A 83-year-old male with a history of angina pectoris presented with massive intracranial hemorrhage in June 2011, and he died 2 days after admission. Previously, he was included in the first in-human feasibility study of biodegradable poly-l-lactic acid (PLLA) coronary stents: the Igaki-Tamai stents (Kyoto Medical Planning Co Ltd, Kyoto, Japan).1,2 To assess the long-term behavior of PLLA coronary stents in humans, postmortem examination of his coronary arteries was performed.

In November 1999, he was diagnosed with stable angina pectoris, and coronary angiography disclosed a single lesion at the middle part of left anterior descending coronary artery (Figure 1A). One Igaki-Tamai stent had been implanted with successful result (Figure 1B). He received follow-up coronary angiography at 6 months, which showed restenosis at the distal edge of the stent (Figure 1C). Because he was asymptomatic, reintervention was avoided. Additional coronary angiography at 2 and 6 years of follow-up revealed late lumen enlargement (Figure 1D and 1E).

The coronary arteries were examined histopathologically by hematoxylin and eosin staining and other histochemical methods. The spaces previously occupied by PLLA struts had disappeared, suggesting complete degradation of PLLA (Figure 2A, 2D, and 2G). Inflammatory cell infiltration, foreign body reaction, and thrombus were not observed. The neointima consisted of connective tissue (Figure 2B, 2E, and 2H) and smooth muscle cells (Figure 2C, 2F, and 2I), and this stable neointimal layer sealed off old preexisting atherosclerotic plaques. The phenomenon of so-called neoatherosclerosis was not observed.

The Igaki-Tamai stent is the first in-human biodegradable scaffold, and this is the first human histology case to show the complete biodegradation of PLLA. Although this is only a single case, the histological examination indicates the biocompatibility and the long-term safety of PLLA. This biodegradable scaffold technology can be one of the ideal treatment choices for coronary artery disease, especially when viewed from a long-term standpoint.

Disclosures
Shiga Medical Center for Adults has participated in a clinical study which evaluates PLLA stent for peripheral artery disease, provided by Kyoto Medical Planning Co Ltd, Kyoto, Japan. The authors report no conflicts.

References
Figure 1. Coronary angiography of the left anterior descending coronary artery (LAD). The index lesion (A). One 4×12-mm Igaki-Tamai stent had been implanted (B). Follow-up angiography 6 months (C), 2 years (D), and 6 years (E) after implantation of the Igaki-Tamai stent. Although restenosis was observed at the distal edge of the stent (C), late lumen enlargement was observed at 2 and 6 years of follow-up (D and E). The yellow arrows indicate the radio-opaque gold markers at the edges of the stent. The white lines (F) indicate the sites corresponding to the histological cross-sections shown in Figure 2.

Figure 2. Cross-sectional histology of the left anterior descending coronary artery (LAD) at the site where an Igaki-Tamai stent had been implanted. A corresponds to the white line A in Figure 1F, and B corresponds to the white line B in Figure 1F. The spaces previously occupied by poly-l-lactic acid (PLLA) had completely disappeared (A, D). Inflammatory cell infiltration, foreign body reaction, and thrombus were not observed. The stable neointimal layer sealed off old preexisting atherosclerotic plaques. The phenomenon of so-called neoatherosclerosis was not observed. Magnified histology of the neointima (G, H, I). In the neointima, proliferation of connective tissue and smooth muscle cells are shown using Elastiva van Gieson (EVG) staining (B, E, H) and α-smooth muscle (SM) actin staining (C, F, I), respectively. H.E indicates hematoxylin and eosin.
Decade of Histological Follow-Up for a Fully Biodegradable Poly-l-lactic Acid Coronary Stent (Igaki-Tamai Stent) in Humans: Are Bioresorbable Scaffolds the Answer?
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