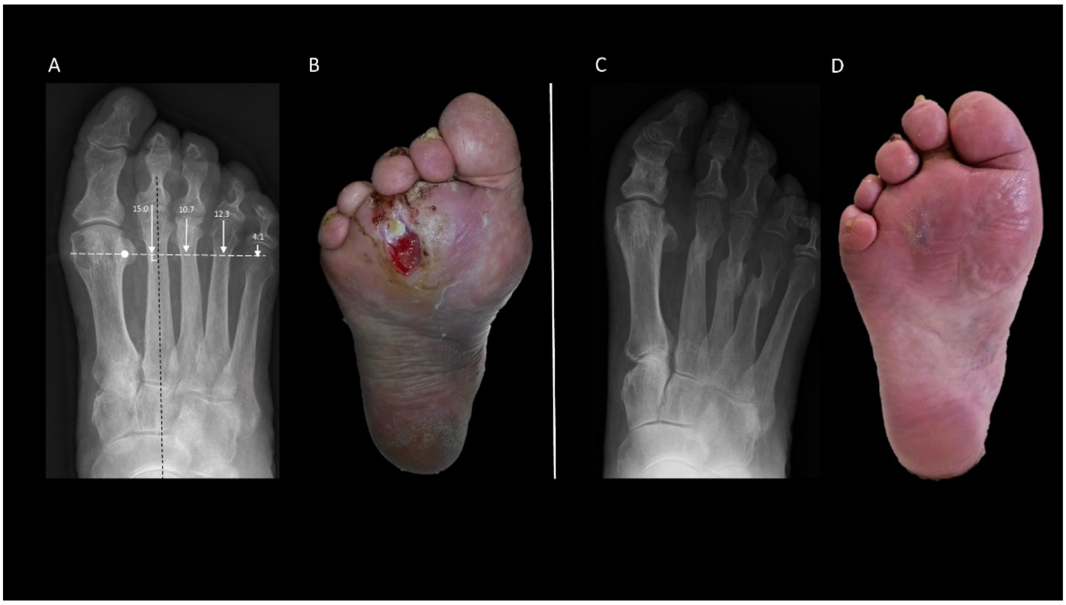

Figure 5: a 76-year-old diabetic female patient having undergone DMDO of the 2nd, 3rd, and 4th MB for a CPDFU (II B, UTDWC) and percutaneous osteotomy of P1 of the 1st, 2nd, and 3rd toes associated to percutaneous tenotomy procedures for claw deformity. Radiographic and clinical images at 18-month follow-up, showing a more harmonious forefoot morphotype, bone callus consolidation of percutaneous osteotomies performed (D), and the conservation of complete healing of the ulcer, which was reached after 3 months from MIS (E).

Operative aspect

Equipment

For a correct operative procedure, the following are necessary:

- a small scalpel blade (SM64);
- periosteal elevator and bone rasp;
- a Shannon Isham burr (2.0 x 12 mm);
- a 20-cc syringe with normal saline solution;
- a fluoroscopy system for radiographic check;
- a power-driven burr, which has to provide a speed of approximately 2000 to 6000 rpm to avoid bone necrosis;
- bandages and tubular gauze for the final dressing.

Regional Ultrasound-guided Anaesthesia

According to the anaesthetist’s experience, two different types of ultrasound-guided regional anaesthesia are recommended: sciatic-femoral block or ankle-block.

To improve patient cooperation and comfort the standard premedication should be administered using intravenous Midazolam (1-2 mg) and Fentanyl (0.1 mg) while the intra-operative sedation is obtained using Propofol 1.5 mg/kg to 2.5 mg/kg for initiation and a continuous infusion of 4-8 mg/kg/h for maintenance [47].

Positioning during the operation

The patient is in a supine position with the operated foot protruding from the table, the C-arm is positioned under the foot for direct and continuous control of the procedure.

No ankle joint tourniquet is applied for two reasons: blood is necessary to facilitate the removal of bone debris to be eliminated in the form of bone paste; and more importantly, it is not indicated in diabetic lower limb surgery because of the compromised vascular peripheral system [34], [38].

Surgical Technique [34], [38], [46]

The following procedure describes an operation performed by a right-handed surgeon on a left foot (Figure 6-11).

- Portals: the top of the MH must first be palpated with the left thumb. Then, moving a few millimetres proximally at this level in the interspace on the right side of the MH, an incision of 5 mm is made parallel to the extensor tendons with a small scalpel blade (SM64), held by the dominant hand of the surgeon, at the dorsal side of the medial border of each MH that needs to be shortened. The side of the incision depends on whether the surgeon is right- or left-handed and which foot is being operated on.
- Osteotomy site: the scalpel is moved forward at an oblique angle of about 45° until it reaches the dorsal aspect of the distal MB, proximal to the neck, to undergo osteotomy. Through the same incision, first a bone rasp is inserted, and the periosteum is separated at the level of the osteotomy. A path is then prepared for the burr by using a periosteal elevator and positioning it obliquely at a 45° angle to the metatarsal axis, against the neck. This can be done by feel, using the instrument to move along the flare on the proximal part of the neck, from neck to distal diaphysis, mirroring

the movement needed then for the osteotomy and detaching the tissues, which tend to be very stiff in diabetic feet.

- Osteotomy: a Shannon Isham burr (2.0 x 12 mm) is introduced until it reaches the metatarsal neck. It is then retracted a few millimetres proximally where the periosteum was previously removed (Figure 6A). Fluoroscopy allows confirmation of the correct position of the osteotomy site on the distal diaphysis of the MB. In this position, cutting is started with an angle of approximately 45° with respect to the long axis of the MB in a dorsal-distal to proximal-plantar direction, with rotary motion, extending to the contralateral cortex. The lateral or medial cortical surface, respectively for left or right foot, is cut first in this way, followed by the plantar, medial or lateral, and lastly, the dorsal cortical surface. Beginning with the section of the lateral cortex, the osteotomy is started with the motorized burr moving in a plantar and medial direction and ends with the section of the dorsal cortex. This is carried out by pivoting in a rotational movement from the point of skin entry, involving a supination of the wrist of 90°. Thus, the burr comes to lie nearly flat on the foot at 90° to the metatarsal axis in the anteroposterior plane.
- Portal irrigation: the incision site is irrigated by normal saline during osteotomy because the burr can cause excessive heat, first burning the skin and subsequently resulting in fibrosis and pseudoarthrosis at the bone level [46], [48], [49]. The lavage is also useful to remove bone debris, preventing periarticular ossifications in the stab canal.
- Compacting of osteotomy sides: the bone is manually compacted upon completion of the osteotomy by exercising pressure in the distal-proximal direction, pushing the MH dorsally and producing contact of the trabecular bone since no internal fixation is performed (Figure 6B-C).
- Ulcer debridement: by accurate ulcer debridement, the CPDFU is converted into an acute wound to enable the normal stages of healing [50], [51]: primary, when wound closure is possible by suture; secondary, in other cases.

- Bandage: because no internal fixation is performed in this surgery, the bandage is very important to maintain the MH position achieved after DMO After having covered the debrided ulcer by gauze, it useful to use tape for bandages, bent and crisscrossed, tracing between all inter-metatarsal spaces, crossing them over the medial (lateral) aspect of each of the osteotomies performed (depending on the foot side) to reinforce the strength of the bandage. A gentle traction is needed to maintain the toe in slight plantar inclination if possible. Finally tubular gauze is used to cover the forefoot, except for the distal part of the toes and nails to check distal vascularization of the foot.

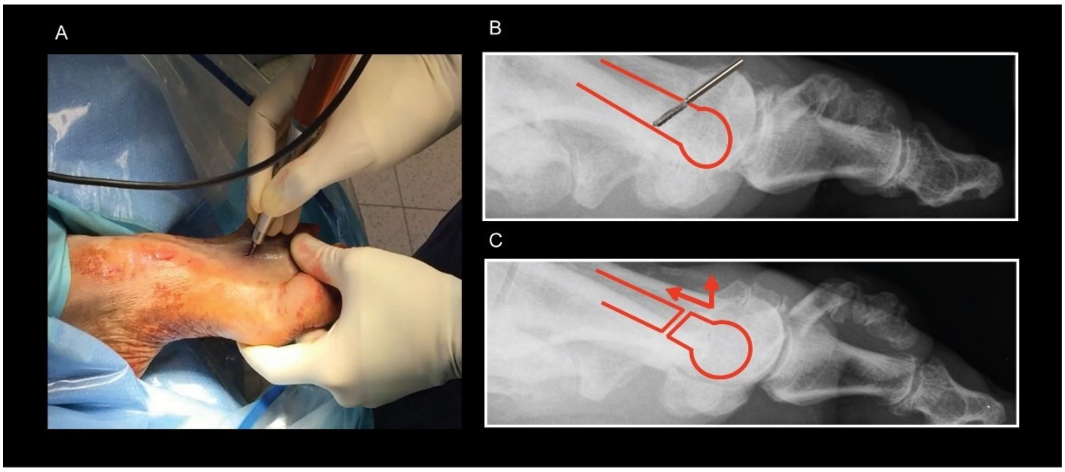

Figure 6: A DMO is performing by a 12-mm Shannon Isham burr with an angle of approximately 45° with respect to the long axis of the lesser MB in a dorsal-distal to proximal-plantar direction (A). Lateral view X-rays of a left DF on weightbearing before (B) and after (C) the osteotomy performed proximal to the neck with potentially greater elevation of MH from the ground

Figure 7: clinical (A-B) and radiographic images (C-D) of the ulcerated left Charcot foot at time of DP's presentation.

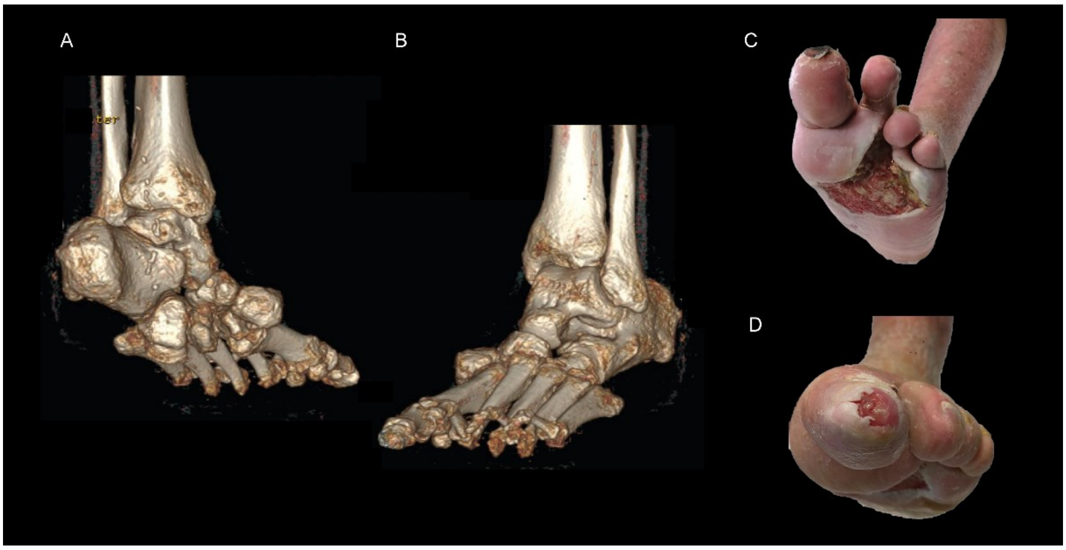

Figure 8: 3D CT-scan Charcot foot images: posterior and anterior view (A-B), respectively. Clinical images after soft-tissue debridement sections (C-D).

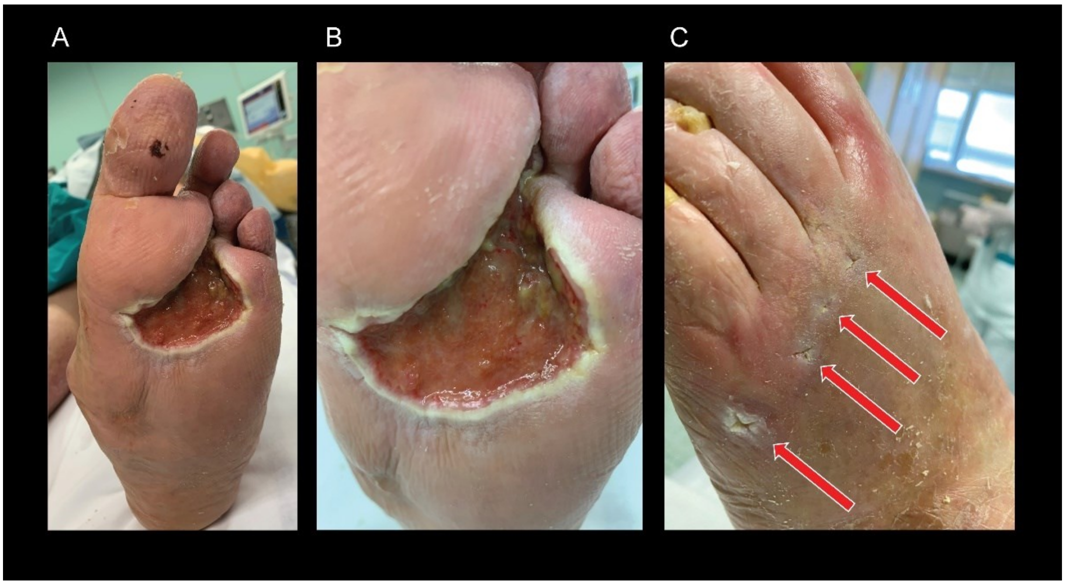

Figure 9: clinical images of the Charcot foot at time of surgery showing the reduction of the plantar lesion after conservative treatment, the healing of the associated ulcers (IA, UTDWC47,48) (A-B), and the 3-millimeter portals on the dorsal aspect of the left foot (red arrows) through which DMOs were performed on the 2nd to 5th MBs (C).

Figure 10: clinical (A-C) and radiographic images (B-D) during post-operative period respectively, showing the progressive healing of the main plantar lesion and the DMOs performed on 2nd to 5th MBs.

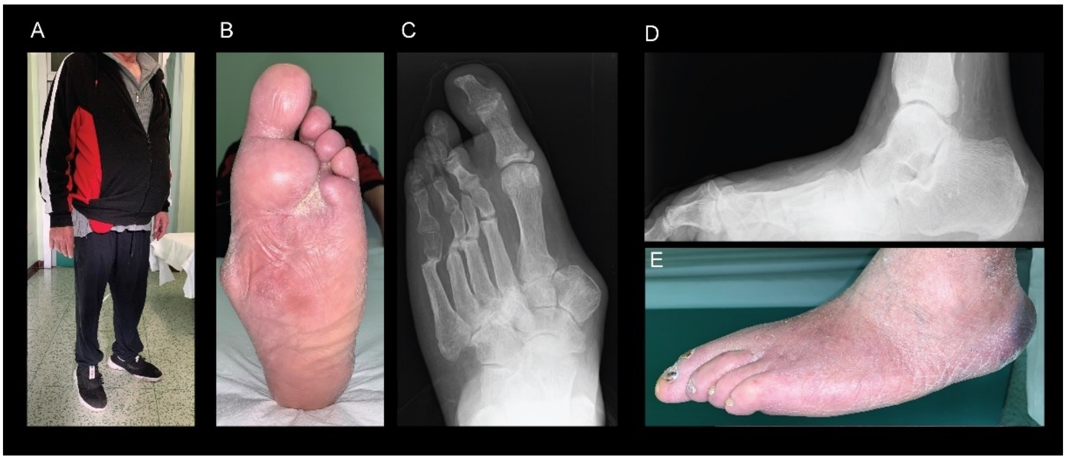

Figure 11: clinical and radiographic images at 10-month follow-up showing the patient standing and able to walk (A), complete healing of ulcers and their maintenance over time (B-E), and bone union (partial only for 2nd MB) after the DMOs (C-D).

Postoperative protocol

Several studies [34], [38], [46] reported the following postoperative protocol:

- Day 0: before the patient's discharge, antero-posterior and lateral X-rays of non-weightbearing feet should be taken.
- Days 1-7: an oral antibiotic prophylaxis for a week is recommended starting from the day of the surgery.
- Days 1-30: thromboembolic prophylaxis and an anti-edema therapy are prescribed for 30 days. Further, an analgesic therapy is advised in the morning for only 2 weeks, also to prevent heterotopic ossification. During the first month, the patients are allowed to walk using a rigid flat-soled orthopaedic shoe for the following 30-day period. This is very important as metatarsal length is set automatically upon weightbearing of the foot.
- Days 7-30: each of the patients is seen once a week for a month on an outpatient basis. The first control is 8 days after surgery. The original bandage is removed and substituted by a simpler bandage. At the next 3 weekly visits, the bandage is changed in the same way.
- Day 30: The bandage is totally removed one month after surgery if the ulcer is completely closed, and antero-posterior weight-bearing and lateral X-rays are taken. The patient is then able to walk with comfortable shoes; or

orthopaedic footwear usually used (according to previous foot deformity); or new orthosis (if the foot deformity has been improved after the operation), allowing total load on the operated foot. If the CPDFU is not completely healed, the patient is seen every week for a medication until total healing of the lesion.

Clinical outcomes

Studies presented in literature report encouraging and promising results following DMOs regarding ulcer healing (91.9%, range 74.9%-97.8%), mean healing time (range from 1 to 2 months) and recurrence rates (7.2%, 95% CI 3.6-14.2) [52].
Preoperative AOFAS score was reported only in one study [38]. It was computed at 55.3±8.3 (range 42–71), whereas AOFAS at last follow-up was 81.4±9.1 (range 64–100). Postoperative VAS for satisfaction was reported in the study by Biz et al. [38] and was computed at 9.8±0.7 (range 7–10).

Complications

DMOs show an overall complication range between 44.9% to 68.2%, mostly minor. The most common complications reported in the literature in order of frequency are:

- Foot swelling (56.3%): it is generally persistent and moderate, affecting the forefoot for more than 6 weeks without infection, which improves after some months with complete callus formation at the osteotomy sites and without further treatment [52].
- Radiographic non-union (4.5%-30.0%): it is often described as asymptomatic probably because of the sensory neuropathy of these patients [37], [39], [41].
- Infections (4.2%-25.2%) [52]: infections often adversely affect the healing of plantar ulcers. Usually, they are mainly superficial and treated successfully with oral or intravenous antibiotics. However, when

exceptionally deep infections appear, subsequent surgical treatment is mandatory. When fixation is used to prevent non-union, using temporary K-wires or cancellous bone screws, a higher infection rate (31.8%) has been reported [53].

- Non-healing wound (23.8%) and bone necrosis (4.8%): their rates are reported only by Tamir et al. [39]
- Transfer Lesions (9.1%-26.5%): these lesions are usually described under the heads of adjacent metatarsals [36], as they occur when a correct metatarsal parabola is not re-established in the forefoot. This is probably due to the resumption of patients' normal walking and incorrect overloading of the lateral MBs.
- Ulcer recurrence (7.2%): recurrence rate is higher in the first studies from the 90s [36], while drastically decreases in later years [41].

Associated procedures

In case of hallux valgus, with or without ulcers, DMOs can be performed in association with:

- Reverdin-Isham percutaneous osteotomy, +/- Akin osteotomy: in case of HV from mild to moderate;
- MIND/Endolog technique +/- Akin osteotomy: in case of HV from moderate to severe.

Reverdin-Isham percutaneous osteotomy

Reverdin-Isham technique is a percutaneous osteotomy performed with minimally invasive approach that allow 1-day hospitalization decrease post-operative morbidity as well as recovery and rehabilitation times [48]. The Reverdin-Isham percutaneous osteotomy was in fact described as a novel intra-articular medial closing wedge osteotomy of the distal metatarsal, in combination with an Akin osteotomy, both performed without fixation, to align the first ray by medial rotation of the first metatarsal head and distal metatarsal articular angle (DMAA) correction [54], [55]. However, Reverdin-Isham is not a complete osteotomy, as the MTT-1 lateral cortex is preserved [56].

This technique is performed in case of mild to moderate HV, usually in association with Akin osteotomy at the proximal phalanx.

According to the Mann and Coughlin parameters [44], [57], [58], HV can be defined Mild when the Hallux Valgus Angle (HVA: the angle between the long axis of I metatarsal and proximal phalanx) is minor of 20° and the Intermetatarsal Angle (IMA: the angle between long axis of I and II metatrsal) is minor of 11°. If HVA is of 20° to 40° and IMA is of 11° to 16° HV is classified as Moderate.

Historical note

As already said, minimally invasive surgery became widespread first in Spain and then in Europe by M. De Prado and P.L Ripoll since the end of the last century [59]. Ripoll through their surgical practices and international theoretical-cadaveric courses, supported by the anatomical studies of Pau Golanó [59]. In 2002, the group GRECMIP (Groupe de Recherche et d'Enseignement en Chirurgie Mini-Invasive du Pied) began a project to develop and promote this new surgical treatment [60].

In 1980 Mr. Isham modified the Reverdin osteotomy with the Isham osteotomy by performing the medial wedge osteotomy in the head of the first metatarsal at an angle form dorsal-distal, just proximal to the articular surface on the dorsal side of the metatarsal head, to plantar-proximal direction just proximal to the articular surface on the plantar side of the metatarsal head at the purpose to preserve and reposition the articular surface [56].

Indications and contraindications

Reverdin-Isham osteotomy find its applications in case of mild to moderate HV [48], [56], [61].

Planning

In the preoperative clinical evaluation are considered complete clinical history of the patients, their main characteristics (gender, age at the time of surgery, affected side) and physical examination of the foot.
Standing antero-posterior, lateral and sesamoid X-ray views were routinely obtained before surgery at the purpose to evaluate the intermetatarsal angle (normal value <10°), proximal articular surface angle (normal value <6°), hallux valgus angle (normal value <15°), and tibial sesamoid position. The relationship among the IMA, HVA values and tibial sesamoid displacement was then used to classify the deformities into three groups according to the presence of one of Mann and Coughlin parameters [57], [58].

Operative aspect

Equipment
Specific tools are required for this procedure, among them, various burrs of different size and form, adapted for Mm960 (produced by Medic Micro, Switzerland), a modular power driver for MIS, were used [48].
Prophylaxis
Prophylactic antibiotic (Cefazolin 2 g) was administered before surgery [48]
Anaesthesia
The performed anaesthesia consists in a conscious sedation in association with a regional ankle block, which combines five nerves: three superficial: saphenous, sural and superficial peroneal nerves, and two deep: tibial and deep peroneal nerves.

Positioning during the operation

The patient was in a supine position, with the operated foot protruding from the table. No ankle joint tourniquet was applied, as it is not required for this technique.

Surgical Technique

According to literature [48], [62], [63], in Riverdin-Isham osteotomy it is possible to recognise five major steps: exostosectomy, Reverdin-Isham osteotomy itself, tenotomy of the adductor hallucis tendon and lateral capsulotomy, Akin osteotomy, always associated to this technique, and bandage.

- Exostosectomy: an incision of 3–5 mm long was made at the plantar side of the medial border of the first metatarsal head. Through this medial approach, a small scalpel was introduced within the joint capsule of the metatarsophalangeal joint of the big toe. By a sweeping movement, the medial capsule was separated from the exostosis, subsequently using also a rasp. The location of this incision prevents damage of the dorsomedial cutaneous nerve of the hallux. Then, a cylindrical burr (3.1 × 15 mm) was introduced, and the dorsal medial prominence was removed from the first metatarsal head until a flat surface was obtained, assessed under manual palpation and fluoroscopic control. Finally, the bony detritus was extruded manually.
- Reverdin-Isham osteotomy: through the same incision used for the exostosectomy, a Shannon Isham burr (2 × 12 mm) was introduced at the junction of metaphysis and epiphysis. It was applied to the flat bone surface, achieved previously by exostosectomy, at an angle of approximately 45° to the long axis of the first metatarsal bone, keeping the articular cartilage surface of the first metatarsal head as reference point on the dorsal cortex, and the medial sesamoid bone as the reference point on the plantar cortex. In this position, under fluoroscopic control, the osteotomy was started following a distal-dorsal and proximal-plantar direction, extending until the lateral cortex, but without cutting it. At this point, the burr was slightly withdrawn in order to preserve a few millimetres of the lateral cortex, and

the osteotomy of the plantar cortex was performed completely. Then, a Wedge burr (3.1 × 13 mm or 4.1× 13 mm, depending on the DMAA value) was used to create a wedge with a medially oriented base. At the point of closing the wedge, osteoclasis of the preserved lateral cortex was achieved, modifying the orientation of the articular surface, normalizing the DMAA value and adding intrinsic stability to the osteotomy by producing contact of the trabecular bone.

- Tenotomy of the adductor hallucis tendon and lateral capsulotomy: a longitudinal skin incision was performed on the first web space, 2–3 mm lateral to the extensor hallucis longus tendon. The blade was longitudinally introduced in contact with the lateral surface of the base of the proximal phalanx; then, the blade was rotated 90° laterally and the first toe forced in varus, causing the adductor hallucis tendon to be sectioned and the lateral part of the capsule joint to be cut. Movement of the blade was carefully controlled in order to avoid a complete capsulotomy, which could produce joint instability.
- Akin osteotomy: once lateral soft-tissue release was performed, a new incision 3 to 5 mm long on the lateral surface of the base of the proximal phalanx of the first toe was performed, just medial to the extensor tendons. Using a small scraper, the periosteum was removed from the lateral surface of the base of the proximal phalanx. Then, using a Wedge burr (3.1 × 13 mm), a wedge osteotomy (with medial base) was performed; as in the osteotomy on the head of the first metatarsal, the lateral cortex was preserved. Closing of the osteotomy and osteoclasis of the lateral cortex was achieved by means of a forced varus movement of the toe.
- Bandage: After completing the surgery with suture of the capsule and cutaneous sutures of related cuts, a bandage was applied. Because there is no osteosynthesis material in this surgery, the bandage is a very important tool in order to maintain the correction obtained with the operation. Consequently, its application was performed with the utmost care and attention. The first toe was gently placed in overcorrection. Then, with a

tape for bandages, the bend of the crisscross bandage was traced between the first and second toes, crossing them over the medial aspect of the exostosectomy in order to reinforce the strength of the bandage. Gentle traction was used to maintain the toe in light hypercorrection and plantar inclination. Finally, the forefoot was covered with tubular gauzes, except for the distal part of the toes and nails.

Postoperative protocol

According to the studies of Biz et al. [48] and Bauer [62], [63], the postoperative care of patients should be managed as follow:

- Day 0: antero-posterior and lateral X-rays of nonweight-bearing feet were taken before the patients were discharged.
- Day 1-14: an analgesic therapy was prescribed for 2 weeks with Etoricoxib (90 mg, 1 cp/day) in the morning, also to prevent articular ossification; if pain persisted, Paracetamol/phosphate Codeine (1 g, max ×3/day) was prescribed.
- Day 1-30: thromboembolic prophylaxis (Natrium Enoxaparin: 4000 IU/day) and anti-edemigen therapy (Leucoselect, Lymphaselect and Bromelina: 1 cp/day) are recommended for 30 days, starting from the day of the surgery. The patients were allowed to walk as much as they could tolerate the same evening after surgery at discharge, using a rigid flat-soled orthopaedic shoe for the following 30-day period.
- Day 7-30: all of the patients were seen once a week for a month. The first visit was 8 days after surgery. The original bandage was removed and substituted by a simpler bandage, but always with a slight overcorrection. During the three weekly visits, the bandage was changed in the same way.
- Day 30: One month after surgical treatment, the bandage was totally removed.

- Day 30- 120: after taking anteroposterior weight bearing and lateral X-rays (and sesamoid view when possible), an interdigital silicone orthoses space maintainer was positioned between the first and second toes. Patients were instructed to wear it for 3 months to help the first toe maintain its correct position until complete osteotomy consolidation. They were then able to walk with comfortable shoes, allowing total load on the operated foot.
- Other recommendations: the only recommendations for the patient were to be careful with rough surfaces, sports and any other activities with forefoot overload. No specific physiokinesis therapy was suggested to restart daily activities.

Clinical outcomes.

A systematic review conducted by Malagelada et al. [64] shows a mean increase of AOFAS score of 39,2 points (range 33,1-49,8), furthermore, the mean correction for HVA is 13,25° (range 8,6-17,1) and for IMA is 3,1° (range 0,9-5,2).

Complications.

Among minor complications related to this technique, the more common is the loss of normal range of MTP joint motion. The major complications include recurrence of HV and severe stiffness of MTP joint. Malagelada et al. [64] reported a rate of minor complications of 1% and major complications of 11%.

Endolog Technique

Endolog technique is a minimally invasive technique that shares with DMMOs and Riverdin-Isham procedure a decrease of recovery times, smaller scars and a greater range of early postoperative motion, but in this procedure intramedullary nail (the Endolog) it is required for fixation.

This technique is performed in case of moderate to severe HV, usually in association with Akin osteotomy at the proximal phalanx.

According to Mann and Coughlin parameters [44], [57], [58], if HVA is of 20° to 40° and IMA is of 11° to 16° HV is classified as Moderate, HV is defined Severe if HVA > 40° and IMA > 16°.

Historical note

The Endolog, produced since 2006 by Medical2, Castel nuovo del Garda, Verona, Italy, is a curved titanium endomedullary nail device (TA6V ELI - ASTMF 136), treated with anodic oxidation and laser marking [65]. The term Endolog was coined by its inventor Giuseppe Lodola with reference to the endomedullary component of the nail (Endo) and his own initials (Lo-G) [65].

Indications and contraindications

Endolog technique is recommended in case of HV from moderate to severe. [61], [64]

Planning

In the preoperative clinical evaluation are considered complete clinical history of the patients, their main characteristics (gender, age at the time of surgery, affected side) and physical examination of the foot. Also, standing antero-posterior, lateral X-ray views were routinely performed.

Although clinical and radiographic preoperative planning was useful for choosing which size of the implant could guarantee adequate translation of the head according to the severity of the HV and width of the I-MTT bone medullary cavity, it was not possible to standardize the exact lateral translation of the I-MTTH. Hence, trial nails in the different sizes were used intraoperatively.

Operative aspect

Equipment

The Endolog is available in three sizes (44, 45, and 46) with three different degrees of curvature (32°, 40°, and 42°) and three different lengths (26, 31, and 33 mm). It is fixed to the metatarsal head using a 3.66-mm titanium angular stable screw, available in three different lengths (15, 20, and 25 mm), which stabilizes the osteotomy sides and the translation of the metatarsal head. The complete kit of the device includes impactor blade for its application, trial nails for test during surgery, and burr to make the screw hole [66].

Prophylaxis

Prophylactic antibiotic (Cefazolin 2 g) was administered before surgery [65], [66].

Anaesthesia

The performed anaesthesia consists in a conscious sedation in association with a regional ankle block, which combines five nerves: three superficial: saphenous, sural and superficial peroneal nerves, and two deep: tibial and deep peroneal nerves.

Positioning during the operation

The patient was in a supine position, with the operated foot protruding from the table. A tourniquet was applied and left in place at the level of the ankle.

Surgical Technique [65]– [67]

- Portals: a 4 cm dorsal-medial longitudinal incision was made at a point corresponding to the exostosis of the first metatarsal, avoiding the dorsal digital branch of the medial cutaneous nerve, and the neurovascular bundle was protected appropriately. Then, the capsular incision was performed in a dorsal longitudinal orientation along the line of the skin incision. Capsular and ligamentous tissues were freed around the first metatarsal head dorsally and medially, and the bone was liberated from the periosteum.
- Exosteoctomy: using a standard oscillating saw in a distal to proximal direction, a very minimal, oblique exostosectomy was performed to remove the medial eminence and to produce a flat surface on the head in order to support the impactor's blade upon which the device was assembled. For a correct position of the device, perfect coplanarity and maximum adherence of the pallet support to the flat surface previously created on the metatarsal head is crucial. The oblique exostosectomy was carried out with a thickness

of no more than 2–4 mm from the distal part of the medial eminence, close to the articular surface, to zero at the level of the metatarsal neck, making a lateral translation of the head possible, pushed and maintained by the nail after its application, and correcting both the DMAA and the dislocated sesamoid apparatus due to pronation of the big toe during the following derotation of the metatarsal head. For this purpose, two 1.8-mm Kirschner wires, acting as joysticks, were inserted to allow the derotation of the metatarsal head during its lateral translation.

  - Implantation: a linear osteotomy, at times perpendicular to the proximal level of the neck and at times oblique in order to lengthen or to shorten the metatarsal, was performed. Once the trial Endolog device was assembled on the impactor, it was gently introduced into the medullary cavity with progressively lateral displacement of the head and contemporary derotation of the metatarsal head, using the K-wires like joysticks and correcting the DMAA and sesamoid subluxation.
  - Stabilisation: The correction attained was checked clinically and under fluoroscopy before the final device was applied. The correction and the implant were stabilized applying temporary 1.2-mm Kirschner wires through the holes of the device. The head was fixed to the implant with a screw long enough to provide angular stability. Once the wire was removed and before closing the capsule and suturing the skin with 2–0 reabsorbable stitches, it was necessary to regulate the medial angle of the metatarsal neck in order to prevent conflict of the bone with the soft tissues and skin.
- Bandage: A compression dressing and tape were applied to maintain a slight hypercorrection of the hallux; these were changed weekly. Finally, the duration of the surgery was recorded.

Postoperative protocol

- Day 0: patients were seen within 12 h, and the gauzes and tape compression dressing were changed. Antero-posterior and lateral X-rays of nonweight-bearing feet were taken before the patients were discharged.
- Day 1-10: thromboembolic prophylaxis (Natrium Enoxaparin: 4000 IU/day) and anti-edemigen therapy (Leucoselect, Lymphaselect and Bromelina: 1 cp/day) are recommended for 10 days, starting from the day of the surgery.
- Day 1-30: The patients were allowed to walk as much as they could tolerate the same evening after surgery at discharge, using a rigid flat-soled orthopaedic shoe for the following 30-day period.
- Day 7-30: all of the patients were seen once a week for a month. The first visit was 8 days after surgery. During the three weekly visits, the bandage was changed.
- Day 30: One month after surgical treatment, the bandage was totally removed, and antero-posterior and lateral X-rays of nonweight-bearing feet were taken.

Clinical outcomes

Systematic reviews in literature agreed reporting a mean increase of AOFAS socre of about 60 points, 63,56 points (range 56,8-66,1) in Malagelada et al. [64] and 59.9 (range 57,5-66.1) in Zaveri et al [61]. Concerning the angles correction, the mean HVA correction is between 15° and 17° (15° with a range of 13,9°-16,8° according to Malagelada [33] 17° (range 12,2° – 20,1°) reported in Zaveri et al. [61], and the mean IMA correction is between 7° and 8° (7,9 (range 5,9°-9,9° according to Malagelada [33] and 7,1° (range 5,9°-9,9°) in Zaveri [61].

Complications

Endolog technique shows an overall rate of complications from 4% to 7,5%, mostly minor [61], [66].

Among minor complication, recurrence occurs in 2,8% of operated feet; the infection of a superficial wound interests 2,5% of cases [61].

Removal of implant because of pain was required in 2,2% of cases, that is the only major complication reported [61].

PURPOSE OF THE STUDY

The aim of this prospective study is to analyse and compare the medium- to long-term clinical and radiographic results of patients with a diagnosis of ulcerative or preulcerative plantar lesion in diabetic patients underwent minimally invasive surgical treatment (DMMO) by percutaneous distal metatarsal osteotomies, performed at the Orthopaedic and Traumatology Clinic of the University of Padua.

The main purpose of this study is to evaluate the efficacy and clinical-functional results of this innovative technique in the treatment of CPDFUs in patients unresponsive to conservative medical therapy. Outcomes after surgery were considered, particularly in terms of functional recovery, residual disability, improved quality of life, absence of recurrence.

The secondary goals of the study are:

- The evaluation of the DMMO surgical technique: its reliability and reproducibility. Complications compared to traditional open techniques.
- The radiographic evaluation of the restoration of the metatarsal formula according to Maestro's criteria.

MATERIAL AND METHODS

Setting

The study took place in the department of the Orthopaedic and Traumatology Clinic of the University of Padua (70 beds), within the complex of the Azienda Ospedaliera di Padova, a first level centre that offers 1572 beds. The computerised database of the intra-hospital system Galileo and the MedStation imaging archiving programme was used. The medical records were examined at the general archive of the Azienda Ospedaliera. All patients were assessed at the last follow-up at the same institution.

Patients

Between January 2014 and December 2019, a consecutive series of diabetic patients, who had not responded to nonoperative treatment during at least a 6-month period for one or more neuropathic ulcerations under their metatarsal heads (second to fifth), except the first, or who presented a high risk of ulceration due to severe plantar hyperkeratosis area, were enrolled in this prospective cohort study at this institution. Each patient with CPDFU underwent a percutaneous operative procedure that was performed by the senior author, who followed and checked the patients personally during the postoperative period. Before surgery, all patients followed the same standardized nonoperative care protocol at our institution's multispecialty diabetic foot clinic. This involved previous preliminary educational section and, according to the lesion grade, daily topical medications and dressing, low-level periodic debridement and oral or intravenous antibiotic therapy (if infected and/or necrotic wounds), and use of pressure-relieving diabetic shoes or custom-made footwear.

All patients participating in this prospective study received a thorough explanation of the risks and benefits and gave their informed consent. This study was approved by the Institutional Ethics Committee and performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000 and those of Good Clinical Practice.

Seventy-one enrolled patients met the inclusion criteria, all patients underwent DMMO, performed by a single surgeon, C.B., trained in minimally invasive surgery (MIS), who followed and checked the patients personally during the postoperative period. However, eleven of them are deceased for reason not related to the surgery at the time of this study, so 60 patients were considered in the analysis.

There were 28 women and 32 men. The mean patient age at the time of the surgery was 66,10±9,42 (range, 40-80) years. A total of 55 of 60 patients had type 2 diabetes mellitus (DM) (21/60 treated with insulin, and 32/30 treated with only oral therapy), while 5 of 60 had type 1 DM (5/60 treated with insulin). The mean duration of their diabetes history at the time of the surgery was 24,05±8,15 (range, 4-45) years, and all patients presented with peripheral neuropathy. The mean value of hemoglobin A1c (HbA1c) was 7,1%±0,83% (range, 5.9%-8.4%). Mean follow- up was 48,73±11,62 (range, 29-76) months, and none of the patients was lost during the follow-up period. Regarding risk factors, the mean BMI was 27,87±4,01 (range 19,4-39,2), 26 of 60 (43,3%) patients were overweight, 20 of 60 (33,3%) patients were obese, and 19 (31,7%) patients were active smokers. Hence, according to the ASA (American Society of Anesthesiologists) classification for globally estimated surgical risk, there were, 32 ASA 2 patients (53,3%), and 26 ASA 3 patients (43,3%) and 2 ASA 4 patients (3,3%) (Table 2).

Table 2: Charateristics of the patients

Charateristics	Value
Age	66,10±9,42 (67,5)
Sex Male Female	 32 (53,3%) 28 (46,7%)
BMI >30	27,87±4,01 20 (33,33%)
Type of Diabetes Type 1 Type 2	 5 (8,3%) 55 (91,7%)
Duration of Diabetes (years)	24,05±8,15 (24,5)
Smoke No Yes	 41 (68,3%) 19 (31,7%)
ASA 2 3 4	 32 (53,3%) 26 (43,3%) 2 (3,3%)
Affected side Left Right Both left and right	 29 (48,3%) 29 (48,3%) 2 (3,3%)
Dominant side affected No Yes	 31 (51,7%) 29 (48,3%)

Inclusion and Exclusion Criteria

For the inclusion criteria of this study, patients had to present a unilateral, plantar CPDFU, under the heads between the second and fifth metatarsal bones that did not heal after at least 6 months of nonoperative treatment or with a plantar preulcerative lesion according to the University of Texas Diabetic Wound Classification System (UTDWC). Furthermore, they had to be diagnosed with DM for a duration of at least 4 years with HbA1c less than 8.5%. Every patient was followed-up for at least

24 months. Exclusion criteria were as follows: ulcer under the first metatarsal head, bilateral foot ulceration or associated diabetic toe ulcers, absent distal pulse on clinical examination, peripheral vascular disease associated with TcO2 on the dorsum of the foot less than 25 mm Hg, active infection as determined by abnormal blood parameters (alteration of C-reactive protein [CRP] >150 mg/L), or local signs of infection (cellulitis or suppuration). Furthermore, patients with a history of contralateral partial foot or leg amputation, foot trauma or foot and ankle surgery were excluded.

Preoperative Planning

Both clinical and radiological assessment were used for preoperative planning. The general aspect of diabetes and ulcerative or preuclerative lesions were evaluated: affect side, site of the lesion; the UTDWC, which takes into account the size and depth of the ulcer, as well as the presence or absence of infection and ischemia, was used to grade and preoperatively evaluate the lesions, while the size of the ulcers was determined as described by Coughlin et al using a transparent sheet at each clinical evaluation to determinate the ulcer’s diameter. The major axes of the wounds were measured manually from the areas of the ulcers.

Using these data, it was decided where the osteotomy should perform to rebalance plantar pressures and create a harmonious curve according to Maestro criteria, at the purpose to promote healing of lesions. The DMMO was carried out only on the metatarsal head causing lesions unless this shortening would make the neighbouring metatarsal too long, resulting in a disharmonious morphotype with a high risk of a transfer lesion. The adjacent metatarsal was also shortened in these cases.

In a second step, associated deformities, when present, were assessed and then corrected during the same operation. Surgical procedures on the first ray were performed according to our institutional protocol: HV correction by Reverdin-Isham percutaneous osteotomy for mild-moderate deformity, or Endolog technique for moderate-severe deformity, both generally followed by percutaneous Akin osteotomy. In addition, percutaneous lateral soft-tissue release and percutaneous tenotomy of extensor and/or flexor, in association with (or not) phalange percutaneous osteotomies, were tailored based on the lesser toe deformities, flexible or fixed.

Operative technique

Minimally invasive DMDO. During the operation, the patient was in a supine position and adequately anesthetized by a regional ankle block, with the operated foot protruding from the table. No tourniquet was required for this technique, and more important, it was not indicated in this diabetic lower limb surgery. The surgery was performed after administration of a prophylactic antibiotic (cefazolin: 2 g) and under image intensifier guidance. An incision of 5 mm was made parallel to the extensor tendons at the dorsal side of the medial (or lateral) border of each metatarsal head that needed to be shortened. The side of the incision depended on the surgeon being right- or left-handed and which foot was being operated on. The scalpel was advanced at an oblique angle of about 45 degrees until it reached the dorsal aspect of the distal metatarsal bone, proximal to the neck, to undergo osteotomy. Through the same incision, first a bone rasp specific for percutaneous surgery was inserted, using it to separate the periosteum at the level of osteotomy. Then, a Shannon Isham burr (2.0 × 12 mm), adapted for Mm960 (produced by MedicMicro, Sainte-Croix, Switzerland), was introduced until it reached the metatarsal neck and then retracted a few millimetres proximally where the periosteum was previously removed. Fluoroscopy was used to confirm the correct position of the osteotomy site on the distal diaphysis of the metatarsal bone. In this position, the cutting was started with an angle of approximately 45 degrees with respect to the long axis of the metatarsal bone in a dorsal-distal to proximal-plantar direction, with rotary motion, extending to the contralateral cortex. In this way, the lateral cortical surface was cut first, then the plantar and medial surface, and, last, the dorsal cortical surface. During the osteotomy process, the incision site was irrigated by normal saline as the burr can cause excessive heat, causing a skin burn resulting in a nonhealing wound or in fibrosis and/or pseudoarthrosis of the osteotomy. Furthermore, this lavage was useful to remove bone debris, preventing periarticular ossifications. Upon completion of the osteotomy, the bone was manually

compacted, exerting pressure in the distal-proximal direction of the metatarsal, pushing the metatarsal head dorsally and producing contact of the trabecular bone, since no internal fixation was performed.

After accurate ulcer debridement, a chronic ulcer was converted into an acute wound, permitting the normal stages of healing to ensue, while the rest of the wounds were closed with absorbable sutures.

Bandage. A bandage soaked in saline solution was applied. Because there is no osteosynthesis material in this surgery, the bandage is a very important tool to maintain the correction obtained after the operation. With a tape for bandages, the bend of the crisscross bandage was then traced between all inter-metatarsal spaces, crossing them over the medial (lateral) aspect of the number of osteotomies performed (depending on the foot side) to reinforce the strength of the bandage. Gentle traction was used to maintain the toe in slight plantar inclination. Finally, the forefoot was covered with tubular gauzes, except for the distal part of the toes and nails.

Postoperative Protocol

All patients followed the same postoperative protocol previously described. The patients were allowed to walk as much as they could tolerate the day after surgery using a rigid flat-soled orthopaedic shoe for the following 30-day period. This aspect is very important as metatarsal length was set automatically upon weightbearing. Anteroposterior and lateral x-rays of nonweightbearing feet were taken before the patients were discharged. We recommended antibiotic oral prophylaxis for a week, as well as thromboembolic prophylaxis (natrium enoxaparin: 4.000 IU/d) and an antiedema therapy (Leucoselect, Lymphaselect, and Bromelina: 1 tablet/d) for 30 days, starting from the day of the surgery. Moreover, analgesic therapy was prescribed for 2 weeks of etoricoxib (60 mg, 1 cp/d) in the morning, also to prevent heterotopic ossification when the comorbidities of the patient permitted, or alternatively paracetamol (1 g, 1 tablet ×2/d).

Each patient was seen once a week for a month in our outpatient clinic. The first visit was 8 days after surgery. The original bandage was removed and replaced with a simpler bandage. At the next 3 weekly visits, the bandage was changed in the same way. One month after operative treatment, if the ulcer was completely closed, the bandage was totally removed, and after taking anteroposterior weightbearing and lateral x-rays, the patient was then able to walk with comfortable shoes, allowing full weight on the operated foot. If the ulcer was not completely healed, the patient was seen every week until total lesion closure. After healing, the only recommendations for the patient were to be careful with rough surfaces, sports, and any other activities with forefoot overload. No specific physical therapy was suggested.

Patient assessment

The clinical and radiological analyses were carried out by the junior author (L.S.), not involved in the operative treatment of the patients. Each patient underwent radiographic assessment with the same protocol before surgery, as well as at 1, 3, and 6 months and at final follow-up, according to the American Orthopaedic Foot and Ankle Society (AOFAS) accepted guidelines and based on the criteria of Maestro et al.

Clinical Functional Outcome Measures.

The clinical preoperative evaluation included a complete clinical history of the patients, their main characteristics (age, gender, BMI, dominant side, smoking and anaesthesia ASA class), and physical examination of the foot for preoperative planning, as well as the percutaneous procedures to perform (number of metatarsals to treat). To evaluate clinical outcomes at the preoperative period and last follow-up (FU), the following and most used questionnaires for forefoot assessment were used according to our study protocol:

- The European Foot and Ankle Society (EFAS) score [68] composed by six questions, was used to measure foot covers pain and physical function, in its Italian version (Figures 7)
- The Foot Functional Index (17-FFI) [69], [70] in its Italian version to measure the persistence of pain, disability, and restriction of activity with 17 number rating scales from 0 to 10 (Figure 8);
- The Manchester-Oxford Foot Questionnaire (MOXFQ) [69] to establish how frequent the restrictions in specific situations were, including 16 questions divided into three basic domains: pain (five), walking/standing (seven), and social interaction (four) (Figure 9);
- The Short Form 36 (SF-36) [71], in its Italian version, composed by 36 items, 35 of which are used in the calculation of 8 separate scale scores. The physical functioning scale (10 items) is the longest scale. The general health and mental health scales have 5 items each, and the vitality and role physical scales have 4 items each. The role emotional scale has 3 items, and the bodily pain and social functioning scales have 2 items each. The remaining item of the SF-36 is a health transition question that asks about a change in general health over the past 12 months (Figure 10).
- The Visual Analog Scale (VAS) to quantify patient satisfaction with a score from 0 to 10.

Each questionnaire was submitted before the surgical and at the last follow-up and the difference of median values (Δ) between preoperative and the last evaluation was calculated, with the exception of the SF-36 and ASA, that were only submitted at the last evaluation.

Additionally, any complications were recorded.

No.	Domanda	Risposta
1 N/A ◯	Ha dolore quando è a riposo?	Sempre 0 · quasi sempre 1 · talvolta 2 · quasi mai 3 · Mai 4
2 N/A ◯	Quanto riesce a camminare prima di provare dolore?	Impossibile 0 · poco 1 · abbastanza 2 · tanto 3 · Nessuna limitazione 4
3 N/A ◯	Quanto le è cambiato il di camminare a causa del suo problema al piede e/o caviglia?	Cambiamento Estremo 0 · tanto 1 · abbastanza 2 · poco 3 · Nessuno cambiamento 4
4 N/A ◯	Ha difficoltà a camminare sulle superfici non-livellate (sconnesse)?	Sempre 0 · quasi sempre 1 · talvolta 2 · quasi mai 3 · Mai 4
5 N/A ◯	Ha dolore mentre cammina?	Sempre 0 · quasi sempre 1 · talvolta 2 · quasi mai 3 · Mai 4
6 N/A ◯	Quante volte ha dolore durante l'attività fisica?	Sempre 0 · quasi sempre 1 2 · talvolta 3 · quasi mai 4 · Mai

Figure 12: EFAS score

DATA: ________________

NOME ______________________________ COGNOME ______________________________

Questo test è stato ideato per fornire al suo curante informazioni riguardo il modo in cui il dolore al piede ha influenzato la sua capacità di gestire le attività di vita quotidiana. La preghiamo di rispondere ad ogni domanda, assegnando a ciascuna di esse un punteggio da 0 a 10. Il punteggio 0 corrisponde a "nessun dolore" o "nessuna difficoltà" o "mai". Il punteggio 10 corrisponde al "peggior dolore immaginabile o "una difficoltà tale da dover chiedere aiuto" o "sempre".
Il punteggio totalizzato descrive lo stato di salute del suo piede durante la scorsa settimana. Si prega di leggere ogni domanda e di inserire un segno lungo la linea.

QUANTO E' STATO SEVERO IL DOLORE AL PIEDE?

ESEMPIO: Nell'ultima settimana quanto dolore ha avuto?
NESSUN DOLORE ——————✖—————— IL PEGGIOR DOLORE IMMAGINABILE
0 1 2 3 4 5 6 7 8 9 10

1. **Al momento della massima intensità?** 0 1 2 3 4 5 6 7 8 9 10
2. **All'inizio della mattina?** 0 1 2 3 4 5 6 7 8 9 10
3. **Quando stava in piedi?** 0 1 2 3 4 5 6 7 8 9 10
4. **Quando camminava?** 0 1 2 3 4 5 6 7 8 9 10
5. **Alla fine della giornata?** 0 1 2 3 4 5 6 7 8 9 10

QUANTA DIFFICOLTA' HA AVUTO:

ESEMPIO: Quando cammina in casa?
NESSUNA DIFFICOLTA' ————✖———————— DIFFICOLTÀ TALE DA DOVER CHIEDERE AIUTO
0 1 2 3 4 5 6 7 8 9 10

6. **Quando camminava in casa?** 0 1 2 3 4 5 6 7 8 9 10
7. **Quando camminava all'aperto?** 0 1 2 3 4 5 6 7 8 9 10
8. **Quando camminava per 500 m?** 0 1 2 3 4 5 6 7 8 9 10
9. **Quando saliva le scale?** 0 1 2 3 4 5 6 7 8 9 10
10. **Quando scendeva le scale?** 0 1 2 3 4 5 6 7 8 9 10
11. **Quando stava in piedi?** 0 1 2 3 4 5 6 7 8 9 10
12. **Quando si rialzava da una sedia?** 0 1 2 3 4 5 6 7 8 9 10
13. **Quando superava un ostacolo di 20 cm?** 0 1 2 3 4 5 6 7 8 9 10
14. **Quando correva o camminava velocemente?** 0 1 2 3 4 5 6 7 8 9 10

PER QUANTO TEMPO LEI HA...

ESEMPIO: Limitato le sue attività
MAI ——————✖———— SEMPRE
0 1 2 3 4 5 6 7 8 9 10

15. **Usato un ausilio (bastone, deambulatore, stampelle, ecc.) in casa** 0 1 2 3 4 5 6 7 8 9 10
16. **Usato un ausilio (bastone, deambulatore, stampelle, ecc.) all'aperto?** 0 1 2 3 4 5 6 7 8 9 10
17. **Limitato le sue attività?** 0 1 2 3 4 5 6 7 8 9 10

Sezione 3: Compilata dal curante
PUNTEGGIO TOTALE: __ /170 x 100= ___%

Figure 13: FFI-17

Circle as appropriate: RIGHT / LEFT ***<u>During the past 4 weeks</u> this has applied to me:***	*Please tick ✓ one box for each statement*				
	None of the time	**Rarely**	**Some of the time**	**Most of the time**	**All of the time**
1. I have pain in my foot/ankle	❑	❑	❑	❑	❑
2. I avoid walking long distances because of pain in my foot/ankle	❑	❑	❑	❑	❑
3. I change the way I walk due to pain in my foot/ankle	❑	❑	❑	❑	❑
4. I walk slowly because of pain in my foot/ankle	❑	❑	❑	❑	❑
5. I have to stop and rest my foot/ankle because of pain	❑	❑	❑	❑	❑
6. I avoid some hard or rough surfaces because of pain in my foot/ankle	❑	❑	❑	❑	❑
7. I avoid standing for a long time because of pain in my foot/ankle	❑	❑	❑	❑	❑
8. I catch the bus or use the car instead of walking, because of pain in my foot/ankle	❑	❑	❑	❑	❑
9. I feel self-conscious about my foot/ankle	❑	❑	❑	❑	❑
10. I feel self-conscious about the shoes I have to wear	❑	❑	❑	❑	❑

<u>During the past 4 weeks</u> this has applied to me:	*Please tick ✓ one box for each statement* None of the time	Rarely	Some of the time	Most of the time	All of the time
11. The pain in my foot/ankle is more painful in the evening	❑	❑	❑	❑	❑
12. I get shooting pains in my foot/ankle	❑	❑	❑	❑	❑
13. The pain in my foot/ankle prevents me from carrying out my work/everyday activities	❑	❑	❑	❑	❑
14. I am <u>un</u>able to do all my social or recreational activities because of pain in my foot/ankle	❑	❑	❑	❑	❑

15. During the past 4 weeks how would you describe the pain you <u>usually</u> have in your foot/ankle? *(please tick one box)*

None	Very mild	Mild	Moderate	Severe
❑	❑	❑	❑	❑

16. During the past 4 weeks have you been troubled by <u>pain from your foot/ankle</u> in bed at night? *(please tick one box)*

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
❑	❑	❑	❑	❑

Figure 14: MOXFQ score

<u>During the past 4 weeks</u> this has applied to me:	*Please tick ✓ one box for each statement*				
	None of the time	**Rarely**	**Some of the time**	**Most of the time**	**All of the time**
11. The pain in my foot/ankle is more painful in the evening	❑	❑	❑	❑	❑
12. I get shooting pains in my foot/ankle	❑	❑	❑	❑	❑
13. The pain in my foot/ankle prevents me from carrying out my work/everyday activities	❑	❑	❑	❑	❑
14. I am <u>un</u>able to do all my social or recreational activities because of pain in my foot/ankle	❑	❑	❑	❑	❑

15. During the past 4 weeks how would you describe the pain you <u>usually</u> have in your foot/ankle? *(please tick one box)*

None	Very mild	Mild	Moderate	Severe
❑	❑	❑	❑	❑

16. During the past 4 weeks have you been troubled by <u>pain from your foot/ankle</u> in bed at night? *(please tick one box)*

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
❑	❑	❑	❑	❑

***During the past 4 weeks** this has applied to me:*	*Please tick ✓ one box for each statement*				
	None of the time	**Rarely**	**Some of the time**	**Most of the time**	**All of the time**
11. The pain in my foot/ankle is more painful in the evening	❑	❑	❑	❑	❑
12. I get shooting pains in my foot/ankle	❑	❑	❑	❑	❑
13. The pain in my foot/ankle prevents me from carrying out my work/everyday activities	❑	❑	❑	❑	❑
14. I am unable to do all my social or recreational activities because of pain in my foot/ankle	❑	❑	❑	❑	❑

15. During the past 4 weeks how would you describe the pain you usually have in your foot/ankle? *(please tick one box)*

None	Very mild	Mild	Moderate	Severe
❑	❑	❑	❑	❑

16. During the past 4 weeks have you been troubled by pain from your foot/ankle in bed at night? *(please tick one box)*

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
❑	❑	❑	❑	❑

During the past 4 weeks ***this has applied to me:***	*Please tick ✓ one box for each statement*				
	None of the time	**Rarely**	**Some of the time**	**Most of the time**	**All of the time**
11. The pain in my foot/ankle is more painful in the evening	❑	❑	❑	❑	❑
12. I get shooting pains in my foot/ankle	❑	❑	❑	❑	❑
13. The pain in my foot/ankle prevents me from carrying out my work/everyday activities	❑	❑	❑	❑	❑
14. I am unable to do all my social or recreational activities because of pain in my foot/ankle	❑	❑	❑	❑	❑

15. During the past 4 weeks how would you describe the pain you usually have in your foot/ankle? *(please tick one box)*

None	Very mild	Mild	Moderate	Severe
❑	❑	❑	❑	❑

16. During the past 4 weeks have you been troubled by pain from your foot/ankle in bed at night? *(please tick one box)*

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
❑	❑	❑	❑	❑

Figure 15: SF-36 scale

Radiographical Outcomes

Radiographically, routine standing anteroposterior x-ray views were obtained before surgery and at different follow-ups, according to our protocol. For methodological reasons, the immediate postoperative x-ray at discharge was not included for the radiographic evaluation because it was a nonweightbearing radiograph. The radiographic evaluations included the M1M2 index and Maestro 1 (M1), Maestro 2 (M2), and Maestro 3 (M3), according to criteria by Maestro et al, using the preoperative and the last follow-up x-rays (Figure 10). This index quantifies the levels of disorders of harmony of the forefoot and the metatarsal length, which can cause metatarsalgia and skin lesions. Finally, callus formation in anteroposterior and lateral view radiographs and the absence of radiolucent lines were checked to determine bone union.

Figure 16: Exemple of misurement of Maestro Criteria

Statistical analysis.

Before proceeding with statistical analysis, data were visually inspected for capturing potential outliers and data normality distribution was verified by means of Shapiro-Wilks test. This test was preferred over other normality tests, given the small sample size employed in our study. Descriptive statistical analyses were carried out, by computing means, standard deviations (SD) and, when appropriate, medians for continuous variables. Categorical variables were expressed as absolute counts and percentages. Pre- versus post (LFU) mean differences were assessed through Wilcoxon's test for paired samples and expressed as Hodges-Lehmann differences (together with their 95% confidence interval). A cut-off of p-value equal to or less than 0.05 was chosen as the threshold for statistical significance. All analyses were carried out by means of the commercial software "Statistical Package for Social Sciences" (SPSS for Windows, version 28, IBM, Armonk, NY, USA).

RESULTS

Patients

During a five years periods, 60 diabetic patients with preulcerative or ulcerative lesions were treated by DMMO in our institution. Two of them was operated bilaterally at the same time (total 62 feet).

Table 3: Charateristis of ulcers according to UTDWCS

UTDWCS	
0 A	12 (20,0%)
0 B	7 (11,7%)
0 C	17 (28,3%)
0 D	2 (3,3%)
II A	2 (3,3%)
II B	2 (3,3%)
III A	1 (1,7%)
III B	12 (20,0%)
III C	2 (3,3%)
III D	3 (5,0%)

CDPFUs had been diagnosed in 22 of 62 (35,5%) feet. The mean duration of the CPDFUs at the time of surgery was 10,27±3,24 (range, 6-18) months. Before DMDO, plantar ulcers had a mean diameter of 1,57±0,66 (range, 0,5-2,5) cm. According to the UTDWC, there were 2 of 22 of grade IIA, 2 of 22 of grade IIB, 1 of 22 of grade IIIA, 10 of 22 (45,45%) of grade IIIB, 2 of 22 of grade IIIC, and 3 of 22 of grade IIID.

The remaining 40 of 62 (64,5%) feet were affected by preulcerative lesions with high risk to progress in CPDFU due to sever plantar hyperkeratosis area, classified according to the UTDWC too: there were 13 of 40 (30%) of grade 0A, 7 of 40 of grade 0B, 18 of 40 (42,5%) of grade 0C, and 2 of 40 of grade 0D (Table 3).

During the 62 operations, 162 DMDO procedures were performed to treat 22 CDPUs and 40 preulcerative lesions in a total amount of 62 feet as follows: 46 involving the second, 46 the third, 39 the fourth, and 31 the fifth metatarsals. Single osteotomies were performed in 12 of 62 feet (19,4%), among them 3 were localised on M2, 1 on M3 and 8 on M5; multiple osteotomies were carried on 50 of 62

(80,6%) feet as follow: 17 of 62 were performed on two MTT bones (11 involving M2-M3, 1 M2-M5, 2 M3-M and 3 M4-M5); 16 of 62 were localised on three metatarsals (14 on M2-M3-M4 and 2 on M3-M4-M5) and least 17 of 62 were involved all minor metatarsals bones (M2-M3-M4-M5) (Table 4-5). In 24 (38,7%) of the 62 feet, associated procedures were performed tailored to patient's clinical presentation. Reverdin-Isham percutaneous osteotomy was performed in 7 feet for the correction of mild-moderate HV deformities and Endolog technique in 17 feet for moderate-severe ones, followed by percutaneous Akin osteotomy and percutaneous lateral soft-tissue release in some cases, according to our protocol. Further, we carried out flexor and extensor tenotomies in 18 feet for the correction of clawtoe flexible deformities and associated osteotomies of the proximal phalange in 8 feet for the correction of fixed ones. In 29 cases (48,3%), the dominant limb was affected, while the nondominant limb was affected in 31 cases (51,7%).

Table 4: Number of osteotomies for single MTT

MMT	total		neck		head		right		left	
II	46	28%	6	24%	40	29%	22	30%	24	27%
III	46	28%	7	28%	39	28%	22	30%	24	27%
IV	39	24%	7	28%	32	23%	18	24%	21	24%
V	31	19,00%	5	20,00%	26	19,00%	12	16,00%	19	22,00%
Tot	162	100,00%	25	100,00%	137	100,00%	74	100,00%	88	100,00%

Table 5 Number of Osteotomy for combinations of MTT

II MTT	3
III MTT	1
V MTT	8
II - III MTT	11
II - V MTT	1
III - IV MTT	2
IV - V MTT	3
II-III-IV MTT	14
II-III-V MTT	2
II-III-IV-V MTT	17

All patients were considered healed at the final followup for lesion resolution. Their mean healing time was 8,46±4,19 (range, 4-17) weeks. As for the UTDWC grade II ulcers required 4 weeks to close completely, while grade III ulcers took 9,45±4.0 (range, 4-17) weeks. With respect to their dimensions, ulcers with a diameter 1.5 cm or less required 7,46±4,5 (range, 4-17) weeks to heal, while ulcers with a diameter more than 1.5 cm required 9.89±3,4 (range, 4-16) weeks.

Clinical Functional Outcomes

At the preoperative evaluation, the mean EFAS score of the patients was 7,42±4,14 (range 1 to 16) points, while it was 14,98±4,36 (range 1 to 20) points at last FU. Hence, in our cohort, the EFAS score improved significantly after surgery with respect to the preoperative value ($p < 0.0001$) (Table 6) (Figure 12). The mean preoperative 17-FFI was 39,23±17,75 (range 8 to 75,9) points, while the average at last FU was 14,85±15,01 (range 1 to 65,9) points (Table 7) (Figure 13). Hence, also the 17-FFI improved after surgery with respect to the preoperative value ($p < 0.0001$), however, neuropathy must be taken into account when considering this data. The mean MOXFQ Pain, -Walking, and -Social preoperative scores were 53,33±18,63 (range 10 to 90) points, 53,42±14,90 (range 0 to 75) points, and 48,30±9,10 (range 31,2 to 68,2) points, respectively, while their mean values at last FU were 21,92±14,38 (range 0 to 75) points, 20,75±14,13 (range 0 to 82,1) points, and 41,88±9,35 (range 25 to 62,5) points, respectively (Table 8) (Figure 14-16). It means that all MOXFQ parameters improve significantly ($p<0,0001$). The eight components of the SF-36 (Physical functioning, Role limitations due to physical health, Role limitations due to emotional problems, Energy/fatigue, Emotional well-being, Social functioning, Pain, General Health) had, respectively, an average of 70,75±24,28 (range 10 to 100) points, 76,83±32,02 (range 0 to 100) points, 67,64±31,03 (range 0 to 100) points, 59,92±23,42 (range 5 to 100) points, 67,87±20,00 (range 20 to 100) points, 66,25±33,77 (range 0 to 100) points, 57,92±32,15 (range 0 to 100) points and 57,62±20,92 (range 0 to 87,5) point at the last FU. The mean VAS for satisfaction score was 9,03±1,22 (range, 5 to 10) points at last FU.

Table 6: EFAS score pre-operative and at Last Follow-Up (LFU)

EFAS	EFAS PRE	EFAS LFU
value	7,42±4,14 (6,5)	14,98±4,36 (15)

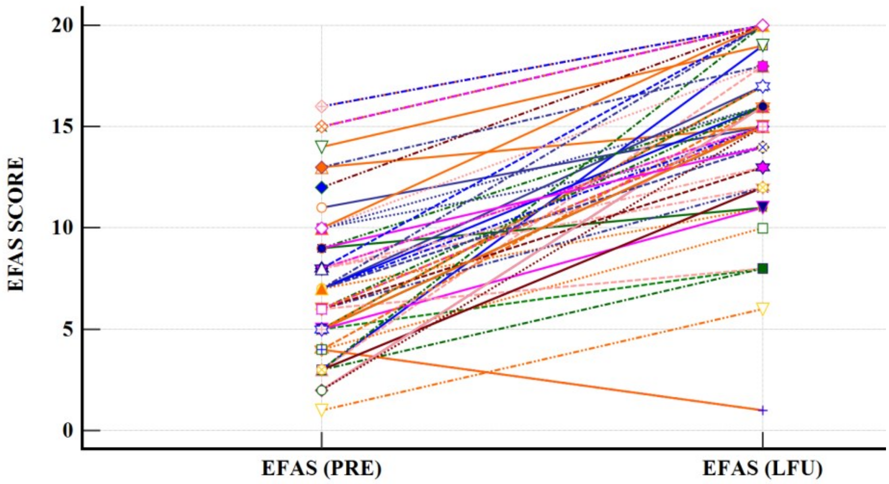

Figure 17: EFAS score pre-operative and at Last Follow-Up (LFU) trend

Table 7: FFI-17 score pre-operative and at the Last Follow-Up (LFU)

FFI-17	FFI-17 PRE	FFI-17 LFU
value	39,23±17,75 (41)	14,85±15,01 (10)

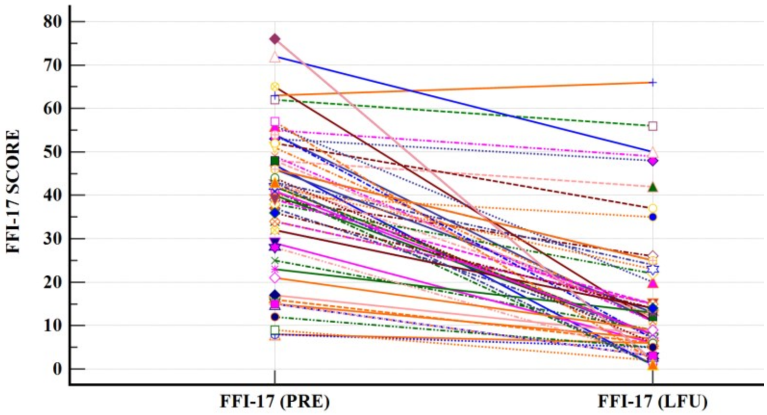

Figure 18: FFI-17 score pre-operative and at Last Follow-Up (LFU) trend

Table 8: MOXFQ score pre-operative and at the Last Follow-Up (LFU)

MOXFQ		
Foot pain	**Foot pain PRE**	**Foot pain LFU**
Value	53,33±18,63 (55,0)	21,92±14,38 (20,0)
Walking standing	**Walking standing PRE**	**Walking standing LU**
value	53,42±14,90 (56,5)	20,75±14,13 (19,5)
Social interactions	**Social interactions PRE**	**Social interactions LFU**
Value	48,30±9,10 (48,0)	41,88±9,35 (43,0)

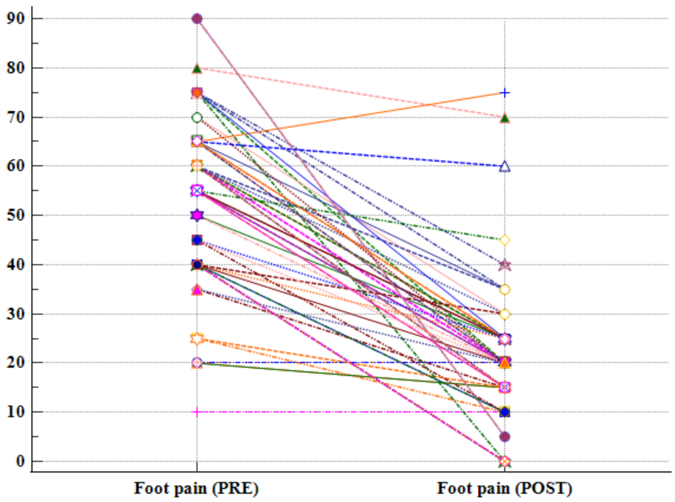

Figure 19: MOXFQ for Foot Pain score pre-operative and at Last Follow-Up (LFU) trend

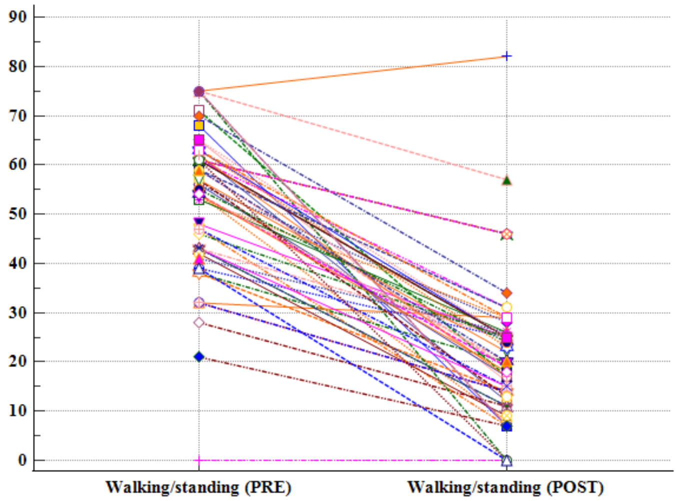

Figure 20 MOXFQ for Walking/Standing score pre-operative and at Last Follow-Up (LFU) trend

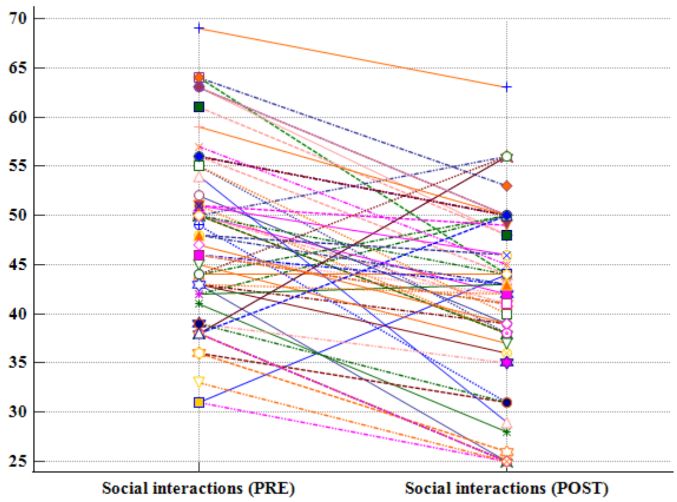

Figure 21: MOXFQ for Social Interactions score pre-operative and at Last Follow-Up (LFU) trend

Table 9: Results of SF-36

SF-36		
Category	**Mean**	**SD**
Emotional well-being	67,87	20,00
Energy/fatigue	59,92	23,42
Physical functioning	70,75	24,28
Social functioning	66,25	33,77
Role limitations due to emotional problems	67,64	31,03
Role limitations due to physical health	76,83	32,02
Pain	57,92	32,15
General Health	57,62	20,92

Radiographic Outcomes

At the last follow-up, all feet presented signs of definitive bone consolidation, including Akin osteotomies when performed. According to Maestro et al criteria, the M1M2 index was -5,73±4,75 (range, −18,75 to 11,7) mm before surgery and -3,66±4,39 (range, –15.5 to 15.3) mm at last follow-up. Furthermore, Maestro 1, Maestro 2, and Maestro 3 changed at the last follow-up with respect to the preoperative period (Table 10). However, all parameters of Maestro et al criteria were only slight significantly different at the last follow-up compared to the preoperative period (P < .05), that confirm the absence of predictive value [46] in this score.

Table 10: Maestro criteria at pre-operative and post-operative time

Maestro Criteria Evaluation		
M1M2 index	**M1M2 index PRE**	**M1M2 index POST**
value	-5,73±4,75 (-5,6)	-3,66±4,39 (-4,1)
Criterion 1	**Criterion 1 PRE**	**Criterion 1 POST**
value	5,45±4,35 (4,7)	4,28±2,91 (4,8)
Criterion 2	**Criterion 2 PRE**	**Criterion 2 POST**
value	6,51±4,27 (7,2)	5,48±3,26 (5,5)
Criterion 3	**Criterion 3 PRE**	**Criterion 3 POST**
value	12,37±3,79 (13)	10,73±4,82 (10,7)

Complications

Thirty-seven complications were recorded in 36 patients.

Major complications occurred in only 1 patient because of wound infection by Streptococcus agalactiae. He was 73-year-old man with a 20-year DM history and a history of insulin therapy, neuropathy, and vascular disease, presenting a grade IIIB ulcer. He recovered in 17 weeks after intravenous antibiotic therapy. Furthermore, persistent moderate swelling of the forefoot for more than 6 weeks without infection was noted in 32 of 62 feet, which improved after some months with complete callus formation at the osteotomy levels and without further treatment, and in 4 of 62 feet transfer ulcers occurred. Finally, no cases of healing failure, or recurrence were encountered at last follow-up. No cases of wound infection or wound breakdown, metatarsal bone osteomyelitis, or acute Charcot osteoarthropathy were found. No cases of malunion, delayed union, or nonunion were recorded. There were no cases of thromboembolism, avascular necrosis, or displacement of the metatarsal head.

DISCUSSION

Diabetic foot syndrome (DFS) is a major complication of diabetes mellitus. Its occurrence is not uncommon at the stage of initial diagnosis of diabetes mellitus type 2. It has been estimated that approximately 25% of hospitalizations are directly related to foot problems, which are responsible for nearly 50% of the hospital bed days caused by diabetes, while the lifetime risk of developing diabetic foot ulcers (DFUs) is estimated around 19–34%.8 More than half of these lesions become infected, and approximately 15% to 20% of them lead to some level of amputation.

In this context, the purpose of our study was to test the application of percutaneous

distal metatarsal osteotomy for the treatment of CPDFUs, representing a valid opportunity for the improvement of diabetic patients' outcomes.

In this percutaneous technique, osteotomy fixation by pinning or any other internal hardware is not indicated because of the high risk of infection in diabetic patients.

Even though we did not use them, a single case of deep infection occurred in our series. Nevertheless, it was successfully resolved by hospitalization with intravenous antibiotic therapy. Transfer lesions were reported in 7% of patients while a metanalysis reported a 17.4% rate of transfer lesion [52], no cases of osteotomy nonunion were recorded, while literature [52] reported a 16.9% rate of nonunion, and no evidence of metatarsal head avascular necrosis was found. There was no case of acute Charcot disease, no transfer or recurrent lesions were observed at last followup, and in most cases, the normal arch of the foot was restored. These are good short-medium term outcomes, although it is possible that with a longer follow-up and a larger patient group, secondary transfer pressure lesions could raise, increasing the number of complications.

In our cohort, the mean CPDFU healing time was 8,46±4,19 (range, 4-17), which was directly influenced by the diameter and degree of the ulcers. Ulcers with a diameter of more than 1.5 cm took longer to heal compared to smaller ones while grade I and II ulcers took less time to heal than those of grade III. However, despite the dimensions and the UTDWC grade of the ulcers, at the medium follow-up of 48,73±11,62 months they were all heal.

All the clinical parameters using for subjective evaluations for the patients' life quality (EFAS, FFI-16, MOxFQ) improved at the last follow-up comparing to the preoperative values and the VAS for satisfaction show a high level of enjoyment concerning the surgery. Because of it was only partially validated [72], AOFAS score was not used in this study and was replaced by EFAS score. Given the patients' neuropathy and their altered pain sensitivity, the VAS for pain was not considered adequate and not take in account for this study.

However, the aim of DMDO was not only to reduce pressure caused by the single collapsed metatarsal bone on the related ulcer but also to restore a harmonic balanced forefoot arch as much possible by operating also on the adjacent bones to prevent the risk of transfer lesions.

Plantar metatarsal ulcers due to pressure under the metatarsal heads, similar to the painful hyperkeratotic areas of metatarsalgia in nondiabetic patients, were initially hypothesized to be lesions caused by overactivity of both the long extensor and long flexor [73]. However, some authors [38], [74] believe this muscle imbalance is not the major causative factor and that the progressive collapse of the transverse axis of the foot, with consequent depression of the metatarsal heads, distal migration of the metatarsal fat pad, and increase in the local pressure, seems to be implicated in recalcitrant ulcer pathogenesis. By percutaneous osteotomies, modifying the position of the metatarsal heads to a mild dorsally translated position, it is possible first to achieve a better distribution of plantar pressure on the metatarsal bone, resulting in a decrease of the load under the ulcer and in a promotion of its healing [75], [76], and, second, to restore the original harmonic distal parabola of the forefoot or create a new balanced forefoot arch. According to the Maestro et al [45] criteria, our series showed changes in the average values. These results are probably due to the percutaneous floating osteotomies, which permit the retraction and dorsiflexion of the metatarsal heads. In this way, adapting to the load, the metatarsal heads ossify in a new dorsal position. However, changing in the Maestro criteria seems not related to the clinical outcomes.

The main limitation of this preliminary report was, to our knowledge, the absence in literature of studies that applied to diabetic patients the same quality-of-life score used in this study. Furthermore, as there is no specific method for the evaluation of metatarsal diabetic ulcers, some clinical aspects may have been overlooked. Consequently, the application of a specific clinical score to assess diabetic foot problems would increase the validity of this study.

Another weakness is the lack of a control group, which would be useful to compare the results of this percutaneous technique. However, all of our patients had previous nonoperative management of the ulcer for at least 6 months that was not effective. Finally, we lacked plantar pressure measurements.

CONCLUSIONS

In conclusion, the present study showed that minimally invasive DMDO, sometimes combined with percutaneous extensor and flexor tenotomies in cases of claw toe deformity and percutaneous Akin osteotomy for interphalangeal HV, was a safe and effective method in successfully promoting ulcer healing in diabetic patients with CDPFUs under the heads of lateral metatarsal bones (second to fifth), regardless of their UTDWC grade severity and dimensions.

We believe the most important aspects of this method was the reduction of the previous high plantar pressure by restoration of a harmonic balanced forefoot arch. Finally, this minimally invasive modified technique, performed under ankle block with minimal surgical scars and absence of osteosynthesis, improved functional and radiographic outcomes of our diabetic patients with few complications at short- to medium-term follow-up.

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