

HydrofiberTM dressing with silver in wound healing after surgery for anal fistula[★]

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Abstract

BACKGROUND: Much clinical evidence have proved the effect of HydrofiberTM dressing with silver in other wounds healing, but the reports on the effect of HydrofiberTM dressing with silver in wounds healing after surgery for anal fistula are rare.

OBJECTIVE: To observe the therapeutic efficacy of HydrofiberTM dressing with silver in wounds healing after surgery of anal fistula.

METHODS: Fifty-seven patients with anal fistula surgery were randomly divided into treatment group ($n=29$, HydrofiberTM dressing with silver, once every 3 days) and the control group ($n=28$, Vaseline gauze, once per day). The level of wound pain during treatment, wound exudates situations, the frequency of dressing changes, the healing time and the cost of dressing changes were observed and compared.

RESULTS AND CONCLUSION: The wound pain level during treatment, wound exudates situations, the healing time and the frequency of dressing changes in treatment group were all significantly less than those in the control group ($P < 0.05$), but the cost of dressing changes in the experimental group was significantly higher than that in the control group ($P < 0.05$). HydrofiberTM dressing with silver for wounds healing after anal fistula surgery can obviously reduce the wound pain level during treatment, provide moist repair environment, accelerate wound healing, reduce the frequency of dressing changes and improve patient satisfaction.

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INTRODUCTION

Most of the anal fistulas are formed after anorectal abscess rupture or incision. In traditional Chinese medicine, the anal fistula is also called as "anal leakage" or "dirty drug", it is the granulomatous pipeline around the anus caused by anorectal abscess rupture and unhealed for a long time. Anal fistula often occurs on male patients aged 20–40 years. The anal fistula is consists with general primary internal opening, fistula and secondary external aperture. The internal opening often locates on the dentate line and often one internal opening there, the external aperture often locates on the skin around the anus, and it can be one or more. The incidence of anal fistula incidence accounting for 1.67%–3.60% of anorectal diseases in China, and 8%–25% abroad, and the recurrence rate is high. Anal fistula can be observed in patients with different ages and the male to female ratio was about (5–6): 1. The main clinical features of anal fistula include anal induration, local repeated ulceration pus, pain, moisture, and itching, etc^[1].

To date, surgery is still the most effective way for the treatment of anal fistula, and the specific procedures include traditional anal fistula incision, incision and thread-drawing therapy, analfistulectomy, internal opening repair with biological mesh and intersphincteric fistula ligation, but the key of any kind of surgery is to accurately explore the internal opening, completely remove all infected fistula and dead cavity, protect the physiological function of anal sphincter and anus, and correctly handle the relationship between the anal fistula recurrence and fecal incontinence^[2-9]. Hyman *et al*^[10] have reported the results of forward-looking anal fistula incision in 13 hospitals, finding that the cure rate was 87.0%. Roig *et al*^[11] thought that the effect of anal fistula surgery on the anal function is noteworthy. While promoting the post-operative wound healing is also the key of anal fistula treatment, and how to improve the effectiveness of postoperative wound dressing, protect and promote the wound healing is the urgent problem for the anorectal surgery clinicians.

With the development of the bio-medical treatment technology, the silver ions dressing

appeared and was continuously applied in the treatment of clinical surgery, the silver ion dressing as a new kind of wound surface covering material, is a new silver morphology with the combination of Ag⁺ and active silver ions^[12], which can continuously provide a certain concentration of dynamic active silver, in order to maintain a potent and long-lasting bactericidal concentration. The basic components of the dressing are the sodium carboxymethyl cellulose with an open mesh structure, as well as the silver with the content of 1.2%. Sodium carboxymethyl cellulose has the characteristics, such as the absorption of wound exudates formed gel, which can maintain the suitable temperature and humidity of the wound, support the wound surface, isolate from the external pollution sources and protect the exposed nerve endings, and relieve the pain; the sodium carboxymethyl cellulose with an open mesh structure imposes the micro-mechanical force on the wound and generates about 16.615 kPa negative pressure, which can promote the cell proliferation and the generation of granulation, and based on the characteristics of silver ion dressing, such as the broad spectrum antibiotic, efficient, non-toxic, antibacterial lasting and promoting wound healing, and the effect on promoting the wound healing has been confirmed. At present, the silver ion dressing has been used by the domestic and foreign scholars and clinicians for the treatment of lower limb ulcer, diabetic foot ulcers, burns, and other refractory wound, as it has the significant effect in accelerating the wound healing and controlling the wound infection^[13-18]. But the reports on the rehabilitation after anal fistula operation are rare. The experiment observed the therapeutic efficacy of Hydrofiber™ dressing with silver in healing wounds after surgery of anal fistula through randomized controlled clinical trials under the guidance of moist healing concept.

SUBJECTS AND METHODS

Design

A randomized controlled clinical trials.

Time and setting

The patients diagnosed with anal fistula and treated with surgical treatment were selected from the Department of Anorectal Surgery, Nanjing Hospital of Integrated Traditional Chinese and Western Medicine during February 2011 to May 2012 as the research subjects.

Subjects

Diagnostic criteria

The diagnosis of anal fistula was referenced to the international universal Parks classification method. ① Intersphincteric anal fistula. ② Anal fistula across the sphincter. ③ Anal fistula on the sphincter. ④ Anal fistula outside the sphincter^[19].

Inclusion criteria

Patients between 18–65 years old; the patients diagnosed with anal fistula through cavity B ultrasound and treated with surgery; patients complied with dressing arrangements; patients fully informed and consented with the treatment, and could complete the follow-up. The patients should be truthfully informed about the treatment and the risks according to the regulation of Hospital Management Regulations made by the state council, and the patients should sign the informed consent and the treatment programs should be approved by the hospital medical ethics committee.

Exclusion criteria

Patients that sensitive to sodium carboxymethyl cellulose or silver ions or had an allergic reaction; patients with diabetes, tuberculosis, inflammatory bowel disease, and other factors that affect the wound healing; maternal or breast-feeding women; patients with cardio- cerebrovascular, liver, kidney and hematopoietic system severe primary disease or the psychiatric patients; patients that failed for the treatment, aborted caused by the adverse reactions, unable to determine the efficacy or information incomplete that affected the efficacy judgments. A total of 57 patients meet the criteria above, including 30 males and 27 females. The patients were divided into experimental group ($n=29$) and control group ($n=28$) according to random number table in the order of admission time. Among the 29 patients in the experimental group, including 16 males and 13 females, the age was (32.63 ± 6.54) years old; the type of anal fistula: 19 cases had the intersphincteric type, 7 cases had anal fistula across the sphincter, and 3 cases had anal fistula on the sphincter; among the 28 patients in the control group, including 14 males and 14 females, the age was (33.26 ± 9.32) years old; the type of anal fistula: 18 cases had the intersphincteric type, 8 cases had anal fistula across the sphincter, and 2 cases had anal fistula on the sphincter. There was no significant difference of gender, age and anal fistula type between two groups.

Materials

Hydrofiber™ dressing with silver AQUACEL-Ag® [SFDA (forward) No.3640024] produced by British ConvaTec Ltd. was a kind of soft and sterile strip dressing consisted with Hydrofiber® and silver ion which could release the silver ions slowly to form a long-lasting anti-bacterial environment, and it could absorb a large amount of wound exudates and bacteria to form the soft and sticky gel and attached on the wound surface tightly in order to keep the wound moist, and that was helpful for eliminating the organization that could not survive, promoting the wound healing and reducing the risk of wound infection.

Aseptic Vaseline gauze produced by Xinxiang Huaxi Sanitary Materials Co., Ltd., the implementing standard: YZB/State 0353-2010, SFDA (quasi-) words: 2010 3640604. Production batch number was 110102. The aseptic Vaseline gauze consisted with absorbent cotton gauze, Vaseline and paraffin oil and used for skin protection and wounds protection.

Induction methods

Anal fistula postoperative dressing

The experimental group received the conventional disinfection of the wound around the skin with the iodophor, and the normal saline was used to scrub the wound pus and abnormal secretions, then the Hydrofiber™ dressing with silver that suitable for the wound size was filled into the wound, left 2 cm in tail, and the wound was covered and fixed with aseptic gauze, and the frequency was one time every three days. The control group received the conventional disinfection of the wound around the skin with the iodophor, and the normal saline was used to scrub the wound pus and abnormal secretions, then the wound was filled and fixed with aseptic Vaseline gauze, the frequency was one time every day.

Wound pain degree of the first dressing

The wound pain degree of the first dressing was determined according to the international accepted pain grading standards. 0 degree: no pain; 1 degree: tolerable pain, the patients had the normal life and the sleep was undisturbed; 2 degree: intolerable pain, the patients had to take analgesic drugs and the sleep was disrupted; 3 degree: severe pain that cannot tolerate, the sleep was severely disrupted and the analgesic required.

Significant reducing time of wound exudates

The inner gauze was changed when the wound was dry and no obvious exudata, the observation time was determined when the yellow stained area less than 1 cm².

Frequency of wound dressing

The frequency of wound dressing of each patient was recorded.

Time of wound healing

The wounds of all the patients were judged by two designated associate chief physician of anorectal surgery department, the healing standards was all the physicians had the common opinion that the wound was completely epithelium, and thus determined and recorded the healing time.

Dressing cost

Accounted and recorded the total cost of dressing.

Designer, implementers and assessor

The designer was the first author, the implementers were the relevant person in the department of the first author, and the assessor was the second author. During the treatment process, the dynamic observation was performed by two authors, and then the wound rehabilitation situation was checked and the information was assessed.

Main outcome measures

The wound pain degree after first dressing in the experimental group and the control group, time for exudates reducing, frequency of dressing, wound healing time and dressing cost were measured.

Statistical analysis

All the data was statistical analyzed with SPSS 17.0 software, and the measurement data was represented as mean±SD, the comparison between groups was performed using independent sample *t*-test, and the measurement data was detected with chi-square test, the ranked data was tested with Wilcoxon rank sum test of two independent samples, *P* < 0.05 was considered statistically significant.

RESULTS

Quantitative analysis of the subjects

Treated according to the intentional analysis, all the 57 patients were involved in the results analysis without shedding.

Comparison of the baseline information of the subjects in the experimental group and the control group (Table 1)

Item	Experimental group (n=29)	Control group (n=28)	χ^2 (t)	P
Gender (n%)				
Male	16/55	14/50	0.136	0.164
Female	13/45	14/50		
Age ($\bar{x} \pm s$, yr)	32.63±6.54	33.26 ± 9.32	1.057*	0.743
Type of anal fistula (n%)				
Intersphincteric anal fistula	19/66	18/64	0.263	1.237
Anal fistula across the sphincter	7/24	8/29		
Anal fistula on the sphincter	3/10	2/7		
Anal fistula outside the sphincter	0	0		

* is the *t* value; Hydrofiber™ dressing with silver was used for dressing in the experimental group after anal fistula surgery, the dressing was performed once every 3 days, aseptic Vaseline gauze was used for dressing in the control group after anal fistula surgery, the dressing was performed once a day

Concluded from Table 1, there was no significant difference in patients' gender, age and different types of anal fistula between two groups ($P > 0.05$).

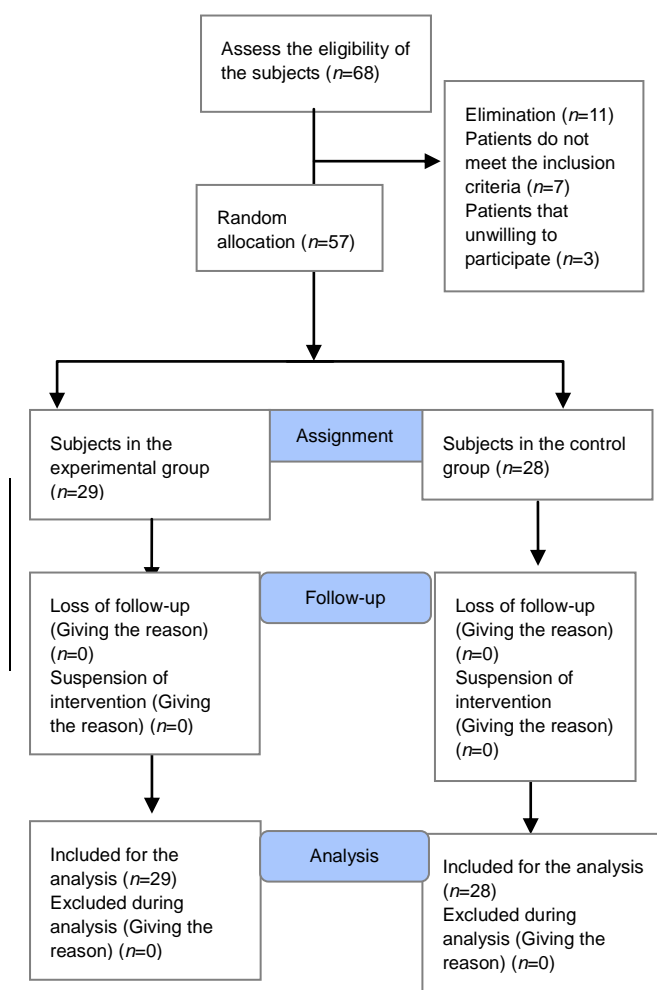
Wound pain during first dressing in the experimental group and the control group (Table 2)

Table 2 Comparison of wound pain between two groups during first dressing after anal fistula surgery (n)

Group	n	0 degree	1 degree	2 degree	3 degree
Experimental	29	18	11	0	0
Control	28	3	8	12	5
u			5.628		
P			0.000		

Hydrofiber™ dressing with silver was used for dressing in the experimental group after anal fistula surgery, the dressing was performed once every 3 days, aseptic Vaseline gauze was used for dressing in the control group after anal fistula surgery, the dressing was performed once a day

Flowchart of randomized grouping



The wound pain in the experimental group during dressing with Hydrofiber™ dressing with silver was

lighter than that in the control group during dressing with aseptic Vaseline gauze.

Comparison of the significant reducing time of wound exudates, frequency of dressing changes and cost of dressing changes between the experimental group and the control group

There was a significant difference in reducing time of wound exudates, frequency of dressing changes and cost of dressing changes between two groups ($P < 0.05$), and the results were determined by the two designated associate chief physicians from anorectal surgery department. When the two physicians identified that the wound had complete epithelialization, that time point was the healing time of anal fistula. The wound healing time was (19.39 ± 5.16) days in the experimental group and (30.27 ± 5.68) days in the control group. The healing time in the experimental group was significantly shorter than that in the control group ($P < 0.05$) (Table 3).

Table 3 Comparison of the significant reducing time of wound exudates, frequency of dressing changes and cost of dressing changes between two groups (x±s)

Item	Experimental group (n=29)	Control group (n=28)	t	P
Reducing time of wound exudates (d)	3.14±0.73	9.35±2.89	1.632	0.043
Frequency of dressing changes	7.29±1.63	26.04±5.73	-3.863	0.000
Wound healing time (d)	19.39±5.16	30.27±5.68	2.316	0.036
Cost of dressing changes (yuan)	985.69±29.46	546.27±22.82	14.327	0.032

Hydrofiber™ dressing with silver was used for dressing in the experimental group after anal fistula surgery, the dressing was performed once every 3 days, aseptic Vaseline gauze was used for dressing in the control group after anal fistula surgery, the dressing was performed once a day

Adverse reactions

There was no material related reverse reaction in two groups.

DISCUSSION

Anal fistula is the chronic pathological pipeline between perianal skin and anorectal, and often formed after perianal abscess ulceration and incision and drainage. According to statistics, about 90% of anal fistula caused by infection anal crypt, as the anal crypt infection can make the inflammation gradually spread from the local lesion and then form around the anus and rectum inflammation perianal inflammation, and then leading to the decreased disease resistance of the tissue spaces around the anus and rectum, and thus the formation of the anorectal abscess. Dressing after the perianal

abscess ulceration or incision and drainage, there will left a gap fistula in the middle of the fistula and the connective tissue will be found on the cavity of the fistula, then the fistula will be formed, therefore, fistula is generally consisted with primary internal opening, fistula wall and external aperture^[1, 20]. At present, the treatment of anal fistula is mainly depending on surgery. With the development of anorectal specialist medical level, a variety of minimally invasive therapies are maturing, and the cure rate is gradually increased. In addition to the appropriate choice of minimally invasive surgical procedures and treatment of internal opening and external aperture correctly and thoroughly, postoperative rehabilitation is also a key link to cure the anal fistula. The routine postoperative dressing is mainly depend on aseptic Vaseline gauze, and the main role is to drainage, avoid pseudo-healing, and promote the benign healing of wounds, but due to the special lesion of anal fistula, daily defecation caused wounds repeatedly pollution, intolerable pain during dressing and repeated incision bleeding and abnormal secretions, the patient satisfaction and treatment compliance is reduced^[21-22]. Therefore, finding a topical dressing that can relieve the postoperative wound pain in patients with anal fistula, effective antimicrobial, reduce the wound infection, reduce the abnormal secretions, and in order promote wound to rehabilitation has become the essential problem that brook no delay. With the development of the medical and biological engineering, various biological dressings that can promote wound rehabilitation emerge and applied in clinic. How to choose the wound dressing correctly and reasonable is the important issue need to be explored for the clinicians, the good topical dressing can not only provide the wound a better rehabilitation environment and prevent wound infection, but also has the advantages of ease of use, safety and little adverse reactions. In recent years, moist healing theory has been widely applied in clinical practice, as the moist dressing can provide the wounds a moist environment that suitable for growth, retain and promote the release of active substances in the exudates, benefit to the dissolution of the necrotic tissue and tissue proliferation and differentiation as well as the migration of epithelial cells; meanwhile, the moist dressing can keep the wound microcirculation in the hypoxia, stimulate and promote the growth of new capillaries and granulation tissues^[23-24]. Hydrofiber™ dressing with silver is a silver-based antimicrobial absorbent dressing based on the moist healing theories, it is consisted with Hydrofiber® and silver ions, and it can maintain the wound moist which is conducive to dissolve and clear necrotic tissue and toxins that impede wound healing, that is autolytic debridement, and it can promote the wound rehabilitation, protect the exposed wound nerve endings in the moist

environment in order to avoid adhesions with the dressings which can protect the wound and relieve pain. This experiment observed the effect of Hydrofiber™ dressing with silver on wound rehabilitation after anal fistula surgery with randomized controlled clinical trial, and finding that there is no significant difference of reducing time of wound exudates, frequency of dressing changes and cost of dressing changes between two groups ($P < 0.05$), and the wound pain during the first dressing with Hydrofiber™ dressing with silver is significantly lighter than that with traditional dressing ($P < 0.05$).

The literatures have reported the exact bactericidal effect of the silver ions; the main mechanism is because the heavy metal ions can lead to the degeneration of the bacterial protein with the characteristics of broad-spectrum bactericidal and rarely drug-resistant, and the experimental and clinical studies have proved the efficacy of silver ion dressing for the treatment of various types of acute and chronic infected wounds^[18]. The center also clinical observed the effect of Hydrofiber™ dressing with silver for the treatment of wound rehabilitation after perianal abscess surgery, and achieve satisfactory effect, this is mainly due to the Hydrofiber™ dressing with silver used in the experiment contains a large number of silver ions, and it can absorb wound exudates and bacteria and form the soft and sticky gel and adhered on the wound bed tightly, and then release silver ions slowly and form a continuous antibacterial environment. And just because of its strong adsorption capacity, it can protect the normal skin around the wound and wound from the erosion of the secretions, and then avoid the exudates caused cross-infection^[25]. The wound healing of anal fistula is a complex and regular biological process, including the inflammatory response exudative phase, cell proliferation phase and epithelial tissue remodeling phase, and the process presents a high degree of orderliness, coordination and integrity in the regulation of the body. Hydrofiber™ dressing with silver can used for the treatment of wound rehabilitation after anal fistula surgery, the main mechanism is that the dressings can shorten the inflammatory response exudative phase and growth of granulation in the cell proliferation phase under the guidance of moist healing theories, and then accelerate the wound rehabilitation, and the Hydrofiber™ dressing with silver used in the experiment can absorb the wound secretions rapidly and form the gel and then lock wound bacteria and necrotic tissue, and the dressing should be changed every 3 days, but the effect is obviously better than the daily traditional dressing, as the Hydrofiber™ dressing with silver can effectively debride, keep the wound granulation fresh and shorten the exudative phase; meanwhile, Hydrofiber™ dressing with silver absorbed moisture can form a protective gel effectively

on the wound which can prevent secondary infection caused by fecal contamination effectively, and it can keep moist environment for the wound as well as promote the proliferation of granulation and epithelial tissue remodeling. The more important thing is for the patients with complex anal fistula, such as high lesion location, complex disease and deep wound, Hydrofiber™ dressing with silver can play a role in wound supporting and isolation, in order to prevent pseudo-healing, reduce the complications and the possibility of multiple surgeries; and the using of Hydrofiber™ dressing with silver can significantly reduce or even avoid the pain and bleeding caused by drainage Vaseline gauze stimulate the nerves and blood vessels of the perianal wound during traditional dressing. The market price of Hydrofiber™ dressing with silver is high which can increased the economic burden of dressing part, but it is worth mentioning that the Hydrofiber™ dressing with silver can effectively reduce the frequency of dressing changes, save the medical time and resources and reduce the burden of both doctors and patients. Therefore, the authors suggest that the advantages of Hydrofiber™ dressing with silver for treatment of wound rehabilitation after anal fistula surgery including: keep wound moist and effective autolytic debridement; release silver ions slowly and form the sustained antimicrobial environment; reduce stimulation and significantly reduced the pain; provide the moist repairing environment that can accelerate the wound healing; reduce the frequency of dressing changes and improve patient satisfaction; provide new ideas for wound rehabilitation after anal fistula surgery. Whether the Hydrofiber™ dressing with silver can be widely used in the wound rehabilitation therapy after anorectal surgery and widely used in the clinical treatment yet to be clarified by large-scale scientific and standardized clinical trials.

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亲水性纤维含银敷料覆盖肛瘘术后创面的作用★

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文章亮点: 试验采用的亲水性纤维含银敷料即是一种基于湿性愈合理论指导的含银抗菌吸收性敷料, 由Hydrofiber®和银离子组成, 能够保持创面湿润有利于溶解和清除妨碍伤口愈合的坏死组织及毒素即自溶清创, 促进创面康复, 且在湿润环境下可保护创面暴露的神经末梢, 避免与敷料粘连, 具有保护创面、减轻疼痛等作用。

关键词: 亲水性纤维含银敷料; 肛瘘; 创面康复; 覆盖; 疼痛程度; 创面愈合; 生物材料; 凡士林纱布; 换药次数

摘要

背景: 亲水性纤维含银敷料在其他创面治疗中目前已取得较多临床证据, 但其

对肛瘘患者术后创面康复的作用研究较少。

目的: 观察亲水性纤维含银敷料覆盖对肛瘘患者术后创面康复的作用。

方法: 将57例肛瘘术后患者随机分为试验组29例和对照组28例, 试验组在术后给予亲水性纤维含银敷料换药, 3 d 1次, 对照组术后给予无菌凡士林纱布换药, 1次/d, 观察两组患者的首次换药创面疼痛程度、渗液明显减少时间、换药次数、创面康复时间及换药费用等指标。

结果与结论: 试验组首次换药时创面疼痛程度明显轻于对照组($P < 0.05$), 渗液明显减少时间、换药次数、创面康复时间明显少于对照组($P < 0.05$); 但试验组换药费用明显高于对照组($P < 0.05$)。表明亲水性纤维含银敷料覆盖于肛瘘患者术后创面可减少刺激, 明显减轻疼痛, 提供湿性修复环境, 加速创面愈合, 减少换药次数, 提高患者满意度。

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来自本文课题的更多信息——

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伦理要求: 按国务院《医院管理条例》规定对患者的治疗及风险进行如实告知, 患者对治疗均签署知情同意书, 治疗方案经医院医学伦理委员会批准。

研究的创新之处与不足: 试验为肛瘘术后康复治疗提供了新的思路, 而能否将亲水性纤维含银敷料更为广泛应用于肛肠外科术后创面的康复治疗, 并在临床加以推广应用, 尚待于通过大规模科学、规范的临床试验加以阐述。

作者声明: 文章为原创作品, 数据准确, 内容不涉及泄密, 无一稿两投, 无抄袭, 无内容剽窃, 无作者署名争议, 无与他人课题以及专利技术的争执, 内容真实, 文责自负。

(Edited by Li YK/Chen X/Wang L)