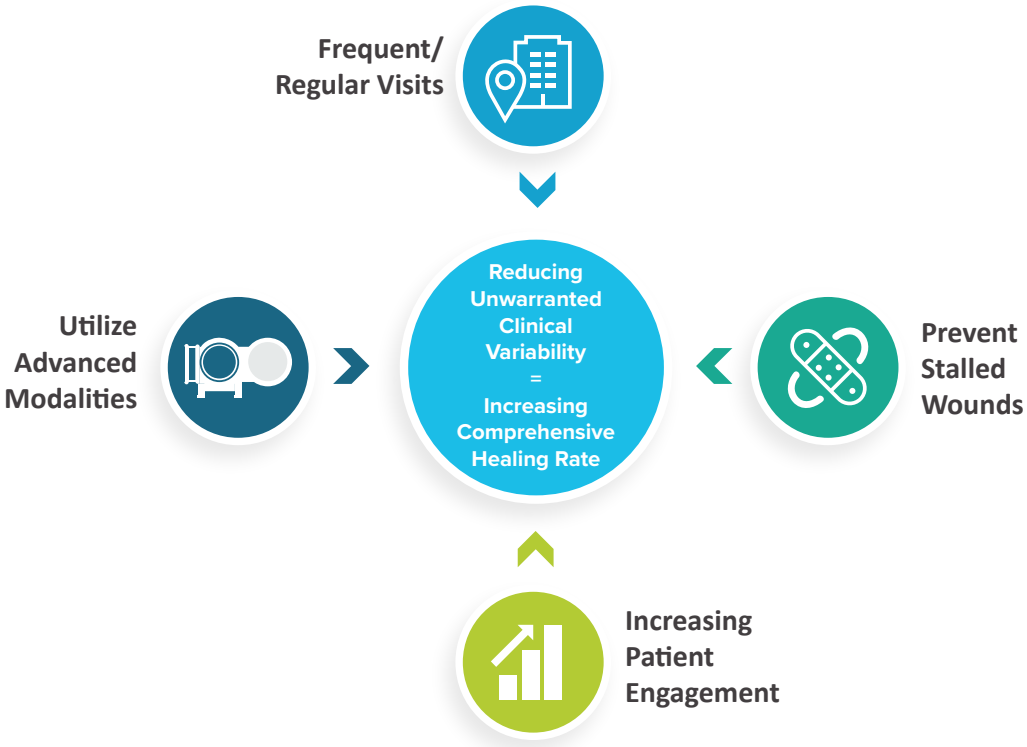
The Use of Modalities in Wound Care Part 1: Debridement

William Ennis, DO, Chief Medical Officer

Mary Sheridan, PhD, Data Consultant

INTRODUCTION

In this white paper, we will review the use of modalities as a lever for reducing unwarranted clinical variability. This is the fourth in a series of white papers that have tried to provide evidence and clinical guidance for providers managing complex wound patients. As in all previous white papers, the literature has been reviewed, the data has been updated and refreshed using a 2019 research database from Healogics and recommendations have been formulated for consideration.

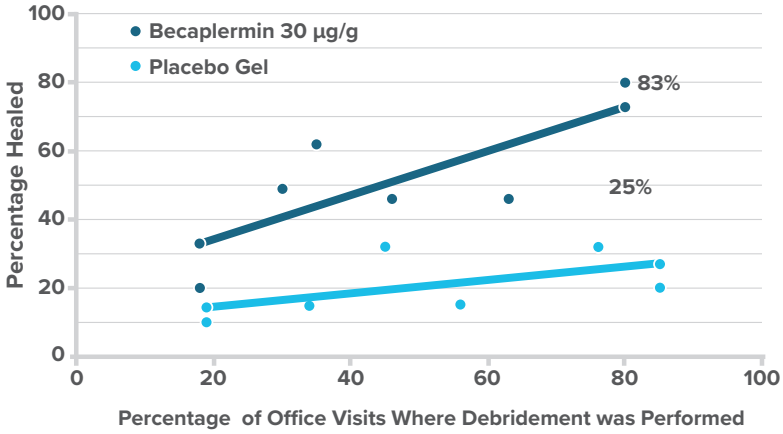


DEBRIDEMENT

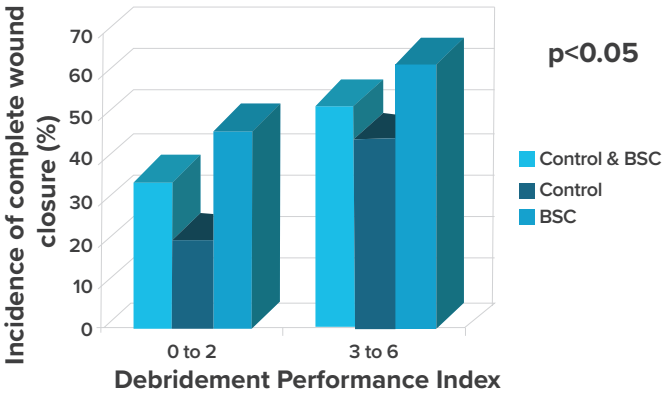
Debridement has been an integral component of the surgical management of wounds for hundreds of years. Initially thought to be described by Henri Francois Le Dran, debridement referred to the use of an incision to promote drainage and reduce tension under the skin.[1] Ultimately, the definition was expanded to include the removal of nonviable or contaminated tissue that impedes normal growth while eliminating biofilm, infection and senescent cells. This review of debridement will highlight the most quoted and influential early papers on the subject,

review prior Healogics data and close with updated information from the Healogics database and recent literature. Interestingly, controversy has always surrounded debridement from early surgical literature to the current day. Even the term debridement cannot be accurately associated with an individual surgeon. Over the course of hundreds of years, medical debates have ensued as to whether surgical debridement was necessary, how much tissue to remove and the most optimal surgical instruments that should be used for the task. On this, not much has changed.

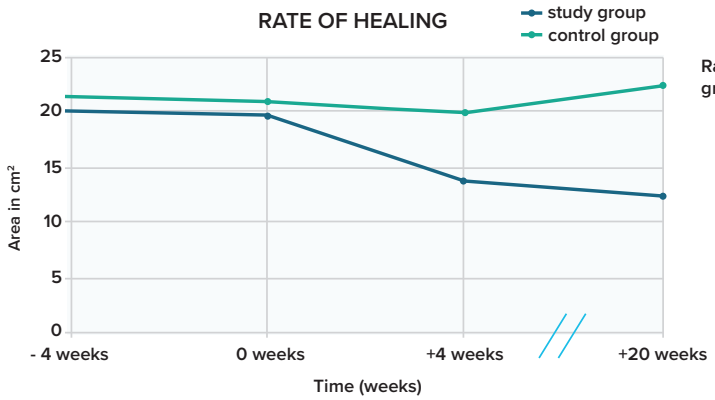
The most influential paper published on debridement was written by Dr. David Steed when he was at the University of Pittsburgh. Dr. Steed conducted a multicenter trial which resulted in the Food and Drug Administration approval of the product Regranextm. The results of this paper included the utilization of debridement on all patients initially, and then whenever the provider felt it was clinically necessary.[2] Results from this trial, performed at the center level, demonstrated that the use of debridement either with the active drug or even in the control arm resulted in higher healing. This paper is where the concept of 80% of office visits having a debridement resulted in 80% healing rate was generated.



These results however need to be taken within the proper context. To begin, the initial trial was not conducted to determine the superiority of debridement or absence of debridement. Secondly, the study results were tabulated at the center level leaving open the possibility of an ecological fallacy. Ennis et-al., published on 432 consecutive patients and analyzed the impact of surgical debridement conducted in the operating room, at any point during the treatment course for the patient's wound.[3] Despite the fact that the overwhelming majority of patients did not receive surgical debridement, when evaluating overall healing rates, statistical significance in favor of the use of surgical debridement was found at $p< 0.04$. Another publication evaluating debridement was written by Dr. Saap and Dr. Falanga.[4] In this frequently cited paper, the data set from an FDA clinical trial looking at skin substitutes performed in a randomized control fashion was analyzed for the effectiveness of debridement. A debridement performance index was created and blinded reviewers analyzed photographs pre-and post-debridement to score the results of the debridement. The previously discussed paper by Steed did not have an analysis of the effectiveness or completeness of debridement, which is why this index was created. The results of this paper confirmed previous reports that the concomitant use of debridement along with standard of care, in this case skin substitutes, resulted in higher healing rates in both active and control arms.



Williams and colleagues turned their attention to the effect of debridement on venous leg ulcers in a prospective cohort study.[5] Due to small sample size, statistical significance was not achieved over the entire study period, however, the signal was clear that those wounds debrided between 0 and 4 weeks had an improved healing trajectory over those not debrided. The authors also looked to answer the question if debridement might induce infections by transferring bacteria deeper into the tissues and were unable to substantiate that concern. The design of the trial, for ethical reasons, did not randomize patients with necrotic tissue to the non-debridement group potentially impacting the results. The paper, however, clearly demonstrates early improvement with debridement.

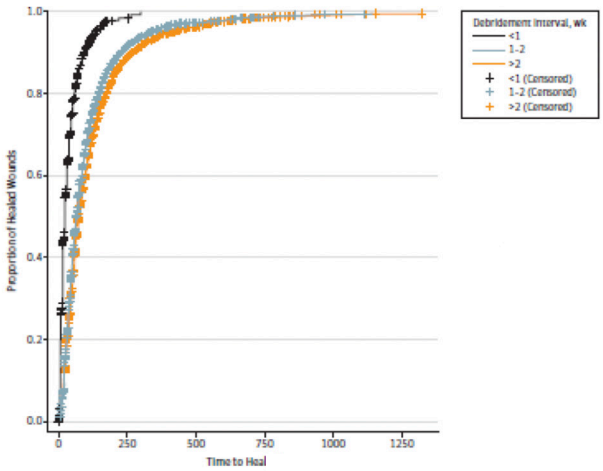


Rate of healing of the two patient groups over the 24 weeks of the study.

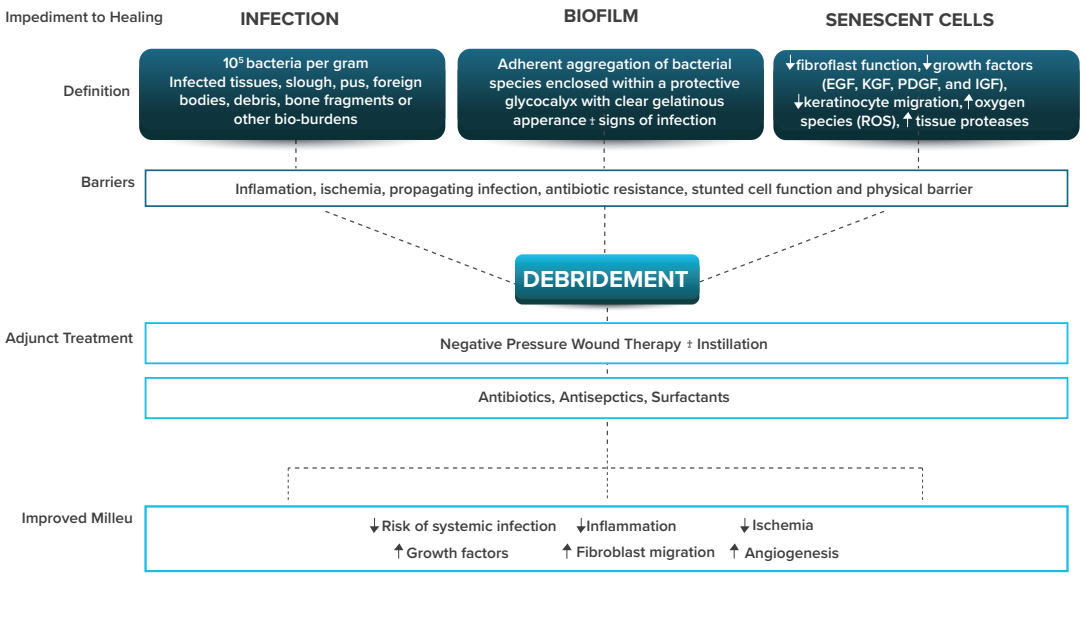
Cardinal and colleagues reported on the impact of serial debridement on both venous leg ulcers and diabetic foot ulcers again using a data set from an FDA clinical trial designed to evaluate the impact of biological skin substitutes on healing.[6] These results failed to achieve statistical significance at the individual patient level. Trends and directionality towards improved outcomes with increasing episodes of debridement were noted, however.

One previous published study looking at a 2008 data set from Healogics showed a correlation between the frequency of debridement and healing, specifically for diabetic foot ulcers.[7] In this paper, the interval between debridements was found to be significantly related to the overall time to healing.

Kaplan-Meler Plot of Diabetic Foot Ulcers Showing that Shorter Intervals Between Debridement Improve Time to Heal



There has been little agreement in how to describe debridement. Dr. Mark Granick proposed an interesting scoring system, but few providers have adopted its terminology.[8] Another group of authors attempted to identify molecular markers that would help aid the provider in determining the extent of debridement.[9] This novel approach does not allow point of service decision–making and, therefore, has been relegated to only academic studies. A recent paper by a team of plastic surgeons describes the current concepts and debridement and provides algorithms which have practical approaches for the wound care provider.[10] In this paper, the physiological basis for performing debridement is described. Benefits include the removal of senescent tissue, reduction in bioburden/biofilm, removal of necrotic tissue and the reestablishment of an acute wound environment, which is more conducive to healing.



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	Method	Indications	Contraindications	Adverse Effects	Pain
Mechanical	Wet-to-dry	Short term for infected necrotic	Long term use	Gauze remnants act as foreign body	Significant
	Dry gauze	Temporizing agent			Significant
Biologic	Autolytic	Necrotic, fibrous wounds	Infected; bleeding wounds	Potential for maceration	Minimal
	Enzymatic	Moist and/or fibrotic wounds	Highly exudative wounds	Allergic reaction	None
	MDT	Necrotic tissue; O.R. not possible	Exposed vessels; Ischemic; or malignat wounds	Maggot loss, patient anxiety	Minimal
Adjunctive devices	Hydrosurgery	Infected/chronic wounds	Inexperienced operator	Over-excision; aerosolization; bleeding	Significant
	High-frequency US	Infected/chronic wounds			None
	Negative pressure	Intra-operative	Uncontrolled infection: necrotic tissue	Maceration, blood loss, infection	Moderate
Surgical	Bedside	Infected, necrotic tissue	Uncontrolled pain; bleeding	Risk of infection; bleeding	Moderate
	Operation room	Emergency/urgent	Medically Unstable	Over/under-excision; surgical risks	Significant

Significant Moderate Minimal None

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Summary of debridement techniques indications, contraindicatiors, adverse effects and pain. Adapted from the 2013 European Wound Management Association guidelines. MDT, maggot debridement therapy: O.R., operating room: US ultrasound.

The Cochrane review process has failed to demonstrate the benefit of one form of debridement over another. These findings were noted in both surgical wounds and venous leg ulcers.[11,12] Both systematic reviews stated that there were too few randomized trials to render a firm conclusion however. Due to ethical reasons, it is highly unlikely that there will ever be a study in which debridement is deemed necessary by a physician, and the patient is subsequently randomized to either a debridement or non-debridement arm making it unlikely that hard data would ever be available.

MECHANICAL DEBRIDEMENT

As noted in the tables above, there are multiple methods to debride a wound. Each of them has benefits and potential problems. The first debridement method is mechanical debridement. This includes wet-to-dry dressings, pulse lavage therapy and whirlpool. Whirlpool therapy has been eliminated in almost all wound care programs and physical therapy due to infection control issues and the non-selectivity of the process. Pulse lavage, while useful in the operating room, suffers from significant aerosolization in the clinic and bedside. There is also a high cost to the disposable equipment required. Very few doctors even recognize that using wet-to-dry dressings is a form of debridement. Over the years wet-to-dry dressings have been described in the literature as an ineffective way of healing wounds and that they should be avoided. In fact, wet-to-dry dressings can be a useful form of debridement

for a grossly infected wound to gain control of bioburden and to stabilize the wound bed. The problem with using mechanical debridement techniques is that the providers often forget to convert to moist environmental products once the wound establishes a granular bed. Wet-to-dry dressings also cause evaporative fluid loss, surface cooling and vasoconstriction. Bacteria are capable of infiltrating as many as 64 layers of gauze, thereby clearly not providing bioburden management.[13]

BIOLOGICAL DEBRIDEMENT

Many authors group the next section of debridement methods under the heading "biological". Included in this category are enzymatic debridement, autolytic debridement and the use of medicinal maggot therapy.

Enzymatic therapy in the past had several products available, but over the years only collagenase is available for use – an expensive prescription medication that has several advantages, including minimal to no damage to healthy tissue and a rapid biological response. Some of the disadvantages include cost and occasional burning or stinging with use. In addition, collagenase should be applied by a trained provider so as not to waste the product. Enzymes selectively digest devitalized tissue causing less trauma to the healthy tissue than surgical debridement. Enzymes are useful in patients that have no access to surgical or sharp debridement or who are not surgical candidates.

Autolytic debridement refers to hydrogels, hydrocolloids and other dressings that exploit the body's inherent ability to digest necrotic tissue while enhancing granulation tissue formation. These dressings are readily available, cost effective and rarely cause discomfort. Disadvantages include the time it takes to achieve a fully granular bed. Autolytic debridement would not be appropriate for patients with a large surface area of necrotic, nonviable tissue. Sharp or surgical removal of necrotic debris from a large surface area would be more expeditious.

Maggot therapy has been around for years and the use of medicinal maggots has found its way into some practices around the country and throughout Europe. The radiated larvae of the blowfly can be a cost-effective alternative for treating drug-resistant chronically infected wounds and poor operative candidates. A recent meta-analysis evaluated safety and effectiveness and revealed significant improvements in the rate and efficiency of chronic wound healing, longer antibiotic free intervals in the lower amputation risk and diabetic foot ulcer patients.[14]

ADJUNCTIVE MODALITIES

Adjunctive modalities can be used for debridement as well. These options include hydro-surgery, ultrasonic debridement and the use of negative pressure with instillation. Hydro-surgery uses a powerful jet stream of water which aspirates surrounding tissue and then pulverizes it. There is little vaporization and minimal aerosol effect. Studies have been able to show decreased bacterial counts than high jet pulsatile lavage.[15] Hydro-surgery has also been shown to reduce bacterial counts when compared to sharp debridement.[16] Ultrasound can be used to debride wounds as well. There are high frequency and low frequency versions. While hydro-surgery is most often conducted in the operating room, ultrasonic debridement can be conducted in the clinic. Lastly, debridement can now be achieved by using specially designed foam dressings in combination with the instillation of fluid during negative pressure wound therapy.

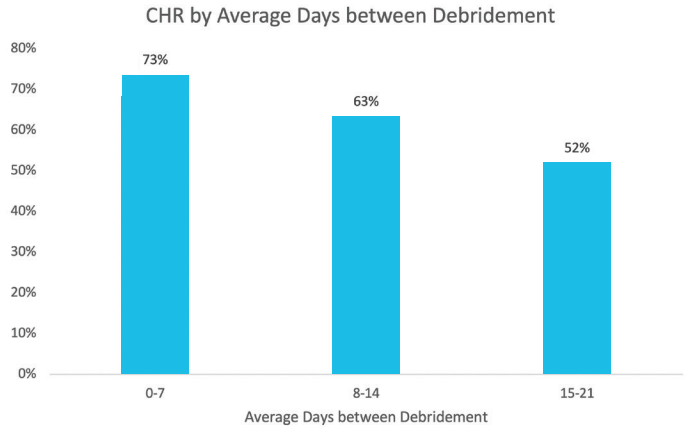
SHARP AND SURGICAL DEBRIDEMENT

Sharp debridement refers to the use of pickups and scissors to remove nonviable tissue and surgical debridement includes full excision and the use of surgical instruments. Some of the difficulty in determining the outcomes and results from debridement are due to differences in provider skill, instruments used, extent and depth of debridement and postoperative management. Questions, such as how many debridements are necessary to heal the wound and how frequently should a wound be debrided, have been discussed in wound care meetings for the past 20 years. The Cochrane reviews have made it clear that there is inadequate evidence to support one form of debridement over

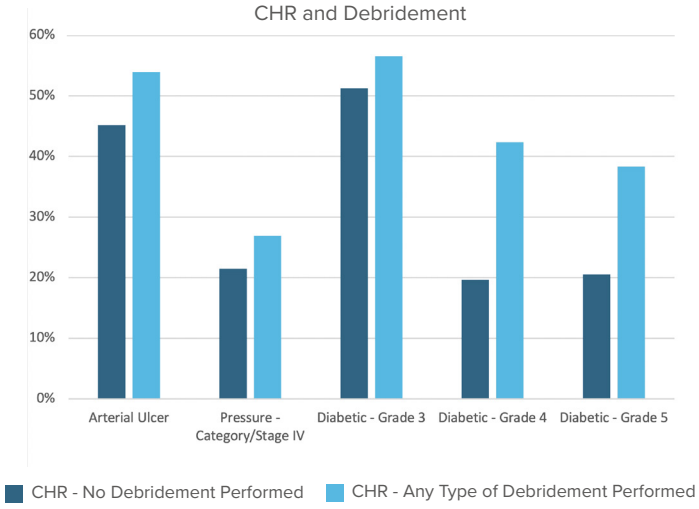
another in the published literature. Due to this paucity of information, we evaluated the 2019 full data set and were able to find some trends and outcomes.

HEALOGICS DATA ON DEBRIDEMENT

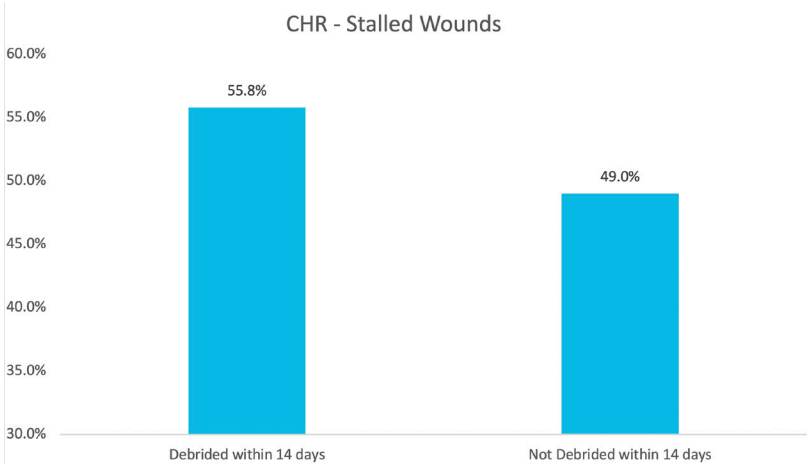
The first finding should not be a surprise given the first lever that we reviewed in the "Big 4" was visit frequency. In the visit frequency white paper, we were able to describe a correlation between the patient's healing rate and the frequency in which they were seen. Our most recent findings show a 73% healing rate for all wounds when the average number of days between debridement was less than one week. The Comprehensive Healing Rate (CHR) was 63% and 52% when debridement intervals were between 8 and-15 days, or greater than 15 days, respectively.



A second finding in our study of debridement demonstrated that the CHR was improved when debridement was performed at least once compared to patients that never received debridement. These findings were notable for the most complex wounds including arterial, pressure and diabetic grades 3, 4 and 5.



Another important concept that we have discussed in prior white papers was the importance of identifying wounds that stall. A stalling wound is defined by small reductions in size/area over time when compared to wounds that are on a typical healing trajectory. We now have information showing that when stalled wounds are debrided within two weeks of the stalling episode, their healing rate can be improved to 55.8% compared to 49% when those wounds are not debrided within two weeks.



SUMMARY AND CONCLUSIONS

Clinicians have debated the merits of debridement for hundreds of years. While all surgeons are aware that necrotic tissue and infected tissue must be removed, the literature fails to provide the evidence to support one debridement method over another, the frequency of the procedure or the timing during the wound episode. This evidentiary gap led Healogics to analyze our own data to begin to answer these questions.

Debridement has been shown to be beneficial for wound healing going back to the 1996 paper by Dr. David Steed. There are many forms of debridement, each with its own set of pros and cons. In the advanced wound care center, sharp and surgical debridement can lead to improved healing and complex wounds when applied at regular intervals.

Stalled wounds lead to patient cancellations in patients quitting their treatment. Surgical debridement can reestablish a healing trajectory in stalled wounds if performed shortly after the stalling event is noted.

The correlation between debridement frequency and overall visit frequency highlights the difficulty in separating the individual contribution for each of these towards the overall healing of a patient. It is likely, however, that visit frequency and debridement frequency are proxies for centers that provide aggressive, comprehensive wound healing as they are correlated with higher healing rates than centers that see patients less frequently and debride less frequently.

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