Brief Report

Rigicon ContiClassic and ContiReflex artificial urinary sphincter devices

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Abstract: The modern AMS 800 artificial urinary sphincter (AUS) is often considered the standard of care for the treatment of moderate to severe stress urinary incontinence in male patients. Nonetheless, the AMS 800 device has several inherent limitations, and these factors can potentially impact its clinical utility and impede excellent clinical outcomes. The new Rigicon AUS devices such as ContiClassic and ContiReflex urinary sphincters are designed to overcome some of the existing issues pertaining to the AMS 800 device. The ContiClassic device is similar in terms of device design to the AMS 800 apart from the inclusion of a hydrophilic coating, has a greater range of cuff sizes with 0.25-cm diameter increments, and an Easy Clink Connectors which negates the need for an assembly tool. In contrast, The ContiReflex device differs from the ContiClassic model in that it features an extra stress relief balloon (SRB) to provide a safeguard on the urethral occlusive mechanism against any sudden increase in intra-abdominal pressure, and a larger pump system that is responsible to cycle fluid between the higher pressure two-balloon system and the sphincteric cuff. The following brief report evaluates the current device design and technology of the Rigicon ContiClassic and ContiReflex AUS devices.

Keywords: Artificial urinary sphincter (AUS); stress urinary incontinence (SUI); device design; technology advances

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Introduction

The modern artificial urinary sphincter (AUS), specifically the AMS 800® (Boston Scientific, Minnetonka, MN, USA) is considered by many as the standard of care in treating moderate to severe stress urinary incontinence (SUI) in male patients (1-3). The AMS 800 device is also designed for patients with radiation-induced SUI and can provide an effective salvage surgical option for those who failed male sling surgery too (1-3). While the initial prototype of this hydraulically controlled sphincter was first performed more than 50 years ago (4), the modern version of this AMS 800 was first introduced in 1982 (5).

Over the past five decades, considerable innovations in the design of this device and refinements in various technical aspects have improved clinical outcomes in the AMS 800 surgery (6). Longer-term studies showed up to 79% of AUS to remain functional without revision at 5 years with high patient satisfaction rates above 80% and the mean expected mechanical lifespan of an AMS 800 device is estimated around 7–10 years (7-9). Despite its proven track record as an effective and safe treatment for male SUI, this device has inherent limitations and can be associated with a unique set of complications such as mechanical failures and non-mechanical adverse events, despite the best surgical

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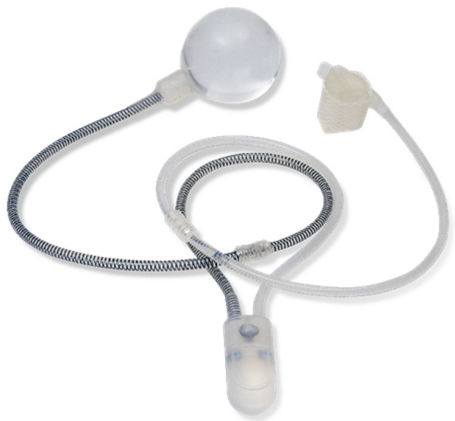

Figure 1 ContiClassic® artificial urinary sphincter device (with a circumferential occlusive cuff, a pressure regulating balloon, and a pump unit).

techniques and optimal patient selection (2,3,10-12).

Over the years, several AUS-like devices have been developed to replicate the clinical outcomes of the AMS 800 and are designed to overcome some of the limitations of the AMS 800 device such as a simpler design with fewer components, easier components assembly or potentially adjustable cuff or balloon (2,3). The new Rigicon ContiClassic and ContiReflex AUS devices are the latest AUS devices designed by the Rigicon company (Rigicon INC, NY, USA) to treat male SUI in the commercial market (13). The following brief report evaluates the current device design and technology of the Rigicon ContiClassic and Conti Reflex AUS devices.

Methods

Available literature pertaining to the ContiClassic and Contireflex AUS devices was reviewed. Given that both devices are new, there is no published clinical trial or previously presented data available in the literature. The authors are surgeons who have expert knowledge and experience in implanting these Conti-AUS devices. To our knowledge, this is the first paper that reviews both Conti-AUS devices. The material provided in this article was made independently by the authors with no direct input from the Rigicon company. This brief report is not designed to review other AUS-like devices in the commercial market but to compare the Conti-Classic and Conti-Reflex AUS devices against the "standard-of-care" AMS 800 device.

The AMS 800 AUS device *vs.* the Rigicon AUS devices

ContiClassic® AUS device (Figure 1)

The Rigicon ContiClassic® AUS device was introduced worldwide 2 years ago with the first case being implanted in September 2021 (14). Whilst similar in the overall design to the AMS 800 device in that it consists of a circumferential occlusive cuff, a pressure regulating balloon (PRB), and a pump, the ContiClassic device has several new features. In contrast to the InhibiZone-coated (comprises of rifampicin and minocycline antibiotics) AMS 800 device which covers the cuff and pump units only (2), the ContiClassic device has a hydrophilic (HydroShield®) coating which covers the entire device system and allows for specific antibiotic tailoring according to the surgeon's preference and patient's sensitivity. This is a significant step forward given that AMS 800 device is provided in the uncoated version in many parts of the world (15) and that antimicrobial resistance is on the rise with more antibiotic-resistant organisms potentially increasing the risk of prosthetic infection in the high-risk populations (16,17). The components of the ContiClassic device can be easily connected on the EasyClink® Connectors which does not require an additional assembly tool. The ContiClassic PRB is available in five different sizes namely 40–49, 50–59, 60–69, 70–79, and 80–89 cmH_2O.

Another unique feature of the ContiClassic device is the smaller increments in diameter of the sphincteric cuff at a 0.25-cm increment between 3.5- and 5.0-cm cuff sizes. Theoretically, these smaller increments in cuff sizes offer a greater but more precise occlusive cuff size selection, especially in the setting where the measurement of the urethral diameter is not half or full centimetre (for example 4.25 or 4.75 cm) (18). This more exact urethral cuff use provides better urethral circumferential coaptation for continence level and avoids the need to downsize the cuff to the next 0.25 cm resulting in a lower risk of early urethral atrophy or future cuff erosion.

While the Conticlassic® AUS is scheduled for the onset of clinical investigation to achieve United States (US) Food and Drug Administration (FDA) clearance in late 2023, this device has been implanted in many countries outside the US since its introduction (14). The first publication on Conti-Classic this year showed a revision rate of 6.90% in 116 patients, with three cases of fluid loss, four cases of iatrogenic mistaken sizing, and one case of patient

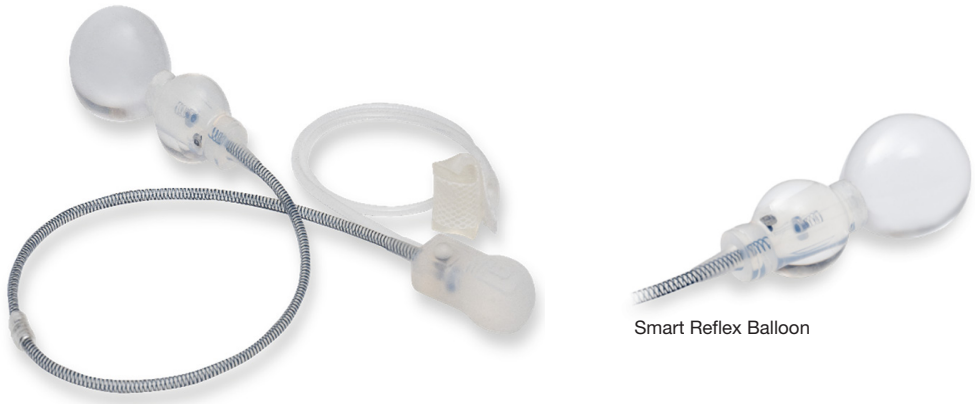

Figure 2 ContiReflex® artificial urinary sphincter device (incorporating an additional stress regulating balloon, otherwise known as a Smart Reflex Balloon, and a larger control pump system).

dissatisfaction, while the Kaplan-Meier calculation showed a survival rate of 93.2% at 12 months. This study shows the early safety outcomes for the Rigicon ContiClassic® sphincter device to be comparable to others presently on the market (18).

ContiReflex® AUS device (Figure 2)

The ContiReflex device is released later than ContiClassic device (19,20) and incorporates a second PRB and has a larger control pump unit. One of the key improvement areas in this second-generation Rigicon AUS device is its ability to sense and adapt the occlusive cuff pressure in a real-time manner against any sudden increase in intra-abdominal pressure changes by the addition of an extra balloon system known as the stress relief balloon (SRB) to the first PRB, that has the capability to sense intra-abdominal pressure changes and constantly equalize the occlusive cuff pressure. This unique dual-pressure Smart Reflex Balloon system requires an additional effort to prepare (30 mL of sterile saline to fill both the PRB and SRB) but is implanted in the same manner as the conventional PRB of the AMS 800 device. The higher pressure in the reflex balloon means that cuff occlusion pressure is no longer limited by the PRB labeled maximum pressure and that the lower resting pressure of the PRB could potentially prolong urethral viability and urethral atrophy (19). The ContiReflex PRB is also available in five different sizes specifically 40–49, 50–59, 60–69, 70–79, and 80–89 cmH_2O (20).

Given the more complex and larger two-balloon system, the control pump unit is also larger in size, and instead of a single compression to cycle the AUS, the ContiReflex device requires 4–5 pumps each time to empty not only the occlusive cuff but the SRB that acts as the intra-abdominal pressure sensor. The ContiReflex pump system is deactivated and re-activated in the same manner as the AMS 800 and ContiClassic pump units.

Similar to the Conticlassic device, data is currently being collected for the ContiReflex device and this device has been implanted in a few countries (14).

Conclusions

The AUS is designed to mimic the natural urethral sphincteric action to restore urinary continence. While the AMS 800 device is widely regarded as the standard of care in surgical devices for male SUI, it has some limitations in terms of device configuration and that complete urinary continence may not be possible especially when the patient exerts himself during strenuous physical activity. The ContiClassic and ContiReflex devices are designed to overcome these existing limitations and may prove to be superior continence devices. Nonetheless, only with larger clinical trials, ideally incorporating a direct comparative study against the AMS 800 device, and on a longer-term follow-up outcome, will ContiClassic and/or ContiReflex devices be considered the new standard of care replacing the current AMS 800 device.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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