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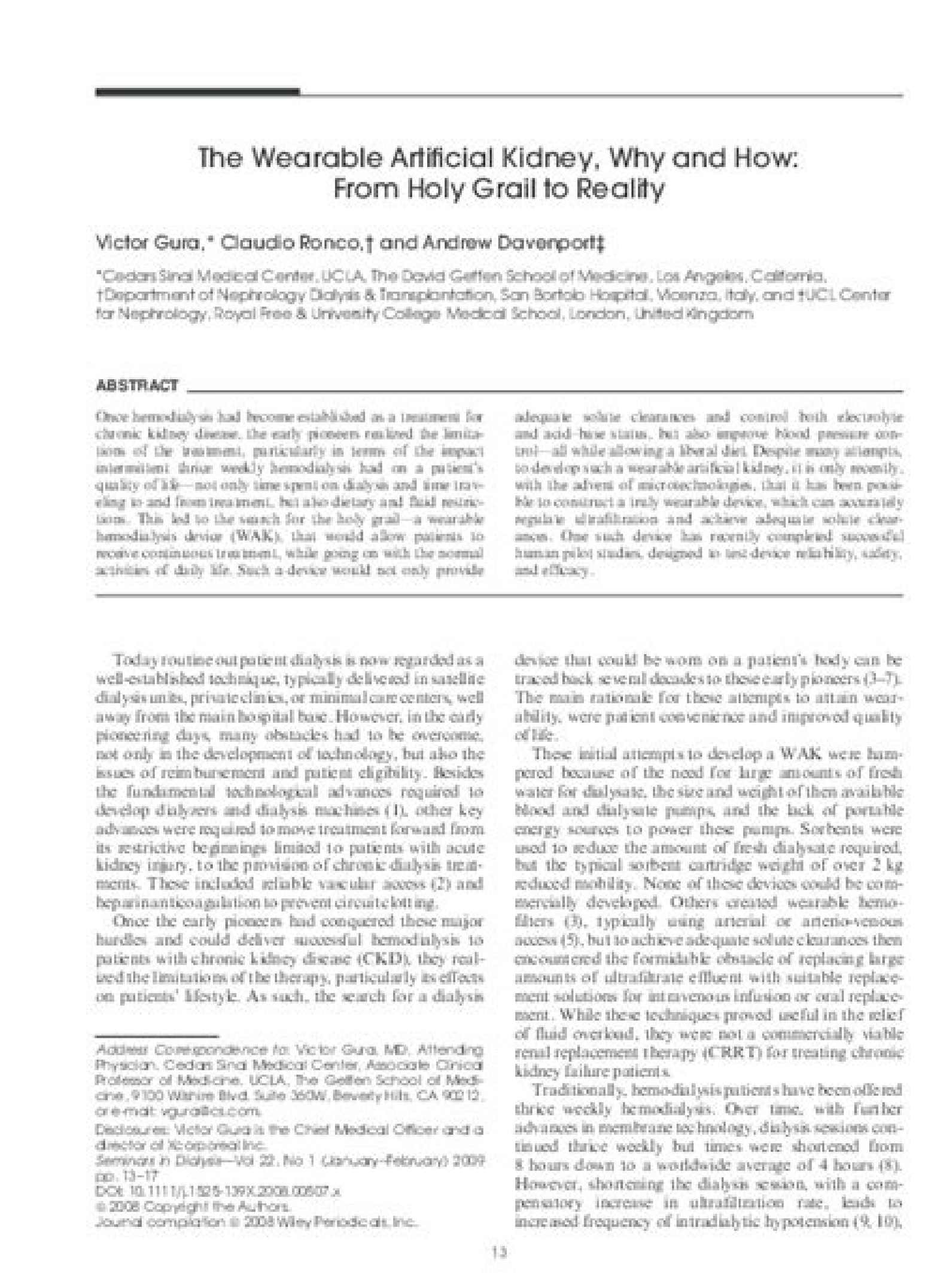

The Wearable Artificial Kidney, Why and How: From Holy Grail to Reality

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ABSTRACT

Once hemodialysis had become established as a treatment for chronic kidney disease, the early pioneers realized the limitations of the treatment, particularly in terms of the impact intermittent thrice weekly hemodialysis had on a patient's quality of life—not only time spent on dialysis and time traveling to and from treatment, but also dietary and fluid restrictions. This led to the search for the holy grail—a wearable hemodialysis device (WAK), that would allow patients to receive continuous treatment, while going on with the normal activities of daily life. Such a device would not only provide adequate solute clearances and control both electrolyte and acid–base status, but also improve blood pressure control—all while allowing a liberal diet. Despite many attempts, to develop such a wearable artificial kidney, it is only recently, with the advent of microtechnologies, that it has been possible to construct a truly wearable device, which can accurately regulate ultrafiltration and achieve adequate solute clearances. One such device has recently completed successful human pilot studies, designed to test device reliability, safety, and efficacy.

Today routine outpatient dialysis is now regarded as a well-established technique, typically delivered in satellite dialysis units, private clinics, or minimal care centers, well away from the main hospital base. However, in the early pioneering days, many obstacles had to be overcome, not only in the development of technology, but also the issues of reimbursement and patient eligibility. Besides the fundamental technological advances required to develop dialyzers and dialysis machines (1), other key advances were required to move treatment forward from its restrictive beginnings limited to patients with acute kidney injury, to the provision of chronic dialysis treatments. These included reliable vascular access (2) and heparin anticoagulation to prevent circuit clotting.

Once the early pioneers had conquered these major hurdles and could deliver successful hemodialysis to patients with chronic kidney disease (CKD), they realized the limitations of the therapy, particularly its effects on patients' lifestyle. As such, the search for a dialysis device that could be worn on a patient's body can be traced back several decades to these early pioneers (3–7). The main rationale for these attempts to attain wearability, were patient convenience and improved quality of life.

These initial attempts to develop a WAK were hampered because of the need for large amounts of fresh water for dialysate, the size and weight of then available blood and dialysate pumps, and the lack of portable energy sources to power these pumps. Sorbents were used to reduce the amount of fresh dialysate required, but the typical sorbent cartridge weight of over 2 kg reduced mobility. None of these devices could be commercially developed. Others created wearable hemofilters (3), typically using arterial or arterio-venous access (5), but to achieve adequate solute clearances then encountered the formidable obstacle of replacing large amounts of ultrafiltrate effluent with suitable replacement solutions for intravenous infusion or oral replacement. While these techniques proved useful in the relief of fluid overload, they were not a commercially viable renal replacement therapy (CRRT) for treating chronic kidney failure patients.

Traditionally, hemodialysis patients have been offered thrice weekly hemodialysis. Over time, with further advances in membrane technology, dialysis sessions continued thrice weekly but times were shortened from 8 hours down to a worldwide average of 4 hours (8). However, shortening the dialysis session, with a compensatory increase in ultrafiltration rate, leads to increased frequency of intradialytic hypotension (9, 10),

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Disclosures: Victor Gura is the Chief Medical Officer and a director of Xcorporeal Inc.

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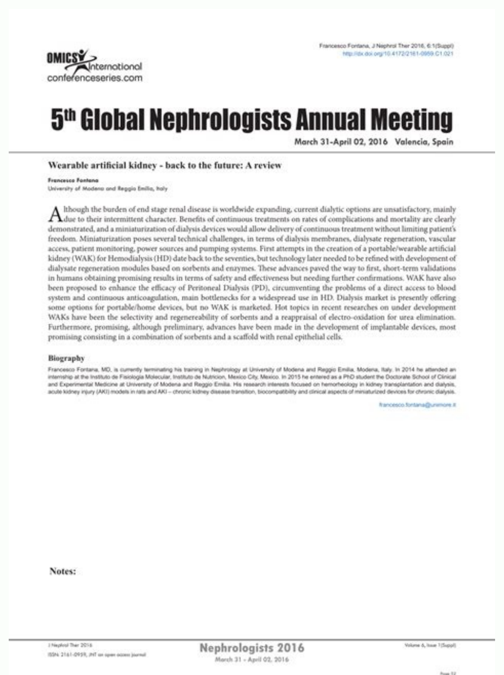

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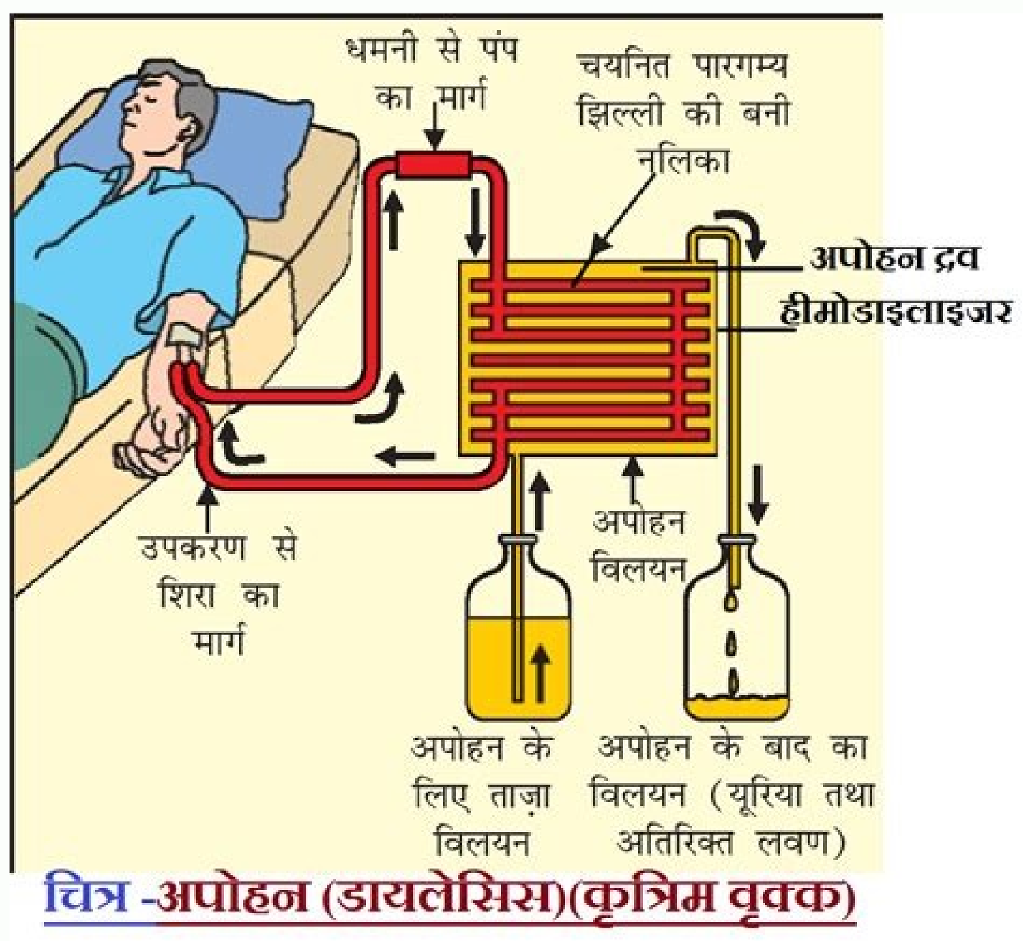

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Available from: Page 2Comparison between wearable artificial kidneys and implantable bio-artificial kidney (adapted with permission from Salani et al. Am J Kidney Dis. 2018[39])Key featureWAKAWAKiBAKType of artificial kidneyHemodialysisPeritoneal dialysisFor implantationCentral principleModified sorbent systemModified sorbent systemBio-hybrid: Hemocartridge (=glomerulus) and bioreactor (=tubular function)Weight

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