



PERSPECTIVE ARTICLE

The impact of the SARS-CoV-2 pandemic on the management of chronic limb-threatening ischemia and wound care

Vickie R. Driver DPM, MS, FACFAS, FAWC¹  |
 Kara S. Couch MS, CRNP, CWCN-AP, FAWC² | Kristen A. Eckert MPhil³ |
 Gary Gibbons MD^{4,5} | Lorena Henderson APRN, MSN, FNP-C⁶ | John Lantis MD⁷ |
 Eric Lullove DPM⁸ | Paul Michael MD FSCAI⁹ | Richard F. Neville MD FACS^{10,11} |
 Lee C. Ruotsi MD, ABWMS, CWS-P, UHM¹² |
 Robert J. Snyder DPM, MBA, MSc, CWSP, FFPM RCPS (Glasgow)¹³ |
 Fadi Saab MD, FASE, FSCAI, FACC¹⁴ | Marissa J. Carter PhD, MA³ 

¹Wound Healing, Limb Preservation and Hyperbaric Centers, Inova Heart and Vascular Institute Inova Health System, Falls Church, Virginia, USA

²Wound Care Services, George Washington University Hospital, Washington, District of Columbia, USA

³Strategic Solutions, Inc., Bozeman, Montana, USA

⁴Center for Wound Healing, South Shore Health, Weymouth, Massachusetts, USA

⁵Boston University School of Medicine, Boston, Massachusetts, USA

⁶PULSE Amputation Prevention Centers, Affiliates, El Paso Cardiology Associates, P.A., El Paso, Texas, USA

⁷Mount Sinai West Hospital, Icahn School of Medicine, New York, New York, USA

⁸West Boca Center for Wound Healing, Coconut Creek, Florida, USA

⁹Palm Beach Heart & Vascular, JFK Wound Management & Limb Preservation Center, Lake Worth, Florida, USA

¹⁰Inova Heart and Vascular Institute, Falls Church, Virginia, USA

¹¹Department of Surgery, Inova Health System, Falls Church, Virginia, USA

¹²Saratoga Hospital Center for Wound Healing and Hyperbaric Medicine, Saratoga Springs, New York, USA

¹³Barry University School of Podiatric Medicine, Miami Shores, Florida, USA

¹⁴Advanced Cardiac & Vascular Centers for Amputation Prevention, Grand Rapids, Michigan, USA

Correspondence

Vickie R. Driver, 1788 North Pierce st
 Arlington Virginia 22209, USA
 Email: drvdriver@aol.com

Funding information

The Global CLI Society

Abstract

In the wake of the coronavirus pandemic, the critical limb ischemia (CLI) Global Society aims to develop improved clinical guidance that will inform better care standards to reduce tissue loss and amputations during and following the new SARS-CoV-2 era. This will include developing standards of practice, improve gaps in care, and design improved research protocols to study new chronic limb-threatening ischemia treatment and diagnostic options. Following a round table discussion that identified hypotheses and suppositions the wound care community had during the SARS-

Abbreviations: ABI, ankle brachial index; BKA, below-knee amputation; CDS, clinical decision support; CLI, critical limb ischemia; CLTI, chronic limb-threatening ischemia; CMS, The Centers for Medicare and Medicaid Services; DFU, diabetic foot ulcer; DRPI, device-related pressure injuries; EMR, electronic medical record; ER, emergency room; ICU, intensive care unit; OR, operating room; PI, pressure injury; PAD, peripheral arterial disease; PPE, personal protective equipment; RCT, randomized controlled trial; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; WCWW, Wound Care Center Without Walls; Wifl, wound, ischemia, and foot infection.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.

© 2021 The Authors. *Wound Repair and Regeneration* published by Wiley Periodicals LLC on behalf of The Wound Healing Society.

CoV-2 pandemic, the CLI Global Society undertook a critical review of literature using PubMed to confirm or rebut these hypotheses, identify knowledge gaps, and analyse the findings in terms of what in wound care has changed due to the pandemic and what wound care providers need to do differently as a result of these changes. Evidence was graded using the Oxford Centre for Evidence-Based Medicine scheme. The majority of hypotheses and related suppositions were confirmed, but there is noticeable heterogeneity, so the experiences reported herein are not universal for wound care providers and centres. Moreover, the effects of the dynamic pandemic vary over time in geographic areas. Wound care will unlikely return to prepandemic practices. Importantly, Levels 2–5 evidence reveals a paradigm shift in wound care towards a hybrid telemedicine and home healthcare model to keep patients at home to minimize the number of in-person visits at clinics and hospitalizations, with the exception of severe cases such as chronic limb-threatening ischemia. The use of telemedicine and home care will likely continue and improve in the postpandemic era.

KEYWORDS

chronic limb-threatening ischemia, COVID-19, SARS-CoV-2, severe acute respiratory syndrome coronavirus 2, wound care

1 | INTRODUCTION

Chronic limb-threatening ischemia (CLTI) is a devastating condition found in 6.5 million patients in the United States, Japan, and Europe.^{1,2} The terminology change from the term critical limb ischemia (CLI) towards CLTI is to distinguish between CLI, which implies that there are minimum threshold values for impaired perfusion, and CLTI, which recognizes that the impaired perfusion occurs on a continuum.^{3,4} Previously, CLI, included hemodynamic data such as an ankle brachial index (ABI) of ≤ 0.3 , absolute ankle pressure < 50 mmHg, a toe pressure < 30 mmHg, and toe brachial index < 0.3 .^{5,6} The ABI can be falsely elevated in patients with diabetes; consequently, the original definition of CLI presented at an International Vascular Symposium in 1982 specifically excluded diabetics.⁷

CLTI is the end stage of peripheral arterial disease (e.g., Rutherford Category 4–6 or Fontaine Class III and IV; peripheral arterial disease [PAD]) and is a clinical syndrome characterized by rest pain, gangrene, and ischemic ulceration and associated with limb loss and increased mortality.^{8–10} It is important to distinguish CLTI, a progressive and insidious process developing over weeks to months, from acute limb ischemia, typically occurring within 0–14 days and usually due to embolus or thrombosis. With diabetes, CLTI may present with ulceration and gangrene and no claudication or rest pain history. Revascularization is required to restore blood flow to the limb, and up to 75% of patients are indicated for endovascular therapy, but amputation rates remain unsettlingly high, with as many as 20% of patients requiring an amputation at 1 year.^{1,2,11} The mortality risk following diagnosis is 24% at 1 year and 60% at 5 years.¹² Poor outcomes compound the reduced quality of life and high pain experienced by patients with CLTI, with 25% dead at 1 year and more than 60% dead

at 5 years.^{6,13,14} Among European patients, male sex, obesity, the 65–67 year age group, and having high cholesterol and triglycerides have been found to be associated with a CLTI diagnosis.¹⁵ Amputation rates due to CLTI are disproportionately higher among racial and ethnic minorities. A univariate model was developed based on data collected from 88,346 White patients (7.2% of whom had a below-knee amputation [BKA]) and 23,115 Black patients (12.3% of whom had a BKA).¹⁶ Among both racial groups, 6465 patients also identified as Hispanic. Univariate analysis revealed that black race (odds ratio 1.93, 95% CI 1.84–2.03) and Hispanic ethnicity (odds ratio 1.62, 95% CI 1.51–1.73) had a significantly higher risk of having a BKA compared to the White reference group ($p < 0.001$).¹⁶ The financial costs of CLTI may be as high as \$12 billion a year among Medicare patients.^{9,17}

Under normal circumstances, managing CLTI and preventing limb loss is extremely challenging. In addition to CLTI management, a multidisciplinary team approach can offer an intensive prevention strategy (that includes patient education, foot care, and therapeutic footwear) to avoid a significant number of amputations.¹⁸ The multidisciplinary team is part of the global transition from clinic-centred to patient-centric health care in chronic diseases that require involvement of multiple specialties.¹⁹ At the end of the 20th century, collaboration between vascular surgery and podiatry demonstrated economic benefit.²⁰

Since March 2020, health systems have been overburdened by the SARS-CoV-2 pandemic, with wound care sometimes being a casualty of lockdowns that deemed these potentially limb-preserving services to be 'nonessential'.²¹ As of 21 October 2021, there have been more than 242 million confirmed global diagnoses of coronavirus and at least 4.9 million known global deaths. Yet the uncalculated toll of the SARS-CoV-2 pandemic on wound care may not be known for

years to come, and a ‘pandemic within a pandemic’ is foreboding, with healthcare providers worried over future increases in mortality rates and amputations as a result of wound care centres closing, services being disrupted, and patients staying home and avoiding medical attention (and risk of SARS-CoV-2 infection).^{21–23}

Given the uncertainty over when the pandemic will end, the CLI Global Society Wound Care Committee began an important dialogue to understand the impact of SARS-CoV-2 pandemic on the CLTI population, especially with tissue loss, and analyse the available evidence regarding impact of the pandemic. Since health care will likely never return to pre-pandemic practices, the CLI Global Society aims to develop improved clinical guidance that will both inform better care standards to reduce tissue loss during the new SARS-CoV-2 era, develop standards of practice, improve gaps in care, and design improved research protocols to study new CLTI treatment and diagnostic options. Following a round table discussion that identified hypotheses and suppositions the wound care community had during the SARS-CoV-2 pandemic, the CLI Global Society Wound Care Committee undertook a critical review of literature to confirm or rebut these hypotheses, identify knowledge gaps, and analyse the findings in terms of what in wound care has changed due to the pandemic and what wound care providers need to do differently as a result of these changes.

2 | MATERIALS AND METHODS

The CLI Global Society Wound Care Committee organized a round table discussion on the likely impact of the pandemic on CLTI patients on 6 January 2021. The discussion was distilled into hypotheses and ancillary suppositions grouped by the following subjects: SARS-CoV-2 status, amputations, pressure injuries (PIs), patient visit frequency (outpatient wound care centres/clinics), telemedicine, and home health care.

A literature search was carried out on PubMed using the search string: (COVID impact) AND [(chronic limb-threatening ischemia) OR (critical limb ischemia) OR (ischemia) OR (amputations) OR (pressure wounds) OR (pressure injuries) OR (pressure ulcers) OR (wound care) OR (diabetic wounds) OR (diabetic ulcers) OR (outpatient services) OR (home healthcare) OR (telemedicine)] AND [(COVID-19) AND ((chronic limb-threatening ischemia) OR (critical limb ischemia) OR (ischemia) OR (amputations) OR (pressure wounds) OR (‘pressure wounds’ pressure injuries) OR (‘pressure injuries’ pressure ulcers) OR (‘pressure ulcers’) OR (wound care) OR (‘wound care’) OR (diabetic wounds) OR (diabetic ulcers) OR (outpatient services) OR (home health care) OR (telemedicine))].

We screened article abstracts for their relevance to CLTI, tissue loss, and/or wound care, and we included general articles about changes made to health care or other areas of medicine during the pandemic that could still be applicable to CLTI and wound care. Few articles were returned from our initial search that were relevant to the impact of COVID on home healthcare; therefore, we did a separate, more generalized search using the terms: home AND healthcare, for articles published since 2020, which then returned articles relevant to the pandemic.

We chose studies or papers mainly on content related to a hypothesis or supposition. Where there were choices, we focused on higher level of evidence studies (e.g., a full-length published cross-sectional study versus published correspondence or a research letter, or editorial). Pre-print articles not indexed on PubMed were not included. Each paper or study was rated according to the Oxford Centre for Evidence-Based Medicine scheme (<https://www.cebm.ox.ac.uk/resources/levels-of-evidence/ocebml-levels-of-evidence>) but was not assessed further.

3 | RESULTS

Table 1 summarizes the overall graded evidence we found in relation to hypotheses and suppositions.

3.1 | SARS-CoV-2 status

3.1.1 | Hypotheses

1. No universal approaches in regard to testing of patients or staff
 2. Many staff members and providers (facilities) are very concerned that they will become infected by patients
 3. Some facilities assume that patients are virus positive (especially for high risk or emergent procedures)
 4. Polymerase chain reaction testing is the most widely used form of testing; rapid testing is not being widely used due to accuracy concerns
- Early in the pandemic, healthcare facilities in the hardest-hit areas of the world developed procedures to protect their healthcare workers from SARS-CoV-2 infection. In Italy, for example, patients wishing to access an outpatient facility, such as the angiology unit, were not allowed to enter until the reception nurse, equipped with personal protective equipment (PPE), had taken their temperature and provided them with a mask and hand sanitizing gel.²⁴ The patients were then given a questionnaire on their health condition, particularly focused on signs and symptoms typical of SARS-CoV-2 as part of their flowchart procedures. Once admitted, patients had to socially distance from one another (1 m). Patients possibly infected with SARS-CoV-2 were sent to the Infectious and Tropical Diseases Unit for further evaluation, whereas patients with a fever but not suspected of infection were sent home and invited to call their general practitioner/primary care practitioner or paediatrician or the regional toll-free number, if their symptoms worsened. Only 1 person accompanying each patient was allowed in the facility and only when absolutely necessary. If overcrowding happened, patients were asked to wait outside the facility until called. Once admitted, patients underwent the scheduled examination during which they were asked to keep their heads turned away from the operator, when possible, to avoid close face-to-face contact. At the end of the visit, patients were invited to wait for the report in

TABLE 1 Summary of evidence-based status of each hypothesis and supposition on the impact of the SARS-CoV-2 pandemic on the population with chronic limb-threatening ischemia and wound care

Topic	Hypothesis/supposition	Status	Level(s) of evidence
SARS-CoV-2 status	• No standard approaches in regard to testing of patients or staff	Confirmed	Levels 4 and 5
	• Many staff members and providers (facilities) are very concerned that they will become infected by patients	Unknown	N/A
	• Some facilities assume that patients are virus positive (especially for high risk or emergent procedures)	Confirmed	Levels 4 and 5
	• Polymerase chain reaction testing is the most widely used form of testing; rapid testing	Unknown	N/A
	• is not being widely used due to accuracy concerns		
Amputations	• Increase in ratio of major to minor non-traumatic amputations	Confirmed	Level 3
	• Increase in rate of all nontraumatic amputations	Confirmed	Level 3
	• Increase in rate of nontraumatic amputations may not be consistent geographically or using other categorical variables	Rebutted	Level 3
	• Issues with amputations seem to reflect late presentation of at-risk foot or leg (often in the ER) because patients are not being seen on a timely basis (i.e., too late to consider other options)	Confirmed	Level 3
	• Issues with amputations seem to also reflect lack of access to OR to prevent more serious situations from developing (example: sepsis is not being treated as a priority or being treated as a Level 1 access)	Unknown	N/A
	• Lack of interoperability (providers cannot easily access patient medical records outside of their healthcare system)	Unknown	N/A
Pressure injuries	• The incidence of pressure injuries is rising	Confirmed	Levels 4 and 5
	• Thought to have arisen in part due to higher patient occupation rates in intensive care units and hospitals, especially when patients are 'proned'	Confirmed	Levels 4 and 5
Patient visit frequency (outpatient wound care centres/clinics)	• Many patients are being seen less frequently	Confirmed	Levels 4 and 5
	• Some patients are not being seen in person at all	Confirmed	Levels 4 and 5
	• Fear of being infected by SARS-CoV-2 by visiting a wound care clinic	Confirmed	Levels 4 and 5
	• Lack of access, which may reflect wound care centres that are temporarily or permanently closed due to financial or other situations; may need to convince system administrators that wound care is an essential service	Confirmed	Levels 4 and 5
	• Some facilities are stepping up all forms of contact with patients ('No patient left behind'.)	Confirmed	Levels 4 and 5
	• Some providers are triaging patients (combination or virtual or physical visits) using a variety of schemes (e.g., cheat sheets/WiFi/validated risk algorithms) to identify those at risk or the highest risk for poor outcomes	Confirmed	Levels 4 and 5
	• Patients are not getting ancillary services such as vascular assessment or interventions, because these are considered 'elective' or nonessential; indeed, wound care is not widely seen as essential	Confirmed	Levels 4 and 5

TABLE 1 (Continued)

Topic	Hypothesis/supposition	Status	Level(s) of evidence
Telemedicine	• Telemedicine (virtual) visits have skyrocketed	Confirmed	Levels 4 and 5
	• Patients often prefer this form of visit to a face-to-face (physical) visit	Confirmed	Levels 4 and 5
	• CMS and private insurers are covering such visits	Confirmed	Levels 4 and 5
	• Getting the complete picture of the patient is hard	Confirmed	Levels 4 and 5
	• Need for more patient education in general	Confirmed	Levels 4 and 5
	• What are best practices?	Confirmed	Levels 4 and 5
Home health care	• Rate of home healthcare visits is much lower	Mixed ^a	Levels 4 and 5
	• Many providers have gone out of business or programmes discontinued	Rebutted	Levels 4 and 5
	• Some patients may lack access (unable to find provider) because of staff shortages at providers or because there is not a provider in their geographic area	Confirmed	Levels 4 and 5
	• Some patients are fearful of providers infecting them with SARS-CoV-2	Confirmed	Levels 4 and 5

Abbreviations: CMS, the Centers for Medicare and Medicaid Services; ER, emergency room; N/A, not applicable; OR, operating room; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

^aIn the United States, the rate of home healthcare visits is much lower, but in Brazil there has been a surge during the pandemic.

the waiting area outside the unit. Before admitting another patient, the nurse on duty opened the windows for ventilation and disinfected the examination table and all other surfaces that were in contact with the previous patient (chairs, table, etc.) using 2.8% sodium hypochlorite. The nurse disinfected equipment used with disposable alcohol-free disinfectant wipes.²⁴

In ambulatory surgical centres in the United States, procedures were similar, except patients were additionally asked health questions and had their temperatures tested at the facility entrance.²⁵ It was assumed that a proportion of patients were infected asymptotically. Most operating rooms (ORs) were dedicated to procedures that were not airway-aerosol-producing and could be performed without general anaesthesia. Throughput was increased by performing nerve blocks before patients entered ORs. The phase I postanesthesia care unit was bypassed whenever possible by appropriate choices of anaesthetic approach and drugs. For cases in which the surgical procedure did not cause aerosol production, but general anaesthesia was used, initial (phase I) postanesthesia recovery was recommended to occur in the OR where the surgery was done. Anaesthetic practices that achieved fast initial recovery of the brief ambulatory cases were also done. When surgical procedures caused aerosol production (e.g., bronchoscopy), phase I recovery was conducted in the OR, and multimodal environmental decontamination effected after each case. Finally, anaesthesia and nursing teams staggered cases in more than 1 room, so that they were doing one surgical case while the other room was being cleaned.

A survey of 535 vascular surgeons conducted in April of 2020 found that 91.7% had dedicated SARS-CoV-2 OR protocols at their hospital, and 49% had preoperative testing of patients for SARS-

CoV-2 available.²⁶ Less than 20% of surgeons operated on a patient with a confirmed SARS-CoV-2 infection. In the majority of cases, the surgeons waited outside the OR during intubation (53.6%), and most used N95 masks during the operation. The majority indicated they had adequate PPE (94.8%). Ninety-six respondents (17.9%) operated on a patient who was later found to have a SARS-CoV-2 infection. Few subsequently self-quarantined (6%) and/or tested for the virus (10.4%), and only 0.7% reported testing positive for the virus subsequently.

Although elective surgeries were largely postponed in the spring of 2020, to some extent, and depending on geography, many such surgeries were still being done albeit at a lower rate compared to 2019.²⁷ Among our facilities, some allowed surgery to continue on a graded basis using protocols from the American College of Surgeons and Society for Vascular Surgery. Other facilities allowed outpatient wound debridements, if the patient's wound deterioration warranted surgical intervention.

One survey of states having a high level of SARS-CoV-2 cases found that facilities in such states were less likely to perform a lower extremity intervention for CLI compared to states where cases were lower (60.8% vs. 77.5%).²⁷

Low evidence studies (Levels 4 and 5) reveal that, at present, there is no consensus on a standard to managing patients during the pandemic. In part, this reflects different mandates from different healthcare systems, as well as the lack of high-level studies comparing different procedures. The limited evidence was inconclusive about providers' fear of infection and SARS-CoV-2 testing protocols. Protocols at facilities were designed to assume patients are possibly infected with coronavirus or were asymptomatic.

3.2 | Amputations

3.2.1 | Hypotheses

1. Increase in ratio of major to minor nontraumatic amputations
2. Increase in rate of all nontraumatic amputations

3.2.2 | Additional suppositions

- Increase in rate of nontraumatic amputations may not be consistent geographically or using other categorical variables
- Issues with amputations seem to reflect late presentation of at-risk foot or leg [often in the emergency room (ER)] because patients are not being seen on a timely basis (i.e., too late to consider other options)
- Issues with amputations also seem to reflect lack of access to the operating room (OR) to prevent more serious situations from developing (example: sepsis is not being treated as a priority or being treated as a Level 1 access)
- Lack of interoperability (providers cannot easily access patient medical records outside of their healthcare system)

The changes in amputation trends are an important indicator of the impact of the SARS-CoV-2 pandemic on the population with CLTI. There is considerable Level 3 evidence both for an overall increase in amputations, as well as an increase in the major to minor amputation ratio. For example, a United States study (Ohio) found odds ratios of 10.8 for any amputation compared to prepandemic years²⁸; several other studies noted amputation rates more than doubled or tripled to as high as 60%.^{29,30} Major amputation odds ratios were as high as 12.5,²⁸ and the major to minor amputation ratio was reported to increase from 0.3 to 0.7.³¹ In India, researchers commented that the severity of diabetic foot ulcers (DFUs) ranged from Wagner grade III to grade V, and if patients had come in earlier, more lower extremities could have been salvaged.³² In the United States, the higher proportions of patients with diabetic foot had more severe cases of infection during the pandemic compared to prepandemic times (15% vs. 10% of patients).²⁸ In the Netherlands, higher proportions of Rutherford 5 and 6 classifications were presenting among patients with CLTI.³³ Most of these studies took place early on during the pandemic in the spring or early summer of 2020; therefore, we do not know if the situation still holds.

In the Campania region of Italy, among the hardest hit areas in the spring of 2020, the rate of CLTI-related hospitalization decreased from 74 cases/100,000 residents/year to 25 cases/100,000 residents/year, with physicians again reporting higher grades (Fontaine stage IV) during lockdown of 72.4 vs. 57.0 for prepandemic times.³⁰ There was also a considerable reduction in the rate of urgent revascularization, a finding echoed by researchers reporting from three New York City hospitals about the same time, with a decrease of 74%.³⁴ One prospective international cohort study (1103 vascular interventions, 19 countries) indicated a lower limb revascularization mortality

of 9.8% and that acute limb ischemia was seen in 18.5% of patient presentations for lower limb, with a documented mortality of 20.4%; all of these numbers are high compared to prepandemic years.³⁵

In India, an extremely robust, predictive model using glycemic data from previous disasters (taken as similar in impact to the acute lockdown period) and HbA1c/diabetes-related complications from national databases predicted outcomes for periods of lockdown up to 90 days.³⁶ Lockdowns of 30 and 45 days, respectively, increased HbA1c by 2.3% and 3.7%, respectively, with an annual predicted percentage increase in lower extremity amputation rates at the end of just a 30-day lockdown of 10.5%.

Several groups reported on strategies adopted during the pandemic. The STRIDE approach used a triage protocol of virtual care, electronic medical record data mining, and tracing for rapid risk stratification to derive optimal care delivery methods.³⁷ After implementation, 98% of face-to-face visits were due to DFUs, with the overall outpatient rate dropping by 82%, and minor amputation rates dropping by 56% (major amputation rates were not reported). The International Diabetic Foot Care Group developed a 'fast-track pathway': uncomplicated DFUs should be managed by primary care and supported with telemedicine, and if unstable, referred within 48–72 hr to specialized diabetic foot service.³⁸ Complicated DFUs should be referred within 48–72 hr to specialized diabetic foot service; if stable and foot surgery or revascularization are not required or can be postponed, patients can be managed as outpatients, or in community setting or monitored by telemedicine. Severely complicated DFUs must be referred within 24 hr to specialized diabetic foot service and urgently managed in a hospital setting then stepped in the community setting or by telemedicine follow-up with specialized diabetic foot service. A vascular triage system based on experience at three northern CA hospitals categorized patients with CLTI and gangrene, major tissue loss, advanced ischemia or infection (wound, ischemia, and foot infection [WIFI] stage 4) as tier 3 (most urgent cases) and gave them scheduling priority over patients with pain at rest or a minor ulcer (tier 2B) and scheduled for surgery pending OR availability.³¹ Patients in tiers 1 and 2A were deferred until adequate resources had been secured and in accordance with local public health guidelines. Visits to the centres decreased drastically in the early weeks of the pandemic and resulted in the rate of major amputations increasing until the situation was stabilized. Finally, a review of the situation in the United Kingdom suggested that performing primary amputation may be more appropriate than performing complex vascular reconstructions to reduce prolonged hospital stays.³⁹ In addition, there are issues with vascular assessment of patients with mild to moderate CLTI who are not getting timely vascular assessment. The team suggested that telemedicine consultations should manage the population with CLTI with face-to-face assessments reserved for likely severe or deteriorating symptomatic disease.

Clearly in the absence of a coordinated strategy, the CLTI population is vulnerable to serious complications, especially in prolonged lockdowns. The literature review indicates that Level 3 evidence confirms, for the most part, increases in overall amputation rates or major amputation rates are common and almost universally geographic, and

the evidence does support late presentation of at-risk feet or legs, because patients are not being seen on a timely basis. The review does not cover lack of access to ORs, because of lack of data. Likewise, no data were reported about lack of interoperability between healthcare data systems.

3.3 | Pressure injuries

3.3.1 | Hypotheses

1. The incidence of PIs is rising

3.3.2 | Additional supposition

- Thought to have arisen in part due to higher patient occupation rates in intensive care units (ICUs) and hospitals, especially when patients are 'proned'.

Multiple studies have shown that the incidence of PIs rose in hospitals in 2020 (mostly ICUs) in patients infected with SARS-CoV-2. Early on in the pandemic the incidence of device-related PIs (DRPIs) associated with use of PPE in ICUs was conservatively estimated to be 20%–40%, with patients infected with SARS-CoV-2 in ICUs possibly experiencing between 89,000 and 178,000 hospital-acquired DRPIs with costs of US\$5000 per DRPI case (US\$445–\$890 million as of 5 May 2020), without considering indirect costs and possible litigation.⁴⁰ Based on international studies, up to 57% of patients in the prone position develop a PI, which is a worrisome trend given that up to 28% of patients admitted to the ICU with severe SARS-CoV-2 infection are cared for in the prone position.⁴¹

In Massachusetts (United States), 30 cases of hospital-acquired PIs were reported in a hospital, 42% of which were due to proning patients.⁴² Forty-six PIs developed on the coccyx/sacrum/buttocks (39%), face (39%), and ears (9%). A retrospective analysis of a patient registry in a single Colorado healthcare institution showed that among 87 patients who required intubation and mechanical ventilation, 70% needed proning.⁴³ Pressure injuries were identified on ventral (chest, abdomen, and groin) and dorsal surfaces in 38 and 12 patients, respectively, and the face, chin, nose, and neck in 25 patients. A retrospective chart review of 263 patients infected with SARS-CoV-2 requiring intubation in 2 ICUs located in Washington, DC between March 1st and July 26th, 2020 found that 143 required proning, with the average duration of 5.2 days.⁴⁴ Among these patients, 48% developed a facial PI on the cheek (84%) and the ears (50%). The average duration of proning for patients who developed a PI was significantly longer when compared to those who did not develop PIs (6.8 vs. 3.6 days, $p < 0.001$). In Spain, authors of a case-control study of 57 proned patients infected with SARS-CoV-2 requiring mechanical ventilation and 17 controls indicated that the face was the most affected region (69%), with stage II PIs the most frequent injury.⁴⁵ The main variable associated with an increased risk of PIs was the

total number of days under pronation cycles, and 24 hr was a significant breakpoint.

In regard to prone positioning in a biomechanical study, multilayered silicone foam dressings applied as tissue protectors at the forehead and chin resulted in considerable reductions in soft tissue exposures to effective stresses and strain energy densities, respectively.⁴⁶

While proning engendered a three times higher risk of DRPIs compared to the supine position, good clinical practices to reduce facial DRPIs included using protective suits that include prophylactic dressings to protect the eye globes, forehead, and chin; positioners to offer good immersion and envelopment to adequately distribute the head weight; and drying sheets to wick away salivary secretion fluids for moisture management.^{40,47} Further recommendations included keeping skin clean and well hydrated and using a barrier skin wipe or skin protectant if equipment is to be worn for a prolonged period of time to protect against excess moisture. Additionally, skin assessment should be undertaken before proning and following positioning the patient back into the supine position, with dressings such as hydrocolloids, transparent film, and silicone helpful in decreasing facial skin breakdown.⁴¹

The levels of the evidence of the majority of studies investigating PIs were 4 or 5. The evidence confirms that PI incidence increased in 2020 due to proning hospitalized patients with SARS-CoV-2 and due to extensive use of PPE.

3.4 | Patient visit frequency (outpatient wound care centres/clinics)

3.4.1 | Hypotheses

1. Many patients are being seen less frequently
2. Some patients are not being seen in person at all

3.4.2 | Additional suppositions

- Fear of being infected by SARS-CoV-2 by visiting a wound care clinic
- Lack of access, which may reflect wound care centres that are temporarily or permanently closed due to financial or other situations; may need to convince system administrators that wound care is an essential service
- Some facilities are stepping up all forms of contact with patients ('No patient left behind'.)
- Some providers are triaging patients (combination or virtual or physical visits) using a variety of schemes (e.g., cheat sheets/Wifi/validated risk algorithms) to identify those at risk or the highest risk for poor outcomes
- Patients are not getting ancillary services such as vascular assessment or wound care interventions (including infection assessment and management, treatment evaluations, debridement, and

advanced care treatment options), because these are considered 'elective' or nonessential; indeed, wound care is not widely seen as essential

There is evidence (mostly Levels 4 and 5) that patients have been seen less frequently in person compared to prepandemic times at wound care centres and ancillary services, but it is not a universal experience, and the reported trends are very much a snapshot in time that could have changed from one wave to the next. In June 2020, the World Health Organization reported that 76/155 countries (49%) partially or completely disrupted services related to diabetes and its complications.^{22,23,48} Although the Alliance of Wound Care Stakeholders urged that wound care services should continue without interruption to prevent an increase in complications, ER visits, and hospitalizations,⁴⁹ In the United States, some hospitals closed their wound centres, either because they misclassified the service as non-essential or they limited visitors and outpatients from entering the hospital premises.^{21,23} Analysis made public from Tissue Analytics, a wound-specific electronic health record software company, noted a 40% decrease in wound centre visits in their United States dataset from weeks 12, 13, and 14 in 2020, versus 2019.²¹ Some of us experienced a considerable decrease in wound visits in our centres during the height of the pandemic; others were not as impacted. In some cases where wound centres remain open, there can be staffing shortages as some providers (e.g., emergency medicine, infectious disease) are repurposed for pandemic response. Providers should expect the disruptive effects of the pandemic to impact the healthcare system and patients with wounds for at least 18 months.

At one United Kingdom diabetes community service system, there was a 52% reduction in new DFU events in April 2020 compared to April 2019.⁵⁰ Extrapolated to the population of England, there were 2914 fewer new DFUs compared with the prelockdown mean monthly rate. However, in Germany, a June 2020 survey analysis of 67 patients showed that the pandemic *initially* had no significant impact on ambulatory care or wound-related quality of life at that time.⁵¹ During the first wave of the pandemic from March through June, 2020, Germany fared well in comparison with its European neighbours, with daily infections topping no more than 6000 and deaths peaking at 2.78 per million, less than 10% of what was experienced in Spain, France, Italy, and the United Kingdom.^{52,53} After June 2020, hospitals experienced a catch-up effect in elective surgeries. During the second wave that began in October 2020 and peaked during the end-of-year festivities, a partial lockdown was implemented to prioritize the economy, and daily infections peaked to more than 30,000. Orthopaedic services noticed a significant 70% decrease in surgeries and patient visits by December 2020 as a result of patients cancelling out of fear of infection, and services were also inhibited, because health professionals working in elective units in general had to support the SARS-CoV-2 units.⁵²

In Ontario, Canada, 9 of 18 diagnostic imaging clinics surveyed closed as a result of the pandemic, and those that remained open had decreased hours of operation.⁵⁴ The clinics that closed indicated decreased referrals as the primary reason for closure, followed by

staff shortage, concerns for safety, and suspension of elective imaging. Finally, analysis of visits at a dermatological service in the United Kingdom demonstrated that during lockdown, total appointments reduced to 58%, first attendances to 43%, follow-ups to 51%, and day cases to 37% of prelockdown values.⁵⁵ Postlockdown, first attendances showed the greatest recovery, increasing from 43% to 78% of prelockdown values, which suggests the prioritization of new patients. Total appointments postlockdown remained low, representing only 75% of prelockdown values. In 2020, there were 17% fewer total appointments between April and October compared with the same period in 2019.

In the United State, The Centers for Medicare and Medicaid Services (CMS) have promoted the concept of 'hospitals without walls', giving flexibility to temporarily expand sites of care outside of the hospital (i.e., hotel, dormitory, cruise ship, tents) to surge bed capacity to treat patients during the pandemic.²¹ The Wound Care Center Without Walls (WCWW) is an emerging, pandemic wound care model that describes an effective and easy-to-use triage system (Pandemic Diabetic Foot Triage System) to aid in the decision-making process.²¹ In the United Kingdom, the Vascular Society of Great Britain and Ireland suggested that performing primary amputation may be more appropriate than performing complex vascular reconstructions to reduce prolonged hospital stays, though this may depend on infection rates.³⁹ 'Foot in Diabetes UK', who are experts in the management of diabetic foot disease, have published guidance to assist the identification of and management of people with CLTI or infection.³⁹ The aim of the guidance is to support all lower limb clinicians working within the United Kingdom health system during pandemic situation in line with current best practice. The focus is on clinical assessment and decisions on urgent triage, referrals and access to high-risk podiatry, acute vascular, diabetic foot, infectious diseases, or orthopaedic teams for potential life and limb salvage interventions. In Turkey, a simple protocol based on whether the presenting patient has fever or not and the severity of infection of the chronic wound was developed.⁵⁶

Recommendations to manage diabetic foot disease during the pandemic include patient education and the use of online resources provide reminders to maintain glycemic control through diet, exercise, and appropriate medication.⁵⁷ Encouraging self-examination of feet and regular foot care prevents the development of pressure points around the foot and callosities. Finally, telemedicine consultations allow for patient triage, new referral assessments, and visualization and assessment of new or recently healed ulcers and the 'at risk' foot.⁵⁷

In a study of dermatology services in the United Kingdom, patient-related factors include patient anxiety surrounding the risk of contracting SARS-CoV-2 when attending general practitioners or hospitals and socioeconomic or age-related barriers to using virtual systems.⁵⁵ Patients may have been reluctant to seek help due to restrictions on face-to-face consultations. In primary and secondary care, some healthcare professionals were also absent due to sickness, self-isolation, shielding or redeployment to different departments. Some dermatology facilities were reallocated to other purposes relating to the pandemic. These factors may all have disproportionately

affected minority groups and elderly patients, who are at greatest risk from SARS-CoV-2. An Italian study of CLTI patients also found that patients may be gun-shy in reporting symptoms for fear of SARS-CoV-2 exposure at hospital admission—also confirmed for patients with acute coronary syndromes.³⁰ Thus, patients' fear is very real. That said, analysis of patient's responses in another Italian survey demonstrated that, for many patients, fear of the consequences of a DFU were higher than fear of contracting SARS-CoV-2, the more so if the patient had had prior diabetic wounds or an amputation.⁵⁸ We can think of this as two competing risks: SARS-CoV-2 and the consequences of not managing wounds; when wounds and/or comorbidities are severe, the sequiturs of not managing the situation outweigh the sequiturs of SARS-CoV-2 infection.

Telemedicine plays a large role in all the different assessment systems that have come into play worldwide, but not without limitations. For example, in a study of clinical decision support (CDS) assessment for an intrapandemic ambulatory setting, clinically significant CDS malfunctions highlighted the importance of reassessing ambulatory CDS performance after telemedicine expansion.⁵⁹ In other words, after introduction of such services, reassessment should be conducted. While there are many new useful technologies that can be incorporated into telemedicine, many patients with wounds tend to be older adults with comorbid conditions, a population that may not be the most comfortable with smartphone and computer use.⁶⁰ Aside from issues of high-speed Internet access, other studies have indicated that given the alternatives, individuals with chronic wounds are willing to learn how to use smartphones for at-home wound monitoring. It would seem, therefore, that education of patients in telemedicine techniques should pay benefits. The next hypothesis covers the benefits, challenges, and potential best practices of telemedicine in greater detail.

Levels 4 and 5 evidence confirm that many, but not all, patients are being seen less frequently and some not at all due to fear of infection, interruption of wound care services, and/or wound care being deemed nonessential in some places. At the same time, by adopting new protocols and telemedicine, many providers are stepping up all forms of contact with patients. Thus, while the literature supports the hypotheses and suppositions surrounding patient visit frequency, the experiences are not universal.

3.5 | Telemedicine

3.5.1 | Hypothesis

1. Telemedicine (virtual) visits have skyrocketed

3.5.2 | Additional suppositions

- Patients often prefer this form of visit to a face-to-face (physical) visit
- CMS and private insurers are covering such visits

- Getting the complete picture of the patient is hard
- Need for more patient education in general
- What are best practices?

The WHO defines telemedicine as the provision of remote health care via communication and information technologies.⁶¹ There is ample Levels 4 and 5 evidence that telemedicine drastically increased at the beginning of the SARS-CoV-2 pandemic in March 2020. Telemedicine has been used during the pandemic for diagnosis, triage, treatment, surveillance and follow-up care, rehabilitation, and to successfully mitigate the risk of SARS-CoV-2 infection.^{21,27,37,60,62–65} With wound care declared nonessential at the pandemic start, virtual visits were quickly organized via telephone calls and video calls, and remote care and monitoring has largely been augmented by the use of artificial intelligence and portable technology to monitor blood pressure, glucose, foot temperatures, and other vital signs relevant to the population with CLTI. The NYU Langone Health system reported that daily telemedicine visits increased from 102 to 801 between 2 March and 14 April 2020. Within 10 days, 70% of ambulatory visits (over 7000 visits) were video visits.⁶⁷ A 22,900% increase in virtual visits (from 0 to 220) for diabetic foot was reported after just 1 week of implementing telemedicine.³⁷ Among 535 vascular surgeons responding to a national survey of the Society for Vascular Surgery Wellness Task Force in April 2020, 81.3% reported performing virtual ambulatory visits.²⁷ Among 100 plastic surgeons responding to a survey conducted by the American Academy of Facial and Plastic Reconstructive Surgery, 91% reported using telemedicine.⁶³ However, in an international survey of 465 vascular surgeons in 53 countries by the Vascular and Endovascular Research Network, only 29.0% cancelled outpatient visits and only 14.9% reported using telemedicine.⁶⁵ The marked differences in telemedicine usage among surgeons is likely a reflection of the 'digital divide' in health care.^{60,66–70} Nearly 40% of all patients in the United Kingdom did not have access to online consultations in 2019 and additional patients were unfamiliar with the technology.⁶⁹ Elderly, immigrant, and lower-income populations are traditionally considered to have a disadvantage to accessing telemedicine.^{60,65,67–70} The limited availability of broadband and its high costs in some regions are major barriers for the patient population, as well as an inadequate infrastructure for information technology. However, low-to-middle income countries, such as Iran and China, found that the widespread use of smartphones facilitated remote care via social media apps such as WhatsApp, Facetime, and Skype to communicate with their providers.^{64,70,72}

Patients are very satisfied with telemedicine, which they perceive as improved care, and it is much more convenient to them as a time-savings alternative to in-person visits and (in many areas) more affordable. They prefer remote care and monitoring due to the major benefit that they do not have to risk exposure to SARS-CoV-2 at a hospital or health centre. Among 3962 patients receiving telemedicine in a large, private academic health network in Santiago, Chile, they reported even greater access to care compared to in-person visits in 2019 ($p < 0.001$), although access was similar to in-person visits in 2020.⁷³ In Tuscany, Italy, patients with diabetic foot reported on a scale from

0 to 5 that telephone monitoring was useful (mean 4.35), including for the future (mean 4.34).⁵⁸ In Saudi Arabia, only 6.9% of patients with diabetes thought the quality of telemedicine was less than in-person care.⁷⁴ Privacy concerns was a major factor in accepting telemedicine in Korea ($p < 0.001$), and data protection must be ensured.⁶⁷

The coverage and reimbursement of telemedicine visits by CMS, national health systems in the United Kingdom, France, China, and Chile, and private insurers across the globe has greatly facilitated the increased use of telemedicine.^{21,73,75–77} In March 2020, CMS announced that ‘telehealth visits’ are reimbursed at the same rate as in-person visits to further incentivize provider use.²¹ CMS also reimburses ‘virtual check-ins’, which are brief communications (including text messages) to avoid unnecessary office visits, and ‘e-visits’, which a patient initiates using an on-line patient portal. Private insurers such as BlueCross Blue Shield, Humana, UnitedHealthcare, Cigna, and Aetna are expanding telemedicine coverage.⁷⁶

The principal barrier to adopting telemedicine among providers is physician unwillingness. In the American Academy of Facial Plastic and Reconstructive Surgery survey, 69.2% of providers identified physical examination as the main difficulty to using telemedicine.⁶³ In wound care, where the physical examination is particularly crucial, providers are concerned that it is very challenging to comprehensively assess the wound using telemedicine if they cannot smell the wound or touch the wound for temperature differences.^{21,60} Assessing the wound for edema, depth, undermining, and tunnelling is also difficult using telemedicine. Patients who live alone need assistance with photographing wounds in difficult locations, such as the sacrum.^{21,60,78} It has been suggested that initial wound assessment and complex, ischemia, and/or deteriorating wounds should be seen in-person. However, the evidence supports that assessment via videos and photographs are comparable to in-person assessments and can be used successfully to detect infection and produce good outcomes.^{21,68,79} A standard protocol detailing instructions on how to photograph or video the wound should be provided to the patient, caregiver, or remote provider to ensure appropriate lighting, background for contrast, distancing, ruler positioning, and visual field positioning to optimize the remote wound assessment. A French, Level 2 RCT carried out in 2011 was published during the pandemic that demonstrated that video consultations in wound care had similar healing rates to wound care provided at a wound centre and via home care.⁷⁹ The 6-month healing rates were 68.5% (61/89; mean 66.8 days) for telemedicine, 64.4% (38/59; mean 69.3 days) for wound home health care, and 62.9% (22/35; mean 55.8 days) for the wound centre. The authors felt the video visit provided an adequate assessment to determine wound management. For difficult and complex cases, CMS reimburses for simultaneous visits during which a wound care provider provides a virtual visit to a home health provider to provide a clear and accurate wound assessment.²¹ In two case reports, remote consultation between wound care providers and other providers ensured the continuity of care among critical care patients and patients with multiple comorbidities who require hospitalization for reasons beyond wound care.⁶⁸

Traditionally, the goal of wound care was wound closure.²¹ During the pandemic, this goal has shifted to wound management to provide good wound care at home, control associated pain, prevent

wound deterioration and hospitalizations, reduce emergency department visits, and minimize exposure to the virus by limiting unnecessary in-person visits.^{21,37} This means that a healed wound is not the expected outcome, and longer healing times have to be accepted. Before the pandemic, there were no established or comparative best practices in telemedicine in wound care. Over the past year, authors have multiple published triage and treatment algorithms and telemedicine recommendations based primarily on Levels 4 and 5 literature reviews or case reports of their wound centre's overnight experience of shifting to telemedicine.^{21,37,38,55–58,60,80–82} The WCWW model is a geographically fluid telemedicine model that shifts care from the hospital to the outpatient clinic to the physician's office to the home, depending on whether the wound is stable or has complications and/or shows deteriorations.²¹ In this model and other wound care telemedicine models, there are commonalities reported from which emerges a potential best practice hybrid model that uses triage to integrate telemedicine with home care and clinic/hospital visits. An example of a remote wound care consultation provided by a wound care physician to a home healthcare nurse is depicted in Figure 1. Stable wounds, including uncomplicated venous ulcers, stable PIs, recently healed foot ulcers, and healed amputations should be treated at home via telemedicine, home care, and patient self-care (as appropriate), using culturally appropriate and privacy compliant technology, remote monitoring devices, and home delivery of dressings, medications, and other necessary supplies. If the patient is undergoing self-care at home, with or without the help of a household member, it is important to consider the appropriate offloading device. A removable offloading device is recommended to be used whenever possible in a patient that is highly compliant,⁵⁷ although total contact casts can be applied by wound care specialists during home visits to ensure optimal offloading.^{21,80}

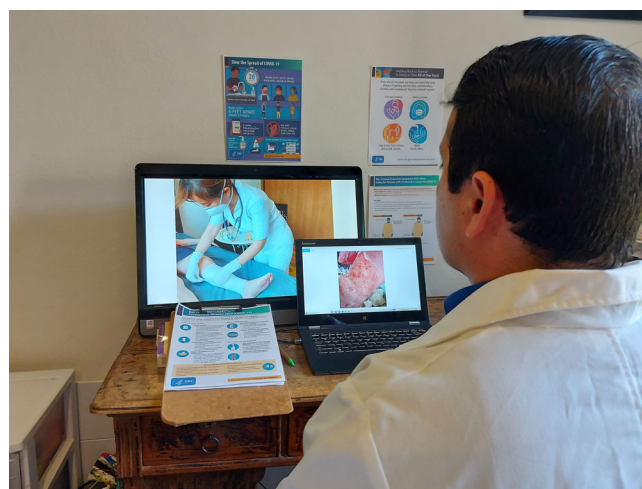


FIGURE 1 A wound care physician provides a remote wound care consultation to a home healthcare nurse. On the computer screen on the right, a digital photograph of the wound was sent by the nurse to the physician to assess. On the computer screen on the left, the nurse, wearing personal protective equipment (a N95 mask) is seen in the patient's bedroom dressing the patient's wound, while the physician guides her through the standard of care process

High-risk, unstable wounds, including those with ischemia, moderate-to-severe infection, and increasing wound size and pain (especially in patients with diabetes), should be treated in-person by a wound care specialist.^{21,37,38,56–58,60,80–82} Limb- or life-threatening infection, especially with diabetes, must be attended to as a surgical emergency. Patients with PAD can participate in telemedicine, but should they develop CLTI, they must be referred to a vascular specialist for in-person care.^{27,33} Urgent intervention is required for CLTI; procedures may be postponed for a short time, in patients with peripheral vascular disease with rest pain or tissue loss. Patient hospitalized for wound infections and/or other complications should be discharged as soon as their wound is stable.^{21,37,38,56–58,60,80–82}

Because patients with CLTI and/or diabetes are at greater risk of hospitalization due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), this hybrid model also introduces a new opportunity for wound care to be provided via remote consultation between a wound care specialist and the patient's provider to ensure the continuity of wound care during SARS-CoV-2 infection.^{21,37,60,68} Providers also face ongoing risk of SARS-CoV-2 infection, and so, organizing teams of providers that rotate between in-person contact and remote care is recommended.³⁷ Given the risk providers have to be quarantined at home, the coordination of teams needs to also be fluid. Those who are quarantined without suspected SARS-CoV-2 could still provide remote care from their homes.

For telemedicine to be successful, it is imperative that all patient data are documented in the electronic medical record (EMR) system.^{37,68,72,74,76} This will be a challenge where EMRs are not used; more increased coordination between all providers and caregivers will be necessary. Protection of patient data must be guaranteed, and before any remote consultation begins, it is necessary to first confirm the patient's identity and obtain patient (or their caregiver's) consent.^{37,67,68,72,74,76} Upon obtaining patient consent, a remote wound consultation during the pandemic should involve^{21,37,38,56–58,60,80–82},

- Documentation of medical history (check for neuropathy and ischemia)
- Patient counselling and education on hygiene and SARS-CoV-2 prevention
- Comprehensive wound assessment involving digital wound photographs using a standardized protocol, videos (if appropriate), and importantly ask if the wound has any odour or local heat
 - All patient data should be documented in their EMR
- Supervision of wound dressing and cleansing (as appropriate)
- Identification of high-risk patients requiring immediate referral to a wound centre or hospital for surgery
- Wound education, especially on wound surveillance, and referral information for the patient in case the wound deteriorates before the next telemedicine visit
- Identification of SARS-CoV-2 infection or suspected infection; confirm patient has been tested for SARS-CoV-2 or direct patient to nearest testing facility. Remote wound care should be provided until the patient is confirmed to be free of infection; limb-saving

surgeries should be carried out using personal protection equipment and strict SARS-CoV-2 protocols.

With patients and/or their caregivers becoming more involved with their care through telemedicine, more patient education is needed. Patient awareness and lack of knowledge of diabetic foot disease was an issue prior to the pandemic, with patients accustomed to surrendering their foot to care at their regular visits with their primary care physician or podiatrist. With the onus now on patients and/or their caregivers at home to take on board advice and regularly look after their feet, a proactive attitude and engagement with the process is required to achieve positive outcomes.^{21,37,38,56–58,60,80–82} Most importantly, it cannot be reiterated enough that patients need to be provided with adequate information on who they can contact if their symptoms are deteriorating, as often urgent intervention may be required, to make telemedicine successful.^{60,66–70}

Authors have reported that their telemedicine models resulted in reduced hospitalizations and comparable outcomes to in-person visits or before the pandemic.^{37,75,79} However, authors acknowledge that, due to the short-term time horizon of these studies, the long-term consequences of minimizing in-person visits could mean a future increase in incidence of amputations and major surgeries as well as increased mortality. Access of care and quality of care has been restricted by the pandemic, especially among new referrals. New diabetic foot referrals decreased by a worrisome 34.8% at one institution.³⁷ While in the postpandemic future, telemedicine may be used with in-person care to improve patient care and engagement; in the context of the pandemic, it must be understood that it is never going to replace in-person care and serves as an urgent alternative care delivery system to ensure that minimal standard of care is provided and prevent serious complications and hospitalizations, whenever possible.

Thus, the drastic increase in telemedicine is confirmed by Levels 4 and 5 evidence, with patients largely preferring virtual visits during the pandemic and private insurers and governments reimbursing these services. While it can be difficult to get the complete picture of the patient, telemedicine can comprehensively assess patients and their wounds. More patient education is still needed. An emerging best practice confirmed by mostly Levels 4 and 5 evidence (and a prepandemic, Level 2 RCT) is a fluid, hybrid telemedicine and home care model that uses triage to provide good care at home whenever possible, while serious cases such as CLTI are treated in-person.

3.6 | Home health care

3.6.1 | Hypothesis

1. Rate of home healthcare visits is much lower

3.6.2 | Additional suppositions

- Many providers have gone out of business or programmes discontinued
- Some patients may lack access (unable to find provider) because of staff shortages at providers or because there is not a provider in their geographic area
- Some patients are fearful of providers infecting them with SARS-CoV-2

There is conflicting evidence, mostly Level 4 and some Level 5, that the rate of home healthcare visits is much lower during the pandemic. This finding is regionally dependent; countries, such as Brazil, with established home care systems integrated into their health systems have seen a surge in visits.⁸³ In wound care, patients are encouraged to receive care at home as much as possible.²¹

In the United States, a national survey of 238 home healthcare agencies in 36 states revealed that during the lockdowns, many patients' family members were working from home and were able to take care of them, reducing the need for a home health aide.⁸⁴ Some patients were fearful of aides infecting them with SARS-CoV-2, with 19.8% of agencies ($n = 238$) reporting SARS-CoV-2 infection or exposure among their aides. Staffing shortages due to absenteeism, whether it be because of SARS-CoV-2 infection, fear of infection (with limited PPE and SARS-CoV-2 prevention protocols available), childcare responsibilities, or confusing policies over whether they were essential workers during lockdowns also reduced visits. Furthermore, it has been difficult to train new recruits. Some patients and their families sought alternative caregiving services. CMS and many states have encouraged alternative home care during the pandemic.^{20,85} There has been an increase in self-direction, in which the patients hire their own staff (including relatives) and manage a government-provided budget for supplies, services, and assistive devices.⁸⁵ Such a programme may be of limited use to patients with CLTI, as the severity of their condition requires in-person care by a wound care/vascular specialist. These findings are also supported in a June 2020 survey of 94 home healthcare care agencies in Massachusetts, with 98.7% of agencies reporting less visits and/or reduced hours.⁸⁶ The majority of Massachusetts agencies had aides who tested positive, were symptomatic, and/or quarantined (59.6% and 73.7%, respectively). Most agencies (61.8%) reduced visits, because their aides were on medical leaves. All the literature revealed the lack of PPE available to home health aides and the exclusion of home healthcare in government guidance and policies related to SARS-CoV-2 prevention and management as major barriers.

Home healthcare visits were also reduced during the pandemic as a result of skilled nursing facilities and assisted and independent living facilities prohibiting all visitors, including providers, to mitigate the risk of SARS-CoV-2 exposure and infection.⁸⁴ The lack of access to care in nursing homes is a particular concern for the population with CLTI, with a considerable proportion living in nursing homes. In the Netherlands, among 449 elderly patients with CLTI who underwent surgical/endovascular treatment, 15.1% ($n = 68$) lived in a nursing

home before their procedure.⁸⁷ Among 1472 surgical cases, 45.8% were discharged to rehabilitation or a nursing home for the first time.⁸⁸ The lack of care available to these patients in nursing homes could cause an increase in amputations and mortality. Primary care-led outbreak mitigation was implemented among 1794 residents in 101 assisted living facilities.⁸⁹ Practitioners visited once or twice per week, first undergoing diagnostic testing for SARS-CoV-2 prior to each visit, and employees used a secure, cloud-based smartphone app to self-screen for SARS-CoV-2 symptoms and isolate at home, as necessary. Only 7 residents (0.4%) tested positive for SARS-CoV-2, 1 of whom died, demonstrating that it was safe to continue to offer primary care at assisted living facilities.

There was no evidence in the literature that home healthcare providers went out of business or had their programmes discontinued. However, providing paid time off during the pandemic, as a result of childcare responsibilities and/or illness, could result in them going out of business.^{84,85} However, it has been our experience that the nursing shortage dramatically worsened as the pandemic continued. For example, many registered nurses working in home healthcare and in hospitals have left bedside care to work in vaccine clinics, have taken travel assignments, or they have simply left nursing altogether. This resulted in delayed discharges from acute care and placed more burden on wound care centres to assume all care post discharge. Therefore, a new care delivery model is needed so that home healthcare agencies can adapt and provide a safe and flexible environment to both their employees and their patients.

The use of telemedicine and home care together has exploded during the pandemic, indicating that the traditional home healthcare model is transforming to a hybrid model of in-person care at home with remote monitoring and management (Figure 1).^{21,71,72,80,83,90} A private home care agency in Brazil, where wound care is often performed at home, reported a 15% increase of 305 patients/month between January and May 2020.⁸³ There were 2931 patients (mean age: 73 years) treated in home care during the 1st quarter of the pandemic, with virtual consultations making up 54% of doctor visits and 44% of nurse visits. There were only 31 confirmed cases of SARS-CoV-2 in only 1% of the study sample, with only 10 hospitalizations (6.1%) and 1 death (0.6%). Thus, remote home care was a safe alternative to traditional in-person visits during the pandemic. In the United States, the WCWW model promotes the combined use of telemedicine and home healthcare in wound care to maintain patients safe at home and provide good standard of care.²¹ Wound care providers and home healthcare providers can be reimbursed by CMS through a simultaneous telehealth visit. In New York, medical students have provided social calls and appropriate referrals to vulnerable patients at home.⁹⁰ In China, patients with mild wound infections are treated at home with oral antibiotics, with house call practices by general practitioners provided to elderly patients and those who live alone.⁸⁰ In Tuscany (Italy), prior to the pandemic, remote monitoring using specialized home nurses began for patients with chronic wounds unable to access the hospital.⁵⁸ A French, Level 2 RCT described in the Telemedicine section confirmed that remote monitoring for wound care via home healthcare had the same good outcomes as in-

person clinic care.⁷⁹ In a Level 2 RCT that was carried out in Taiwan before the pandemic, Liang et al. demonstrated that nurse-led remote home care provided to 100 patients with chronic illnesses was more effective than traditional home care provided to 100 patients, with significantly reduced mortality (8% vs. 19%, $p = 0.027$) and emergency department visits (12% vs. 26%, $p = 0.013$) at 6 weeks.⁹¹ Remote home care involved 24/7 remote monitoring and surveillance using a one-touch smartphone, blood pressure monitor, glucometer (for diabetes), medication dispenser, and a necklace emergency call button. The smartphone provided patients with twice daily reminders to check vital signs and take medication, and all data were automatically transmitted to the 24-hr call centre and electronic health record system. This methodology stresses the importance of using integrated, accessible electronic health records for all providers, including home care aides. Such an integrated approach would allow for telemedicine to provide access to nursing home staff and patients and overcome many of the barriers to home healthcare identified during the pandemic.

In conclusion, while there is no evidence that home health care has gone out of business, Levels 4 and 5 evidence confirms that traditional home healthcare visits have declined during the pandemic, with staffing shortages, lack of providers in some areas, a patient, and their caregivers discontinuing home health care out of fear of contracting SARS-CoV-2. In other regions, home care has seen a surge. Importantly, Levels 2–5 evidence reveals a paradigm shift in home healthcare with the integration of telemedicine to keep patients at home and minimize the number of in-person visits at clinics and hospitalizations. This has increased the accessibility and use of home health care in wound care. Home healthcare agencies that are slow to adapt to use new technologies and coordinate with wound care providers will likely continue to see a reduction in visits.

4 | DISCUSSION

In 2021, countries are racing against time to vaccinate at least 65%–85% of their populations to achieve herd immunity, while managing severe local epidemics due to the latest group of strains that are more infectious and may escape the neutralizing antibodies provided by vaccines, such as the particularly worrisome B.1.351 in South Africa, B.1.1.7 in the United Kingdom; B.1.617 in India and its ubiquitous daughter strain, B.1.617.2 (delta); P1 in Brazil, and others.^{92,93} The United States is now in a relatively good position with vaccination programmes proceeding apace, and the main barrier to achieving herd immunity sometime this year is likely vaccine hesitancy. However, globally, the rampant politicization of unequal vaccine distribution means that billions of people may not have their first vaccinations for another 2 or 3 years, making herd immunity, especially in low- to middle-income countries, an impossible target for 2021.^{92,94} In addition, booster shots aimed at increasing immunity to later strains of the virus will almost certainly be necessary.⁹³ Consequently, many patients with CLTI in many regions of the world will be at higher risk

for adverse events for several years, and wound care will still have to operate using pandemic models.

Research trials are another casualty of the pandemic. In general, many sites of existing trials were shut down for long periods, thus delaying their completion and creating outcome issues, while the launch of new trials, including those involving oncology, has been delayed.^{95,96} The United States Food and Drug Administration issued new guidelines for conducting such trials and waivers for certain kinds of events during the pandemic.⁹⁷ As far as trials of new devices, drugs, or biologics involving patients with PAD and CLTI, this means their completion will be delayed for up to a year or more depending on where the sites are geographically, prolonging access to potentially limb-saving therapies.

As a group, we set out to answer many questions that we formulated based on our own observations of wound care during the pandemic. In the vast majority of cases, these were confirmed through a review of the literature (Table 1). However, there were several instances in which this was not true. For example, there is no published evidence in wound care operations that many staff members and providers (facilities) are very concerned that they will become infected by patients. That does not mean a significant percentage of staff members do not have this fear, as it has been common among healthcare workers and home health aides.^{84,98,99} Likewise, we did not discover what kind of testing was apparent, because SARS-CoV-2 testing at healthcare facilities is widely disparate and country- and facility-dependent. In the case of amputations, we could find no evidence that the increase was due to lack of OR access or lack of priority for those with sepsis, but again absence of evidence is not equal to evidence of absence. This might equally apply to amputation metrics in particular countries or regions, or even cities. Finally, we saw no reports that many home healthcare providers had discontinued programmes or gone out of business, although it was clear that reduced services were common in many areas for a variety of reasons.^{84,86}

Among hypotheses and suppositions that were supported by the evidence, the evidence base was generally weak (Levels 4 and 5), with the exception of trends in amputations during the pandemic, which had moderate levels of evidence (Level 3) (Table 1). This is not surprising, given the short timeframe during which the evidence was quickly published after the pandemic was declared, the waiving of open access fees by journals during the pandemic in a push to make related medical information more accessible to all, and the negative impact of lockdowns on implementing clinical trials. A limitation of undertaking a critical review is that we did not include all the possible evidence published since the onset of the pandemic, so there may be some publication bias in our findings, particularly when considering the speed and volume at which pandemic-related articles have been produced. Any Epublications (ahead of print) indexed on PubMed were considered for inclusion, but we did not search for preprint publications beyond those indexed on PubMed.

One main limitation of this study methodology is that we did not review what we did not originally discuss during the roundtable. A good example of this is the effect of racial disparities, socioeconomic

strata, and rural versus urban settings for patients. These fault lines existed long before the pandemic, but they have been highlighted in terms of testing and treatment for SARS-CoV-2 and technological barriers to accessing telemedicine.^{60,65,67–72,100,101} These factors should be considered, as many patients with CLTI fall into these categories, and they are significantly likely to have worse outcomes (and undergo amputations).¹⁶ There are likely other examples that we must bear in mind as we go forward.

Our search of the literature tells us that there are several tools we can employ to mitigate risks for the global CLTI population while the pandemic is ongoing, including better patient education, telemedicine visits, employment of camera systems to study wounds during those visits, and keeping in contact. Most importantly, we need to better triage our patients so that those at highest risk for severe events can be identified, seen quickly, and a plan of care instituted. Many patients in wound care can be managed remotely and/or at home, but it must be emphasized that patients whose wounds are increasing in size, ischemic, and/or have moderate-to-severe infection must have in-person care by a wound care specialist.^{21,37,38,56–58,60,80–82} Limb- or life-threatening infection must be emergently drained or debrided no matter what the circulation is, but vascular evaluation begins immediately once sepsis is controlled. Furthermore, a vascular specialist must treat in-person all patients with CLTI.^{27,33} Some patients will be vaccinated this year, but some will not for various reasons, and so a significant proportion of patients with CLTI could still have limited access to care.

If there is a silver lining to the pandemic, it is that we have the potential to permanently take better care of our patients based on what we have learned over the last year. Importantly, during the pandemic, there has been a paradigm shift in wound care towards a hybrid telemedicine and home healthcare model to keep patients at home to minimize the number of in-person visits at clinics and hospitalizations, with the exception of severe cases such as CLTI. Our patients generally prefer remote care, and it is unlikely that they will want to return to traditional ways of accessing care in the postpandemic era. While PPE and SARS-CoV-2 protocols may not be a long-term issue, if herd immunity and efficient global vaccine distribution is eventually achieved, the majority of the recommendations that have emerged during the pandemic will likely continue in practice, such as PI prevention protocols for prone patients. It is likely the hybrid telemedicine model of care will continue to be offered by wound care providers to low-risk patients, with the aim to avoid unnecessary visits while improving communication, contact, and coordination that will translate to better patient/caregiver engagement and, hopefully, outcomes. Having these models in place will make healthcare systems better equipped to manage and adapt to future pandemic threats, as well as any other crises that may risk patient and provider safety and possibly overburden health systems. The long-term benefits of these new, adaptive models in the postpandemic era will be that they will ensure continuity of wound care when the patient is unable to visit the wound care centre, is hospitalized for another condition, and/or is in a nursing home.

Ultimately, improved wound care could be a viable outcome in the postpandemic future.

CONFLICT OF INTEREST

Marissa J. Carter: paid consultant of CLI Global Society for this study; Kristen A. Eckert: paid consultant of Strategic Solutions for this study.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study

ORCID

Vickie R. Driver  <https://orcid.org/0000-0002-5148-5365>

Marissa J. Carter  <https://orcid.org/0000-0002-2265-6639>

REFERENCES

- Farber A, Eberhardt RT. The current state of critical limb ischemia: a systematic review. *JAMA Surg.* 2016;151(11):1070-1077.
- Fereydooni A, Gorecka J, Dardik A. Using the epidemiology of critical limb ischemia to estimate the number of patients amenable to endovascular therapy. *Vasc Med.* 2020;25(1):78-87.
- Conte MS, Bradbury AW, Kohl P, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *J Vasc Surg.* 2019;69(6S):3S-125S.e40 Erratum in: *J Vasc Surg.* 2019;70(2):662.
- Van Den Berg JC, Driver VR, Holden A, et al. Modern multidisciplinary team approach is crucial in treatment for critical limb threatening ischemia. *J Cardiovasc Surg (Torino).* 2021;62(2):124-129.
- Carter SA, Tate RB. Value of toe pulse waves in addition to systolic pressures in the assessment of the severity of peripheral arterial disease and critical limb ischemia. *J Vasc Surg.* 1996;24(2):258-265.
- Davies MG. Critical limb ischemia: epidemiology. *Methodist Debaquey Cardiovasc J.* 2012;8(4):10-14. doi:10.14797/mdcj-8-4-10
- Raines JK, Darling RC, Buth J, Brewster DC, Austen WG. Vascular laboratory criteria for the management of peripheral vascular disease of the lower extremities. *Surgery.* 1976;79(1):21-29.
- Kobayashi N, Hirano K, Nakano M, et al. Prognosis of critical limb ischemia patients with tissue loss after achievement of complete wound healing by endovascular therapy. *J Vasc Surg.* 2015;61(4):951-959.
- Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. *J Vasc Surg.* 1997;26(3):517-538. Erratum in: *J Vasc Surg.* 2001;33(4):805.
- Fontaine R, Kim M, Kieny R. Surgical treatment of peripheral circulation disorders (Article in German). *Helv Chir Acta.* 1954;21(5-6):499-533.
- Duff S, Mafilios MS, Bhounsule P, Hasegawa JT. The burden of critical limb ischemia: a review of recent literature. *Vasc Health Risk Manag.* 2019;15:187-208.
- Mustapha JA, Katzen BT, Neville RF, et al. Disease burden and clinical outcomes following initial diagnosis of critical limb ischemia in the Medicare population. *JACC Cardiovasc Interv.* 2018;11(10):1011-1012.
- Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA. Fowkes FGR; on behalf of the TASC II working group. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg.* 2007;45(1 Suppl):S5-S67.
- Jämsén TS, Manninen HI, Tulla HE, Jaakkola PA, Matsi PJ. Infrainguinal revascularization because of claudication: total long-term outcome of endovascular and surgical treatment. *J Vasc Surg.* 2003;37(4):808-815.

15. Ciocan RA, Bolboacă SD, Rădulescu Ş, Stancu B, Ciocan A, Gherman CD. Demographic and comorbidity pattern of patients with critical limb ischemia. *Folia Med (Plovdiv)*. 2017;59(1):14-22.
16. Traven SA, Synovec JD, Walton ZJ, Leddy LR, Suleiman LI, Gross CE. Notable racial and ethnic disparities persist in lower extremity amputations for critical limb ischemia and infection. *J Am Acad Orthop Surg*. 2020;28(21):885-892.
17. Driver VR, Fabbi M, Lavery LA, Gibbons G. The costs of diabetic foot: the economic case for the limb salvage team. *J Vasc Surg*. 2010;52(3 Suppl):175-225.
18. Mustapha JA, Katzen BT, Neville RF, et al. Determinants of long-term outcomes and costs in the management of critical limb ischemia: a population-based cohort study. *J Am Heart Assoc*. 2018;7(16):e009724.
19. Joret MO, Osman K, Dean A, Cao C, van der Werf B, Bhamidipaty V. Multidisciplinary clinics reduce treatment costs and improve patients outcomes in diabetic foot disease. *J Vasc Surg*. 2019;70(3):806-814.
20. Van Gils CC, Wheeler LA, Mellstrom M, Brinton EA, Mason S, Wheeler CG. Amputation prevention by vascular surgery and podiatry collaboration in high-risk diabetic and nondiabetic patients. The operation desert foot experience. *Diabetes Care*. 1999;22(5):678-683.
21. Rogers LC, Armstrong DG, Capoportto J, et al. Wound center without walls: the new model of providing care during the COVID-19 pandemic. *Wounds*. 2021;32(7):178-185.
22. Bornstein SR, Rubino F, Ludwig B, et al. Consequences of the COVID-19 pandemic for patients with metabolic diseases. *Nat Metab*. 2021;3(3):289-292.
23. Rogers LC, Snyder RJ, Joseph WS. Diabetes-related amputations: a pandemic within a pandemic. *J Am Podiatr Med Assoc*. 2020 Nov;3:20-248. doi:10.7547/20-248 Epub ahead of print.
24. Avruscio G, Adamo A, Tonello C, et al. Wound care during the COVID-19 emergency in Padua Hospital (Italy). *Disaster Med Public Health Prep*. 2020;1-14. doi:10.1017/dmp.2020.448. Epub ahead of print. PMID: 33208205; PMCID: PMC7943949.
25. Dexter F, Elhakim M, Loftus RW, Seering MS, Epstein RH. Strategies for daily operating room management of ambulatory surgery centers following resolution of the acute phase of the COVID-19 pandemic. *J Clin Anesth*. 2020;64:109854.
26. Latz CA, Boitano LT, Png CYM, et al. Early vascular surgery response to the COVID-19 pandemic: results of a nationwide survey. *J Vasc Surg*. 2021;73(2):372-380.
27. Mouawad NJ, Woo K, Malgor RD, et al. The impact of the COVID-19 pandemic on vascular surgery practice in the United States. *J Vasc Surg*. 2021;73(3):772-779.
28. Casciato DJ, Yancovitz S, Thompson J, et al. Diabetes-related major and minor amputation risk increased during the COVID-19 pandemic. *J Am Podiatr Med Assoc*. 2020;20-224. doi:10.7547/20-224. Epub ahead of print.
29. Caruso P, Longo M, Signoriello S, et al. Diabetic foot problems during the COVID-19 pandemic in a tertiary care center: the emergency among the emergencies. *Diabetes Care*. 2020;43(10):e123-e124.
30. Stabile E, Piccolo R, Franzese M, et al. A cross-sectional study evaluating hospitalization rates for chronic limb-threatening ischemia during the COVID-19 outbreak in Campania, Italy. *Vasc Med*. 2021;26(2):174-179.
31. Lancaster EM, Wu B, Iannuzzi J, et al. Impact of the coronavirus disease 2019 pandemic on an academic vascular practice and multidisciplinary limb preservation program. *J Vasc Surg*. 2020;78:1850-1855.
32. Mehanathan PB, Edwards AA, Athsayamani RT. Experience of a surgeon at the emergency department during COVID-19 pandemic. *Ann Med Surg (Lond)*. 2020;60:245-248.
33. Schuivens PME, Buijs M, Boonman-de Winter L, et al. Impact of the COVID-19 lockdown strategy on vascular surgery practice: more major amputations than usual. *Ann Vasc Surg*. 2020;69:74-79.
34. Ilonzo N, Koleilat I, Prakash V, et al. The effect of COVID-19 on training and case volume of vascular surgery trainees. *Vasc Endovasc Surg*. 2021;55(5):429-433.
35. Benson RA, Nandhra S. Outcomes of vascular and endovascular interventions performed during the coronavirus disease 2019 (COVID-19) pandemic: the vascular and endovascular research network (VERN) Covid-19 vascular service (COVER) tier 2 study. *Ann Surg*. 2020;273(4):630-635.
36. Ghosal S, Sinha B, Majumder M, Misra A. Estimation of effects of nationwide lockdown for containing coronavirus infection on worsening of glycosylated haemoglobin and increase in diabetes-related complications: a simulation model using multivariate regression analysis. *Diabetes Metab Syndr*. 2020;14(4):319-323.
37. Schmidt BM, Munson ME, Rothenberg GM, Holmes CM, Pop-Busui R. Strategies to reduce severe diabetic foot infections and complications during epidemics (STRIDE). *J Diabetes Complications*. 2020;34(11):10769.
38. Meloni M, Bouillet B, Ahluwalia R, et al. Fast-track pathway for diabetic foot ulceration during COVID-19 crisis: a document from international diabetic foot care group and D-foot international. *Diabetes Metab Res Rev*. 2021;37(3):e3396.
39. Chadwick P, Ambrose L, Barrow R, Fox M. A commentary on podiatry during the Covid-19 pandemic: podiatry during the Covid-19 pandemic. *J Foot Ankle Res*. 2020;13(1):63.
40. Gefen A, Ousey K. Update to device-related pressure ulcers: SECURE prevention. COVID-19, face masks and skin damage. *J Wound Care*. 2020;29(5):245-259.
41. Moore Z, Patton D, Avsar P, et al. Prevention of pressure ulcers among individuals cared for in the prone position: lessons for the COVID-19 emergency. *J Wound Care*. 2020;29(6):312-320.
42. Martel T, Orgill DP. Medical device-related pressure injuries during the COVID-19 pandemic. *J Wound Ostomy Continence Nurs*. 2020;47(5):430-434.
43. Douglas IS, Rosenthal CA, Swanson DD, et al. Safety and outcomes of prolonged usual care prone position mechanical ventilation to treat acute coronavirus disease 2019 hypoxemic respiratory failure. *Crit Care Med*. 2021;49(3):490-502.
44. Shearer SC, Parsa KM, Newark A, et al. Facial pressure injuries from prone positioning in the COVID-19 era. *Laryngoscope*. 2021;131:E2139-E2142. doi:10.1002/lary.29374
45. Ibarra G, Rivera A, Fernandez-Ibarburu B, Lorca-García C, Garcia-Ruano A. Prone position pressure sores in the COVID-19 pandemic: the Madrid experience. *J Plast Reconstr Aesthet Surg*. 2021;74(9):2141-2148.
46. Peko L, Barakat-Johnson M, Gefen A. Protecting prone positioned patients from facial pressure ulcers using prophylactic dressings: a timely biomechanical analysis in the context of the COVID-19 pandemic. *Int Wound J*. 2020;17(6):1595-1606.
47. Gefen A, Alves P, Ciprandi G, et al. Device-related pressure ulcers: SECURE prevention. *J Wound Care*. 2020;29(Sup2a):S1-S52.
48. World Health Organization. COVID-19 significantly impacts health services for noncommunicable diseases. 2020. <https://www.who.int/news/item/01-06-2020-covid-19-significantly-impacts-health-services-for-noncommunicable-diseases>. Accessed April 21, 2021.
49. Alliance of Wound Care Stakeholders. Wound care is an essential-not elective-service that prevents hospital admissions and ED visits among a fragile cohort of patients at high-risk of COVID-19. https://www.woundcarestakeholders.org/images/Final2_Statement_-_Wound_Care_as_Essential.pdf. Accessed April 21, 2021.
50. Lipscomb D, Smith AS, Adamson S, Rezazadeh EM. Diabetic foot ulceration in COVID-19 lockdown: cause for concern or unexpected benefit? *Diabet Med*. 2020;37(8):1409-1410.

51. Schlager JG, Kendziora B, Patzak L, et al. Impact of COVID-19 on wound care in Germany. *Int Wound J*. 2021;18:536-542. doi:10.1111/iwj.13553
52. Graichen H. What is the difference between the first and the second/third wave of Covid-19? German perspective. *J Orthop*. 2021;24:A1-A3.
53. Liverpool L. Germany hit hard by second wave. *NewScientist*. 2020; 248(3307):10.
54. Maizlin NN, Ohorodnyk P. Investigating the initial effect of COVID-19 on the functioning of outpatient diagnostic imaging facilities. *J Med Imaging Radiat Sci*. 2020;51(4):574-578.
55. Ibrahim LS, Venables ZC, Levell NJ. The impact of COVID-19 on dermatology outpatient services in England in 2020. *Clin Exp Dermatol*. 2021;46(2):377-378.
56. Kelahmetoglu O, Camlı MF, Kirazoglu A, et al. Recommendations for management of diabetic foot ulcers during COVID-19 outbreak. *Int Wound J*. 2020;17(5):1424-1427.
57. Jaly I, Iyengar K, Bahl S, Hughes T, Vaishya R. Redefining diabetic foot disease management service during COVID-19 pandemic. *Diabetes Metab Syndr*. 2020;14(5):833-838.
58. Iacopi E, Pieruzzi L, Goretti C, Piaggese A. I fear COVID but diabetic foot (DF) is worse: a survey on patients' perception of a telemedicine service for DF during lockdown. *Acta Diabetol*. 2021;58(5): 587-593.
59. Feldman J, Szerencsy A, Mann D, et al. Giving your electronic health record a checkup after COVID-19: a practical framework for reviewing clinical decision support in light of the telemedicine expansion. *JMIR Med Inform*. 2021;9(1):e21712.
60. Mills EC, Savage E, Lieder J, Chiu ES. Telemedicine and the COVID-19 pandemic: are we ready to go live? *Adv Skin Wound Care*. 2020; 33(8):410-417.
61. World Health Organization. A health telematics policy - in support of WHO's Health-for-all strategy for global health development. Report of the WHO Group Consultation on Health Telematics, 11-16 December, Geneva, 1997.
62. Mann DM, Chen J, Chunara R, Testa PA, Nov O. COVID-19 transforms health care through telemedicine: evidence from the field. *J Am Med Inform Assoc*. 2020;27(7):1132-1135.
63. Salehi PP, Torabi SJ, Lee YH, Azizzadeh B. Telemedicine practices of facial plastic and reconstructive surgeons in the United States: the effect of novel coronavirus-19. *Facial Plast Surg Aesthet Med*. 2020; 22(6):464-470.
64. Doraiswamy S, Abraham A, Mamtani R, Cheema S. Use of telehealth during the COVID-19 pandemic: scoping review. *J Med Internet Res*. 2020;22(12):e24087.
65. Betancourt JA, Rosenberg MA, Zevallos A, Brown JR, Mileski M. The impact of COVID-19 on telemedicine utilization across multiple service lines in the United States. *Healthcare*. 2020;8(4):380.
66. Vascular and Endovascular Research Network (VERN) COVER study collaborative. Global impact of the first coronavirus disease 2019 (COVID-19) pandemic wave on vascular services. *Br J Surg*. 2020; 107(11):1396-1400.
67. An MH, You SC, Park RW, Lee S. Using an extended technology acceptance model to understand the factors influencing telehealth utilization after flattening the COVID-19 curve in South Korea: cross-sectional survey study. *JMIR Med Inform*. 2021;9(1):e25435.
68. Engels D, Austin M, Doty S, Sanders K, McNichol L. Broadening our bandwidth. A multiple case report of expanded use of telehealth technology to perform wound care consultations during the COVID-19 pandemic. *J Wound Ostomy Continence Nurs*. 2020;47(5): 450-455.
69. Mustafa H, Alradhawi M, Al-Hussein M, Dewji A. A commentary on 'impact of the coronavirus (COVID-19) pandemic on surgical practice—part 1' (international surgery 2020; 79:168-179) the effectiveness of telemedicine during the COVID-19 pandemic. *Int J Surg*. 2020;83:115-116.
70. Ramsetty A, Adams C. Impact of the digital divide in the age of COVID-19. *J Am Med Inform Assoc*. 2020;27(7):1147-1148.
71. Bhaskar S, Bradley S, Chattu VK, et al. Telemedicine as the new outpatient clinic gone digital: position paper from the pandemic health system REsilience PROGRAM (REPROGRAM) international consortium (part 2). *Front Public Health*. 2020;8:410.
72. Chelongar K, Ajami S. Using active information and communication technology for elderly homecare services: a scoping review. *Home Health Care Serv Q*. 2021;40(1):93-104.
73. Garcia-Huidobro D, Rivera S, Valderrama Chang S, Bravo P, Capurro D. System-wide accelerated implementation of telemedicine in response to COVID-19: mixed methods evaluation. *J Med Internet Res*. 2020;22(10):e22146.
74. Al-Sofiani ME, Alyusuf EY, Alharthi S, Alguwaihes AM, Al-Khalifah R, Alfadda A. Rapid implementation of a diabetes telemedicine clinic during the coronavirus disease 2019 outbreak: our protocol, experience, and satisfaction reports in Saudi Arabia. *J Diabetes Sci Technol*. 2021;15(2):329-338.
75. Baudier P, Kondrateva G, Ammi C, Chang V, Schiavone F. Patients' perceptions of teleconsultation during COVID-19: a cross-national study. *Technol Forecast Soc Change*. 2021;163:120510.
76. Lin JC, Humphries MD, Shutze WP, Aalami OO, Fischer UM, Hodgson KJ. Telemedicine platforms and their use in the coronavirus disease-19 era to deliver comprehensive vascular care. *J Vasc Surg*. 2021;73(2):392-398.
77. Bokolo AJ. Exploring the adoption of telemedicine and virtual software for care of outpatients during and after COVID-19 pandemic. *Ir J Med Sci*. 2021;190(1):1-10.
78. Corden E, Rogers AK, Woo WA, Simmonds R, Mitchell CD. A targeted response to the COVID-19 pandemic: analysing effectiveness of remote consultations for triage and management of routine dermatology referrals. *Clin Exp Dermatol*. 2020;45(8): 1047-1050.
79. Téot L, Geri C, Lano J, Cabrol M, Linet C, Mercier G. Complex wound healing outcomes for outpatients receiving care via telemedicine, home health, or wound clinic: a randomized controlled trial. *Int J Low Extrem Wounds*. 2020;19(2):197-204.
80. Liu C, Shi WL, You JX, Li HY, Li L. An internet-based algorithm for diabetic foot infection during the COVID-19 pandemic. *J Foot Ankle Res*. 2020;13(1):37.
81. Hsieh MW, Lee CC, Ou SF, Kuo YR. Telemedicine algorithm for chronic wound care during COVID-19. *Int Wound J*. 2020;17(5): 1535-1537.
82. Shin L, Bowling FL, Armstrong DG, Boulton AJM. Saving the diabetic foot during the COVID-19 pandemic: a tale of two cities. *Diabetes Care*. 2020;43(8):1704-1709.
83. Gaspar HA, Oliveira CF, Jacober FC, Deus ER, Canuto F. Home care as a safe alternative during the COVID-19 crisis. *Rev Assoc Med Bras (1992)*. 2020;66(11):1482-1486.
84. Rowe TA, Patel M, O'Conor R, McMackin S, Hoak V, Lindquist LA. COVID-19 exposures and infection control among home care agencies. *Arch Gerontol Geriatr*. 2020;91:104214.
85. Mahoney KJ. Self-direction of home and community-based services in the time of COVID-19. *J Gerontol Soc Work*. 2020;63(6-7): 625-628.
86. Sama SR, Quinn MM, Galligan CJ, et al. Impacts of the COVID-19 pandemic on home health and home care agency managers, clients, and aides: a cross-sectional survey, March to June, 2020. *Home Health Care Manag Pract*. 2021;33(2):125-129.
87. Roijers JP, Rakké YS, Hopmans CJ, et al. A mortality prediction model for elderly patients with critical limb ischemia. *J Vasc Surg*. 2020;71(6):2065-2072.



88. Iannuzzi JC, Boitano LT, Cooper MA, et al. Risk score for nonhome discharge after lower extremity bypass. *J Vasc Surg.* 2020;71:889-895.
89. Mills WR, Buccola JM, Sender S, et al. Home-based primary care led-outbreak mitigation in assisted living facilities in the first 100 days of coronavirus disease 2019. *J Am Med Dir Assoc.* 2020;21(7):951-953.
90. Seminara D, Szerszen A, Maese JR, Shah Z. Medical home visit programs during COVID-19 state of emergency. *Am J Manag Care.* 2020;26(11):465-466.
91. Liang HY, Hann Lin L, Yu Chang C, Mei Wu F, Yu S. Effectiveness of a nurse-led tele-homecare program for patients with multiple chronic illnesses and a high risk for readmission: a randomized controlled trial. *J Nurs Scholarsh.* 2021;53(2):161-117.
92. Forman R, Shah S, Jeurissen P, Jit M, Mossialos E. COVID-19 vaccine challenges: what have we learned so far and what remains to be done. *Health Policy.* 2021;125(5):553-567.
93. Dejnirattisai W, Zhou D, Supasa P, et al. Antibody evasion by the P.1 strain of SARS-CoV-2. *Cell.* 2021;184(11):2939-2954.
94. Alaran AJ, Adebisi YA, Badmos A, et al. Uneven power dynamics must be levelled in COVID-19 vaccines access and distribution. *Public Health Pract (Oxf).* 2021;2:100096.
95. Lamont EB, Diamond SS, Katriel RG, et al. Trends in oncology clinical trials launched before and during the COVID-19 pandemic. *JAMA Netw Open.* 2021;4(1):e2036353.
96. Degtyarev E, Rufibach K, Shentu Y, et al. Assessing the impact of COVID-19 on the clinical trial objective and analysis of oncology clinical trials—application of the estimand framework. *Stat Biopharm Res.* 2020;12(4):427-437.
97. U.S. Food and Drug Administration. FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency. 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency>. Accessed April 21, 2021.
98. García-Reyna B, Castillo-García GD, Barbosa-Camacho FJ, et al. Correction to: fear of COVID-19 scale for hospital staff in regional hospitals in Mexico: a brief report. *Int J Ment Health Addict.* 2021;1. doi:10.1007/s11469-021-00487-1. Epub ahead of print.
99. Cawcutt KA, Starlin R, Rupp ME. Fighting fear in healthcare workers during the COVID-19 pandemic. *Infect Control Hosp Epidemiol.* 2020;41(10):1192-1193.
100. Tan TQ, Kullar R, Swartz TH, Mathew TA, Piggott DA, Berthaud V. Location matters: geographic disparities and impact of coronavirus disease 2019. *J Infect Dis.* 2020;222(12):1951-1954.
101. Holmes L Jr, Enwere M, Williams J, et al. Black-white risk differentials in COVID-19 (SARS-COV2) transmission, mortality and case fatality in the United States: translational epidemiologic perspective and challenges. *Int J Environ Res Public Health.* 2020;17(12):4322.

How to cite this article: Driver VR, Couch KS, Eckert KA, et al. The impact of the SARS-CoV-2 pandemic on the management of chronic limb-threatening ischemia and wound care. *Wound Rep Reg.* 2022;30(1):7-23. doi:10.1111/wrr.12975