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OPEN A retrospective study to compare the clinical effects of individualized anatomic singleand double-bundle anterior cruciate ligament reconstruction surgery

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To evaluate the clinical efficacy of single- and double- bundle individualized anatomic anterior cruciate ligament (ACL) reconstruction, we retrospectively analyzed the data and charts of 920 patients with ACL rupture who received individualized anatomic ACL reconstruction surgery at our center. All of the patients underwent arthroscopic ACL reconstruction with autologous hamstring tendons. The patients were divided into two groups: the single-bundle individualized anatomic reconstruction group (N = 539), and the double-bundle individualized anatomic reconstruction group (N = 381). The IKDC, Lysholm and Tegner scores were used to subjectively evaluate the function of the knee joint during the postoperative follow-up. The Lachman test, pivot shift test and KT-3000 were used to objectively evaluate the stability of the knee. All 920 patients participated in clinical follow-up (average duration: 27.91 ± 3.61 months) achieved satisfied outcomes with few complications. The postoperative IKDC, Lysholm and Tegner scores, and the objective evaluation of knee joint stability were significantly improved compared to the preoperative status in both groups (P < 0.05). No statistically significant difference was observed between the two groups at the final follow-up (P > 0.05). Therefore, no difference in terms of the IKDC, Lysholm and Tegner score, or KT-3000 was observed between the individualized anatomic single- and double-bundle ACL reconstruction techniques. Both techniques can be used to restore the stability and functionality of the knee joint with satisfactory short-term efficacy.

Anatomic single-bundle (SB) and double-bundle (DB) reconstruction are currently the most widely applied surgical treatments for anterior cruciate ligament (ACL) rupture¹. Specifically, the ACL SB reconstruction procedure

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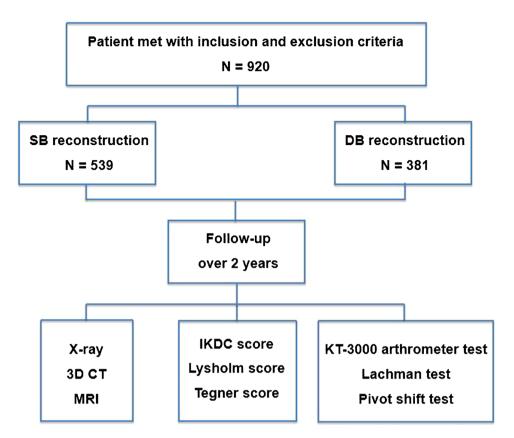


Figure 1. Flow diagram of the study design.

		Gender			Side				
Groups	Number	Male	Female	Age (years)	Left	Right	Injury time (months)	Follow-up (months)	
SBR	539	341	198	28.76±7.25	209	330	17.65 ± 21.96	21.06 ± 1.59	
DBR	381	221	160	27.76 ± 7.05	213	168	21.65 ± 28.71	24.28 ± 1.94	
t/χ2		$\chi^2 = 0.425$		t=0.647	$\chi^2 = 0.751$	•	t=0.743	t=0.735	
P		0.503		0.455	0.367		0.452	0.712	

Table 1. General information of patients. *SBR* single-bundle reconstruction, *DBR* double-bundle reconstruction.

restores the anterior and posterior stability of the knee only by reconstructing the anteriormedial (AM) bundle; this traditional ACL reconstruction technique cannot restore knee kinematics and is associated with a reduced return to sport rate^{2,3}. Many researchers believe that DB reconstruction, as the treatment closest to the original anatomical structure of the intact ACL, shows a biomechanical advantage^{4,5}. This procedure has been reported to outperform SB reconstruction for better rotation stability of the knee joint and fewer graft failures⁶. However, several studies indicated that the number of bundles did not seem to influence clinical and subjective outcomes^{7,8}. In addition, the drawbacks of DB reconstruction, such as extended operation time, high cost, increased risk of bone bridge fractures, and challenge in revision surgery, etc., also urge us to reconsider the necessity of this technique⁹.

In 2015, we proposed a concept of individualized DB ACL reconstruction¹⁰. With deepened understanding of the individual differences in ACL anatomic footprint, we further considered a number of indicators for the selection of appropriate surgical method¹¹. We then retrospectively analyzed and compared the clinical outcomes between the arthroscopic SB and DB individualized anatomic ACL reconstruction with over two years of follow-up, in order to provide evidence for the DB individualized anatomic ACL reconstruction theory.

Results

Flow diagram of the study design was presented in Fig. 1. The demographic characteristics of the patients are listed in Table 1. There was no statistical difference between the single-bundle reconstruction (SBR) group and double-bundle reconstruction (DBR) group in terms of gender, age, left and right knee, injury time interval and follow-up duration (P > 0.05).

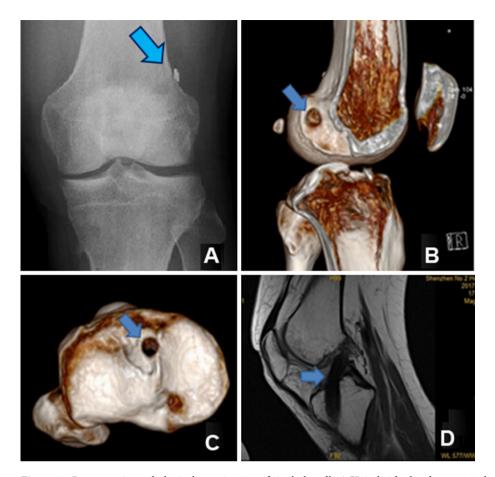


Figure 2. Postoperative radiological examination of single-bundle ACL individualized anatomical reconstruction after over 2 years. (**A**) X-ray: arrow shows the fixation of Endobutton. (**B**) 3D CT: arrow shows the femoral socket. (**C**) 3D CT: arrow shows the tibial socket. (**D**) MRI: arrow shows the graft.

The follow-up duration ranged between 18 and 55 months with an average of 27.91 ± 3.61 months. All the patients recovered after surgical treatment without graft failure or deep venous thrombosis of the lower extremities. There was no statistically significant difference between the two groups in terms of complications (SBR group vs. DBR group, P>0.05): knee joint infections (5 vs. 8), foreign-body reaction (4 vs. 3) and stiffness (4 vs. 3). The postoperative X-ray and three-dimensional computed tomography (3D CT) showed accurate bone tunnel and properly positioned screw, and magnetic resonance imaging (MRI) showed complete healing in both groups (Figs. 2, 3).

In the SBR group, 393 out of 539 patients managed to recover their pre-injury exercise level (excellent rate of 72.9%), and 119 patients were able to perform daily activities (e.g., walking, deep squatting, and walking up and down stairs) and mild physical activities. In the DBR group, 286 out of 381 patients recovered their pre-injury exercise level (excellent rate of 75%), and 76 patients were able to perform daily activities and mild physical activities. 27 patients from the SBR group and 19 patients from the DBR group reported occasional pain and residual subjective and objective joint instability.

The postoperative International Knee Documentation Committee (IKDC), Lysholm and Tegner scores were significantly improved in both groups compared to the pre-operative status (P < 0.01): IKDC scores increased from 59.03 ± 14.12 (40-77) to 89.40 ± 3.67 (83-95), Lysholm scores increased from 64.18 ± 19.11 (43-84) to 92.26 ± 5.12 (85-99), Tegner scores increased from 2.47 ± 0.82 (1-4) to 6.59 ± 0.51 (4-9) in the SBR group; IKDC scores increased from 60.15 ± 13.77 (42-76) to 90.03 ± 4.30 (83-96), Lysholm scores increased from 65.87 ± 18.94 (45-84) to 93.20 ± 4.83 (86-100), Tegner scores increased from 3.30 ± 1.27 (1-4) to 6.63 ± 0.79 (4-9) in the DBR group. But there was no significant difference between the two groups (P > 0.05, Table 2). In addition, no significant difference was found between the Lachman test and the pivot shift test according to the clinical examination at the final follow-up (P > 0.05, Table 3).

The KT-3000 results of both groups showed that the difference between the affected and unaffected knee was significantly reduced after surgery (P < 0.01): in the SBR group decreased from 7.66 ± 6.32 (5.0-8.5) to 1.47 ± 1.15 (0.5-2.3); in the DBR group decreased from 6.82 ± 4.01 (5.0-8.2) to 1.40 ± 1.26 (0.5-2.1). No significant difference was found between the two groups (P > 0.05, Table 4).

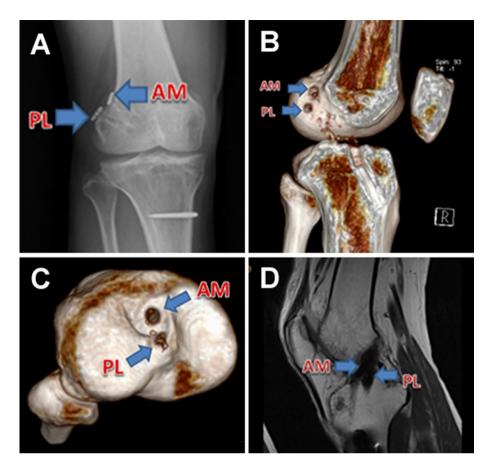


Figure 3. Postoperative radiological examination of double-bundle ACL individualized anatomical reconstruction after over 2 years. (**A**) X-ray: arrow shows the fixation of Endobuttons. (**B**) 3D CT: arrow shows the femoral socket. (**C**) 3D CT: arrow shows the tibial socket. (**D**) MRI: arrow shows the graft.

	IKDC score			Lysholm score			Tegner score		
Groups	Preoperative	Follow-up	P value	Preoperative	Follow-up	P value	Preoperative	Follow-up	P value
SBR	59.03 ± 14.12	89.40 ± 3.67	0.000	64.18 ± 19.11	92.26 ± 5.12	0.000	2.47 ± 0.82	6.59 ± 0.51	0.000
DBR	60.15 ± 13.77	90.03 ± 4.30	0.000	65.87 ± 18.94	93.20 ± 4.83	0.000	3.30 ± 1.27	6.63 ± 0.79	0.000
P value	0.672	0.630		0.593	0.602		0.572	0.697	

Table 2. Comparison of IKDC, Lysholm and Tegner scores before operation and at the last follow-up in both groups. Postoperative follow-up compared with pre-treatment, P < 0.01, comparison between follow-up after treatment, P > 0.05. SBR single-bundle reconstruction, DBR double-bundle reconstruction.

		Lachman test				Pivot shift test			
Groups	Number	(+)	(-)	Positive rate	P value	(+)	(-)	Positive rate	P value
SBR	539	37	502	0.069	> 0.05	51	488	0.095	> 0.05
DBR	381	25	356	0.066	70.03	22	359	0.058	Z0.03

Table 3. Comparison of clinical findings between the two groups at the last follow-up. The comparison between the follow-up groups after treatment, P > 0.05. SBR single-bundle reconstruction, DBR double-bundle reconstruction.

	30° of knee flexion		
Groups	Preoperative	Follow-up	P value
SBR	7.66 ± 6.32	1.47 ± 1.15	0.000
DBR	6.82 ± 4.01	1.40 ± 1.26	0.000
P value	0.659	0.8002	

Table 4. Comparison of KT-3000 results before operation and at the last follow-up in both groups. Postoperative follow-up compared with pre-treatment, P < 0.01, comparison between follow-up after treatment, P > 0.05. SBR single-bundle reconstruction, DBR double-bundle reconstruction.

Discussion

The results of our large-sample study with over 2 years of follow-up showed that the postoperative scores of IKDC, Lysholm and Tegner in both the SBR and DBR groups were significantly higher than the preoperative status, indicating that the knee joint function was recovered after SB or DB reconstruction. However, all the indicators showed no significant difference between the two groups at the final follow-up.

ACL cannot heal on its own after rupture. Reconstruction surgery under arthroscopy is the optimal method for treating ACL rupture at present¹². The anatomic ACL reconstruction technique was proposed based on an extensive series of biomechanical, imaging, and clinical studies. This technique does not damage the inherent structure of the knee joint and is operated in accordance with the anatomical and biomechanical characteristics of the knee joint, which makes it more conducive to the recovery of the knee joint and the rotational stability than the traditional surgical method¹³.

Currently, there is a great deal of disagreement in the academic community regarding the choice of SB vs. DB reconstruction after ACL rupture. Meredick et al. reported that the SB reconstruction could restore most of the function (anterior–posterior stability) of the AM bundle, but not the posterolateral (PL) bundle. Meanwhile, it failed to restore the rotational stability as well, leading to relaxation in knee extension¹⁴. Freddie. Fu put forward the theory of maximizing the restoration of the ACL anatomical structure with DB reconstruction firstly in 2010¹⁵, the basic principle of which is to restore the size and shape of the patient's ACL footprint to the best extent. DB reconstruction is to restore the AM and PL bundle simultaneously to ensure the alternating tension and relaxation of the two bundles during knee motion, which is close to the normal physiology¹⁶. The results of several biomechanical studies supported that the anatomic DB reconstruction could better restore the anterior–posterior and rotational stability of the knee, while SB reconstruction was not satisfactory in controlling the rotation and valgus torsion^{17,18}.

However, other researchers found that under a simulated physiological load of quadriceps femoris, the DB reconstruction excessively limited the internal rotation of the tibia, which altered the normal trajectory of the patellofemoral joint, increased the contact pressure of the patellofemoral joint, and eventually led to cartilage damage^{19,20}. In addition, many problems and difficulties may be encountered during the implementation of the DB reconstruction technique in clinical practice. Compared with SB reconstruction, the DB reconstruction technique is more time consuming and challenging for surgeons as it requires four bone tunnels and must be operated with a higher location accuracy. A larger amount of bone mass loss of the knee joint is not conducive to ACL reconstruction and revision, as the risk of lateral femoral condyle fracture and intraoperative bone bridge fracture between bone tunnels, as well as the probability of intercondylar fossa impaction will increase. An earlier study has also shown that it is difficult to establish a double bone tunnel for patients with smaller intercondylar fossa and shorter anteroposterior diameter of the tibia²¹. For these patients, SB reconstruction is a better choice due to the narrowness of the intercondylar fossa, the undersized area of the ligament stop point, and the finer diameter of the hamstring tendon. Since there is currently no objective and reliable method for detecting the stability of the knee joint rotation, the preferential results of DB reconstruction in restoring rotational stability remains to be further confirmed²¹. Our results were in line with previous studies. Kondo et al. reported that both SB and DB reconstructions could restore the knee joint anteroposterior and rotational stability with no significant differences in clinical outcomes 18. Streich et al. found that both SB and DB achieved good clinical outcomes with no statistically significant differences in IKDC and Lysholm scores²².

The present study demonstrated satisfactory results in patients who received either SB or DB reconstruction based on a large sample with over 2 years of follow-up. From the perspective of anatomy and biomechanics, DB reconstruction is undoubtedly the best choice for completely restoring the normal function of the knee joint. Many indicators, including the size of the footprint, the shape of the femoral condyle as well as the AM and PL bundles, and the width of the intercondylar fossa, must be comprehensively considered. Individualized anatomic DB reconstruction can be chosen when the ACL footprints of the femur and tibia side are both greater than 14 mm and the width of the intercondylar fossa is greater than 12 mm. If such requirements are not fulfilled, individualized anatomic SB reconstruction is technologically friendlier, and can achieve equivalent clinical outcomes for most of the patients, especially those without special requirements on knee joint rotational stability. Our method of individualized anatomic DB reconstruction is proven to be able to achieve satisfactory clinical outcomes, but it is advisable to perform preoperative radiology evaluation and take accurate intraoperative measurements.

This study also presents with some limitations. Firstly, as a retrospective study, more prospective research including randomized controlled trials should be performed to provide stronger evidence. Secondly, the follow-up is relatively short, and long-term detection should be conducted in the future.

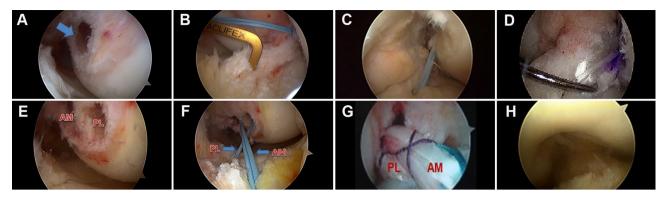


Figure 4. Surgical procedures of single- and double bundle ACL individualized anatomical reconstruction under arthroscopy. (**A**) Femoral insertion in SBR. (**B**) Tibial insertion in SBR. (**C**) Graft passed tibial tunnel in SBR. (**D**) Reconstructed ACL in SBR. (**E**) Femoral insertion in DBR. (**F**) Grafts passed tibial tunnel in DBR. (**G**) Reconstructed ACL in DBR. (**H**) Impingement test. *AM* anteromedial, *PL* posterolateral, *SBR* single-bundle reconstruction, *DBR* double-bundle reconstruction.

In conclusion, compared with SB individualized anatomic reconstruction, the DB individualized anatomic reconstruction does not exhibit any obvious advantage in terms of the postoperative IKDC score, Lysholm score, Tegner score and KT-3000 measurement of knee joint. The stability and functionality of knee joint can be well restored well in both groups with satisfactory short-term curative effect.

Methods

Patient recruitment. This retrospective study was approved by the ethics committee of Shenzhen Second People's Hospital. All the participants had surrendered informed consent preoperatively. All methods were carried out in accordance with relevant guidelines and regulations. The patients who underwent primary ACL reconstruction at our department from October 2009 to May 2016 were reviewed. Patients would be included if they met the following criteria: (1) ≥ 18 years of age; (2) primary ACL surgery; (3) no concomitant ligament injury; (4) unilateral ACL injury; (5) no previous surgery on the affected knee; (6) no chondral lesion worse than Outerbridge grade 2; and (7) ACL rupture confirmed clinically and by MRI. The exclusion criteria included: (1) damage of multiple ligaments or injury of articular cartilage; (2) radiographic evidence of Kellgren-Lawrence grade 3 or 4 osteoarthritis and/or severe osteoporosis; (3) ACL injuries of both sides of the knees; (4) partial ACL rupture; (5) concomitant total or subtotal meniscectomy; or (6) young patients with unclosed growth plates. Overall, 920 patients were confirmed to meet all our inclusion criteria. The duration between injury and surgery ranged from 1 day to 8 years. All the included patients underwent both the initial surgery and individualized anatomic reconstruction. There were 667 patients with meniscus injury, for whom, the menisci were sutured, shaped, or resected according to the type of injury. All the surgeries were performed by the same senior surgeon. The patients were divided into two groups, the SBR group (N = 539) and the DBR group (N = 381).

Surgical procedure. Every patient, regardless of group, was treated with combined spinal-epidural anesthesia. After placing the patient supine, the upper thigh was bound up with an inflatable tourniquet, and the surgical area routinely disinfected. Routine arthroscopy was performed in order to confirm the diagnosis of torn ACL.

The medial, lateral, and anterior internal approaches were adopted as described in previous literature²³. Parameters including the length of ACL footprint, width of intercondylar nest, distance between bone tunnels, and distance between the bone and cartilage could be accurately measured and confirmed in all these approaches. A 3 cm longitudinal incision was created at the medial 1.5 cm of the tibial tubercle. Serving as grafts, the semitendinosus and gracilis tendons were exposed and harvested. For SB grafts, a double Krackow suture was performed with the EthiBond II non-absorbable line (Johnson & Johnson Medical N.V., Belgium) at both ends of the tendon. Then, the two sutured tendons were folded to create 4 strands. Finally, the diameter and length of the grafts were measured. The length was measured to be over 7 cm, and the diameter was 7–9 mm. For the DB grafts, a Double Krackow suture was performed with the EthiBond II non-absorbable line at both ends of the semitendinosus and gracilis tendons. Each sutured tendon was folded into 2 strands separately. The semitendinosus tendons were used as the AM bundles, and the gracilis tendons were used as the PL bundles. The diameter and length of the two grafts were measured respectively. In general, the AM bundle is over 6.5 cm in length and 6–7 mm in diameter, while the PL bundle is over 5.5 cm in length and 5–6 mm in diameter.

In accordance with the individualized anatomic reconstruction method proposed by Lu et al.²⁴, the following principles are implemented: if there is a clear stump, the stump center is preferred as the center of the femur tunnel; if there is no stump or the stop point of the ligament is indistinguishable, the femur tunnel should be located according to the bony landmarks. The latter can be achieved by positioning the knee in 90° and observing from the anteromedial portal. The center of the bone canal was located at the lateral crest of the intercondylar fossa below the resident ridge. If the bony landmarks aren't clear, it can be located between 30 and 35% below the lateral wall of the intercondylar fossa (Fig. 4A). However, the location of the tibial tunnel is usually determined by the center of ligament stump or the extension line of the lateral meniscus anterior angle (Fig. 4B). When a

DB reconstruction is carried out, the length of the ACL footprint on the tibia side must be over 14 mm, and the width of the intercondylar fossa must be over 12 mm. If the ACL footprint completely disappears, both the anterior and posterior diameter of the resident ridge should be over 20 mm. If the measurement fails to meet any of the criteria above, DB reconstruction should not be performed. The detailed methods for creating femoral and tibial bone tunnels can be found in previous literature²⁴.

The graft was first introduced into the tibial tunnel with a guide wire. In SB reconstruction, the graft was pulled directly into the femoral tunnel and fixed on the femoral side by flipping over the Endobutton (Smith & Nephew, MA). Then on the tibial side, the graft was manually tightened and fix at 30° knee flexion by a doorshaped nail (2.3 mm Kirschner's needle). Subsequently, the fixation needed to be further strengthened using a hydroxyapatite interference screw with a diameter of 1 mm larger than the graft (Fig. 4C,D).

In the DB reconstruction, after creating the femoral tunnels (Fig. 4E), the AM and PL grafts were firstly passed through the respective tibial tunnels (Fig. 4F) and then pulled out of the femoral tunnels. The femoral side was fixed by Endobutton suspension. On the tibial side, the graft sutures were tightened and knotted separately. A 2.3 mm Kirschner needle was used to fix the grafts (AM fixed at 30° flexion and PL at the full extension position), which were then reinforced using an interference screw with a diameter of 1 mm larger than the grafts (Fig. 4G).

Following the ACL reconstruction, flexion of the knee joint from 90° to full extension was performed in order to observe whether the femoral condyle and posterior cruciate ligament demonstrated any impingement (Fig. 4H).

Postoperative treatment and rehabilitation. All patients were treated with 1 g cefoxitin BID for 48 h to prevent infection, and the affected limb was wrapped with cotton pad for 3 days. X-ray and 3D CT were performed immediately after surgery to evaluate the bone tunnel and fixation, and MRI was performed to check the ligament healing at 3, 6, 12 and 24 months after surgery respectively.

The same postoperative rehabilitation plan was implemented for the patients in both groups. Specifically, the affected limb was immobilized with adjustable support. On the second day postoperatively, the patients were requested walk with crutches under protection of knee braces (the specific walking time was determined based on whether the meniscus was sutured). The patients were encouraged to flex their knees from 0 to 90° within the second to the fourth week, and up to 120° within the sixth to the eighth week. However, they were instructed not to flex the affected knee over 120° in the first 3 months postoperatively. The braces were used for at least 2 months. Six patients were allowed to swim and cycle 6 months after the operation, to begin jogging 10 months after the operation, and to participate in strenuous exercises 18 months after the operation.

Observation indicators. Knee function was assessed by IKDC, Lysholm and Tegner scores before operation and during the follow-up. The preoperative and follow-up KT-3000 arthrometer (MEDmetric, San Diego, CA, USA) measurements of the tibial anterior displacement were taken by applying a tension of 134 N with knee joint flexion at 30°. The Lachman test and pivot shift test were performed to evaluate the knee joint stability. A positive Lachman test is defined as: with the knee flexed 20°-30°, the tibia is displaced anteriorly relative to the femur with either a soft endpoint or a displacement greater than 4 mm. The pivot shift test is considered positive if the proximal tibia subluxes anteriorly on the distal femur at about 30° of flexion.

Statistical analysis. The study data was expressed as mean \pm standard deviation (SD) and analyzed by SPSS 18.0 software (SPSS Inc., Chicago, IL, USA). Independent samples t-test and χ^2 test were done on the general data of the patients. The preoperative and postoperative IKDC, Lysholm, Tegner scores, and KT-3000 measurements were tested for paired t-test. Chi-squared test was used for the analysis of Lachman and pivot shift tests. The threshold for statistically significant differences is defined as P < 0.05.

Received: 16 May 2020; Accepted: 18 August 2020

Published online: 07 September 2020

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Acknowledgements

This study was supported by the National Natural Science Foundation of China (81672234, 81902303, 81902558, 81902682), Guangdong Basic and Applied Basic Research Foundation (2020A151501048), Shenzhen Science and Technology Project (GJHZ20180416164801042, JCYJ20180305124912336, JCYJ20190806164216661), Science and Technology Commission of Shanghai Municipality (Shanghai Sailing Program 19YF1408900), Clinical Research Project of Shezhen Second People's Hospital (20173357201814, 20203357007, 20203357028).

Author contributions

All authors had full access to the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Z.H.D., W.L. and W.M.Z were responsible for conception and design. K.C. and Z.H.D. contributed to study retrieval and drafted the manuscript. K.C., Z.H.D., K.O., L.Q.P., H.F.L., and W.Z.F. contributed to data collection. Y.Z.Z., F.J.Z., and Y.H. performed data analyses. G.Z. contributed to language editing. All the authors contributed to the interpretation of the data and critically reviewed the manuscript for publication.

Competing interests

The authors declare no competing interests.

Additional information

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