ROY NORREI

20344017 PubMed Identifier 10888104 Authors

Adamczyk MM. Lee TC. Vesely I. Institution

Department of Biomedical Engineering, The Lerner Research Institute, The Cleveland Clinic Foundation, Ohio, USA. Title

Biaxial strain properties of elastase-digested porcine aortic valves. Source

Journal of Heart Valve Disease. 9(3):445-53, 2000 May. Local Messages

MU HSL owns some issues. Check Library Catalog Holdings. Abstract

BACKGROUND AND AIMS OF THE STUDY: Previous studies have suggested that elastin in porcine aortic valve cusps is responsible for restoring collagen fibers to their original configuration between loadingunloading cycles. METHODS: Biaxial loading tests were performed on intact aortic valves before and after elastase treatment to further investigate the role of elastin. RESULTS: Degradation of elastin caused an increase in the radial dimensions of the cusps (mean increase in gauge length, 29%), which corresponded to a significant decrease in radial extensibility (mean decrease, 61%) and a threefold increase in radial stiffness. Changes in circumferential extensibility and stiffness were smaller and, for most cusps, were not statistically significant. Control experiments, in which the valves were treated with buffer only, resulted in the opposite changes in radial dimensions and extensibility (7% decrease in gauge length and doubling of extensibility). CONCLUSION:

mechanical properties of the aortic valve cusps following incubation in elastase were due to elastin damage, and not incidental to soaking in buffer. As many explanted bioprosthetic valves have mechanical characteristics similar to those of the elastase-treated valves, elastin damage may be a factor in the progressive degeneration and ultimate failure of bioprosthetic heart valves.

Citation <3> Unique Identifier 20377409 PubMed Identifier 10916068 Authors Morsi YS. Sakhaeimanesh AA. Institution Bio-fluid Dynamics Group, Center for Modeling and Process Analysis, School of Engineering and Science, Swinburne University of Technology, Hawthorn, Victoria, Australia. ymorsi@groupwisewin.edu.au Title Flow characteristics past jellyfish and St. Vincent valves in the aortic position under physiological pulsatile flow conditions. Source Artificial Organs. 24(7):564-74, 2000 Jul. Local Messages Owned by MU HSL Abstract Thrombus formation and hemolysis have been linked to the dynamic flow characteristics of heart valve prostheses. To enhance our understanding of the flow characteristics past the aortic position o valve in the left ventricle, in vitro laser Doppler an NORRED EXHIBIT 2032 - Page 1 Medtronic, Inc., Medtronic Vascular, Inc., & Medtronic Corevalve, LLC v. Troy R. Norred, M.D. Case IPR2014-00110

Find authenticated court documents without watermarks at docketalarm.com.



20344017 PubMed Identifier 10888104 Authors

Adamczyk MM. Lee TC. Vesely I. Institution

Department of Biomedical Engineering, The Lerner Research Institute, The Cleveland Clinic Foundation, Ohio, USA. Title

ROY NORREI

Biaxial strain properties of elastase-digested porcine aortic valves. Source

Journal of Heart Valve Disease. 9(3):445-53, 2000 May. Local Messages

MU HSL owns some issues. Check Library Catalog Holdings. Abstract

BACKGROUND AND AIMS OF THE STUDY: Previous studies have suggested that elastin in porcine aortic valve cusps is responsible for restoring collagen fibers to their original configuration between loadingunloading cycles. METHODS: Biaxial loading tests were performed on intact aortic valves before and after elastase treatment to further investigate the role of elastin. RESULTS: Degradation of elastin caused an increase in the radial dimensions of the cusps (mean increase in gauge length, 29%), which corresponded to a significant decrease in / radial extensibility (mean decrease, 61%) and a threefold increase in radial stiffness. Changes in circumferential extensibility and stiffness were smaller and, for most cusps, were not statistically significant. Control experiments, in which the valves were treated with buffer only, resulted in the opposite changes in radial dimensions and extensibility (7% decrease in gauge length and doubling of extensibility). CONCLUSION: Changes in the!

Lew 6

mechanical properties of the aortic valve cusps following incubation in

elastase were due to elastin damage, and not incidental to soaking in buffer. As many explanted bioprosthetic valves have mechanical characteristics similar to those of the elastase-treated valves, elastin damage may be a factor in the progressive degeneration and ultimate failure of bioprosthetic heart valves. Citation <3> Unique Identifier 20377409 PubMed Identifier 10916068 Authors Morsi YS. Sakhaeimanesh AA. Institution Bio-fluid Dynamics Group, Center for Modeling and Process Analysis, School of Engineering and Science, Swinburne University of Technology, Hawthorn, Victoria, Australia. ymorsi@groupwisewin.edu.au Title Flow characteristics past jellyfish and St. Vincent valves in the aortic position under physiological pulsatile flow conditions. Source Artificial Organs. 24(7):564-74, 2000 Jul. Local Messages Owned by MU HSL Abstract Thrombus formation and hemolysis have been linked to the dynamic flow characteristics of heart valve prostheses. To enhance our understanding of the flow characteristics past the aortic position of a Jellyfish (JF) valve in the left ventricle, in vitro laser Doppler anemometry (LDA)

Find authenticated court documents without watermarks at docketalarm.com.



nox Worred

Kunzelman KS. Grande-Allen KJ. Cochran RP. Reinhall PG. Institution

Department of Biomedical Engineering, Cleveland Clinic Foundation, Cleveland, OH, USA.

Title Re-creation of sinuses is important for sparing the aortic valve: a finite element study.

Source 119(4 Pt 1):753-63, Journal of Thoracic & Cardiovascular Surgery. 2000 Apr.

Local Messages

Owned by MU HSL

Abstract

OBJECTIVE: The treatment of choice for aortic valve insufficiency due to root dilatation has become root replacement with aortic valve sparing. However, root replacement with a synthetic graft may result in altered valve stresses. The purpose of this study was to compare the stress/strain patterns in the spared aortic valve in different root replacement procedures by means of finite element modeling. METHODS: Our finite element model of the normal human root and valve was modified to simulate and evaluate three surgical techniques: (1) "cylindrical" graft sutured below the valve at the anulus, (2) "tailored" graft sutured just above the valve, and (3) "pseudosinus" graft, tailored and sutured below the valve at the anulus. Simulated diastolic pressures were applied, and stresses and strains were calculated for the valve, root, and graft. Leaflet coaptation was also quantified. RESULTS: All three root replacement models demonstrated significantly altered leaflet stress patter!

ns as compared with normal patterns. The cylindrical model showed the greatest increases in stress (16%-173%) and strain (10%-98%), followed by the tailored model (stress +10%-157%, strain +9%-36%). The pseudosinus model showed the smallest increase in stress (9%-28%) and strain (2%-31%), and leaflet coaptation was closest to normal. SONCLOSION, Valve-sparing techniques that allow the potential for sinus space formation (tailored, pseudosinus) result in simulated leaflet stresses that are closer to normal than the cylindrical technique. Normalized leaflet stresses in the clinical setting may result in improved longevity of the spared valve.

Citation <9> Unique Identifier 20175579

PubMed Identifier 10708772 Authors

Schreurs PJ. Peters GW. Cacciola G. Institution

Department of Mechanical Engineering, Eindhoven University of Technology, P.O. Box 513, 5600 MB Eindhoven, The Netherlands. giovanna@wfw.wtb.tue.nl Title

A three-dimensional mechanical analysis of a stentless fibrereinforced aortic valve prosthesis.

Source 33(5):521-30, 2000 May. Journal of Biomechanics. Local Messages

MU HSL owns some issues. Check Library Catalog Holdings. Abstract

Failure of bioprosthetic and synthetic three-leaflet valves has been. shown to occur as a consequence of high tensile and bending stresses,

Warred rov

acting on the leaflets during opening and closing. Moreover, in the stented prostheses, whether synthetic or biological, the absence of contraction of the aortic base, due to the rigid stent, causes the leaflets to be subjected to an unphysiological degree of flexure, which is related to calcification. It is shown that the absence of the stent, which gives a flexible aortic base and leaflet attachment, and leaflet fibre-reinforcement result in reduced stresses in the weaker parts of the leaflets in their closed configuration. It is postulated that this leads to a decrease of tears and perforations, which may result in a improved long-term behaviour. The effect of a flexible leaflet attachment and aortic base of a synthetic valve is investigated with a finite element model. Different fibre-reinforced structures are analysed with respect to!

the stresses that are likely to contribute to the failure of fibrereinforced prostheses and compared with the results obtained for a stented prosthesis. Results show that for the stentless models a reduction of stresses up to 75% is obtained with respect to stented models with the same type of reinforcement.

Citation <10> Unique Identifier 20140328 PubMed Identifier 10677158 Authors

Sakhaeimanesh A. Clayton BR. Morsi YS. Institution

1- The

Centre for Research and Technology Development, School of Engineering and Science, Swinburne University of Technology, Hawthorn, Victoria, Australia. ymorsi@swin.edu.au Title

Hydrodynamic evaluation of three artificial aortic valve chambers. Source

Artificial Organs. 24(1):57-63, 2000 Jan.

Local Messages Owned by MU HSL

Abstract

The effect of chamber geometry on the characteristics of turbulent steady flow through a newly designed artificial heart valve, "the jellyfish valve," has been investigated for flow rates matching those of peak systole. Laser Doppler Anemometry (LDA) was employed to determine the velocity and shear stress distributions at various locations downstream of the jellyfish valve. Three geometrically different aortic valve chambers have been investigated: namely, a chamber with sinuses of Valsalva, an ellipsoidal chamber, and a cylindrical chamber. The results of this investigation indicated that the aorta with sinuses of Valsalva model had the highest turbulent shear stresses whereas the ellipsoidal model gave the highest-pressure drops. However, for the various flow rates examined, including the systole peak value of 26 L/min, it appears that the ellipsoidal model displays better hydrodynamic characteristics in terms of shear stress and uniformity of axial velocity distributions

downstream of the jellyfish valve.

Citation <11> Unique Identifier 99438602 PubMed Identifier 10509186

Photocopy

Find authenticated court documents without watermarks at docketalarm.com.

Udrren

Authors

Sung HW. Chang Y. Chiu CT. Chen CN. Liang HC. Institution

Department of Chemical Engineering, National Central University, Chung-Li, Taiwan, ROC. hwsung@cc.ncu.edu.tw Title

Mechanical properties of a porcine aortic valve fixed with a naturally occurring crosslinking agent. Source

Biomaterials. 20(19):1759-72, 1999 Oct.

Local Messages

MU HSL owns some issues. Check Library Catalog Holdings. Abstract

The study investigates the mechanical properties of porcine aortic valve leaflets fixed with a naturally occurring crosslinking agent, (genipin) at distinct pressure heads. Fresh and the glutaraldehyde fixed counterparts were used as controls. Subsequent to fixation, the changes in leaflet collagen crimps and its surface morphology were investigated by light microscopy and scanning electron microscopy (SEM). Also, the crosslinking characteristics of each studied group were determined by measuring its fixation index and denaturation temperature. In the mechanical testing, tissue strips made from each studied group were examined in both the circumferential and radial directions. Histological and SEM comparisons between fresh porcine aortic valve leaflet and those fixed at medium or high pressure revealed that the following changes may occur: elimination of the natural collagen crimping, and extensive loss of the endothelial layer. The denaturation temperatures of the glutaralde!

hyde-fixed leaflets were significantly greater than the genipin-fixed leaflets; however, their fixation indices were comparable. Generally, fixation pressure did not affect the crosslinking characteristics of the genipin- and glutaraldehyde-fixed leaflets. It was found that fixation of porcine aortic valves in genipin or glutaraldehyde did not alter the mechanical anisotropy observed in fresh valve leaflets. This indicated that the intramolecular and intermolecular crosslinks introduced into the collagen fibrils during fixation is of secondary importance to the presence of structural and mechanical anisotropy in fresh leaflet. Tissue fixation in genipin or glutaraldehyde may produce distinct crosslinking structures. However, the difference in crosslinking structure between the genipin- and glutaraldehyde-fixed leaflets did not seem to cause any significant discrepancies in their mechanical properties when compared at the same fixation pressure. Nevertheless, regardless of the !

crosslinking agent used, changes in mechanical properties and ruptured patterns were observed when the valve leaflets were fixed at distinct pressures.

Estimation of the shear stress on the surface of an aortic valve

Biomedical

Citation <12> Unique Identifier 99396317 PubMed Identifier 10468241 Authors

hotoc

Weston MW. LaBorde DV, Yoganathan AP. Institution

Institute of Bioengineering and Bioscience, School of Biomedical, Engineering, Georgia Institute of Technology Atlanta 30332-0535, USA. Title

leaflet.

Find authenticated court documents without watermarks at doce BEPREXHBIT 2032 - Page 4

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.