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Transvalvular pressure gradients for different methods of mitral valve repair: only neochordoplasty achieves native valve gradients

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Abstract

OBJECTIVES: Many surgical and interventional methods are available to restore patency for patients with degenerative severe mitral valve regurgitation. Leaflet resection and neochordoplasty, which both include ring annuloplasty, are the most frequently performed techniques for the repair of posterior mitral leaflet flail. It is unclear which technique results in the best haemodynamics. In this study, we investigated the effect of different mitral valve reconstruction techniques on mitral valve haemodynamics and diastolic transvalvular pressure gradient in an *ex vivo* porcine model.

METHODS: Eight porcine mitral valves were tested under pulsatile flow conditions in an *in vitro* pulsatile flow loop for haemodynamic quantification. Severe acute posterior mitral leaflet flail was created by resecting the posterior marginal chorda. The acute mitral valve regurgitation was corrected using 4 different repair techniques, in each valve, in a strictly successive order: (i) neochordoplasty with polytetrafluoroethylene sutures alone and (ii) with ring annuloplasty, (iii) edge-to-edge repair and (iv) triangular leaflet resection, both with ring annuloplasty. Valve haemodynamics were measured and quantified for all valve configurations (native, rupture and each surgical reconstruction). The results were analysed using a validated statistical linear mixed model, and the *P*-values were calculated using a 2-sided Wald test.

RESULTS: All surgical reconstruction techniques were able to sufficiently correct the acute mitral valve regurgitation. Neochordoplasty without ring annuloplasty was the only reconstruction technique that resulted in haemodynamic properties similar to the native mitral valve (*P*-values from 0.071 to 0.901). The diastolic transvalvular gradient remained within the physiological range for all reconstructions but was significantly higher than in the native valve for neochordoplasty with ring annuloplasty ($P < 0.000$), edge-to-edge repair ($P < 0.000$) and leaflet resection ($P < 0.000$). Neochordoplasty without ring annuloplasty resulted in a significantly better pressure gradient than neochordoplasty with a ring annuloplasty ($P < 0.000$). Additionally, neochordoplasty with a ring annuloplasty resulted in significantly lower transvalvular pressure gradients than edge-to-edge repair ($P < 0.000$) and leaflet resection ($P < 0.000$).

CONCLUSIONS: Neochordoplasty with or without ring annuloplasty was the reconstruction technique that almost achieved native physiological haemodynamics after repair of posterior mitral leaflet flail after acute isolated chordal rupture in our *ex vivo* porcine model.

Keywords: Mitral valve repair • Transvalvular pressure gradients • Neochordoplasty • Ring annuloplasty

INTRODUCTION

Surgical mitral valve reconstruction is the current treatment of choice for patients with severe mitral valve regurgitation (MR) caused by posterior mitral leaflet (PML) flail, especially when located at the P2 segment [1, 2]. The most frequently performed techniques for the repair of PML flail are leaflet resection and neochordoplasty, both with ring annuloplasty. Leaflet resection has excellent long-term results [1, 3, 4]. Carpentier *et al.* [5–7] pioneered the technique of leaflet resection followed by annulus plication or sliding plasty. More recently, neochordoplasty using polytetrafluoroethylene sutures for chordal replacement has led to a shift from leaflet resection towards repair techniques that try to preserve as much leaflet tissue as possible [6, 8, 9]. Especially in patients with PML flail caused by acute chordal rupture, the leaflet resection approach may not be fully adequate, due to the minimal leaflet distension in the early phase of MR [10, 11]. In 1991, Alfieri introduced the concept of surgical edge-to-edge repair for more complex lesions, especially those associated with anterior leaflet prolapse [12]. This technique creates a double

†The first two and the last two authors contributed equally to this work.

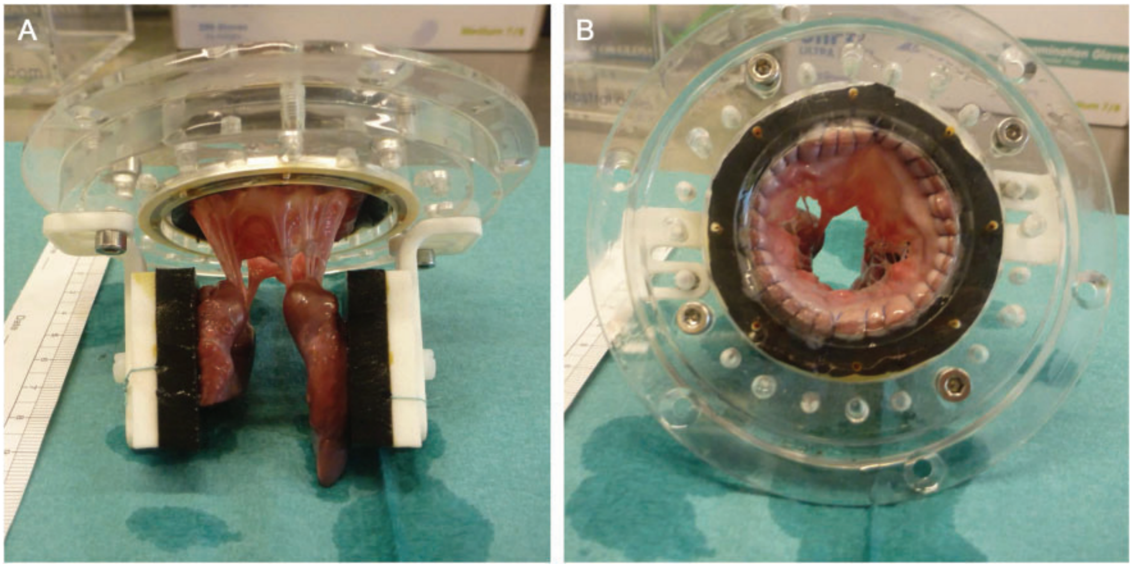


Figure 1: Porcine mitral valve inserted in the valve holder. (**A**) The valve holder in side view and the positioning of the papillary muscles sutured to the legs of the valve holder is shown. (**B**) The valve holder in top view and the sutures to the neoprene ring are shown.

orifice by suturing the central part of the anterior and posterior leaflets together, thereby reducing MR [12]. In recent years, the percutaneous mitral valve repair system, the MitraClip (Abbott Laboratories, Abbott Park, IL, USA), which employs the original idea of Alfieri, has emerged as a safe and feasible treatment option for high-risk or inoperable patients with severe functional or degenerative MR [13, 14].

Preserving leaflet tissue has been shown to maintain the most physiological mitral valve function and leaflet kinematics after repair of PML flail [9, 15, 16]. However, the influence of the various surgical and interventional procedures on left ventricular function and mitral valve dynamics is not completely understood [17]. Direct quantitative comparison of the surgical reconstruction techniques with measurement of transvalvular pressure gradients has not been done before. Therefore, we examined the effects of different surgical methods (neochordoplasty with and without ring annuloplasty, edge-to-edge repair and leaflet resection) on the mitral valve haemodynamics and transvalvular pressure gradient in an experimental *ex vivo* porcine model.

METHODS

Valve preparation

The mitral valve (annulus, leaflets and chordae) including a margin of left atrial tissue and the papillary muscles were dissected from 8 porcine slaughter hearts (labelled A–H), and sutured onto a neoprene ring inside a custom-made polymethyl metacrylate valve holder (Fig. 1). The papillary muscles were sutured to the neoprene-covered adjustable legs of the valve holder. Thereafter, the position and the length of the legs were adjusted for optimal closure of the valve.

Pulsatile flow loop

The valve holder was placed and locked into a pulsatile flow loop. Figure 2 shows the set-up of the pulsatile flow loop and a picture of the inserted valve holder. The valve holder was placed between 2 polymethyl metacrylate chambers representing the left atrium (LA) and the left ventricle (LV). The systemic arterial compliance and resistance were mimicked using a partly air-filled chamber and a resistance element, respectively. A mechanical tilting disk valve representing the aortic valve separated the LV chamber from the compliance chamber. The fluid used in the pulsatile flow loop was deionized water, which was recirculated back into the LA chamber via the compliance chamber and the gated valve.

Instrumentation

The LV chamber was actuated using a computer-controlled piston pump (ViVitro Systems Inc., Victoria, Canada) attached to the LV chamber. The pumping volume was determined from the piston position continuously measured with a linear variable differential transformer sensor mounted on the piston. An ultrasonic flow probe (TS410/ME-11PXL, Transonic Systems, Inc., Ithaca, NY, USA) was connected to the tube between the LV chamber and the piston pump to measure the LV flow. Two pressure sensors (PX600F 150B, Edwards Lifesciences, Irvine, CA, USA) were used to measure the pressure in the LA and LV chambers just above and below the mitral valve, respectively, to measure the LA and LV pressures as well as the transvalvular pressure gradient (dP). A high-speed camera (Basler piA640–210gc GigE, Basler AG, Ahrensburg, Germany), mounted above the mitral valve (Fig. 2), was used to capture the leaflet kinematics. The haemodynamic measurements were acquired at 200 Hz, and the camera frames at 100 frames/s. The measurements were synchronized, using a synthetic trigger signal created by the ViVitro pump system. Haemodynamic measurements were recorded for 15 s and camera frames for 1 s.

Measurement protocol

Haemodynamic assessments were performed in the pulsatile flow loop at heart rates of 60 and 80 bpm with all 8 porcine

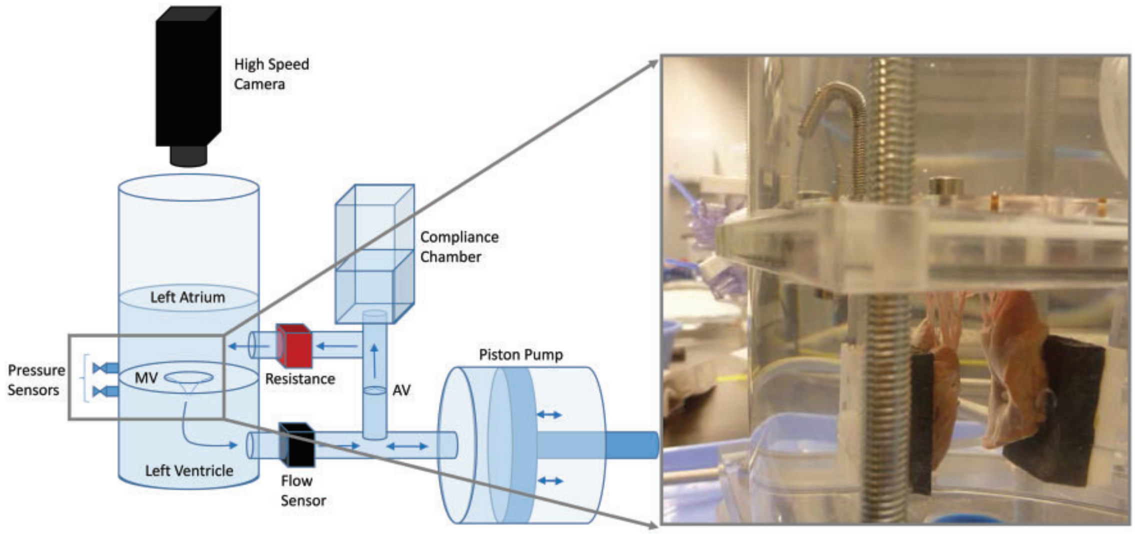


Figure 2: Schematic drawing of the pulsatile flow loop with a picture of the valve holder inserted in the set-up. The valve holder was attached to a polymethyl methacrylate plate positioned between the left atrium and the left ventricle. AV: aortic valve; MV: mitral valve.

mitral valves for the physiological case (native valve), the pathological case (chordae rupture) and for all surgical reconstructions. On all the valves, the same strictly successive series of surgical reconstructions were performed. The measurement protocol of each valve started with haemodynamic measurements of the intact native valve that served as baseline measurement of the competent valve. After the native valve measurement, severe acute PML flail was created in the valve, by resecting the posterior marginal chordae in the P2 segment. Haemodynamic measurements were repeated to obtain baseline data for the insufficient valve. The flail was then repaired, such that the regurgitation was eliminated, in a strictly successive order using 4 different methods of repair:

1. Neochordoplasty with expanded polytetrafluoroethylene sutures without ring annuloplasty (neochordae).
2. Neochordoplasty with expanded polytetrafluoroethylene sutures with ring annuloplasty by Physio II Edwards Lifesciences 30mm (annuloplasty with neochordae).
3. Edge-to-edge repair (Alfieri stitch) with ring annuloplasty.
4. Leaflet resection (triangular resection) with ring annuloplasty.

The valve haemodynamics were measured for each repair method following the same protocol as for the 2 baseline measurements. Supplementary Material, Table S1 gives an overview of the measurement protocol for all the valves labelled A–H. Figure 3 and Video 1 shows valve F during diastole (open) and systole (closed) for the native configuration, for chordae rupture, and for all 4 reconstruction methods.

Data analysis

Data analysis and post-processing were performed using MATLAB (the MathWorks, Natick, MA, USA). Haemodynamic parameters were calculated for each heartbeat (12 beats for 60 bpm and 17 beats for 80 bpm) for all measurements as well as the mean values and the standard deviations of these parameters. The first and the last heartbeats were excluded to have the same number of full heartbeats for each measurement. Additionally, the ensemble-averaged heartbeat was calculated for all haemodynamic parameters, for each measurement.

A validated statistical linear mixed model was used to analyse the effect of each surgical reconstruction on the haemodynamic parameters compared with the native valve. The *P*-values were calculated using a 2-sided Wald test. The statistical analysis was first performed on all data together adding a factor for the different haemodynamic measurements at 60 and 80 bpm. After that, the analysis was stratified for the haemodynamic measurements at 60 bpm and at 80 bpm. A *P*-value of < 0.05 was considered significant.

RESULTS

Figure 4 shows the LV flow rate and the pressure for valve F at 60 bpm, together with images of the valve at given time points. The valve closes approximately 0.05 s after onset of systole and remains closed until onset of diastole (approximately after 0.40–0.45 s). The closed leaflets oscillate during systole, which can be seen as fluctuations in the flow rate waveform, but the valve remains closed (verified by inspection of the video frames).

The ensemble-averaged LV flow rate, pressure for the native valve and the insufficient valve with ruptured chordae are shown in Fig. 5 for the ensemble-averaged heartbeat of valve G at 80 bpm. Clearly, the ruptured chordae lead to a decrease in LV pressure during systole and create a large insufficiency of the valve.

In Fig. 6, the ensemble-averaged LV flow rate and pressure for valve G for all surgical reconstructions are displayed including the native valve and the ruptured valve. These results clearly show that all the surgical reconstructions are able to eliminate the valve insufficiency.

The diastolic transvalvular pressure gradient of valve G, for all surgical reconstructions, together are presented in Fig. 7 with the physiological case (native valve) and the pathological case (chordae rupture).

All diastolic transvalvular pressure gradients remained within a physiological range. However, the pressure gradients were significantly higher than those of the native valve, for the following reconstruction techniques: neochordoplasty with annuloplasty ($P < 0.000$),

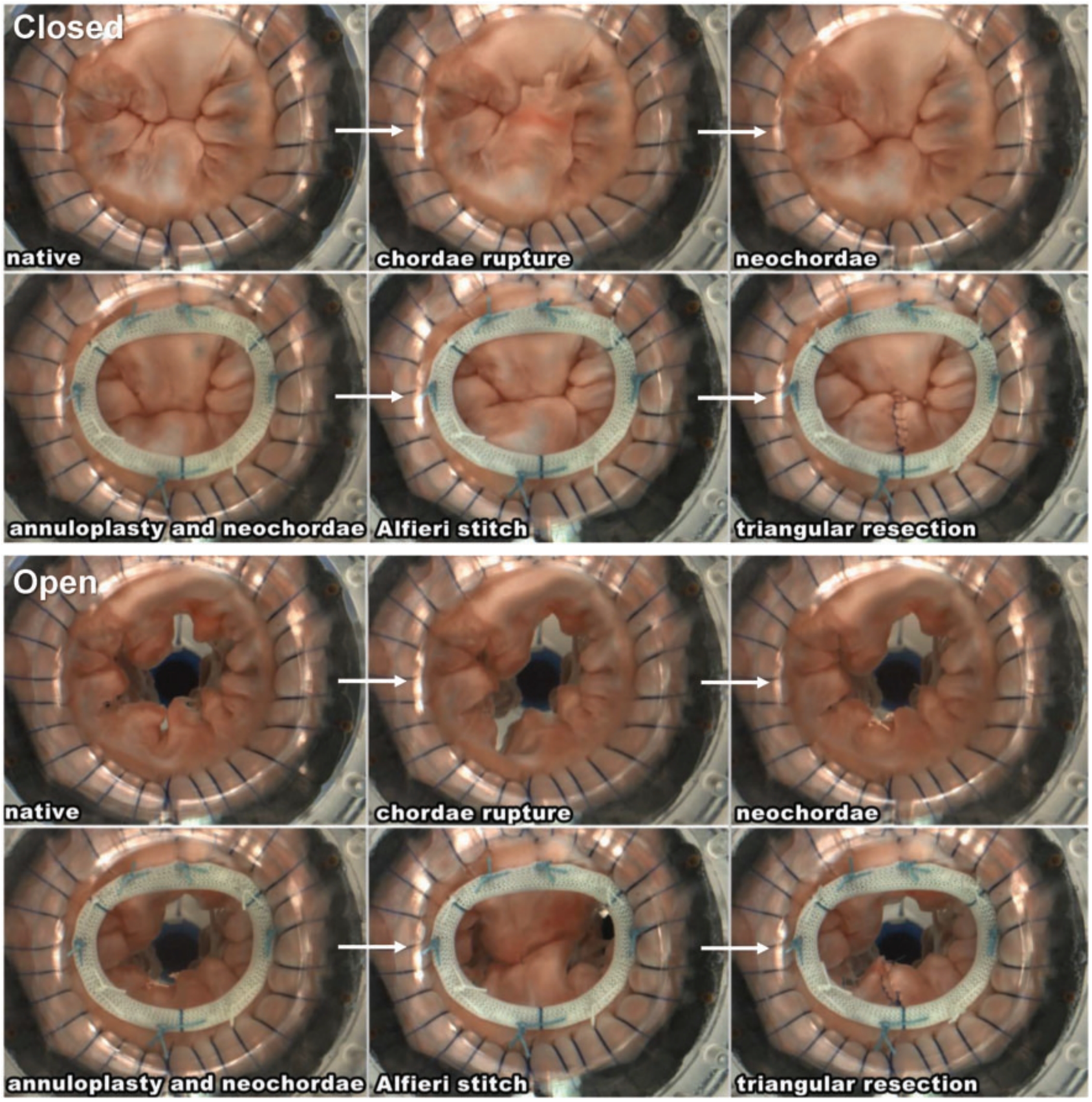
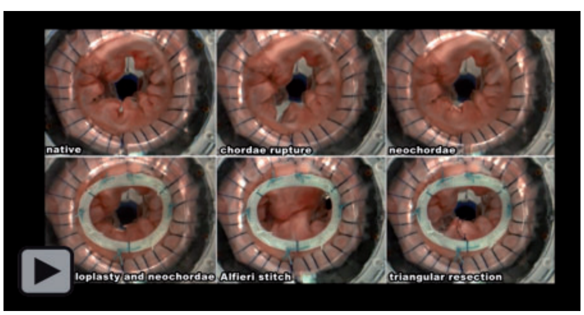


Figure 3: The porcine valve F in closed (systole) and open (diastole) configuration for all measured configurations: native, chordae rupture, neochordae, annuloplasty and neochordae, Alfieri stitch and triangular resection.



Video 1: Video of porcine valve F (pulsatile flow loop) in closed (systole) and open (diastole) configuration for all measured configurations: native, chordae rupture, neochordae, annuloplasty and neochordae, Alfieri stitch and triangular resection.

leaflet resection with annuloplasty ($P < 0.000$) and edge-to-edge repair with annuloplasty ($P < 0.000$). Neochordoplasty, without annuloplasty, is significantly better in terms of transvalvular pressure gradients compared to neochordoplasty with annuloplasty ($P < 0.000$). Additionally, neochordoplasty with annuloplasty has significantly lower transvalvular pressure gradients than leaflet resection with annuloplasty ($P < 0.000$) and edge-to-edge repair with annuloplasty ($P < 0.000$). Only neochordoplasty without annuloplasty achieves a transvalvular diastolic pressure gradient similar to that of the native valve ($P > 0.050$). These results are stable regardless of heart rate. Figure 8 shows box plots of the normalized mean values of the diastolic transvalvular pressure gradients as well as the statistical significance compared with the mean value of the native valve. Clearly, only neochordoplasty is not significantly different from the native valve.

DISCUSSION

The aim of this experimental study was to investigate the effects of different surgical techniques to reconstruct the mitral valve and their effects on valve motion and transvalvular pressure gradients in an experimental *ex vivo* porcine model. According to

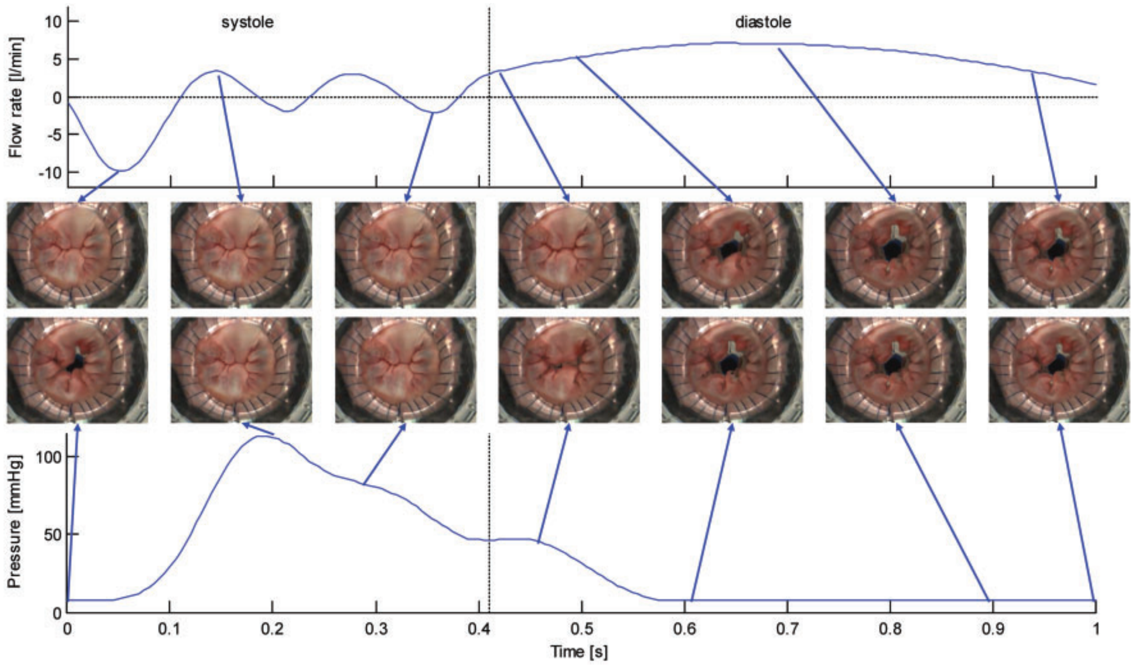


Figure 4: The flow rate and pressure in the left ventricle for the native valve (valve F) at 60 bpm. The images show the valve at the time points indicated by the arrows.

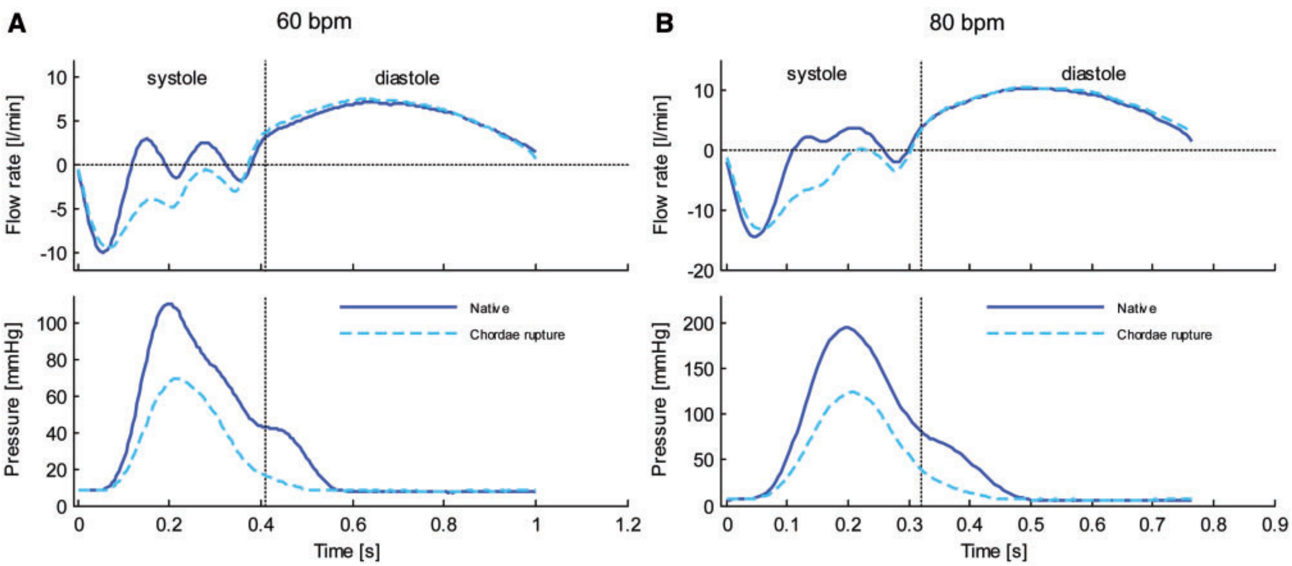


Figure 5: Left ventricular flow rate and pressure at (**A**) 60 bpm and (**B**) 80 bpm for valve G (ensemble-averaged heartbeat), for the physiological case (native valve) and for the pathological case (chordae rupture).

the current literature, the main surgical options to reconstruct the mitral valve in case of PML prolapse or flail for the P2 segment are neochordoplasty, ring annuloplasty, leaflet resection and edge-to-edge repair [5, 9, 17]. Excellent survival rates and freedom of reinterventions have already been described, especially for neochordoplasty and leaflet resection [5–7, 15]. We report on an *ex vivo* porcine model that simulates a PML flail, resulting from acute chordal rupture in the P2 segment. Our goal was to do a direct quantitative comparison of several established surgical techniques on the same valve under the same controlled haemodynamic conditions in a developed *in vitro* flow loop with measurements of transvalvular pressure gradients, and to the best of our knowledge, this has never been done before.

The haemodynamic results showed that all reconstruction techniques allowed a sufficient correction of the regurgitation, with acceptable transvalvular pressure gradients. However, some of the repair techniques altered the haemodynamics compared to the physiological case of the native valve.

In this study, only neochordoplasty without ring annuloplasty achieved haemodynamics similar to those of the native mitral valve. This suggests that the preservation of the valve leaflets and reconstruction of the ruptured chordae lead to close-to-normal function of the valve by minimizing the transvalvular pressure gradients and the restriction of the leaflet motion. Several studies, which compare the use of neochordoplasty and leaflet resection for PML prolapse or flail [6, 8, 9, 11, 15, 18], support this

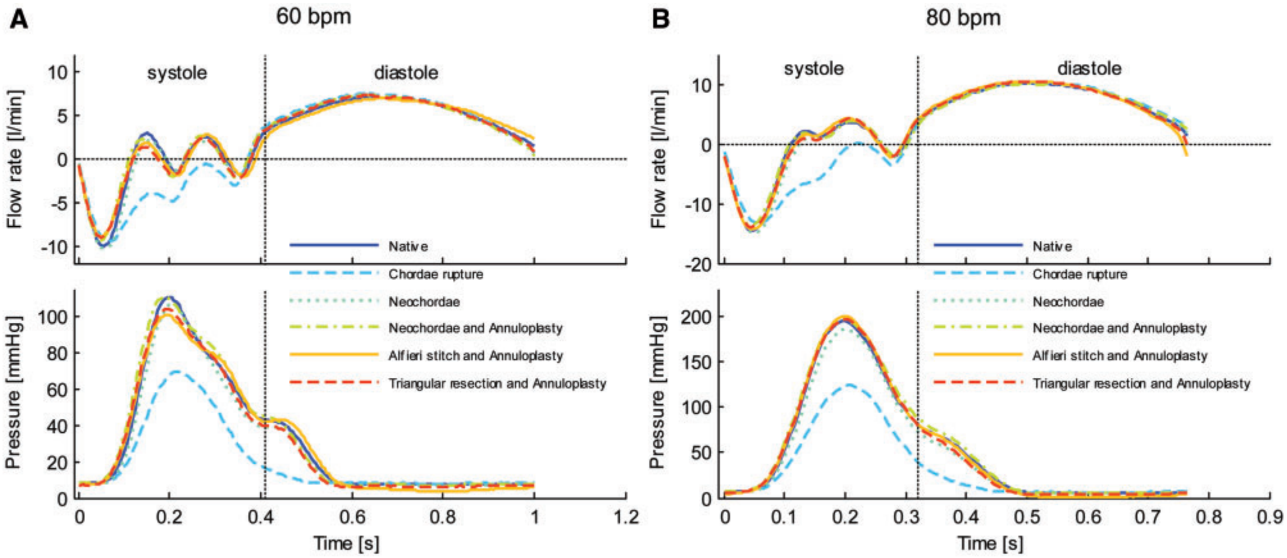


Figure 6: Left ventricular flow rate and pressure at (**A**) 60 bpm and (**B**) 80 bpm for valve G (ensemble-averaged heartbeat), for all surgical reconstructions, together with the physiological case (native valve) and the pathological case (chordae rupture).

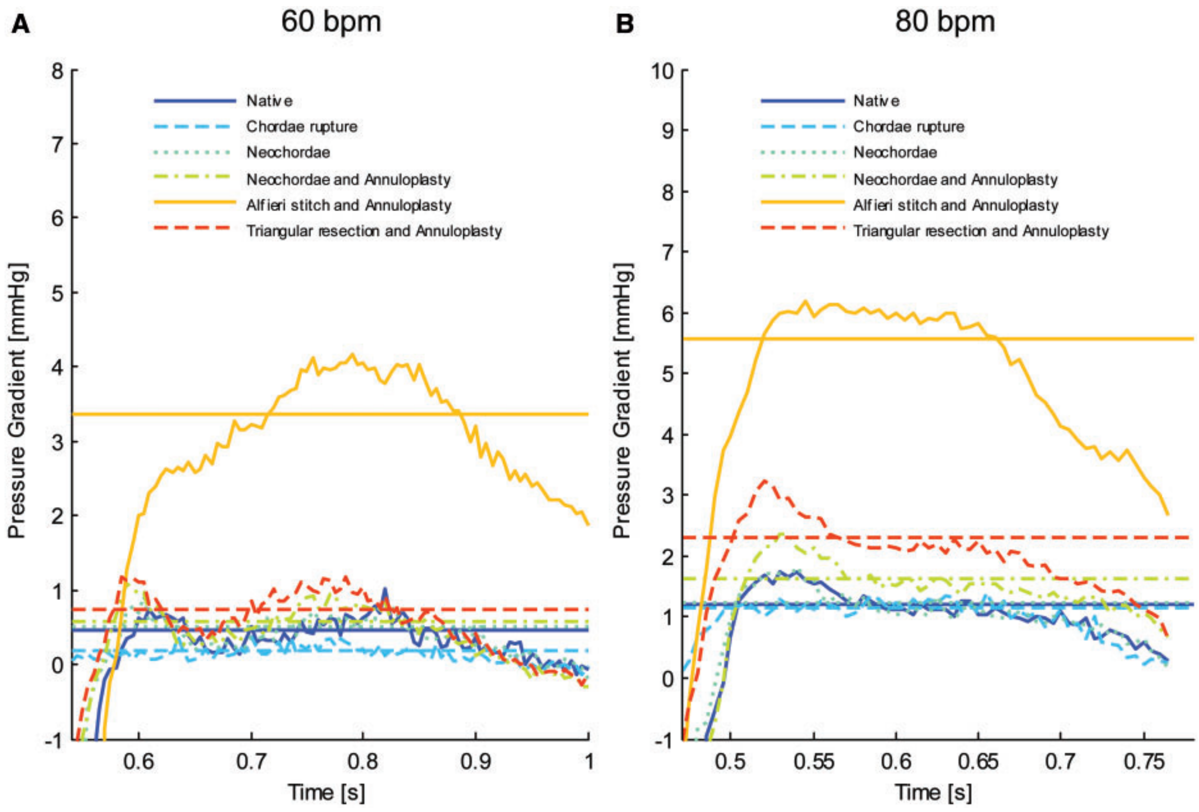


Figure 7: The diastolic transvalvular pressure gradient (ensemble-averaged heartbeat) for all surgical reconstructions for valve G at (**A**) 60 bpm and (**B**) 80 bpm.

observation. Seeburger *et al.* [6] found no difference in mid-term survival, although, reoperation was less likely following a leaflet preservation strategy with artificial chordae. In early postoperative echocardiographic assessments, Seeburger *et al.* also found that the mitral orifice area was greater and that the mean transvalvular pressure gradients were lower following a leaflet preservation approach. Cochran *et al.* [18] showed that by preserving the posterior leaflet tissue in combination with the use of artificial chordae, the anatomical and dynamic relationships of the mitral leaflets could optimally be preserved. This allows for a more physiological distribution of forces and stresses on leaflet and subvalvular apparatus components and better preservation of the function of the left ventricle [9, 18]. A study by Padala *et al.* [11] confirmed that neochordoplasty would restore the physiological function of the valve without disturbing the native leaflet structure.

The size and form of the annuloplasty ring might affect transvalvular pressure gradients as well. Chan and Mesana *et al.* [17, 19]

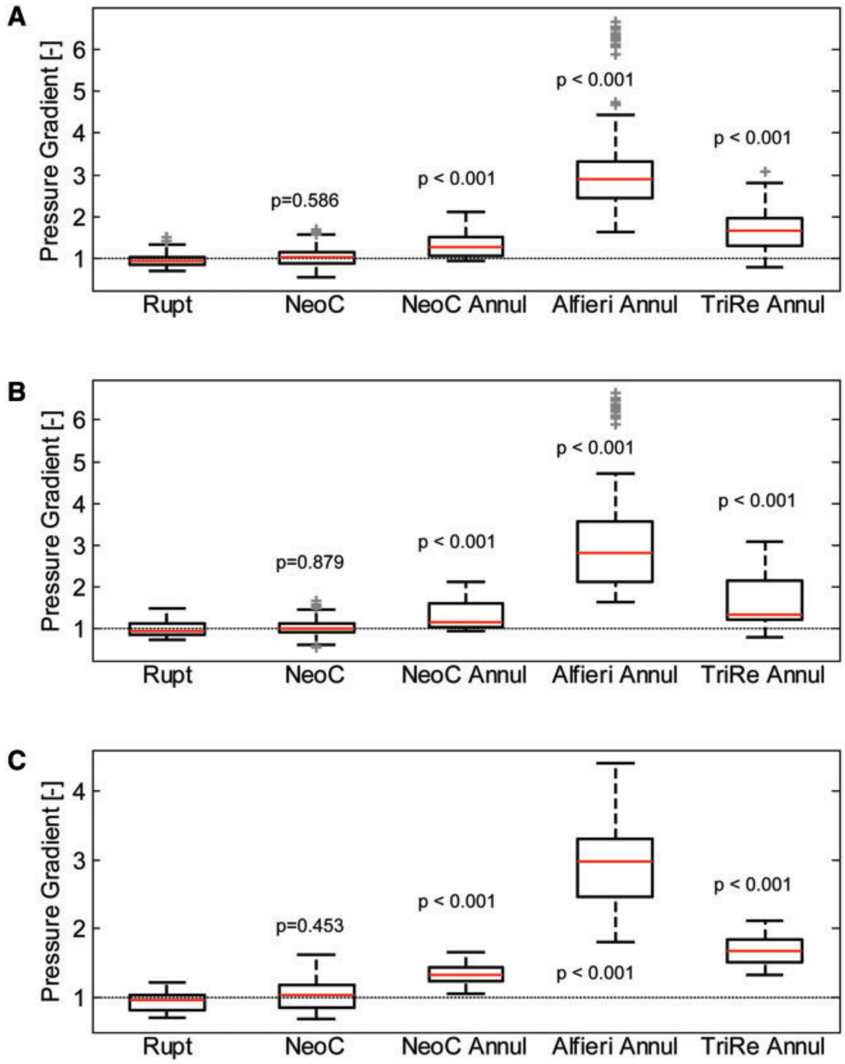


Figure 8: Box plots of the normalized mean diastolic transvalvular pressure gradients compared with the mean of the physiological case (native valve): (**A**) for all haemodynamic measurements, (**B**) for the haemodynamic measurements at 60 bpm and (**C**) for the haemodynamic measurements at 80 bpm. The *P*-values indicate the significance of the mean value compared with the value of the physiological case (native valve). A *P*-value <0.05 is considered significant. Alfieri: Alfieri stitch; Annul NeoC: annuloplasty with neochordae; NeoC: neochordae; Rupt: chordae rupture; TriRe: triangular resection.

compared transvalvular pressure gradients of patients who underwent mitral repair with either a complete ring or a partial band. The mean transvalvular pressure gradient and right ventricular systolic pressure were found to be lower following repair with a partial band as opposed to a complete ring [19]. The group concluded that functional mitral valve stenosis was more likely to occur in patients who underwent mitral repair with a complete ring versus a partial band [19]. However, in our study, the statistical results were found to be stable in terms of annuloplasty ring size.

Additional clinical research is necessary to clarify the influence of different reconstructive techniques on late mitral leaflet function and transvalvular pressure gradients in the long term. Especially the significantly higher transvalvular pressure gradients of the edge-to-edge repair, as shown in this case of isolated chordae rupture repair, should be considered with caution, when choosing a therapeutic strategy. The results of this study confirm that a PML flail might not be the ideal indication for the Alfieri stitch. When considering edge-to-edge repair for PML flail, it is important to apply the Alfieri sutures as closely as possible and to choose a sufficiently large annuloplasty ring to avoid obstruction.

For interventional edge-to-edge-devices (e.g. MitraClip), the indication is expanding towards degenerative mitral valve disease including PML flail. The implantation of multiple edge-to-edge-devices can be necessary to avoid detachment and achieve favourable results, which might lead to higher transvalvular pressure gradients [20].

Although clinical practice may advise to use larger annuloplasty rings in certain cases, in our study, we applied the same annuloplasty ring size and different techniques to the same valve in order to achieve a comparable situation. Nevertheless, the transvalvular pressure gradients of the edge-to-edge repair were not close to obstruction or significant stenosis (with a mean value of 4 mmHg), although they were statistically significantly higher than the other surgical techniques in this study. Rocha *et al.* [21] concluded that the edge-to-edge technique reduced the operative times, but that it mildly increased the transvalvular pressure gradients and mildly decreased valve opening areas (despite a larger annuloplasty ring). The observed transvalvular pressure gradients for edge-to-edge repair are in accordance with the results of Rocha *et al.*, only mildly increased compared with the other repair techniques.

Improved understanding of mitral valve physiology, and the influence of the different reconstructive techniques on leaflet function, is necessary to choose the best individual treatment option for the patient. Future research should also take into account the complex integrated structural and functional relationship of the mitral valve with the left ventricular function.

Limitations

The clinical implication of this *in vitro* model must be stated thoroughly. The model represents a PML flail caused by acute isolated chordal rupture, without further pathological valvular changes. The porcine mitral valves were of normal function, and without any noticeable tissue pathologies. In a chronic pathological process, with additional annular dilatation and leaflet distention, as well as annular calcification, the optimal choice of reconstruction method might differ from the results reported in this study. Furthermore, the use of the same strictly successively repair protocol on all valves is a limitation, even though it was necessary not to destroy the native leaflets too early. The same yields for the annuloplasty ring which had the same size for all repair techniques in each valve to avoid damage to the valve leaflets by several explantations and reimplantations.

CONCLUSION

In conclusion, we have shown that neochordoplasty with or without ring annuloplasty achieved lower diastolic transvalvular pressure gradients compared with edge-to-edge repair and leaflet resection. These findings support the 'respect rather than resect' [9] approach with the aim to preserve leaflet tissue and restore good leaflet coaptation and mobility. Neochordoplasty without ring annuloplasty was the only repair technique able to achieve almost native physiological haemodynamics, after surgical reconstruction in our *ex vivo* porcine model of acute chordal rupture.

In this *in vitro* analysis, the concept of ring annuloplasty was not essential to facilitate a successful repair in contrast to the results of other experimental studies [11]. However, in the clinical setting, the ring annuloplasty is currently a recognized step to maintain annulus geometry over time, which was not tested in this study.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

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Conflict of interest: none declared.

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