Comparison of the Hemodynamic and Thrombogenic Performance of Two Bileaflet Mechanical Heart Valves Using a CFD/FSI Model

The hemodynamic and the thrombogenic performance of two commercially available bileaflet mechanical heart valves (MHVs)—the ATS Open Pivot Valve (ATS) and the St. Jude Regent Valve (SJM), was compared using a state of the art computational fluid dynamics-fluid structure interaction (CFD-FSI) methodology. A transient simulation of the ATS and SJM valves was conducted in a three-dimensional model geometry of a straight conduit with sudden expansion distal the valves, including the valve housing and detailed hinge geometry. An aortic flow waveform (60 beats/min, cardiac output 4 l/min) was applied at the inlet. The FSI formulation utilized a fully implicit coupling procedure using a separate solver for the fluid problem (FLUENT) and for the structural problem. Valve leaflet excursion and pressure differences were calculated, as well as shear stress on the leaflets and accumulated shear stress on particles released during both forward and backward flow phases through the open and closed valve, respectively. In contrast to the SJM, the ATS valve opened to less than maximal opening angle. Nevertheless, maximal and mean pressure gradients and velocity patterns through the valve orifices were comparable. Platelet stress accumulation during forward flow indicated that no platelets experienced a stress accumulation higher than 35 dyne×s/cm², the threshold for platelet activation (Hellums criterion). However, during the regurgitation flow phase, 0.81% of the platelets in the SJM valve experienced a stress accumulation higher than 35 dyne×s/cm², compared with 0.63% for the ATS valve. The numerical results indicate that the designs of the ATS and SJM valves, which differ mostly in their hinge mechanism, lead to different potential for platelet activation, especially during the regurgitation phase. This numerical methodology can be used to assess the effects of design parameters on the flow induced thrombogenic potential of blood recirculating devices. [DOI: 10.1115/1.2746378]

Introduction

Although tremendous research and development efforts are dedicated to improve the performance of mechanical heart valves, the risk of cardioembolic stroke is still a major impediment to MHVs. There is still a wide margin for improvement in the existing designs. In recent years it has been shown that chronic platelet activation and the initiation of thrombus formation is the salient aspect of flow induced blood trauma in MHVs. In particular, the influence of the hinge design on platelet activation and anticoagulation therapy remains a major clinical issue [1–3], with a clear need for improved valve design requiring minimal anticoagulation therapy. In addition to the material properties and contact activation, the valve hemodynamics plays a major role in the thrombogenic potential of MHVs. Blood flow through the valve should avoid stagnation zones with recirculation of flow and prolonged residence times of blood borne particulates, as well as turbulence and high shear stress zones that initiate platelet activation or lead to hemolysis.

In recent years, computational techniques are being utilized more frequently for heart valve design [4–6]. The recent advances in computational fluid dynamics (CFD) and the development of numerical algorithms that account for the interaction between the fluid and the valve leaflets (fluid-structure interaction (FSI)) [7–10], facilitate subjecting different valve designs to “virtual bench tests.” We have previously simulated the motion of the leaflets of a bileaflet heart valve under laminar flow conditions, and calculated valve performance indices that were in good quantitative agreement with in vivo and in vitro data [11]. Nevertheless, numerical FSI models have not been utilized to compare the performance of different types of mechanical bileaflet valves, although this has been routinely done in detail in various in vitro [12,13] and in vivo [14,15] studies. With the availability of a validated numerical code [8,9], this methodology offers many advantages, as the valves can be tested side by side using precise control parameters and applying the same boundary conditions. Accordingly, the calculated pressure and flow distributions are not subject to variability inherent to an experimental
setting (accuracy and stability of measuring equipment and the pulse duplicator system, position of catheters, variability of valve samples, etc.).

More importantly, in addition to comparing general valve behavior (time course of leaflet excursion, opening angles, etc.) and hemodynamic performance (pressure gradients), we aimed to compare the thrombogenic potential of the bileaflet valves by quantifying stress accumulation of platelets along trajectories within the flow fields of both bileaflet valves.

**Methods**

**Valves and Valve Housing Geometry.** Two MHV designs were compared: a 22 mm Open Pivot (OP) ATS and a 21 mm SJM Regent valve. Although these sizes are of two different valve companies, they closely match, given that their inner diameter and true orifice size are more closely matched than their nominal sizes (given by the tissue annulus diameter, or TAD, see Table 1).

For this comparative study, the aortic sinuses were excluded from the model. Aortic valve replacement requires partially dissecting the aortic root sinuses, so that after MHV implantation only a portion of the sinuses remain. Additionally, unlike the native aortic valve, MHVs do not utilize the sinus vortex as a part of their opening and closing mechanism. Accordingly, the modeling geometry of the valves consisted of an expanding tube with a diameter ratio of 1.3, following Feng et al. [16]. It has been shown in previous in vitro [16] and in vivo [17] studies that the expanding geometry has an important influence on leaflet movement, emulating certain physiological conditions and pathologies. The inlet diameter was 22 mm, which results in an outlet diameter of 28 mm. The inlet and outlet conduits were 50 mm in length each, at relevant proximal and distal distances for the calculation of pressure gradients across the valves.

The valves are depicted in open position in Fig. 1 and in closed position in Fig. 2, showing in detail both valves. The hinge designs of the two valves differ significantly, with the ATS open pivot design departing from the characteristic St. Jude “ear” type of hinge mechanism (Fig. 2(c)). This may have an important influence on the valve performance and platelet activation.

**Computational Models.** We previously developed [18,19] and validated [9] a fluid-structure interaction model for 3D simulations of bileaflet MHVs. Briefly, the computer algorithm is based on the dynamic mesh model of the commercial CFD software package FLUENT (Fluent Inc.). Meshing the geometries was achieved with GAMBIT 2.1 (Fluent Inc.). In order to avoid contact problems between a moving leaflet and the housing while retaining an acceptable level of skewness for the smallest cells and reasonable cell volumes, the leaflet size of each valve was reduced to 98% of its original size. The fluid was assumed to be laminar, incompressible, and Newtonian with a density of 1050 kg/m³ and viscosity of 0.004 kg/m·s, representing human blood properties at 37°C. The FSI technique was implemented in FLUENT using journal files and user-defined functions. An external FSI code (in C++) was written to perform the transient calculation. This code runs a subiteration loop for every time step in order to solve the blood-leaflet interaction problem. The valve leaflet position is ad-
and for the structural problem velocity profile.

Inlet aortic velocity-time pattern and spatial profile. (a) Inlet aortic velocity-time pattern. (b) Trapezoidal spatial inlet velocity profile.

justed using a stabilizing subiteration scheme based on the numerical derivative of the moment on the leaflet [18,19], and a new flow solution is computed, starting from the results at the previous time step. This process continues until the equation of motion is satisfied, at which point the time is incremented by the FSI code, and a new valve leaflet position for the new time step is computed. At least two subiterations are required at every time step. The FSI problem typically converged within three or four subiteration steps. The fully implicit coupling procedure was therefore achieved by using a separate solver for the fluid problem (FLUENT) and for the structural problem (the FSI code). More details on the numerical code and validation can be found in [9,11,18,19]. This code has previously been validated for a 2D model of an aortic valve leaflet [9].

Boundary Conditions. The boundary conditions used in this computational study are based on the experimental work reported by Feng et al. [16], who compared the ATS and SJM valves. Inflow conditions are prescribed 50 mm proximal to the valve. The inflow pattern was a standard aortic inflow pattern (Fig. 3) with a systole lasting 0.4 s and a diastole of 0.6 s. Cardiac output was 4 l/min. From previous in vitro studies [16], it was shown that a difference of the closing volumes is crucial to ensure efficient closure of both valves. Accordingly, this difference in closing volume was applied to the inflow conditions in order to ensure near simultaneous closure of both valves. Accordingly, the percentage of the closing volumes were 2.5% for the ATS valve and 5.5% for the SJM valve, correspondingly. A spatial trapezoidal velocity distribution was applied at the inlet (Fig. 3(b)) and allowed to develop into a parabolic velocity profile. The trapezoidal velocity distribution facilitates better convergence of the CFD code and helps the development of the boundary layers [20].

Valve Leaflet Excursion and Hemodynamic Indices. In addition to the position of the valve leaflets (opening angles) throughout the cardiac cycle, the results of the numerical simulations (pressure and velocity in each node of the numerical grid at any instant during the cardiac cycle) were used to calculate the following hemodynamic indices:

- \( \Delta P_{\text{max}} \): the maximal difference between the inlet pressure (50 mm upstream the valve) and the outlet pressure (50 mm downstream the valve);
- \( \Delta P_{\text{mean}} \): the mean pressure difference during the acceleration phase (from zero to maximum velocity) [12,16].

Shear Stress and Platelet Stress Accumulation. Shear stress (\( \tau \)) is regarded as a primary biomechanical trigger for thrombotic events [21–24]. We calculated the distribution of shear stress over the leaflets and also calculated:

- \( \tau_{\text{avg}} \): the spatial average shear stress on the leaflet (as a function of time);
- \( \max \tau_{\text{avg}} \): the maximum value of \( \tau_{\text{avg}} \).

In addition, platelet shear stress histories were calculated for a large number of platelet trajectories within the flow field. This was performed for both valves, maintaining the leaflets in a fixed position during (a) the peak systolic phase with the maximum calculated opening angle obtained from the FSI calculation, and (b) the regurgitation phase when the bileaflet valves are in their fully closed position. About 15,000 particles were released during the forward flow phase (at \( t=0.15 \) s for a duration of 0.2 s) at a plane located 10 mm upstream the valve, and during the regurgitant flow phase (at \( t=0.6 \) for a duration of 0.25 s) at a plane 10 mm downstream the valve. This number (15,000) represents a typical physiologic count of platelets (10^5–3 x 10^5 per 1 \( \mu l \) of blood, translated into cross-sectional density, assuming a typical platelet diameter of 4 \( \mu l \)). The time period chosen for particle insertion during the forward flow phase corresponds to the peak systole and the deceleration of the flow towards leaflets closure. This flow phase is characterized by the appearance of shed vortices in the wake of the valve that provides optimal conditions for further platelet activation and for the clotting reactions to occur [1,2]. The period chosen during the backward flow phase represents well-established regurgitation jets and flow patterns through the closed leaflets of the valve. While the valve leaflets were kept in a fixed position, the stress accumulation was performed as a transient simulation, with the velocity waveform (Fig. 3) applied during the periods of particle release. The platelet shear stress histories were calculated for a large number of platelet trajectories within the flow field following the methodology of Bluestein et al. [1–3]. Briefly, the trajectories were computed using the Lagrangian approach of particulate two-phase flow [2,3]. The cumulative effect of shear stress and exposure time (\( \Delta t \)) was then computed by summation of the product of their instantaneous absolute values in each computational node along these platelet trajectories, i.e.,

\[
\Sigma(\tau_{ij} \times \Delta t),
\]

where

\[
\tau_{ij} = \mu \left( \frac{\partial u_i}{\partial x_j} + \frac{\partial u_j}{\partial x_i} \right).
\]

Platelets were considered activated if the stress accumulation was higher than 35 dynes x s/cm^2, according to the Hellums criterion [25]. For the forward flow phase, particles were released 0.15 s after the valve opening (Fig. 3(a)). The regurgitant flow velocity was set to \(-0.02 \) m/s, according to the inflow velocity boundary condition (Fig. 3(a)).

Results

The ATS valve opened to less than maximal opening angle (76.75 deg) while the SJM valve leaflets opened to their fully open excursion angle of 85 deg (Fig. 4(a)), conforming with results from similar studies. Both valves closed at the same time (0.395 s) during the flow cycle. Velocity profiles in the central and side orifices of both the ATS and SJM valves were similar (Fig. 4(b)).
(4(b)). Pressure gradients were also similar for both valves, with a smaller negative peak for the ATS valve. $\Delta P_{\text{max}}$ was 8.8 mm Hg for both valves (Fig. 4(c)). The mean pressure gradient ($\Delta P_{\text{mean}}$) was 3.9 mm Hg for the ATS valve and 4.3 mm Hg for the SJM valve.

Velocity vector flow fields at three distinct time instants during the leaflets opening phase ($t=0.02, 0.08, \text{and } 0.12$ s, corresponding to the mid-acceleration phase, an instant before peak systole, and peak systole) are depicted, showing the interaction between the accelerating flow field and the leaflets opening (Fig. 5). The flow deceleration and its interaction with the valve closure phase is depicted and at three distinct time instants ($t=0.30, 0.35, \text{and } 0.40$ s, Fig. 6). Color-coded wall shear stress contour plots were superimposed on the valve leaflets for all these time instants, corresponding to where colors towards the red end of the spectrum represent higher shear stress values.

Contours of the wall shear stress distribution over the valve leaflets (Fig. 7(a)) and the average shear stress (Fig. 7(b)) indicate that higher spatially averaged leaflet wall shear stress is found for the SJM valve, with maximum spatial average value $\tau_{\text{avg}}$ of 24 Pa for the SJM valve versus 19 Pa for the ATS valve.

Using the calculated shear data from the CFD results, the stress accumulation computation was performed along the corresponding trajectories of 15,000 particles $0.05$ s after their release. Their position and the resulting dispersion patterns at this time instant are depicted (Fig. 8(a)). A comparison of the percentages of the particles for different stress accumulation intervals indicated similar activation patterns during the forward flow phase for the two valves, but diverging activation patterns during regurgitation through the closed valves (Fig. 9). For the forward flow phase, five stress accumulation intervals were employed: (0–5), (5–15), (15–25), (25–35), and (35–45) dyne/$\text{s}/\text{cm}^2$. As most of the leaflets do not patent flow through the elevated shear stress regions, most of them (~98%) populate the lower stress accumulation range of 0–5 dyne/$\text{s}/\text{cm}^2$. For the regurgitant flow phase seven stress accumulation intervals were employed: (0–5), (5–15), (15–25), (25–35), (35–45), (45–55), and (55–65) dyne/$\text{s}/\text{cm}^2$. During forward flow 1.37% of the leaflets in the SJM valve experienced a stress accumulation greater than 5 dyne/$\text{s}/\text{cm}^2$ (0.5 N/s/m²) as compared to 2.07% of the leaflets for the ATS valve (Fig. 9, top panel). No leaflets experienced a stress accumulation of 35 dyne/$\text{s}/\text{cm}^2$ (3.5 N/s/m²), the threshold for platelet activation according to the Hellums criterion [25]. During the regurgitant flow phase, 0.81% of the leaflets in the SJM valve experienced a stress accumulation higher than 35 dyne/$\text{s}/\text{cm}^2$ compared to 0.63% of the leaflets for the ATS valve (Fig. 9, bottom panel). To guarantee that the percentage activation is independent of variations in the number of seeded particles and spatiotemporal variations, a sensitivity analysis was conducted by performing bootstrapping statistics—using the “R” package (http://www.r-project.org/), an open source statistics package developed at Bell Laboratories. The bootstrapping analysis indicated that above 2000 random samples, the percentage of activated leaflets essentially did not change.

**Discussion**

Various recent efforts were recently dedicated to assess the flow fields in MHVs using a FSI modeling approach [6,7,11]. To our knowledge, this is the first numerical study using a dedicated 3D FSI model to compare the hemodynamics of two commercially available mechanical bileaflet MHVs with a validated algorithm, and to comparatively study their thrombogenic potential by computing the stress accumulation of platelets flowing through the valves.

Comparing our simulations to in vitro measurements, both the time course of the valve leaflets and the maximal leaflet angle predicted by the FSI modeling are in good agreement with the values reported by Feng et al. [12,16], who also found the SJM valve to open up to its maximal opening angle, and a submaximal opening of the ATS valve (up to about 74.8 deg). Feng et al. found slightly higher values for $\Delta P_{\text{mean}}$ for 25 mm valves and higher values (for the same cardiac output of 4 l/min) for the ATS valve (4.8 versus 4.1 mm Hg). Although this difference was not confirmed by our CFD study, the measured absolute value of $\Delta P_{\text{mean}}$ was close to the values obtained by our simulations (3.9 mm Hg for the ATS valve and 4.3 mm Hg for the SJM valve). Direct comparison of the absolute values is difficult given the different valve sizes, and the fact that the downstream pressure was measured by Feng et al. further downstream (85 mm).

The calculation of platelet stress accumulation, computed along the pertinent trajectories within the valvular flow fields for both valves, served for assessing the thrombogenic potential of each MHV. Our results suggest that for both valves, less than 1% of the particles were subjected to stress levels, surpassing the activation threshold of 35 dyne/$\text{s}/\text{cm}^2$, the critical phase for potential platelet activation being the regurgitation phase and not the forward flow phase (Fig. 9). During the forward flow phase (Fig. 8(a)), more platelets were exposed to higher (subcritical; 5–35 dyne/$\text{s}/\text{cm}^2$) levels for the ATS valve. We believe that this is due to the fact that this valve exhibits a stronger jet through the central orifice as compared to the SJM valve. This jet entrains more strongly the platelets flowing through the side orifices, thus
exposing more platelets to the elevated shear stresses in the shear layers generated between the jet and the surrounding fluid. In the SJM valve, with its slightly weaker jet, one can observe a smaller dispersion pattern for the platelets flowing through the side orifices, resulting in fewer platelets exposed to elevated shear stresses. However, for the regurgitant flow phase (Fig. 8(b)), the SJM exhibits a stronger regurgitant jet, particularly in the hinges region. Owing to its different open pivot hinge design for the ATS valve, this jet is broken into two much weaker jets. Regurgitant jets were previously implicated in mechanical heart valve hemolysis and platelet activation [5,6,10,22,26]. These studies, focusing on the closure of mechanical valves, indicated large negative pressure transients in the peripheral clearance region as well as relatively large velocities in the central and peripheral clearance region. Accordingly, fewer platelets are carried beyond the activation threshold with the weaker leakage jets of the ATS valve. This offers a viable explanation to the disparities observed in the thrombogenic behavior of different types of bileaflet heart valve designs [13,27]. A similar explanation was offered when comparing the hinge flow dynamics (measured with laser Doppler velocimetry) of a CarboMedics bileaflet MHV to that of the SJM Regent MHV (used in our study) and the Medtronic Parallel MHV [28]. The slightly higher leakage velocities and turbulent shear stresses found in the CarboMedics valve were attributed to the sharper corners associated with the hinge design of the CarboMedics valve.

The seemingly small difference during the regurgitant flow phase (0.81% for the SJM as compared to 0.63% for the ATS valve) may appear so, due to the low percentages of platelets exceeding the Hellums activation threshold criterion (higher than 35 dyne×s/cm²) during a single passage through the valve. However, this is only to be expected. If prosthetic heart valves were inducing higher levels of platelet activity, it would have been impossible to implant them in patients. Yet, all MHVs do induce a chronic low level of platelet activation. It is well established that patients with MHVs are predisposed to thromboembolic disorders and must undergo lifelong anticoagulation therapy, while still developing thromboembolic complications at a linearized rate of between 0.7% and 6.4% per patient year [29]. Thus, a seemingly small difference may translate into a significant difference in the overall thrombogenic performance of these two valves. The difference between the two values reported here represents an almost 30% increase in the number of platelets reaching full activation during regurgitation in the SJM over the ATS valve. Over a lifetime of a MHV, platelets will be repeatedly exposed to these el-

Fig. 5 Flow field and wall shear stress results during opening of the valves (ATS (left panel), SJM (right panel)) at three different timesteps: 0.02 s, 0.08 s, 0.12 s
evated stresses. The lifetime of platelets in the normal circulation is about 10 days. On average, a platelet passage through the valves occurs every 30–90 s, corresponding to \( \sim 9600–28,800 \) valve passages during the average platelet lifetime. Eventually, the cumulative effect of the seemingly small percentage of platelets that get fully activated, even during a single passage through the valve, may initiate thromboembolic events. Thus, this small value may translate into a significant difference in the thrombogenic performance of the valve. It clearly indicates how a difference in the hinge design may translate into a difference in the thrombogenic potential of otherwise very similar bileaflet MHVs.

In this study, we compared the shear stress histories and total stress accumulation to values obtained from literature, where the shear stress level and exposure time leading to platelet activation was established by keeping the shear level constant, while measuring the time to reach activation \([25]\). When plotted on a log-log plane, the locus for incipient platelet activation depicts a hyperbolic relation between shear stress and exposure time. It is acknowledged that in vivo, as well as in our simulations, platelets experience continuously varying levels of shear and exposure times \([21]\). Calculated values also represent a single passage of the platelets through the valve, while in vivo, the platelets are subjected to numerous repeated passages through the valve. It is still unclear what is the “memory” of platelets to dynamic shear stress loading history. However, as some studies indicate that platelets exposed to cyclic stresses may be activated earlier, the Hellums steady shear based threshold for platelet activation represents a higher, more conservative threshold. It still provides a basic criterion for estimating the risk of thrombogenic complications in devices such as mechanical heart valves. The applied methodology is certainly suitable for comparing the thrombogenic potential of different valve designs, and its numerical predictions are validated by measuring platelet activity in an in vitro setup \([1–3]\).

Although numerical computational techniques are powerful tools in the design and virtual assessment of medical devices in general, and heart valves in particular, they still have limitations. FSI requires physical separation of the fluid domain from the structural domain, dictating an inclusion of a gap between the closed valve leaflets and their housing. Additionally, the dimensions of the actual gaps in these valves are proprietary information. Accordingly, the clearance gaps were achieved by slightly reducing the size of the leaflets to 98% of their actual size, yielding identical gaps of 0.14 mm for both MHVs. Although the reconstructed models include all features of actual ATS and SJM valves, there may be small (but potentially significant) differences in the actual dimensions of the gap. Given these limitations, the dimensions eventually used may underestimate the shear stress.

![Fig. 6 Flow field and wall shear stress results during deceleration of the flow and closing of the valves (ATS (left panel), SJM (right panel)) at three different timesteps: 0.30 s, 0.35 s, 0.40 s](image-url)
levels in the leakage jets, and accordingly the platelet stress accumulation values during the regurgitant phases. However, as this was identically imposed on the two valves, the results appear to be valid for comparative purposes. Caution, however, is warranted when translating the values calculated in this study to the actual, commercially available valves.

The cumulative shear stress results were computed assuming fixed leaflets. While the leaflet excursion could influence the platelet movement and thus the platelet activation, the valve closure phase is very brief (10–20 ms), during a flow deceleration period characterized by lower shear stress levels and shorter exposure times, most likely with little impact on platelet activation. The flow fields mostly implicated in platelet activation are mostly attributed to differences in valve and hinge design during peak flow conditions and the regurgitation phase. During these flow phases, the leaflets hardly move and can be approximated by a fixed position.

Despite these limitations, the CFD-FSI results of the current study demonstrate the capabilities of numerical models to compare heart valve performance indices and probably other types of artificial organs containing parts that passively move along with the fluid.

Conclusions

Using advanced numerical techniques, we have demonstrated that bileaflet MHV hemodynamics are dependent on geometric design parameters of the valve. The numerical model was able to detect subtle differences of velocity patterns and pressure gradients, which are difficult to detect with current clinical measurement techniques. The different flow patterns affect the shear stress and platelet stress accumulation rates. During the forward flow phase, the ATS valve led to higher platelet activation rates in the 5–15 dynes/cm² range, while the SJM had higher activation rates at the 15–25 dynes/cm² range (both valves shared the same activation levels at the 25–35 dynes/cm² range). However, the SJM valve generated higher platelet activation values during the regurgitant flow phase at all ranges of shear stress accumulation. As this flow phase was previously implicated in high levels of platelet activation, it indicates that overall, the ATS valve may offer a lower thrombogenic potential owing to its different hinge mechanism design. While a relatively small number of the platelets are exposed to these higher activation levels, with

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**Fig. 7** Wall shear stress results in space (top panel) and in time (bottom panel). (a) Max wall shear stress at t=0.14 s for central and side orifice (ATS (left panel), SJM (right panel)). (b) Average leaflet shear stress during cardiac cycle.

**Fig. 8** Dispersion patterns of platelets used for the stress accumulation computations during forward (top panel) and regurgitant flow (bottom panel). (a) Dispersion patterns of platelets during forward flow. (b) Dispersion patterns of platelets through the closed valve and the hinges during regurgitant flow.

**Fig. 9** Bar charts showing the stress accumulation results during forward (top panel) and regurgitant flow (bottom panel). (a) Platelet stress accumulation during forward flow. Black bars → % scale on the left; gray bars → % scale on the right. (b) Platelet stress accumulation during regurgitant flow. Black bars → % scale on the left; gray bars → % scale on the right.
many repeated passages through the MHV, this chronic platelet activation may translate into a significant difference of the thrombogenic potential.

Acknowledgment

This work was supported in part by an Established Investigator Award from the American Heart Association and by the National Science Foundation under Grant No. 0302275 (DB). The help of Dr. Rissland in the bootstrapping statistics is acknowledged.

References


