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Diabetic foot surgery "Made in Italy". Results of 15 years of activity of a third-level centre managed by diabetologists

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ABSTRACT

Aim: To evaluate clinical outcomes in patients who underwent diabetic foot surgery (DFS) managed directly by diabetologists in a third-level Centre over 15-year.

Methods: We retrospectively evaluated 1.857 patients affected by diabetic foot (Age 67.1 ± 12.3 yrs, diabetes duration 19.2 ± 9.8 yrs, HbA1c 8.1 ± 2.0%) treated in our Department between 2001 and 2015 and divided them into 3 groups: Group 1, treated between 2001 and 2005 (448 pts), group 2, between 2006 and 2010 (540 pts) and Group 3, between 2011 and 2015 (869 pts). Main clinical outcomes [peripheral revascularization rate (PR), healing rate (HR), healing time (HT), recurrences after healing (R), major amputation (MA) and death (D) rates] were compared between groups.

Results: The overall outcomes of our cohort were: HR 81.6% (HT 143 ± 54 days), PR 84.8%, MA 4.9% and D 27.9%. There were no differences in clinical characteristics, except for age, higher ($p < 0.05$) in Group 3 (70.6 ± 14.7 yrs) than in Groups 1 (64.4 ± 11.6 yrs) and 2 (65.1 ± 11.2 yrs). No differences emerged when comparing HR and MA; HT was shorter ($p < 0.05$) in group 3 (104 ± 44 days) than in Group 2 (169 ± 72 days) and 1 (235 ± 67 days). D was higher ($p < 0.05$) in Group 3 (43.8%) than in Group 1 (23.1%) and 2 (28.1%). PR was 19.4% in Group 1, 28.1% in Group 2 and 53.8% in Group 3 ($p < 0.05$).

Conclusions: Despite the increasing age and complexity of patients our data show improvement of outcomes throughout 15 years, probably due to better surgical techniques, more aggressive medical therapy and more effective treatment of critical limb ischemia.

1. Introduction

The surgical management of acute DF has grown in importance over the years. A prompt and early surgical approach has been demonstrated, when associated with an adequate blood flow restoration, to be not only safe, but also effective in increasing the chances of healing and in reducing limb loss even in patients at high risk for amputation [1].

During the last decades DF surgery has radically changed its vision: from radical surgery performed in extreme cases to save the life of otherwise lost patients, to a more complex discipline, with specialists focusing on reparative and pro-

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phylactic aspects [2]. Today radical surgery represents only the first line of surgical management of acute DF, and is usually followed by reconstruction.

Despite the increasing need for, and popularity of, surgery among DF specialists, there is still a gap between the U.S., where the podiatrist, a specialized health professional with surgical training, rules this field, and Europe, where DF surgery is performed by a variety of figures which change according to the local standards [3].

In Italy, since the late 80 s, some diabetologists have taken the initiative of upgrading DF surgery, setting up DF multidisciplinary clinics which have given a practical response to the many patients who were substantially left alone by the other specialists [4].

The DF Section of the University of Pisa was one of the first to implement a surgical program in a third level University Hospital, as part of the multidisciplinary teamwork on DF [5]. In an operation theatre setting, diabetologists in Pisa from the early 90′s to present times performed a considerable number of surgical procedures on DF, covering all aspects of the pathology, with the exclusion of major amputations or interventions with external fixation, which were performed by orthopaedic surgeons [6].

The aim of this study was to evaluate the outcomes of 15 years of surgical procedures performed by diabetologists on DF in a specialized setting in a third-level University Hospital.

2. Methods

We retrospectively searched the databases of our Department for all the patients admitted between 1st January 2001 and 31st December 2015. From them we selected patients admitted for DF-related diagnosis by means of the ICD code (250). From the operating room (OR) database we selected patients who had undergone surgical procedures.

Once we had found patients who had been operated on for diabetic foot, we reviewed the Department's records and operative registers. From the medical records we extracted data regarding patients' clinical history, focusing both on diabetes, its chronic complications, and on co-morbidities. All the clinical and laboratory assay results performed during admission (where not otherwise defined, all the parameters were assessed by common laboratory kit assays), were derived from patients' folders. Based on the information obtained from patients' case records, the Charlson co-morbidity index was calculated to grade the severity of co-morbidities; we also extracted data on revascularization procedures, performed before the surgical procedure except in cases of acute infections for which urgent surgical intervention was needed. All the revascularization procedures were performed by interventional radiologists, if percutaneous, or by the vascular surgeons if open.

Operative registers showed us the details of surgical procedures and the number of re-interventions needed, defined as a second surgical intervention performed within 15 days of the first procedure; in Table 1 the ICD-9CM codes and description of the procedures performed are reported.

Table 1 – ICD-9-CM codes and descriptions of the procedures performed.

Procedure and ICD-9CM code performed
77.08 Tarsus and metatarsal sequestrectomy
77.68 Local excision of tarsus and metatarsal bone
77.88 Other partial ostectomy of tarsus and metatarsal
77.98 Total ostectomy of tarsus and metatarsal
80.98 Other excision of foot joints
83.14 Other fasciotomy
84.11 Amputation of toe
84.12 Amputation through foot
84.38 Revision of amputation stump
86.04 Other incision with drainage of skin and subcutaneous tissue
86.22 Excisional debridement of wound, infection, or burn
86.60 Free skin graft, not otherwise specified
86.65 Heterograft to skin
Others (<1%)

Major adverse events and complications related to the surgical procedures were also considered and recorded as deaths, or major cardiovascular events, occurring within the index admission.

We divided the patients into three groups: Group A, patients admitted from 2001 to 2005, Group B, patients admitted from 2006 to 2010 and Group C, patients admitted from 2011 to 2015.

As per standard protocol of our hospital, patients at admission had provided formal consent to the introduction of their data in a database and to their non-nominal use in an aggregate form. The protocol of the study was submitted to our local Ethical Committee and received its approval.

After discharge, patients underwent regular follow up in our outpatient clinic as standard procedure. All clinical data were collected by appropriate Software (E-upodi@, Percorsi multimediali, Roma, I).

We searched the outpatient clinic database in order to obtain data regarding wound status and achievement of complete healing, defined as complete re-epithelialisation of the wound, confirmed on two consecutive visits. We also searched for evidence of recurrences, new ulcerations or the necessity of further surgical or vascular procedures. In particular we investigated to find out whether patients had needed a major amputation or had died.

In the period between October and December 2018, all patients underwent structured phone interviews, all carried out by the same physician (E.I.) who asked about the actual status of the feet, recurrences or re-ulcerations, and the need of new surgical or vascular procedures. Patients and relatives were also asked about any major amputation and, in the case of death, for its cause.

Outcomes.

Healing rate (HR) and healing time (HT) as well as peripheral revascularization rate (PR) and major amputation (MA) rate, were calculated with relation to the procedures carried out during admission.

Recurrence rate, major amputation rate and deaths were evaluated at follow up for the three groups of patients.

2.1. Statistical analysis

Quantitative variables were expressed as mean and standard deviation, and qualitative variables as frequencies and percentages. Data were compared with Chi-square and Fisher's exact test for the categorical data and with ANOVA test for the continuous variables. The statistical analysis was performed with the SAS software (SAS Institute, Cary, NC). A p value of less than 0.05 was considered statistically significant.

The impact of time on outcomes was evaluated by a multivariate analysis, which considered time as a categorical variable, using Group 1 as referring period, and comparing between the Groups using the method of Contrasts.

Kaplan-Meier survival estimation was performed for mortality rate, and the difference among the groups was assessed by the log rank test.

3. Results

We retrospectively evaluated a total of 3320 patients admitted to our department between 2001 and 2015 for diabetes related diagnosis. Among them, 2267 (68.3%) were admitted for diabetic foot, while the other 1053 (31.7%) for other diabetes related diagnoses, like glycol-metabolic decompensation or acute complications of the disease (hypoglycaemia or diabetic ketoacidosis). Among DF patients, 1857 (82%) were surgically treated, while the other 410 (18%) required only medical treatment. In Fig. 1 the Consort diagram of the study is reported. The outcomes of the cohort taken as a whole were: HR 81.6%, HT 143.3 ± 53.8 days, PR 84.8%, total MA 4.9% and D 27.9%.

Of the unhealed patients (18.4%), 4.9% underwent major amputation, 12.3% died unhealed, while 1.2% remained unhealed at the end of follow up, which was 178.4 ± 21.1 months in Group 1, 130.9 ± 23.7 months in Group 2 and 70.2 ± 20.6 months in Group 3, respectively.

Clinical characteristics were super-imposable between the three Groups, as reported in Table 2. The only demographic difference observed was for age, significantly higher in Group 3 (70.6 ± 14.7) versus Group 1 (64.4 ± 11.6) and Group 2 (65.1 ± 11.2) ($p < 0.05$).

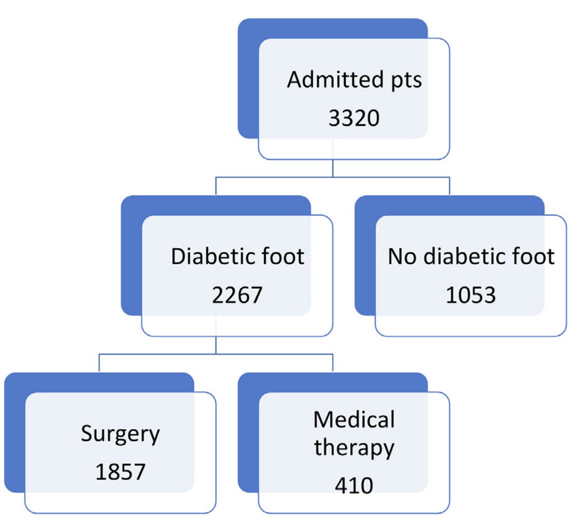

Fig. 1 – Consort's diagram of the study.

Among chronic complications and diabetes-related co-morbidities, only proliferative retinopathy was significantly more represented in Group 3 versus Group 1 and Group 2 ($p < 0.05$).

The complexity of patients, evaluated through the Charlson co-morbidity index, progressively increased between the groups, ranging from 5.6 ± 3.1 in Group 1, to 5.8 ± 2.3 in Group 2 and to 6.6 ± 2.0 in Group 3 (ANOVA $p < 0.05$ Group 3 vs Group 2 and Group 1).

No differences were found in terms of severity of local conditions: as reported in Table 2 the prevalence of lesions graded as 3D according to the Texas University score was similar in three groups (ns).

During the 15-year period, 2107 surgical procedures on diabetic foot were performed on 1857 patients (1.13 procedure/-patient); in Table 3 the numbers of surgical procedures with their ICD-9CM in the three periods are detailed.

No deaths occurred during index admissions, while one myocardial infarction and two strokes were recorded in 15 years, all of which were treated within the same admission.

A trend from radical surgery to conservative and especially to reconstructive surgery was observed during the period considered in the study.

In particular, statistically significant differences were found in digital amputation, which decreased (40% in Group 1, 34% in Group 2 and 27% in Group 3 – $p < 0.05$ Group 3 and Group 2 versus Group 1), in escarectomy, strongly related to ischemic, not susceptible to revascularization patients, which decreased from 11% in Group 1 to 8% in Group 2 and to 5% in Group 3 ($p < 0.05$ Group 3 and Group 2 versus Group 1) and in *trans*-metatarsal amputation (24% in Group 1, 20% in Group 2 and 11% in Group 3 – $p < 0.05$ Group 3 vs Group 1 and Group 2). Conversely, we observed an increase in osteoartrectomy or osteotomy, with a significantly increased prevalence (18% in Group 1, 23% in Group 2 and 28% in Group 3 - $p < 0.05$ Group 3 vs Group 1 and Group 2).

Drainages or fasciotomies increased as well: 3% in Group 1, 6% in Group 2 and 12% in Group 3 - $p < 0.05$ Group 3 vs Group 1 and Group 2) as well as grafting and other reconstructive techniques, with a significantly increased prevalence over the years: 1% in Group 1, 3% in Group 2 and 8% in Group 3 ($p < 0.05$ Group 3 vs Group 1 and Group 2).

The number of patients who required a second surgical procedure, meaning those patients who needed to undergo more than one surgical procedure during the same admission, strongly decreased over the years: From 20.4% in Group 1 to 16.4% in Group 2 and to 8.2% in Group 3 (χ^2 10.4, $p < 0.02$ Group 3 vs Group 1 and Group 2).

The number of revascularization procedures constantly increased over time. 74.6% of patients in Group 1 underwent revascularization procedures versus 82.2% in Group 2 and 91.6% in Group 3 (χ^2 8.2, $p < 0.05$ Group 3 vs Group 1 and Group 2).

The majority of the procedures (93.7%) were percutaneous angioplasties, both transluminal and subintimal. Only a minority of cases (6.3%) underwent surgical revascularization, without any difference between the periods.

Table 2 – Demographic and clinical characteristics of the patients.

Characteristic	Group 1	Group 2	Group 3	p
Number of patients (n)	448	540	869	—
Male/Female (%/%)	73/27	75/25	69/31	n.s.
Mean age (yrs)	64.4 ± 11.6	65.1 ± 11.2	70.6 ± 14.7	<0.05*
Type of diabetes (1-2-%)	13/87	8/92	7/93	n.s.
Duration of diabetes (yrs	16.4 ± 13.4	15.4 ± 13.4	16.1 ± 12.3	n.s.
Smoke habits (Yes-No-Former-%)	34/27/39	38/25/37	18/38/44	n.s.
Systolic blood pressure (mmHg)	129 ± 35	124 ± 36	125 ± 24	n.s.
Diastolic blood pressure (mmHg)	75 ± 12	76 ± 12	76 ± 12	n.s.
BMI (Kg/m^2)	28.2 ± 6.4	27.8 ± 5.5	28.0 ± 6.1	n.s.
Fasting glycemia (mg/dl; mmol/l)	143 ± 62/7.9 ± 1.9	144 ± 64/8.0 ± 2.0	138 ± 58/7.6 ± 2.0	n.s.
C Peptide (ng/ml)	4.1 ± 1.6	3.0 ± 2.9	3.1 ± 2.3	n.s.
HbA1c (%; mmol/mol)	7.9 ± 1.9/63 ± 19	7.8 ± 1.9/62 ± 18	7.9 ± 1.8/63 ± 16	n.s.
Total cholesterol (mg/dl)	134 ± 45	130 ± 45	144 ± 39	n.s.
HDL cholesterol (mg/dl)	57 ± 14	61 ± 12	62 ± 15	n.s.
LDL cholesterol (mg/dl)	74 ± 35	70 ± 35	68 ± 31	n.s.
Tryglicerides (mg/dl)	208 ± 185	227 ± 188	240 ± 179	n.s.
Creatininemia (mg/dl)	1.6 ± 1.4	1.6 ± 1.5	1.3 ± 1.5	n.s.
eGFR (ml/min)	45.3 ± 26.3	46.2 ± 24.6	44.3 ± 21.9	n.s.
Fibrinogen (mg/dl)	353 ± 183	343 ± 197	376 ± 194	n.s.
Cardiovascular disease (%)	44.2	46.2	41.2	n.s.
PCI treated pts (%)	12.3	12.6	11.4	n.s.
CABG treated pts (%)	11.8	12.1	10.7	n.s.
Peripheral vascular disease (%)	84.2	83.8	85.5	n.s.
Cerebrovascular disease (%)	29.8	29.9	28.6	n.s.
Carotid vascular disease (%)	40.1	39.0	43.9	n.s.
Hypertension (%)	78.8	76.6	77.4	n.s.
Dyslipidemia (%)	63.6	63.9	59.7	n.s.
Diabetic retinopathy (%)	71.7	72.3	71.1	n.s.
Laser photocoagulation (%)	37.5	36.4	46.1	<0.05*
Diabetic neuropathy (%)	48.2	51.9	50.0	n.s.
Charcot disease (%)	7.9	7.0	10.3	n.s.
Renal disease (%)	60.1	58.8	67.3	n.s.
Renal failure (%)	34.7	36.2	30.9	n.s.
Emodalysis (%)	2.1	2.3	1.9	n.s.
Texas 3D (%)	37.2	39.0	38.4	n.s.

* $p < 0.05$ Group 3 vs Group 1 and Group 2 and °$p < 0.05$ Group 3 and Group 2 vs Group 1.

Table 3 – Number of procedures divided according to the three periods considered.

Procedure and ICD-9CM code per intervention	Group 1	Group 2	Group 3
77.08 Tarsus and metatarsal sequestrectomy	19	26	41
77.68 Local excision of tarsus and metatarsal bone	35	68	159
77.88 Other partial ostectomy of tarsus and metatarsal	35	30	67
77.98 Total ostectomy of tarsus and metatarsal	28	14	22
80.98 Other excision of foot joints	2	3	4
83.14 Other fasciotomy	14	22	106
84.11 Amputation of toe	136	144	152
84.12 Amputation through foot	138	169	138
84.38 Revision of amputation stump	49	35	38
86.04 Other incision with drainage of skin and subcutaneous tissue	31	39	52
86.22 Excisional debridement of wound, infection, or burn	42	59	80
86.60 Free skin graft, not otherwise specified	2	7	15
86.65 Heterograft to skin	4	9	60
Others (<1%)	4	3	6
Total	539	628	940

Table 4 – Multivariate analysis to compare time period with clinical outcomes.

Outcome	Univariate (HR e 95% CI)	p	Multivariate (HR e 95% CI)	p
Group 3 vs Group 2				
Healing rate	1.34 (0.78–1.66)	0.15	1.25 (0.96–1.42)	0.09
Healing time	0.65 (0.40–0.87)	**0.001**	0.77 (0.59–0.92)	**0.014**
Major amputation	0.89 (0.40–1.87)	0.89	1.12 (0.65–1.42)	0.17
Death	1.75 (1.50–1.82)	**0.001**	1.69 (1.30–1.84)	**0.02**
Group 2 vs Group 1				
Healing rate	0.87 (0.63–1.23)	0.34	1.27 (0.76–1.52)	0.13
Healing time	0.58 (0.40–0.69)	**0.001**	0.76 (0.65–0.83)	**0.001**
Major amputation	0.85 (0.40–1.22)	0.16	1.04 (0.69–1.82)	0.23
Death	1.33 (1.18–1.43)	**0.04**	1.45 (1.18–1.67)	**0.04**
Group 3 vs Group 1				
Healing rate	1.17 (0.67–1.34)	0.29	0.82 (0.33–1.78)	0.15
Healing time	0.40 (0.28–0.55)	**0.001**	0.65 (0.48–0.82)	**0.001**
Major amputation	1.13 (0.77–1.35)	0.12	0.89 (0.60–1.23)	0.34
Death	1.65 (1.44–1.79)	**0.001**	1.55 (1.33–1.72)	**0.02**

The rate of patients who had undergone revascularization procedures performed before the index admission also significantly increased over the years, from 16.9% in Group 1 to 27.9% in Group 2 to 42.2% in Group 3 (χ^2 8.8, $p < 0.05$ Group 3 vs Group 2 and Group 1; $p < 0.05$ Group 2 vs Group 1).

The patients were regularly followed in an outpatient clinic with a mean follow up of 81.9 ± 29.4 months (range 36–210).

During the follow up period the overall HR was 81.6%. No differences were observed between the groups: 79.6% in Group 1, 80.1% in Group 2 and 82.5 in Group 3.

Mean HT of the general population was 143 ± 54 days (235 ± 67 days in Group 1, 169 ± 72 days in Group 2, 104 ± 44 days in Group 3 - $p < 0.02$ Group 3 vs Group 1 and Group 2 and $p < 0.02$ Group 2 vs Group 1) Table 4.

The overall prevalence of surgical recurrences in the follow up was 40.5% (44.6% in Group 1, 42.2% in Group 2 and 37.4% in Group 3, $p < 0.05$ Group 3 vs Group 1 and Group 2).

Overall MA rate at follow up was 4.9%, and remained stable throughout the years with no difference between the groups: 5.2% in Group 1, 4.7 in Group 2 and 5.0 in Group 3.

Overall mortality rate was 27.9% during the follow up. The rate increased over the years: 23.1% in Group 1, 28.1% in Group 2 and 43.8% in Group 3 ($p < 0.01$ Group 3 vs Group 1 and Group 2) Table 4.

In more than 3/4 of the cases (78.4%) deaths were related to major cardiovascular events, either alone (67.1%) or in combination with another terminal disease, while cancer represented the second most frequent cause of death, accounting for 18.9% of events.

Finally, we compared the mortality in the three groups through a Kaplan Meier analysis, reported in Fig. 2, which confirmed the significant mortality increase in the three groups (Chi square 11.25, Log rank test: 0.0036). The ouctomes, both overall and according to the different groups are reported in Table 5.

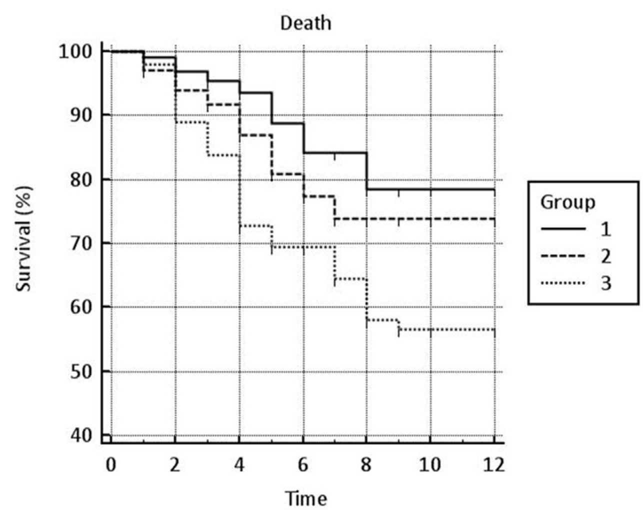

Fig. 2 – Kaplan Meier analysis for Mortality rate (Chi square 11.25, Log-rank test: 0.0036).

4. Discussion

Our data confirm that surgery, carried out by diabetologists in a third-level centre as part of an integrated approach to the disease, is effective in healing more than 80% of patients in an average time of less than six months, containing major amputation to under 5% of cases.

Despite many papers in recent years that have been produced by diabetologists on surgical procedures related to DF [7–9], this is the first time that quantitative data has been produced on this feature of the Italian Health Care system, for a long period of time.

Born in the late eighties as an attempt to give effective answers to an increasing, and in many cases, urgent problem, surgery performed by diabetologists has gradually developed, becoming a component of the multi-professional team approach to DF, as defined in the Italian version of the IWGDF Guidelines [10].

Faglia et al. showed, in 2006, how an early surgical debridement performed by diabetologists, could reduce the need for major amputation in acute infected DF. The Authors found the reasons for this improvement in a earlier referral of the cases to surgery and revascularizations, compared to those managed by general or orthopaedic surgeons [11].

Table 5 – Outcome measures in overall population and in Groups.

Outcomes measures	Overall	Group 1	Group 2	Group 3	p
Healing rate (%)	81.6	79.6	80.1	82.5	ns
Healing time (days: mean ± DS)	143 ± 54	235 ± 67	169 ± 72	104 ± 44	<0.02*
Revascularization rate (%)	84.8	74.6	82.2	91.6	<0.05°
Major amputation (%)	4.9	5.2	4.7	5.0	ns
Death (%)	27.9	23.1	28.1	43.8	<0.01#

* $p < 0.02$ Group 3 vs Group 1 and 2 and Group 2 vs Group 1.
° $p < 0.05$ Group 3 vs Group 1 and 2 and Group 2 vs Group 1.
# $p < 0.01$ Group 3 vs Group 1 and 2 and ns Group 2 vs Group 1.

The same Group reports variable healing rates from 57% to 94%, according to the different series, with average healing times of 165 days, similar to our data, showing a healing rate of 82% in the overall population with an average healing time of 143 days [12,13].

As a matter of fact, when compared to the outcomes of other centres where DF is performed by orthopaedic [14], vascular [15] and plastic surgeons [16], our data do not show a worse profile in terms of hard outcomes. Data are superimposable with those derived by similar experiences in similar settings [9,10,17–20]).

Armstrong et al, evaluating the outcomes of an integrated surgical teamwork, including vascular and podiatric surgery in 374 consecutive DF patients, found a significant decrease (−45.7%) of below knee amputation, paralleled by an increase of peripheral revascularization [19].

In our experience, we did not observe important complications in surgical procedures, neither analyzing the overall population, nor in relation to different approaches.

Lazaro Martinez with his group focused on possible complications related to primary closure, compared to healing by secondary intention, and on different technical surgical approaches, showing that primary closure reduces healing time and re-infection risk, without increasing complications rate [21].

In this perspective, the increasing number of procedures over the years (+20% in Group 2 compared to Group 1 and +61% in Group 3 compared to Group 2) demonstrates the efficacy of this approach in responding to the problem of DF patients, while the 3% increase of healing rates, although not significant, and the significant decreases in healing times (−66 days in Group 2 compared to Group 1 and −65 days in Group 3 compared to Group 2, respectively), and of recurrences (−2.4% in Group 2 compared to Group 1 and −4.8% in Group 3 compared to Group 2, respectively), demonstrate the quality of the program, as does the decrease of recurrences over time.

Although we have no direct evidence of it, we might speculate that the positive outcomes of the program could be explained by its insertion in a multi-professional team approach, of which surgery is only one component, as can be observed in the parallel increase of revascularization procedures in patients undergoing DF surgery, which scored +8.7% in Group 2 compared to Group 1 and +25.7% in Group 3 compared to Group 2 [22].

Also, the progress of technologies and techniques plays its part: in recent years reconstructive methods have been developed which strongly increase the possibility of saving limbs, even in the case of extensive loss of substance [23]. Technologies, like bone substitutes, dermal grafts and negative pressure, also give a better chance of achieving healing even in severely compromised patients [24].

On the other hand, MA rates did not change between the three groups, ranging between 4.7% and 5.2%. These figures are similar to those reported by other authors: Wukich et al, comparing the results of surgery for osteomyelitis vs soft tissue infection in an orthopaedic setting in 229 patients, found a major amputation rate of 16.7% in those with osteomyelitis, and 5.3% in those with soft tissue infection (Table 6).

The lack of improvement in the statistics for major amputations in our cohort of patients over the years can be explained both by the selection bias, because over time the centre attracted more and more severe cases, and by the increasing rates of patients who underwent multiple revascularization because of critical limb ischemia, with an increase of 25% in the study period. In these conditions the containment of MA rates to around 5% can be considered a positive outcome rather than a failure.

The mortality rate increased significantly in our cohort (+5.0% in Group 2 compared to Group 1 and +15.7% in Group 3 compared to Group 2, respectively). This can be explained both by the increasing age of the patients treated (more than 6 years older on average in 15 years) and by their complexity, as demonstrated by the Charlson index, which increased more than 1 point in 15 years on average. As is well known, DF is a marker of co-morbidity, and mortality and life expectancy at 5 years is as poor as for some forms of cancer, so it is not surprising that in our cohort we confirmed this dramatic trend.

We are aware of the limitations of the study, related to the characteristics of a retrospective analysis and to the bias associated with a single centre analysis. Our data can be partially influenced by the impact of a tertiary referral level diabetic foot centre, they reflect our surgical experience, and cannot be generalized. Nevertheless, being the first cohort on a model which has been implemented nationwide in a country with a population of 60 M, with 4 M diabetic patients, it demonstrates how, when integrated in a multidisciplinary approach, DFS carried out by diabetologists, can be effective in managing acute DF cases, with the possible advantage of

Table 6 – Comparison with surgical similar experience of Diabetic foot clinics.

Author	Year	Population analysed	Intervention	Outcomes
Faglia E et al. [12]	2006	106 pts with DFS	Immediate surgical debridement vs debridement after referral by other hospitals	A delay in surgical debridement increase the level needed of amputation
Armstrong DG et al. [20]	2012	2923 surgical procedures	Toe amputation, forefoot amputation or other kind of debridement	An integrated approach distalized level of amputation and reduced urgent procedures
Caravaggi C. et al. [9]	2012	45 pts with deformities secondary to Charcot foot	Tibiocalcaneal arthrodesis	Healing rate free from amputation 86.67%
Garcia Morales E. et al. [22]	2012	46 pts with osteomyelitis who underwent surgical resection	Surgical bone resection and comparison of primary closure or healing by secondary intention	Primary closure reduced healing time and reinfection risk with no difference in terms of complications
Faglia E et al. [13]	2012	207 pts with osteomyelitis of mts head or phalanx	Amputation compared to internal bone resection	Internal resection reduce relapse and contralateral ulcer.
Dalla Paola L. et al. [8]	2015	28 pts with osteomyelitis of 1st metetarsophalangeal joint	Osteoartrectomy, bone cement replacement and external fixation	Healing rate 96.43% Recurrences 3 pts (10.71%)
Faglia E. et al. [7]	2016	83 pts with forefoot gangrene and/or osteomyelitis	Chopart amputation and eventual revascularization	Healing rate 56.6%Healing time 164.7 daysRecurrences 31.9%Major amputation 27.7%Death 45.8%
Wukich DK et al. [21]	2016	229 pts with DF infection (155 osteomyelitis)	Surgical and internal management	Major amputation 16% (37.2% in patients with Charcot disease
Caravaggi C et al. [26]	2016	23 pts with neuropathic or neuro-ischemic plantar ulcers	Bone resection and creation of a fascio-cutaneous plantar flap	Healing rate 100%Healing time 44 ± 31 days
Traddaguilla-Garcia et al. [27]	2018	108 pts with osteomyelitis who underwent metatarsal head resection	Dorsal or plantar approach	Similar healing times between the approaches. More complication in dorsal.
Lee HJ et al. [19]	2019	2 pts with osteomyelitis of first toe and second ray	Minimally invasive debridement of osteomyelitis and bone replacement	Healing of both patients.
Waibel FWA et al. [18]	2019	268 pts with calcaneal osteomyelitis	Partial or total calcanectomy	Healing at 6 weeks 80%Major amputation 10.5%

a faster and more conservative pathway when compared to more “traditional” models [25].

5. Conclusions

Our study demonstrates the safety and effectiveness of a surgical program for DF managed by diabetologists, despite the increasing complexity of cases, over 15 years in a specialized Centre.

When inserted in a multi-professional integrated strategy it provides timely and adequate answers to the increasing number of patients with acute DF in need of surgical management.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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AP, EI, and AC designed the study. EI, CG and AC researched the data, EI, LP, CG and AC analyzed the data, EI did all the telephone interviews, AP revised the data, AP and EI wrote the manuscript, AP, EI, LP and CG reviewed the manuscript, AP is the guarantor of the study.

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