

Research on the Technical Architecture and Clinical Efficacy of Nxstage System One Home Hemodialysis Equipment

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Abstract: NxStage System One, as the world's first portable home hemodialysis device certified by the FDA, has become a technical benchmark in the HHD field. This study focuses on the Nxstage System One home hemodialysis equipment, comprehensively analyzes its technical architecture, and deeply explores its clinical efficacy. By disassembling the technical architecture of the equipment, analyzing its hardware composition and working principle, and clarifying its unique design. In terms of clinical efficacy, by integrating multi-dimensional data and comparing it with traditional hemodialysis methods, the performance of this equipment in terms of therapeutic effect, improvement of quality of life and complications is expounded. Studies have shown that the innovation in the technical architecture of Nxstage System One brings new possibilities for clinical applications and has significant advantages in improving the quality of life of patients and optimizing treatment effects.

1. Introduction

Chronic kidney disease (CKD) has become a global public health issue. With the progression of the disease, the number of patients with end-stage renal disease (ESRD) is constantly increasing. Hemodialysis, as one of the main renal replacement treatment methods for ESRD patients, plays a key role in maintaining patients' lives and improving their quality of life. Traditional central hemodialysis requires patients to visit hospitals or dialysis centers regularly, which brings many inconveniences to patients' lives and increases the risks of infection and other issues^[1]. Against this backdrop, home hemodialysis (HHD) emerged, offering patients a more flexible and convenient treatment option.

As a representative household hemodialysis device, Nxstage System One has received extensive attention since its debut due to its unique design and performance. This device is designed to

provide patients with safe and effective hemodialysis treatment in a home environment, while minimizing the impact on their daily lives as much as possible. This study aims to deeply explore the technical architecture of the Nxstage System One family hemodialysis equipment and conduct a systematic evaluation of its clinical efficacy, with the expectation of providing a scientific basis for clinical practice and equipment improvement.

2. Nxstage System One technical architecture

2.1 Overall Architecture Overview

The Nxstage System One family hemodialysis equipment is mainly composed of the console host, dialysis fluid supply system, dialysis pipeline and dialyzer components, etc. Its overall design is compact, with dimensions of 381×381×457mm and a weight of approximately 30.5kg, which is convenient for moving and placing in the home environment. It can also meet the dialysis treatment needs of patients in different scenarios, including daily home dialysis and to a certain extent, support the dialysis needs of patients when they travel.

2.2 Console Host

The console host is the core control unit of Nxstage System One, which integrates a precise microprocessor and complex control circuits internally for precisely regulating various parameters throughout the dialysis process^[2]. The host panel is equipped with a simple and intuitive human-machine interaction interface. Through a large-sized display screen, key information of dialysis treatment, such as blood flow, dialysate flow, treatment time, transmembrane pressure, etc., is clearly shown, facilitating patients and medical staff to monitor the treatment progress in real time. Meanwhile, the operation interface is designed simply, with only necessary function keys set, making it easy for patients to learn and operate, and greatly reducing the difficulty for patients to operate it by themselves at home. In addition, the main unit integrates multiple sensors inside to monitor the operating status of the equipment and various treatment parameters in real time. Once an abnormal situation is detected, the alarm system will be triggered immediately to ensure the safety of the treatment.

2.3 Dialysate supply system

Table 1 Comparison of Two dialysis fluid Supply Methods

Supply mode	Operation process	Advantage	Insufficient
Finished dialysis fluid bag	Connect directly to the device without the need for liquid preparation	The operation is simple and convenient, and no complex equipment is required	The long-term usage cost is relatively high and it requires storage and transportation
Stage PureFlow SL system	Purify tap water → Mix with concentrated liquid → Prepare dialysis solution	Reduce long-term costs and minimize the inconvenience of storage and transportation	The initial equipment investment is relatively high, and the filtration system needs to be maintained regularly

The dialysis fluid supply System of Nxstage System One is innovative and flexible, providing strong support for the wide application of the equipment in the home environment. This system is

equipped with two dialysis fluid supply methods (Table 1).

Finished dialysis fluid bags can directly use pre-mixed finished dialysis fluid bags. This method does not require a complex solution preparation process. Patients only need to connect the dialysis fluid bag to the device, and the operation is simple and convenient. The connection between the dialysis fluid bag and the equipment adopts a quick connection interface design to ensure a tight connection and prevent leakage. During the dialysis process, the equipment precisely controls the flow of dialysis fluid from the dialysis fluid bag to the dialyzer through the built-in peristaltic pump, ensuring the stability of the dialysis treatment.

Another type is the Stage PureFlow SL system, which can convert tap water into pure dialysis water and prepare the dialysis fluid on-site in the equipment by mixing it with concentrated dialysis fluid^[3]. This process first uses a series of advanced filtration technologies to deeply purify tap water, removing impurities, microorganisms, heavy metal ions and other harmful substances in the water, ensuring that the quality of dialysis water meets strict medical standards. The purified water and concentrated dialysate are thoroughly mixed in the mixing chamber in the preset proportion to form dialysate with precise concentration. The Stage PureFlow SL system has an efficient dialysate preparation capacity. When connected to a water source, it can prepare 60 liters of dialysate within 7 hours, and the prepared dialysate can be stored for up to 96 hours, which can meet the needs of patients for multiple dialysis treatments. This on-site preparation method of dialysis fluid not only reduces the long-term cost for patients to use finished dialysis fluid, but also minimizes the inconvenience caused by the storage and transportation of dialysis fluid.

2.4 Dialysis tubing and dialyzer components

The dialysis tubing and dialyzer components are the key parts for realizing the material exchange function of hemodialysis. The dialysis tubing is made of medical-grade materials with good biocompatibility, featuring low resistance and resistance to blood clotting, ensuring smooth blood flow in the tubing. The connection parts of the pipelines adopt a special sealing design, effectively preventing blood leakage and air from entering the blood circulation system.

The Nxstage System One is equipped with a specially designed dialyzer, which has efficient solute removal and water ultrafiltration performance. The dialysis membrane inside it is made of advanced polymer materials, featuring appropriate pore size and high permeability. It can selectively remove small molecule toxins (such as urea, creatinine, etc.), medium molecule substances and excess water from the blood, while retaining as much beneficial substances for the human body (such as proteins, amino acids, etc.) as possible^[4]. The design of the dialyzer optimizes the flow paths of blood and dialysate, enabling good convection and diffusion between the two on both sides of the dialysis membrane, thereby enhancing the dialysis efficiency.

3. Clinical efficacy research

3.1 Solute removal efficiency

In terms of solute removal, Nxstage System One has demonstrated excellent performance. Multiple clinical studies have shown that this device can effectively remove small molecule toxins and medium molecule substances from the blood (Table 2). Taking urea clearance rate (Kt/V) as an important indicator to measure the clearance effect of small molecule toxins, research data show that for patients undergoing home hemodialysis treatment with Nxstage System One, the average standardized Kt/V can reach about 1.99. This value indicates that the device can to a certain extent meet the patient's need to clear small molecule toxins and maintain the nitrogen balance in the patient's body.

For the removal of medium molecular substances, Nxstage System One also performs well. By monitoring the clearance rates of medium molecular substances such as β 2-microglobulin, it was found that they can significantly reduce the levels of medium molecular substances in patients' blood during clinical treatment, which is helpful in preventing related complications caused by the accumulation of medium molecular substances, such as dialysis-related amyloidosis, etc.^[5]

Table 2 Comparison of solute removal Efficiency between Nxstage System One and Traditional Hemodialysis Equipment

Solute type	Clearing effect index	Performance of Nxstage System One	Performance of traditional hemodialysis equipment
Small molecule toxin	Average standardized Kt/V	Around 1.99	1.2-1.8
Medium-molecular substances	Clearance rate	Significantly reduce the content in the blood	The clearing effect is relatively weak

3.2 Water Ultrafiltration efficiency

Precise water ultrafiltration control is one of the key links in hemodialysis treatment, directly related to the cardiovascular stability and dialysis tolerance of patients. Nxstage System One is equipped with an advanced water ultrafiltration control system, which can precisely set the ultrafiltration volume and ultrafiltration rate according to the individual conditions of patients, such as body weight, dry body weight, degree of fluid retention, etc.

Clinical practice shows that this device has high accuracy and stability in water ultrafiltration. During the treatment process, it can smoothly remove the excess water in the patient's body according to the preset ultrafiltration plan, effectively correct the patient's water and sodium retention state, and reduce the burden on the heart. Meanwhile, through real-time monitoring and automatic adjustment of parameters such as transmembrane pressure, the equipment can minimize complications such as hypotension and muscle spasms caused by overly rapid or excessive ultrafiltration while ensuring the ultrafiltration effect, thereby enhancing the dialysis tolerance and comfort of patients^[6].

3.3 Impact on the Quality of Life of Patients

One of the greatest advantages of home hemodialysis over traditional central hemodialysis is that it can significantly improve the quality of life of patients. Nxstage System One, as a device specially designed for home dialysis, has played an important role in this regard. Patients do not need to frequently visit the dialysis center, which saves a great deal of time and energy, enabling them to better integrate into family and social life and participate in daily work, study and social activities. Many patients have reported that after undergoing home dialysis with the Nxstage System One, their autonomy in life has been greatly enhanced. They can arrange their lives at their own pace and reduce the sense of restraint caused by dialysis treatment.

Meanwhile, the home dialysis environment is relatively familiar and comfortable, reducing the risk of cross-infection that patients may face in dialysis centers, and also helping to relieve patients' psychological stress and anxiety^[7]. From a psychological perspective, patients have a stronger sense of control over their own treatment process, enabling them to better participate in treatment

decisions and improving their compliance and satisfaction with the treatment.

3.4 Clinical safety assessment

As a medical device, its safety has always been a key concern. In the actual usage process, this device has adopted a series of safety protection measures to ensure the safety and reliability of the treatment process. The equipment is equipped with multiple alarm systems that can promptly monitor and alert various abnormal situations during dialysis, such as abnormal blood flow, abnormal dialysis fluid flow, excessively high or low transmembrane pressure, and air entering the circulatory system, etc.^[8] Once an abnormality is detected, the equipment immediately stops running and issues an audible and visual alarm signal to prompt patients and medical staff to take corresponding measures. Meanwhile, the equipment is designed with full consideration of electrical and mechanical safety factors. It adopts reliable grounding protection and leakage protection devices, as well as a sturdy and durable mechanical structure, reducing the risk of equipment failure during use.

However, like all hemodialysis treatments, home hemodialysis using the Nxstage System One is not completely risk-free. In clinical practice, some complications related to dialysis treatment may still occur, such as hypotension, hypertension, arrhythmia, and vascular access infection, etc.^[9] Overall, however, through adequate training and guidance for patients, as well as regular follow-ups and monitoring by medical staff, these risks can be effectively controlled and managed.

4. Correlation analysis between Technical Architecture and clinical efficacy

4.1 The influence of technical architecture on Solute removal efficiency

The unique technical architecture of Nxstage System One lays the foundation for its excellent solute removal efficiency. From the perspective of the dialyzer's design, the advanced dialysis membrane material and optimized internal structure it adopts enable the blood and dialysis fluid to fully contact on both sides of the dialysis membrane, forming efficient convection and dispersion, thereby ensuring the effective removal of small molecule toxins and medium molecule substances.

The dialysis fluid supply system also plays a key role in solute removal. Whether using finished dialysate bags or preparing dialysate on-site through the Stage PureFlow SL system, the equipment can precisely control the composition and flow rate of dialysate, maintain the concentration gradient between dialysate and blood, and provide power for the diffusion of solutes. For instance, when using the Stage PureFlow SL system, through strict purification of tap water and precise proportionization with concentrated dialysate, the concentration of various ions in the dialysate can be ensured to be stable, creating favorable conditions for solute removal.

4.2 The Influence of Technical Architecture on the Efficiency of Water Ultrafiltration

The technical architecture of the equipment also plays a significant role in the ultrafiltration efficiency of water. The console host monitors various parameters during the dialysis process in real time through built-in precision sensors, such as transmembrane pressure, blood flow rate, and dialysate flow rate, and precisely controls the ultrafiltration pump based on these parameters to achieve precise adjustment of ultrafiltration volume and rate^[10].

The characteristics of the dialysis tubing and dialyzer can also affect the efficiency of water ultrafiltration. The low-resistance design of the dialysis tube ensures that blood can enter the dialyzer smoothly, while the highly permeable dialysis membrane of the dialyzer provides the necessary conditions for ultrafiltration of water. In addition, the equipment is designed with full

consideration of pressure balance and liquid flow stability during the ultrafiltration process. By optimizing the inlet and outlet paths of the dialysate and flow control, the fluctuations during the ultrafiltration process are reduced, and the accuracy and stability of ultrafiltration are improved.

4.3 The Impact of Technical Architecture on patients' Quality of life and safety

The compact and portable design as well as the simple and easy-to-use operation interface of Nxstage System One have greatly improved the quality of life of patients. Patients can undergo dialysis treatment in a familiar home environment without spending a lot of time traveling back and forth between the hospital and home. This not only saves time and energy but also reduces the psychological stress that may be caused by treatment in a dialysis center.

The security design of the equipment in terms of technical architecture provides a reliable guarantee for clinical application. Multiple alarm systems and strict quality control measures can promptly detect and handle abnormal situations during dialysis, reducing treatment risks. Meanwhile, through real-time monitoring and data analysis of the equipment's operational status, medical staff can remotely understand the treatment situation of patients, promptly adjust the treatment plan, and further enhance the safety and effectiveness of the treatment.

5. Conclusion

The Nxstage System One home hemodialysis equipment, with its unique technical architecture, has demonstrated significant advantages in clinical efficacy. In terms of technical architecture, the console host, dialysis fluid supply system, dialysis tubing and dialyzer components work in collaboration, achieving portability of the equipment, ease of operation and precise control of the dialysis process. In terms of clinical efficacy, this device performs well in treatment effects such as solute removal and water ultrafiltration, and can effectively maintain the stability of the patient's internal environment. At the same time, by providing home dialysis treatment for patients, the quality of life of patients has been greatly improved, and their compliance and satisfaction with the treatment have been enhanced. In future research and development, it is possible to further explore how to enhance the performance and safety of the equipment through technological innovation, providing patients with end-stage renal disease with more high-quality, efficient and safe home hemodialysis treatment plans.

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