CLINICAL STUDIES & EVIDENCE OF BENEFITS

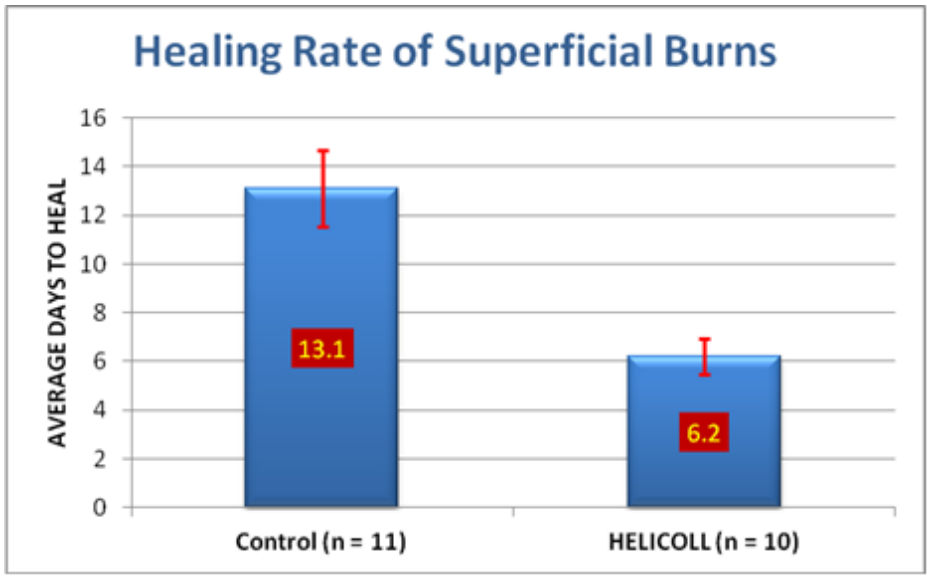
Clinical Experience with Helicoll

Figure 1: Clinical indications of subjects in Helicoll studies[11]

Clinical Situation	Helicoll Used Patients	Control Patients
Donor Site	81	77
2nd Degree Burns	10	11
Diabetic Ulcers	6	5
Chronic Venous Ulcers	10	10
Contracture release & Bare tendons, bones and joints	10	10

158 patients with split thickness skin grafts (STSG) were successfully treated with Helicoll in 2010. Study included measurement of pain reduction of patients treated with Helicoll compared to control patients.[11]

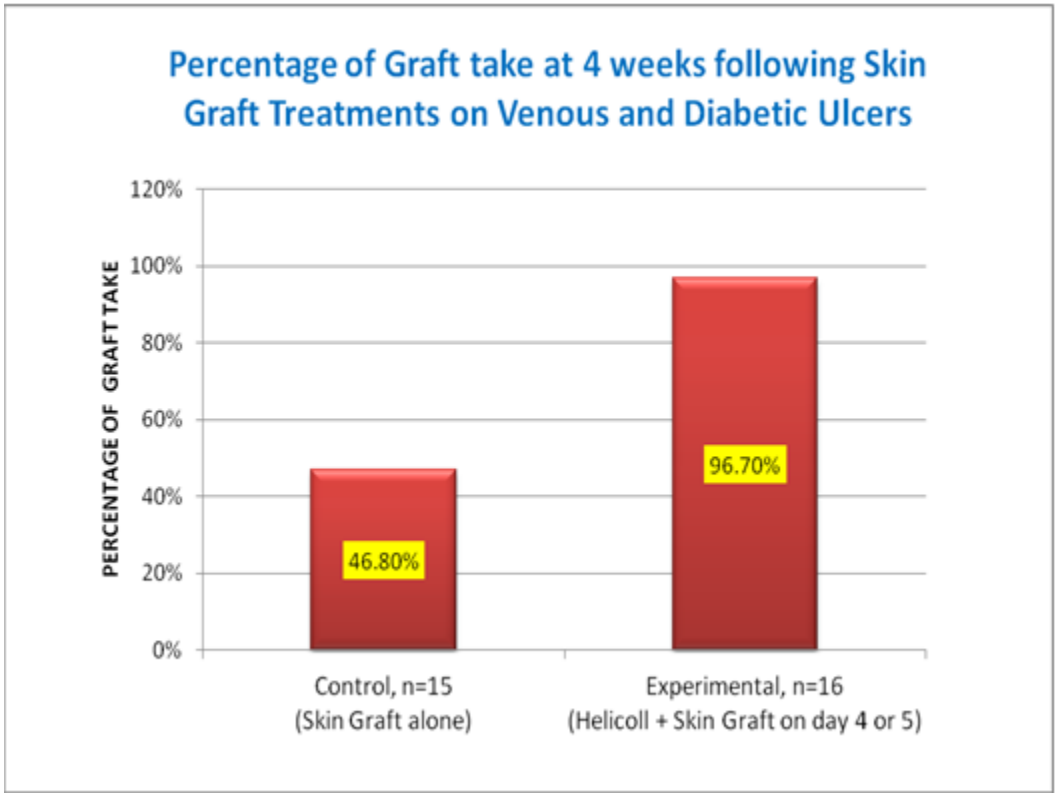
Figure 2: Healing rate of superficial burns treated with Helicoll or control[11]



Helicoll, in the clinical setting[11] significantly reduced burn healing time, provided rapid pain relief at the wound site, achieved 99.9% skin graft retention and reduced scarring, as well as return of native skin color to the patient after several months. Helicoll also significantly reduced the amount of hospital staff time required (dressing changes are less frequent as, Helicoll can remain on wound for several days, wound inspection simplified as Helicoll is semitransparent and wound can be assessed without removal of Helicoll), as well as total cost of care by up to 50% over

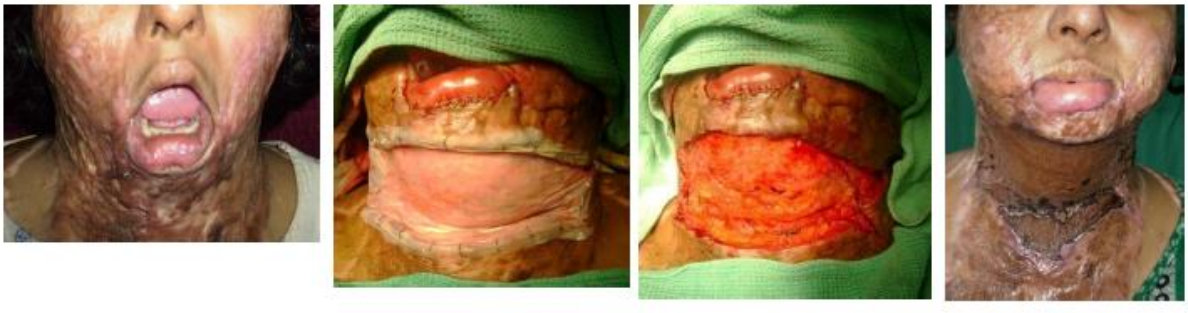
current therapies (product cost is up to 92 less expensive than some competitors (Figure 7). Helicoll is available in large sizes so burns can be covered quickly.

Figure 3: Graft take following skin grafts in venous and diabetic ulcers[11]



Helicoll is used for first and second degree burns, partial and full-thickness wounds, post laser treatment, as well as pressure, venous, vascular, and diabetic ulcers. Trauma wounds such as: Abrasions, lacerations, skin tears and donor sites are also indicated uses.

Figure 4: Treatment of Post-Burn Contracture with Helicoll[11]



Post-burn neck contracture

Contracture release and Helicoll application

Day 5 post-Helicoll application

After graft has taken

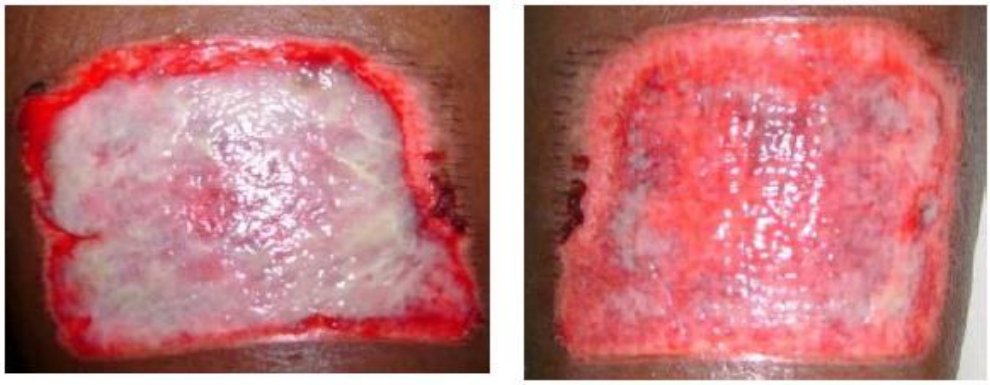
Helicoll can be placed on wounds caused by soft tissue necrosis secondary to radiation, chemical burns or corrosives. The Helicoll is moistened with sterile water or normal saline for six to ten minutes and placed in direct contact with the necrotic tissue. Daily dressing changes are recommended with mechanical debridement of the necrotic tissue to reduce the bioburden of the necrotic tissue and assist with autolysis.

Oxygen enhances the wound healing activity of collagen so Helicoll can be applied to wounds that are undergoing treatment with hyperbaric oxygen.

It does not matter which surface of the Helicoll Wound Dressings is placed against the wound surface. Helicoll must remain in contact with the wound by light pressure to ensure the contact of the wound surface with the collagen to ensure proper healing.

Only areas with skin damage will interact with Helicoll. Any excess collagen (see Figure 5) can be rinsed away with saline irrigation, so removal of the dressing does not interfere with healing granulation tissue nor does it cause a painful experience for the patient. Helicoll is also semi-translucent so that observation of the healing can be accomplished without disturbing the healing tissue.

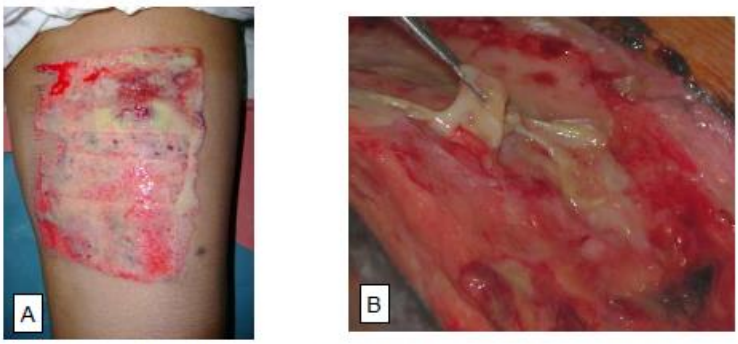
Figure 5: Photographs of wounds treated with Helicoll[11]



Helicoll degradation product (White gel-like substance) incorporating into collagen matrix on Day 4

Incorporation of Helicoll into deeper structures on Day 9

Figure 6: Photograph of wounds showing Helicoll incorporation[11]



Collagen consistently is incorporated into the wound by Day 4-5. Capillary bleeding and incorporation of Helicoll into deeper structures seen above. Induction of neo-vascularization and incorporation of collagen was assessed using histological and electron microscopic studies (not shown).

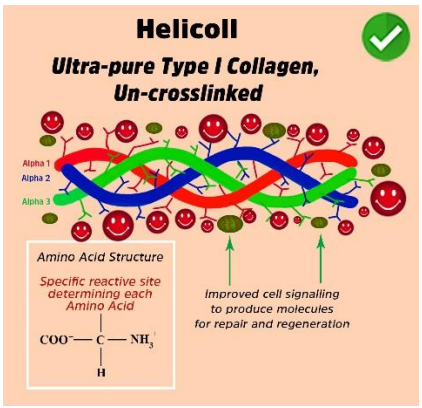
Helicoll Advantages:

The usefulness of Helicoll over any other dressings in the market is well documented for the treatment of diabetic ulcers, donor sites, burn treatments and other types of wounds. Refer to Figure 1 for distribution of types of wounds treated in clinical studies.

With Helicoll, epithelialization occurs even in the inner areas of the wound site. This did not happen with other collagen preparations used on the same wounds.[7]

As described in Section 1.3 of this document, native type-I collagen creates adhesion sites for growth factors and also triggers "cell signal transduction" through which floating stem cells convert into appropriate cell-lines to regenerate damaged tissue. Other collagen preparations may not maintain the native chemistry of type-I collagen. The high purity type I collagen dressing of Helicoll avoids any potential health risks normally caused by contaminating immunogenic molecules like type-III, type-II collagens, elastin, glycosaminoglycans, some proteolipids, oligopeptides etc. Accordingly, the other dressings are cross-linked to minimize the immunogenicity of contaminants at the expense of the needed bio-activity of collagen for enhanced wound healing.

Biochemical Advantages of Helicoll



EnColl Corporation's patented process uses a unique enzymatic process that result in a highly purified collagen that is relatively non-immunogenic. It also renders a native un-crosslinked collagen. Certain preparation methods of collagen products use crosslinking by chemicals such as aldehyde without realizing that the resulting collagen is cross-linked and no longer bioactive. If a collagen molecule is crosslinked, it loses the natural binding abilities to adhere to cell surface receptors, growth factors, and other potential active molecules necessary for the healing process to move forward. This impedes the natural cell-signaling properties of collagen and thereby the crosslinked collagen reduces the wound healing capabilities of un-crosslinked native collagen. If the collagen is native the cell-matrix interactions and the bioactivity of cells will increase. Helicoll collagen provides this environment. It works to reduce pain, scar formation and loss of pigmentation. Further it may also help to heal wounds with limited blood supply in cases of arterial insufficiency.

Another advantage of Helicoll is that it has been shown to be safe for use on patients of all ages from birth to centenarians. Helicoll provides hemostasis and accelerates tissue remodeling and acts as an acellular dermal replacement product similar to Integra http://www.helicoll-sfo.com/pdf/Comparison_of_type-I_collagen_with_Integra_skin_substitute.pdf. Like the Integra model, Helicoll promotes healing and neo-vascularization.

Some dressings are considered cytotoxic. Helicoll, however, has been shown to be extremely bioactive, biocompatible and non-cytotoxic in vivo and in vitro.

Common benefits of Helicoll over other commercially available collagens in the market are:

- ✓ Improved biocompatibility
- ✓ Non-immunogenicity
- ✓ Controlled bioresorbability
- ✓ Cell attractability
- ✓ Hemostatic ability
- ✓ Structural stability
- ✓ Target specificity

The disadvantages of using human skin allografts that do not apply to Helicoll include:

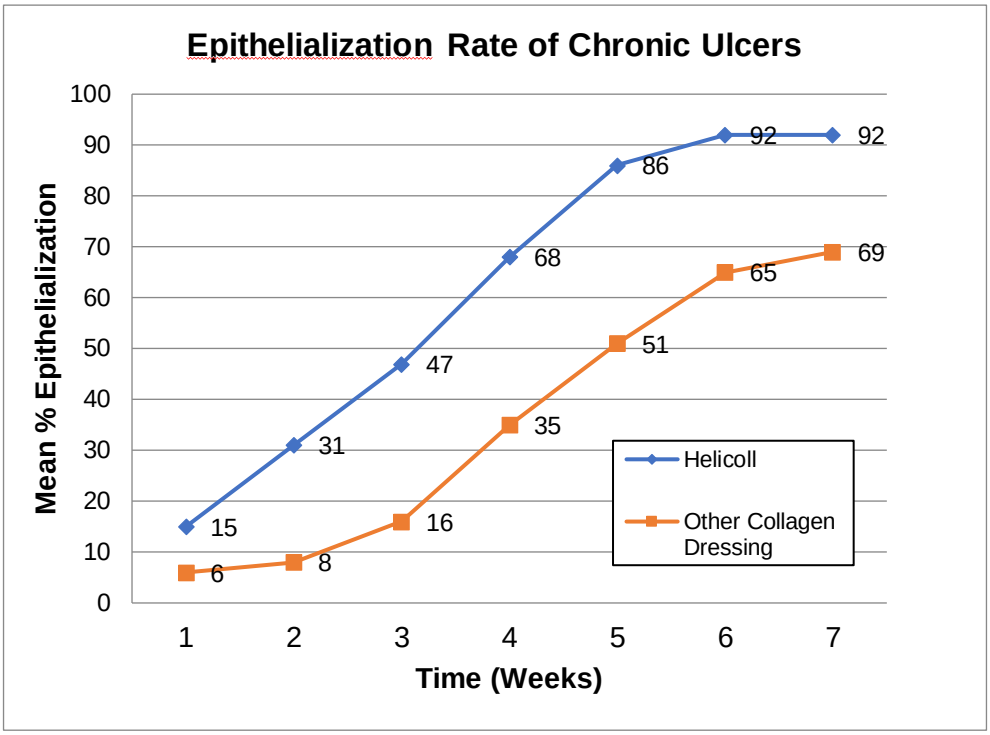
- ✓ fear of HIV and other human infections
- ✓ cross-linking or use of preservatives that can reduce the bioactivity of the graft
- ✓ biohazardous material disposal concerns
- ✓ immediate availability is quite difficult
- ✓ limited shelf life
- ✓ possible bacterial contamination
- ✓ many eventually are rejected, making them a temporary rather than permanent wound covering

CLINICAL TRIALS:

Use of Helicoll to treat skin ulcers:

64 patients with ulcers were selected at random from different centers and treated with varied acellular dermal replacement collagen dressings to compare the effectiveness of Helicoll dressing with other collagen dressings. Healing was visible as early as the 5th day after Helicoll treatment. There was no pain on opening the dressing and patients had no discomfort. No adverse events were reported.[6]

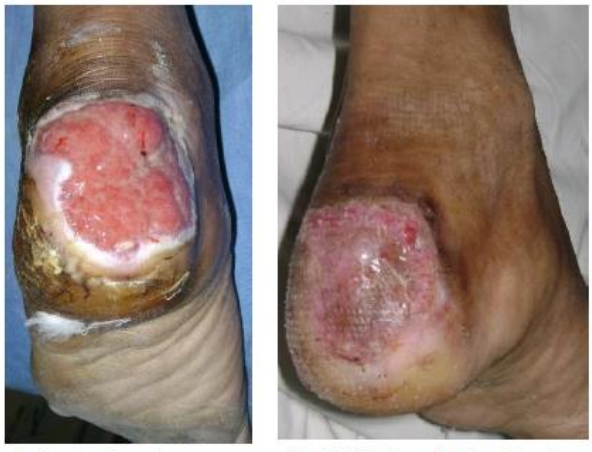
Figure 7: Rate of healing of wounds over 7 weeks in 64 patients with chronic ulcer wounds using Helicoll[6]



20 patients with ulcers were included to undergo treatment with Helicoll. In all cases, wounds closed after a few bi-weekly and weekly applications. The wounds remained closed for several months. It was noticed that epithelialization occurred even in the inner areas of the wound sites, which did not occur when other dressings were used.[7]

Helicoll was compared to traditional cotton gauze dressings for the management of lower extremity ulcers in 18 patients. Although both study groups were comparable at baseline, data indicate that the use of Helicoll resulted in faster re-epithelialization.[29]

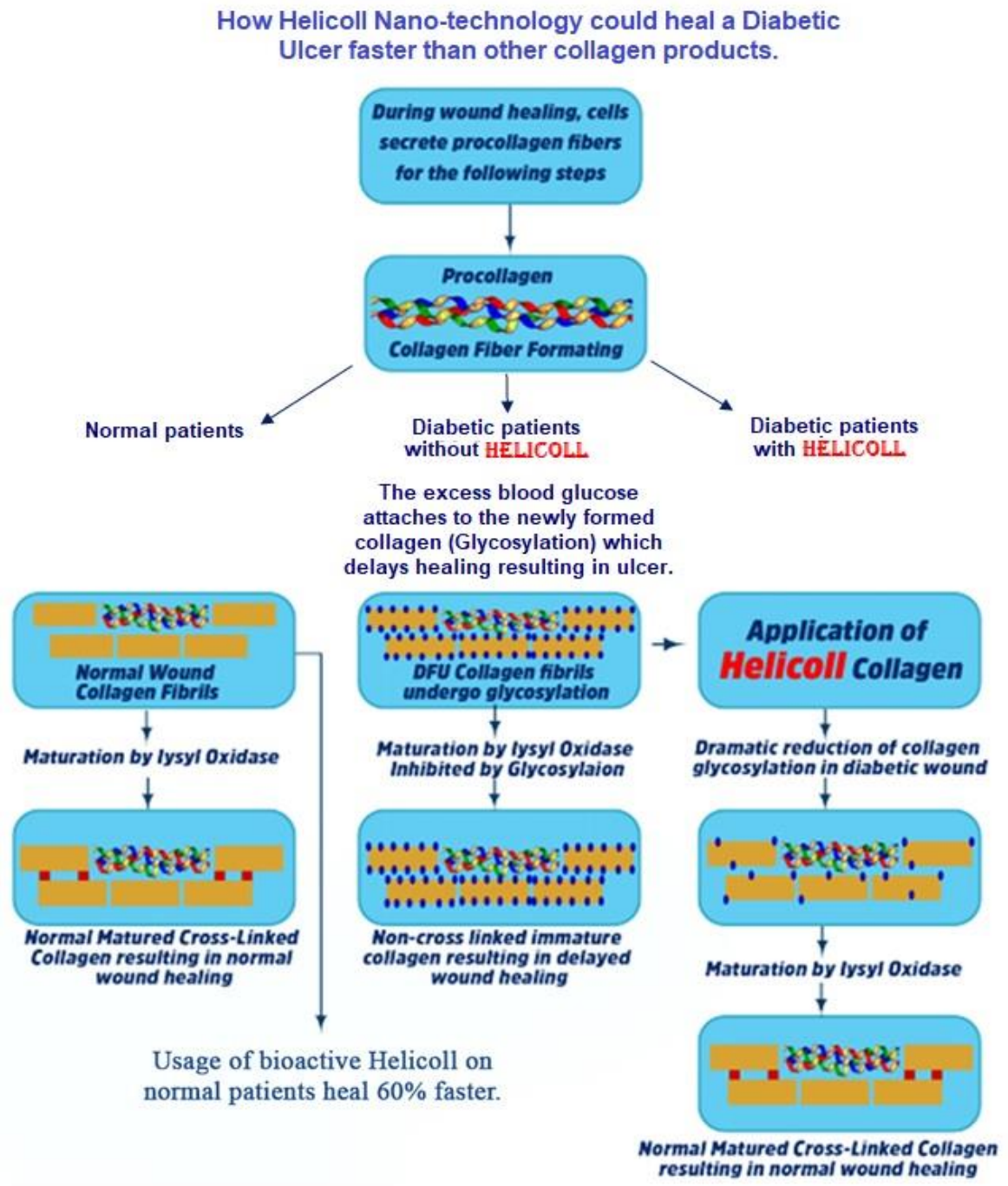
Figure 8: Diabetic Foot Ulcer Treated with Helicoll[25]



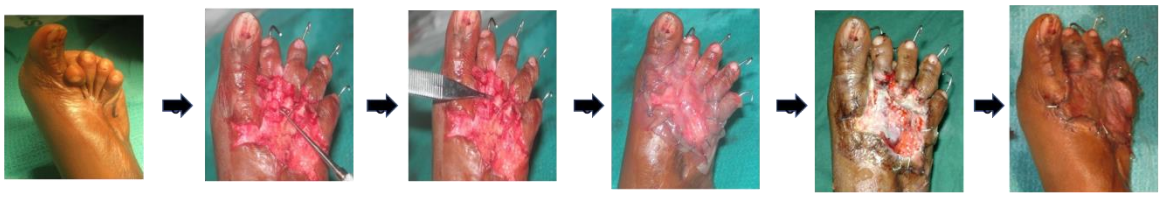
Before treatment

Post-Helicoll application, Day 9

The role of Helicoll collagens in foot care was demonstrated[25] in independent clinical studies showing at least 45% epithelialization of the foot ulcer wound in 6 days. Further 30% healing improvement was observed with Helicoll over other collagen products used for leg ulcer treatments.



Successful Usage of Helicoll on Exposed Bones



Bone-exposed wounds were successfully healed with Helicoll without the immediate need of for skin graft.

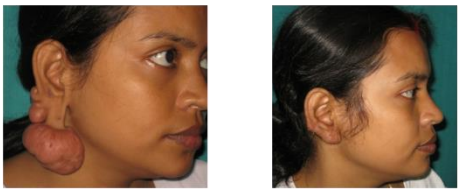
Sacral Pressure Sore

Stage 4 pressure sore | 10 Days Post Helicoll application | Completely healed using Helicoll

Complete Recovery in 6 weeks

Courtesy: Vinoth Philip , MD, DNB, Plastic Surgeon

Keloid excision and closure



Before | After

No re-occurring of Keloid after healing with Helicoll

Usage of Helicoll in treating Burns

Clinical study of 43 patients with second degree burns, age range 1 to 57 years were randomized to receive Helicoll (n=23) or 1% silver sulphadiazine (n=22). Helicoll resulted in a statistically significantly shorter time to healing (7.2 days vs. 14.5 days, p=0.005). Healing was enhanced by 49.7% in the Helicoll group compared to the silver sulphadiazine group. Itching was significantly decreased in the Helicoll group (90.5% vs. 71.1% without itching).[8,30]

26 burn patients were treated with Helicoll, compared to conventional dressings in a multi-center study. There was a 4-fold increase in rate of healing in the Helicoll group compared to the control gauze group.[31]

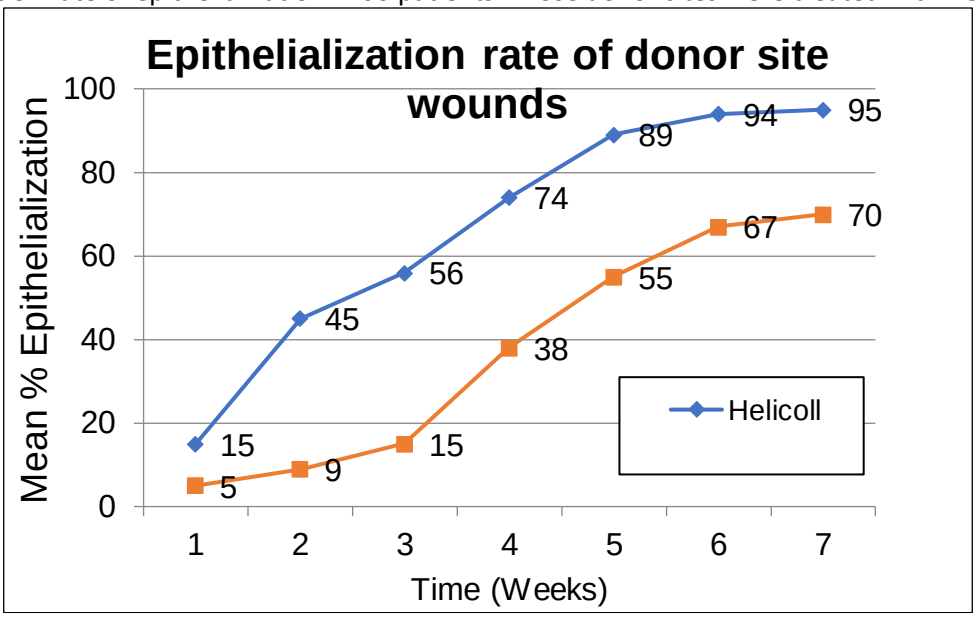
Vishal Mago, MD, unpublished report on "First & Second-Degree Burn Treatment Trial of Collagen [Helicoll] Dressing vs. Silver Sulphadiazine Alone," as randomized, controlled study of efficacy and safety on 15 patients with clinical burns, 2007. Better wound pain control with Helicoll.

Helicoll usage in treating pediatric and adult burn cases: http://helicoll-sfo.com/vizient/videos.html

Helicoll used to Heal Split Thickness Skin Grafts (STSG)

60 patients with donor sites were selected at random at different centers and treated with varied acellular dermal replacement collagen dressings to compare the effectiveness of Helicoll with other collagen dressings. There was no pain on opening the dressing and patients had no discomfort. Helicoll achieved a greater patient comfort level as well as an accelerated healing rate compared to other collagen dressings.[6]

Figure 9: Rate of epithelialization in 60 patients whose donor sites were treated with Helicoll[6]



22 patients with skin graft donor site wounds were included to undergo treatment with Helicoll. Twenty of these patients had no pain, no restriction of mobility, no infection when used per the protocol and the time to heal was significantly faster when compared to other conventional dressings.7

158 patients with STSG were successfully treated with Helicoll in 2010 http://www.helicoll-sfo.com/pdf/Comparison_of_Helicoll_with_Scarlet_Red_&_Opsite_split_thickness_skin_graft.pdf. Study included measurement of pain reduction of patients treated with Helicoll compared to control patients.

Reduced itching, increased range of motion, and overall increased patient comfort were also experienced by patients treated with Helicoll for burns and STSGs in this study (see Figure 10).11

Helicoll collagen dressing treatment showed 41% improvement over other Standard Care Treatments in a Clinical Study of split skin graft donor sites. Helicoll treated wounds healed in 7-10 days compared with 10-12 days with a traditional treatment.11

Collagen reduces post-operative donor site pain. There was a significant reduction in post-operative pain in the collagen dressings upon application of the product, at days 1 and 2, and

throughout the treatment process until complete healing when compared to the other gauze groups ($p < 0.02$).11

Figure 10 below shows slight increase in pain on Helicoll patients on days 4 and 5 which corresponds to the infiltration of the live tissue cells into Helicoll as part of normal healing process.

Figure 10: Pain Response in Helicoll and Control Wounds[11]

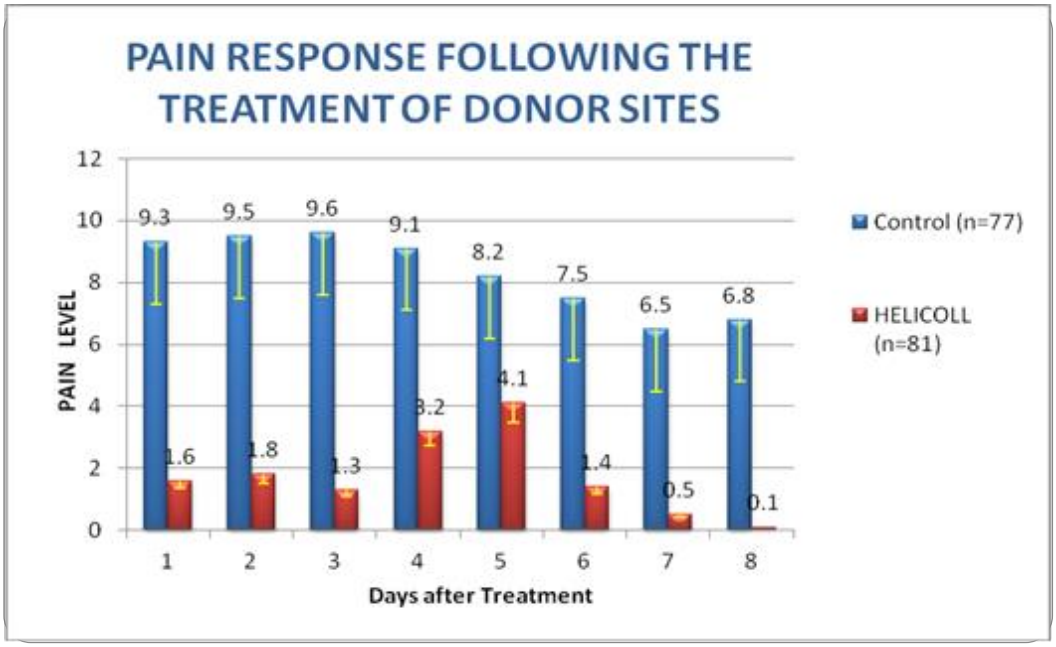
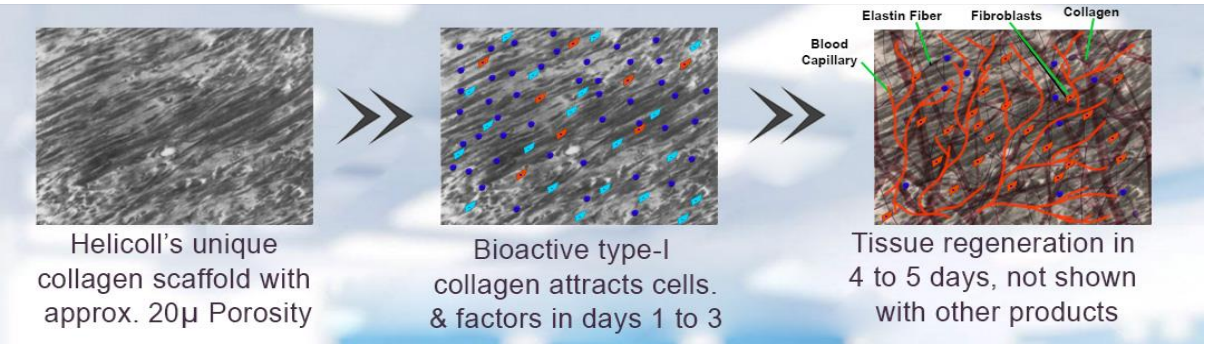


Figure 11: Donor site treatment using Helicoll[11]

Unique Features:
How Helicoll Collagen Differs From Other Collagen Products:

EnColl holds patented and proprietary technology and methods to manufacture highly-purified, medical-grade, non-immunogenic Type-I collagen, and to make other surface modifications to enhance the bioactivity of the protein. This method addresses the problems presented by commonly used other collagen preparations. EnColl's patented process removes all non-collagenous materials, while retaining the native molecular quaternary structure and other characteristic features of collagen (e.g., length, diameter, and periodicity of collagen Type-I fibrils, (Ref. US Pat # 6,548,077, Purifying type I collagen using two papain treatments and reducing and delipidation agents, 2003).

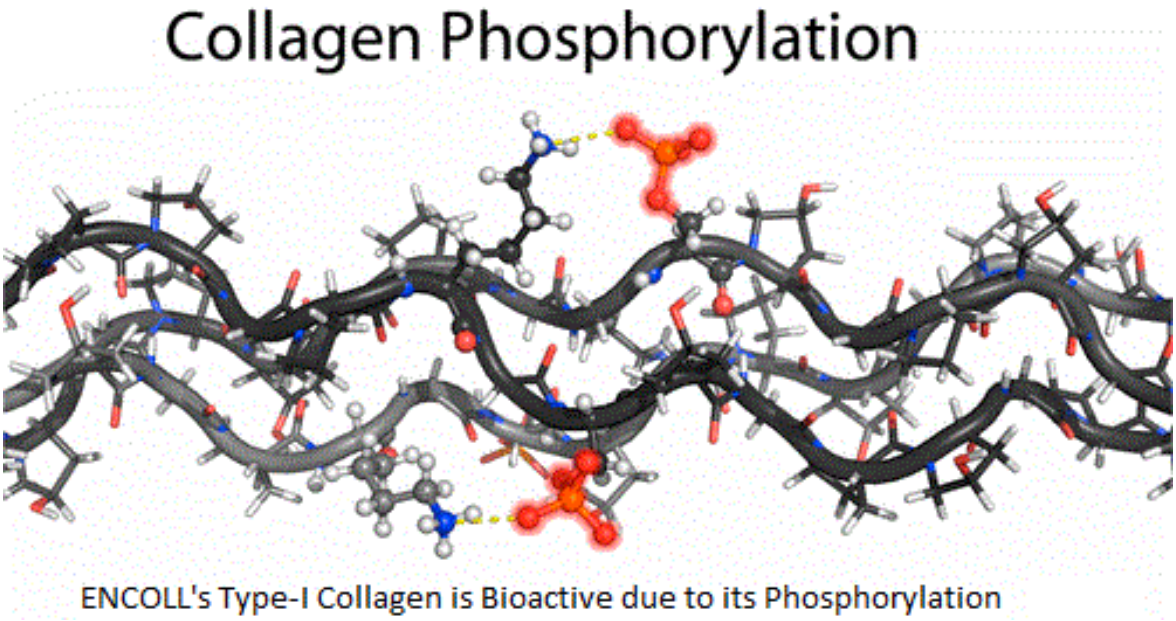
Structural Advantage of Helicoll Collagen Compared to Others



The clinical efficacy of our product Helicoll, is proven by the clinical studies (http://www.helicoll-sfo.com/pdf/Helicoll_published_Stanford_Article.pdf) conducted at the Dermatology Department of Stanford University to document the fast wound healing. Also the study shows when Helicoll is used, the patients expressed immediate pain relief upon the application to the wounded area. (see the Clinical data attached)

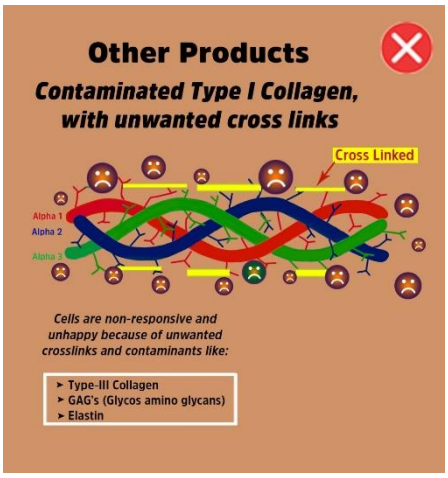
Helicoll's Unique Features: It contains native collagen that is pure and non-immunogenic, it will possess all the natural binding sites to all the cytokines, including epidermal growth factor (EGF), fibronectin, fibrinogen, histamine, platelet-derived growth factor (PDGF), serotonin, and von Willebrand factor etc…A cross-linked or contaminated Type III collagen cannot effectively achieve such wound healing characteristics. Additionally, a native collagen product also has cell membrane binding sites that would attract the neutrophil (for debris scavenging, and bacteria destruction) and leukocytes along with the macrophages/monocytes (for wound healing via secretion of enzymes and cytokines for tissue reconstruction). Subsequently, epithelialization, angiogenesis, granulation tissue formation, and collagen deposition are the principal steps in this anabolic portion of wound healing. Above all these unique features to Helicoll, in order to boost the product's bio-activity, the purified type-I collagen is further taken through a native biological surface modification process called phosphorylation. This is a normal physiological biochemical pathway of collagen during the process of tissue growth or repair or remodeling. This has been adopted to increase our collagen's bio-activity through cell-signal transduction commonly

happening via protein phosphorylation methods.



Unfortunately, most other collagen preparations or all of the intact tissue derived products made from amnion, pericardium, intestinal wall, urinary bladder etc. They all have to be contaminated with approximately 15% Elastin, and type-III collagen lipids and other proteo-glycans which are all highly immunogenic. All such products to be tolerated by the host tissue, have to follow chemical cross-linking method to minimize their immunogenicity. While they are compelled to do chemical cross-linking to their constructs, it damages the native chemistry of the biologically valuable type-I collagen also - and thereby then entire construct loses its bioactivity and also other binding abilities and significantly impaired with its wound healing abilities.

Biochemical Comparison of other Collagens



Helicoll is highly biocompatible, non-immunogenic and bioactive. US patents prove the purity of type-I collages as well as the surface chemistry modification through phosphorylation enhances the cell signaling practically reduces the healing time and would have better patient care and safety by default compared to other products.

HELICOLL IS UNIQUE IN ITS CLINICAL OUTCOME AS IT IS BASED ON PATENTED HIGH PURITY TYPE-I COLLAGEN AND DOES NOT CONTAIN ANY IMMUNOGENIC ELASTIN OR OTHER POTENTIAL IMMUNOGENIC MOLECULES, LIKE ALL OTHER INTACT TISSUE DERIVED PRODUCTS POSSESS. AS A RESULT, HELICOLL IS THE ONLY PRODUCT CLINICALLY PROVEN TO HAVE THE NEW BLOOD CAPILLARIES FORMED IN THE MATRIX WITHIN 4 TO 5 DAYS UPON APPLICATION. (SEE USP MONOGRAPH ATTACHED). ANOTHER STUDY ALSO HAS PROVEN THE CHEMOTACTIC CELL ATTRACTION TOWARDS HELICOLL COLLAGEN IN A CELL CULTURE MODEL.

EVIDENCE OF BENEFITS OF HELICOLL

Based on the above Preclinical and CLINCIAL EVIDENCE, Helicoll skin substitute membranes offers the following benefits:

- biocompatible and hypoallergenic, US Patents – see below.
- Clinical evidence for product efficacy, shown by the above clinical studies
- faster wound healing[11]
- wound granulation and epithelialization in 4-5 days instead of 21–28 days (see Figure 6)
- reduced pain (see Figure 10)
- lesser scar formation, (Clinically shown)
- return of native skin pigmentation, (see Figure 11)
- Helicoll expedited healing in all cases and contained infection,
- Promoted healthy granulation tissue, and stimulated a wound bed that better supported a skin graft. Ref: http://helicoll-sfo.com/vizient/images/pdf/Helicoll_as_Ideal_Tissue_Regenerative_Scaffold.pdf
- Itching was reduced.
- Time to healing was hastened, and hence, total cost of treatment was also lessened (see Figure 7 and Figure 9)

Helicoll, biological skin substitute collagen membrane normally comes in sizes from 2x2 inch to 23.62 x 23.62 inches. Smaller or Larger sizes to cover larger body areas can be easily produced.

To date, Helicoll has been used on over 97,000 patients (by May 2018) primarily by private and university hospital professional health care providers. There have been no signs of adverse reactions. We believe that the product Helicoll is the most effective (faster wound healing), efficient (shorter time to apply and less dressing changes are required), durable (has high tensile strength) and easy to use (training physicians, nurses, medical assistants, patients and care givers takes less than 15 minutes) wound-healing product on the market. It is safe for neonates and infants or geriatrics and is currently used on wounds and burns.

Unique Benefits or Advantages to Clinical Outcomes:

- **High purity Type-I Collagen:** Healicoll is a patented reconstituted bioactive collagen sheet, free of immunogenic proteins, lipids, and elastin. The native structure of collagen is not altered or cross-linked which maintains its high bioactivity.
- **Faster Healing:** Collagen phosphorylation attracts cells, regenerates tissue, and stimulates blood capillaries/granulation within 4 to 5 days.
- **Innovative Technology:** Better than intact tissue-based membranes like amnion, intestinal wall, urinary bladder etc. which contain 15% elastin.
- **Pain Control:** Effectively reduces pain.
- **Easy Application**: No washing needed prior to use. The overall clinical usage of Healicoll is simple and easy as it can be cut, sutured or stapled.
- **Cost-Effective**: Accelerated wound healing and tissue remodeling with minimal applications reduce the treatment cost by over 40%.
- **Various Sizes:** Choose from standard or customized dimensions.
- **Long Shelf Life:** Remains clinically usable for 3 years when stored in room temperature conditions.
- **High Reimbursement:** Medicare recognizes Helicoll as a high-cost skin substitute continuously since 2017.

A list of some users

Name of Reference Clinical Users:

Dr. Christopher Cox Dayton, OH 45402 Travis Perry, MD Dayton, OH 45409 Morris Brown, MD Dayton, OH 45402 Dr. Tanisha Richmond, DPM Charles Drew Health Center Dayton, OH 45402 Dr. Sekhar Sompalli The Perry Orthopedic & Sports Med Clinic Chicago, Il 60611 Dr. Walter F. D'Costa Santa Rosa, CA 95403 Dr. Howard Sutkin Advanced Aesthetics and Plastic Surg Clinic Los Gatos, CA 95032 Dr. Marilyn Kwolek Danville, CA 94526 Dr. Prasad Kilaru Wound Clinic Washington Hospital Fremont, CA 94538	CCS Medical Englewood, CO 80112 O' Conner Hospital San Jose, CA 95128 Dr. Benninghoven Scott W MD St. Louise Hospital, Gilroy, CA 95020 St. Francis Mem. Hospital San Francisco, CA 94109 Healthy Living Foundation Pinole CA 94564 Dr. Robert Beer Balfour Dermatology Brentwood, CA 94513 Capitol Logistics Muscat, Oman Dr. Renuka Bhatt Fine Skin Orland Park, IL 60467 Dr. Larry Woodcox Podiatric Foot and Ankle Surgery Oakland, CA 94612

Dr. Tariq Mirza Ariba Healthcare Group San Jose, CA 95112 Stanford University Dept. of Dermatology Redwood City, CA 94063	Dr. Mark Miller Vista, CA 92081

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