Evaluate Vantage

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AHA – Early success for Humacyte's off-the-shelf blood vessels

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Lab-grown blood vessels are a step closer. The first human trials of a bioengineered tissue-based vascular graft have indicate it to be safe and with the potential to avoid problems of tolerability and infection seen with synthetic or autologous vessels.

Crucially, the grafts, developed by North Carolina company Humacyte, can be created ahead of time and stored, meaning that they could become an off-the-shelf product. Initially tested as vascular dialysis shunts in patients with end-stage renal disease (ESRD), the technology could have utility in many more arenas. But it is early days yet, and first of all Humacyte will have to show that the grafts stay open and remain safe over a much longer term.

Decellularised

ESRD patients must undergo haemodialysis three times a week, necessitating a graft onto a blood vessel to enable the rapid extraction, filtration and reinfusion of blood. Currently, these are either made of polytetrafluoroethylene, in which case they are prone to becoming blocked and require frequent replacement, or of a vessel harvested from the same patient, which involves a separate procedure.

Humacyte's vascular graft is created by growing donated vascular cells on tubular scaffolds in a bioreactor. The grafts are then decellularised with detergents, yielding an extracellular matrix composed primarily of collagen.

Results of the pilot human trial of the grafts, presented yesterday at the American Heart Association's annual meeting in Dallas, showed that after six months of implantation the vessels were associated with no infections, dilatations, or aneurysms. Flow rates suitable for dialysis were maintained for up to a year in 25 patients. 22 of the patients used the bioengineered vessels for dialysis three times per week, Humacyte said.

Eight of the 28 ESRD patients implanted with grafts saw loss of primary patency, requiring eight thrombectomies and two venous anastomosis angioplasties, giving a 71% rate of unassisted primary patency. For comparison, around 50% of polymer grafts fail within a year.

Remodelling

The patients in the European trial will be followed for a further six months, and a 20-patient US study is already underway. In preclinical trials, the grafts were remodelled to become living – in other words, the animals' epithelial cells grew into the collagen. It will be interesting to see whether this occurs in humans too.

Remarkably, considering the early stage of development, Humacyte is already talking about the technology's potential to cut costs. Should the technology gain approval – several years away and no easy task considering the less-than-clear regulatory pathways for tissue-based technologies – the company says it will cut surgeries and hospitalisations.

The bioengineered blood vessels have potential in other areas of vascular surgery, Humacyte says, and the technology can also form other shapes such as sheets or particles. If the grafts succeed in ESRD they will have a potential market of around 320,000 patients in the US alone who require regular dialysis. They may reach far further than that – but only if they can build on these results long-term.

Trial	Trial ID
28-patient pilot study of bioengineered tissue graft in end-stage renal disease	NCT01744418

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