An Overview of the CTO Device Market

As the number of lower-limb PAD treatments increases, the market for CTO crossing aids to permit these treatments will develop, driving this market to $355 million by 2011.

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The market for chronic total occlusion (CTO) crossers was valued at $19 million in 2005. However, with promising entries by LuMend (acquired in September 2005 by Cordis Corporation, a Johnson & Johnson company, Miami, FL), Spectranetics (Colorado Springs, CO), and IntraLuminal Therapeutics (Carlsbad, CA), the market is poised to explode. A major limitation for interventions in the lower limbs, particularly for interventions below the knee, are calcified occlusions that do not permit guidewires to cross. By removing this limitation, the release of pent-up demand for treatments will drive this market to $355 million, with an associated compound annual growth rate (CAGR) of 65% by 2011.

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New Endovascular Treatments

The appearance of new treatment options in the lower limbs drives the growth in the demand for CTO crossing solutions, and synergistically the availability of CTO crossing aids drives the demand for lower-limb endovascular treatments. Treatments such as cryoplasty and plaque excision

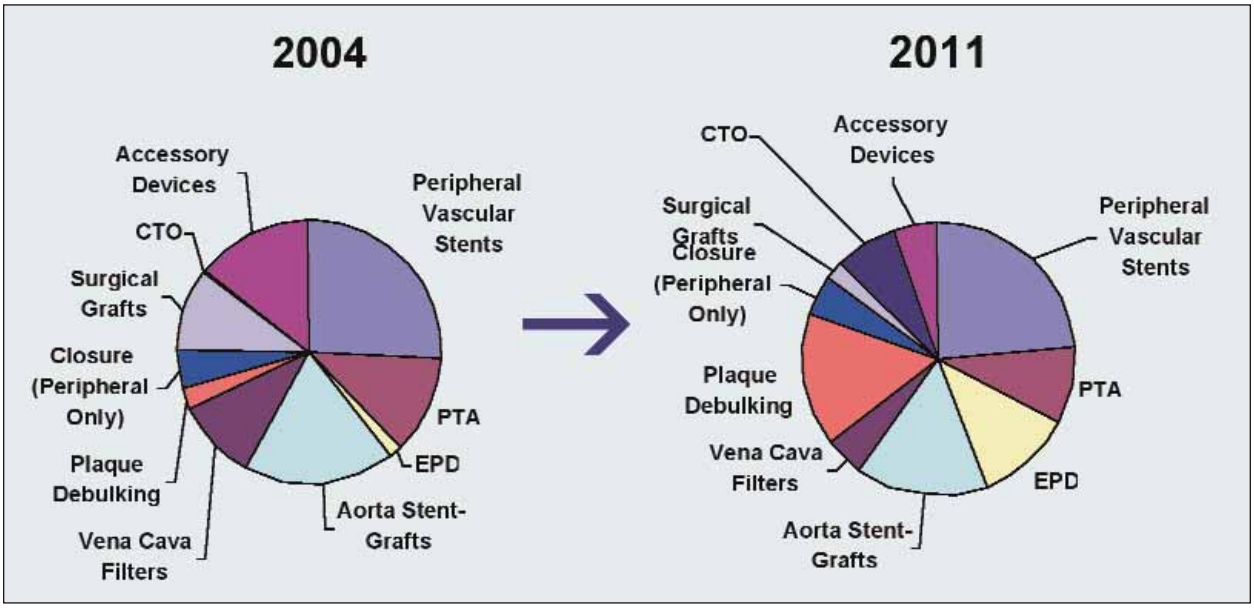

Figure 1. Estimated change from 2004 to 2011 in the US peripheral vascular device market, by segment.

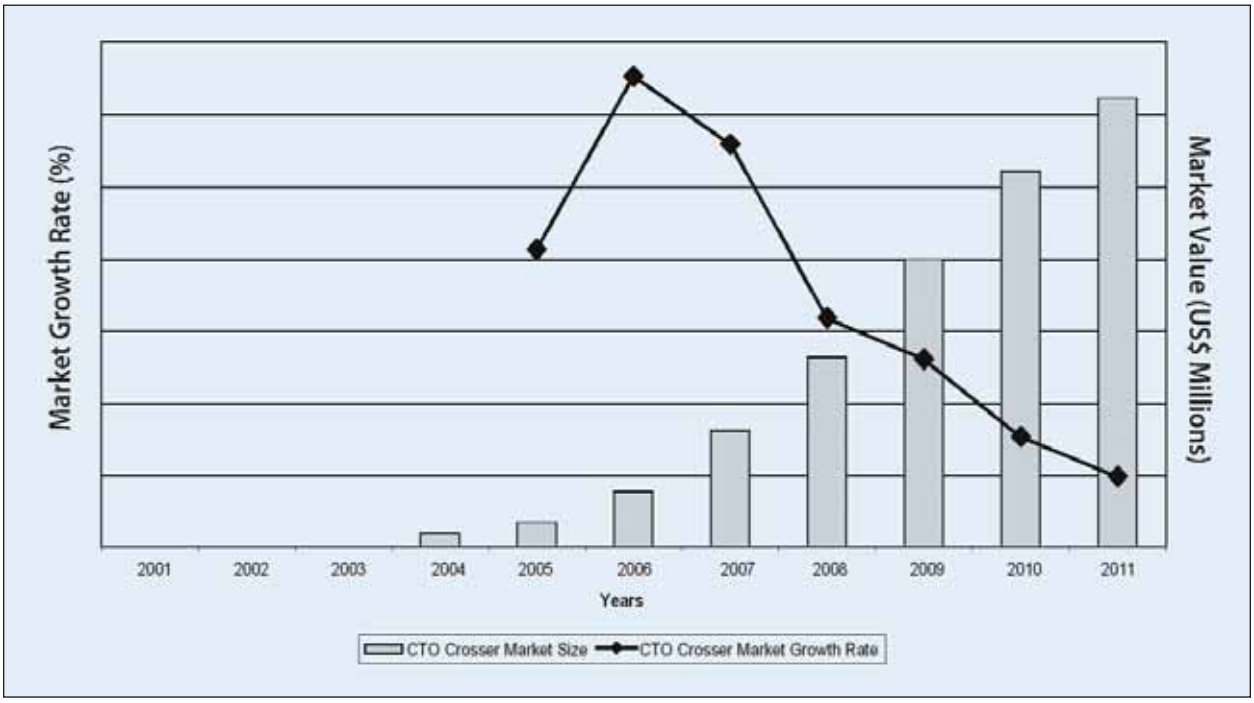

Figure 2. Estimated total peripheral CTO crosser market growth versus market value in the US from 2001 to 2011.

present the potential for the successful treatment of CTO lesions in the lower limbs, but these treatments cannot be used if the lesion cannot be crossed.

Re-Entry Technologies

Devices such as the LuMend/Cordis Frontrunner would not be able to penetrate and develop this market without having an option available to permit re-entry into the vessel lumen should the crossing device become misdirected into the subintimal space. The LuMend/Cordis and Medtronic (Minneapolis, MN) re-entry catheters have been an enabling technology for these types of devices. Other device manufacturers such as IntraLuminal Therapeutics (SafeCross) seek to prevent exiting the lumen into the subintimal space in the first place, to avoid dependence on re-entry technologies.

MARKET LIMITERS TO PAD

Prior Reputations

Some of these devices (from LuMend/Cordis and Spectranetics) were previously available for use in the coronary for some time before finding a new market in the periphery. For example, the LuMend Frontrunner was initially launched for the coronary application, but due to frequent problems maintaining position within the lumen, could not penetrate the coronary market. A key challenge to overcome here is a certain perception that the product "didn't work," a reputation that can color the entire CTO crossing field by association. However, with re-entry catheters and continued favorable clinical data, this market limiter should subside rapidly as both the LuMend/Cordis and other CTO crossing devices prove their worth in the periphery.

Devices for Difficult Lesions

Because of poor visualization and calcified heterogeneous lesions, there are many cases in which standard crossing mechanisms are insufficient. Consider that in critical limb ischemia, more than 80% of patients will need a more specialized crossing technique, and failure to present an effective treatment will generally lead to surgical bypass at best and amputation at worst; the unrealized demand for an effective crossing aid is therefore great. Recently, several devices have entered the market that may enable treatment of these difficult lesions. These devices get past the calcified plaque using rather different physical principles, such as blunt microdissection, radiofrequency energy, or laser light.

MARKET FORECAST

In 2005, the total market for peripheral CTO crossing aids was valued at more than $60 million. The majority of this market, however, consists of specialty crossing guidewires. The market for CTO crossing devices only was valued at $19 million in 2005. Although currently small, the market is

expanding rapidly (Figure 1) and is expected to increase to more than $40 million by the end of 2006. By 2011, the market for CTO crossing devices is expected to increase to $355 million. Figure 2 depicts the trends for both the growth in market value and fluctuations in the rate of growth over the forecast period. Other atherectomy devices in development will also function as CTO crossing aids, further overlapping this market segmentation. In 2005, the average selling price of a CTO crossing device was more than $1,500, decreasing at a CAGR of 1.6% over the forecast period.

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COMPETITIVE ANALYSIS

In 2005, the leader in the CTO market was Spectranetics (Colorado Springs, CO), who had more than 50% of the market, mostly due to the rapid adoption of their ClirPath device. A key component of their success has been the advantage of ClirPath to also operate as an atherectomy device in small artery lesions, found in the infrapopliteal segment. LuMend/Cordis, with both their Frontrunner CTO crosser and Outback Re-entry catheter, was a close second. As of February 15, 2006, IntraLuminal Therapeutics reports that it has suspended its business, leaving the rest of the market to Medtronic, Inc.

CONCLUSION

The arrival of CTO and plaque debulking devices as enablers to the treatment of totally occluded lesions has opened a new door of hope for thousands of patients who were reliant on higher-risk surgeries. This market is becoming more concentrated with the mergers and acquisitions of smaller companies by larger corporations, indicating the interest and opportunities presented by these new technologies. The future success of the CTO devices market now depends on the successful mix of product offerings, training modules for specialists, increasing awareness of patients, and proper implementation and deployment of treatments using CTO devices in the peripheral vascular market. ■

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