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The Effects of Extracorporeal Shock Wave Lithotripsy on Urological Prostheses and Endoprostheses

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Summary. The combination of ESWL and Endourology (EU) enables a wider range of stones to be treated without open surgery than either modality alone. EU frequently involves the maintenance of a plastic prosthesis in or near the area of maximal shock wave concentration during ESWL. Prostheses subjected to a standard test treatment by ESWL and others removed from patients after ESWL were examined visually, microscopically and biochemically by electron microscopy (SEM) and X-ray emission spectroscopy (XES) to investigate the effects of ESWL on the prosthesis itself. Foley catheter balloons leaked. Previously smooth surfaces were disrupted and possibly toxic additives may be released. Care should be taken in selecting indewelling EU prostheses if ESWL treatment is likely to follow.

Key words: ESWL, Endourology, Prostheses, Disruption, Additive release.

Introduction

Extracorporeal Shock Wave Lithotripsy (ESWL) has become established as the primary treatment for most upper urinary tract stones [1, 3, 9] Over 30,000 patients have been treated world wide and ESWL has been shown to be a safe and effective technique [4, 11].

As experience has been gained, the treatment of larger and more complex stones has been undertaken. These require a wide range of supportive procedures, collectively known as Endourological techniques (EU). They include percutaneous nephrostomy (PCN), percutaneous nephrolithotomy (PCNL) and ureterorendoscopic surgery (URS) and have become an essential adjunct to ESWL to widen the range of stones that can be managed without open surgery and for dealing with the complications that may occur after the treatment of any stone. Using these combinations over 95% of all upper urinary tract stones can be treated by ESWL and EU [9].

Combining EU procedures with ESWL results in a wide range of EU prostheses being in contact with or in close proximity to the stone during the shock wave application.

Large renal calculi may be debulked by PCNL. A large nephrostomy tube is then left in the kidney alongside the remaining stone to act as an alternative conduit for stone debris and urine following ESWL to these endoscopically inaccessible fragments.

Smaller stones presenting with obstructive complications may require a fine PCN to decompress the kidney. The nephrostomy then remains in situ during ESWL which is performed when a stable clinical state has been achieved. Lucent stones may be identified by the injection of radioopaque contrast through a retrograde ureteric catheter to enable localisation of the stone prior to or during ESWL. A retrograde catheter may also be introduced to act as a useful "signpost" to assist in the radiological definition of difficult stones such as multiple small calculi or those whose position is obscured by overlying ribs, calcified costal cartilage or mesenteric nodes and so will lie close to the stone during shock wave application.

To treat calculi in the upper third of the ureter by ESWL the stone should be manipulated back into the kidney. A guide wire is passed transurethrally to the stone. Gentle manipulation often dislodges the stone back to the kidney. If unsuccessful an angiographic catheter is introducted over the guidewire to just below the stone and a jet of sterile saline injected to displace the calculus upwards. The guidewire, angiographic catheter or ureteric catheter are left in the ureter to prevent re-entry of the stone before or during ESWL. Other centres have reported the use of ureteric balloon catheters for this purpose. In over 80% of our cases the stone has been successfully returned to the kidney.

In the case of long standing ureteric calculi that cannot be replaced in the kidney, the guidewire and catheter are manoeuvred past the calculus to create a "capillary slit", thus partially surrounding the calculus with urine and pushing the ureteric wall away from the stone which greatly assists fragmentation by ESWL. In addition several patients

Table 1. ESWL and urological prostheses-experimental and clinical details

Prosthesis	Opacifier	Shock waves in vivo	Shock waves in vitro	Most damage
Ureteric catheter polyvinyl-chloride (PVC)	bismuth	2,000	2,000	
Nephrostomy tube (PVC)	none	4,000	2,000	
Angiocatheter (Polyethylene)	bismuth	1,000	2,000	
Ureteric stent polydimethylsiloxane (silicone)	barium	–	2,000	
Angiocatheter polytetrafluoroethylene (PTFE)	bismuth	700	2,000	
				Least damage

Table 2. Balloon catheters

	Shocks in vivo	Shocks in vitro
Silicone	2,000	2,000
Latex	–	2,000

In each case two catheters were tested in vitro, one with an air filled and one with a water filled balloon

have been referred for ESWL to residual stones with balloon catheter nephrostomies in situ after surgery elsewhere.

No information was available regarding the effects of ESWL on EU prostheses. This lack of information combined with the experimental [5, 10] and clinical reports [6] of damage to the ureter from electro hydraulic shock waves used in the ureter without endoscopic control was a source of great concern. Furthermore ESWL is known to produce more focussed shock waves of higher energy than a lithotripter probe [12] and our own clinical experience had already confirmed that ESWL will fragment some calculi resistant to EHL. The pressures experimentally measured at the shock wave focus are extremely high (600 bar or 8,400 pounds per square inch) [2].

Materials and Methods

Table 1 records the endoprostheses studies in vivo and in vitro. For the experimental evaluation of the effects of ESWL the objects chosen were subjected to a standard procedure designed to mimic the clinical situation. The water bath was filled to the normal level and the object suspended from the hydraulic patient support frame of the Dornier systems lithotripter over the shock wave source in the bath. The frame was manoeuvred under fluoroscopic control so that the prosthesis lay precisely in the second focus of the shock wave generator. Every object was positioned so that the clinically appropriate segment remained within the second focus. If the object itself was radiolucent then radio-opaque contrast material or a radiodense marker was positioned to allow localisation of the target without interference to the shock waves.

A minimum of 2,000 shocks at 23 kV were given to the objects in volleys of 100 as these are the maximal parameters used in clinical practice for a single treatment.

The effects of the shock waves were observed by fluoroscopic screening during the treatment and after each volley of 100 shocks and the target always maintained within the second focus.

Target objects were removed from the bath and examined visually. With the exception of the balloon catheters all prostheses were examined in detail for microscopic and biochemical alterations to their surfaces by electron microscopic scanning techniques (SEM) and backscattered x-ray energy spectroscopy (XES). All prostheses were studied in vitro and these surface effects were compared with those found in prostheses removed from patients treated by ESWL.

The scanning electron microscope was a Joel 35 CF fitted with a backscattered electron detector and a Kevex x-ray energy spectrophotometer.

Results

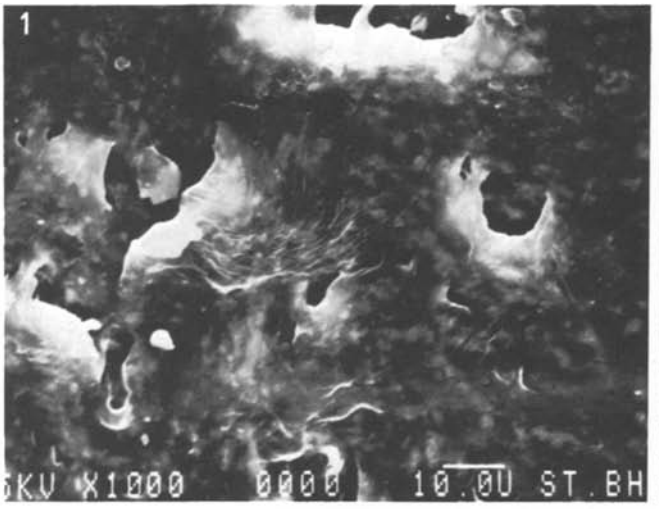
Tables 1 and 2 record the prostheses and endoprostheses tested in vivo and in vitro.

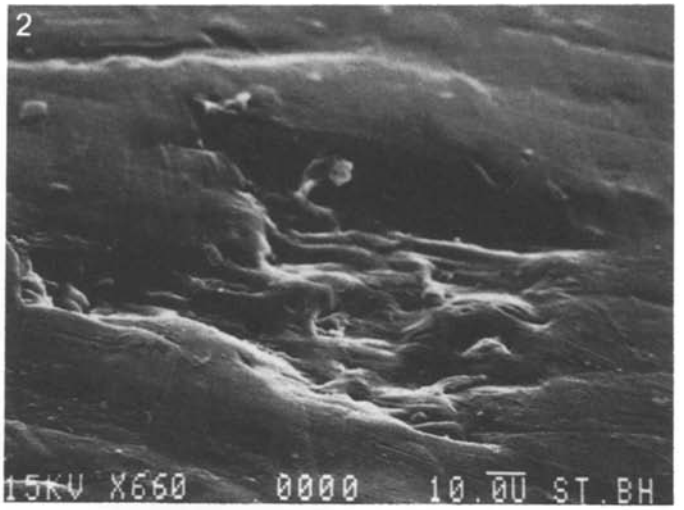
Both fluid filled catheter balloons experimentally tested leaked. Those containing air were intact as was the single fluid filled silicone balloon catheter shocked in vivo. No other prosthesis was obviously damaged on visual examination. On examination by SEM at magnifications of 600x–4,000x disruption of the surfaces of all plastics was evident (Figs. 1–5). Similar appearances were found in those examined after in vivo and in vitro exposure to shock waves.

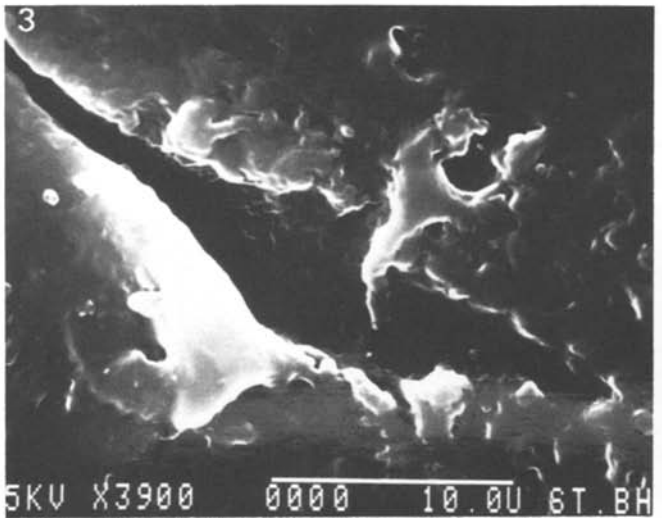
Disruption was equivalent in the polyvinylchloride formulations and less in the polyethylene, and polydimethylsiloxone prostheses. The polytetrafluoroethylene article showed least damage.

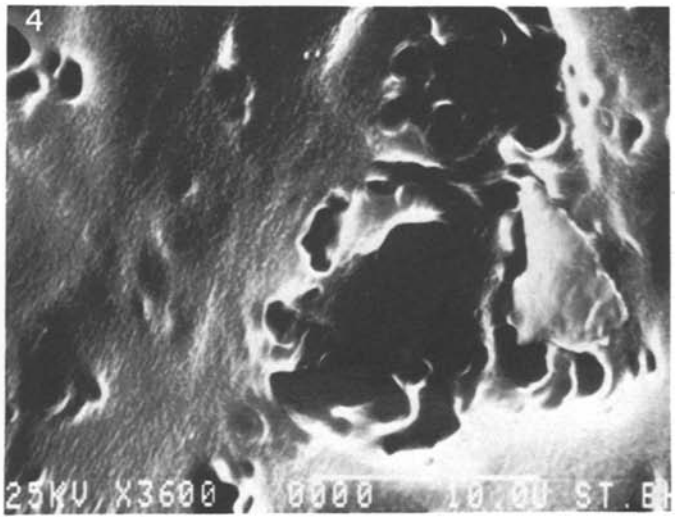
Backscattered XES revealed the presence of inorganic elements (barium and bismuth), used to radio-opacify the plastics. Detection of the presence of such additives exposed or close to the surface could also be used as markers of the disruption of surfaces of the plastics.

The disruption of the polyethylene catheters was such that bismuth particles were released (Fig. 6). Even though the surface of the PTFE was also disrupted a layer of fluorine still covered the added bismuth (Fig. 7) preventing its escape.









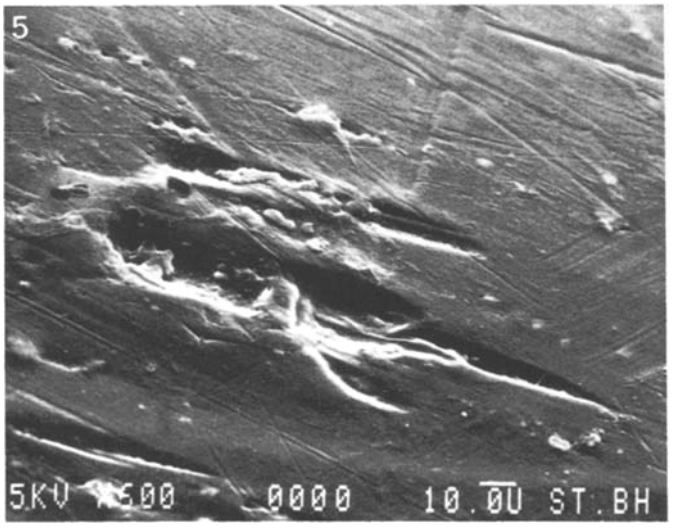


Fig. 1. PVC bismuth impregnated catheter after ESWL

Fig. 2. PVC nephrostomy tube after ESWL

Fig. 3. Polyethylene bismuth impregnated catheter after ESWL

Fig. 4. Silicone ureteric stent after ESWL

Fig. 5. Teflon (PTFE) bismuth impregnated catheter after ESWL

Discussion

Urologists can be reassured that EU prostheses are unlikely to fracture or deform as a result of ESWL exposure. Fluid filled nephrostomy catheter balloons may burst. We would recommend caution in their use and prefer to use nephrostomy catheters without balloons.

This study does suggest that ESWL causes disruption of the smooth polished surfaces of polymers. The surface treatment of medical polymers ("polishing") produces smooth

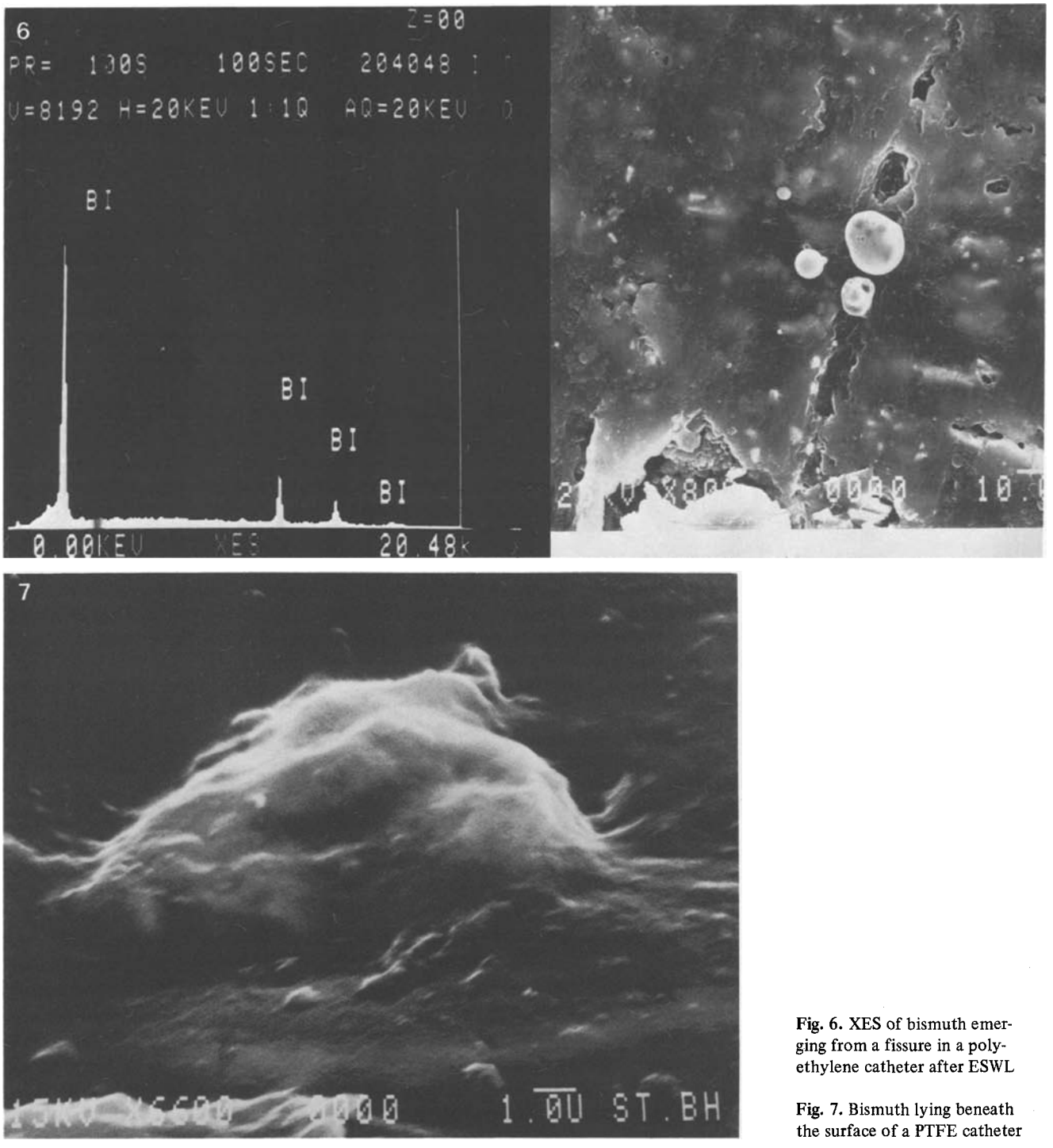


Fig. 6. XES of bismuth emerging from a fissure in a polyethylene catheter after ESWL

Fig. 7. Bismuth lying beneath the surface of a PTFE catheter

surface properties which are desirable for ease of insertion and removal, enhanced biocompatibility and to seal in additives and plasticisers which might otherwise be toxic to mammalian cells.

The theoretical significance of the surface disruption is twofold. Encrustation of the roughened surface of an indwelling nephrostomy tube may occur but is probably of little clinical importance.

However, the release or direct exposure of possibly toxic additives to the urothelium may be important. An "epidemic" of urethritis and urethral strictures was related to additives in latex urethral catheters [8]. The upper urinary tract epithelium may be equally susceptible to cytotoxic damage.

Identification of the presence or nature of other possibly cytotoxic additives apart from the radio-opacifiers detected by XES was not attempted and is not revealed by the manufacturers. However Fig. 6 shows bismuth emerging from a fissure in a polyethylene ureteric catheter following exposure to shock waves. The cytotoxicity of bismuth itself has not been studied in the urinary tract. It has been impli-

cated in calculus formation following long term ureteric catheterisation in experimental animals [7]. Whether or not bismuth is itself toxic, it is clear that if it can be released or exposed then so may other cytotoxic substances if present. Urologists should be on their guard against the possibility of any similar epidemic of injuries to the upper urinary tract epithelium as a result of ESWL damage to EU prostheses.

PTFE appeared particularly resistant to shock waves. Although the smooth surface was disrupted radio-opaque additives were not released or exposed. A "fluorine blanket" remained, covering the bismuth particles. The silicone stent which XES showed to contain barium demonstrated a similar protective effect, preventing exposure of the barium.

Therefore on the basis of these findings PTFE or silicone prostheses can be recommended. In practice silicone is not suitable for many applications and PTFE has advantageous handling properties and metal or other plastic attachments can be more easily bonded to it. Should PVC be necessary then a formulation not containing additives should be used.

Care should be taken in the choice of material for prostheses exposed to ESWL. EU prostheses should be tested for resistance to ESWL prior to their widespread clinical use.

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