A flexible, rotating tip catheter (Kensey catheter) was used to recanalize 24 segments of diseased superficial femoral arteries (from cadavers) that were sewn as xenografts into the femoral, carotid, or aortic-renal arteries of 14 dogs. One perforation occurred; there were emboli in some brains and kidneys, the consequences of which remain unknown. No signs of gross neurologic deficits or limb ischemia were seen at 0-11 days.

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Ballooning angioplasty is widely used in patients who have stenotic lesions in the coronary, mesenteric, renal, aortoiliac, femoropopliteal, and distal vessels (1-5) and, in particular, in patients with short-segment lesions in vessels of the lower extremity, which cause claudication (6). The procedure has limited success when used to salvage limbs in patients who have long-segment lesions and poor circulation, and lesions in smaller distal vessels (6, 7).

Anatomic factors (vessel tortuosity, sharply angled arteries) and the nature of the lesion (pouchlike, fibrotic, calcified) limit the applicability of balloon angioplasty. In an effort to circumvent these limitations, we developed a new technology for transluminal dilation of arterial stenoses and recanalization of totally occluded arteries. A new device named the Kensey catheter (Theratek International, Miami) is key to this technology.

MATERIALS AND METHODS

Device Description

The Kensey catheter (Figs. 1-3) is made of flexible polyurethane in a size range of 5–9 F. A rotating cam at the distal tip is driven at speeds of up to 100,000 rpm by an internal-torsion-drive wire. The cam varies in size with the size of the catheter.

The catheter also contains a continuous channel through which fluid under pressure flows. At the base of the cam, the fluid exits as fine jet sprays that are directed laterally against the artery wall. These jets cool and lubricate the rotating cam, dilate the artery, and serve to keep the cam centered in the lumen.
The proximal end of the catheter is coupled to a rotational drive and to a fluid injection tube that is fitted to a Luer connection. Power to the torsion-drive wire is provided by a direct current electric motor with a speed-up transmission. Fluid is delivered to the injection tube, and therefore, into the continuous channel of the catheter by two syringes that are pressurized by air cylinders. A hose-harness assembly—complete with check valves, stopcocks, and end fittings—provides for the interconnection of intravenous bags, injector syringes, and the catheter.

The rate of fluid flow and the rotational speed of the cam are controlled with a console powered from a remote medical-grade isolation transformer.

**Experimental Studies**

Twenty-four segments of diseased superficial femoral arteries from cadavers were sewn as xenografts (11 femoral, seven carotid, six aorticorenal) into 14 mongrel dogs. The extent of lumen occlusion in the xenografts, determined with angiography following completion of the anastomoses, was <50% in 13, >50% in six, and 100% in five.

When angiography was completed, the Kensey catheter was advanced through the respective native artery to the site of the proximal anastomosis. The xenograft then was recanalized by advancing the catheter tip in a gentle, to-and-fro motion until it passed the distal anastomosis, then another angiogram was obtained.

All animals were observed closely for signs of gross neurologic deficits and limb ischemia. The dogs were killed either on the same day as recanalization (n = 8), or 3–11 days later (n = 6), and each xenograft, including the anastomoses and a 2-cm segment of proximal and distal native artery and appropriate organs and limbs, was removed for histologic studies to determine the presence of emboli distal to the xenograft. No biologic parameters were measured.

**RESULTS**

Angiograms showed that recanalization was successful in all xenografts. In one of the xenografts, a totally occluded segment of femoral artery was perforated by the catheter. This perforation was due to excessive force applied to the catheter tip and the autolytic nature of the graft. Recanalization was eventually successful. Perfusion in the brains and kidneys of dogs with carotid and aorticorenal xenografts, respectively,
was excellent, as indicated by Figure 4. All dogs remained in apparent good health until they were killed; none had signs of neurologic deficits or limb ischemia.

Histologically, all xenografts had fragmentation of the superficial layer of the fibrous cap, loss of intima, hemorrhage into the media, and separation of the periphery of the plaque. The adventitia, however, was intact.

In the xenografts with stenosis of <50%, the degree of separation of the plaque was greater than in the nonstenotic xenografts. In those with stenosis of >50%, the dilated adventitia was associated with an increased size of the lumen (Fig. 5).

All the brains of the dogs with carotid xenografts showed small petechial hemorrhages (Fig. 6). Hemosiderin-laden macrophages (a sign of chronic bleeding) was present in a single area of one of these brains, and there was an embolus of fatty atheromatous material in another.

Small emboli were present in the glomeruli and arterial circulations of four of the six dogs that had aortoiliac xenografts. Small calcium and collagen emboli were seen in 2%–5% of glomeruli and arteries in two of these six dogs, but there was only one embolus per glomerulus (Fig. 7). The emboli in the cases of arterial involvement were mainly in arterioles, with an occasional embolus in a larger artery. No emboli or necrotic tissue were found in any other organs or limbs.

**DISCUSSION**

Insofar as the xenografts in this study were concerned, recanalization with the Kensey catheter produced early results compared with those obtained with balloon angioplasty.

The presence of emboli in the brains of the dogs with carotid xenografts and in the kidneys of those with aortoiliac xenografts was expected. However, the biologic effects of embolization, if any, were not studied, and we only can say that embolization produced no signs of early gross neurologic deficits or limb ischemia.

Future studies may resolve this issue, and the size of the particulate matter generated by the revolving cam may be determined. Such studies may indicate that clinical use of the catheter should be limited to peripheral vessels where the microemboli will have no opportunity to reach vital organs.

On the other hand, safety, with respect to perforation of the vessel being recanalized, seems to have been established in our study. The only perforation that occurred was the result of operator error and the autolytic nature of the xenograft; the latter will not be and the former should not be factors in the clinical use of the device.

We conclude that angioplasty with the Kensey catheter as a primary treatment and its suitability for use with other procedures, such as balloon angioplasty, endarterectomy, and surgical bypass, merit further study.

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**References**