Experience with the Mentor α-1

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CONTENTS

INTRODUCTION
MENTOR α-1 THREE-PIECE INFLATABLE PENILE PROSTHESIS
COMPARISON OF α-1 TO AMS 700 CX MECHANICAL FAILURE RATES
AUTOINFLATION
SEVERE CORPORAL FIBROSIS
PATIENT SATISFACTION
CONCLUSION
REFERENCES

INTRODUCTION

Ten years after the introduction of the Scott three-piece inflatable penile prosthesis in 1973 (American Medical Systems, Minnetonka, MN) (1), Mentor Corporation introduced their first three-piece inflatable penile prosthesis, the Mentor IPP (Surgitek, Racine, WI) (2). This device provided an alternative for improving the mechanical reliability of the three-piece inflatable penile prosthesis, which had been reported to be as high as 42% in some series (3). The most important advance that Mentor brought to the field of penile prosthetics was the introduction of a new material, known as Bioflex. Bioflex is an aromatic polyether urea urethane elastomer that provided a tensile strength seven times higher than that of silicone without sacrificing biocompatibility and hemocompatibility (4–6). The physical characteristics of this material, virtually
eliminated cylinder failures as a result of aneurysms or wear-induced abrasion, and provided the widest inflatable cylinder girth expansion available. As with other devices, continuous modifications of the Mentor IPP followed such as: a) modification of the pump in 1983 to improve patient identification of the deflation valve; b) use of nylon reinforced tubing in 1984 to eliminate tubing kinks; c) reinforced cylinder base in 1985 to avoid separation of the input tubing from the cylinder; d) use of a flange to the plastic clamps of the snap-on connectors in 1987 to improve stability (7), yield improved clinical results (8).

MENTOR α-1 THREE-PIECE INFLATABLE PENILE PROSTHESIS

The second generation of the Mentor inflatable penile prosthesis was introduced in May 1989. The Mentor α-1 was designed to improve device reliability and reduce device failure from connector leakage. This inflatable penile prosthesis (see Fig. 1) was the first connectorless, single pump-cylinder unit. Although continued minor modifications have occurred over the years, the basic design of the Mentor α-1 has remained the same for the last 11 yr. Some of these minor modifications to the α-1 included lengthening and reinforcement of the tubing at the exit from the pump in late 1992. The enhanced version (see Fig. 2) of the Mentor α-1 model increased the 5-yr survival rate from 75.3 for the original to 92.6% and lowered the failure rate of approx 5.6% for the original model to 1.3% (9). Cylinder, reservoir, and pump malfunctions are rarely observed in contemporary Mentor three-piece inflatable penile prosthesis. Current data reveals device malfunction consists of tubing fluid leaks (10–13).

COMPARISON OF α-1 TO AMS 700 CX MECHANICAL FAILURE RATES

In 1993, Pescatori and Goldstein reported a 16% mechanical failure rate in the AMS 700 CX as a result primarily of leaks at or near the connector site. A 4% mechanical failure rate was observed in the Mentor α-1. A common malfunction site in the AMS device was observed in the tubing from one of the cylinders as its inlet to the pump. One explanation for the difference was found to be the lower intraluminal device pressures in the Mentor device during inflation and the absence of connectors in the pump cylinder unit. This comparative paper between Bioflex (Mentor IPP and Mentor α-1) and silicon-based devices (AMS 700 CX and AMS Ultrex) revealed markedly elevated values of intraluminal