A scanning electron microscopic study of biliary stent materials

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ABSTRACT

Background: Clogging of biliary stents remains an important problem. In vitro studies have shown less sludge formation in Teflon stents. Recently, clinical studies with Teflon stents have produced contradictory results. The aim of this study was to investigate whether the surface properties of the endoprostheses could explain the variation observed in clinical studies.

Methods: A total of 9 different types of unused 10F endoprostheses were examined by scanning electron microscopy (SEM): polyethylene Amsterdam-type, polyurethane Amsterdam-type, Teflon Amsterdam-type, Teflon Tannenbaum-type and a Tannenbaum-type stent with a thin stainless steel mesh between inner and outer layers.

Results: All polyethylene stents had a relief with tiny lumps. All Teflon stents had multiple shallow pits and ridges along the entire longitudinal axis. Both Tannenbaum-type stents also had multiple particles protruding into the stent lumen with adjacent holes in the wall of the stent. The polyurethane stent had an extremely smooth surface.

Conclusion: SEM of Teflon made stents showed a markedly irregular inner surface, which may explain the controversial results of clinical studies. Our results indicate that the inner surface of a new stent should first be evaluated by SEM before clinical trials are initiated.

INTRODUCTION

Endoscopic insertion of biliary stents is the standard method of palliation for pancreato-biliary malignancies. A major limitation is stent clogging. Different attempts to prolong patency by changing stent size, stent design or altering bile composition have been investigated, but stent clogging remains an unsolved clinical problem. In vitro studies have shown that stents constructed of Teflon have a lower friction coefficient compared with stents made of other plastics and therefore have the maximum potential for preventing stent blockage (1). In the in vivo studies it was shown that polyethylene stents with side holes accrued significantly more sludge than stents of the same material without side holes (1).

Soehendra and colleagues designed the so-called Tannenbaum stent, a Teflon stent without side holes, and they reported a substantially longer patency of these stents (2,3). It is not known which factor, the Teflon material or the absence of side holes, contributes most to this favorable result. Sung et al (4) showed in a randomized trial that polyethylene stents with and without side holes perform equally well. Recently, we compared polyethylene and Teflon Amsterdam-type stents in a randomized trial and could not show any difference in patency (5). The results of these clinical studies are contradictory. The combination of Teflon material and the absence of side holes results in superior patency rates, whereas omitting side holes in the design of a polyethylene stent or the use of Teflon material in a conventional design does not improve stent patency. In both studies, it was emphasized that the smooth-
ness of the stent surface is of great importance, either by omitting side holes or by using material with a low friction coefficient. We performed scanning electron microscopy (SEM) of unused commercially available biliary endoprostheses, made of different materials and manufactured by different companies, to study the smoothness of the stent surface. In addition, we measured the inner and outer diameters of the 10F stents.

METHODS
A total of 9 unused 10F endoprostheses were examined by SEM: polyethylene Amsterdam-type (Olympus Optical Co., Ltd., Tokyo, Japan), (PBN Medicals, Stenoese, Denmark), (Scandimed, Glostrup, Denmark), (Wilson Cook, Winston-Salem, N.C.); polyurethane Amsterdam-type (Biosearch, Sommerville, N.J.); Teflon Amsterdam-type (PBN Medicals); Teflon Tannenbaum-type (Wilson Cook) (Prof. Soehendra, Hamburg, Germany); and a Tannenbaum-type stent (Olympus) with a thin stainless steel mesh embedded between an inner Teflon coating and an outer polyamide layer.

SEM of the inner surface of biliary stents was performed in the following manner. Stent segments of about 2 cm in length were mounted on stubs, sputter coated with approximately 15 nm of gold, and random areas were examined with a scanning electron microscope (SEM 525; Philips, Eindhoven, The Netherlands). The elemental composition of the added x-ray contrast additives of the stents was determined with an energy dispersive x-ray analysis (EDAX) 9900 system on a scanning electron microscope (SEM 525; Philips).

The scanning electron microscope was operated at 25 kV; however, in some stents imaging of the surface was impossible at 25 kV because the x-ray contrast additives under the stent surface were a much better source of secondary electrons than the stent surface. To minimize this interference, imaging of the surface of these stents was done at low accelerating voltage (5 kV); these low energy electrons do not reach the additives because they are not able to penetrate into the stent material, contrary to the case with 25 kV electrons.

Measurement of internal and external stent diameter was performed by light microscopy.

RESULTS
Polyethylene stents manufactured by Olympus, PBN Medicals, Scandimed and Wilson Cook were examined at operating voltages of 5 and 25 kV. At 5 kV all had a relatively smooth surface with tiny lumps protruding into the lumen (Fig. 1A).

The inset in Figure 1A shows the stent image at 25 kV. At this voltage the image of the stent surface is disturbed by the back scatter and secondary electrons generated by the granular additives (contrast material) in the plastic material. Although most of the surface was relatively smooth, the polyethylene stents manufactured by
Scandimed and PBN also had areas with barbs (Fig. 1B). Small discrete particles protruding into the lumen and an occasional longitudinal shallow pit were seen in the polyethylene stents manufactured by Olympus.

All types of Teflon stents had multiple shallow pits and ridges along the entire longitudinal axis (Fig. 1C and 1D). Both Teflon Tannenbaum-type stents also had multiple particles protruding into the stent lumen with adjacent holes in the wall of the stent (Fig. 1D).

The stent with a stainless steel mesh and an inner Teflon coating had the same inner surface as the Teflon Tannenbaum stent with less explicit shallow pits and ridges along the longitudinal axis (Fig. 1E). At low magnification a relief of the stainless steel mesh on the inner surface was visible (Fig. 1F). The polyurethane stent had an extremely smooth surface, virtually free of irregularities (Fig. 1G).

All stents contained x-ray additives meant to augment visualization under fluoroscopy. The nature of these additives was investigated by EDAX. In most cases it was bismuth (4x), but barium (2x), tungsten and chromium (both 1x) were also found. The Wilson Cook Tannenbaum-type contained barium and bismuth. The nature of the x-ray additives found in the different stents are listed in Table 1.

Bismuth and tungsten were mostly found in the form of fairly coarse particles. In contrast, barium and chromium were found as much smaller particles homogeneously distributed in the stent material. Depending on the roughness of the inner stent surface and granule size, the bismuth granules in particular were sometimes found exposed at the lumen of the stent.

The internal and external diameters of 10F biliary stents were determined via light microscopy and are presented in Table 1.

**DISCUSSION**

During the past decade many randomized clinical trials have been performed with the goal of optimization of stent design. Although the smoothness of the stent wall has been considered to be an important factor for stent function (1,6,7) to date detailed quality analysis of the commercially available stents used in the various trials has not been performed. By using SEM we show in the present study that few stents have surfaces with the desired perfect smoothness. Except one, all stents had various surface defects that are favored sites for microbial adherence.

SEM of stents made of Teflon demonstrated the most irregular inner surface of all stents examined. It seems that the manufacturing process itself has an influence on the surface smoothness, especially for Teflon stents. The shallow pits and ridges along the longitudinal axis are the result of the extrusion process used in manufacturing these stents. The particles protruding into the stent lumen, which were only observed in the Teflon Tannenbaum stent, were caused by the use of large granular additives. Clearly, this significantly contributes to the roughness of the stent surface. In addition, it cannot be excluded that biliary components bind to the x-ray additives.
protruding in the lumen. Whether the release of these additives plays a role in clogging of the stents requires further investigation. The irregular surface could provide an explanation for the discrepancies between in vitro performance and results of clinical trials with Teflon stents. Only Binmoeller et al (2) reported superior performance in an uncontrolled clinical trial of the Teflon Soehendra-type Tannenbaum stent. Their results could, however, not be confirmed in a controlled clinical trial (8). The stent with a thin stainless steel mesh and an inner Teflon coating had an irregular inner surface that was less explicit than the Teflon Tannenbaum stent. The difference in surface smoothness between a Teflon stent and a Teflon coated stent may be due to the fact that the latter stent is probably not manufactured by means of extrusion. This stent is supposed to have a greater internal diameter compared with other polyethylene stents (9). This prompted us to determine the internal diameter of the stents investigated in this study. It turned out that this diameter varies; we could not confirm an increased internal diameter of the Teflon coated stent (Table 1). In conclusion, the surface smoothness of commercially available biliary endoprostheses is highly variable. Additional damage to the stent surface may occur during the mechanical process of placing the stent (10). Because the smoothness of the surface has been shown to influence stent performance considerably, we suggest evaluation by SEM of stents that are to be evaluated in clinical trials.
Table 1. Characteristics of 10F biliary stents.

<table>
<thead>
<tr>
<th>Material</th>
<th>Manufacturer</th>
<th>Design</th>
<th>External diameter (mm)</th>
<th>Internal diameter (mm)</th>
<th>Wall thickness (mm)</th>
<th>Contrast additives</th>
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<tr>
<td>Polyethylene</td>
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<td>3.4</td>
<td>2.5</td>
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<td>Bismuth</td>
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<td>Chromium</td>
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<td>Barium, bismuth</td>
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<td>Tannenbaum-type</td>
<td>3.2</td>
<td>2.4</td>
<td>0.40</td>
<td>Barium</td>
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Fig. 1.
A. SEM of a polyethylene stent showing a relief with tiny lumps (5 kV). Inset shows the stent image with 25 kV at the same magnification. Bar at bottom = 100 μm.
B. SEM of a polyethylene stent showing areas with barbs (5 kV). Bar = 100 μm.
C. SEM of an Amsterdam-type Teflon stent showing multiple shallow pits and ridges along the entire longitudinal axis (25 kV). Bar = 100 μm.
D. SEM of a Teflon Tannenbaum stent showing multiple shallow pits and ridges along the entire longitudinal axis and multiple particles protruding into the stent lumen with adjacent holes in the wall of the stent (25 kV). Bar = 100 μm.
E. SEM of a Teflon coated stent showing a few shallow pits and ridges along the longitudinal axis and particles protruding into the stent lumen (5 kV). Bar = 0.1 mm.
F. Low magnification image of a Teflon coated stent showing a relief of the stainless steel mesh (25 kV). Bar = 1 mm.
G. Low magnification of a polyurethane stent (bar = 1 mm). Inset shows the surface of the stent at high magnification (bar = 20 μm; 25 kV). The surface was extremely smooth and the white particle in the right upper corner was placed to enable focusing on the stent surface. In the absence of surface structure this is otherwise extremely difficult.
REFERENCES