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ORIGINAL ARTICLE

Comparing Two Kinds of Bioabsorbable Steroid Implants Following Endoscopic Sinus Surgery：A Randomed，Controlled，Single-Blind，Prospective，Multi-Center Study

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Abstract

Objective : To assess the safety and effectiveness of a bioabsorbable steroid implant which produced by BREATH MEDICAL following endoscopic sinus surgery.

Methods: A prospective, multi-center, randomized, single-blind,controlled design method was adopted, a total of 180 cases were enrolled, and there were 6 clinical trial institutions. The test group used the stent produced by BREATH MEDICAL.The control group used the stent produced by PUYI BIOTECHNOLOGY which was the first one used in China. Observe the clinical evaluation indicators of the subjects during the treatment process after1 week, 1 month, 2 month and 3 month respectively.

Results: There were no statistical significance in the disease control evaluation results, visual analog scale(VAS) results, and nasal endoscopy Lund-Kennedy score between the test group and the control group (P>0.05). The Sino-Nasal Outcome Test-20(SNOT-20): there was no significant difference in the SNOT-20 measured at the 1 week, 1 month, and 2 month postoperative (P>0.05), but there was a significant difference at the 3 month postoperative (P<0.05). The SNOT-20 measures in the test group was higher than that in the control group. The safety evaluation results showed that the laboratory tests (blood routine, urine routine, blood biochemistry-liver and kidney function), electrocardiogram, and eye examination (fundusscope and ophthalmology) of the two groups before surgery and 3 month after surgery has no significant difference(P>0.05).And there was no statistical difference in the occurrence of adverse events and serious adverse events between the two groups (P>0.05).

Conclusions: This study demonstrated the safety and effectiveness of the bioabsorbable steroid implant produced by BREATH MEDICAL and it can be used in clinical.

Key Words: Chronic rhinosinusitis(CRS);endoscopic sinus surgery(ESS); bioabsorbable steroid implant.

Introduction

Chronic rhinosinusitis (CRS) is a common disease. Most patients cannot be cured by drugs alone and often suffer from recurring attack. In this case, endoscopic sinus surgery (ESS) is needed for treatment. Surgery can keep the nasal sinus opening and smooth, but there are local edema, vesicles, adhesions, and external migration of the middle turbinate postoperative, which can lead to stenosis and obstruction of the sinus opening, and lead to surgical failure. The

inflammation can affect mucosal recovery and cause polyps postoperative[1]. Such reasons may further reduce the effectiveness of surgery and make other problems. The application of glucocorticoids after endoscopic sinus surgery can reduce inflammatory reaction, reduce postoperative edema and granulation tissue formation[2]. Long-term systemic use of corticosteroids can result in serious long-term or short-term adverse effects. Therefore, a safer and more effective alternative is sought. The bioabsorbable steroid implant is a new method for local application of glucocorticoids, which breaks through the traditional method by stably releasing glucocorticoids. The method of administration is conducive to keep the surgical area unobstructed [3,4]. Therefore, a variety of stents have been developed and produced to prevent adhesion after ESS surgery, keeping the nasal cavity open, and reducing inflammation[5]. The stent produced by PUYI BIOTECHNOLOGY which was the first one used in China, but there are still some problems. BREATH MEDICAL has improved its stent to test its clinical effectiveness and safety.

Materials and Methods

Study Design

There were 180 patients with CRS diagnosed in the Department of Otolaryngology Head and Neck Surgery in 6 clinical research centers (The First Affiliated Hospital of Sun Yat-sen University, Zhejiang Provincial People's Hospital, the Second Hospital of Jilin University, Shandong Provincial Otolaryngology Hospital, Dalian Municipal Central Hospital and the First Affiliated Hospital of Baotou Medical College of Inner Mongolia University of Science and Technology).Clinical datas were collected from October 20, 2020 to May 15, 2023. The test group:the stent produced by BREATH MEDICAL; the control group:the stent produced by PUYI BIOTECHNOLOGY. A bioabsorbable steroid implant is composed of a self-expanding degradable stent, a glucocorticoid drug coating, a delivery system and auxiliary tools. After the stent is expanded, it forms a mesh shape, adapting to the irregular sinus cavity and making it difficult to move. Each stent contains approximately 650ug of mometasone furoate, which releases an average of 20ug per day and begins to degrade and absorb approximately 30 days after implantation[6].After a patient was enrolled in the research center, the same rhinologist performed ESS surgery under general anesthesia. During the operation, a stent was implanted in the ethmoid sinus according to a random method.

Inclusion Criteria and Exclusion Criteria

(1)Inclusion criteria:①The diagnostic criteria for sinusitis with nasal polyps set by the "Chinese Guidelines for the Diagnosis and Treatment of Chronic Sinusitis (2018)"; ②Patients who have been treated with standardized drugs for >3 months with poor results and are willing to surgery;③Aged between 18 and 75 years old, regardless of gender;④Patients with chronic sinusitis who clinically need to undergo endoscopic sinus surgery must have a Lund-Mackay score of not less than 6 on CT examination of each sinus (preoperative CT examination results within 3 months);⑤No serious systemic diseases;⑥Those with good compliance and able to cooperate the entire clinical trial;⑦Before the study, the patients are willing and able to sign the approval of the Institutional Review Board (IRB) and Informed consent form approved by the Ethics Committee (EC) or Ethical Review Board (ERB).

(2) Exclusion criteria:①Those who are allergic to the structural components of the test device, such as those who are allergic to mometasone furoate and its derivatives, glycolide-lactide copolymers and their degradation products Allergy sufferers, etc; ②Subjects who have suffered or are currently suffering from glaucoma or ocular hypertension;③Cataract patients; ④Patients who require long-term oral steroid drugs;⑤Subjects are receiving immunosuppressive treatment or are known to have immunosuppression or autoimmune diseases;⑥Patients with acute bacterial or fungal sinusitis;⑦Pregnant or lactating women;⑧Those who cannot tolerate surgery;⑨ Poor compliance is expected;⑩Have participated in other drugs, biological agents or device clinical investigators;⑪Those who are mentally incapacitated or unable to understand the requirements for participating in the research;⑫Other researchers deem it inappropriate to participate in the trial.

Evaluation Index

(1)The disease control status of the subjects was evaluated at 1 month, 2 month, and 3 month after surgery, and the treatment efficacy of the subjects was divided into complete control, partial control, and no control. Refer to the treatment efficacy evaluation standards in the Chinese Guidelines for the Diagnosis and Treatment of Chronic Sinusitis 2018 (CPOS 2018) and the European Position Paper on Sinusitis and Nasal Polyps 2020 (EPOS 2020).

(2)The conditions were assessed using the Visual Analog Scale (VAS) before surgery, at 1 week, 1 month, 2 month, and 3 month after surgery, and the scores were calculated according to the VAS The condition is divided into: mild 0-3 points, moderate >3-7 points, severe >7-10 points. If VAS >5 points, it means the patient's quality of life is affected.

(3)Twenty-item nasal and sinus outcome measurements (the Sino-Nasal Outcome Test-20, SNOT-20) were performed using the SNOT-20 scale before surgery, at 1 week, 1 month, 2 month, and 3 month after surgery. Subjects were assessed for sinus-related symptoms.

(4)Nasal endoscopy Lund-Kennedy score, the subjects' nasal endoscopy conditions were evaluated at 1 week, 1 month, 2 month, and 3 month after surgery. Scoring criteria (points): 1) Polyps: 0 = no polyps, 1 = polyps only in the middle meatus, 2 = polyps beyond the middle meatus; 2) Edema: 0 = none, 1 = mild, 2 = severe; 3) Rhinorrhea: 0=none, 1=clear, thin rhinorrhea, 2=thick, purulent rhinorrhea; 4) Scars: 0=none, 1=mild, 2=severe; 5) Scab: 0=none, 1=light, 2=heavy; 0-10 per side, total score 0-20.

(5)Record the laboratory examination (blood routine, urine routine, blood biochemistry-liver and kidney function), electrocardiogram, and eye examination (fundoscopy and intraocular pressure) results before surgery and 3 month follow-up, and determine whether there are abnormal. The incidence of adverse events and serious adverse events that occurred during the trial, and analyze their causes, consequences and relationship with the trial product.

Statistical Analysis

The description of the measurement index will calculate the mean, standard deviation, median, minimum value, maximum value, lower quartile (Q1), and upper quartile (Q3). The description of the counting index will calculate the number of cases of each type and percentage. Grouped t-test was used for comparison of measurement indicators between groups; Chi-square test was used for count indicators, and Wilcoxon rank-sum test was used for grade indicators. All statistical tests were two-sided, and a P value less than or equal to 0.05 was considered statistically significant. Statistical analysis will be performed using SPSS22.0 software.

Results

A total of 180 subjects were finally enrolled in this clinical trial. 3 patients were lost to follow-up, 1 dropped out due to cancellation of surgery, 1 subject voluntarily withdrew, and 1 was terminated by the researcher. All treatments and 174 cases were followed up, including 88 cases in the test group and 86 cases in the control group. The age, gender, height, weight, body temperature, respiration, heart rate, blood pressure, preoperative sinus CT score, VAS, and SNOT-20 of the two groups of subjects which were no statistical difference (all P >0.05). The baseline data of the two groups were balanced and comparable, （Table 1）.

Table 1 Difference analysis of basic information

Clinical data	Chi-square	t	Z	P value	result
age(year)	/	/	-0.102	0.919	P>0.05
gender	0.06	/	/	0.94	
height cm	/	/	-0.119	0.905	
weight kg	/	/	-0.683	0.495	
Temperature ℃	/	/	-0.004	0.996	
respiration（time/min）	/	/	-0.35	0.726	
heart rate（time/min）	/	/	-0.548	0.584	
systolic mmHg	/	0.342	/	0.733	

Diastolic mmHg	/	-1.182	/	0.239	
sinus CT score	/	/	-1.12	0.263	
VAS	/	/	-0.169	0.866	
SNOT-20	/	/	-0.738	0.461	

Clinical evaluation index

(1) The disease control status was evaluated respectively at 1 month, 2 month, and 3 month after the operation, and the evaluation results were divided into control, partial control, and uncontrolled. The disease control evaluation results at each follow-up time point were compared, and the P values were all > 0.05. There was no statistical significance in the evaluation results of the two groups at each stage,（Table 2）.

Table 2 Disease control evaluation

	group	control	partial control	uncontrolled	total N (Missing)	z	P value	result
1 month	test	39	31	15	85(5)	-0.518	0.605	P>0.05
	control	41	31	12	84(4)			
	total	80	62	27	169(9)			
2 month	test	48	25	9	82(8)	-1.27	0.204	
	control	55	20	6	81(7)			
	total	103	45	15	163(15)			
3 month	test	60	20	8	88(2)	-0.484	0.628	
	control	55	24	7	86(2)			
	total	115	44	15	174(4)			

(2) The subjective condition assessment (VAS) was evaluated at 1 week, 1 month, 2 month, and 3 month after surgery. Comparing the subjective condition assessment results of the patients, the P values were all >0.05. There was no statistical significance in the evaluation results of the two groups at each stage,（Table 3）.

Table 3 Subjective condition assessment

	1week		1month		2month		3month	
group	test	controll	test	controll	test	controll	test	controll
N(Missing)	90(0)	87(1)	88(2)	87(1)	84(6)	86(2)	88(2)	87(1)
mean	4.172	4.455	3.239	3.207	2.655	2.413	2.21	1.799
median	4	5	3	3	3	2	2	2
standard deviation	1.8007	1.7772	1.5974	1.6523	1.4767	1.6201	1.6413	1.4656
minimum value	0	1	0	0	0	0	0	0
maximum value	9	10	7	8	7	7	7	7
lower quartile	3	3	2	2	1.25	1	1	1
Upper quartile	5	6	4	4	3	3	3	2
z	-1.202		-0.271		-1.395		-1.699	
t	/		/		/		/	
P value	0.229		0.787		0.163		0.089	
result	P>0.05							

(3) The total scores of the 20 (SNOT-20) nasal cavity and sinus results at 1 week, 1 month, 2 month, and 3 month after surgery were evaluated. At the visit points of 1 week, 1 month, and 2 month after surgery, the P values of the statistical analysis results of the two groups were all >0.05, and the difference was not statistically significant.But at 3 month after surgery, the

statistical analysis results of the two groups were P=0.033<0.05. There was a statistical difference. The total score of 20 nasal cavity and sinus results of the test group were higher than that of the control group, （Table 4）.

Table 4 Nasal sinus results measurement 20 (SNOT-20)

	1week		1month		2month		3month	
group	test	controll	test	controll	test	controll	test	controll
N(Missing)	90(0)	87(1)	88(2)	87(1)	84(6)	86(2)	88(2)	87(1)
mean	10.12	9.7	8.44	7.16	6.86	5.42	5.91	3.91
median	7.00	8.00	5	5	4.5	4.00	4.00	3.00
standard deviation	9.063	7.504	8.292	6.687	6.775	5.383	6.062	4.363
minimum value	0	0	0	0	0	0	0	0
maximum value	42	35	38	40	30	28	25	18
lower quartile	3.00	4.00	3.00	3.00	1.25	2.00	1.00	0.00
upper quartile	15.25	14	11.75	9.00	11.00	8.00	9.00	6.00
z	-0.37		-0.308		-0.98		-2.135	
t	/		/		/		/	
P value	0.711		0.758		0.327		0.033	
result	P>0.05						P<0.05	

(4) The total nasal endoscopy Lund-Kennedy score at 1 week, 1 month, 2 month, and 3 month after surgery was evaluated. The results are as follows: the total scores of the Lund-Kennedy score of nasal endoscopy were compared, and the P values were all >0.05. There was no statistical significance in the evaluation results of the two groups at each stage,（Table 5）.

Table 5 Total score results of Lund-Kennedy score of nasal endoscopy

	1week		1month		2month		3month	
group	test	controll	test	controll	test	controll	test	controll
N(Missing)	90(0)	87(1)	87(3)	85(3)	82(8)	81(7)	88(2)	86(2)
mean	4.78	5.22	4.71	4.91	3.44	2.93	2.00	2.31
median	4.00	6.00	4.00	4.00	2.00	2.00	2.00	2.00
standard deviation	3.344	3.571	2.579	2.950	2.889	2.296	2.144	2.353
minimum value	0	0	0	0	0	0	0	0
maximum value	13	12	12	14	12	12	10	10
lower quartile	2.00	2.00	3.00	2.00	2.00	1.00	0.00	0.00
upper quartile	7.25	8.00	6.00	6.00	6.00	4.00	2.00	4.00
z	-0.922		-0.138		-0.615		-0.805	
t	/		/		/		/	
P value	0.356		0.890		0.538		0.421	
result	P>0.05							

Safety Evaluation Analysis

(1) Auxiliary examination analysis of the laboratory tests (blood routine, urine routine, blood biochemistry-liver and kidney function), electrocardiogram, and eye examination (fundoscopy and intraocular pressure) before surgery and at 3 month follow-up.The results are as follows: P values were all>0.05, and there was no statistical significance in the evaluation results of the two groups, （Table 6） and（Table 7）.

Table 6 Preoperative auxiliary examination results

evaluation index	group	normal	abnormal without clinical significance	abnormal with clinical significance	Total N(Missing)	Chi-square value	P value	result
blood routine	test	17	61	12	90(0)	3.043	0.218	P>0.05
	controll	9	63	16	88(0)			
	total	26	124	28	178(0)			
urine routine	test	35	50	5	90(0)	2.879	0.237	
	controll	38	40	10	88(0)			
	total	73	90	15	178(0)			
liver and kidney function	test	13	62	15	90(0)	4.953	0.084	
	controll	6	73	9	88(0)			
	total	19	135	24	178(0)			
electrocardiogram	test	54	34	2	90(0)	0.437	0.804	
	controll	55	30	3	88(0)			
	total	109	64	5	178(0)			
eye examination	test	69	5	16	90(0)	0.870	0.647	
	controll	66	8	14	88(0)			
	total	135	13	30	178(0)			

Table 7 Auxiliary examination results 3 month after surgery

evaluation index	group	normal	abnormal without clinical significance	abnormal with clinical significance	total N(Missing)	Chi-square value	P value	result
blood routine	test	29	54	5	88(2)	0.453	0.797	P>0.05
	controll	28	50	7	85(3)			
	total	57	104	12	173(5)			
urine routine	test	34	47	7	88(2)	1.958	0.376	
	controll	39	36	9	84(4)			
	total	73	83	16	172(6)			
liver and kidney function	test	24	53	11	88(2)	0.026	0.987	
	controll	23	52	10	85(3)			
	total	47	105	21	173(5)			
electrocardiogram	test	48	38	1	87(3)	2.791	0.248	
	controll	54	26	2	82(6)			
	total	102	64	3	169(9)			
eye examination	test	73	4	11	88(2)	4.104	0.128	
	controll	69	10	6	85(3)			
	total	142	14	17	173(5)			

(2) During this trial, a total of 160 adverse events (73 in the test group and 87 in the control group). There were a total of 6 serious adverse events (2 in the test group and 4 in the control group). The results are as follows: There was no statistical difference in the number of adverse events and serious adverse events between the two groups of subjects.

Discussion

ESS is a minimally invasive surgery that uses an endoscope to clearly identify and removes lesions

in the sinus cavity and reconstructs the structure of the nasal cavity. Its purpose is to reconstruct the ventilation of the patient's nasal cavity and sinus, restore the mucociliary clearance function, and return the nasal cavity function to normal[7]. ESS surgery has the advantages of less blood loss, minimal invasiveness, and significantly improved nasal ventilation, and has been widely recognized in the clinical treatment of CRS. Clinical surveys show that the incidence of complications after ESS is high, and re-debridement due to unsatisfactory recovery results seriously affects the patient's quality of life and causes both psychological and physical pressure on the patient[8]. Glucocorticoids can promote early mucosalization after sinus surgery, reduce edema, granulation tissue and fibrin deposition[9], reduce the patient's need for postoperative drugs and surgical intervention, and reduce the displacement of the middle turbinate and surgical cavity adhesion[10,11-12]. Traditional administration methods include oral hormones, nasal hormones, hormone irrigation and infusion, etc. However, there are some problems with these treatment methods.First, patient compliance may affect the treatment effect.Second, drugs, whether taken orally or nasally sprayed, cannot act on the lesion accurately and sustainably.Third, due to the presence of hormones themselves,there are certain side effects. It is difficult to achieve the goal of reducing the intake of hormones into the human body as much as possible while achieving the best therapeutic effect with traditional treatment methods. For example, the biggest problem with nasal spray hormone is that it is not precise and continuous enough. While the biggest problem with oral hormone is that it has very high side effects. As a new method of local glucocorticoid treatment, the sinus stent keep the surgical cavity open through physical support, while the drug coating of the stent can sustainably and stably release glucocorticoid for about 30 days[13]. Its safety and effectiveness have been demonstrated in many studies[14]. Compared with nasal spray hormone, sinus stents are not subject to patient compliance and can adapt to irregular sinus cavities.Compared with oral hormone, they are less likely to cause systemic adverse reactions [15]. The European Sinusitis and Nasal Polyps Diagnostic Opinion 2020 (EPOS 2020) recommends stent implantation as an important method for the treatment of adult CRS, and the recommendation level is level la. Bioabsorbable steroid implant (steroid-eluting implants, SEI) have been developed and applied clinically, providing new ideas for comprehensive treatment after nasal endoscopic surgery.

This study shows that the effective disease control rates of the test group were 82.4%, 89.0%, and 90.9% at 1 month, 2 month, and 3 month after surgery, respectively, and that of the control group were 85.7%, 92.6%, and 91.9% respectively. There was no statistical difference in the disease control evaluation results. Studies have shown that the bioabsorbable steroid implants serve as carriers to accurately place drugs within a controllable and known time period, which can better exert drug effects, enhance anti-inflammatory effects, and improve surgical success rates [16].

The VAS scores of dryness/crusting in the nasal cavity of the two groups of patients were evaluated, and the formation of scab/condensation in the ethmoid sinus was observed. The study found that during the entire follow-up process, patients' subjective ratings of nasal dryness and scabbing were mild; compared with the control group, the VAS scores of nasal dryness and scabbing in the test group increased at each follow-up time point, but the difference was no statistical significance.

The SNOT-20 was used to evaluate patients' postoperative quality of life. There was no statistically significant difference in the total scores of the 20 nasal and sinus outcome measures at the 1 week, 1 month, and 2 month postoperative visit points ($P>0.05$). There was a statistical difference at the 3month visit point ($P<0.05$). The total score of 20 nasal cavity and sinus results in the test group were higher than that in the control group. Stent implantation can significantly relieve patients' symptoms such as nasal congestion and runny nose 1 month after surgery, and the application of stents can help inhibit postoperative mucosal edema, external migration of the middle turbinate and adhesion formation, and promote early epithelialization of the mucosa[17]. These findings are similar to the benefits of intraoperative stent implantation reported in other studies [10, 18, 19]. The study by Murr[20] et al.showed that there was no significant difference

in the outward migration rate of the middle turbinate between the drug-loaded stent side and the non-drug-loaded stent side, which may be due to the physical support of the stent. In this study, stents were implanted in both the test group and the control group. The anti-inflammatory and physical supporting effects of the stent ensured smooth drainage of the sinus cavity, effectively inhibited mucosal edema and adhesion, improving the patient's symptoms.

There was no statistically significant difference in the Lund-Kennedy score (score of polyps, edema, and rhinorrhea scars) between the two groups of trials. The main reason is that the physical support of the stent improves nasal ventilation and prevents adhesions; the stent carries nasal drugs that directly act on it. It overcomes the problems caused by the use of nasal sprays such as the inability of the drug to reach the affected area and low drug absorption[21].

The safety evaluation results showed that the laboratory tests (blood routine, urine routine, blood biochemistry-liver and kidney function), electrocardiogram, and eye examination (fundusscope and ophthalmology) of the two groups before surgery and 3 month after surgery ($P>0.05$); there was no statistical difference in the occurrence of adverse events and serious adverse events between the two groups ($P>0.05$)[22,23]. There were 2 serious adverse events in the test group, including right vocal cord paralysis and multiple contusions all over the body, which were not related to the implantation of the stent. There were 4 cases of serious adverse events in the control group, of which 2 cases had headaches and vomiting which may be related to stent implantation, and the other 2 cases were complicated by cerebrospinal fluid rhinorrhea and nasal NK cell lymphoma and were not related to stent implantation.

There was no difference in the recurrence rate between the two groups of patients, indicating that the bioabsorbable steroid implant is safer.The sinus drug stent has three major characteristics: First, it is precise. Wherever there is a problem, the stent is placed and the drug is released directly and accurately at the lesion. The second is continuous. The degradation period of the bioabsorbable steroid implant is about one month. During this period, the stent can continuously and quantitatively release drugs at the lesion 24 hours a day, which is equivalent to a sustained-release drug delivery process. The third is safety. Because it is accurate and sustained, it can greatly reduce the dosage of hormones and minimize the side effects of hormones while ensuring the therapeutic effect.

Conclusion

The bioabsorbable steroid implant is clinically effective in patients with CRS after ESS. It can promote the recovery of the nasal mucosa, improve nasal cavity function, and effectively control the occurrence of complications. The clinical safety and effectiveness of the bioabsorbable steroid implant produced by BREATH MEDICAL meet the requirement and can be used in clinical setting.

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