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**THE IMPACT OF RESEARCH
AND INNOVATION
ON CARDIAC SURGERY:
The Translational experience
of University Hospital
of Novara, Italy**

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RESEARCH

Mechanical Behavior of Artificial Mitral Chordae:

ex Vivo Study and Analysis of Literature.

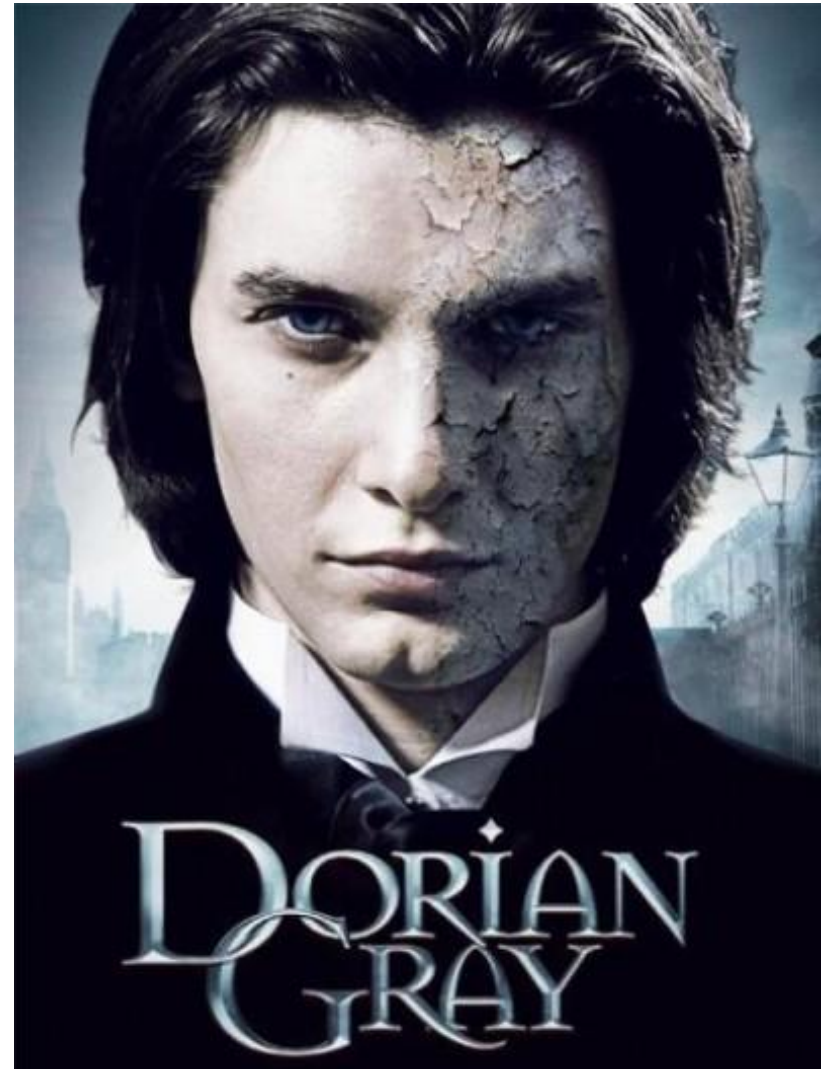
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Background

The aging of the Western population is increasing very much in health care costs and the improvement of social conditions has increased the level of quality of health perceived by the patients. The biomedical industry in turn offers new and attractive technologies to treat less invasively a growing number of diseases. All this has led to a significant rise in healthcare spending while it is controversial at the time the real positive impact on public health.



Innovation in the Italian cardiac surgery

A true revolution shakes the Italian cardiac surgery. The existing 107 centers, with over a thousand cardiac surgeons, will be reduced by almost 50%. The decree of the past Minister Balduzzi introduces criteria aimed at improving efficiency. The most effective way to reduce costs and improve outcomes is to offer patients the most appropriate treatment. Studies in countries like the United States and the Netherlands suggest that in at least 30% -40% of patients do not receive care according to current scientific knowledge, while 20% or more of the treatment is not necessary or potentially harmful to patients.



Innovation and Productivity and Effectiveness

Scientific innovation in Europe in the Middle Ages contributed to increasing labor productivity. The invention of eyeglasses has made possible the medieval craftsman, whose work depended on the fine view, to be productive up to sixty.



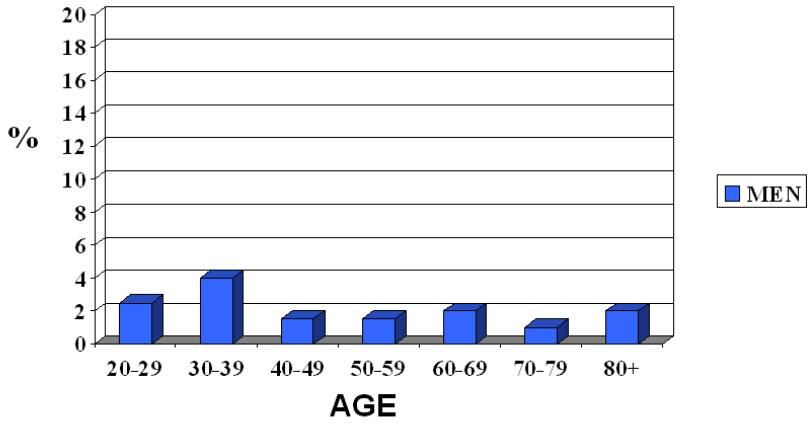
Detail of the portrait of Fra Ugone di Provenza, Tommaso da Modena, 1352. One of the first representations of eyewear, and a reproduction of hinged spectacles.

The purpose of Surgical Telescopes is to enhance or magnify an image to insure the highest quality results in surgical procedures.

- Mitral valve prolapse (MVP) is the most common heart valve abnormality in the United States and west countries with an annual incidence of 250,000 newly diagnosed patients in the U.S.
- Recent studies estimate that approximately 2 to 6% of the adult population in the United States and west country has MVP.
- Recent studies have found that 10% of healthy men and women between the ages of 23 and 35 have some degree of MR, and 93% of these people have mild MR.
- Ten percent of those over age 65 have MR, and approximately 26% have moderate to severe regurgitation.

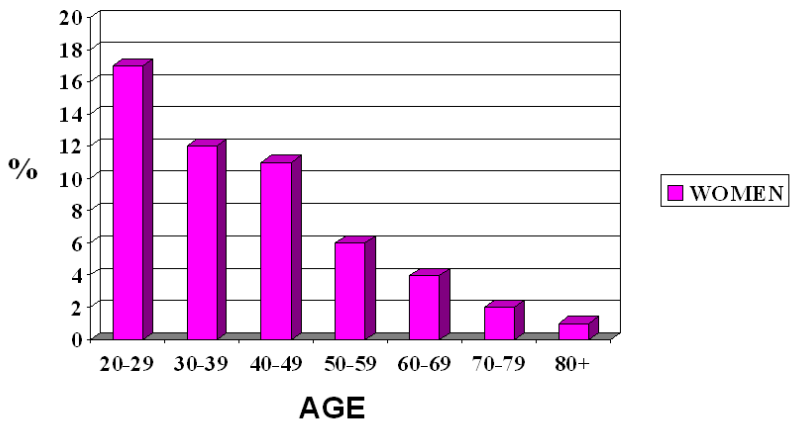
MVP in MALES

Echocardiographic Incidence



MVP in FEMALES

Echocardiographic Incidence



The Framingham Study. Graph adapted from 1992 conference by NHLBI on Cardiovascular Health and Disease in Women.

The Framingham Study. Graph adapted from 1992 conference by NHLBI on Cardiovascular Health and Disease in Women.

- Mitral valve repair by the use of artificial chordae in expanded polytetrafluoroethylene (ePTFE) has become the gold standard in treatment of mitral regurgitation (MR) due to mitral valve prolapse (MVP).



However there is no available evidence in the literature comparing the mechanical behavior of ePTFE chordae to human ones, nor to alternative types of artificial chordae.

Methods

- Mechanical properties of native and synthetic chordae tendineae of mitral valve were tested with an Instron servo hydraulic testing machine (Instron Load Frame 5564).
- In particular, stress/strain curves and Young modulus of the different chordae were evaluated.
- Every specimen were strained at a speed of 30 mm/min, to a maximum tension of 0,75 N (75 g) load, to obtain the same tension to which chordae are exposed on average in the human body.
- The test has been repeated 20 times, obtaining 20 stress/strain curves for every sample.
- For every stress/strain curve, the curve trend were calculated.

Instron servo hydraulic testing machine
(Instron Load Frame 5564).

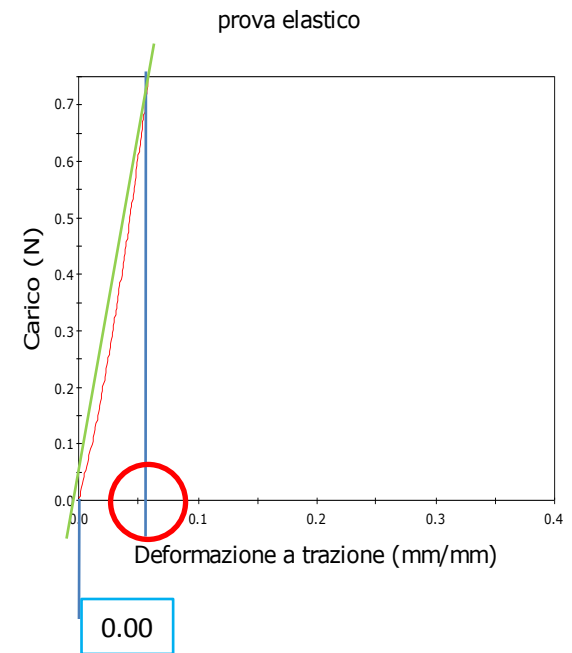
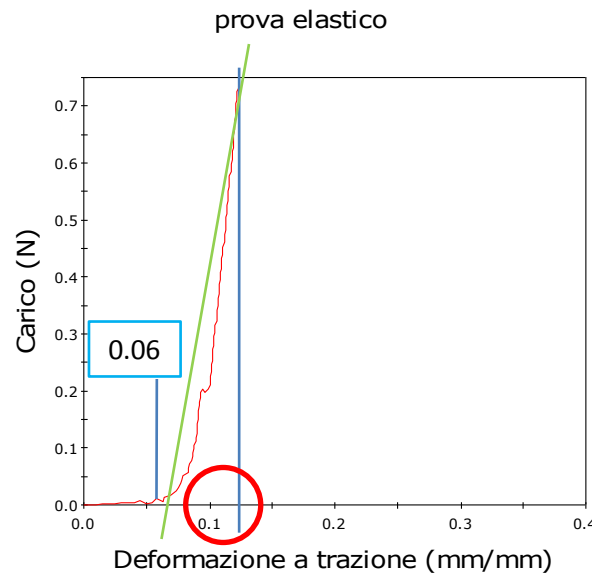
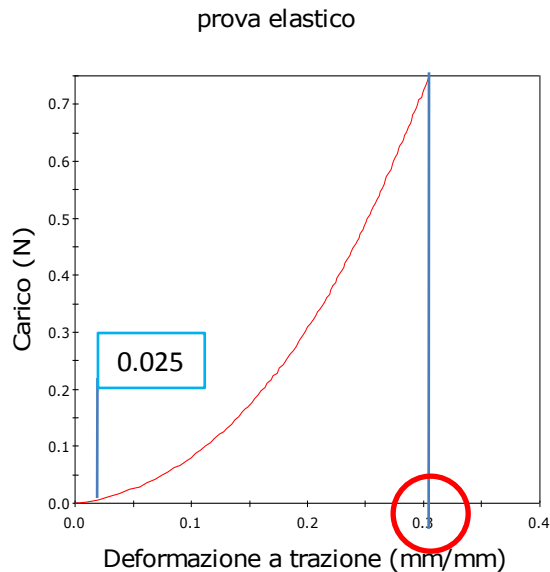


The native chordae has been isolated from the fresh specimen excluding any portion of leaflets and papillary muscle in order to avoid any influence of these remnant on mechanics of native chordae. For the same reason we used an highly efficient and selective pneumatic branching device to eliminate any influence of point of connection between native or synthetic chordae to the Instron .

Results

- Initial strain was: 0.06mm for e-PTFE, 0.025mm for human chordae, 0.0mm for Polypropilene.
- Final strain (stress 0.75N) was: 0.13mm for e-PTFE shows of, 0.31mm for human chordae and 0.06 mm for Polypropilene.

The stress/strain curve of e-PTFE presents a bimodal hysteresis: the second half of curve is very similar to the curve of Polypropilene



Conclusions

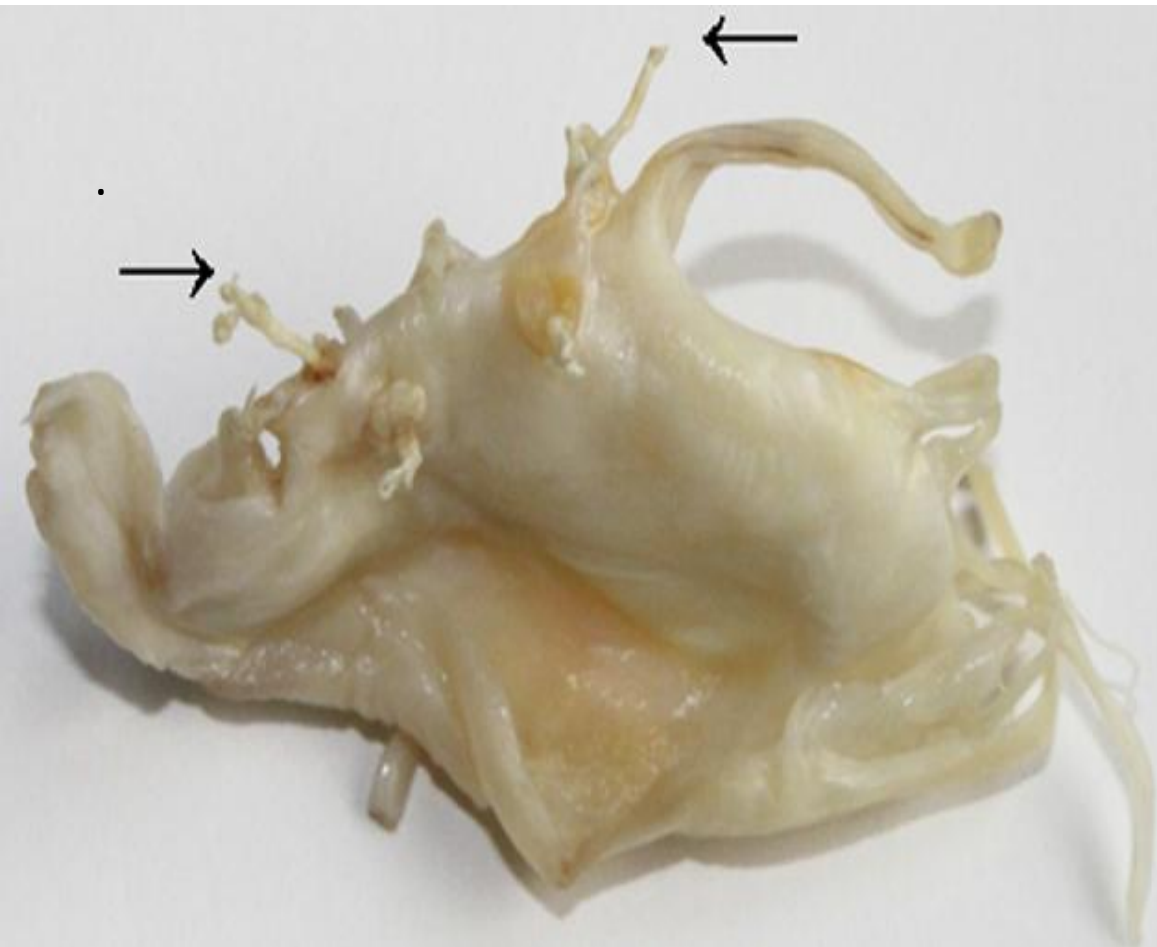
According to the findings, e-PTFE shows a stress/strain curve very different to human chordae. In particular, the stress/strain curve of e-PTFE presents significant compliance for very low stress only, for higher stress as those observed in vivo (0.40-0.60N) its mechanical behavior is very similar to Polypropylene.

According with our evidences, the prevalence of ePTFE usage is only due to its ease of handling and its knotted pattern compared to polypropylene but not for its mechanical behavior. In comparison with Polypropylene the favourable properties of PTFE including:

- *Soft and supple for excellent handling and minimizing the irritation caused by knots*
- *No out of package memory*
- *White color is highly visible in the surgical field*
- *Minimal biological tissue response with cellular ingrowth*



•Nevertheless its low compliance to physiologic stress (0.40-0.60 N) may explain the rupture events documented in the literature when e-PTFE is as orthotopic replacement of native chordae:



•Minatoya K, Kobayashi J, Sasako Y, Ishibashi-Ueda H, Yutani C, Kitamura S. Long-term pathological changes of expanded polytetrafluoroethylene (ePTFE) suture in the human heart. *J Heart Valve Dis* 2001;10:139–42.

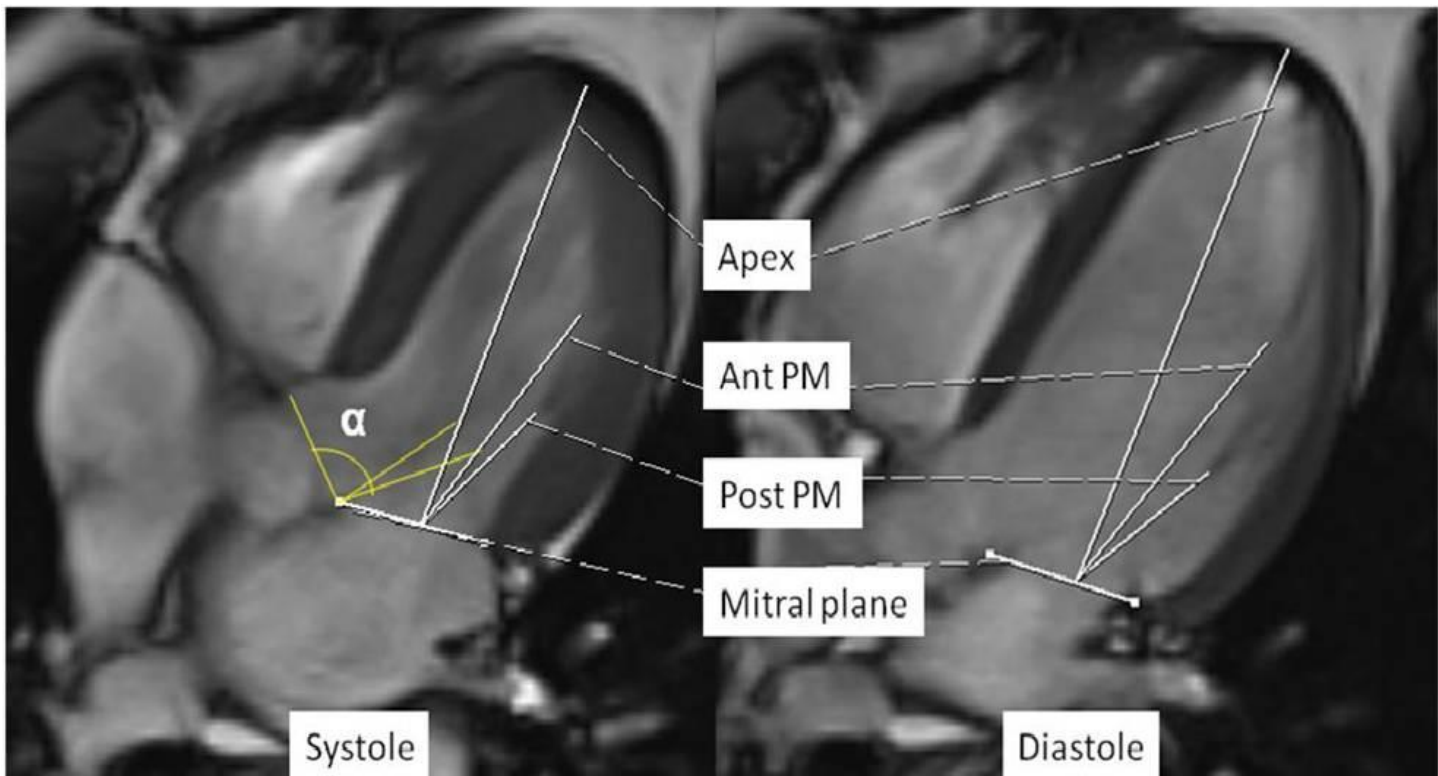
•Butany J, Collins MJ, David TE. Ruptured synthetic expanded polytetrafluoroethylene chordae tendinae. *Cardiovasc Pathol* 2004;13:182– 4.

•Coutinho GF, Carvalho L, Antunes MJ. Acute mitral regurgitation due to ruptured ePTFE neo-chordae. *J Heart Valve Dis* 2007;16:278–82.

•Farivar RS, Sherman SK, Cohn LH. Late rupture of polytetrafluoroethylene neochordae after mitral valve repair. *J Thorac Cardiovasc Surg* 2009;137:504–6.

•Fukunaga S, Tomoeda H, Ueda T, Mori R, Aoyagi S, Ktao S. Recurrent mitral regurgitation due to calcified synthetic chordae. *Ann Thorac Surg* 2010;89:955–7.

- This is more concerning when a transapical repair approach is used in due to the longer length of ePTFE used.
- Since the apical chordae is at least 2time bigger than PM anchored chordae and in particular the systole-diastole length difference for apical chordae is 10 times bigger than for PM anchored chordae, we can argue that the stress charge on e-PTFE apical neo-chordae might rich its structural limit .



The moral life of man forms part of the subject matter of the artist, but the morality of art consists in the perfect use of an imperfect medium. » (Oscar Wilde, from the foreword of «The picture of Dorian Gray»)

