


ORIGINAL ARTICLE

Clinical and medico-economic benefits of remote monitoring of chronic wounds

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Abstract

Through a prospective comparative intention-to-treat study, we studied the impact of remote monitoring of chronic wounds on safety and on the consumption of healthcare system resources. From January to June 2023, 103 consecutive patients were managed according to conventional follow-up (group CF, 61 patients) or to follow-up in which remote wound monitoring (group RM, 42 patients) could be used. Data were collected prospectively. Statistical analysis was performed on an intention-to-treat basis, analysing data on treatment safety (mortality, major amputation, wound healing, use of emergency services), clinical results (closure and time to closure of the wound) organisational effectiveness (consultation, hospitalisation, use of unscheduled care), and estimated cost. The use of telemonitoring did not alter the safety criteria for the management of chronic wounds. It allowed a 35 days reduction of the time to wound-closure ($p = 0.05$). It led to a 55% reduction in hospital consultations ($p \leq 0.01$). These factors have resulted in an estimated reduction in the cost of care of 1666 euros. The constated reduction in unscheduled care (visit of emergency services, emergency hospitalisation) was not significant. Remote monitoring of chronic wounds is safe, and clinically efficient (reduced healing time), compared to conventional monitoring. It decreases the need for in-hospital consultations and the overall cost of the treatment and thus may ease the access to specialised care in wound healing.

KEYWORDS

chronic wound, diabetic foot ulcer, leg ulcer, pressure associated ulcer, telemedicine

Key Messages

- Following on from the work already carried out by our predecessors, we have sought to evaluate the safety, and the clinical and organisational benefits of remote monitoring of chronic wounds.
- This is a prospective study, comparing two homogeneous populations, one with access to remote monitoring of chronic wounds, the other with conventional follow-up in consultation.

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- It shows: an equivalence in terms of safety, a reduction in wound healing time, and a significant reduction in the need for physical consultations. Unfortunately, we were unable to show the statistical significance of a reduction in the use of unscheduled care, regarding to a too limited number of patients.
- This work has two particular features. On the one hand, it concerns chronic wounds in all their diversity, whereas most previous studies often consider a single aetiology. In the other hand, it uses a platform that is easy to use, low cost and therefore easy to deploy (Pixacare).
- We believe that this kind of work can make possible to deploy such remote monitoring.

1 | INTRODUCTION

1.1 | Clinical considerations about chronic wounds

Chronic wounds, mainly varicose ulcers (VU), pressure associated ulcers (PAU) and diabetic foot ulcers (DFU), are common and disabling complications of underlying diseases such as venous insufficiency, arterial insufficiency or diabetes. Their prevalence is estimated to be between 1% and 3% of the general population of developed countries, as shown by Olsson.¹ Their pathophysiology is complex, involving peripheral artery disease, abnormalities in microcirculation, local immunity or innervation. These wounds are at very high risk of infection, heal slowly and often recur. Their management is complex and multidisciplinary, combining local treatments, antibiotic therapy, discharge and glycaemic control in diabetic patients. Most patients require specialised care such as revascularization or surgical care, ranging from debridement to major amputation. Coordination between outpatient care, usually provided by nurses, and multidisciplinary specialised hospital care, including infectious disease physician, vascular surgeon, interventional radiologist, vascular physician and diabetologist, is often very poor. This results in delayed treatment, sub-optimal care and ultimately an increased risk of amputation (see Primadhi²).

1.2 | Socioeconomic burden

The economic cost of treating chronic wounds is very high,¹ due to a number of factors:

1. The prolonged duration of treatment due to the difficulty of healing these wounds and the delay in referral to specialised centres,

2. The cost of consultations and, in particular, the cost of transport to specialised care centres for these patients, who are often elderly and in vulnerable situations,
3. The frequent emergency or unplanned use of the health care system for the treatment of wounds that are poorly managed at the outset and
4. The need for referral centres that may be far from the patient's home, requiring multidisciplinary care with specialised staff and technical facilities.

The cost of treatment is high, up to more than €14 000 per half-year.³ In addition, these conditions have a significant impact on the quality of life of patients, both physically and psychologically, as well as at work and in social settings. With an ageing population and an overall increase in prevalence, the economic and social burden of chronic wounds will only increase.

1.3 | Place of remote monitoring

The management of chronic wounds could be improved through the development of telemedicine, which allows patients to be monitored remotely.

Remote monitoring would enable:

1. Better coordination between primary care and hospital specialist teams,
2. Easier access to specialist advice for patients,
3. A potential reduction in unplanned and urgent use of the healthcare system and
4. Ultimately, a reduction in the overall cost of care.

However, the actual effectiveness of telemedicine in this area has yet to be proven. There are currently only a few studies available, and their results can be contradictory, as it will be discussed *infra*. In particular, most of these studies focus on specific types of management, such

as diabetic foot ulcers, without being able to assess all aetiologies affecting the lower limb. Finally, the initial management of wounds is often specific to the centre that carried out the study and may be difficult to transfer to other centres. Rigorous, replicated studies with high levels of evidence are needed to:

1. Confirm the expected benefits of these telehealth interventions and
2. Ensure that there is no deterioration in the quality and safety of patient care.

These studies should also assess the medico-economic impact and acceptability of these new monitoring methods for patients and caregivers.

1.4 | Considerations on remote monitoring with Pixacare

Pixacare is an application designed to facilitate and secure the management of photographic images in a clinical use. Its remote monitoring module is unique in that it is easy to set up in terms of IT (cloud-based application that can be interfaced with the computerised patient file) and financial resources, compared with the older, more cumbersome methods tried out in France. Its use in outpatient practice is also geared towards ease of use, with a smartphone application and access to the patient's file by means of a QR code provided to the outpatient nursing team.

1.5 | Aim of the study

Since January 2021, the Vascular Surgery department has been using remote monitoring of chronic wounds via the Pixacare platform. Through this experiment, we were able to gain initial experience with the implementation, effectiveness and safety of the method. With a view to the generalisation of its use, we have decided to carry out a rigorous evaluation of the clinical and medico-economic benefits of this method. The objectives of this study were

1. To evaluate the safety of the remote monitoring of chronic wounds and, in particular, to demonstrate its non-inferiority with respect to the main criteria that have been identified in the literature and in our preliminary experience and
2. To assess its clinical and health economic effectiveness.

2 | POPULATION AND METHODS

2.1 | Trial design

The study focused on patients referred to the vascular surgery department of Haguenau Hospital (Bas Rhin, Alsace, France) for chronic wound management. All patients presenting for the first time were included after informed consent. The only exclusion criteria considered were

1. The patient's inability to consent to the study, especially due to cognitive disorders,
2. A primary indication for major amputation,
3. A primary indication for palliative care and
4. Another indication for repeated hospitalisation (haemodialysis, chemotherapy).

As only one surgeon (GM) had experience with telemonitoring, all patients referred to him were included in the Remote Monitoring group (RM). Patients referred to the other two surgeons were included in the conventional follow-up group (CF), which consisted of in-person visits only.

The study was conducted on an intention to treat basis. Inclusion in the study took place at the time of the first consultation. From that point on, all wound-related and non-wound-related medical events (visits, hospital admissions, telemonitoring episodes, operations, planned or unplanned) were recorded. Patients were followed up for a maximum of 6 months. Early discharge from the study consisted of:

1. Death,
2. Major amputation,
3. Discontinuation of follow-up by the patient (no-show) and
4. Wound closure.

In the CF group, the monitoring was carried out exclusively by physical means, at the 'chronic wound' consultation in the department of vascular surgery. The length of time between two consultations was determined by the surgeon in charge according to the evolution of the wound.

In the RM group, telemonitoring was optional: standard follow-up was the default management, and telemonitoring was used only in situations of favourable wound progression. If telemonitoring was not possible (e.g., if the nursing team refused to use the application), monitoring continued in the conventional way: such a situation was identified as a cross-over, but was not included in the data analysis (intention-to-treat study).

TABLE 1 Characteristics of the RM and CF groups.

	Remote Monitoring (<i>n</i> = 42)	Conventional outpatient monitoring (<i>n</i> = 61)	<i>p</i>
Age at inclusion (years)	82 ± 10	76 ± 11	0.016
Evolution before inclusion (weeks)	19.8 ± 39	19.9 ± 32	NS
BMI (kg/m ²)	26.3 ± 5.2	27.9 ± 5.9	NS
Men (%)	50	65	0.16
Diabetic (%)	61.9	60.6	1
Active smoker (%)	16.6	9.8	0.46
Arteritis (%)	50	55.7	0.44
CKD stage ≥ 3 (%)	16.6	14.7	NS
Ongoing cancer (%)	4.7	3.2	NS
PAU (%)	21.4	14.7	0.54
VU (%)	23.8	29.5	0.67
DFU (%)	19.5	31.1	0.25
Ischemic ulcer (%)	0.62	0.44	0.12
Localisation:			
Forefoot (%)	50	60.6	0.38
Heel (%)	19	4	0.18
Supra-malleolar (%)	31	31	NS
Crossover	6	0	

When telemonitoring was introduced, the treatment protocol was updated. An explanatory flyer was given to the patient for use by the nurses. Remote monitoring was performed through the Pixacare platform, which required the installation of the application on the nurses' smartphones. Access to the patient's file was authorised using a QR code, which allowed accessing the first follow-up images and transferring the completed images to the surgeon performing the follow-up.

Follow-ups were performed directly through the Pixacare web application by the surgeon who set up the remote monitoring. This platform also made it possible to discuss the situation with primary care nursing team through a securized chat provided by the platform. If a decision was made to adjust the treatment, the new protocol was mailed to the patient's home address without the need to see the patient again. If the wound deteriorated, the patient was recalled to the consultation for reassessment and adaptation of treatment.

2.2 | Population studied

From January to June 2023, 103 consecutive patients were enrolled in the study, 61 in the conventional follow-up (CF) group and 42 in the RM group.

Univariate analysis of the data collected at enrolment showed that the two groups were comparable in all aspects studied—comorbidities, wound aetiology, duration of pre-operative evolution—except for age, with the population in the RM group being significantly older (82 vs. 77 years, $p = 0.015$). These data are summarised in Table 1.

2.3 | Methods

2.3.1 | Safety considerations

Our first objective was to show that the remote monitoring of chronic wounds does not have an impact on the safety of the management of wounds. The safety criteria used were

1. Mortality,
2. Major amputation,
3. Loss of follow-up,
4. Emergency room visits and
5. Emergency hospitalisation related to the wound, duration of the unscheduled hospitalisations.

Compliance for study completion was considered when follow-up reached 6 months, without wound closure or complication.

2.3.2 | Clinical implication

Comparison between RM and CF groups:

1. Closure rate of the chronic wound during the follow-up and
2. Time to closure of the chronic wound.

2.3.3 | Medico-economic aspect

Comparison between RM and CF groups:

1. Cost induced by in-hospital consultation, including cost relative to transportation and
2. Cost induced by emergency room visits and emergent hospitalisation.

2.3.4 | Statistical analysis

We carried out an univariate statistical analysis. We used the *t*-test method to compare the means of the continuous variables, whereas we used the χ^2 method to compare Boolean variables.

3 | RESULTS

3.1 | Safety considerations

3.1.1 | Mortality

Death occurred in six patients (14.2%) in the RM group, compared with three patients (4.9%) in the CF group. This difference was not statistically significant ($p = 0.19$).

3.1.2 | Major amputation

Such intervention was required in three patients (7.1%) in the RM group compared with two patients (3.3%) in the CF group. The difference was not significant ($p = 0.66$).

3.1.3 | Loss of follow-up

It concerned 11 patients (18%) in the CF group compared with 4 (9.7%) in the RM group. The difference was not significant ($p = 0.36$).

3.1.4 | Compliance with study completion

Ten (23.8%) patients achieved the 6 months follow-up without major complications and a wound still opened in the RM group, versus 16 (26.2%) in the CF group.

3.1.5 | Emergency department use

A consultation in the emergency department was required eight times in the CF group, compared with one in the RM group. This led to three unscheduled hospitalisations, representing 64 days of hospitalisation in the CF group, compared with 0 in the RM group. This corresponded to an average emergency hospital stay of 1.03 days per patient in the CF group, compared with 0 in the RM group. This difference was not significant ($p = 0.32$).

3.2 | Clinical results

We found a wound closure rate during the study period of 45% (19/42) in the RM group compared with 47.5% (29/61) in the CF group. The difference was not significant ($p = 0.97$). However, we found that the average time to wound closure was significantly reduced in the RM group (78 vs. 115 days, $p = 0.05$).

3.3 | Medico-economic aspect

3.3.1 | Consultation

The mean number of consultations per patient over the period was 1.5 in the RM group, compared with 3.2 in the CF group, corresponding to a reduction of 55%. This difference is significant ($p \leq 0.01$).

3.3.2 | Hospitalisation

The length of planned hospitalisation was comparable (10.3 in the RM group, 10.5 in the CF group), with no significant difference.

3.3.3 | Medico-economic analysis

It was carried out over the 6 months of the study, focused on three essential criteria: wound-related consultations; transport costs associated with these consultations and reduction in healing time.

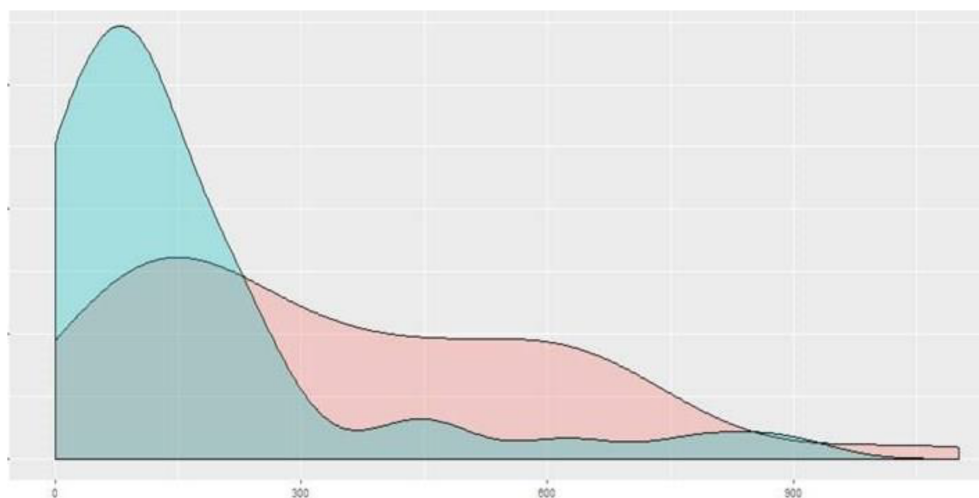


FIGURE 1 Distribution of the cost in euros for consultations and related transport. In blue: RM group. In pink: CF group. CF, conventional follow-up; RM, remote monitoring.

TABLE 2 Cost estimation regarding to remote monitoring versus conventional follow-up.

	Remote monitoring	Conventional follow-up	Difference (euros)
Consultations	36.14	74.66	38.52
Transportation	123.74	267.89	144.15
Home care	3127.8	4611.15	1483.35
Total	3286.88	4828.55	1666.02

Note: Those differences are statistically significant ($p \leq 0.01$). Bold values indicate significance ($p < 0.01$).

As the duration and number of scheduled hospitalisations were comparable in the two groups, this criterion was not taken into account. Similarly, as the reduction in the use of unscheduled care was not statistically significant, it was not taken into account in the analysis.

The analysis of consultation and transport costs was based on current reimbursement rules in France.

The calculation of costs related to the reduction in healing time was based on the average reduction in healing time, considering that the average daily cost of care was 40.1 euros (CPAM 2015 data, after deduction of ancillary expenses unrelated to the wound). The distribution of costs for consultations and related transport is shown in Figure 1.

Table 2 summarises these elements:

4 | DISCUSSION

4.1 | Remote monitoring is safe

This study enables us to confirm the safety of remote monitoring of chronic wounds compared with conventional monitoring. There was no significant difference in any of the major outcomes studied (mortality, major amputation, wound healing at 6 months, loss of follow-up).

However, there are two closely related factors, which merit further study. First, telemonitoring seems to us to enable more consistent follow-up of patients, in particular with a reduction in loss of follow-up. Second, there is a trend towards a reduction in the need for emergency consultations and hospitalisations. This is in line with our practical experience, in which telemonitoring enables complications, particularly infectious ones, to be managed upstream. Unfortunately, due to our small number of patients, we were unable to identify a statistically significant correlation on those two topics.

We have summarised these elements in Figure 2, which shows the expected evolution of two equivalent populations composed of 1000 patients each according to the safety criteria adopted.

This Sankey diagram presents the evolution of two cohorts of patients derived from our RM and CF group, over a period of 6 months: to allow an easier visual comparison of event frequencies between these two populations of different sizes, we normalised the counts to a common baseline of 1000 patients per cohort. Specifically, this involves applying a normalisation factor of 1000/42 for population RM and 1000/61 for population CF. The numbers of events observed in each cohort were multiplied by their respective normalisation factors. This process does not affect event rates within a given population, but makes the counts directly comparable in

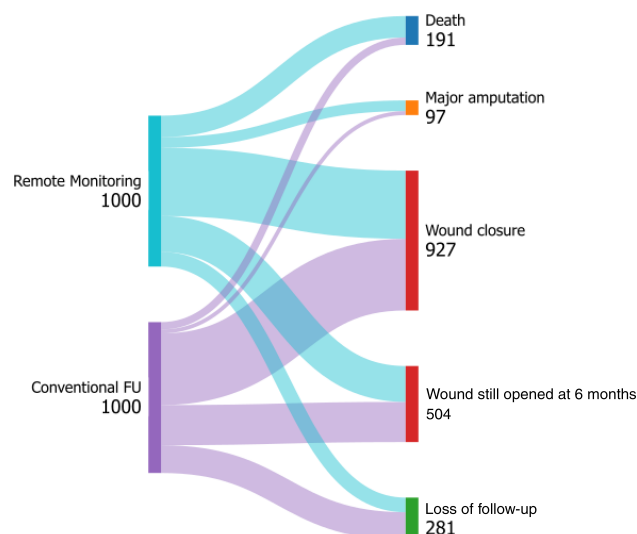


FIGURE 2 Visualisation of the outcomes of two extrapolated cohorts from CF and RM groups. CF, conventional follow-up; RM, remote monitoring.

absolute terms between the two cohorts represented on the diagram.

The data found in the literature are consistent with our results. For example, Salmhofer,⁴ Téot,⁵ Rastogi⁶ and Dardari⁷ found no difference in terms of safety when using remote monitoring of chronic wounds.

Smith-Strøm⁸ found a reduction in the need for amputation in his randomised clinical trial published in 2018. However, this criterion also included minor amputations in this study, and the number of major amputations was very low (5 cases out of 182 patients included). A same reduction of the amputation requirement was found by Santamaria,⁹ with six amputations in the control group, and only one in the RM in the intervention group.

Only Rasmussen¹⁰ found a worsening of the safety criteria, with a significant increase in mortality during remote monitoring, in his randomised clinical trial published in 2015. However, the contribution of wound-related complications is not detailed in the published data, with five of the nine deaths attributed to pneumopathy.

All these factors lead us to conclude that telemonitoring of chronic wounds is a safe method that has no negative impact on patient outcomes, and is therefore suitable for widespread use.

4.2 | Remote monitoring has a clinical benefit

Remote monitoring of chronic wounds is clinically beneficial in our study. The wound closure rate at 6 months was similar in both groups, approximately 45%. However,

the time to wound closure was reduced by a third (78 vs. 115 days, $p = 0.05$). We didn't find any obvious difference in the delivered cares between the two groups, which were however similar.

An explanation for this difference could relate to the reporting structure of wound closure. In the RM group, monitoring was carried out on an ongoing basis, whereas in the CF group, this was only reported during consultations, which took place every 6–8 weeks. Unfortunately, it is impossible to rule out this aspect. But if such a difference were the result of a structural bias in reporting, it should be systematic: however, numerous studies, in particular Teot⁵ and Dardari⁷ which are comparable with us in term of population and healthcare organisation, do not find such difference. It is therefore impossible not to consider this element as a bias.

Other studies have also found a significant reduction in course of the wound. Zarchi¹¹ found a significant reduction of the one-year closure rate (45 vs. 70% at 1 year). Wickström¹² showed a significant reduction in healing time (49 vs. 70 days) when remote monitoring was used. Santamaria⁹ showed a reduction of the size of the wound (mean: 6.8% per week) in the RM group, whereas the control group demonstrated a mean increase of the size of the wound of 4.9% per week.

It is difficult to explain such a difference in terms of quantifiable elements: in our practise, we have found that remote monitoring does not simply involve checking the wound, but more radically changes the way in which we collaborate with primary care nursing teams. There is, may be, a Hawthorne effect, with an improvement in results thanks to the introduction of external monitoring. This seems to us to be reductive. Discussions about the evolution of patients and their wounds are leading to a shift from a prescriber/executor relationship towards genuine collaboration, in which the primary care team—paradoxically—sees its autonomy strengthened by the possibility of easy recourse to the expert centre.

4.3 | Remote monitoring is cost-effective

The patient's interactions with the healthcare system as described in our study are summarised in Figure 3.

This Sankey diagram presents the evolution of two cohorts of patients derived from our RM and CF group, over a period of 6 months: to allow an easier visual comparison of event frequencies between these two populations of different sizes, we normalised the counts to a common baseline of 1000 patients per cohort (cf. supra).

We saw above that telemonitoring enabled savings estimated at 1666.02 euros, divided between 182.67 euros for the reduction in consultations and related transport

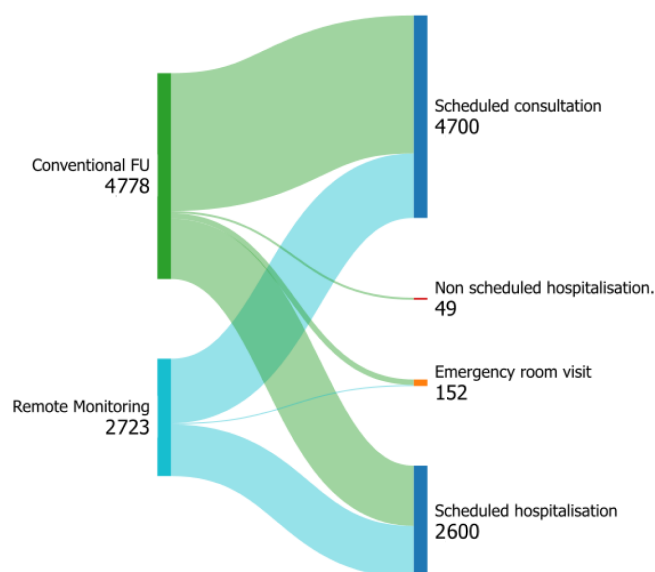


FIGURE 3 Visualisation of the interaction of two extrapolated cohorts with the healthcare system. CF, conventional follow-up; RM, remote monitoring.

costs ($p \leq 0.01$) and 1483.15 euros corresponding to an estimate based on the reduction in healing times (see Table 2).

Our rough medico-economic study is not sufficiently robust. However, other studies that have taken this into account ab initio have also found a reduction in treatment costs. However, it is consistent with Dardari⁷ particularly, that demonstrated a significant reduction in costs (€3471 vs. €7185) due to a decreased need for hospitalisation with a study designed to ensure a maximum follow-up of 12 months. Similarly, Téot⁵ found a reduction in costs due to a reduction in transport costs (follow-up: 6 months). These two studies, which were carried out under the same health and financial conditions as our study, support the cost savings estimated in our study. Santamaria,⁹ in a rural setting, showed a comparable benefit of remote monitoring.

However, a true medico-economic study remains extremely complex, and the financial scope considered is fundamental. Fasterholdt,³ who conducted the health economic study whose clinical results were published by,¹⁰ found a reduction of 2039 euros (12 356 vs. 14 395 euros), but without statistical significance, with a mean study duration of 74 days versus 91 days, respectively, in remote and conventional monitoring groups.

5 | CONCLUSION

This study confirms the safety of remote monitoring of chronic wounds. The use of a lightweight, secure

platform, based on the use of a smartphone, enables easy access to these methods.

In addition to the safety of the method, we were able to confirm its effectiveness, with a reduction in wound healing time, probably due to a more precise adaptation of management. The result was a reduction in the estimated cost of management.

These elements are now backed up by a large number of concordant clinical studies, and telemonitoring should become the standard of care of the chronic wound.

However, there is still considerable room for improvement in remote monitoring, and the topic will be the subject of considerable innovation. An active monitoring of the active file may lead to a reduction of the patients loss to follow-up. The commitment of nursing teams can be enhanced by the upstream design of therapeutic protocols. Quality may be improved by diffusion of management guides. The clinical field may be considered beyond wound management as Wickström demonstrated for analgesia¹³ and antibiotic therapy.¹² Implementing such practises is fundamental, as it will improve both the quality of care and the quality of life of patients.

Finally, computer vision methods, derived from deep learning algorithms, will allow us to measure the wound surface semi-automatically: quantifying wound monitoring should make it possible to fine-tune local care and enhance remote monitoring by bringing expertise to primary care teams.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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