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ORIGINAL ARTICLE

Transcatheter heart valve crimping and the protecting effects of a polyester cuff

Sertissage des valves cardiaques percutanées et la protection possible d'une collerette de tissu

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KEYWORDS
Transcatheter valves;
Crimping;
Fabric skirt;
Bovine pericardium

Summary
Introduction. — Prior to deployment, the percutaneous heart valves must be crimped and loaded into sheaths of diameters that can be as low as 6 mm for a 23 mm diameter valve. However, as the valve leaflets are fragile, any damage caused during this crimping process may contribute to reducing its long-term durability in vivo.
Material and method. — Bovine pericardium percutaneous valves were manufactured as follows. The leaflets were sutured on a nitinol frame. A polyester cuff fabric served as a buffer between the pericardium and the stent. Two valves were crimped and one valve was used as control. The valves were examined in gross observation and micro-CT scan and then the leaflets were processed for histology and analyzed in scanning electron microscopy, light microscopy and transmission electron microscopy.
Result. — Crimping of the valves resulted in the increase thickness of the leaflets and there was no evidence of additional delamination. The heavy prints of the stents were irregularly distributed on the outflow surface in the crimped devices and were shallow and did not penetrate throughout the thickness of the leaflets. However, the wavy microscopy of collagen fiber bundles was well preserved. They were found to remain individualized without any agglutination as shown by the regular banding appearance.

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Conclusion. — Crimping of self-deployable valves per se caused only minor damages to the leaflets. However, the procedure could be refined in order to minimize areas of high pressure and swelling of the tissue that can be accompanied with flow surface disruption and increase of the hydraulic conductance. The incorporation of a polyester buffer serves to prevent the deleterious effects that may be caused if the pericardium tissue were in direct contact with the nitinol stent.

MOTS CLÉS
Valves percutanées ;
Sertissage ;
Collerette de suture ;
Péricarde de veau

Résumé
Introduction. — Les valves cardiaques percutanées doivent être serties avant d'être déployées afin de pouvoir les introduire dans des cathéters de diamètres aussi faibles que 6 mm pour une valve de 23 mm de diamètre. Cependant, comme les feuillets des valves sont fragiles, tout dommage résultant du sertissage pourrait contribuer à réduire la durabilité in vivo à long terme.
Matériel et méthode. — Les valves percutanées en péricarde de veau furent montées comme suit : les feuillets furent suturés sur un tuteur en nitinol comportant une collerette de tissu placée entre le péricarde et le stent pour prévenir leur contact. Deux valves furent serties et la troisième servit de contrôle. Les valves furent observées à l'œil nu et au micro CT-scan avant de préparer les feuillets pour les examens histologiques, en microscopie électronique à balayage, en microscopie optique et en microscopie électronique à transmission.
Résultats. — Les dommages structuraux causés par le sertissage des valves se sont caractérisés par une augmentation de l'épaisseur de la paroi. Les marques des fils de nitinol étaient réparties de façon irrégulière à la surface séreuse (éjection) des valves après sertissage. Ces marques étaient superficielles et ne pénétraient pas dans toute l'épaisseur des feuillets. Les faisceaux de collagène ont conservé leur structure ondulée et chaque filament de collagène demeurait bien individualisé sans aucune agglutination et les striations périodiques étaient bien mises en évidence et régulières.
Conclusion. — Le sertissage des valves autodéployables n'a pas entraîné de lésions dramatiques. Cependant, cette procédure doit être raffinée afin de restreindre les zones ou les tissus sont soumis à une pression élevée afin de prévenir les fractures de surface. Le gonflement des tissus contribuerait à l'augmentation de la conductance hydraulique. L'incorporation d'une collerette de tissus a vraisemblablement permis de prévenir les dommages profonds qu'aurait entraîné le contact direct entre le feuillet de péricarde et le stent de nitinol.

Introduction

The non-surgical valve replacement is a recent and vibrant development in minimally invasive procedures for the treatment of frail and elderly patients with vascular disease who are not fit to undergo complex open-heart surgery. Since the early experimental work of Andersen in pigs in 1992 [1] and the first clinical intervention in patients by Cribier in 2002 [2], probably more than 100 000 patients worldwide have received an implanted aortic valve by way of placement, through either a retrograde transarterial or an antegrade transapical access [3—5].

Over the past decade, the increasing number of reports on the clinical efficacy and safety of this emerging minimally invasive technique [6,7] is evidence of a rapidly maturing innovation [8,9], thanks to numerous physician driven initiatives and investments from the industry, together with accessibility to more sophisticated imaging capabilities. This technology has gained clinical acceptability and there is an emerging consensus that its restriction to frail patients should be extended to less risky patients as the technique is highly effective and it is anticipated that this procedure may soon exceed the number of open surgical cases [10]. It compares favorably with open surgery in frail patients with multiple comorbidities. However, the pressure to treat a broader range of patients percutaneously is pushing the medical community to extend the indications [6]. In addition, many patients express a preference for the minimally invasive procedures as recovery time is much shorter.

It is thought, however, that the handling procedures i.e. crimping with or without balloon inflation, of the valves in the operating room can severely damage the tissues and thus reduce the potential longevity of the valves. Prior to transcatheter deployment, the valve must be loaded in a sheath after crimping. Balloon-expandable valves which are made of stainless steel or cobalt-chromium stents require mandatory balloon inflation to be properly deployed and fixed in situ. The traumatic effects of the balloon inflation on these devices were recently highlighted by Zegdi et al. [11] and others [12], raising questions about the long-term durability of the devices in vivo [13]. The precise impact of these injuries remains unknown but thrombosis and possible kidney and cerebral embolization cannot be ignored [14—17]. These adverse events which are classified as either patient-related or device-related do occur and deserve proper attention [18,19]. They are probably under-reported as evidenced by the irreversible damages caused to the structure of the leaflets during the handling procedures

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