



*TaurusWave*<sup>®</sup>

## 冲击波瓣膜治疗系统

产品介绍及首次人体临床试验介绍

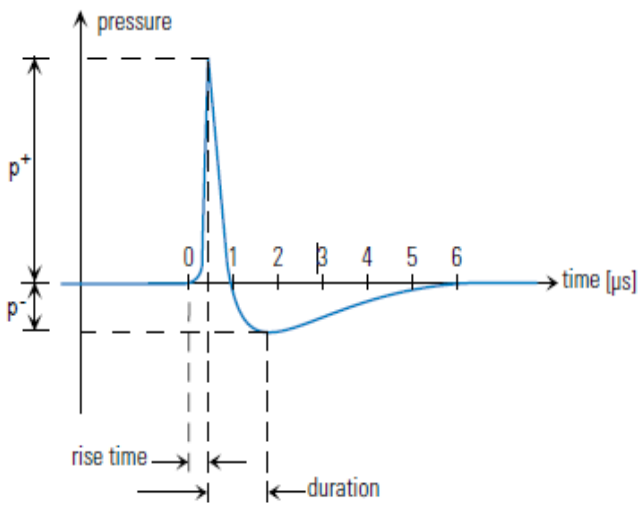
至善尽心 敬畏生命

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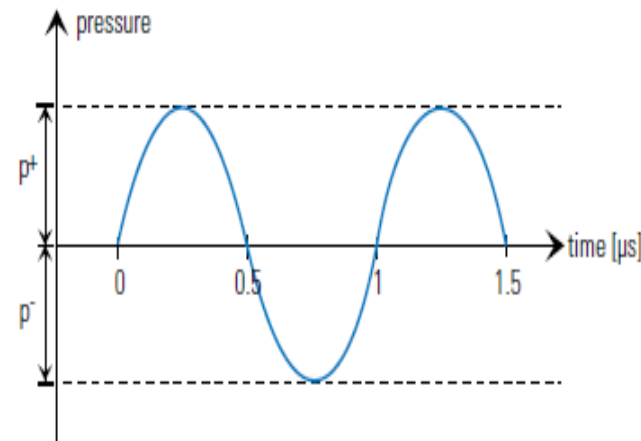
- 01 冲击波治疗原理及介绍
- 02 TaurusWave® 冲击波瓣膜治疗系统
- 03 动物实验与可行性测试
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# 什么是冲击波(Shock Wave)?



## 冲击波

- ✦ 高能波
- ✦ 单个高压峰&压力谷
- ✦ 宽频域, 由多频率组成

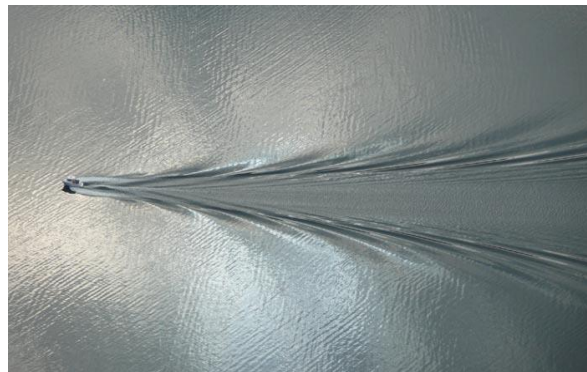


## 超声波

- ✦ 正弦波
- ✦ 具有特征频率
- ✦ 交替的压缩和稀疏



超声波



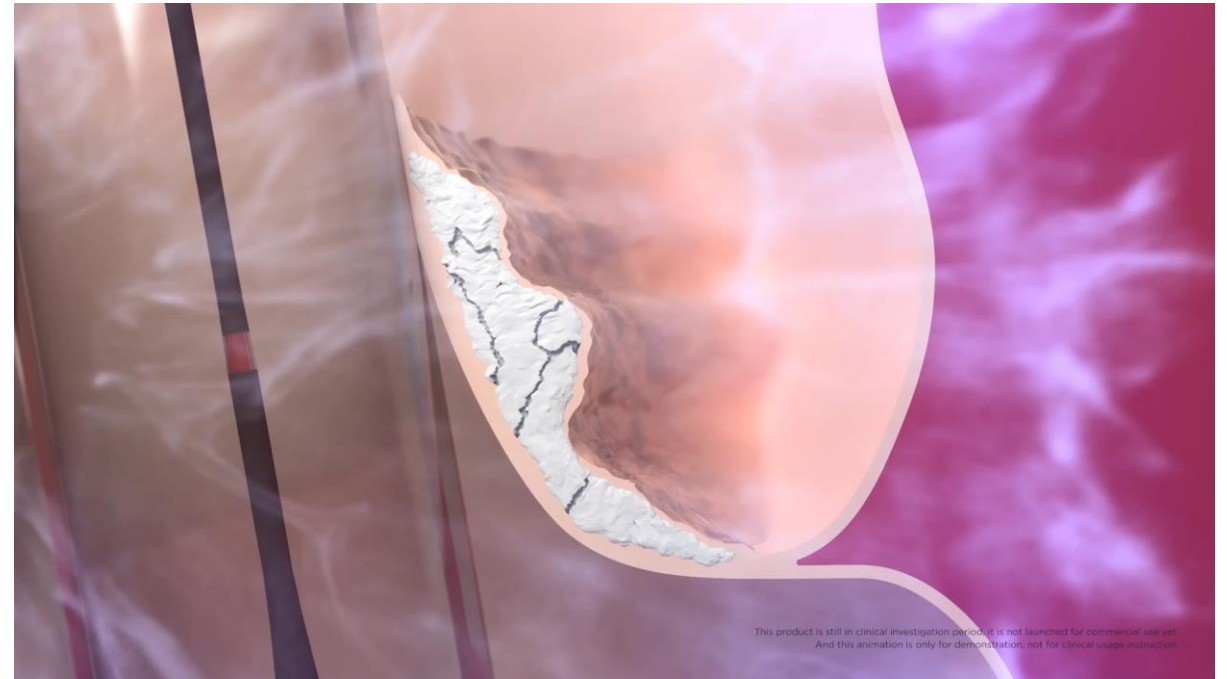
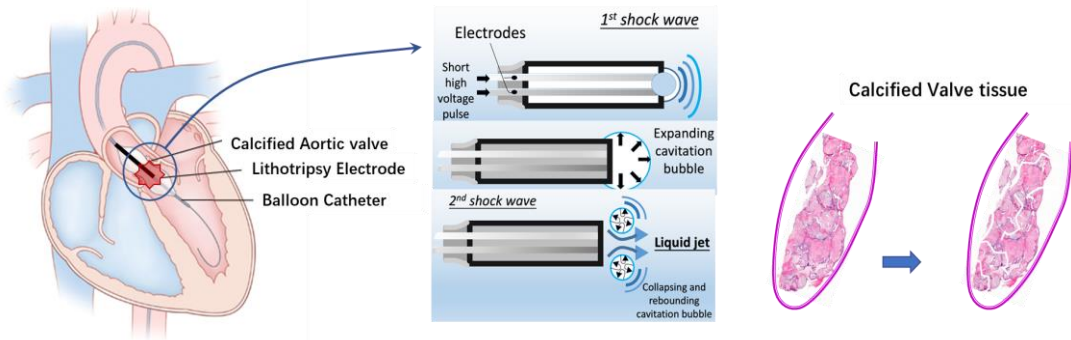
冲击波

## 医学应用中冲击波的优点

- 冲击波在人体中传播时衰减比超声波小
- 冲击波对人体组织的热损伤远小于超声波

Reference: 《Shock Wave Physics for Urologists》 by Achim M. Loske, Ph.D.

基于冲击波带来的复合机械效应，通过精准定向的脉冲式冲击波释放，达到安全、高效地松软破坏浅层与深层病灶钙化的效果，并从机理上避免软组织损伤。



钙化瓣膜的无植入治疗技术	TaurusWave®	超声波技术	瓣膜成形术	瓣膜瓣叶压刻
能量/方式	声学能量+ 物理扩张	声学能量	物理扩张	物理压刻
软化钙化组织	++	++	-	+
软组织保护性	++	++	-	-
增加瓣口面积	++	-	+	+



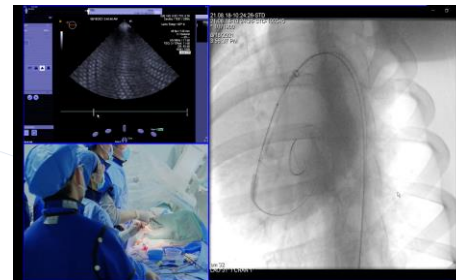
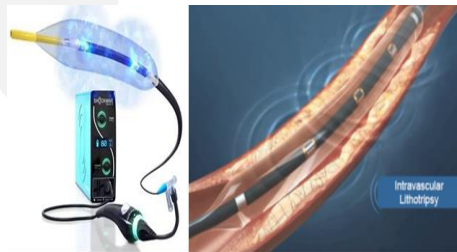
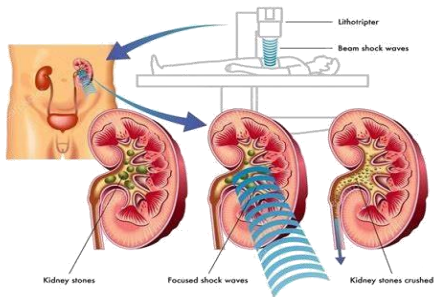
自1980s以来，冲击波技术是久经考验的治疗肾结石的技术

2000年左右，冲击波技术应用在血管内的钙化病变上

TaurusWave® 开启瓣膜冲击波技术的探索

TaurusWave® 开始动物实验，探索临床可行性

2021年10月19日  
TaurusWave® 全球首次  
人体临床研究首例入组



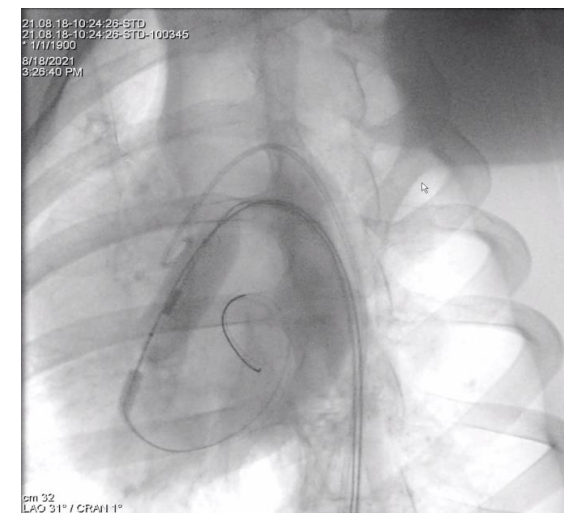
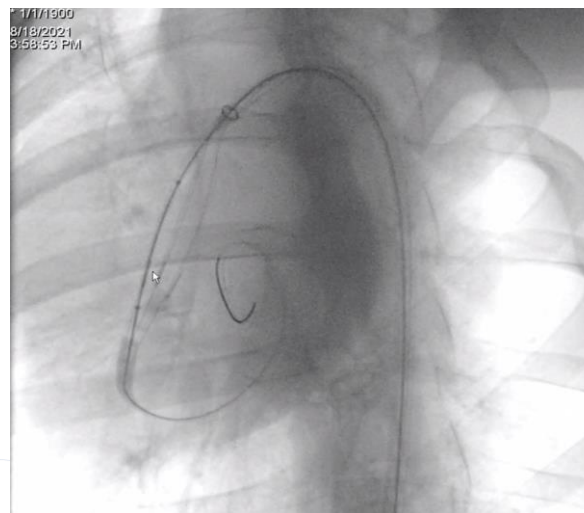
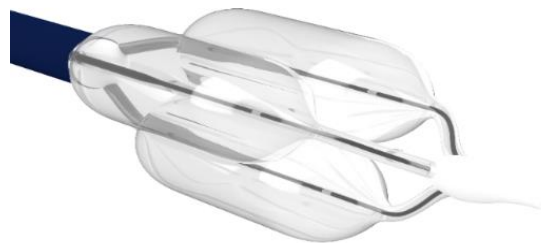
- 01 冲击波治疗原理及介绍
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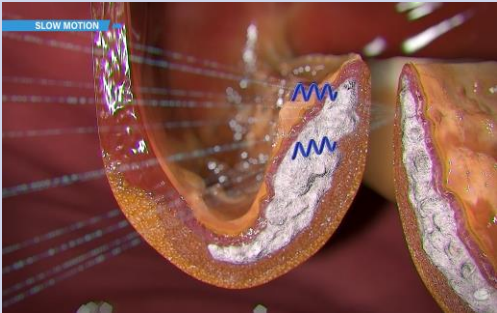
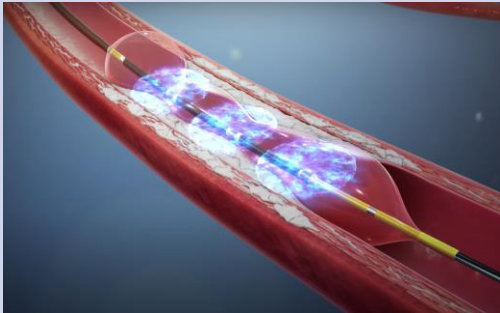
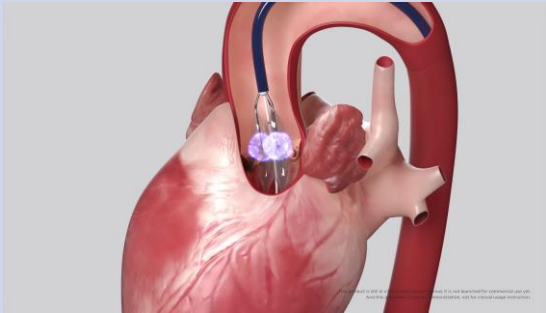
## 体内冲击波瓣膜治疗仪

## 冲击波瓣膜球囊扩张导管

- 3D系列球囊：无需起搏
- 1D系列球囊：冲击波+球囊扩张





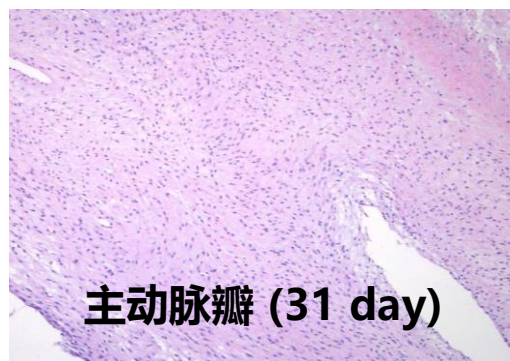
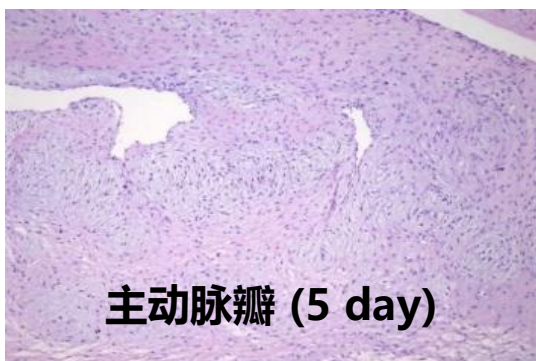
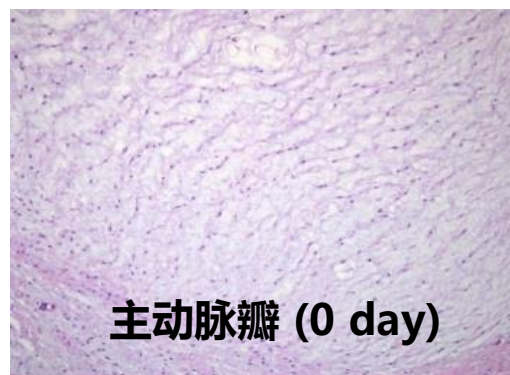
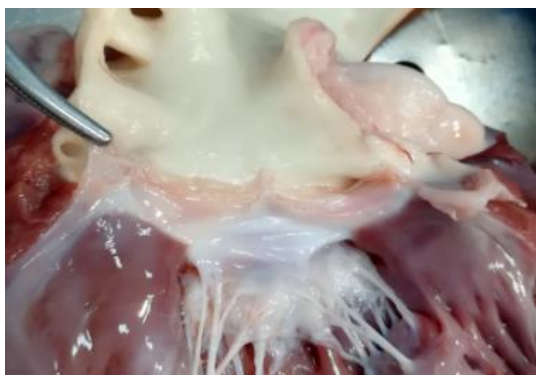
	Valvosoft®	Shockwave IVL	TaurusWave®
厂家	Cardiawave	Shockwave	Peijia
产生机制	聚焦式超声波	冲击波	冲击波
术中影像	超声影像	透视	透视
松软钙化机制	聚焦式超声引发的空化	冲击波扩散	冲击波扩散
优势	<ul style="list-style-type: none"> <li>无创</li> </ul>	<ul style="list-style-type: none"> <li>高效</li> <li>冠脉与外周血管应用</li> </ul>	<ul style="list-style-type: none"> <li>高效</li> <li>专为结构性心脏病应用设计</li> </ul>
劣势	<ul style="list-style-type: none"> <li>相对低效</li> <li>较长的治疗时间</li> </ul>	<ul style="list-style-type: none"> <li>专为小尺寸血管设计，不适合钙化瓣膜</li> </ul>	<ul style="list-style-type: none"> <li>有待更多临床样本验证</li> </ul>
示意图			

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## 即刻安全性分析及随访31天结果

解剖分析及组织染色：

主动脉瓣膜处无异常，证实冲击波技术在瓣膜治疗上的安全性



## 长期实验研究 - 安全性评估

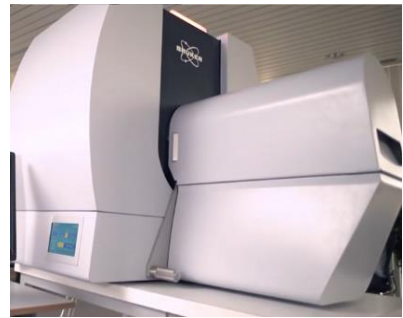
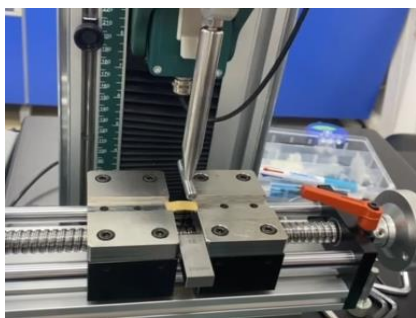
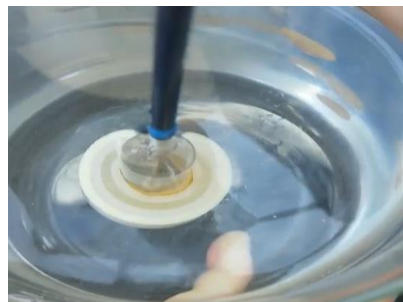
- 主动脉造影：主动脉瓣关闭正常
- 心电图：器械使用前后无异常出现
- 心脏超声：主动脉瓣正常，心室运动正常。
- 血液分析：指标正常
- 组织病理学分析：未见明显改变

## 柔韧性分析显示

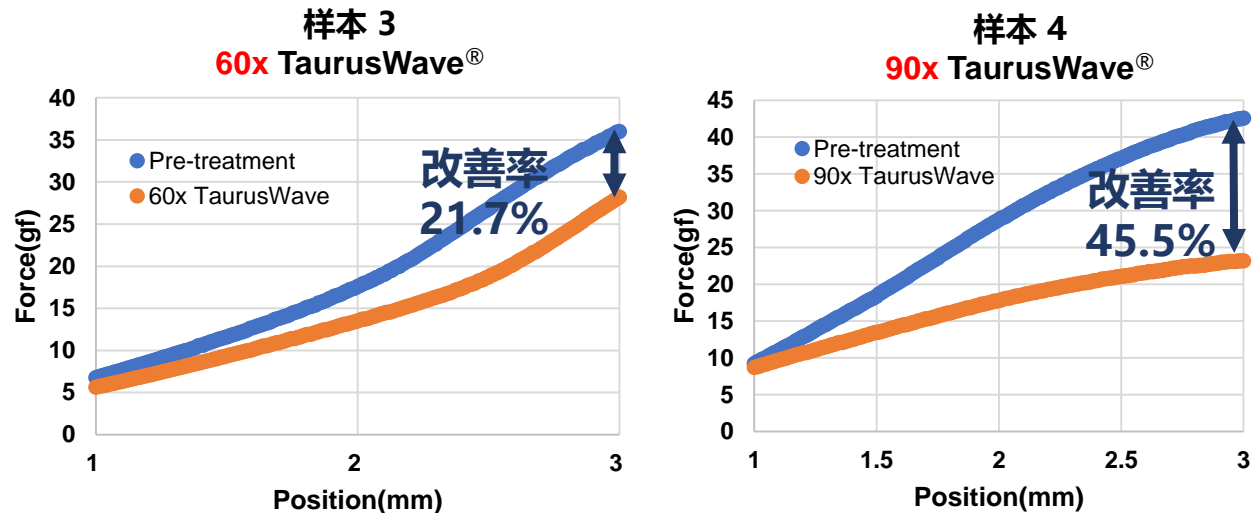
冲击波治疗能增加钙化瓣膜柔韧性  
冲击波治疗次数与柔韧性改善程度呈正相关

## Micro-CT 分析显示

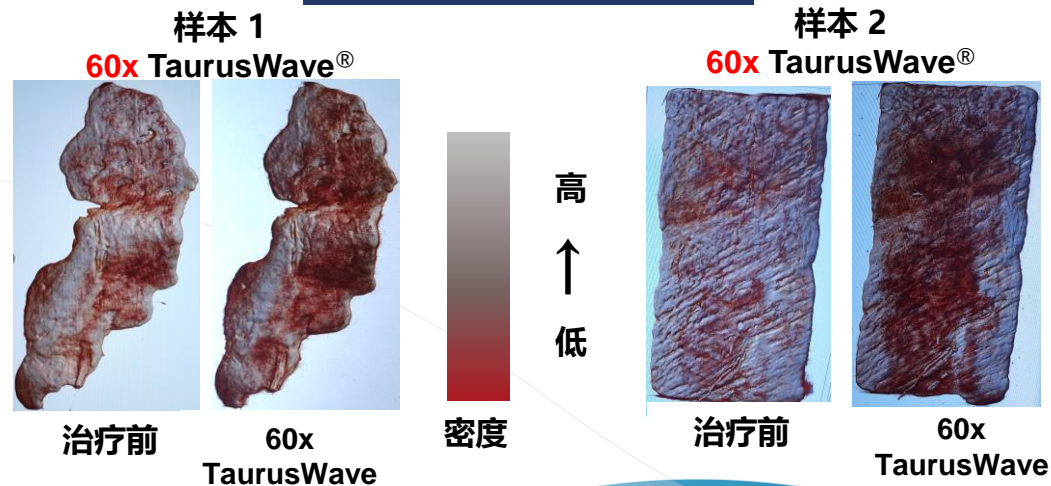
冲击波放电后钙化物表面密度降低



## 柔韧性分析



## Micro-CT 分析

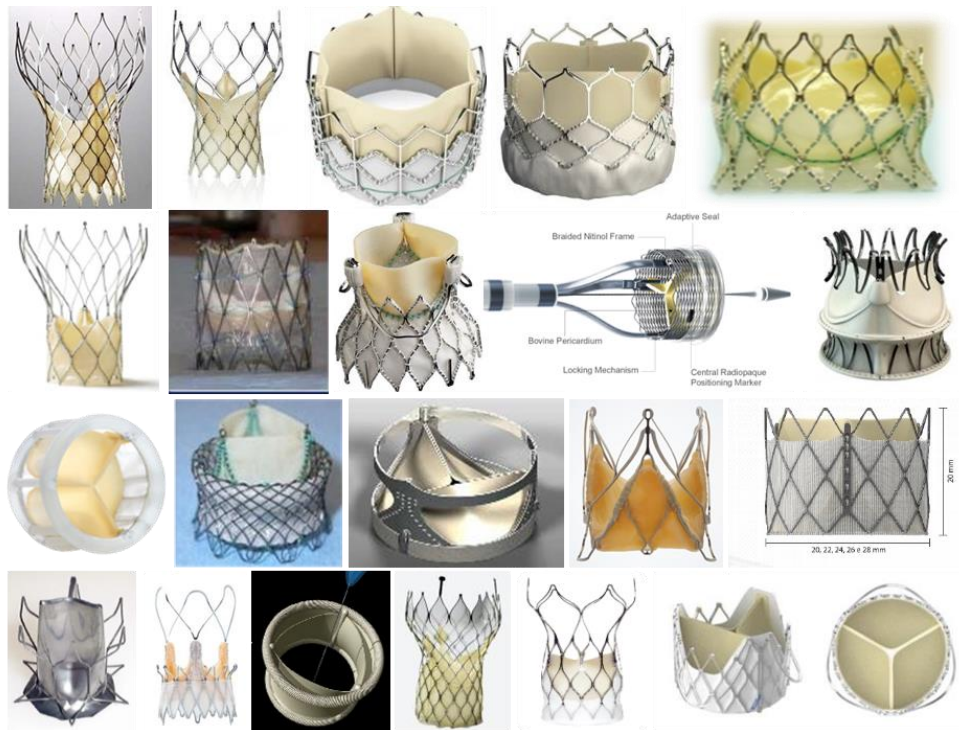


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## 经导管介入瓣膜置换治疗

中重度症状性主动脉瓣钙化狭窄治疗策略



## 并非所有患者适合TAVI

患者的基础合并症及其他因素制约着TAVI的长期预后



European Heart Journal (2016) 37, 2217–2225  
doi:10.1093/eurheartj/ehv756

REVIEW

Clinical update

## TAVI or No TAVI: identifying patients unlikely to benefit from transcatheter aortic valve implantation

Rishi Puri<sup>1,2,3</sup>, Bernard Lung<sup>4,5</sup>, David J. Cohen<sup>6</sup>, and Josep Rodés-Cabau<sup>1\*</sup>





解剖结构不适合

中、重度钙化性主动脉狭窄

严重钙化患者行TAVR前

人工瓣膜的再钙化

更年轻的患者

药物不耐受

## 术中过程

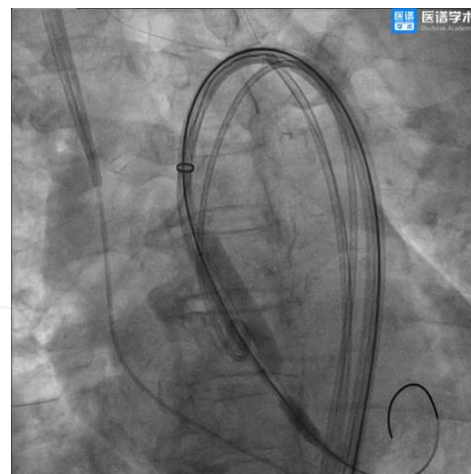
- 仅第一例病例使用了脑保护装置
- 经右侧股动脉入路，使用TaurusWave® 冲击波瓣膜治疗系统进行冲击波治疗
- 治疗前未使用球囊预扩张
- **术中过程无起搏**



过弓



冲击波治疗



球囊充盈



术后取出的脑保护装置

- TaurusWave® 冲击波瓣膜治疗系统 在目前临床阶段的使用中证明了其安全性
  - 第一例术后脑保护装置中无血栓
  - 根据术者建议，后续病例无需使用脑保护装置
- 术后即刻结果证明了TaurusWave®的初步治疗效果
  - 目前试验病例都在跨瓣压差或主动脉瓣口面积上取得了明显提升
- 将会进行更多临床试验以确认最能获得临床受益的患者人群，探索进一步的临床应用



感谢聆听

至善尽心 敬畏生命