

Specializing in the treatment, reconstruction, and management of
Acute and chronic wounds • Diseases and defects of the soft tissues • Injuries,
diseases, and defects of the hand and extremities • Defects of the head and trunk

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INTEGRA AND THE MEDICARE PATIENT

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INTEGRA

and the
Medicare
patient

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Integra Artificial Skin is an implant that is used for closing wounds and reconstructing missing skin. Originally developed for treating burns, this material has been of exceptional value in treating many types of acute wounds and chronic ulcers. This presentation is a brief look at the kinds of patients and problems that Integra is used to treat, with the emphasis on elderly Medicare patients.

INTEGRA

is a unique implant
which reconstructs healthy skin

there is no substitute,
nothing comparable

It solves difficult problems
easily, at low risk and utilization

it saves limbs,
lives, and livelihoods

it saves large sums of money
in the care of individual patients

it fits perfectly into to the burgeoning
infrastructure of outpatient wound care

**superior to
conventional paradigms of care**

effective, dependable, superior results,
with less risk and less cost



The following are the main points to be made.

- Integra is an implant, applied to the surface, which has two main functions: in the short term, it is an effective artificial skin, serving as a high quality skin substitute useful for problems like burns, fasciitis, degloving injuries, and any other wound, large or small, which would benefit from biological “closure” without having to take additional skin from the patient’s own body. It has the second effect of actually regenerating healthy new tissue, transforming in the process from an empty sponge to a lamina of autogenous dermis.
- It is unique. There is no comparable product. Without it, surgical practices for wounds and burns would have to revert to principles and standards of ten years ago.
- Integra is nominally simple to use: debride the wound and lay the material on. It creates tissue and heals wounds without using any autogenous donor material. It’s unique properties allow it to solve difficult problems easily. For example, it’s spongy nature allows regenerating tissue to advance tangentially through the material, allowing new tissue to form over bones, joints, tendons, and hardware, situations which classically need to be covered with flaps. These properties mean that good results are achieved with low resource utilization and extremely low risk to the patient.
- It’s abilities to heal certain wounds and salvage complex situations with low risk and morbidity mean that Integra saves lives (fasciitis, burns, etc.), saves limbs (for the many problems such as diabetic or arterial foot ulcers which often result in leg amputation), and thereby saves the lifestyle and livelihood of many patients.
- By simplifying care, by avoiding complex surgery, by diverting care out of the hospitals and into outpatient venues, by avoiding secondary morbidity and treatment failures, Integra minimizes the direct expenses of care compared to conventional approaches to treatment of many wounds.
- It’s simplicity of use and the nature of the required pre-operative and post-operative care mean that, for most patients, all of the required care can be managed through outpatient venues - office or clinic, and outpatient surgery centers.

- For many problem wounds, Integra achieves good results when nothing else will, and it does so with minimum risk and expense compared to conventional care. Integra is a young product, not yet widely adopted, but penetrating the market further as it is appearing in meetings, journal papers, and textbooks. It's superiority to conventional care for certain problems means that it is itself becoming the standard of care among those who use it.

NOTES on the Technical Use of Integra

This is a summary of Integra for those not familiar with it.

- The material was first developed in Boston beginning about 30 years ago. A collaboration between Dr. Burke, a burn surgeon, and Dr. Yannas, a chemical engineer, the original intent of the material was to be a skin substitute for severe burns. Integra was FDA approved for market in 1996.
- The main component of Integra is a spongy material made of type 1 collagen (from bovine achilles tendon) and chondroitin-6-sulfate (from shark cartilage). The collagen gives structural stability. The chondroitin is a glycosaminoglycan (gag) that flags cells that it is a normal embryonic constituent of the body. The sponge has been deliberately engineered to have a reticulum size comparable to the collagen in normal human dermis, another essential property that tells host cells to regenerate tissue rather than make scar. The Integra sponge is prepared in thin sheets (approx 1mm thick), and then overlaid with a thin sheet of silicone rubber which acts as a protective barrier, an artificial epidermis. It is sterilely packaged and can be stocked in unlimited quantity, available for use whenever needed.
- Indications for Integra, and the rationale for selecting it versus other methods of closure will be illustrated in the subsequent case studies. While there are a number of indications for using Integra, the details of its use are comparable regardless of diagnosis. Surgeons have certain criteria by which they judge a wound ready to be closed (be it skin grafts, flaps, Integra, or anything else). All wounds, patients, and their physicians must practice some basic care to get a wound ready for surgical closure. The essentials of preparatory debridement, wound hygiene, and control of edema and inflammation are essential to any wound closure, including Integra. These activities are practiced until the wound is ready for closure.
- Once the wound has been prepared, closure of the wound with Integra is done in the operating room. The existing wound, all exposed surfaces, are excised. The Integra is placed on the wound and secured with sutures or staples. Protective dressings are applied to maintain firm contact between the material and the underlying wound.
- Dressings are typically changed at one week intervals, in office or clinic. Because the outer silicone layer is transparent, the regeneration process, the formation of a new dermis in the underlying matrix, can be readily observed. The material is "regenerated", i.e. ingrown with healthy new tissue, on average at about 4 weeks (typical range 3 - 8 weeks). Whenever the dermal regeneration is complete, a second procedure is done to peel off the silicone and place skin grafts, thin autogenous grafts using epidermis only, thereby completing the reconstruction.
- Follow-up dressings and other basic care are required for a few weeks until fully healed, all managed as a an outpatient.

The physical, chemical, and biological properties of Integra which confer its dependability and high quality results are too numerous and technical to detail here, but a couple of examples will give some insight into why Integra is superior to other conventional options for the care and closure of certain wounds:

- Integra is comparable in some ways to using cadaver skin, pigskin, and even the patient's own skin as a "biological dressing" to help control a wound and provide temporary skin closure. Unlike these other materials, Integra is not alive to begin with, so it does not die nor degrade as those other materials do. Therefore, it need not be replaced every few days, and autogenous grafts need not be wasted from the patient himself. Instead, Integra can be placed once only. As a true artificial skin, it will protect the wound as long as it needs protection, and then it does double duty as the agent of autogenous skin regeneration.
- The ability of the material to conduct tissue growth tangentially means that new tissue can form over bone, tendon, internal organs, even open joints and alloplastic hardware, eliminating the need for autogenous flaps.
- The normal response to injury is an integrated process known as inflammation-wound repair. The moment that Integra is placed on a wound, inflammation ceases and the normal repair process never occurs. This means that progressive wound damage due to inflammation ceases, making Integra a valuable and dependable choice to close wounds subject to "pathergy" (an unanticipated adverse reaction of tissues to trauma, resulting in necrosis, ulceration, dehiscence, etc., typically in cases of severe vascular insufficiency and abnormal immunopathic disease). Integra instead regenerates by a process of embryonic histogenesis., leading to healthy new tissues that seem resistant to the effects of the diseases that caused the original ulcers.



To examine the role of Integra in Medicare patients, this presentation will focus on a few of the common classes and causes of chronic wounds and ulceration. The first class is arterial diseases. There are various causes of vasculopathy and arterial insufficiency. The most common by far is atherosclerosis, a very common and high profile problem in the Medicare population. Arterial insufficiency due to atherosclerosis can be of variable severity and clinical consequence. Once necrosis and ulceration develop on the foot or leg, the natural history of the problem is one of progressive necrosis, ulceration, infection, and gangrene, leading to loss of limb or life.

The general plan of care for ulcerated vascular patients is to first provide some basic protective wound care and then assess the severity and vascular anatomy of the problem. Revascularization of the extremity is of paramount importance (by surgical bypass or endovascular procedures), but it is not always technically possible. Pharmacological agents and hyperbaric oxygen are helpful adjuncts to care for some patients. Once these preliminary components of care and correction are in place, then the wounds themselves must be managed. These wounds are typically slow to heal. If surgery is contemplated, there is an important caveat: for any given ulcer or skin defect and the set of conventional wound closure methods that might close that defect, these choices are much riskier than in any other patient (e.g. a comparable trauma wound in a young healthy patient). The problem is twofold, (1) the arterial insufficiency inhibits healing, making it harder for flaps to heal or harder for a skin graft to even stay alive on the wound, and (2) any additional incisions or donor sites, such as for creating a flap, are subject to the risk of further necrosis and ulceration. This is why conventional surgery has always opted for amputation: remove the diseased part at a level high enough to avoid the effects of the vascular insufficiency make sure that the amputation incision heals.

(NOTE: all of the cases presented here are elderly patients who were either covered by Medicare, or else presumed to be covered by Medicare or at least eligible for Medicare because of their age.)



This patient is a paradigm example of the patient with atherosclerosis, arterial insufficiency, foot necrosis, and expected leg amputation. The patient was placed on basic temporizing protective wound care (good hygiene and silver sulfadiazine), and vascular evaluation was done, leading to a femoral-tibial bypass. The wound healing process began to appear. However, extensive exposure of bone and joint would normally have led to below-knee amputation, even after the revascularization (top left photo).

At this point, a précis of contemporary surgical history is worthwhile. Vascular evaluation leading to vascular reconstruction is the standard of care for managing peripheral arterial disease and its complications. However, it is still quite common for patients such as this one to be seen first by an orthopedic surgeon, and to have a hasty and indiscriminate leg amputation, without any vascular surgery input. In bygone eras when wound care concepts were abysmal, there were no antibiotics, and the surgery of atherosclerosis was a fantasy, pre-emptive amputation was the proper thing to do. The foundation concepts and tools which permit “limb salvage” began to appear after World War II. By the mid 1970’s, vascular surgeons had firmly established what is still the nominal standard of care for ischemic leg ulceration: vascular assessment and revascularization. However, for most vascular surgeons, their concept of limb salvage means that either a simple wound heals after revascularization, or a complex wound (exposed bones and joints, etc) can then be safely amputated, knowing that the amputation will heal reliably after the revascularization. The idea that the complex open foot itself could be treated and salvaged remains an odd concept to most surgeons. Rightly so, because all of the modern arts and sciences of complex wound closure - aka plastic surgery, current standards in place by the mid 1980’s - are confounded by peripheral arterial disease. The reasons are that it is hard enough to find a dependable flap on the foot, arterial diseases make the risk of flap complications very high, the chances of wound complications are high with or without flaps, and a free flap (used when there are no nearby flaps) cannot be used because the vascular disease prevents revascularization of the flap.

So, the current standards of care, pioneered by vascular surgeons in the 1960’s are still the common standards of care for arterial leg and foot ulcers: revascularize the limb, let the simple ulcers heal, and amputate the complex problems, knowing that the amputation will heal after revascularization. Complex foot salvage, i.e. closing ulcerated bones and joints and so on, cannot easily be done, so don’t bother to try. However, times change and advances are made, and Integra is one of the tools which has made complex foot

salvage a successful reality. Preliminary revascularization is still vital, but now, the damaged foot itself can be closed, with low morbidity, few risks and complications, low resource utilization, and good likelihood of success.

In this particular case, after revascularization, the foot had a final debridement, and Integra was used to close all of the open structures of the foot. As the material regenerated (upper right photo), skin grafts were placed (photos left center and below show the intermediate stages of recovery), leading to a healed foot (bottom right).

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**ARTERIAL
ulcers & complications**

Problems

- amputations - loss of function
- multiple complications - redo surgery
- high acuity - morbidity - hospitalization

Benefits of Integra

- save limbs - preserve function
- avoid & correct complications
- avoid unplanned surgery & care
- low acuity - low morbidity
- avoid hospitalization - minimize cost

This patient was cared for along the “pre-vascular surgery” philosophy of care. An orthopedic surgeon amputated toes for complications of vascular disease, without checking circulation nor getting a vascular surgery consult. The amputation failed, leading to foot necrosis, leading to below knee amputation, which in turn failed leading to above knee amputation. This too failed. The orthopedic surgeon then wanted to do a hip disarticulation. Contra-indicated for many reasons, that too would have failed because of the high (aorto-iliac) level of vascular occlusion. At this point consultation was placed. After some initial good topical wound care, the thigh was healed by excision of the defect, Integra, and two weeks of hyperbaric oxygen support. Going forward from the point of starting good wound care and skin reconstruction with Integra, he was cared for as an outpatient. There were no complications, no treatment failures, no unanticipated therapy. Even hyperbaric oxygen was used for a deliberate short period of time in support of the acute post-operative wound. The key ingredient was the Integra, which by its ability to control inflammation and inflammatory tissue injury, allowed this very high risk wound to heal without further necrosis. The net result of a successful and uncomplicated treatment plan was not only a healed patient, but a minimum of resource utilization by eliminating complications, failed care, and redo surgery.

Arterial ulcers and their care share much with ulcers of any cause, but they have some notable features. It is the only class of diseases which predictably and unavoidably leads to leg amputation (diabetic ulcers are the other problem which predictably lead to amputation, but many of these amputations are avoidable even with good conventional care). Amputation leads to loss of function and independence, and for many elderly patients starts a downward trend of increasing morbidity and dependence leading to death. Failed

amputations and wound care lead to multiple unplanned operations. Vascular disease implies significant co-morbidities, and these patients are at risk for numerous complications and prolonged care after their in-patient amputations and related operations.

Integra applied to arterial ulcers closes complex wounds, thereby saving limbs and associated function. Integra avoids the conventional pathology and tissue injury complications of surgery, and it can correct these problems when such complications have already occurred. Its use tends towards a single successful planned reconstruction (two stages, Integra then skin graft), rather than a series of unplanned cleanup procedures as each fails. By minimizing the operative and anesthetic risk to the patient, and by keeping the care within outpatient venues, secondary complications and accrued expense are minimized or eliminated.

Slide 6



“Venous disease”, meaning venous hypertension and insufficiency, venous vasculitis, venous reflux, and venous stasis dermatitis, is the most common cause of chronic leg ulceration. This problem never leads to limb necrosis and amputation, but it does cause significant interference in normal activities, lifestyle, and economic productivity. Recurrent episodes of stasis dermatitis are often erroneously misdiagnosed as infection, leading to numerous hospitalizations. Large sums of money are wasted on inept “wound care”. Misguided and premature attempts to “heal” the wound with skin grafts usually fail. With good care, these problems can be avoided. “Good care” generally means good wound hygiene, and the control of venous hypertension and leg edema by the use of compression bandages or stockings, exercise, and habits of leg elevation. With good care, most venous ulcers heal. These forms of good care have low resource utilization, and as maintenance or preventive care, ulcer recurrence can be avoided. Used as palliative care on older or more refractory ulcers, the open wounds can be kept healthy and need not interfere with the rest of a patient’s normal daily activities. For some patients, ulcer excision and skin reconstruction with skin grafts is a suitable and conventional treatment strategy, but recurrent ulceration through the old skin grafts is a common problem.

Venous disease and venous ulcers affect people of all ages. It is not a disease of aging, but in elderly patients who have had venous leg ulcers for many years, the ulcers become progressively harder to treat, due to the chronic accumulation of scar tissue and iron-

laden debris within the tissues. Also, as people age, the essentials of good treatment for venous ulcers (hygiene, compression, elevation, etc.) become harder for patients to administer to themselves. Age, infirmity, arthritis of back, hips, and hands, obesity, visual impairments, tremors, senile skin fragility, and other factors mean that these treatments, which are simple and low tech in principle, become impossible to manage when people cannot bend over to wash their feet, wrap on dressings, and apply stiff elastic stockings. Thus, venous ulcers become more problematic in the elderly Medicare population, incurring more failed care, more morbidity, and more expense.

Slide 7



These are two examples of typical chronic venous ulceration in elderly patients. On the left, this 77 year old man has typical chronic stasis changes of the medial leg and ankle. A dead piece of recent skin graft is in the middle, a well-intended but misguided operation doomed to fail because the dermatitis, debris, and inflammation have not been controlled. After some basic wound and skin care, and control of edema and venous hypertension, the leg was relatively healthy, and the wound repair process proliferated. For many patients, the ankle would have healed on its own (by the natural process of wound contraction and epithelialization). In this case, the longevity of the disease and ulcer meant that wound contraction could not overcome the non-compliant dense surrounding scar. Therefore, wound excision and skin reconstruction were indicated. Simple skin grafts would have been perfectly reasonable, but experience has taught that an Integra reconstruction is more likely to be healthy, less prone to re-ulceration, over long intervals compared to conventional skin grafts. The bottom picture shows a healed stable ankle after Integra. All care was as an outpatient.

On the right, this 86 year old woman has a similar history. The difference is that the longevity and severity of the ulcer have caused perforation into the ankle capsule and various major tendons. According to the conventions of plastic surgery, this situation requires coverage with a flap of some sort, not just a skin graft. With Integra, the issue is moot, because Integra will work in many of the situations where flaps are traditionally used, in this case to cover open joint and tendon. After many years of ulceration, the ankle is healed and stable after Integra. Care was rendered as an outpatient.

VENOUS ulcers & complications

Problems

multiple failed care - redo surgery
prolonged wasted high utilization
variable disability - high expense

Benefits of Integra

success when all else has failed
avoid prolonged care & multi-surgery
correct disability - low morbidity
resistant to recurrence
avoid hospitalization - minimize cost



This 88 year old woman has also had Integra to close chronic venous ulcers of both legs. Note the erythema, edema, and incipient ulceration of the medial right leg. This is a flare-up of acute stasis dermatitis. The acute pathology affects the native skin and subcutaneous fascias, but not the Integra reconstructed skin elsewhere on the right leg and left legs.

With venous disease and ulceration, patient histories are marked by multiple failed operations and non-operative care. Because venous problems rarely cause any life-and-limb threatening systemic morbidity, their disease persists, despite patients and their doctors, for many years. Therefore, the net accumulation of failed care and wasted resources and expenses becomes very high for some patients. While patients do not die nor lose limbs from venous disease, symptoms, expense, and interference with lifestyle and vocational productivity can become major problems.

Integra typically repairs these patients when all else has failed. The predictable and dependable course of an Integra reconstruction means that complications, failures, prolonged care, and redo surgery are avoided. Stable durable results mean that patients can return to lifestyle and vocational competence with only minor intrusions from some basic daily care to control venous reflux or hypertension. The regenerated Integra seems to be relatively resistant to recurrent pathology. Effective and successful planned care, as opposed to failures, complications, and unplanned redo care, mean that costs are minimized over the lifetime of each ulcer and of the patient as a whole. The care is made even more economical by remaining in outpatient venues.



INTEGRA

and the
Medicare
patient

DIABETIC
ULCERS

Diabetic ulcers are a thorny problem, generally perceived as difficult to treat and associated with a high rate of leg amputation. The “diabetic ulcer” is not a distinctive form of diabetic pathology, but rather a syndrome of biomechanical and vascular disorders which collude to create pressure ulcers of the foot. The causes of the diabetic foot include: (1) diabetic peripheral neuropathy, which impairs feeling, so that patients do not know injury is occurring, and which cause abnormal foot mechanics by paresis of the intrinsic muscles of the foot (similar “neuropathic ulcers” occur in conjunction with any form of advanced peripheral neuropathy); (2) glycosylation of tendons and other structures, leading to abnormal foot mechanics via ligaments and extrinsic tendons; (3) accelerated atherosclerosis, leading to the same problems that plague any patient with arterial insufficiency. The problems start as indolent occult plantar pressure ulcers, usually unnoticed by the insensate patient. Persistent and neglected ulcers are prone to progressive joint destruction, then septic osteitis, arthritis, and tenovaginitis (tendon sheath infections).

Diabetes and the diabetic foot are not exclusive to the elderly population, but many of them are Medicare patients, due to age or disability. Associated peripheral vascular disease compounds the severity and recalcitrance of the foot problems. Amputations occur commonly, sometimes appropriately so (severe life threatening infections, uncorrectable severe vascular disease, and unreconstructable bone and joint degeneration causing an unstable ankle or midfoot). Amputations often occur inappropriately, for simple benign plantar ulcers that can easily be healed by basic judicious wound care, but which are not, because amputation is how many surgeons, even today, have been trained to approach the diabetic foot.

Life threatening infection and amputation are real risks for diabetic patients, and most diabetic patients and their doctors are aware of these risks. The reality though is that diabetic foot problems run a spectrum of severity, from simple to life-and-limb threatening. Assuming that care is being prescribed and administered by a knowledgeable physician with expertise in this problem, all that can accurately be said is that effective care can be simple and outpatient, or it may be prolonged in the intensive care unit, or anything in between, and it must be planned individually for each patient. Where Integra fits in this picture is that it will shift patients in the middle away from the complex, expensive, failed, morbid, amputation end of the scale toward the simpler, less expensive, more successful, saved-from-a-major-amputation end of the scale



This patient has diabetes, vascular disease, end stage dialysis-dependent renal disease, and related diabetic complications. The right toes are missing from previous vascular problems. The patient required (appropriately) left leg amputation after developing septic gangrene from a diabetic plantar ulcer. However, as he recuperated from the left leg amputation, he was allowed to get a large pressure ulcer of the right heel. The first urge of his surgeons was to do a below knee-amputation of the remaining right leg. This was unnecessary.

The problem though is that the calcaneus projects outward far enough that surrounding skin cannot contract over it. There is not enough nearby skin to create a suitable flap, and even if there was, the vascular disease guarantees that the flap will fail, making problems much worse. A free flap of remote tissue is excluded by the vascular disease. Simple posterior calcaneotomy and closure with Integra is a simple, effective, and dependable way to solve the problem, with caveats nor contraindications to its use, and no risk to the patient. It is all manageable as an outpatient, as was largely done here. The images show the healed Integra (left panel), the healed foot in a weight bearing stance (upper middle), and the insert the patient wraps around his heel so that his foot is stable within a regular sneaker (upper right). By using the insert and shoe on the salvaged right foot, and by using his left leg prosthesis and a walker, the patient has maintained mobility and independence (lower right), all without any complications, nor failed care, nor unanticipated expense and revised treatment plans.

DIABETIC ulcers & complications

Problems

amputations - loss of function

multiple complications & failed care

high acuity - morbidity - hospitalization

Benefits of Integra

save limbs - preserve function

avoid prolonged care

avoid multi-surgery

correct disability - low morbidity

avoid hospitalization - minimize cost



The most recognizable “diabetic foot” problem is the mal perforans ulcer under the metatarsal heads. While pre-emptive leg amputation (unnecessary, but unfortunately still practiced by many surgeons) is the late outcome that all good care works to avoid, amputation of toes and forefoot is another story. The destruction of the metatarsal heads means that forefoot amputation may be categorically necessary, and this is completely acceptable, because it need not result in any significant disability.

This patient illustrates the conventional caveat that even salvage- and reconstruction-minded surgeons must face in this situation. After transtarsal amputation of the forefoot, the remaining tissues are healthy and suitable for wound closure. However, there is not enough skin to close the open bones and joints. In principle, more bone could be removed, recessing the bone far enough behind the skin edges to allow the skin to close. The problem though is that this is currently a functionally good amputation, with all major ankle controlling tendons still attached. Further bone resection would detach these tendons, making the ankle flail and unstable, unsuitable for walking, and making a below knee amputation more sensible. If the bone is to be kept as is, how do you get enough skin to cover it? Conventional plastic surgery principles dictate that flaps are needed for this situation, not skin grafts, but there are no flaps around. Even if there was an available flap, it would likely fail due to vascular disease, and free flaps are likewise excluded. Conventional attempts at salvage and reconstruction will result in risky operations, complications, progressive disability, and a good chance of still doing the leg amputation.

Integra obviates these issues. Its dependable ability to close bone and joint means that the bone can be kept as is, no flaps need to be made, and there are no further risks due to additional incisions and vascular disease. The foot healed, the patient got a custom fitted shoe, and he walks without disability. Care was mostly outpatient, without complications nor variances from the expected course of treatment.

With diabetic foot ulcers, the problems and complications are comparable to those of arterial insufficiency. Amputations and loss of function are the feared outcomes. There are numerous complications and failures of care, and conventional principles of surgery are confounded by the acuity and morbidity of some of these patients. Care is typically costly and incurs significant resource utilization.

Integra is by no means meant for every diabetic foot problem. The “diabetic foot” means many things, and many treatment modalities must be selected for many individual circumstances. However, in those circumstances in which disease and surgery have resulted in loss of skin, but bones and joints and other viscera are present and create a functional extremity, Integra can reconstruct skin and heal the wound in lieu of leg amputation. Because rehabilitation, orthotics, and disability costs are so much less for foot salvage compared to leg amputation, the patients get better care, better outcomes, and better lifestyle, all at less expense, less resource utilization, and less risk with fewer complications and treatment failures.

Slide 12



INTEGRA

and the
Medicare
patient

RHEUMATOID
ULCERS



Connective tissue disorders are a major category of leg ulceration. These disorders have various names and nomenclatures, and they include diseases such as rheumatoid arthritis, lupus, scleroderma, polymyositis, Sjögren’s syndrome, and the vasculitides. These diseases are part of an extended family of immunopathies which includes diverse disorders such as pyoderma gangrenosum and Crohn’s disease of the skin. They can all cause leg ulcers and wound complications. They will be referred to collectively as “rheumatoid ulcers” or “immunopathic ulcers”. Data compiled in the wound clinic in which I work show that these immunopathic ulcers have the longest length-of-treatment of all of these various categories of disease and ulceration.

Pain, drainage, odor, progressive ulceration, and progressive disability are the norm. Unlike arterial diseases, there is no risk of amputation, and no sudden dramatic conclusion to the problem. Unlike venous ulcers which oftentimes have relatively benign symptoms which people can live with easily enough, symptoms in rheumatoid ulcers are usually severe and intrusive. Thus, the ulcers and their symptoms and disabilities tend to linger and slowly progress over long periods of time, typically months to years. Treatment of the ulcers is difficult enough itself, but is further complicated by the disease: these ulcers do not get better until underlying disease is controlled, which is a challenge because these ulcers tend to occur during disease flare-ups, and controlling these diseases can be notoriously challenging. When disease is controlled, it is often due to antimetabolite drugs and steroids which can have their own adverse effects on wound healing.

This is another group of diseases which can affect almost all age groups. “Rheumatoid ulcers” are difficult to treat in all age groups, but in the elderly Medicare population, the problem is often compounded by concurrent arterial or venous disease. As with any of these disorders, infirmities and disabilities of the elderly can make it difficult for these patients to care for themselves. For these patients, prolonged duration of the ulcers means prolonged duration of the the required care, including home health services, medications and supplies, and related resources. Integra has been valuable because it can not only heal these wounds, but the regenerated “juvenile” skin seems to be durable and resistant to recurrent disease.

Slide 13



The 71 year old woman at top had long standing rheumatoid arthritis and leg ulceration of nearly 30 years duration. The left and center photos show aspects of the ulcer, which covered the entire ankle and distal half of the leg. After excision of skin and fascias, and skin reconstruction with Integra, the leg is healed.

The 77 year old woman below had a comparable history. Both legs were ulcerated continuously ever since her first pregnancy nearly 50 years ago, and all attempts at care have failed. Although she has all of the classic symptoms of Sjögren’s syndrome, nobody ever made the diagnosis. When seen in consultation, the diagnosis was made, and anti-inflammatory treatment was started. As the legs and ulcers improved with introductory therapy, successful surgery could finally be done to close the wounds. However, the extensive chronic ulceration will neither support skin grafts nor permit natural epithelialization. Flaps are an option in principle, and they are even more indicated to cover the multiple tendons that will be exposed after excision. Nevertheless, flaps are both unavailable and risky in this older sicker patient. Instead, the diseased skin and fascias can be excised, and the tendons covered and healthy new skin regenerated with Integra. Photos on the left show the leg ulcers after some of the introductory care and with Integra in place. Photos on the right show the reconstructed healthy skin.

IMMUNOPATHIC ulcers & complications

Problems

multiple failed care - redo surgery
prolonged wasted high utilization
high recurrence - high expense

Benefits of Integra

success when all else has failed
avoid prolonged care & multi-surgery
correct disability - low morbidity
resistant to recurrence
avoid hospitalization - minimize cost



The photos show a 73 year old woman with longstanding leg ulceration. Although it is a very characteristic rheumatoid ulcer (upper left photo), it was misdiagnosed and mistreated as a venous ulcer for a long time, and even the rheumatoid arthritis itself was overlooked. After consultation, the correct diagnosis was made and anti-rheumatoid treatment was started. The ulcer was then excised, and Integra was used to reconstruct skin directly over underlying muscles, tendons, and bone (in lieu of flaps, as would be required by conventional plastic surgery teachings, upper right photo). The leg healed completely (lower left photo), all with outpatient care. Approximately two years later, the patient had a severe flare-up of rheumatoid arthritis, resulting in multiple new ulcers in the surrounding native skin, but not in the Integra reconstructed skin.

Rheumatoid and immunopathic ulcers are characterized by misdiagnosis and misdirected care. However, even with correct diagnosis and conventional care, there is a high rate of treatment failures, wasted skin grafts, and pointless hospital admissions. Short term successes are plagued by predictable recurrences, and the costs of recurrent disease and ineffective care add up.

With Integra, success is most likely. As with all of the other diagnostic categories profiled here, proper diagnosis and proper preliminary treatment of the wound and disease are essential. Once these preliminary activities are accomplished, some patients will be on a pathway to complete wound closure by simple topical care in support of natural wound contraction, and some will do well with the simplest of operations such as a skin graft. But for those in which ulceration is extensive or long-standing, for those in which the tissues have advanced sclerosis or residual disease and inflammation, and for those in which bone, tendon, joint, and other working structures are exposed, Integra succeeds where all else has failed. It creates healthy disease-resistant new skin, and it does so with no autogenous donor sites (except for the final skin grafts) nor any added risk to the patient. All care is manageable as an outpatient, and resource utilization is minimized compared to conventional forms of ineffective care.

The slide features a decorative border at the top and bottom with a repeating pattern of stylized, colorful geometric shapes. On the left side, there is a rectangular photograph of a vast, flat, arid landscape under a heavy, overcast sky. The terrain is covered with sparse, dry vegetation, and a single, bare tree stands in the middle ground. In the distance, a range of low mountains or hills is visible. On the right side of the slide, the word "INTEGRA" is written in a stylized, purple, blocky font, flanked by decorative symbols. Below it, the text "and the Medicare patient" is written in a simple, black, sans-serif font. At the bottom right, the words "OTHER ULCERS" are written in a large, green, hand-drawn, brush-stroke font.

The foregoing disease categories are some of the more common forms of chronic ulceration, but there are many others. No attempt is made here to further categorize them. The purpose of this last section is simply to show that there are many forms of chronic ulceration in elderly and disabled Medicare patients, and Integra has a role in treating many such patients.



On the left is a woman with end stage renal disease due to hypertension, with tertiary hyperparathyroidism. This leads to extensive small vessel arteriosclerosis and subsequent skin ulceration (the problem of hyperparathyroid arterial calcinosis is today commonly referred to as “calciophylaxis”, an erroneous use of this term). The ulcers tend to be on the trunk and thighs, centered over the flanks and hips. These ulcers are notoriously painful, disabling, and difficult to treat. The risk of pathergy and surgical complications is high, and resolving the wounds with topical care alone typically involves months or years. Because of Integra’s ability to control pathergy, these lesions can be excised and closed with Integra, with a rapid resolution of pain, and an uncomplicated regeneration leading to closed wounds along typical Integra timelines.

On the right are two patients with pressure ulceration of the heel and achilles tendon. Comparable to the heel ulcer previously shown, Integra was able to easily and completely close these wounds which for many physicians trigger a leg amputation. Recall that conventional plastic surgery principles dictate using flaps over structures like this, but flaps are hard enough to find in these areas, and the associated vascular disease makes flaps risky or impossible. Simply debriding the wounds and laying Integra over them allows for a benign, uncomplicated, low utilization resolution of the problem. Most small heel ulcers heal with topical care only, but when large ulcers have a protruding calcaneus necessitating bone resection, Integra is categorically simpler, cheaper, more effective, and an almost risk free way to ensure a successful outcome.



The center panel is a chronic ulcer due to a chronic non-union pseudarthrosis of an old malleolar fracture. Workup failed to reveal any other diagnosis. While this is a limited and localized pathology unlike the systemic or diffuse disorders such as vascular and rheumatoid diseases, nevertheless it caused such persistent inflammation that all attempts to care for and close the wound failed for several years. Debridement and sequestrectomy (removal of the bone fragments) is required, but the persistent dermatitis created concerns that conventional forms of closure would fail. After the wound was debrided, the ankle joint was open, necessitating flaps according to conventional principles. Closure with Integra controlled inflammation (middle photo) and allowed the wound to heal without complication (bottom).

The right panel shows an ulcer of many years duration in a patient with severe protein S deficiency (a hypercoagulable disorder leading to recurrent thrombosis and problem wounds; the patient herself had had multiple venous thrombosis of the leg). This case is similar to the first in that persistent inflammation was impossible to control, necrosis and ulceration were impossible to suppress, and wound healing was impossible to induce with any other customary diligent approach to care. Wound excision and closure with Integra immediately controlled inflammation (middle photo), and the reconstructed skin remained healthy and durable (bottom).

Regardless of underlying cause or diagnosis, chronic and pathological wounds are all marked by prolonged morbidity, multiple failed care, surgical and non-operative, and high expense due to hospitalization and miscellaneous care. Loss of lifestyle and economic productivity are also significant.

With Integra, recalcitrant long standing problems can be effectively resolved, even when all other efforts to close a wound have failed. Amputations and disabilities are avoided. By resolving the problem expeditiously (along a typical timeline of Integra regeneration and reconstruction), wasted expenses and utilization are eliminated. Care is largely kept out of the hospital.



The place of Integra in modern wound medicine and surgery must be understood in relationship to other products. Wound medicine is a complex subject with many therapeutic options, some effective and well studied, and some persistent hokums and nostrums held over from the patent medicine era of 100 years ago. Among legitimate therapies, each has a mechanism and a meaningful use, but they are not interchangeable. In the world of heart medicine, digoxin, propranolol, lidocaine, stents, and balloon pumps are not interchangeable treatments for generic “heart disease”, and the same is true for wounds. Each good wound therapy has a defined role. There is in fact nothing even remotely similar to Integra, neither in its manufacture and materials, nor in its indications and methods of use. However, administrative simplifications have lumped Integra together with other products such as Apligraf and Dermagraft under the designation “bilaminate skin substitute”. This term is a nominally correct description of Integra, but there is no more similarity between Integra and these products as there is between any of them and an open face peanut butter sandwich (also a bilaminate material).

Integra has two layers. The working spongy layer of collagen and chondroitin is made from biological materials (biochemicals, not cells), but it is not alive. The outer artificial “epidermis” is made of pure synthetic non-biological silicone. On the market since FDA approval in 1996, it is made by Integra Life Sciences, and managed by Ethicon / Johnson & Johnson. As discussed here, it’s role is to reconstruct skin. It is used as a surgical implant (implanted on the surface), applied in the operating room. It is typically applied only once, just as an artificial joint or ocular lens is placed only once (barring complications).

Apligraf and Dermagraft are very similar products, direct competitors in the marketplace and essentially identical tools for the wound doctor. My own experiences are that Apligraf is a more effective product, and throughout this discussion I will refer only to Apligraf, with the implicit understanding that for the sake of this discussion, “Dermagraft” can be used interchangeably with “Apligraf” with regard to clinical indications and application.

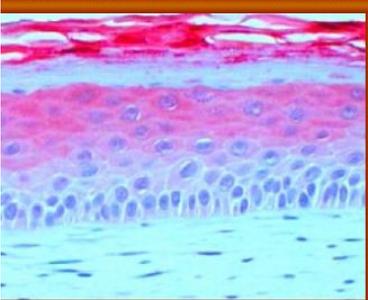
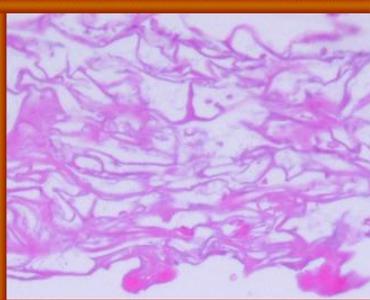
Apligraf and Dermagraft are LIVING materials. They are manufactured from donor neonatal foreskins. Cells are stripped from the original skin, then grown in cell culture with nutrients and biochemicals. For Apligraf, new dermis is grown first, then a living

epidermis is grown on top of the dermis. The result is a “re-engineered” living skin, living in the petri dish in which it was grown. To be used, a physician must order it in advance. It is delivered in an elaborate package which oftentimes includes a battery driven electronic heater to maintain temperature within the package. Just before sealing and shipping, the package is charged with precise amounts of oxygen and carbon dioxide to keep the cells healthy. The culture medium substrate has a pH color indicator to show whether the material is still viable and usable. It must be used within about 24-48 hours of delivery. Apligraf is made by Organogenesis, a small biotech company. On the market since about 1999, it was managed by Novartis until January 2003, at which time business disputes between the two companies suspended manufacture and shipping of the material for 6 months. It is now available again (as of June 2003), under the sole management of Organogenesis.

When Organogenesis first made Apligraf, their belief and their marketing campaign were both organized around the idea that Apligraf was handy-dandy skin graft in a box - “McSkin”, suitable for use by non-surgeons who wanted to use a skin graft, and readily available to real surgeons as easily as pulling Kleenex out of a box. Great for burns and trauma and whatever - in principle. But this concept was based on rat models, and rats have different immunological barriers than people. McSkin works on McRat, but not on non-veterinary patients. Every clinician and human biologist knows this - people reject allograft skin. Every physician who follows this was perplexed about how Organogenesis got FDA approval for the product. Most surgeons who followed these things tried Apligraf once or twice, realized it didn’t work, just as they expected, and lost interest in the product, including me. As a skin graft, it is a non-product. But it turned out that in the right circumstances, Apligraf was doing something wonderfully good for chronic pathological wounds. It took a while for practitioners to understand how to use the product, but it is now an important part of the wound doctor’s toolbox. Simply put, Apligraf acts like a pharmaceutical, a drug delivered within a living material, that stimulates wound healing in recalcitrant or retarded wounds. Somehow, these juvenile cells confer something beneficial to the problem wound, stimulating a healthier and more active wound repair process. Novartis later retrenched their position on “skin in a box”, and at all their later symposia, they were very forthright, forthcoming, and up front in their acknowledgement that the “skin in a box” concept was wrong. Their latter research has all been focused on trying to understand what these neonatal cells are doing to the recipient wound.

I am personally a fan of Apligraf. It does wonderful things. I was also a speaker for Novartis, involved with their physician education symposia. Meaning - I know something about the product, I know something from more of an insiders point of view, and I like and support the product. Therefore, any comparison of Apligraf and Integra is NOT adversarial nor antagonistic nor mutually exclusive. As a practitioner who depends on both of these products, I have a vital interest in seeing that both products survive and do well, because both have become an integral part of modern wound practice. Any discussion of the differences is objective, analytical, and inherently favorable to both products. What must be realized is that while both products have a role in wound care, their roles are different, just as digoxin and stents both have roles, in “heart disease”.

Against this history, the nature of the original “bilaminate material” designations can be appreciated. When Integra was developed and first marketed, It was meant to be a skin substitute for severe burns. It’s ability to induce embryonic new skin formation and the full panoply of its remarkable uses were not the least bit anticipated. When Apligraf was first approved and marketed, within about two years of Integra, it’s intent was to be a skin graft or skin substitute for any wound. Its failure as a generic skin graft and its real role as an effective biopharmaceutical to treat pathological non-healing wounds were not anticipated. So, both products were forward thinking bioengineering devices from small biotechnology companies. Both products hit the market nominally as a skin replacement. Both products were manufactured with two layers of “stuff” (Integra sponge-silicone, Apligraf dermis-epidermis). Therefore, both were seen as bilaminate competitors for the same problems and market segments. Now we see how naive those early days were. Unfortunately, the original reimbursement designations for these products, developed in good faith during the early but conceptually flawed days of these products, are now hampering the ability to deliver these products for their real uses and benefits to all of their potential beneficiaries, especially for Integra.

Apligraf & Dermagraft	Integra	
	<p align="center">  Similarities  </p> <p align="center"> engineered bilaminar material used for some aspect of treating wounds comparable cost per unit </p>	
<p align="center">  Differences  </p> <ul style="list-style-type: none"> living material biological dressing bio-pharmaceutical <ul style="list-style-type: none"> small (many) units applied frequently clinic / office service not final nor definitive inflated net costs <p align="center">agent & accelerant of wound healing</p>	<p align="center">  Differences  </p> <ul style="list-style-type: none"> non-living material induces histogenesis implant <ul style="list-style-type: none"> one (few) units applied once outpatient surgery service final, definitive, durable predictable net costs <p align="center">agent of skin reconstruction</p>	

Apligraf (and Dermagraft) and Integra share some properties. They are all manufactured. They are all “bilaminar”. They are all utilitarian and effective for some aspect of wound care. They all have a comparable cost per packaged unit (current charges are approximately \$950 for a 44 sq cm (3" diameter) circle of Apligraf: \$500 for a comparable size piece of Dermagraft: \$1250 for a 250 sq cm (4" x 10") sheet of Integra). The similarities end there.

The left photomicrograph shows Apligraf. It is living skin, epidermis on top of dermis. On the right is Integra, an acellular matrix of biochemicals (the upper silicone layer is not seen because it usually comes off for histology processing). This is an emphatic portrayal of how there is nothing at all structurally similar about these two products.

Differences between the products are far more important than the nominal similarities. Apligraf is living. Integra is not living. Apligraf functions as a drug, delivered in a living vehicle, which stimulates the wound healing process of the recipient wound. Integra is an implantable scaffold which suppresses normal wound repair and instead gives host cells a place in which to regenerate new tissue (histogenesis). Apligraf does its job, dies, and disappears. Integra becomes incorporated into the host.

As a WOUND STIMULATING PRODUCT, Apligraf is not the definitive nor final closure of the wound, but rather a topical treatment that forces the wound to do its own healing. It is usually applied in office or clinic, as part of an ordinary outpatient wound visit. It is applied as small standard units (44 sq cm circles), as many as needed to cover the wound. It's per-square-centimeter cost (approx \$21.60) makes its use economically prohibitive for large wounds. It is usually used on relatively small wounds, up to a few centimeters in diameter. It will often successfully heal a wound after one application, but if it is effective but incomplete, subsequent “doses” can be applied. The Apligraf treatment paradigm: (1) use it in office or clinic; (2) use small units, as many as needed, applied as often as needed; (2) wait for the right time, keeping an eye on the bottom line, because the costs can run up with large wounds and multiple doses.

As a SKIN RECONSTRUCTION PRODUCT, an Integra reconstruction is meant to be the final definitive closure of the wound. It is used in the operating room. It is applied in large standard units (typically 250 sq cm, or other stock sizes suited to the size of the defect). As many sheets are used as needed to close the defect. The per-square-centimeter cost of \$5.00 is economically sound, especially because it is used only once to build a successful reconstruction. It's low cost makes it economically sound for treating large wounds such as burns and trauma. The Integra treatment paradigm: (1) it is an implant to be placed in the operating room; (2) use it to cover any size defect, large or small, applied once; (2) intervene to reconstruct early, because early successful use of this economical product minimizes long term net costs by prompt resolution of the problem.

Slide 20

Apligraf & Dermagraft	Integra
	
<p>TWO ENTIRELY DIFFERENT PRODUCT CLASSES BOTH are exceptionally important to modern wound care BOTH have different and distinct indications, methods, and outcomes</p>	
<p>Differences</p> <p>APLIGRAF and DERMAGRAFT are used as pharmaceutical agents to stimulate healing in non-healing wounds</p> <p>they are WOUND HEALING products</p>	<p>Differences</p> <p>INTEGRA is a histoinductive implant which regenerates normal tissue in lieu of injured or diseased tissues</p> <p>it is a SKIN REGENERATION product</p>

While Apligraf and Integra still carry the designation of “bilaminate skin substitute”, these two cases illustrate the different therapeutic functions and uses of these two very important but dissimilar products.

On the left is patient with a chronic ulcer over the achilles tendon. Skin is ulcerated, but the wound has not perforated through the skin and subcutaneous fascias into the tendon itself. Ulcers in this area can be notoriously hard to heal, predominantly because the biomechanics of this moving area are adverse to normal wound healing. On first glance (left end photo), this looks like a normal healthy healing wound which should be closing by ordinary wound contraction, but it isn't. Although managed by good topical wound care and splints for 4-5 months, the ulcer never varied from this appearance nor size. If this was a healthy acute trauma wound, surgical closure would be done with ordinary autogenous skin grafts because there are no special features of the wound which warrant anything more elaborate. However, surgical closure cannot be done because successful surgery depends on a healthy wound healing process (and if this wound was healing properly, it is small enough to close without surgery). This is the perfect place for Apligraf: the wound appears healthy (no disease, no inflammation, well cared for), and wound repair is evident but going nowhere. The seemingly healthy wound needs a friendly “kick in the butt” to start behaving properly, and this is what the pharmaceutical effect of Apligraf does to a wound. The middle photo shows the wound about 5 weeks after placing Apligraf, and the 9 week photo on the

right shows the wound fully healed, a typical time frame for Apligraf to heal a wound. (This 44 year old man is the one patient in this presentation who is younger and was not a Medicare or Indian Health Services beneficiary.)

The right hand panel is another achilles ulcer, but this one cannot be managed by Apligraf. This 65 year old woman has Wegener's granulomatosis, a potentially life threatening connective tissue disorder, held in control by steroids and antimetabolite therapies. Her severe pulmonary complications make her a poor risk for surgery. The ulcer has perforated into the achilles tendon. Basic topical wound care is needed to keep the wound safe and prepared for surgery, but because the wound cannot heal over the tendon, topical care alone will not work, including Apligraf. Conventional principles of plastic surgery demand that this exposed tendon be closed with a flap. While there is indeed evidence of wound repair in the wound, her disease and its therapy make any local flap prone to complications and a larger wound. A free flap from a remote location is likewise risky, and even more so in this patient because of her pulmonary status and the higher risks and potential morbidity in these long procedures. This is an ideal Integra case. It will generate new tissue across the tendon, serving the same function as a flap. It requires no autogenous donor sites. All that is required is a simple wound debridement and then the application of the Integra. The procedure is very short, outpatient, inherently not risky, and it can even be done easily with local rather than general anesthesia. Post-operative care is basically nothing at all, other than weekly observation to see when the Integra is regenerated and ready for the completion skin graft. The left photo shows the ulcerated achilles tendon, the middle photo shows the regenerated Integra at the time of skin grafting, and the right photo is the healed result.

Integra and Apligraf share some nominal indications. According to the provisions of its FDA authorization, Apligraf is indicated for diabetic and venous wounds. Integra is indicated for burns. In actual practice, these products are all used for all of these conditions. However, these products are used at different times, under different circumstances, their usage defined by medical indications rather than regulatory indications. Both are valuable products, essential in modern wound practice, but their medical indications are as divergent as the indications for pronestyl and porcine valves in the treatment of heart disease. These two cases illustrate those important differences. Apligraf and Dermagraft are wound healing products, stimulating a refractory, recalcitrant, retarded or delayed wounds healing process to turn on. Integra is a tissue regeneration product, creating new tissue to cover structures and close wounds in circumstances where even a healthy wound healing process needs some surgical help.



INTEGRA

and the
Medicare
patient

THE UNIQUE
IMPORTANCE
OF INTEGRA



It should be evident at this point that Integra is a valuable product that solves difficult problems easily and with low risk.

It is important to emphasize that the product is unique. In the seven years that this product has been on the market, I have used it nearly 250 times. In a practice that is devoted to difficult tertiary problems, I have done far more than just 250 operations in 7 years, and I have seen thousands of patients in outpatient wound clinics. Integra is not to be used indiscriminately as a substitute for simple skin grafts, necessary flaps, topical wound care, wound stimulating therapies, nor anything else. Each therapeutic modality has its indications, its time and place. When Integra is indicated, it is often because it is the only thing that will work, or the patients are too sick for conventional flaps or grafts, or economics and availability of resources make it desirable, or because the end results are superior. When it is needed, it is really needed, and there is simply no substitute.

INTEGRA

is a unique product

there is no substitute

it solves problems that could not be solved before

it saves limbs

it saves lives

it saves morbidity

it saves livelihoods

it saves large sums of money in the care of individual patients

it is perfectly adapted to the burgeoning infrastructure of outpatient wound care

Here are three final examples of difficult problems easily solved by Integra.

The hand belongs to a patient with vascular disease. Thrombosis or embolism resulted in gangrene (top photo). An important principle of hand surgery is to try to preserve length and parts, because patients will always find a way to do something useful with parts of a hand, and the more parts missing, the more disabled the patient is. Debridement of necrotic tissue resulted in bare metacarpals without soft tissue coverage (middle photo). The situation is similar to the trans-tarsal amputation shown earlier. Bone could be removed until remaining skin can close over them, but this would shorten the hand to the wrist - not nearly as useful a hand as if the metacarpal rays could be preserved. Flaps would be the conventional approach. Integra has been so good on hands that it is redefining all of the conventional approaches to hand coverage, but the discussion is moot in this patient, because vascular disease precludes any kind of flap. Closure with Integra saves all salvageable parts of the hand and preserves length and function (bottom photo).

The right upper panel is a below knee amputation gone bad. As already illustrated with the previous case of thigh stump necrosis, many surgeons' first impulse with a bad amputation is to amputate higher. Below knee amputation at least preserves a fair bit of function and options for the patient, but above knee amputation is always a poor choice in elderly patients with vascular disease and related problems. In cases like this one, some necrosis of skin and fat need not trigger an above knee amputation. Instead, basic wound care and then Integra reconstruction over bone and joint salvages an important piece of anatomy and function. (Top, the open amputation stump after debridement and preparation. Middle, the stump soon after placing skin grafts over regenerated Integra. Bottom, the healed stump, with a straight knee.)

The ankle at the bottom is has a chronic ulcer due to rheumatoid activity. Refractory to all prior care, it healed without incident with Integra, all care rendered as an outpatient.

This slide recapitulates the benefits of Integra. The issue of outpatient services warrants special discussion. Concepts about fixing wounds, and the tools and techniques to do so, have made meaningful progress over the past decade. Along with new tools like

Apligraf and Integra, four “administrative” or logistical conditions have significantly impacted the way wounds are managed: (1) the advent of dedicated wound clinics, (2) the ready availability and high quality of home health nursing and related services, (3) the prevalence of outpatient surgical centers (including general advances in the safety of anesthesia), and (4), rightly or wrongly, the pressure by managed care and third party payors to move people out of acute care facilities. What these conditions have resulted in is an infrastructure for caring for wound patients that has its best and most dependable resources outside of the inpatient hospital. Even most of the surgery illustrated by the cases in this presentation is now done as an outpatient. Many of these are sick, high acuity patients having procedures which, until beginning in the mid 1980’s, were guaranteed to be accompanied by an inpatient admission of a week or two.

Keeping patients out of acute care is a GOOD IDEA. Predictable expenses for nominal prescribed care are kept much lower. Irrelevant tests and consultations are virtually eliminated, and complications and related prolonged care are kept to a minimum. Patients’ morale and sense of well being are kept higher, and post-operative bed confinement and resulting disabilities and complications due to deconditioning are kept very low. These benefits are especially noticeable in the elderly Medicare population where apriori diseases, weakness, disabilities, and geropsychiatric problems are significant predispositions to costly complications and irreversible downturns in lifestyle. With the looming public health crisis of an ageing baby-boomer population retiring but living longer, strengthening outpatient services and models of care is of pre-emptive importance. For wounds, much of the outpatient infrastructure of good care is already in place and generally getting better.

Slide 23



INTEGRA

and the
Medicare
patient

GOOD STUFF
WE NEED IT
THEY NEED IT
OUTPATIENT WOUND CARE

Integra solves tough problems. It save lives (burns and fasciitis), limbs, and lifestyles. It does so with little or no risk to the patient, and it does so largely as an outpatient. It is an effective and dependable tool ideally suited to the shifting paradigm of outpatient wound management. It is a unique product, and when it is really needed, there is simply no alternative choice. The Medicare population in particular is a group of patients most likely to get dramatic medical benefits while also realizing important economic

savings by use of this product. Unfortunately, current reimbursement regulations, established in the early days of these new “bilaminar skin substitutes” now impede the use of this product in Medicare patients.

In my own practice in Phoenix, Arizona, Medicare reimbursement policies have had a tangible effect on using this product in people who need it. I do most of my surgery, inpatient and outpatient, at St. Joseph’s, a major urban general hospital and medical center, owned and administered by CHW (Catholic Healthcare West). I also do some of my surgery at a free standing outpatient surgical facility. The free standing facility will not allow me to do outpatient Integra cases, because they are not reimbursed the cost of the material. Because of managed care contracts, these patients may have no choice as to venue. For these patients, unless something can be done to finagle an inpatient admission somewhere, they cannot have Integra. This has been a de facto reality for a few patients, and more conventional but less effective modes of care have had to be used. At St. Joseph’s, they too do not get reimbursed for the outpatient use of the material. As a Trauma 1 center in a Mexican border state, the hospital must assume a lot of debt on unreimbursed care for undocumented aliens, the problem compounded by the very high managed care penetration in Arizona, all putting significant financial pressures on the facility. Nevertheless, they permit me to do these outpatient Integra cases anyway, because I bring almost all of my business there, and because they have a charitable mission to take care of all patients. The special favor that I receive to do these cases is beneficial to the “system” as a whole by keeping direct costs of care to a minimum, and it is certainly beneficial to the patients. However, not all facilities are likely to be so tolerant or charitable, and in many other communities or facilities, many potential beneficiaries of this amazing product will not receive that benefit.

As a physician in private practice, my own motivation in all of this is simply to do the best I can do to take care of these patients. Doing the best often means using Integra, and my interest in preparing and presenting this lecture is simply to help ensure that the product survive, flourishes, and is freely available when needed.

Marc E. Gottlieb, MD, FACS
Phoenix, Arizona
July 11, 2003

END