Total-contact cast efficacy in diabetic foot ulcers: Clinical and pedographic points of view

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Plantar pressure measurements were conducted before and after total-contact cast (TCC) application in 30 people with diabetic foot ulcers. The main outcome measures were reduction of pressure in both the ulcer area and the whole foot, and healing rate. TCC reduced foot peak pressure by 20% and ulcer area peak pressure by 55%. Ulcers healed in 21 patients (70%). Median healing time was 30 days. TCC was stopped in nine cases due to patient request or the treatment being ineffective. Acute Charcot foot with ulcer, ulcer colonisation/infection by resistant bacteria, and higher ulcer colonisation signs score were risk factors for treatment inefficiency ($P<0.05$). It was concluded that TCC is an effective offloading method that lead to ulcer healing in 70% of everyday practice patients. In-cast pedography may be successfully used in routine practice to analyse pressure reduction degree in TCC, especially in cases of slow healing.

It is generally accepted that the total-contact cast (TCC) is the most effective method of offloading diabetic foot ulcers. However, some people with neuropathic superficial non-infected ulcers do not respond to this treatment. We assessed degree of pressure reduction in TCC and several clinical factors which can influence TCC efficacy.

TCC is considered as the gold standard in plantar diabetic foot ulcers treatment (International Working Group on the Diabetic Foot [IWGDF], 2007), based on results of six randomised controlled trials (RCTs) (Mueller et al, 1989; Caravaggi et al, 2000; Armstrong et al, 2001; Katz et al, 2005; Caravaggi et al, 2007; Piaggesi et al, 2007). In these RCTs (where only neuropathic non-infected ulcers were included), the 12 week healing rate was 83–95% for the patients who completed the study (but was lower in intention-to-treat analysis). According to an observational study by Nabuurs-Franssen et al (2005), ulcer healing rate with TCC in day-to-day practice was 76%. So despite the efficacy of this method, some superficial neuropathic ulcers do not heal even with TCC. Insufficient pressure reduction in the ulcer area, wound moisture balance and subclinical wound infection are possible causes of treatment failure.

Degree of pressure reduction in TCC was studied by pedography and reviewed by Cavanagh et al (2001). But TCC application techniques vary widely and pedography data can hardly be extrapolated to all TCC modifications. Pressure reduction in "classic" rigid TCC reaches 80–90% for forefoot. As a result, forefoot peak pressure in TCC equals 39–155 kPa (Lavery et al, 1996b; Baumhauer at al, 1997; Lavery et al, 1997; Shaw et al, 1997). Midfoot and hindfoot offloading is less successful: pressure reduction 28–49%, pressure in TCC 66–185 kPa (Cogley et al, 1991; Shaw et al, 1997; Armstrong and Stacpoole-Shea, 1999).

Burns and Begg (2011) recently demonstrated that semi-rigid TCC reduces peak pressure at the ulcer site only by 37–47% or to 149±123 kPa. The authors suggest addition of a cellular urethane cushioned inlay which can increase the offloading capacity of the TCC.

The supposition is that in some people (especially with severely deformed feet), ulcer site pressure appears to be higher than necessary for healing, even in TCC. The literature considers 100 kPa as the threshold pressure, with pressure reduction below this necessary for healing (Meinders et al, 1996; Connelley, 1999; Cavanagh et al, 2001; Katz et al, 2005; Piaggesi et al, 2007).

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Article points

1. Total-contact casting (TCC) is an effective offloading method that leads to ulcer healing in 70% of patients in everyday practice.
2. Some patients (even without contra-indications for contact casting) do not respond to this treatment and causes of this are usually not obvious.
3. In ulcers not responding to TCC treatment (after exclusion of ischemia and osteomyelitis) critical colonisation (including resistant bacteria) and insufficient pressure reduction in TCC should be considered.

Key words

- Contact casting
- Diabetic foot ulcer
- Offloading
- Pedography
- Pressure measurement

Authors

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Table 1. Patient characteristics (*n*=30).

Age (years)	Median 60 (range 28–80)
Sex	Men, 21; Women, 9
Diabetes duration (years)	Median 13 (range 1–48)
Diabetes type	Type 1, 5; Type 2, 25
Antidiabetes treatment in type 2 patients	Oral agents, 4; Insulin, 18; Combination, 3
Ulcer types at baseline (Texas classification; Lavery, 1996a)	1A, 11; 1B, 7; 1C, 3; 1D, 1; 2A, 4; 2B, 3; 2C, 0; 2D, 1
Ulcer equivalent radius (mm)	4.4 (0.75–34.3)
Ulcer location	Forefoot, 15; Midfoot, 12; Hindfoot, 3
Charcot arthropathy (stage)	Acute (with ulcer), 3; chronic (with ulcer), 6; none, 21

Figure 1. In-cast pedography.

Additional (not pressure-related) mechanisms of TCC efficacy are shear stress reduction, promotion of venous blood return, shortening of gait and forced compliance to offloading. Reduction of walking activity is also an important factor (Cavanagh et al, 2001), leading some authors (Bem et al, 2006) to prescribe crutches to all patients with TCC.

Aim and methods

The aim of our study was to assess pressure reduction degree in a semi-rigid cast, and to analyse factors which can diminish ulcer response to TCC treatment.

Thirty consecutive patients with diabetic foot plantar ulcers took part in the study. All of them were under care of one outpatient diabetic foot clinic from January 2009 to June 2011 and gave consent to in-cast pressure analysis (pedography). Contrary to RCT populations, these consecutive patients were closer in characteristics to those seen in clinical practice (*Table 1*).* Three had acute Charcot foot with ulcer and five had non-critical limb ischemia. All patients were supervised until complete ulcer epithelialisation or TCC treatment discontinuation. Where a patient had more than one ulcer (*n*=8), the largest plantar ulcer was assessed.

Patients underwent general clinical examination (blood cell count, blood chemistry, HbA_{1c}, Doppler vascular assessment and ankle–brachial pressure index [ABPI]). X-ray, duplex ultrasound (or transcutaneous oxygen pressure [TCO_2P]) and wound culture were carried out if necessary. Arterial blood flow was considered as normal if ABPI ≥0.9, stenosis grade on duplex scan <50% or TCO_2P ≥40 mmHg. Non-critical limb ischemia was diagnosed in cases of ABPI 0.7–0.89, stenosis grade 50–70% or TCO_2P 30–40 mmHg.

Ulcer size was measured and the radius calculated as (length+width)/4 (Hsi et al, 1998).

Wound infection was diagnosed according to IWGDF (2003) guidelines, namely the presence of at least two of pus, erythema, warmth, tissue oedema and pain or tenderness. Critical colonisation signs were validated by the NERDS scale: Nonhealing, Exudate, Red/bleeding granulations, Debris, Smell (Sibbald, 2007).

Plantar pressure measurement (pedography) was undertaken using F-scan system (Tekscan) with sensor insoles. Initially pressure was measured in the patients' usual non-orthopedic shoes, then in TCC (*Figure 1*). Each study included at least 15 steps per foot, as recommended by Arts and Bus (2011). Peak pressure and pressure-time integral were measured for total foot and for "zone of interest" (ulcer surface plus 0.5 cm of surrounding skin). It was detected by overlapping the pedography image and digital photo of the foot (*Figure 2*).

Walking activity was measured with a pedometer attached to the TCC.

Besides offloading, treatment included antibiotics (*n*=20), blood glucose control, regular debridement and wound dressing change every 2–7 days (usually twice a week).

TCC application technique

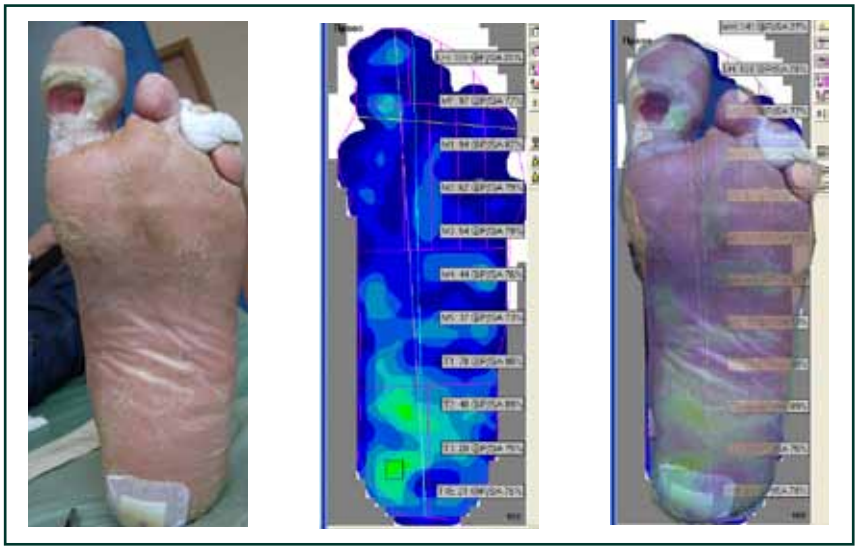
A reusable semi-rigid cast made of Scotchcast™ and Soft Cast™ (3M) was applied (Boogers and Drogmans, 2000; Udovichenko et al, 2010). This technique allows to apply the same cast after each dressing change. The cast was non-removable in all but three patients (in whom constant wearing of cast was maintained by relatives who changed dressings and reapplied the cast at home, with visits to the clinic every 2–3 weeks). The pressure measurement study was undertaken in the second week after TCC application (in order to demonstrate offloading in real practice conditions).

Statistical analysis

Analysis was performed with Excel 2007 (Microsoft) and Primer of Biostatistics 4.03 (McGraw Hill) software. As most numeric parameters did not

*Additional participant details are available in the online edition in *Appendix 1*. Please visit www.diabeticfootjournal.co.uk

Figure 2. This composit shows a digital photo overlayed by the pedography image (far right).



demonstrate normal distribution, they were presented as median (Me) and range. The Mann–Whitney U-test, single-factor analysis of variance, chi-square method and exact Fisher criterion were used where appropriate.

Results

Pedographic assessment of TCC efficacy

TCC application caused significant reduction of main pedographic parameters. Plantar pressure measurements are shown in *Table 2*. Despite this significant effect, pressure was not reduced by TCC in eight patients, including two of the three patients with acute Charcot arthropathy and three of four patients with ulcer on the apex of a claw toe (these are all special cases from the biomechanic point of view). In the Charcot cases, TCC can have no effect due to instability of foot architecture and possible movement of bone parts towards the ulcer. In the claw toe cases, the ulcer can be under intensive stress due to toe movements during gait. The authors usually use toe orthoses ("toe props") inside TCC in these cases, but it was technically impossible to measure pressure under the ulcer if using these. Nevertheless, the small number of patients with these specific problems in this study does not allow any robust conclusions about how these situations influence pressure reduction in TCC.

Table 2. Pedographic parameters after TCC application in the whole patient group (*n*=30).

Parameter	In-shoe	In TCC	Effect of TCC*	*P*†
Peak pressure (for all plantar surface) (kPa)	320 (204–893)	294 (126–639)	–20% (–70%; +84%)	Not significant
Peak pressure in ulcer area (kPa)	199 (15–446)	83 (0–365)	–55% (–100%; +359%)	0.003
Patients with ulcer peak pressure <100 kPa	7 (23%)	17 (57%)	2.4-fold increase	0.017
Pressure-time integral (total foot) (kPa/sec)	50 (24–94)	41 (23–84)	–15% (–52%; +64%)	0.035
Pressure-time integral (ulcer area) (kPa/sec)	46 (7–191)	25 (0–180)	–51% (–100%; +219%)	0.044

*Presented as Me (min–max) for difference between in-shoe and in-TCC results; †Exact Fisher's criterion for qualitative variables, Mann–Whitney U-test for quantitative ones. Me, median; TCC, total-contact cast.

Repeated pressure data analysis after excluding those with acute Charcot arthropathy and ulcers at claw toes was undertaken. Results demonstrate higher efficacy of TCC and are closer to literature findings than data for the whole group (*Table 3*). Influence of TCC on pressure in forefoot, midfoot and hindfoot ulcers was also analysed (*Table 4*), but definite conclusions are not possible due to small subgroup sizes.

Clinical efficacy of TCC

Ulcers healed after treatment with TCC in 21 (70%) patients. TCC was removed at the patient's request in two cases (7%). The treatment was stopped due to lack of TCC efficacy in seven patients (23%) with acute Charcot foot (*n*=3), subcritical limb ischemia (*n*=2), and an unlcear cause (*n*=2; probably unrecognised wound infection).

Among treatment responders, median healing time was 30 days (range 17–278 days). Ulcers healed in 12 weeks in all but two patients (who had neuroischemic heel ulcers). TCC wearing caused pressure sores in nine patients (30%), but only in three patients did these take longer to heal than the primary ulcer.

The influence of pedographic parameters and other factors on TCC efficacy was analysed. For many variables (age, smoking, HbA_{1c}, walking activity and others) there was no influence on results. These findings should be considered as preliminary due to the small study size. Piaggesi et al (2007) also could not demonstrate a link between HbA_{1c} or diabetes duration and offloading device efficacy.

Surprisingly, walking activity was not significantly higher in patients with effective TCC. However,

walking activity at baseline (before TCC application) could not be assessed. It can be supposed that the frequency of walking in TCC is more important than absolute number of steps. Patients with ineffective TCC had also a tendency to higher pressure in ulcer area and the majority of these patients had pressure >100 kPa (although these differences were not significant).

The groups of patients demonstrated statistically significant difference in some parameters. The most notable was acute Charcot foot where TCC was not effective in ulcer treatment. Pressure sores occurred more often in patients with ineffective TCC, but there was no cause–effect relation; TCC treatment was usually stopped due to lack of main ulcer healing, rather than these sores. Antibiotic-resistant bacteria were more common in non-responding patients. As a result, infection was not eradicated in this group with antibiotic therapy. In patients with wound infection (*n*=7) there were three signs of infection in two patients and two signs in the rest. Although classic signs of infection did not predict treatment efficacy, the highest NERDS score appeared to be a significant predictor of nonhealing.

Table 3. Pedographic parameters (Me, min–max) after TCC application after excluding patients with acute Charcot arthropathy and ulcers at claw toes (*n*=23).

Parameter	In-shoe	In TCC	Effect of TCC*	*P*†
Peak pressure (for all plantar surface) (kPa)	318 (204–893)	231 (126–639)	–29% (–70%; +54%)	0.034
Peak pressure in ulcer area (kPa)	201 (15–446)	82 (0–247)	–61% (–100%; +30%)	<0.001
Patients with ulcer peak pressure <100 kPa	4 (17%)	15 (65%)	3.75-fold increase	0.002
Pressure-time integral (total foot) (kPa/sec)	52 (24–94)	39 (23–84)	–24% (–52%; +52%)	0.016
Pressure-time integral (ulcer area) (kPa/sec)	46 (7–154)	22 (0–71)	–60% (–100%; +14%)	0.009

*Presented as Me (min–max) for difference between in-shoe and in-TCC results; †Exact Fisher's criterion for qualitative variables, Mann–Whitney U-test for quantitative ones. Me, median; TCC, total-contact cast.

Discussion

TCC demonstrated quite high but not absolute efficacy (70% healing rate) in our everyday practice. Our results are similar to Nabuurs-Franssen and Sleegers (2005), who reported a 76% healing rate.

It is well known that TCC is contra-indicated in critical limb ischemia, osteomyelitis and other deep foot infections. This study suggests that TCC can also be ineffective in some other patients. TCC may be ineffective where resistant bacteria are present in the ulcer. Resistant pathogens should be considered when the patient in TCC has no obvious signs of wound infection and the ulcer does not heal even after antibiotic treatment. Healing may also not occur where there is not enough offloading in TCC (*Figures 3* and *4*). It may be detected either by pedography or clinically (signs of ulcer overload like massive callus, ulcer border petechiae).

Thus, if an ulcer does not respond to TCC treatment after 1–2 weeks, the above barriers to healing should be excluded. In-cast pedography and wound culture help to do this.

The authors speculate that patients with ulcers on claw toes and acute Charcot foot with ulcer have some peculiarities which make a standard approach to TCC treatment less successful. Due to the small number of such patients in our group, this needs additional studies.

The degree of pressure reduction in ulcer area (median up to 61%) was lesser but comparable with published data. The target pressure <100 kPa was only reached in 65% of our patients in TCC. Many published studies used healthy volunteers without foot deformities. In contrast, many of our patients with severely deformed feet had very high baseline pressure.

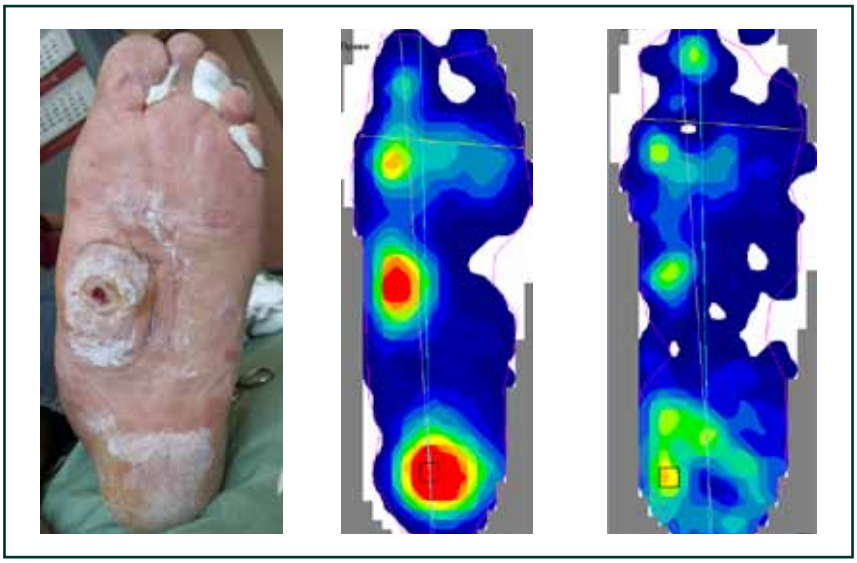


Figure 3. An example of effective offloading in a total-contact cast. Left to right: ulcer location; results of in-shoe pressure measurement; results of in-cast pressure measurement.

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Other causes of the offloading effect of TCC in this study are slightly smaller than seen in the literature may be due to the high frequency of mid- and hind-foot ulcers (where TCC is less effective); the presence of claw toe deformity (where additional offloading device was use, but measures pressured without it); and baseline pressure measurement with in-shoe sensor, which gives slightly lower pressure than the platform study used by some authors.

The data presented here suggest that ulcer area pressure in TCC is more important than the degree of pressure reduction. Pressure–time integrals did not demonstrate any advantages compared to technically simpler peak pressures, in accordance with the findings of Waaijman and Bus (2009).

The predominance of male patients in this study is atypical for the authors' clinic. Normally, men constitute only 45% of our patients. At recruitment, six of the eight patients who refused to start TCC were women; it is possible that our male patients have fewer psychological barriers to such treatment. ■

Table 4. Offloading effect of TCC in different foot regions.

	Forefoot (*n*=11)	Midfoot (*n*=9)	Hindfoot (*n*=3)	*P**
Reduction of peak pressure in ulcer area	–38% (–70%;+27%)	–16% (–53%; +54%)	–41% (–43%; –12%)	0.645
Reduction of pressure–time integral in ulcer area	–47% (–88%; +14%)	–66% (–100%; +3%)	-35% (–60%; –24%)	0.781

*Single-factor analysis of variance. TCC, total-contact cast.

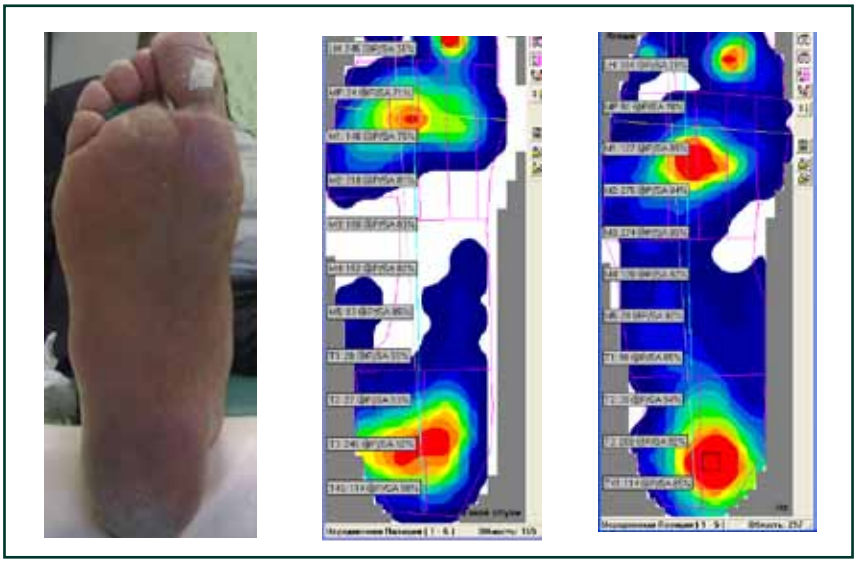

Figure 4. An example of ineffective offloading in a total-contact cast. Left to right: ulcer location; results of in-shoe pressure measurement; results of in-cast pressure measurement.

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Appendix 1. Main characteristics of patients with effective and ineffective TCC treatment (*n*=28).

	Ulcers did not heal (*n*=7)*	Ulcers healed (*n*=21)*	*P*†
Patient data			
Age, years	58 (28–73)	57 (43–80)	>0.05
Gender (M : F)	6 : 1	15 : 6	>0.05
Diabetes type 1 : type 2 ratio	1 : 6	4 : 17	>0.05
Diabetes duration, years	9 (4–31)	13 (0.5–48)	>0.05
Body mass index, kg/m^2	28 (21–35)	29 (23–46)	>0.05
HbA_{1c} level, %	7.6 (5.6–13.8)	7.5 (5.8–9.98)	>0.05
Ulcer data			
Equivalent radius, mm	8.8 (2–22)	4.3 (1–34)	>0.05
Ulcer UT grade (1 : 2)	6 : 1	14 : 7	>0.05
Ulcer location (forefoot: midfoot: hindfoot)	2 : 5 : 0	12 : 6 : 3	>0.05
Ulcer location combined (forefoot : other)	2 : 5	12 : 9	>0.05
Limb ischemia (non-critical) (yes : no)	2 : 5	2 : 19	>0.05
Acute Charcot foot (yes : no)	3 : 4	0 : 21	0.011
Ulcer of a claw toe apex (yes : no)	0 : 7	3 : 18	>0.05
Pressure analysis data (in TCC)			
Reduction of peak pressure in ulcer area, %	–51% (–78%; 359%)	–58% (–84%; –36%)	>0.05
Peak pressure (ulcer area), kPa	156 (19–365)	82 (12–72)	>0.05
Peak pressure in ulcer area <100 kPa (yes : no), number of patients	2 : 5	14 : 7	>0.05
Pressure-time integral (ulcer area), kPa*sec	27 (2–180)	22 (1–107)	>0.05
Peak pressure (the highest for all plantar surface), kPa	301 (143–633)	291 (126–639)	>0.05
Ratio of ulcer peak pressure and total foot peak pressure, %	51% (10–73%)	30% (4–85%)	>0.05
Wound infection-related factors			
Wound infection signs (≥2) at baseline (yes : no)	3: 4	3 : 18	>0.05
Critical colonisation signs (NERDS≥3) at baseline (yes : no)	3 : 4	4 : 17	>0.05
Wound infection signs (≥2) at any moment (yes : no)	4 : 3	7 : 14	>0.05
NERDS≥3 at any moment (yes : no)	6 : 1	10 : 11	>0.05
NERDS≥4 at any moment (yes : no)	5 : 2	7 : 14	>0.05
NERDS = 5 at any moment (yes : no)	4 : 3	1 : 20	0,008
Resistant bacteria in wound culture**	4 : 3	3 : 18	0,04
Antibiotics usage during the TCC wearing	7 : 0	11 : 10	0,03
Other factors			
Walking activity (steps per day)	2341 (825–7340)	4000 (700–12773)	>0.05
Smoking (yes : no)	1 : 6	4 : 17	>0.05
Pressure sores under TCC (yes : no)	5 : 2	3 : 18	0.009

Note: patients who refused TCC wearing (*n*=2) are not included

*Presented as median (Me) (min–max) for difference between in-shoe and in-TCC results; †exact Fisher's criterion or chi-square method for qualitative variables, Mann–Witney U-test for quantitative values; **meticillin-resistant *Staphylococcus aureus, Pseudomonas aeruginosa, Acinetobacter* spp.