Clinical Results and Pump Analysis of the Gyro Pump for Long-term Extracorporeal Life Support

Takamitsu Terasaki, Tamaki Takano, Yuuki Michinaga, Michihiro Yokokawa, , Yuko Wada, Tatsuichirou Seto, Daisuke Fukui, Jun Amano

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Department of Cardiovascular Surgery

Shinshu University School of Medicine, Matsumoto, Japan

Abstract

Rescuing patients in severe cardiac failure with extracorporeal support remains challenging. The Gyro pump is a centrifugal blood pump and now used for cardiopulmonary bypass although it is originally developed for long-term cardiac assist. Little is known about clinical experiences using this pump. We here report the clinical results of long-term extracorporeal life support for over 4 days using the Gyro pump with Excelung, a hollow fiber oxygenator coated with silicone and heparin. Seven patients underwent extracorporeal life support with 15 pump and oxygenator combinations. Gyro and Excelung were used for veno-arterial extracorporeal support in 6 patients and for right ventricular support in one patient. Patient characteristics, pump driving conditions and blood chemistry were obtained retrospectively. All pumps were subsequently disassembled and examined macroscopically, with 6 of the 15 pumps also examined by scanning electron microscopy (SEM). The patient mortality rate was 57.1 %. Mean duration of support was 10.5±7.2 days per pump and oxygenator combination. Lactate dehydrogenase and asparate aminotransferase were generally maintained below 1000 and 100 IU/L, respectively, after the first 4 days of pump driving. Thrombi were found in 2 pumps, one used without anti-coagulation and the other driven at very slow rotational speed of 1077. SEM revealed no wear in the male bearings and very low wear and deformation (0.02 ± 0.03mm) in the female bearings. The combination of Gyro and Excelung may be applicable for long-term biventricular and right ventricular support, although proper anticoagulation should be administrated to avoid thrombus formation inside the pump.

Centrifugal blood pumps are easy to handle and cost less to operate than pulsatile pumps. Centrifugal pumps are widely used as cardiac assist devices for patients in cardiac failure following cardiotomy. The Gyro pump (Medtronic Inc., Minneapolis, USA) is a centrifugal blood pump for cardiopulmonary bypass usually less than 6 hours but considered applicable for long-term use because of its anti-thrombogenicity [1]. In vitro evaluations of the Gyro pump have shown that it is less thrombogenic and induces less blood trauma than the Medtronic BP-80 [2], and its risk of releasing particles from tube fragmentation or debris in circuit is lower than that of roller pumps because the Gyro pump does not compress the tubing to generate blood flow [3]. Although long-term assist with the Gyro pump has been evaluated ex-vivo in animals [4, 5], there have been few reports on the use of the Gyro pump clinically.

We have used the Gyro pump since 2008 at Shinshu University Hospital. We report clinical results of long-term extracorporeal life support (ECLS) for over 4 days using the Gyro pump.

Materials and Methods

Gyro pump

A schematic of the Gyro pump is shown in Figure 1. This pump has an impeller, which is suspended by a double pivot bearing system inside the polycarbonate housing and is driven by magnetic coupling (Fig. 1). The combination of the double pivot bearing and the magnetic coupling system results in a completely seal-less structure. The impeller has primary vanes on the top and secondary vanes on the bottom. These secondary vanes produce a secondary flow to wash around the bottom bearing. Its completely seal-less structure and the secondary flow in the bearing areas make the Gyro pump less thrombogenic [5, 6]. Moreover, the female and male bearings in the Gyro pump are made of the combination of an ultra-high molecular weight polyethylene and Al_2O_3 ceramics. This combination is the same as that used for artificial hip joints, which have been proven durable and safe for long term usage.

Excelung

The Excelung (Senko Medical Instrument Mfg., Tokyo, Japan) is an oxygenator made of hollow propylene fibers coated with ultrathin layers of silicone and heparin, which was developed for long-term use as well as for cardiopulmonary bypass during cardiac surgery. The Excelung demonstrated a lower level of plasma free hemoglobin release than the non-coated oxygenator, both in animals and in vitro [7, 8]. Clinical evaluation showed that use of the Excelung decreased the activation of complement and granulocytes when compared with a non-coated oxygenator, although the differences were not statistically significant [9]. We combined the Gyro pump with the Excelung oxygenator for ECLS in this study.

Patients

Seven patients underwent ECLS with 15 pump and oxygenator combinations. Four patients required ECLS for postcardiotomy cardiac failure, 2 patients required ECLS for cardiogenic shock following acute myocardial infarction (AMI), and one patient required ECLS for cardiogenic shock due to fulminant myocarditis. The Gyro and Excelung were used for veno-arterial extracorporeal support in 6 patients and for right ventricular support in one patient (Table 1).

In the 3 patients with postcardiotomy cardiac failure, a venous cannula was inserted through the femoral vein and an arterial cannula through the femoral artery to reduce the risk of post-operative bleeding although ascending aortic cannulation and right atrial drainage were performed in one patient with postcardiotomy cardiac failure because he suffered acute aortic dissection, and the femoral artery could not be used.

Percutaneous femoral vein and an arterial cannulation were performed in the 2 AMI patients during coronary artery intervention. In one patient, the inflow and outflow cannulae were placed into the right atrium and the pulmonary artery for right ventricular support.

We retrospectively evaluated patient characteristics, pump driving conditions and blood chemistry. After completion of their use, all pumps were disassembled and examined macroscopically, with 6 of the 15 pumps also examined by scanning electron microscopy (SEM) to evaluate bearing wear and deformation. The wear and deformation of female bearings were quantified by measuring the depth of these bearings using a profile meter. The disassembled pumps were sequentially numbered G1 to G15.

Throughout the extracorporeal support, activated clotting time (ACT) was maintained over 180 sec by intravenous infusion of heparin, and oxygen concentration was maintained over 200 mmHg. Pumps and oxygenators were exchanged because of poor oxygenation by the oxygenator, irregular sounds from the pump, pump breakage, and major clots in the pump and oxygenator.

Results

All 7 patients were intubated and on a ventilator under sedation before ECLS, and 2 of 7 patients presented with cardiopulmonary arrest. Systolic blood pressure varied from 42-66 mmHg in the other 5 patients. All patients recovered from shock status immediately after the initiation of ECLS although the level of consciousness could not be evaluated because of sedation. Two of the 7 patients (Patient #3 and #5) were discharged from the hospital after weaning from the ECLS. Patient #3 required 5 days support of ECLS and was weaned from mechanical ventilation 2 months after ECLS stopped. He complicated with respiratory failure, and tracheotomy was performed before hospital discharge. Patient #5 needed ECLS for 7 days and mechanical ventilation for another 2 weeks. He was discharged from the hospital without major complications. Patient #7 with myocarditis was switched to a biventricular assist device, and 4 patients died without weaning from the ECLS, making the mortality rate 57.1 %. Mean duration of support was 10.5±7.2 days (range, 4-26 days) per pump and oxygenator combination and 22.6±16.4 days (range 5-51 days) per patient (Table 2).

The pump and oxygenator were exchanged 4 times in Patient 1 and once each in Patients 2, 4, 6 and 7; in contrast, pumps and oxygenators were not exchanged in Patients 3 and 5. The reasons for exchange included low oxygenation efficiency in 5 patients, a clot on the oxygenator in 1, additional cardiac surgery in 1, and infection in 1 (Table 2).

Mean ACT was 188±29 sec. The mean rotational speed was 2262± 604 rotations/min (RPM), and the mean pump flow was 2.4±0.6 L/min (Table 3).

Figure 2 shows the concentrations of lactate dehydrogenase (LDH) and asparate aminotransferase (AST) during circulatory support with the 15 pump and oxygenator combinations. Initial level of LDH in 2 pumps (G9 and G14) was extremely high. G9 was applied to the patient with AMI and G14 with myocarditis. Patients' condition was severe, and high LDH possibly reflected these severe conditions. After the first 4 days of pumping by 13 pumps (all except G4 and G7) LDH and AST were generally maintained below 1000 and 100 IU/L, respectively. No statistical correlation was found between LDH and driving time (R^2=0.12) and between AST and driving time (R^2=0.043). Use of pumps G4 and G7 increased LDH and reduced AST over time.

We observed thrombi in 2 pumps. G6 had a ring-shaped thrombus on the top shaft (Fig. 3a). The driving duration of this pump was 4 days, its mean rotational speed was 2606±174 RPM, its mean pump flow was 2.4±0.1 L/min, and the mean ACT was 141±23sec. G15 had a ring-shaped thrombus around the bottom shaft (Fig. 3b). This pump was used for right ventricular support for 26 days (with an oxygenator for 6 days and without an oxygenator for 20 days) without pump exchange. Mean pump flow was 2.4±0.2 L/min, and the mean rotational speed was very low, 1143±173 RPM.

Examination by SEM revealed no wear and deformation of the male bearings, even when the thrombus was attached to the shaft (Fig. 4). The machining marks at the top and bottom of the female bearings disappeared in all 6 pumps. Profilometry showed that the mean wear and deformation on the top and bottom female bearings was 0.02±0.03mm and 0.00±0.00mm, respectively. The correlation between deformity and number of driving days is shown in Figure 5. There was no relationship between female bearing deformation and driving period of the Gyro pump (R^2=0.005).

Discussion

Despite ECLS being applied immediately after low output syndrome (LOS) or cardiogenic shock, the mortality rate among our patients was 57.1%, in agreement with reported mortality rates of 54-66% in patients requiring ECLS for cardiac arrest or refractory cardiovascular collapse [10, 11]. Taken together, these results indicate that the use of long-term ECLS to rescue patients with severe cardiac failure remains challenging.

Percutaneous cardiopulmonary support with a centrifugal pump has been widely utilized in patients with acute cardiac failure, but the mean duration of assist per pump was only 2.2-3.8 days [12, 13, 14]. Mean successful pump use for ECLS was 10.5±7.2 days, without any major clinical complications. These findings suggest that the Gyro pump, which showed superior biocompatibility for long-term assistance in a calf model [5], may be utilizable for long-term ECLS in LOS patients.

One pump was used for 26 days as an RVAD. Centrifugal pumps have been reported useful for temporary RVAD in patients who require biventricular support [15]. Use of centrifugal pumps for 6-14 days, with or without an oxygenator for RVAD, resulted in 2 patients recovering from right ventricular failure, although 1 died despite right ventricular support. We found that the Gyro pump was useful for bridging to pulsatile RVAD in a patient with severe right heart failure, although we were unable to wean this patient from RVAD.

LDH and AST were maintained slightly higher than their normal limits, although both were high for 4 days after the pump was attached to the patient. In 13 of the 15 pumps, neither LDH nor AST activity increased with the length of the driving period, suggesting that the Gyro pump induces less blood trauma during clinical long-term cardiac support. In the remaining 2 pumps (G4 and G7), LDH increased while AST decreased relative to the length of the driving period. The increase in LDH of these 2 pumps was not regarded as resulting from hemolysis but might be reflecting patients' severe conditions, although further evaluation may be necessary.

Thrombi were observed inside two pumps. One pump had a thrombus around the top shaft; this pump had operated without anti-coagulation at a mean ACT of 141±23 sec for 4 days due to a severe bleeding tendency and consequent contraindications to heparin. It has been suggested that ACT be maintained over 200 for circulatory support over 2days with a Gyro pump [5]. The thrombus in the first pump apparently formed because of the absence of anticoagulation therapy during support.

The second pump had a thrombus around the bottom shaft. This pump had been used for RVAD and driven at 1143±172 RPM, a relatively low speed compared with other pumps and a speed that may be related with thrombus formation. The Gyro pump has a floating impeller under conditions of proper magnetic balance and rotational speed [16]. A strong magnetic force and/or a low rotational speed can enhance the likelihood of thrombus formation around the bottom bearing.

SEM examination showed no wear on the male bearings and very small wear and tear at the female bearings (20 ± 30μm). In an animal study, the mean wear on and deformation of the female bearings was 2.7±7.7 μm/day for 14-33 days of assist [17]. We found that the mean wear and tear resulting from Gyro pump use was in the same level of previous reports [6] [17], suggesting that the Gyro pump is durable for long-term clinical support.
We observed no relationship between female bearing deformation and driving period.

Former study reported that female bearing deformation includes wear and elastic deformation. Generally, the initial wear or deformation of ultra-high molecular weight polyethylene occurs within a short period after the beginning of rubbing. This initial wear or deformation is large compared to following incline due to rubbing [5]. Observed deformation in this study might not detect that initial large deformation and either marginally increased or reached plateau.

Conclusion

The use of long-term ECLS to rescue patients in severe cardiac failure remains challenging. Combined use of the Gyro and Excelung may be applicable for long-term biventricular and right ventricular support. Proper anticoagulation should be administrated to reduce the likelihood of thrombus formation inside the pump.

References

1 Ichikawa S, Nonaka K, Motomura T, Ishitoya H, Watanabe K, Ashizawa S, et al. Antithrombogenicity of the gyro permanently implantable pump with the RPM dynamic suspension system for the impeller. Artif Organs 2003;27:865-9

2 Takami Y, Makinouchi K, Nakazawa T, Benkowski R, Glueck J, Ohara Y, et al. Hemolytic characteristics of pivot bearing supported Gyro centrifugal pump (C1E3) simulating various clinical applications. Artif Organs 1996;20:1042-9

3 Takano T, Nakata K, Schulte-Eistrup S, Kawahito S, Glueck J, Clarke IC, et al. Particles released from the Gyro C1E3 during simulated extracorporeal circulation. Artif Organs 2000;24:446-9

4 Nakazawa T, Makinouchi K, Ohara Y, Ohtsubo S, Kawahito K, Tasai K, et al. Development of a pivot bearing supported sealless centrifugal pump for ventricular assist. Artif Organs 1996;20:485-90

5 Takano T, Nakata K, Yoshikawa M, Maeda T, Glueck J, Fujisawa A, et al. Development of an antithrombogenic and antitraumatic blood pump: the Gyro C1E3. ASAIO J 2000;46:123-7

6 Orime Y, Shiono M, Yagi S, Yamamoto T, Okumura H, Kimura S, et al. Clinical evaluation of the Gyro Pump C1E3 as a cardiopulmonary bypass pump. ASAIO J. 2000;46:128-33.

7 Iida M, Shiono M, Orime Y, Nakata K, Hata M, Sezai A, et al. A newly developed silicone-coated membrane oxygenator for long-term cardiopulmonary bypass and cardiac support. Artif Organs 1997;21:755-9

8 Niimi Y, Ueyama K, Yamaji K, Yamane S, Tayama E, Sueoka A, et al. Effects of ultrathin silicone coating of porous membrane on gas transfer and hemolytic performance. Artif Organs 1997;21:1082-6

9 Shimono T, Shomura Y, Tani K, Shimamoto A, Hioki I, Tokui T, et al: Clinical evaluation of a silicone coated hollow fiber oxygenator. ASAIO J 1997;43:M735-9

10 Haneya A, Philipp A, Diez C, Schopka S, Bein T, Zimmermann M, et al. A 5-year experience with cardiopulmonary resuscitation using extracorporeal life support in non-postcardiotomy patients with cardiac arrest. Resuscitation 2012;83:1331-7

11 Jaski BE, Ortiz B, Alla KR, Smith SC Jr, Glaser D, Walsh C, et al. A 20-year experience with urgent percutaneous cardiopulmonary bypass for salvage of potential survivors of refractory cardiovascular collapse. J Thorac Cardiovasc Surg 2010;139:753-7

12 Noon GP, Ball JW Jr, Short HD. Bio-medicus centrifugal ventricular support for postcardiotomy cardiac failure: a review of 129 cases. Ann Thorac Surg 1996;61:291-5

13 Orime Y, Shiono M, Hata H, Yagi S, Tsukamoto S, Okumura H, et al. Clinical experiences of percutaneous cardiopulmonary support: its effectiveness and limit. Artif Organs 1998;22:498-501

14 Yamashita C, Ataka K, Azami T, Nakagiri K, Wakiyama H, Okada M. Usefulness of postoperative percutaneous cardiopulmonary support using a centrifugal pump: retrospective analysis of complications. Artif Organs 1999;23:360-5

15 Haneya A, Phillip A, Diez C, Metterlein T, Puehler T, Hilker M, et al. Successful use of temporary right ventricular support to avoid implantation of biventricular long-term assist device: a transcutaneous approach. ASAIO J 2011;57:274-7

16 Nishimura I, Ichikawa S, Mikami M, Ishitoya H, Motomura T, Kawamura M, et al: Evaluation of floating impeller phenomena in a Gyro centrifugal pump. ASAIO J 2003; 49:744-7

17 Nakata K, Yoshikawa M, Takano T, Maeda T, Nonaka K, Linneweber J, et al. Gyro pump wear and deformation analysis in vivo study: Creep deformation. Artif Organs 2000;24:653-5

Fig. 1

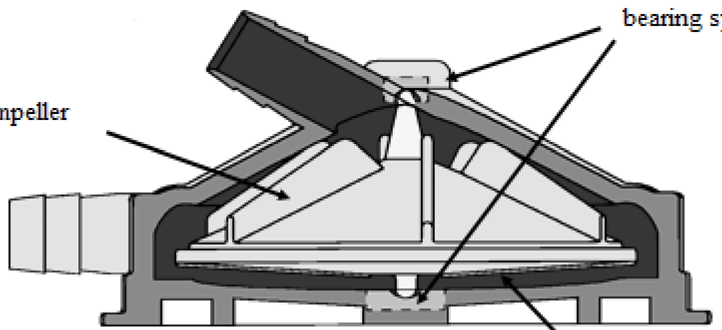


Table 1 : Patient characteristics

Patient	Age (years)	Gender	BSA (m^2)	Indication for ECLS
1	78	Male	1.57	LOS after cardiac surgery (AAD)
2	80	Male	1.57	LOS after cardiac surgery (AS)
3	82	Male	1.73	AMI
4	73	Female	1.68	AMI
5	70	male	1.62	LOS after cardiac surgery (AMI)
6	70	Male	1.66	LOS after cardiac surgery (AR)
7	12	female	1.18	Myocarditis

BSA; body surface area, LOS; low output syndrome, AAD; acute aortic dissection, AS; aortic valve stenosis, AR; aortic valve regurgitation, AMI; acute myocardial infarction

Table 2 : Support duration and clinical course in individual patients

Patient	Pump # (pumping duration; days) Reasons for pump and oxygenator change					Clinical course
1	G1 (6) Low oxgenation	G2 (7) Low oxgenation	G3 (12) Low oxgenation	G4 (7) Low oxgenation	G5 (19)	Dead (MOF)
2	G6 (4) Low oxgenation	G7 (8)				Dead (MOF)
3	G8 (5)					Weaned
4	G9 (7) Blood Clot	G10 (25)				Dead (MOF)
5	G11 (7)					Weaned
6	G12 (8) Infection	G13 (13)				Dead (MOF)
7	G14 (4) Surgery	G15 (26)				Switch to BiVAD

BiVAD; biventricular assist device, MOF; multiple organ failure

Table 3. Parameters of individual pumps

Pump #	Patient	Mean ACT (sec)	Mean blood flow (L/min)	Mean rotational speed (RPM)
G1	1	156 ± 17	3.1 ± 0.2	1402 ± 40
G2	1	161 ± 7	2.8 ± 0.2	1400 ± 84
G3	1	190 ± 18	1.8 ± 0.7	1992 ± 382
G4	1	184 ± 18	1.7 ± 0.2	1915 ± 478
G5	1	255 ± 68	3.1 ± 0.8	2263 ± 200
G6	2	141 ± 23	2.4 ±0.1	2293 ± 632
G7	2	162 ± 27	3.2 ± 0.5	3098 ± 315
G8	3	213 ± 16	1.4 ± 0.5	2357 ± 437
G9	4	192 ± 35	2.1 ± 0.6	2419 ± 491
G10	4	208 ± 31	2.0 ± 0.6	2200 ± 369
G11	5	194 ± 22	2.4 ± 1.4	2552 ± 698
G12	6	161 ± 16	3.6 ± 0.8	3190 ± 435
G13	6	194 ± 47	2.4 ± 0.8	2720 ± 272
G14	7	211 ± 47	2.3 ± 0.2	2681 ± 63
G15 (RVAD)	7	204 ± 36	2.4 ± 0.2	1143 ± 172

RVAD; right ventricular assist device

Fig. 2a

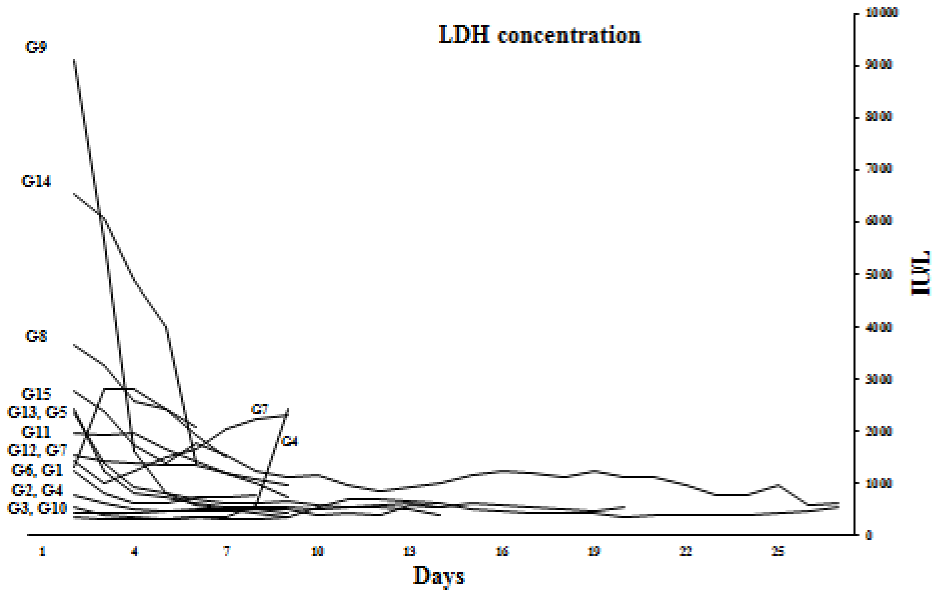

LDH concentration
G9
G14
G8
G15
G13, G5
G11
G12, G7
G6, G1
G2, G4
G3, G10
G7
G4
IU/L
Days

Fig. 2b

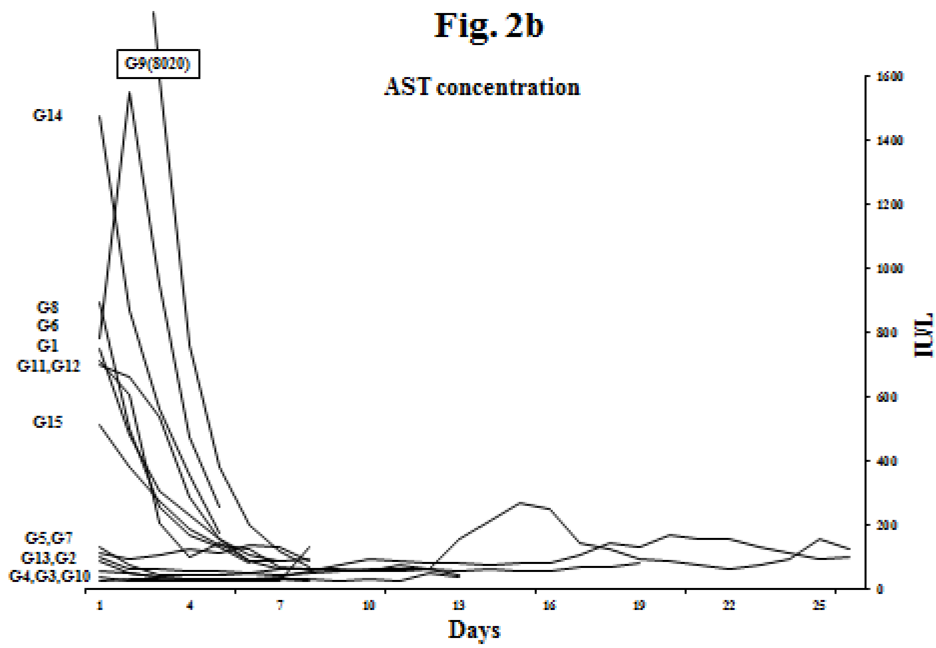

G9(8020)
AST concentration
G14
G8
G6
G1
G11,G12
G15
G5,G7
G13,G2
G4,G3,G10
IU/L
Days

Fig 3

a

b

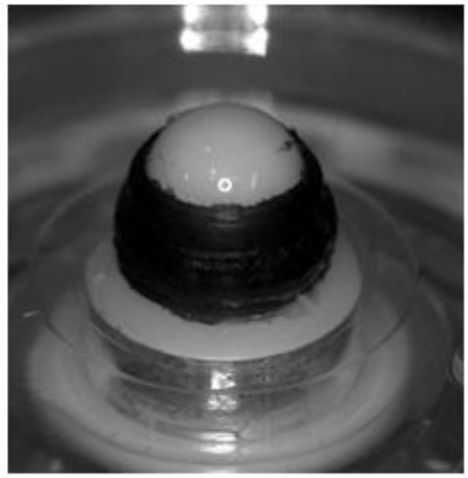
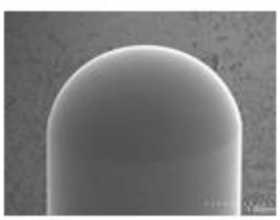


Fig 4

a



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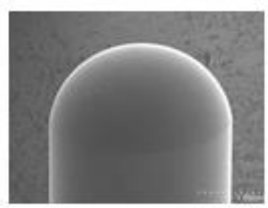
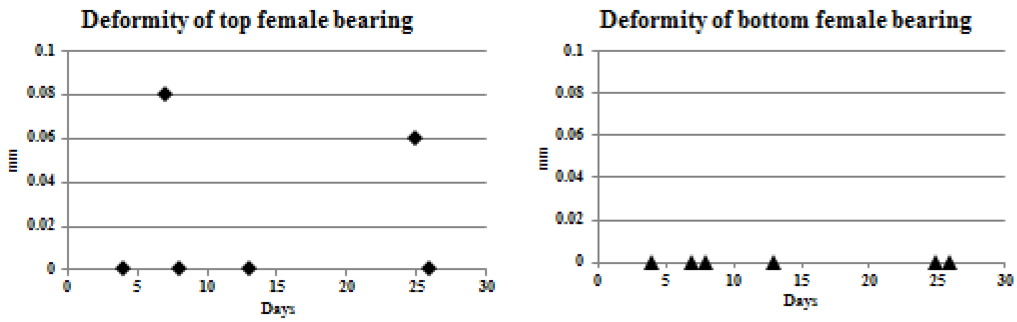


c

d

10

Fig. 5



Legends

Fig. 1 Cross-sectional schema of the Gyro pump. The impeller is suspended by a double pivot bearing system and driven by a magnetic coupling.

Fig. 2 Changes in AST and LDH in during the ECLS. G1 to G 15 indicates pump number.

Fig. 3 a: Ring-shaped thrombus attached around the top shaft of pump number G6.

b: Thrombus around the bottom shaft of pump number G15.

Fig. 4 SEM finding of a G10 bearing used for 25 days.

a: Top shaft, b: bottom shaft, c: top female bearing, d: bottom female bearing

Fig. 5 Correlation between the cumulative duration of ECLS and bearing deformation.