BIOCARBON URETEROSTOMY DEVICE FOR URINARY DIVERSION

Multicenter Clinical Trial*

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ABSTRACT—The bioCarbon ureterostomy device is a stomal prosthesis for upper tract urinary diversion that has had preliminary successes in animal and human trials in Europe and Peru. Implantation of a pure carbon stomal prosthesis offers the potential advantages of high biocompatibility, lack of encrustation, and elimination of stomal stenosis which is frequently associated with cutaneous ureterostomy. Nine bioCarbon ureterostomy devices were implanted from August, 1984 through July, 1985. Although successful implantation was achieved in 2 patients, the complication rate was high. The bioCarbon ureterostomy device has potential as an alternative form of urinary diversion. However, significant problems need to be remedied before it can be recommended for routine clinical application.

The variety of urinary diversions currently in use by urologists are testimony to the absence of a simple, reliable procedure. Because of this, we have evaluated a vitreous carbon prosthesis for cutaneous ureterostomy in 9 patients requiring urinary diversion. Pure carbon in the vitreous or glassy form was first developed and characterized in England in 1963 as an outgrowth of space exploration. The remarkable characteristics of this pure carbon material suggested its potential biologic applicability. Vitreous carbon is a hard, impermeable solid that is chemically inert at ambient temperature and shows no galvanic activity with saline solutions.[1]

Mooney, Hartmann, and McNeal[1] used a pure carbon percutaneous electrical connector and found it to be biologically inert and free of infection for more than two years. Longley and associates[2] evaluated a vitreous carbon urostomy device for vesicostomy and ileal bladder stomata in dogs and documented its feasibility by demonstrating good short-term function. Harzmann, Bichler, and Ideler[3] reported the successful use of biocarbon urinary conduits for vesicostomy stomata in 6 patients for up to fifteen months. The stomas resulted in urinary

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continence without encrustation and with good wound healing.[3] A carbon prosthesis was also evaluated in several animal species as a stomal device for ureterocutaneous anastomoses.[4] A functioning conduit was obtained in 77 percent of the implants. Eleven of 48 stomal prostheses were unsuccessful. Causes of stomal failure included poor healing, parastomal inflammation, urinary extravasation, and severe encrustation.

Pow-Sang and associates[5] implanted bicarbon ureterostomy devices in 20 patients with uterine cervical or bladder cancer. Only 1 patient was alive at the time of the report. She had a functioning implant at one year after two reimplants. Of the remaining patients, 18 died of carcinomatosis and 1 had a cardiac arrest eleven days postoperatively. Eleven implants were functioning at the time of death. Urinary fistulas developed in 7 patients.

A clinical trial with a bioCarbon ureterostomy prosthesis was begun in the United States in 1984. Results of this trial are reported.

Material and Methods

Vitreous (glassy) carbon is the primary component of the bioCarbon ureterostomy device. It is composed of 99.9 percent pure carbon, and its hardness and impermeability enable it to accept a high surface polish. The bioCarbon ureterostomy device is a rigid, transcutaneous prosthesis providing a nonstenosing route for urine drainage from the ureters. The device has a tapered inner spout with an internal circumference of 11.5 F that can be intubated into the ureter. The larger outer spout has a rim to facilitate a leak-free attachment to a drainage device. In addition there is a wide flange in the device which is inserted between the abdominal muscle and external fascia for fixation. The inner spout is covered with Dacron fabric to promote tissue ingrowth (Fig. 1).

Nine people received bioCarbon implants from August 30, 1984 to July 17, 1985. Seven were implanted with devices with a straight inner spout, and two were implanted with devices with a curved inner spout. Indications for the devices included cystectomy or ureteral obstruction. Transureteroureterostomy was performed in the 5 patients who had cystectomy. An indwelling single J ureteral stent through the conduit was routinely employed for up to six weeks after the implantation. Postoperatively, the patients were followed closely and were specifically monitored for infection, encrustation, urinary tract obstruction, fistula,

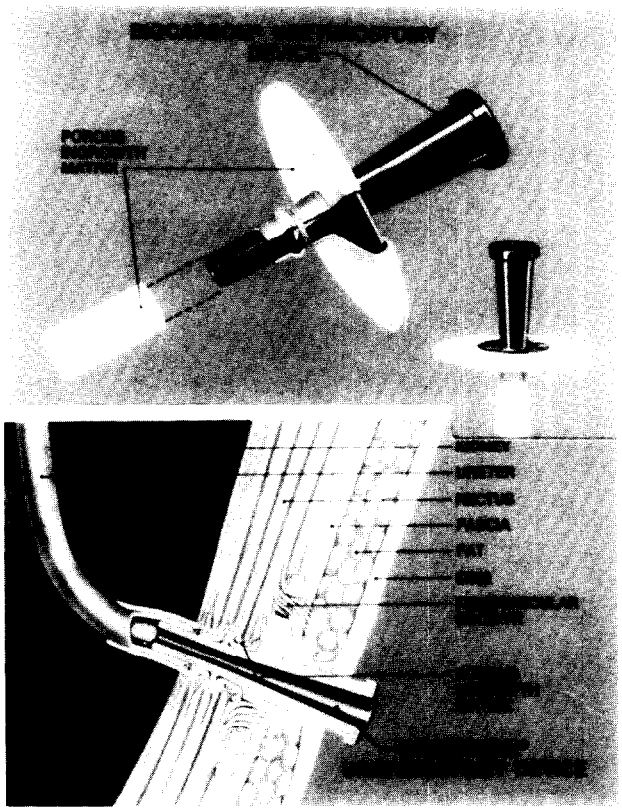

FIGURE 1. *BioCarbon ureterostomy device consists of tapered, flanged, carbon tube with Dacron wrap.*

and biocompatibility. Of the 4 patients who died of their cancer, postmortem examination of the bioCarbon device was not possible in 2. All five devices removed for infection and fistula underwent pathologic examination.

Results

Nine patients with a mean age of sixty-four years (range 56 to 71 years) underwent single bioCarbon ureterostomy implantation. Indications for the device included cystectomy for bladder cancer (5), unilateral obstruction of the ureter (2), and stenosis of a previous cutaneous ureterostomy (2). The 5 cystectomy patients all had transureteroureterostomy at the time of surgery. The mean and median duration of implantation was one hundred thirty days and seventy-six days, respectively. A summary of the results is listed in Table I.

Two patients (LB and WE) died of neoplastic disease with functioning devices. The duration of device implantation in these individuals was thirty-four and one hundred seventy three days. Their devices were not retrieved for examination. Two other patients died of neoplasm but had complications with their devices. One

(WR) had a satisfactorily functioning device. However, for the last two weeks of his life ascitic fluid leaked around the device requiring the use of a urostomy bag over the prosthesis. In the other patient (VL) progressive hydronephrosis developed secondary to lymphocele obstruction which was drained six months after implantation. A sinus near the ureterostomy device started leaking urine six and one-half months after implantation and was managed by his wearing a urostomy bag over the device for the last five months of his life.

In the remaining 5 patients, the device was removed because of device-related complications and urinary diversion was accomplished by other means (4 ileal conduits and 1 cutaneous ureterostomy). Three devices were removed because of urinary fistulas. One patient (FJ) had a device implanted into a stenosed cutaneous ureterostomy. The device was subsequently removed because of ureteral obstruction proximal to the device and Pseudomonas skin infection around the prosthesis. One patient (LC) had an excess of subcutaneous adipose tissue which was partially excised at the time of his implantation. Nevertheless, the device subsequently retracted below the skin level followed by the development of soft tissue infection requiring removal of the prosthesis.

Primary problems were the development of urinary fistulas and soft tissue infections caused by a variety of organisms. Inadequate spout length of the device contributed to a poor result in at least 1 patient (LC). Adequate ingrowth of tissue into the Dacron sheath was generally poor in the devices that were examined (Fig. 2). However, the successful devices were not retrieved for follow-up study. An additional technical concern was the development of significant encrustation clogging the indwelling single J ureteral stent in 2 patients.

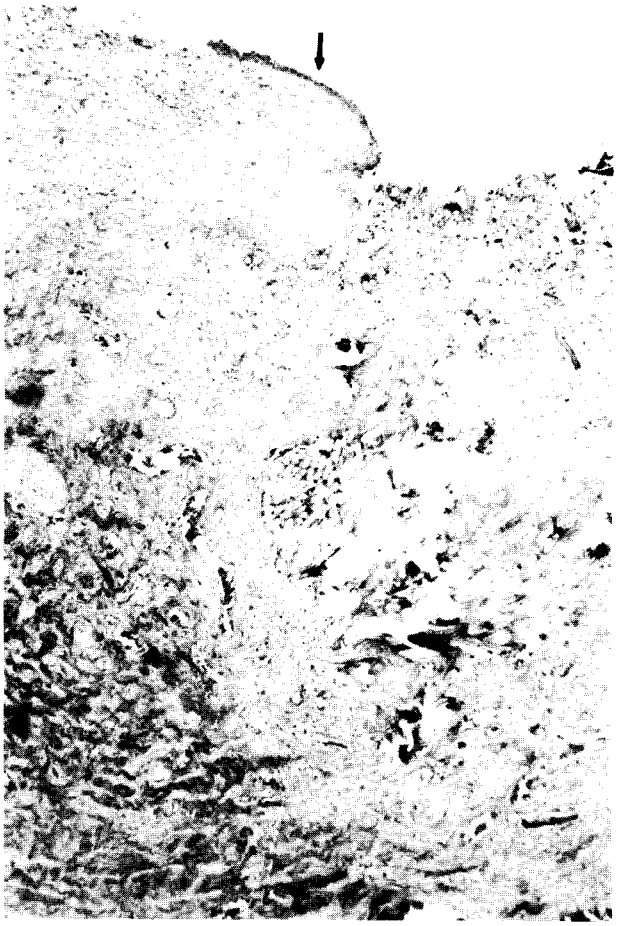

FIGURE 2. *Zone of attachment of ureter to inner wrap Dacron is shown in device explanted after six weeks. Urothelium is marked by arrow. Little collagen in Dacron inner wrap material. (Masson trichrome stain.)*

TABLE I. *Results of bioCarbon implantation*

Patient	Age	Indication	Implant Duration	Outcome
BM	63	Cystectomy	83	Removed—urinary fistula
VL	63	Cystectomy	391	Cancer death—urine leak managed by urostomy bag for five months
LB	62	Cystectomy	173	Cancer death—successful implant
FJ	70	Stenotic cutaneous ureterostomy	40	Removed—ureteral obstruction and infection
WE	71	Ureteral obstr.	34	Cancer death—successful implant
HH	67	Cystectomy	40	Removed—urinary fistula
LC	69	Cystectomy	76	Removed—infection, short device
WR	58	Ureteral obstr.	70	Cancer death—good function (late leakage of ascitic fluid)
BT	56	Stenotic cutaneous ureterostomy	260	Removed—urinary fistula

Comment

Despite the recent trend toward continent urinary diversions, most urinary diversions still require the use of an external collection bag. Furthermore, virtually all urinary diversions require the use of portions of the small and/or large intestine. Cutaneous ureterostomy is one of the few upper tract alternatives for a tubeless external diversion that is simple and does not require a bowel anastomosis. However, cutaneous ureterostomy is not without its complications. The small size of unobstructed ureters results in a high incidence of stomal stenosis. Because of this, enthusiasm for this form of diversion is low. Nevertheless, the relative simplicity of this procedure has prompted Bracken and Kinder[6] to advocate intubated cutaneous ureterostomy for individuals in poor health with normal-sized ureters who require cystectomy.

Vitreous carbon is biologically and chemically inert and has been clinically effective as a material for long-term vascular access.[7] Because of these attributes, we tested a ureterostomy device constructed of bioCarbon. Theoretical advantages include (1) a short, simple procedure, (2) no sacrifice of a bowel segment, (3) no stomal stenosis, and (4) an easily managed external appliance. Although successful device implantation was accomplished in 2 patients, a high complication rate was noted. Urinary fistulas and soft tissue infections around the device were common. Furthermore, a high incidence of poor tissue ingrowth into the Dacron covering the bioCarbon was noted. Whether these represent separate events or are a consequence of one another is unclear. Infections not only may have an adverse effect on wound healing but also may increase the stone-forming ability of urine. Despite the high degree of inertness of bioCarbon, encrustation was noted on two devices. In both cases, the sediments were noted near the tip of the bioCarbon device and were easily removed with a cotton swab. Mechanical problems included devices that were too short for obese patients and the potential for kinking of the ureter at the junction of the device. The role of an indwelling stent in device success or failure could not be determined. In at least 1 case, obstruction by the stent may have contributed to a urinary fistula and device failure.

Although this clinical trial was not without its successes, the demonstrated hazards of the implantable vitreous carbon ureterostomy device in its present form and with the operative technique employed argue against further clinical investigation without significant changes. Urine creates an unfriendly environment for any prosthesis, no matter how inert. This is well demonstrated by the concretions noted on silicone ureteral catheters. BioCarbon was remarkably resistant to this problem but did not obviate it completely. More important, perhaps, is the difficulty we had in achieving good tissue ingrowth into the prosthesis. The carbon is nonporous and does not bind to tissue. The Dacron outer covering in its present form achieved adequate tissue ingrowth for device fixation but did not accomplish a urine-tight seal. A simple nonintubated, stenotic-free prosthesis for cutaneous ureterostomy would be a welcome addition to the urologist's armamentarium. Additional work is required before such a device can be recommended.

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