Impact of fluorescence imaging of bacterial presence, location, and load on wound healing, infections & hospitalizations: retrospective analysis of 193 wounds from Medicare patients

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Summary

Bacterial burden stalls wounds and can quickly escalate to infection[1-3]. Often asymptomatic, its detection presents a clinical challenge that is exacerbated in elderly, diabetic, and otherwise immunocompromised patient populations[4,5]. Long term care (LTC) and skilled nursing facilities (SNFs) are burdened by high wound prevalence and high rates of wound infection[6-8]. Many of these wounds require hospitalization as local wound infections lead to more serious complications such as sepsis. As such, there is a critical need for more objective methods to identify wound infection in these care settings.

Fluorescence (FL) imaging has been shown to have great diagnostic value in detecting pathogenic bacterial loads (>10^4 CFU/g) in wounds and in helping to design treatment plans that are specific to that wound and its bacterial burden[9-13]. To determine the impact of FL-imaging on wound outcomes in SNF and LTC, a retrospective analysis was performed on Medicare beneficiaries in the state of Missouri, which compared patients pre-fluorescence imaging (Jan 2019 to Feb 2020) to those receiving fluorescence imaging (May 2021 to March 2022). 193 wounds from 113 patients were randomly selected in an unbiased manner following pre-determined inclusion and exclusion criteria. Of those, 89 wounds received standard of care only while 104 wounds received standard of care plus FL-imaging. With the addition of FL-imaging, the percent of wounds healed within 12 weeks increased 1.6-fold (32% vs. 20%), mean wound healing time dropped from 17.6 weeks to 12.2 weeks ($p=0.025$), the percentage of patients with severe infection-related complications (cellulitis, sepsis, osteomyelitis, or any wound-associated hospitalization) decreased 5.3-fold (17% vs. 3%), and use of systemic antibiotics decreased by 29% (47% vs. 33% of patients). Additionally, the percent of wounds for which PCR microbiology was performed decreased by 38% (25% vs. 15%) with the addition of FL-imaging. Use of cellular tissue products was minimal (2% of wounds received).

These findings are consistent with randomized controlled trials and cohort studies from hospital outpatient settings[14,15]. Due to the high rates of infected wounds and septic patients from LTC and SNF admitted to the hospital, early detection and appropriate monitoring of wound bioburden would be highly beneficial from both a cost and patient care perspective. These findings demonstrate that addition of FL-imaging led to both clinically and economically significant outcomes for Medicare beneficiaries when adopted in 54 SNF and LTC facilities across Missouri.

Introduction

Long term care (LTC) and skilled nursing facilities (SNF) have a disproportionately high rate of wounds and wound-related infections. The prevalence of pressure ulcers in LTC facilities ranges from 2.6% up to 54%[16-19]. Skin and soft tissue infections are the third most common infection found in this care setting, with a high incidence rate of up to 2.1 cases per 1000 resident days[7]. All too often, infections develop in these wounds due to delayed detection of high bacterial loads; this can result in serious complications requiring hospitalization of these residents, such as osteomyelitis, gangrene, and sepsis. Wounds of all etiologies represent a risk for the development of severe sepsis. Infection and sepsis are particularly hard to fight in the context of a multi-morbid patient, such as those in LTC and SNFs. Appropriate and timely management of wound bioburden and infection is integral to avoid morbidity and mortality due to sepsis. Nursing home residents were 7-fold more likely to have a severe sepsis diagnosis[20] and nursing facility residents experience higher rates of ICU admissions, longer hospital stays and higher in-hospital mortality rates compared to non-nursing facility residents[20-22]. Sepsis is a serious public health issue with an estimated 1.7 million adult cases (mean age 64 y.o.) annually in the U.S.[23]. Sepsis is associated with 270,000 annual US deaths at a cost of over $27 billion USD[24]. The challenges of wound care in the LTC and SNF settings are exacerbated by economic constraints and the high prevalence of residents with drug-resistant pathogens that make subsequent infections more difficult to treat[20,25]. In fact, antimicrobial resistance has substantial impact in determining clinical unresponsiveness to treatment and rapid evolution to sepsis and septic shock[26].

Point-of-care fluorescence (FL) imaging of wound bacterial presence, location, and load has been subjected to extensive research to validate the diagnostic accuracy and utility of FL-imaging for bacterial detection and treatment planning across all wound types and all skin tones[9-13]. Multiple clinical trials have demonstrated that FL-imaging has a positive predictive value of >95% for detecting bacteria at loads of >10^4 CFU/g[9-13] and increases the sensitivity of detecting these loads of bacteria by 3- to 4-fold over assessment by clinical signs and symptoms of infection (CSS) alone[9,10]. It also has been shown to improve detection of wound-associated cellulitis[27]. Treatment plans are reported to change after imaging in ~70% of wounds[9,10]. Delphi consensus guidelines published on this technology in 2021 established what constitutes medical necessity for imaging, the recommended frequency of imaging, and the need for extensive training on the technology and image interpretation[5].

Strong clinical outcome improvements have been reported when this technology was incorporated into the outpatient setting based on these guidelines[14,15,28]. A randomized control trial in a hospital outpatient setting reported over 200% improvements in 12-week healing rates (45% vs. 19%) in foot ulcer wounds randomized to the study arm with FL-imaging[15]. Similarly, a retrospective study in the hospital outpatient setting reported 12-week healing rate improvements of 23% when this imaging technology was implemented in the real world across all patients being treated at a foot ulcer clinic (i.e. no exclusion criteria), as well as a 33% decrease in systemic antibiotic prescribing[14]. Substantial cost savings to the National Health Service were associated with the implementation of this technology[14]. Based on this body of evidence, FL-imaging has been recommended by the International Wound Infection Institute 2022 guidelines[4] and the

International Surgical Wound Complications Advisory Panel 2022 guidelines[29].

SNFs and LTC facilities typically care for patients with greater number of co-morbidities and therefore wounds that are the most challenging to heal[17,30,31]. Randomized control trials (RCTs) and other clinical studies are rarely offered to this patient population due to logistical challenges, including the large number of exclusion criteria the patients would have[32]. Paradoxically, this is the population most likely to benefit from new technology and from advanced wound care. Their wounds are at high risk for infection and related complications that frequently necessitate transfer to acute care for treatment. Published case studies suggest strong benefit of FL-imaging of wound bacteria in SNFs[33], especially as these patients are the most likely to be immunocompromised and therefore fail to mount signs and symptoms of wound and systemic infection[5]. They are also more likely to have adverse reactions to prescribed systemic antibiotics[34]. However, to date there have been no clinical outcome studies on FL-imaging of bacteria from SNF and LTC settings.

This retrospective pre/post intervention analysis was performed on 193 wounds from 113 Medicare-covered patients in the state of Missouri to determine definitively whether this imaging procedure had improved outcomes and reduced associated treatment costs in the SNF and LTC patient population.

Methods

Study population & design. This retrospective chart review (RCR), pre/post interventional study included 193 wounds from 113 patients. Two time periods were evaluated: pre-fluorescence imaging (Jan 2019 to Feb 2020) and post-fluorescence imaging (May 2021 to March 2022). These dates avoided the time during the pandemic when facilities (SNF and LTC) restricted access to outside providers.

Patient selection. First, the Wound Care Plus LLC patient database was filtered to identify patients who (1) received at least one debridement, as indicated by CPT codes 11042, 11045, 97597, and/or 97598, during the study period; (2) were treated by one of 17 Wound Care Plus LLC providers in a SNF or LTC setting; and (3) were covered by Medicare of Missouri. These criteria generated a population of 194 patients, where each patient was allocated to one of two dichotomous cohorts: pre-fluorescence imaging (standard of care; SoC) or post-fluorescence imaging (FL). Patients in the FL cohort must have had at least one FL-imaging procedure during the study period, indicated by CPT code 0598T.

Wound selection. Wounds were included in this analysis if they (1) were present or received care for more than 4 weeks; (2) had an admission date within the study period; (3) had an ICD-10-CM code indicating a diabetic ulcer, pressure ulcer, or mixed etiology ulcer where pressure was a contributing factor. A maximum of three wounds per patient were included in this analysis. Where more than 3 eligible wounds were present on a patient, 3 wounds were selected using a random number generator. 81 patients did not have wounds that met the inclusion criteria and were therefore not included in this analysis. Other than FL-imaging, there were no other additions or changes to services between these time periods.

Data collection. A set of main research questions was scripted and revised by all principal investigators at the beginning of the study and the resulting dataset was designed in line with the research questions. Variables were defined and operationalized in accordance with extensive literature research. The dataset was revised and accepted by all researchers before the data collection took place. A detailed data collection manual (Standard Operating Procedure) was created, and data abstractors were trained prior and monitored throughout data collection. A pilot data collection test was conducted, and operational weaknesses addressed before the data collection could continue. Any discrepancies or doubts regarding coding of a given variable were discussed and resolved. Data collection was focused on accuracy, consistency, and objectivity. The principal investigators took care in providing unbiased information to the data collectors to avoid collection bias. After the dataset was deemed complete, a set of 2 audits was performed by an independent data analyst to ensure reliability.

Statistics. Impact of FL-imaging on the average duration to heal was analyzed for the wounds that healed in either cohort (n=83/193, 43%) using a 2-tailed t-test.

Results

Patient population. The systematic, unbiased method outlined above resulted in a dataset of 193 wounds from 113 patients who had been seen by 17 Wound Care Plus LLC providers across 54 facilities in Missouri, U.S. Of these, 52 patients (89 wounds) were in the SoC cohort; these patients were admitted between January 2019 and March 2020 and received care for at least 4 weeks. 61 patients (104 wounds) were in the FL cohort; these patients were admitted between May 2021 and March 2022, received care for at least 4 weeks, and had at least one FL-imaging session. **Table 1** reports the patient demographics and wound characteristics in these two cohorts, while **Table 2** breaks down the comorbidities identified in each cohort.

Table 1: Patient demographics and wound characteristics.

	SoC Jan 2019-Feb 2020		**FL** May 2021-Mar 2022	
Patients	**n**	**%**	**n**	**%**
113 total	52	46	61	54
Age				
Mean (SD)	73		82	
Range	41-98		56-100	
Sex	**n**	**%**	**n**	**%**
Female	24	46	35	57
Male	28	54	26	43
Type of Facility	**n**	**%**	**n**	**%**
SNF (Skilled Nursing Facility)	50	96	61	100
LTC (Long Term Care Facility)	1	2	0	0
Rehabilitation Center/Hospital	1	2	0	0
Polypharmacy	**n**	**%**	**n**	**%**
Yes	45	87	56	92
No	6	12	5	8
Antibiotic for a non-wound related cause	**n**	**%**	**n**	**%**
	7	13	10	16

Comorbidities	n	%	n	%
≥ 1	42	81	54	89
None	10	16	7	11
Average # comorbidities	2.4		2.1	
Wounds	**n**	**%**	**n**	**%**
193 total	89	46	104	54
Wound Type	**n**	**%**	**n**	**%**
diabetic ulcer	18	9	8	4
pressure injury	67	35	42	22
chronic wound of mixed etiology including pressure	4	2	54	28
Severity	**n**	**%**	**n**	**%**
full thickness	83	93	97	93
partial thickness	3	3	5	5
unstageable	3	3	2	2

Table 2: Detailed breakdown of the comorbidities identified in the study patient population.

	SoC		FL	
Comorbidities	**n**	**%**	**n**	**%**
Diabetes	25	24	32	28
Malnutrition/Anemia	17	17	15	13
Vascular insufficiency	14	14	13	12
Chronic obstructive pulmonary disease	14	14	13	12
Obesity	12	12	16	14
Chronic kidney disease	12	12	5	4
Congestive heart disease	9	9	13	12
Lymphedema	0	0	5	4
Immunodeficiency	0	0	1	1
Total	**103**	**-**	**113**	**-**

Wound healing. This analysis revealed that the **percentage of wounds healed within 12 weeks increased by 57%** (20.2% to 31.7%) after FL-imaging information was added to treatment of this immunocompromised, high risk, infection-prone, and hard to heal patient population, when medically indicated[5]. Similarly, the percentage of wounds healed at 8-weeks increased by 51% (14.6% to 22.6%) with the addition of FL-imaging. Of the wounds that healed at any point, the **average duration of healing was 12.2 weeks with FL-imaging vs. 17.6 weeks before FL-imaging** was available to this patient population (31% decrease, $p = 0.025$). This finding of 12-week healing rates almost doubling is aligned with randomized controlled trial evidence in the outpatient population [15], but the data herein represents a much more compromised and challenging to heal aged population. Further, we achieved this with minimal use of cellular tissue products (only 1.6% of all study wounds received CTPs).

By 20 weeks a smaller percentage of wounds had healed in the SoC cohort (28.1%) than were healed by 12-weeks in the FL cohort (31.7%), **suggesting that 8 weeks of additional standard care was not sufficient to bridge this gap.**

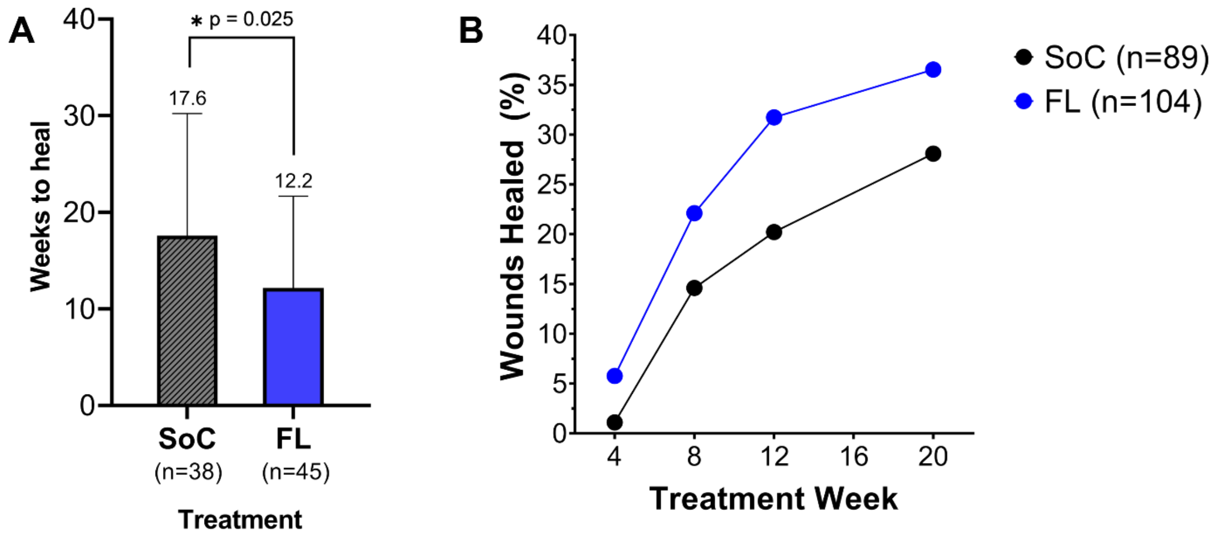

Figure 1: (A) Average duration of study wounds that healed at any point. **(B)** Wound healing rates for wounds pre/post FL-imaging. SoC = standard of care; FL = SoC plus fluorescence imaging.

Infection, antibiotics, & hospitalizations. The **percentage of patients with severe infection-related complications** (cellulitis, sepsis, osteomyelitis, or any wound-associated hospitalization) was **5.3-fold lower** in patients who received FL-imaging (3.3% FL vs. 17.3% SoC). As bacterial burden could be proactively monitored and addressed before it spread to infection, the **use of systemic antibiotics decreased by 29%** (47.2% SoC patients vs. 33.3% FL patients). When prescribed, 1.7 antibiotic courses were required, on average. For reference, the average cost of a course of systemic antibiotics ranges from $2000 to $4500, depending on the specific antibiotic used.

Volume of performed procedures. After incorporation of FL-imaging, we observed a substantial **38% decrease in the percent of wounds for which microbiology (PCR) was performed** (24.7% vs. 15.4%). The median number of fluorescence imaging procedures, when performed, was 5 (range: 1 to 20).

Discussion

When implementing new clinical advances, it is an unfortunate reality that LTC and SNF patients are often the last to benefit. Studies assessing these clinical advances are typically not performed in these settings[32], despite the relevance to this wound-prone patient population and the high cost to treat their frequent wound infection complications, including acute hospitalizations[6,7,20]. This emphasizes the importance of the current study, which directly evaluated these metrics to make conclusions about the care benefit to this vulnerable patient population in these sites of service. The resulting data clearly demonstrates that use of point-of-care FL-imaging for detection of wound bacterial location and loads (>10^4 CFU/g) improves wound outcomes in the SNF and LTC context, consistent with evidence reported in the outpatient setting[14,15]. With SoC, 12-week healing rates in this population were 20%. The longer the wound remains open, the longer it is at risk of severe infection complications[4]. Our analysis revealed that 17% of SoC patients experienced an infection-associated complication with their wound (cellulitis, osteomyelitis, sepsis, amputation, and/or hospitalization). In contrast, the rate of infection complications fell to 3% in patients whose wounds were imaged for bacteria at least once during their treatment, while 12-week healing rates increased to 32%. This study reflects the standard of wound care received by residents across 54 facilities and is therefore generalizable to other facilities across the United States. After completing the required clinician training on the FL-imaging procedure, these outcome improvements (i.e. healing rates and reduction in severe infection complications), would also be expected in facilities across the US that adopted this procedure.

Low wound closure rates prolong poor quality of life and infection risk for patients and incur tremendous financial costs to patients, health systems, and payers. With standard of care, 12-week healing rates in this population were 10% lower than 12-week healing rates for the US outpatient wound population (~30%)[35], as would be expected in these harder to heal patients. National average DFU healing rates outside of clinical trials, within any time frame, have been reported as 45% in the United States[35]. Put another way, 55% of chronic wounds fail to heal in the United States.

The 60% increase in 12-week wound healing rate in this study represents a clinically significant quality of life improvement for these patients, many of whom would likely not have achieved wound closure without this imaging technology.

The single most impactful factor in driving cost in wound care is time to heal[36]. High bacterial loads in wounds increase the cost of care, and this is exacerbated by infection-associated complications[37]. Herein, the average time to healing was 5.4 weeks faster in the FL-imaged cohort (17.6 vs. 12.2 weeks, p=0.025). Each of these eliminated weeks represent eliminated provider visits, time spent charting, debridement, wound dressings (and nursing home FTE time for dressing changes,) possibly high-cost antibiotics or cellular-based tissue products, and costs of infection-related complications.

If bacterial loads can be detected and thoroughly removed pre-infection, antibiotic prescribing is not required, and infection rates decrease.

The findings in this study are attributed to earlier bacterial detection and specific locational information enabled by correctly applied FL-imaging diagnostic information. This facilitated improved treatment planning to remove bacteria more thoroughly through non-systemic interventions (e.g. cleansings, debridement, use of topical antimicrobials, better selection of dressings, knowing not to place a cellular-based tissue product or other advanced therapy contraindicated for high bacterial loads and infection). In large prospective multisite clinical trials, treatment plans changed approximately 70% of the time after incorporating FL-imaging and image interpretation[9,10] and antimicrobial stewardship decisions were specifically impacted in >50% of chronic wounds[10].

Rather than increasing antibiotic use when pathogenic bacterial loads were detected, we found that systemic antibiotic use decreased by 29% after the addition of FL-imaging. This has also been shown in the outpatient setting by Price[14]. Furthermore, we show a 5-fold decrease in severe infection-associated complications.

Infection prevention and treatment is a battle wound clinicians fight daily, often without appropriate diagnostic information. A seminal publication in 2021 by Serena et al. reported the real-world, alarmingly high and haphazard antimicrobial and antibiotic prescribing practices in wound care across the United States[38]. Based on this unacceptable practice, and the supporting evidence for FL-imaging in antimicrobial stewardship, Serena has proposed FL-imaging of bacterial location and load as a foundation of Joint Commission mandated antimicrobial stewardship programs for wound care[39].

The utility of FL-imaging for detecting bacteria in chronic wounds has been well documented. In addition to RCTs reporting the impact on wound outcomes, clinical studies have indicated the value of this imaging procedure in influencing treatment plans[9,10,28,40-43], informing debridement[28,44] and improving overall patient care[9,10,28,43]. Based on this wealth of clinical data, fluorescence imaging was assigned reimbursement codes from the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS). Specifically, the procedure is reimbursed through two CPT codes (category III) for "noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session, first anatomic site (e.g. lower extremity)" (0598T) and "each additional anatomic site (e.g. upper extremity" (0599T)[45]. 0598T was granted an APC assignment to 5722/T effective July 1, 2020. The procedure has also been granted four new ICD-10-PCS (procedural) codes for bacterial autofluorescence based on anatomical site: BW52Z1Z (Other Imaging of Trunk using Bacterial Autofluorescence), BW59Z1Z (Other Imaging of Head and Neck using Bacterial Autofluorescence), BW5CZ1Z (Other Imaging of Lower Extremity using Bacterial Autofluorescence), and BW5JZ1Z (Other Imaging of Upper Extremity using Bacterial Autofluorescence); these went into effect on October 1, 2020. These actions speak to the high level of evidence surrounding the use of FL-imaging in detecting high bacterial loads in chronic wounds.

Conclusion

This systematic retrospective pre/post intervention analysis of Medicare beneficiaries in the state of Missouri undergoing wound treatment revealed substantial outcome improvements and cost savings when FL-imaging of bacterial presence, location, and load procedure was included in their care, when medically indicated[5]. Due to the high rates of infected wounds and septic patients from LTC and SNF admitted to the hospital, early detection and appropriate monitoring of wound bioburden is critical from both a cost and patient care perspective. The outcome improvements observed herein in the SNF and LTC settings included a 60% increase in the percent of wounds healed within 12 weeks, a statistically and clinically significant 5-week decrease in mean wound healing time, and a 5-fold reduction in the percentage of patients with severe infection-related complications (cellulitis, sepsis, osteomyelitis, or any wound-associated hospitalization). Rather than increasing antibiotic use when pathogenic bacterial loads were detected, use of systemic antibiotics decreased by 29%. Consistent with randomized control trials and cohort trials in hospital outpatient settings[14,15], these outcomes are attributed to earlier detection of bacterial load enabled by imaging information and improved treatment planning to more thoroughly remove bacteria through non-systemic interventions (e.g. cleansings, debridement, use of topical antimicrobials, better selection of dressings). Overall, we report that procedure volume decreased with the faster healing times as well as reduced laboratory testing of wound microbiology, equating to clinically and economically significant outcomes for Medicare and its beneficiaries.

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