Market Opportunities and Trends at Desert Foot

SmartTRAK looks at market opportunities and trends in the treatment of diabetic foot ulcers at the recent Desert Foot Conference in Phoenix, AZ

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One of the most significant and unique market opportunities for advanced wound care manufacturers is in providing advanced therapies for diabetic foot ulcers (DFUs) to beneficiaries in the Veterans Health Administration (VHA) and Indian Health Services (IHS). With reimbursement that is not limited by CMS or commercial payers, and a population that has a high incidence of diabetes, the VHA and IHS market for DFUs is considerable and growing.

The VHA services nine million enrolled veterans each year and is the largest integrated healthcare system in the US with 1,243 healthcare facilities that include 170 medical centers and 1,063 outpatient sites of care. IHS provides care to approximately 2.2 million American Indians and Alaska Natives through 26 hospitals, 59 health centers and 32 health stations. Of the > 10 million individuals currently covered by VHA and IHS, almost 2.2 million had diabetes in 2017 and the total number of DFUs was 127,424. (See Table 1).

Table 1: VA and IHS Diabetes and DFU Estimates for 2017

VA and IHS Diabetes and DFU Estimates for 2017

VA System	Individuals	% Diabetes	Diabetes	% DFUs	DFUs
22-44 yrs	1,431,000	4.8%	68,688	2%	1,374
45-64 yrs	2,862,000	20.8%	595,296	3%	17,859
≥ 65	4,707,000	27.0%	1,270,890	8%	101,671
Subtotal	9,000,000		1,934,874		120,904
Indian HS					
20-44 yrs	827,200	17.5%	144,760	2%	2,895
45-64 yrs	364,320	17.5%	63,756	3%	1,913
≥ 65	122,320	17.5%	21,406	8%	1,712
Subtotal	1,313,840		229,922		6,520
Total	10,313,840		2,164,796		127,424

Given this unique market opportunity and the challenges in obtaining insurance coverage on the broader market, it's not surprising that many advanced wound care companies look to the VHA and IHS systems to initially sell their products and establish themselves in the market. Many of these companies were at the recent Desert Foot Conference, held annually, which targets Federal Services Healthcare Professionals (VA, DOD, IHS, PHS) dedicated to managing patients with high-risk conditions of the lower extremities. The conference includes podium presentations, company sponsored symposiums, workshops, poster presentations and exhibits. It is a great opportunity for clinicians and individuals new to the market, to have a crash course on advanced products used to treat hard-to-heal wounds. The meeting has seen strong attendance averaging over 450 per event in the last three years. And because of the opportunity for company-based presentations and workshops, the meeting provides insights into the positioning and product strategy of the companies that participate.

At Desert Foot, SmartTRAK identified the latest trends in the treatment of DFUs and reviews companies and key product segments that are gaining traction in the VHA/IHS market, including skin substitutes/CTPs (cellular and/or tissue-based products), ulcer prevention products, topical oxygen, as well as other notable news.

Battle of the Skin Substitutes (CTPs)

Historically, it has been challenging for skin substitutes/CTPs to be covered by the various CMS Medicare Administrative Contractors and therefore companies have looked for alternative avenues to market, often first establishing themselves in the VA health system. MiMedx began with that strategy when they entered the market in 2011, allowing the company to generate revenue without having all the clinical data required for CMS coverage. The market is extremely competitive with 18 companies showcasing their CTP products at Desert Foot. In fact, 11 of those companies featured amniotic based products with membrane, cord and particulate products, all being discussed. This year, presenters highlighted use of amniotic products for diabetic foot and venous ulcer healing as well as thicker amniotic tissue (AT) products for healing more challenging surgical wounds. Osiris started out the meeting with a presentation on Stravis - their thicker AT product used for complex wounds; MiMedx discussed their family of products with a special emphasis on EpiCord and AmnioCord, and Amniox promoted its Neox1K, which is 10 times thicker than their Neox 100 product.

Several CTP companies demonstrated their seriousness about marketing to the VA by being the subject of podium presentations, hosting company sponsored symposiums, and conducting workshops. (See Table 2 for CTP companies who were active at the meeting.) Notably, one company with a strong US presence that did not participate was Soluble Systems with its TheraSkin product.

Table 2: CTP Products Featured with Presentations and/or Workshops

CTP Products Featured with Presentations and/or Workshops

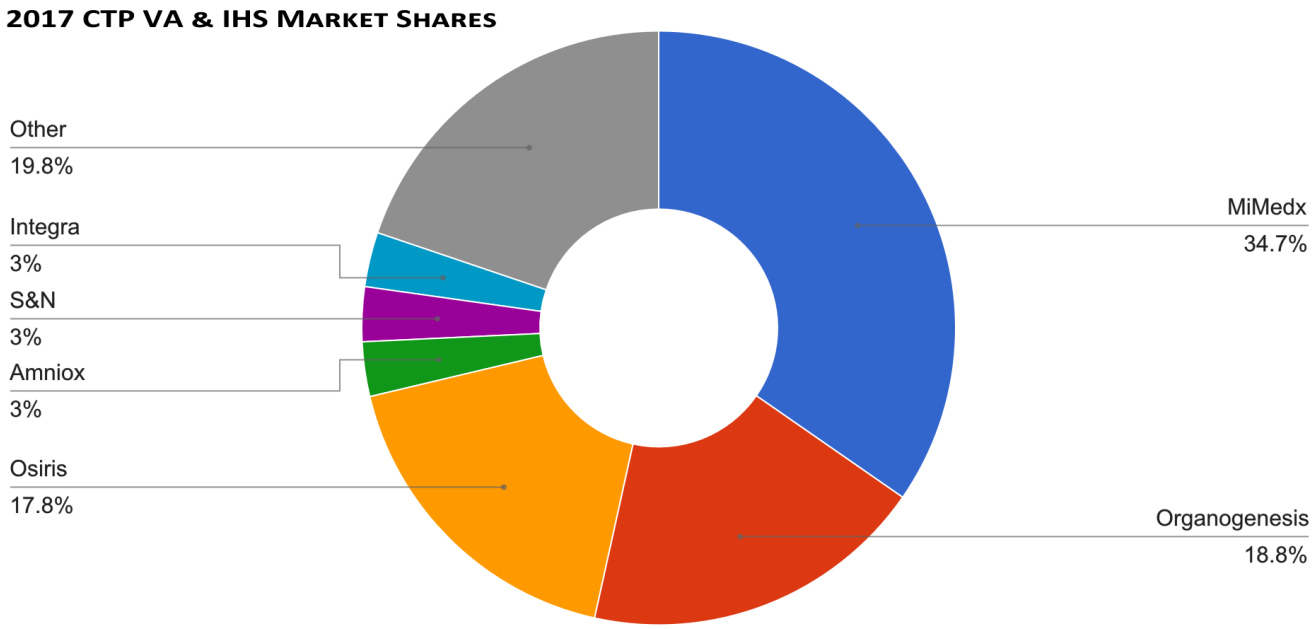
Company	Products	Sponsored Symposium	Podium Presentation	Work Shop
Amniox	Amniotic tissue family of products		X	X
Harbor MedTech	Architect			X
Integra	Family of CTP products	X		X
Kerecis	Omega 3 Fish Skin		X	X
MiMedx	Amniotic tissue family of products	X	X	X
MTF	Family of products	X		X
Organogenesis	Family of CTPs	X		X
Osiris	Amniotic tissue family of products	X		X
Smith & Nephew	Oasis	X		

Although companies do not report what specific CTP revenues are derived from the VHA/HIS system, SmartTRAK estimates this revenue at ~$110MM, led by MiMedx with 35% share followed by Organogenesis and Osiris. (See Table 3 for shares in the VHA/IHS CTP market.)

New entrants exhibiting at the meeting included Axolotl Biologix, an emerging regenerative medicine company, and Acera Surgical. Axolotl was showcasing its amniotic tissue products and pipeline of new products while Acera introduced Restrata Wound Matrix, a novel synthetic, nanofabricated wound care

scaffold which combines the advantages of synthetic construction with the positive attributes of a biologic material.

Table 3: 2017 VA & IHS Market Shares



Emerging Prevention Products

Two diabetic foot ulcer prevention companies, Podimetrics and Orpyx, were featured at the Desert Foot conference as Federal Service facilities reimburse for prevention-type products. Orpyx presented preliminary results of a 36 patient clinical study being conducted in the UK for individuals at risk of developing a diabetic foot ulcer. The study is comparing the use of SurroSense Rx, a device designed to be worn in shoes to alert individuals when high levels of plantar pressure exist to help prevent a foot ulceration, to no alert being provided. After 18 months of follow-up, 29% of patients using the active device developed a foot ulceration while 71% in the control group developed an ulcer.

Podimetrics had both a sponsored symposium presentation and a workshop in which they presented information on its Podimetrics Mat, an in-home monitoring technology that collects foot temperature scans, designed to prevent foot ulceration. A 129-patient prospective, cohort study of individuals at high-risk for developing a DFU and followed for 34 weeks, was able to detect 87% of ulcers, 37 days before ulceration.

Topical Oxygen Products – Getting Traction in the VA

Last year, CMS removed the negative National Coverage Determination associated with topical oxygen and will now leave it up to the local contractors to determine the coverage of topical oxygen for the treatment of chronic wounds in their respective regions. Prior to this change, the VA health system has been one of the few avenues to sell topical oxygen products in the US.

AOTI had a significant presence at the meeting, having a podium presentation and a workshop, promoting its Topical Wound Oxygen (TWO_2) therapy. AOTI provides two systems, one that utilizes a rigid chamber and the

other a disposable sleeve for extremities, and touts its cyclical, pressurized oxygen therapy being an advantage to healing. The Company provided a large amount of clinical evidence and has an on-going 220 patient RCT to compare TWO_2 therapy to standard of care (SoC) in the treatment of DFUs. The primary outcome of the study is percent of wounds healed at 12 weeks with the study to be completed July 2018.

EO2 also held a workshop on their Continuous Diffusion of Oxygen (CDO) Therapy along with its family of OxySpur Dressings. The Company presented results of its DFU clinical trial and clinicians were given the opportunity to apply the oxygen-providing device and dressing. The 100-patient RCT to evaluate the use of CDO Therapy in the treatment of DFUs found a significantly higher proportion of people healed in the active arm compared to sham (46% vs 22%, P=.02), with even greater healing in the chronic wound sub-segment. The article was published in the *Journal of Diabetes Science and Technology*.

Other Notable News

Each year there is one Grand Sponsor for Desert Foot. This year 3M emerged as that sponsor, a new position for them, demonstrating their commitment to serving Federal Systems healthcare professionals. Not surprising, 3M showcased a new total contact cast for off-loading of DFUs, leveraging its expertise in Scotchcast materials. The new product, 3M Softcast Total Contact Cast, was featured in a company-sponsored podium presentation at Desert Foot, along with a workshop presentation.

Medline was front and center showcasing PluroGel Wound and Burn Dressing, a concentrated surfactant technology for hard-to-heal wounds. The Company held both a workshop and a sponsored symposium on the product and its technology. PluroGel's unique micelle gel matrix maintains moisture in the wound and controls fluid loss, helping to protect healthy tissue and to soften wound debris. On the exhibit floor, Medline promoted both its Plurgel and Hyalomatric products and SmartTRAK learned the Company is establishing a direct sales organization to sell these products to the US market.

Acelity featured its SNaP Wound Care System, a small, portable, lightweight, single-use, mechanically driven Negative Pressure Wound Therapy (NPWT) system that can be worn inconspicuously and is designed for low levels of exudate and ambulatory patients. The Company held both a workshop and sponsored a symposium presentation on the product.

Kent Imaging held a workshop featuring its Kent Camera, a handheld, FDA and Health Canada-cleared device that enables immediate real-time visualization of tissue oxygen saturation without the need for injectable dyes or contact. It quickly tracks and identifies tissue viability and wound healing to optimize patient outcomes and is used in amputation, DFUs, limb salvage, venous leg ulcers, vascular assessment trauma, hyperbaric oxygen therapy, surgical wounds and post-operative monitoring.

NormaTec Medical, who recently reemerged in the healthcare market, showcased its newly launched dynamic compression device for lymphedema. With the dynamic compression market growing upwards of +20%, NormaTec – known for its elite athlete devices, created NormaTec Medical to pursue the healthcare market. SmartTRAK interviewed NormaTec's VP of Vascular Medicine at Desert Foot. Click for video of NormaTec interview.

Medi, a compression wrap company, held a workshop on their medi wraps and showcased a simple ABI screening device that provides a readout in only one minute. Medi in the US and several of its European country-based businesses have partnered with MESI (a Slovenian company) to provide the ABI screening tool to support international practice guidelines recommending ABI screening for vascular assessment prior to application of compression wraps.

Next Science sponsored a symposium entitled “The Role of Biofilm in Chronic Wounds and the Use of High Osmolarity Biofilm Disrupting Technology to Treat It”. The Company’s BlastX product is an antimicrobial wound gel powered by Xbio, a patented, non-toxic technology that physically disrupts the biofilm matrix. The symposium explained how Next Science’s technology acts in two modes: dissolution of the biofilm extracellular polymeric substances (EPS) and secondly, bacteria that are enveloped within the Xbio technology experience cell lysis through a high osmolarity imbalance across the bacterial cell membrane. Results of a 43-patient clinical study conducted at the Mayo Clinic comparing BlastX antimicrobial wound gel on chronic wounds to SoC found the average wound area reduction in the BlastX group decreased 72% ± 8% at 12 weeks, with 52% of patients reaching wound closure by week 12. This compares to only 24% and 17%, respectively for the control group. Both represent a statistically significant difference. The study was published online in *Wounds* and will appear in the April 2018 print issue.