Ulcer Recurrence Following First Ray Amputation in Diabetic Patients

A cohort prospective study

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OBJECTIVE — to evaluate the reulceration and reamputation rates in a cohort of diabetic patients following first ray amputation.

RESEARCH DESIGN AND METHODS — We evaluated a cohort of 89 diabetic patients, 63 men and 26 women, who underwent first ray amputation in the period from January 2000 to December 2001. The first ray lesions were Wagner grade 2 in 3 patients, Wagner grade 3 in 47 patients, and Wagner grade 4 in 39 patients. Following surgical wound healing, all patients wore special footwear with rocker bottom soles and custom molded insoles and were put on an intensive secondary prevention program.

RESULTS — The mean follow-up duration was 16.35 ± 6.76 months (range 7–28). Fifteen patients developed new ulcerations, with 11 lesions occurring ipsilaterally and 4 contralaterally to the first ray amputation. In seven patients, the new lesion was treated and healed with dressing. Eight patients underwent a new surgical procedure: panmetatarsal head resection in four patients, toe amputation in two patients, a transmetatarsal amputation in one patient, and Lisfranc's amputation in one patient.

CONCLUSIONS — In the population studied, the first ray amputation presented a lower reulceration and reamputation rate with respect to that reported in the literature. This finding should therefore be attributed to the follow-up program, which uses shoes with a rocker bottom sole and custom molded insoles and intensive ambulatory check-ups.

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In diabetic subjects, reulcerations following first ray amputations are particularly frequent (1,2). Recently, Murdoch et al. (3) has stated how the natural history of first ray amputation is characterized by a reulceration and consequent reamputation rate of 60% at 10 months' follow-up; the number of patients undergoing above ankle amputation (17%) was particularly relevant in their study. No clear indication regarding the amputation level currently exists in the literature, and some authors indicate that a transmetatarsal amputation (TMA) could be the optimum amputation level when the first ray has to be amputated (4–9). The aim of our study is to evaluate reulceration and reamputation rates in a cohort of diabetic patients who underwent first ray amputation and subsequent intensive ambulatory follow-up, as well as the institution of shoes with a rocker bottom sole and custom molded multilayered insoles.

RESEARCH DESIGN AND METHODS

— From January 2000 to December 2001, 89 diabetic patients requiring a first ray amputation were admitted to two centers specialized in the treatment of the diabetic foot.

We define a first ray amputation as an amputation of the phalanxes and of at least part of the metatarsus; therefore, we excluded patients who solely underwent amputation of the phalanxes. Patients with history of previous amputation were also excluded.

All patients underwent our protocol for the diagnosis of peripheral arterial occlusive disease and neuropathy (10). Our protocol for detection of peripheral arterial occlusive disease consists of the evaluation of posterior tibial and dorsalis pedal pulses, determination of ankle-brachial index ratio by Doppler continuous wave technique (DIADOP 50; Mediland srl Varedo, Milan, Italy), and transcutaneous oxygen tension (TcPO2) (TCM 3 Radiometer; TCM, Copenaghen, Denmark) tested on the dorsum of the foot. Duplex scanning (SSA-340 A; Toshiba, Tokyo, Japan) was performed in cases with either reduced or absent foot pulses, ankle-brachial index ratio <1 in absence of arterial calcification, or TcPO2 <50 mmHg (10). If any two or more of these four exams were abnormal, then arteriography was carried out and transluminal peripheral angioplasty (PTA) revascularization was concomitantly performed. Patients in whom PTA was unsuccessful underwent a surgical bypass procedure depending on the severity of obstructive disease and surgical risk factor (11).

Our diagnostic protocol for the diagnosis of diabetic neuropathy involves evaluation of Achille's tendon reflex, determination of vibration perception

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Abbreviations: TcPO2, transcutaneous oxygen tension; TMA, transmetatarsal amputation; PTA, transluminal peripheral angioplasty.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Figure 1—*Temporary shoe.*

threshold measured at the malleolus by means of the biotesiometer (Neurothesiometer SLS, Notthingham, UK), and evaluation of tactile sensitivity by means of the 10-g Semmes-Weinstein monofilament in nine foot areas. In the absence of Achille's tendon reflex, the diagnosis of a motor neuropathy is made. If the vibration threshold is >25 mV and tactile insensitivity is absent in five or more foot areas, then the diagnosis of sensitive neuropathy is made.

In all patients presenting obstructive arterial disease, a revascularization procedure was performed before any elective surgical procedures on the foot. The amputation level was determined evaluating the revascularization procedure results and variations of the noninvasive parameters, especially TcPO2 (12).

In the study population, the causes leading to ray amputation were extensive and deep infection of the soft tissues in three subjects (Wagner grade 2), osteomyelitis in 47 subjects (Wagner grade 3), and gangrene in 39 subjects (Wagner grade 4).

All patients underwent systemic antibiotic therapy. In 73 subjects, the drug chosen was targeted according to the positive culture results, and in the remaining 16 (presenting a negative laboratory response), it was ciprofloxacin in association with either a cephalosporin or clindamycin. Oral antibiotics were maintained for 2 weeks following dismissal from the ward. Furthermore at dismissal, every patient was given a therapeutic shoe with a rigid sole suitable for the medicated foot (Fig. 1), and twice weekly ambulatory medications were prescribed until complete surgical wound healing occurred. When surgical wound healing was completed, the patients entered a follow-up program that included clinical controls and use of secondary prevention orthosis. Clinical controls were used weekly during the first month and monthly thereafter in absence of recurrence.

The aim of the clinical controls was to verify the compliance of the habitual use of the provided shoes and to identify (and correct) the onset of any conflicts as early as possible.

The orthosis consisted of insoles prepared on plaster cast and rigid sole footwear (Fig. 2). The shoes, designed according to Towey guidelines (13), were made with rocker soles, with super depth to fit customized insoles and a soft thermoformable leather that adapts to toe deformities (Buratto, Crocetta del Montello, Italy). The customized insoles were shaped by cast using Alcapy, a material derived from PPT (Professional Protective Technology, Deer Park, NY), to relieve local pressure and by Alcaform, a material derived from plastazote, to absorb high-pressure points. The insoles were modified or changed every 6 months, and the shoes were modified according to wear. Furthermore, we supplied patients with household slippers made of a rigid sole so

Figure 2—*Molded insole and rocker bottom sole footwear with thermoformable leather.*

Figure 3—*Household slippers with rigid sole.*

that the insoles could be used at home (Fig. 3).

RESULTS — The clinical and demographic characteristics of our population are reported on Table 1. The amputation was performed at the level of the metatarsal head in 44 patients, at the diaphysis in 17 patients, and at the metatarsal basis in the remaining 28 patients. Fifty-eight revascularization procedures were performed, 42 PTA and 16 bypass.

All patients were followed until June 2002. The mean follow-up period was 16.35 ± 6.76 months (range 7–28). Follow-up started when the surgical wound was deemed completely healed and did not require dressing and when the patient began utilizing secondary preventive footwear. First-intention wound healing was achieved in 65 patients; in the remaining 24, minor wound openings forming after suture removal healed with dressing in 12 ± 9 days.

During follow-up, 15 (17%) patients developed ulcer recurrence: 11 lesions developed ipsilaterally to the amputation site and four lesions occurred contralaterally. The Wagner grade for the new ulcerations was 1 in five patients, 2 in four patients, 3 in five patients, and 4 in one patient. Reulceration developed in 9 of the 58 subjects who underwent revascularization procedure and in 6 of the 31 subjects without arterial occlusive disease. Localization of the new ulceration is reported on Fig. 4.

In 7 of 15 patients, the new lesion was treated and healed with dressing. In 8 of 15 patients, the new lesion necessitated new surgical procedures: pan-metatarsal head resection in 4 subjects, toe amputation in 2 subjects, TMA in 1 subject, and Lisfranc's amputation in 1 subject. None of the patients underwent an above ankle amputation. All of these subjects healed without further reulcerations during the follow-up period.

CONCLUSIONS — History of a previous amputation is sufficient to classify the patient as at high risk for reulceration (14). This is particularly true for patients having undergone a first ray amputation. From the data in the literature, it emerges that a first ray amputation has a high percentage risk of undergoing a second amputation within 1 year (1–3). Modified biomechanic forces on the foot following a first ray amputation are to be blamed for this high recurrence rate.

The allux and the first metatarsus are essential elements in the intermediate and final phases of the gait cycle. The amputation of these segments breaks the integrity of the medial column of the foot; eventually, the adjacent toes will tend to supply the stabilization (formerly provided by the first ray) with an initial development of flexible deformities and later stiff ones. Many studies have produced evidence that a transferring of a hyperloading to the adjacent rays induced by the surgical intervention will eventu-

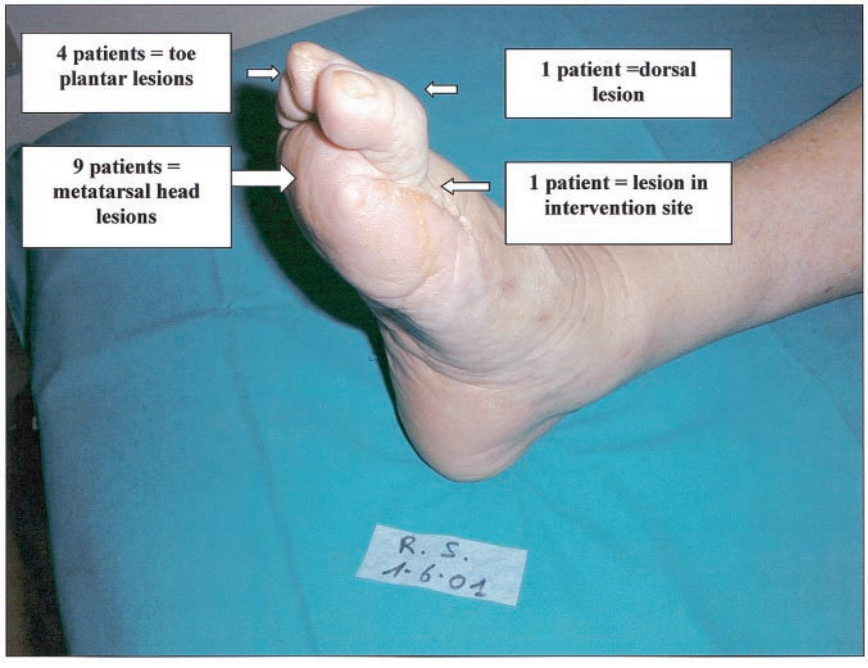

Figure 4—*Site of reulceration.*

Table 1—*Demographic and clinical characteristics of the study population*

n	89
Women/men	26/63
Age (years)	66.33 ± 9.05
Diabetes duration (years)	19.6 ± 5.7
BMI (kg/m^2)	26.4 ± 3.4
HbA_{1c} (%)	7.9 ± 1.2
Diabetes therapy	
Diet	8
Oral therapy	27
Insulin therapy	54
Retinopathy (fundus oculi by ophthalmologist)	62
24-h albumin excretion >30 to <300 mg/l	45
24-h albumin excretion ≥300 mg/l	28
Renal impairment (creatinine value >133 μmol/l)	19
Dialysis	—
Coronary artery disease	46
Smoking habit	21
Ulcer Wagner grade	
2	3
3	47
4	39
Infection (positive culture exam)	73
Arterial media calcifications (X-ray of the feet)	56
Tibial posterior and/or dorsalis pulse absent	58
Ankle-brachial index measured with Doppler continuous wave technique	0.53 ± 0.15
Transcutaneous oxygen tension at the dorsum of the foot (mmHg) (n = 58)	
Before revascularization	21 ± 18
After revascularization	51 ± 12
Achilles reflex absent	86
Vibration perception threshold measured by biothesiometer >25 V	85
Insensitivity in more than five of nine areas using Semmes-Weinstein 10-g monofilament	88
Previous ulceration	0
Previous amputation	0

Data are mean ± SE or *n*.

ally produce secondary biomechanical alterations (1,2). The most important malformations are the development of claw toes and the plantar prominence of the metatarsal head. Furthermore, changes in gait cycle can lead to the development of areas at risk of ulceration on the controlateral limb as well.

Due to the high reulceration and reamputation risk in the literature, there is no viewpoint uniformity of the effectiveness of first ray amputation, and, as such, some authors suggest TMA as an ideal amputation level (4). However, some data exist showing that TMA is burdened by a significant reamputation percentage: between 20 and 40% (5–9). Moreover, the progression to an amputation above the ankle is not to be underestimated (21%) (8).

In our clinical practice, the psychological impact of an amputation of the whole forefoot is high. In most cases, patients accept an amputation limited to the site of the lesion more willingly than a more radical and extensive intervention, even if informed of the better biomechanical result and lesser relapse risk. Amputation limited to the first ray does, however, allow a longer lever to be maintained, thus permitting a more efficient gait.

Compared with a more extensive amputation, a first ray amputation allows for both psychological and functional advantages, as long as it is possible to prevent the deformities caused by postural and biomechanical variations and new ulcerations by hyperloading. The reulceration percentage observed in our study population does seem to justify this approach; the value reported is close to the reulceration percentage in the diabetic population followed by our Foot Centers (15).

We attribute this low reulceration rate to the intensive follow-up program combined with the use of appropriate orthosis (1,2). In the study by Murdoch et al. (3), most patients who underwent a first toe or first ray amputation were not put on an intensive follow-up program, nor was a secondary prevention orthotic treatment set up. In our experience, the use of appropriate orthesis consisting of customized insoles and shoes with rocker bottom soles and thermoformable leather is effective in reducing the risk of recurrence in diabetic patients with a history of foot ulcerations (13,16).

Footwear with a point of the roll of the step placed immediately behind the metatarsal heads is able to guarantee a reduction of peak pressure up to 30% (16). A further reulceration reduction is acquired by the use of customized inserts. A reduction of a further 20% in peak pressure and peak time is possible depending on the materials used and the number of layers composing the insert. Total contact inserts can reduce pressure peaks on the foot by maximizing contact area of the orthotic device to the foot and by spreading the plantar pressures over a larger plantar surface (17,18). The insole inserts available to our patients are constructed using PPT, an open-cell polymer with peculiar mechanical properties such as the capability of absorbing the load and the ability to maintain a memory of the foot form (19–21). The insoles were multilayered because this type is most beneficial in reducing peak pressures

Considering these data, we can deduce that first ray amputation is not burdened by a reulceration risk higher than that of another site of the foot. In particular, the percentage of patients who underwent a second amputation is very low and no above-the-ankle amputation was performed during the follow-up period. As such, we believe that patients presenting with a first ray lesion who require an amputation should undergo a first ray amputation as the first choice. This allows for a longer lever and is psychologically better accepted by the patient who comprehends the need for a surgical correction and is not burdened by a higher reulceration risk with respect to amputations performed on other sites of the foot.

The recent secondary prevention randomized study by Reiber et al. (22) seems to confirm our opinion. The reulceration rate reported in this study (15% in the

treated and 17% in the control group) does not differ from that following our first ray amputation series. However, patients with a history of amputation or major deformities were excluded from the study by Reiber et al., and, as such, the population was at lower risk for reulcerations than that reported here. The study by Reiber et al. has not produced evidence that any advantages are gained by using an orthotic treatment as secondary prevention with respect to the use of usual footwear; therefore, the reulceration rate was attributed to the clinical follow-up performed rather than to the use of orthopedic footwear.

In fact, in the Reiber et al. study, semi- and nonrigid sole footwear was used. Furthermore, insole construction was different: our patients did not use cork insoles covered by neoprene but were equipped with multilayer insoles constructed with materials presenting mechanical properties capable of relieving areas of hyperpressure and helping unloading and maximizing contact areas. We think that it is very important to note that there is an overlapping in the percentage of reulceration between the populations clearly presenting a different risk. In our opinion, the use of orthoses such as the ones in our series allowed for this result.

Our data lead us to assume that the first ray amputation is possible with a low recurrence risk and, above all, with a low reamputation risk. This is probably due to not only an intensive clinical follow-up program, but also the use of effective orthoses.

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