

Prospective Evaluation of the Safety and Compression Performance of Novel Compression Denim Jeans in Healthy Volunteers and Patients With Lymphedema

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Abstract

Objectives: The treatment of lower-extremity lymphedema, whether congenital or acquired, remains challenging. Long-term management aimed at reducing complications and maximizing quality of life is essential. Compression stockings are crucial in this management; however, their application is limited by patient experience (ease of wear, texture, breathability, and appearance). This highlights the need to evaluate alternative compression garments that maintain therapeutic efficacy while improving patient adherence.

Methods: We developed a novel compression denim product (Flow plus Jeans®) using advanced sewing technology. Its baseline performance (compression ability) was evaluated by measuring pressure gradients at three points (ankle, calf, and thigh) using a mannequin-based compression testing system and compared with those of existing stockings. Thereafter, a safety assessment was conducted on healthy volunteers to evaluate potential adverse effects, including changes in lower limb circumference, signs of deep vein thrombosis (DVT) via ultrasound, and skin complications. A clinical trial in patients with lymphedema was then performed to compare its efficacy with that of conventional compression stockings.

Results: Baseline performance testing with a mannequin revealed that Flow plus Jeans demonstrated compression levels and pressure gradients at three calf points comparable to those of standard compression stockings. A safety study involving nine healthy volunteers confirmed that Flow plus Jeans caused no significant changes in lower-limb circumferences after three days of wear, with no cases of DVT or skin complications. In a subsequent clinical trial involving nine female patients with lymphedema, the jeans showed non-inferiority to existing stockings concerning lower-limb circumference measurements at six points (pre-use vs. six months post-use), with patient-reported experiences assessed via questionnaires. Notably, patients reported enhanced satisfaction regarding the jeans' fashionability, which could serve as an incentive for long-term adherence.

Conclusion: Our findings suggest that Flow plus Jeans represent a promising novel option for the long-term management of lymphedema, offering an alternative that balances medical efficiency with improved patient satisfaction and demonstrates safety in healthy individuals.

Categories: Plastic Surgery, Cardiac/Thoracic/Vascular Surgery, Dermatology

Keywords: compression garments, denim jeans, long-term management, lower-extremity lymphedema, quality of life

Introduction

Lymphedema can be classified into primary (congenital or genetic causes) and secondary (resulting from infections, trauma, or surgical and radiation treatments) forms, and it usually causes significantly impaired quality of life [1]. Notably, lower-extremity lymphedema constitutes approximately 74% of cases, and its treatment and management strategies are broadly divided into (i) surgical interventions such as lymphovenous anastomosis, lymph node transplantation, and liposuction, and (ii) non-surgical therapies including compression therapy, exercise therapy, skincare, and anti-inflammatory medications. Secondary lower-extremity lymphedema disproportionately affects women, with a male-to-female ratio of 1:9 [2-5].

How to cite this article

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Regardless of the treatment modality, achieving a complete cure remains challenging, making long-term management and adherence critical. Consequently, maintaining patient motivation and ensuring robust support systems are essential.

In our clinical practice, we have primarily managed patients with lymphedema through long-term compression therapy using medical compression stockings. However, we received consistent complaints, particularly from female patients, regarding the shortcomings of these stockings, such as their appearance, clothing restrictions, discomfort, and complications with donning and doffing. To address these challenges and enhance long-term treatment adherence, we developed a novel compression denim product, Flow plus Jeans®, which is a registered trademark of Stork Visit Co., Ltd. (Okayama, Japan) [6]. This product features compression force and gradient comparable to that of medical compression stockings, is made of denim material, and has a stylish appearance resembling skinny jeans.

To assess the clinical utility of Flow Plus Jeans, the study evaluated its compression performance and compared its usability with conventional medical stockings. In addition to objective measurements, patient-reported surveys were conducted before and after the trial to assess factors such as fashionability and wearing comfort. This study aims to explore whether Flow Plus Jeans can provide a viable alternative to traditional compression therapy by addressing both therapeutic efficacy and patient adherence challenges.

Materials And Methods

The study was conducted at Okayama University Hospital, Okayama City, Japan, from 2018 to 2024.

Development of Flow plus Jeans

The jeans were developed to address the shortcomings of medical compression stockings commonly used for managing lower-extremity lymphedema, particularly regarding fashionability and comfort. Using a specialized sewing technique, a graduated compression function was integrated into denim jeans. The manufacturing method and technical innovations of Flow plus Jeans are detailed in the corresponding patent application [6]. To ensure an optimal fit and effective compression, each pair of Flow plus Jeans was custom-made for individual participants based on their lower limb circumference measurements.

Basic performance testing: three-point measurement on a mannequin

To evaluate the basic performance of Flow plus Jeans, compression force was measured at three points on the lower leg (ankle, distal to the calf, and posterior calf) using an air-pack-based garment pressure measurement device (AMI Techno, Tokyo, Japan) and compared with JOBST compression stockings (Essity AB, Stockholm, Sweden), a widely used conventional medical compression stocking.

Clinical trial for healthy volunteers

The clinical trial was registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) as an interventional study (registration number: UMIN000028657) and was approved by the Okayama University Hospital Ethics Committee (approval number: 1709-005). It was conducted between April 1, 2018, and March 31, 2019.

Participants

Nine healthy participants (three males and six females) with an average age of 38 years were included on meeting the following inclusion criteria: healthy adults (i) with no history of vascular, lymphatic, or neuromuscular disorders affecting the lower limbs, (ii) aged 20–60 years, (iii) willing to participate in the study and adhere to the protocol, (iv) with no prior history of deep vein thrombosis (DVT) or circulatory disorders, and (v) able to wear Flow plus Jeans continuously during daytime hours for three consecutive days. Participants were excluded if they (i) had chronic diseases affecting circulation (e.g., cardiovascular disease, peripheral artery disease, or chronic venous insufficiency), (ii) had a recent lower-limb injury or surgery within 6 months prior to enrollment, (iii) had known allergies or skin sensitivities to the materials used in Flow plus Jeans, (iv) were currently using compression therapy for any medical condition, (v) were pregnant or planning pregnancy during the study period, or (vi) were unable or unwilling to comply with the study protocol.

Measurements and Assessments

All participants underwent lower-limb circumference measurements at three points (ankle, calf, and thigh) to assess potential changes associated with Flow plus Jeans use. Measurements were taken in the morning before wearing the jeans and in the evening after three consecutive days of daytime use. The measurement sites were selected based on anatomical landmarks to ensure consistency, with the ankle measured at its narrowest part, the calf at its thickest part, and the thigh at its thickest part. While these locations allowed for relatively uniform measurements across participants, no physical markings were made to ensure exact placement, which has been acknowledged as a limitation.

Additionally, complication assessments were conducted at the end of the study, including ultrasound evaluation of the lower-limb veins to screen for DVT and visual inspection of the skin for any irritation, rashes, or other dermatological issues related to wearing Flow plus Jeans.

Clinical trial for patients with lymphoedema

The clinical trial was approved by the Okayama University Hospital Ethics Committee (approval number: 2106-045) and was conducted between July 9, 2021, and August 30, 2024. During the study period, all eligible patients who visited the vascular surgery outpatient clinic and met the inclusion criteria were invited to participate. Those who provided informed consent were enrolled. No prior sample size calculation was performed.

Participants

Nine female participants with an average age of 56 years were included on meeting the following inclusion criteria: (i) diagnosis of lower-limb lymphedema following surgery for uterine cancer, confirmed by a certified medical professional, (ii) stable clinical condition without significant progression or acute complications of lymphedema, (iii) aged 30-70 years, and (iv) willingness to participate in the study and adherence to the protocol. Participants were excluded if they met any of the following criteria: (i) presence of severe comorbidities such as cardiovascular, pulmonary, or renal diseases, (ii) active skin conditions such as infections, ulcers, or dermatitis in the affected limb, (iii) known allergies to the materials used in Flow plus Jeans, (iv) recent surgery or injuries to the lower limbs within six months prior to enrollment, or (v) inability or unwillingness to comply with the study protocol.

Measurements and Assessments

All participants underwent an initial evaluation of lymphedema management using conventional medical compression stockings. Lower-limb circumferences were measured at six points from the abdomen to the lower limbs by hospital staff during morning outpatient visits, ensuring consistency in assessment. Measurement sites were clearly defined, allowing for consistent placement before and after wearing the compression stockings. In cases of bilateral lymphedema, the limb with the more severe swelling was selected for measurement to ensure the assessment captured the most clinically relevant side. While this approach helped maintain measurement accuracy, no physical markings were made to ensure exact placement, which has been acknowledged as a limitation.

Questionnaire-Based Analysis of User Satisfaction and Experience

Subsequently, the same participants were evaluated for the efficiency of Flow plus Jeans. To evaluate the user satisfaction and experience of wearing Flow plus Jeans compared with that of conventional medical compression stockings, a questionnaire survey (see Appendices) was conducted with seven assessment items: fit and comfort, compression sensation, fashionability, ease of wear, skin irritation, price range, and overall satisfaction. Participants completed the questionnaire at two time points: (i) immediately after wearing Flow plus Jeans for the first time, and (ii) after six months of continuous use. For each item, a scoring system based on a relative scale was employed. Conventional medical compression stockings were assigned a baseline score of 5 points, and participants rated Flow plus Jeans on a 0-to-10-point scale, where 0 points indicated "much worse than conventional stockings," 5 points indicated "equivalent to conventional stockings," and 10 points indicated "much better than conventional stockings."

Scores for each item were collected and analyzed to evaluate user perceptions of the new product relative to the standard treatment. The mean scores for each category were calculated at both time points to assess changes in satisfaction and experience over time.

Statistical analysis

Statistical analyses were conducted using GraphPad Prism Software version 9.5.1 (Dotmatics, Boston, Massachusetts). For the basic performance test, compression forces within each group (stockings and Flow plus Jeans) at different measurement points (ankle vs. distal to the calf, or posterior calf) were compared using a paired t-test. Similarly, comparisons of lower-limb circumferences before and after six months of use in the clinical trial were performed using a paired t-test. User satisfaction and experience surveys were analyzed with an unpaired t-test to compare the two groups (stockings vs. Flow plus Jeans) at pre-use and six-month follow-up. In the healthy volunteer group, lower-limb circumferences before and after three days of use were also compared using a paired t-test. A value of $p < 0.05$ was considered statistically significant.

Results

Development of Flow plus Jeans

The Flow plus Jeans is shown in Figures [1A](#), [1B](#). The denim is tailored to provide a graduated compression effect, with pressure gradually decreasing from the lower leg to the abdomen. The jeans maintain the

appearance of standard skinny jeans, achieving high fashionability.

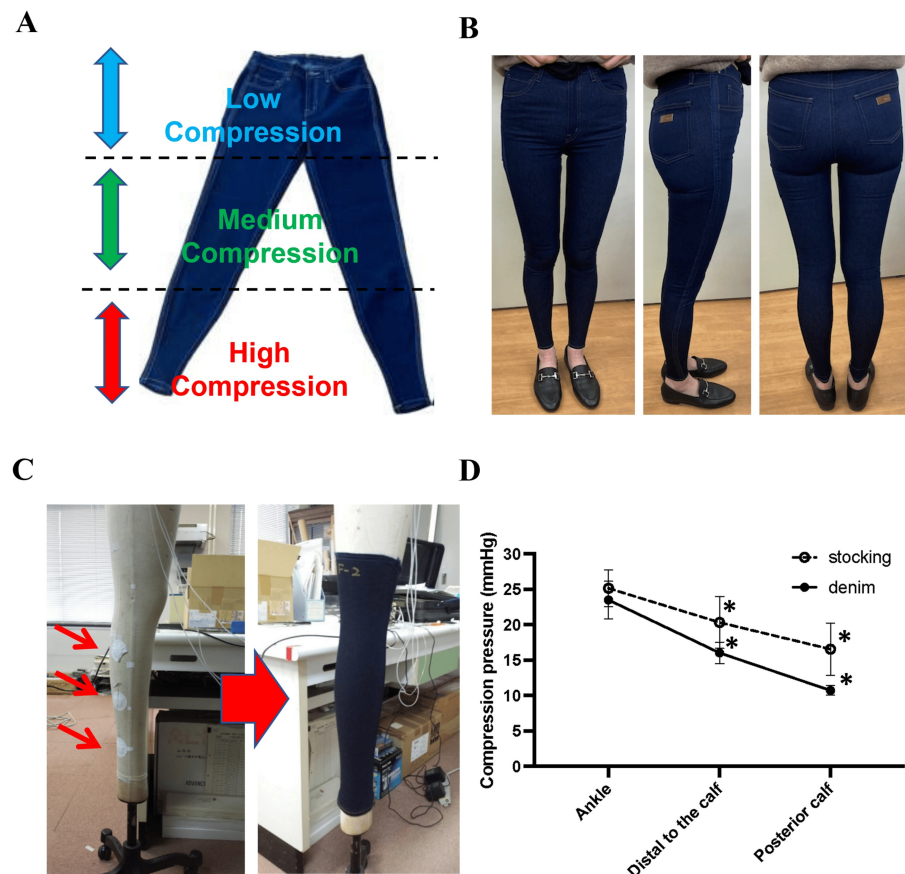


FIGURE 1: Development of denim-style compression jeans using novel sewing technology

(A) Overview of Flow plus Jeans® developed using proprietary sewing technology (patent granted). The jeans appear identical to standard stretch jeans but are tailored to provide a graduated compression effect, with pressure gradually decreasing from the ankle to the abdomen.

(B) Photographs demonstrating the appearance and fit of Flow plus Jeans® when worn. The jeans resemble standard skinny jeans while incorporating a graduated compression function designed for lymphedema management. These images provide a visual reference for the product's integration into everyday wear.

(C) Results of compression gradient testing using a mannequin. Pressure sensors placed at three points on the lower leg measured compression forces for Flow plus Jeans® and conventional medical compression stockings.

(D) Both products exhibit a gradual decrease in compression pressure from the ankle toward the proximal side. Statistical analysis using a t-test showed no significant differences between the two groups at any measurement point. $p < 0.01$: comparison to the ankle within each group ($n = 3$). This figure represents the within-group comparisons of ankle vs. distal to the calf and ankle vs. posterior calf for each group separately. The asterisk (*) indicates significant differences in these within-group comparisons ($p < 0.01$). Error bars indicate standard deviation (SD).

Basic performance testing: three-point measurement on a mannequin

Compression measurements using a mannequin confirmed the non-inferiority of Flow plus Jeans to conventional medical compression stockings concerning therapeutic compression force and gradual pressure change (Figure 1C, 1D). The measured interface pressures were as follows: Stockings: ankle: 25.2 ± 4.5 mmHg, distal to the calf: 20.3 ± 6.3 mmHg, posterior calf: 16.6 ± 6.4 mmHg, and Flow plus Jeans: ankle: 23.5 ± 4.6 mmHg, distal to the calf: 16.0 ± 2.7 mmHg, posterior calf: 10.7 ± 1.2 mmHg. A statistical comparison between the two groups using an unpaired t-test showed no significant difference in compression pressure. These measurements were conducted on three different product samples ($n = 3$), with each sample tested once per measurement site, ensuring that variations between products were accounted for rather than repeated testing of a single product.

Clinical trial for healthy individuals

Nine healthy participants (three male and six female participants, mean age 38 years) successfully completed the study protocol without any withdrawals or deviations. Statistical analysis showed no significant changes in lower-limb circumferences across all measurement points, indicating that wearing Flow plus Jeans did not cause lower-limb swelling or any adverse circulatory effects in healthy individuals (Figure 2).

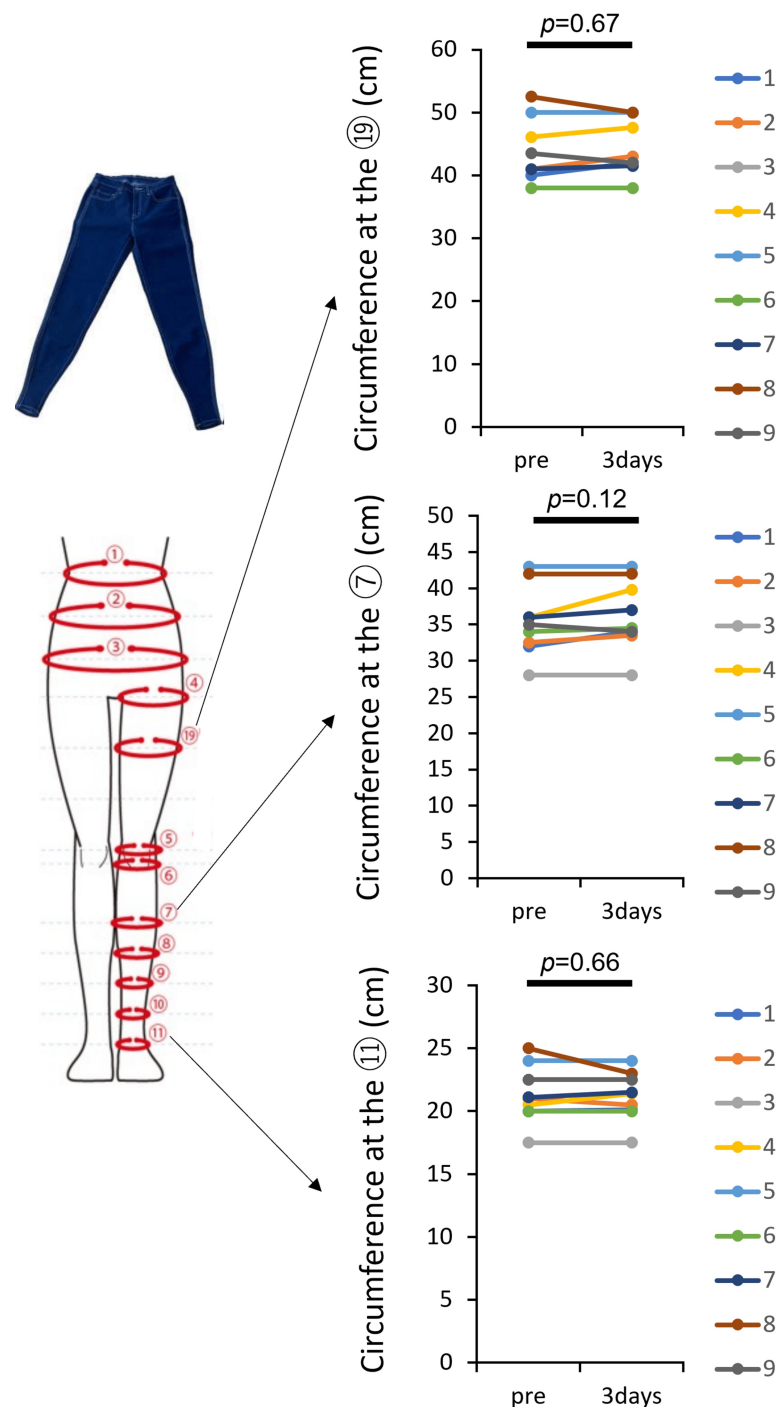


FIGURE 2: Safety evaluation of Flow plus Jeans® in healthy participants

A study was conducted in nine healthy individuals to primarily assess the safety of Flow plus Jeans®. The lower image presents changes in lower-limb circumferences at the ankle (□), calf (□), and thigh (□) before wearing and after three days of use. No significant changes in limb circumference were observed at any measurement site. Statistical analysis was performed using a paired t-test, and no significant differences were detected between pre-use and post-use measurements ($p > 0.05$).

Additionally, to evaluate potential complications, ultrasound examinations of the lower-limb veins were conducted at the end of the study, confirming the absence of DVT in all participants. Furthermore, no skin-related adverse events such as irritation, rashes, or discomfort were reported, as confirmed by visual skin assessments.

Overall, these findings suggest that Flow plus Jeans did not induce any adverse effects in healthy individuals, including circulatory impairment or skin complications, during the three-day wear period. These results support the safety profile of Flow plus Jeans for extended use in a general population.

Clinical trial for patients with lymphoedema

First, the efficiency of conventional stockings in managing lower-extremity lymphedema was evaluated in nine participants (Table 1). Measurements of lower-limb circumferences at six points (Figure 3) before and six months after use revealed no significant increase in circumferences at any site, demonstrating the effectiveness of compression therapy. Subsequently, the same participants were evaluated for the therapeutic effectiveness of Flow plus Jeans. Similar to conventional stockings, there was no significant increase in lower-limb circumferences at six points (Figure 4) after six months of use, confirming the effectiveness of compression therapy. These results indicate the non-inferiority of Flow plus Jeans compared to conventional stockings in managing lower-extremity lymphedema.

Patient	Age (years)	Sex	Weight (kg)	Diagnosis	Affected limb	Medical History
A	56	Female	44	Lymphedema	Both	Hysterectomy for cervical cancer
B	39	Female	48	Lymphedema	Right	Hysterectomy for cervical cancer
C	75	Female	46	Lymphedema	Both	Hysterectomy for cervical cancer
D	65	Female	74	Lymphedema	Both	Hysterectomy for cervical cancer
E	46	Female	58	Lymphedema	Both	Hysterectomy for cervical cancer
F	62	Female	50	Lymphedema	Both	Hysterectomy for endometrial cancer
G	38	Female	51	Lymphedema	Both	Hysterectomy for cervical cancer
H	71	Female	52	Lymphedema	Both	Hysterectomy for endometrial cancer
I	55	F	41	Lymphedema	Left	Laparoscopic surgery for ectopic pregnancy

TABLE 1: Baseline characteristics of study participants with lymphoedema

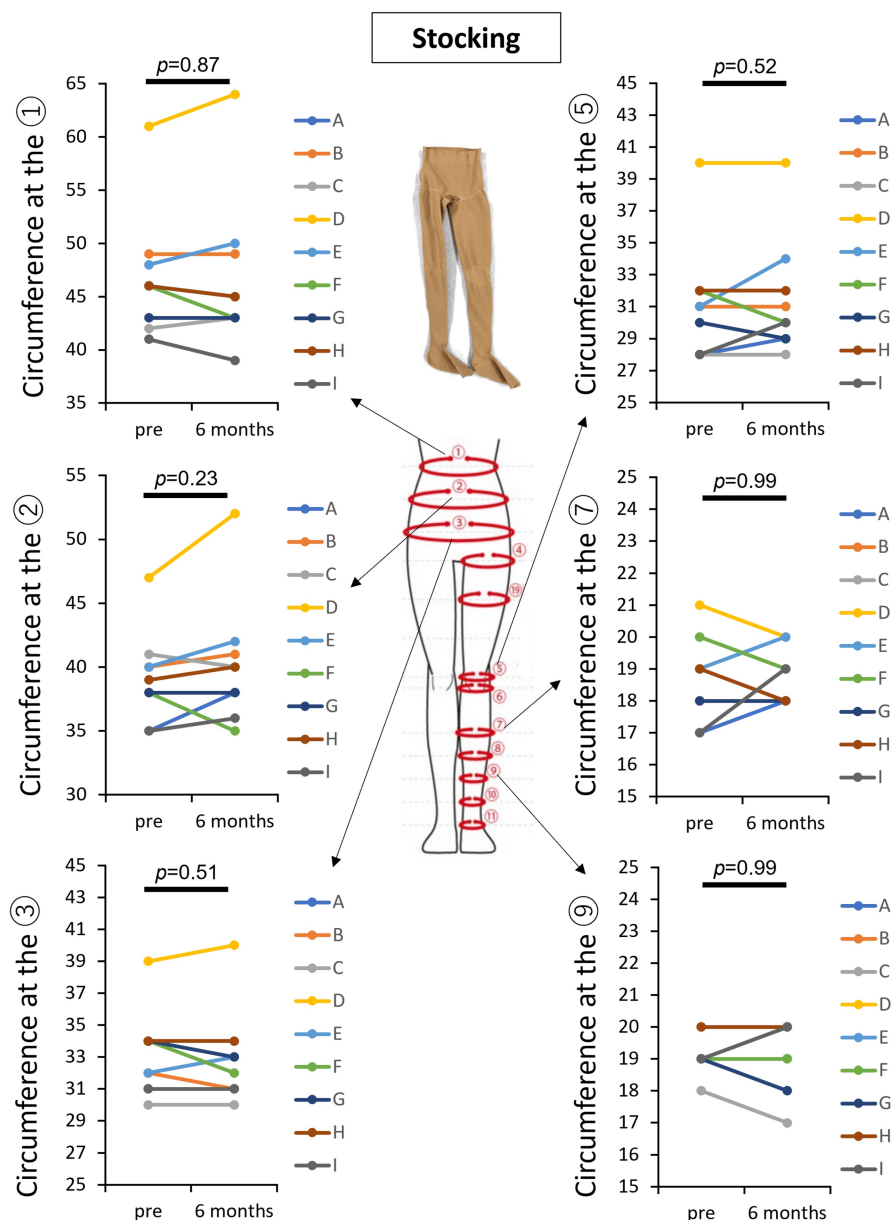


FIGURE 3: Assessment of conventional medical compression stockings in study participants with lymphedema

Changes in circumferences from the abdomen to the lower limbs before and after six months of compression therapy using conventional medical stockings in nine patients with lymphedema (A–I). Measurements were taken at six points (□, □, □, □, □, and □). Statistical analysis using a paired t-test showed no significant increases in circumference between pre-treatment and six-month follow-ups ($p > 0.05$), indicating that compression therapy effectively managed lymphedema without worsening.

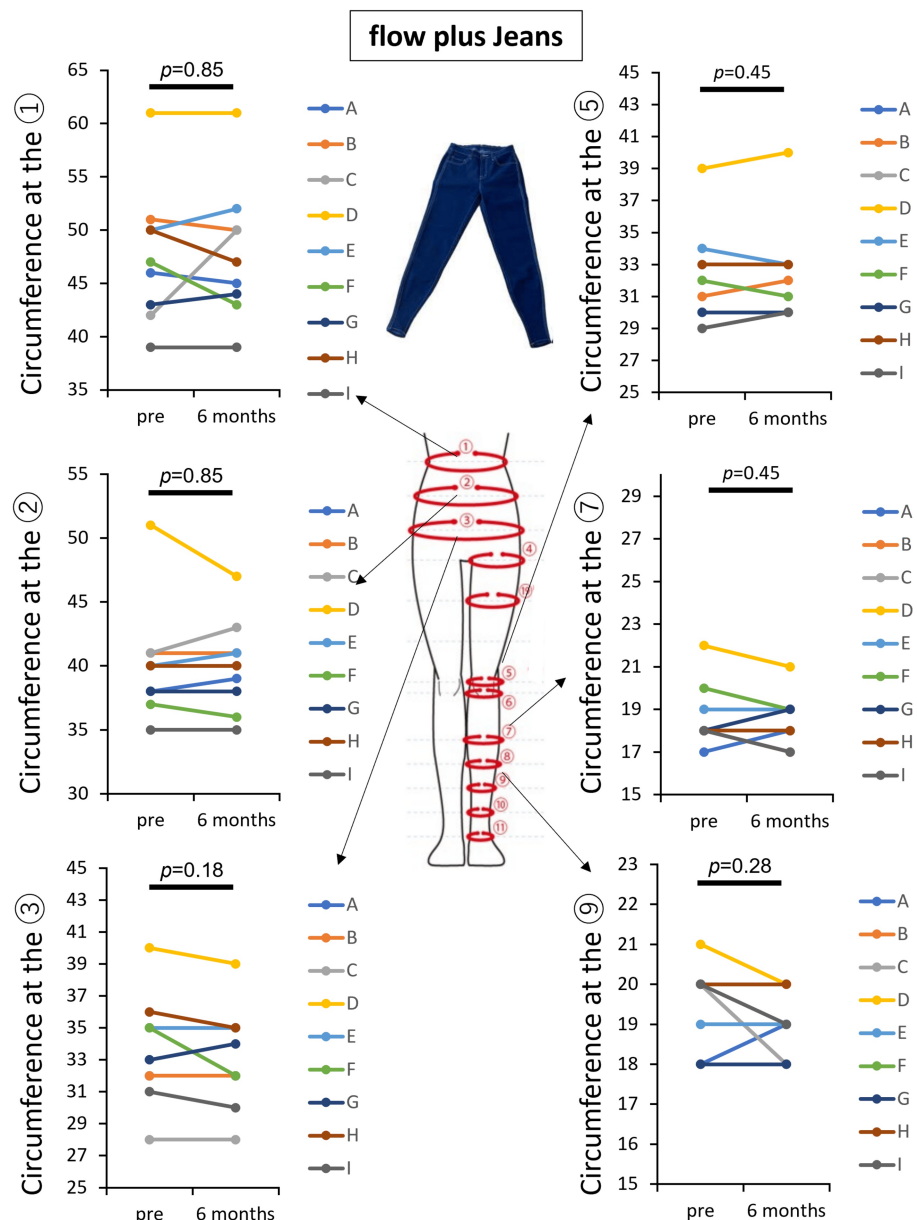


FIGURE 4: Assessment of Flow plus Jeans® in study participants with lymphedema

Changes in circumferences from the abdomen to the lower limbs before and after six months of compression therapy using Flow plus Jeans® in nine lymphedema patients (A–I) are shown. Measurements were taken at six points (□, □, □, □, □, and □). Statistical analysis using a paired t-test showed no significant increases in circumference between pre-treatment and six-month follow-ups ($p > 0.05$), indicating that compression therapy effectively managed lymphedema without worsening.

User Satisfaction Survey

The user satisfaction and experience survey for Flow plus Jeans conducted before use and six months after starting to use indicated that Flow plus Jeans achieved higher satisfaction regarding fashionability than did conventional stockings at both time points (Figure 5A, 5B). However, the ease of wear was inferior to that of conventional stockings at pre-use and six-month follow-ups (Figure 5A, 5B). Other parameters, including fit and comfort, compression sensation, skin irritation, price range, and overall satisfaction, showed no significant differences between the two groups.

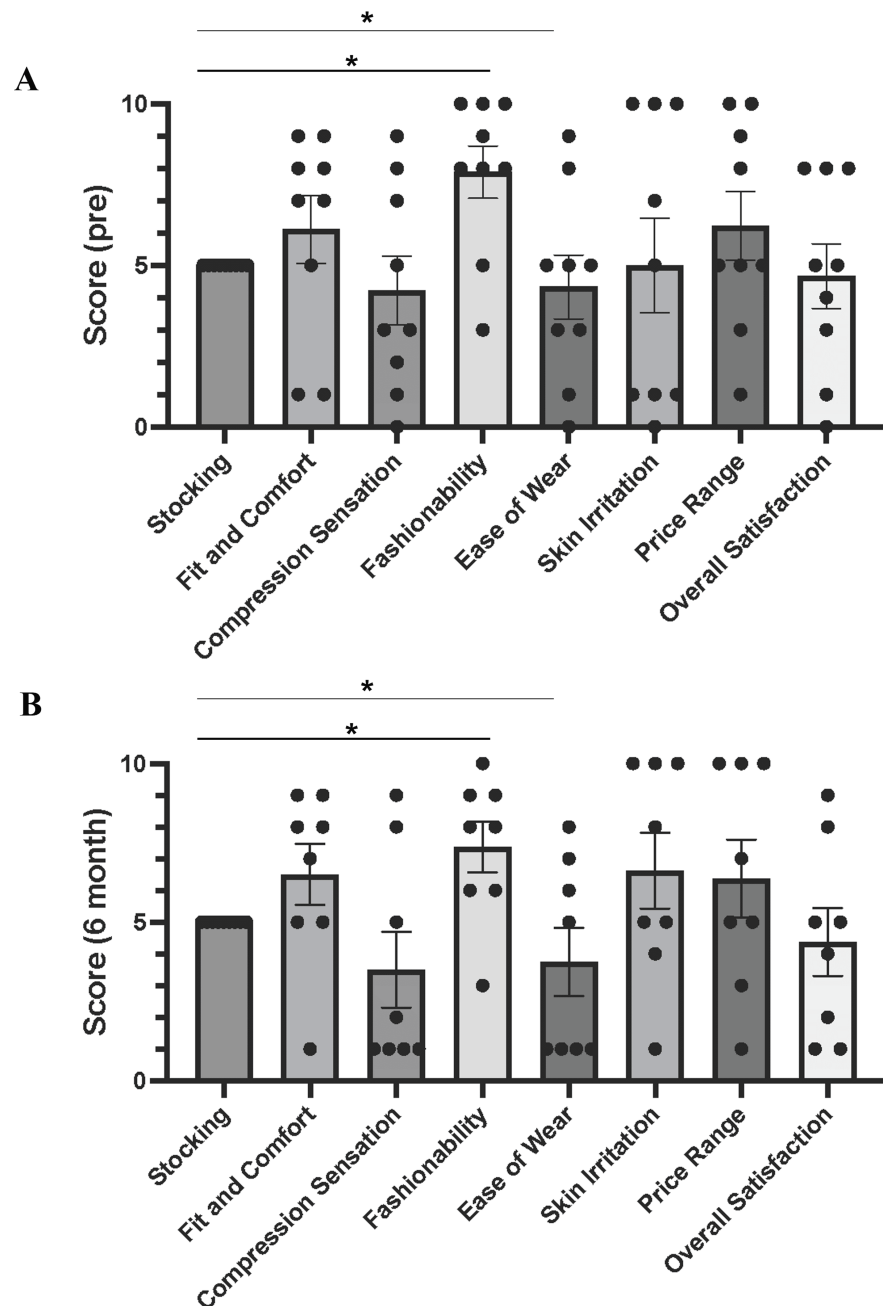


FIGURE 5: User experience survey comparing Flow plus Jeans® and conventional medical compression stockings

(A, B) Results of questionnaires assessing user experience with conventional medical stockings and Flow plus Jeans® immediately after use (pre) and after six months (pre: $n = 9$, 6 months: $n = 8$). Among the seven evaluated parameters, statistical analysis using an unpaired t-test showed that Flow plus Jeans® had significantly higher satisfaction in terms of fashionability than stockings at both pre-treatment and six months ($*p < 0.05$). However, Flow plus Jeans® was significantly inferior to stockings in terms of ease of wear at both pre-treatment and six-month time points ($*p < 0.05$).

Discussion

Several studies have confirmed that compression therapy combined with appropriate exercise is an effective management strategy for lymphedema [7-10]. Compression therapy helps reduce fluid accumulation, maintain limb volume, and prevent disease progression. However, despite its effectiveness, two primary challenges hinder its widespread and long-term use: adherence to long-term therapy and difficulty in selecting appropriate compression levels [11,12].

Adherence to compression therapy is often suboptimal owing to multiple factors, which can be categorized

into the following five key domains. First, regarding physical factors, many patients report discomfort due to heat retention, itchiness, excessive tightness, and difficulty in donning and doffing compression garments [13]. Improper application may lead to uneven pressure distribution, potentially worsening symptoms or causing skin-related complications [14]. Second, regarding psychological factors, the daily requirement for compression garment use can lead to treatment fatigue, decreased motivation, and frustration, particularly if the perceived benefit is not immediate or obvious [15]. Third, regarding social factors, economic burden is a well-documented barrier to compression therapy, because medical-grade compression garments can be expensive and may not be fully covered by insurance [16]. Furthermore, workplace constraints can limit patients' ability to wear these garments throughout the day [17]. Additionally, in rural areas where access to specialized lymphedema care is often limited, adherence to compression therapy may be further hindered by the need for long-distance travel to medical facilities. Studies suggest that non-traditional compression garments, which integrate compression therapy into everyday clothing, may improve adherence in these populations by offering a more practical and sustainable solution [18]. Fourth, regarding cultural factors, many compression stockings have aesthetic limitations, making them conspicuous and difficult to integrate into daily fashion. This is particularly relevant for younger patients and individuals who prioritize personal appearance [19]. Fifth, regarding healthcare-related factors, a lack of structured follow-up systems in many healthcare settings can lead to inconsistent patient compliance and the improper use of compression therapy [20].

To address these barriers, a multifaceted approach is necessary, integrating technological advancements, patient education, psychological support, and financial assistance. Regarding material innovation for comfort and aesthetics, the comfort and wearability of compression garments play a crucial role in patient adherence to therapy. Developing materials that are more breathable, flexible, and lightweight can help reduce discomfort, making long-term use more feasible. Enhanced fabric technology that improves moisture management and elasticity may also contribute to better patient satisfaction. Additionally, integrating compression therapy into everyday clothing rather than maintaining a purely medical appearance could encourage greater acceptance and consistent use, particularly among individuals who prioritize both functionality and aesthetics in their daily attire.

We sought to enhance adherence by developing Flow plus Jeans, a novel denim-based compression garment that was designed to provide both effective compression therapy and improved fashionability. The findings of the current study demonstrated that Flow plus Jeans, developed using proprietary sewing technology, achieved compression levels and graduated pressure comparable to conventional medical stockings, ensuring its therapeutic efficacy. Moreover, the jeans' appearance, identical to that of standard skinny jeans, led to higher satisfaction in terms of fashionability, suggesting a potential improvement in adherence among patients who are hesitant to use traditional compression stockings. Importantly, the psychological benefit of wearing a more aesthetically acceptable garment should not be underestimated, because self-image and confidence can significantly impact treatment compliance [21].

Beyond adherence, Flow plus Jeans may also offer additional therapeutic advantages. First, its compression gradient was found to be comparable to that of medical stockings, suggesting that it may effectively contribute to lower-limb volume maintenance and edema prevention. While this study did not assess physiological markers such as microcirculation or venous return, future investigations could explore whether the fabric composition of denim-based compression garments provides additional benefits. Second, Flow plus Jeans integrates compression therapy into daily clothing, allowing for discreet and sustained compression throughout the day. Unlike conventional stockings, which patients may remove due to discomfort or aesthetic concerns, jeans-based compression may encourage more consistent wear, potentially enhancing long-term therapeutic outcomes.

However, one notable limitation identified was the ease of wear, particularly at the ankle region. Some participants reported difficulty in donning and doffing the jeans, suggesting that further modifications in material flexibility or structural design may be necessary to optimize user experience. Future iterations of Flow plus Jeans should consider incorporating more stretchable fabric blends or adaptive fastenings to improve the ease of use without compromising compression performance.

Several recent innovations in compression therapy have aimed to improve comfort and breathability. For example, Cool Lala® (Batel Plus Corporation, Tokyo, Japan) has introduced compression stockings with enhanced air permeability, addressing one of the major physical discomforts associated with conventional garments. However, these products still maintain a traditional stocking-like appearance, which remains a limitation in terms of patient adherence. To our knowledge, Flow plus Jeans is the first denim-based compression garment designed specifically for lymphedema management. Integrating compression therapy into everyday clothing represents a novel approach to improving both adherence and quality of life for patients. This innovation has the potential to reshape how compression therapy is perceived and utilized, particularly among younger and fashion-conscious patients who may otherwise be resistant to conventional treatments.

Limitations of the study

This study has some limitations. First, the sample size was relatively small ($n = 9$), which may limit the

generalizability of the findings. Future studies with a larger cohort are necessary to confirm the effectiveness and user experience of Flow plus Jeans in a broader population. Future studies will also incorporate statistically determined sample sizes to validate the efficacy and long-term benefits in a larger cohort.

Second, the study duration was limited to six months; the long-term adherence and durability of the product require further investigation. Third, while subjective user satisfaction was assessed through questionnaires, objective measures of comfort and compliance, such as wear time tracking and real-world activity monitoring, were not included. Fourth, although circumference measurements were taken at standardized anatomical landmarks, no physical markings were made to ensure exact placement, which may have introduced variability in the measurements. Similarly, in the clinical trial with conventional compression stockings, all circumference measurements were conducted by hospital staff during morning outpatient visits, but no physical markings were applied to ensure precise consistency between pre- and post-treatment measurements.

Fifth, while both Flow plus Jeans and conventional compression stockings prevented an increase in lower-limb circumference, neither resulted in a significant reduction. Although this suggests that both products helped maintain limb volume, a more precise efficacy assessment would require a control group without compression therapy. However, establishing an untreated lymphedema patient group is ethically and practically challenging.

Sixth, foot swelling was not specifically assessed in this study as Flow plus Jeans does not cover the foot. While no visible swelling or patient complaints were observed during clinical follow-ups, future studies should include foot circumference measurements to ensure a comprehensive evaluation of compression effects.

Seventh, significant variability was observed in patient satisfaction scores, suggesting that Flow plus Jeans may be more suitable for certain subpopulations. Further studies are needed to establish appropriate patient selection criteria. Additionally, individual compression pressures were not measured, as the jeans' design allowed for sewing adjustments based on the lower-limb circumference to provide a degree of pressure control. However, the lack of direct compression pressure measurements may have contributed to the observed variation in satisfaction scores. Future studies should incorporate individual compression pressure assessments to clarify their impact on patient experience and treatment outcomes.

Lastly, the study focused exclusively on female participants in the trial for participants with lymphedema, and the usability and efficacy of Flow plus Jeans in male patients remain to be explored.

Conclusions

We developed a novel compression therapy device, Flow plus Jeans, in the form of denim jeans for managing lower-extremity lymphedema. The study demonstrated its functional non-inferiority to conventional medical compression stockings. While further refinements are needed, Flow plus Jeans offers a highly fashionable alternative and holds promise as a new option for lymphedema management.

Appendices

Questionnaire in Japanese

第1回アンケート（メディカルデニム）

第1回メディカルデニムの着用感アンケート

研究ID:

研究代表 大澤 晋（岡山大学病院医療安全管理部）

研究題目「メディカルデニムの効果検証」

この調査は、岡山大学病院心臓血管外科研究班が備後地区のジーンズメーカーと共同で開発した弾性デニム「メディカルデニム」をご利用いただいた患者様に、着用感や今後のニーズなどをお伺いし、今後の治療や予防効果の向上を目的に解析させていただく調査となります。

個人が特定される形での公表はございませんのでご安心いただき、率直な感想をお聞かせいただければと思います。本アンケート調査（所要時間10分程度）にご協力をお願いします。

以下の質問に当てはまるものに○、もしくは回答をお書きいただき、「その他」の場合はカッコ内に詳細をお書きください。

回答日： 年 月 日

Q1) あなたの性別、年齢をおしえてください

性別 （ 男性、 女性 ） 年齢 （ ） 歳

Q2) 今回、メディカルデニムをオーダーメイドされるのは何回目ですか？

はじめて、 2回目、 3回目以上

Q3) 下肢の浮腫を予防する商品は多数あるなかで、今回、メディカルデニムを選ばれた理由は何ですか？（複数回答可）

- 1、医師に勧められたから
- 2、価格が手頃だったから
- 3、オーダーメイドで自分にあったもの使用できるから
- 4、以前使用してみて、良かったから
- 5、弾性ストッキングより使いやすそうだから
- 6、新しいものを試してみたいと思ったから
- 7、良い評判を聞いたから
- 8、なんとなく
- 9、その他（ ）

p. 1

FIGURE 6: Japanese Questionnaire Page 1

第1回アンケート（メディカルデニム）

Q4) 今回のメディカルデニムの使用頻度についておしえてください

- 1、毎日
2、2～3日おき
3、週に1日以下
4、その他（ ）

Q5) 1日の着用時間はどのくらいですか？ 平均的な日についてお答えください。

合計 約 () 時間

利用することが多い時間帯：午前 () 時 ～ () 時

午後 () 時 ～ () 時

Q6) メディカルデニムを使用した感想を率直におきかせください

各項目について、0～10の11段階のどれに当てはまるか、数字に○をしてください。

1) 履き心地 (フィット感)

悪い 0 1 2 3 4 5 6 7 8 9 10 良い

2) しめつけ感 (圧迫感)

悪い 0 1 2 3 4 5 6 7 8 9 10 良い

3) 他の洋服との適合性 (ファッション性)

悪い 0 1 2 3 4 5 6 7 8 9 10 良い

4) 着用後の脚軽感

悪い 0 1 2 3 4 5 6 7 8 9 10 良い

5) 皮膚トラブル

悪い 0 1 2 3 4 5 6 7 8 9 10 良い

6) 価格帯(定価 35,000 円程度なので、3 割負担の場合は約 1 万円の実費となります)

悪い 0 1 2 3 4 5 6 7 8 9 10 良い

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FIGURE 7: Japanese Questionnaire Page 2

第1回アンケート（メディカルデニム）

7) 全体の満足感



Q7) メディカルデニム着用中に皮膚トラブルが発生した方は、具体的にその内容をおしえてください（赤く腫れた、かゆみがでた、乾燥した、足首がむくんだ等）

[]

Q8) 今回、メディカルデニム以外に併用した商品があれば○をつけてください

- ① 弾性ストッキング（商品名）
- ② 弾性ハイソックス（商品名）
- ③ その他（商品名）

Q9) 上記の Q8 について回答された方は、それぞれの着用方法について、当てはまる方に○をしてください。

Q8-①: デニムと同時（重ねて）に着用、 デニムとは異なるタイミングで着用

Q8-②: デニムと同時（重ねて）に着用、 デニムとは異なるタイミングで着用

Q8-③: デニムと同時（重ねて）に着用、 デニムとは異なるタイミングで着用

Q10) 今回、メディカルデニムの実質購入額（実費）は研究のため無料でしたが、今後の価格設定の参考にさせていただきたいと思いますので、ご希望をおしえてください

※現時点は、定価 35,000 円程度の商品です。医療費 3 割負担の場合は約 1 万円の実費となっています。

3 千円以下、 3 ～ 5 千円、 5 千 ～ 1 万円、 現在の価格設定でよい

Q11) はかの商品との比較についてお答えください。

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FIGURE 8: Japanese Questionnaire Page 3

第1回アンケート（メディカルデニム）

1) 大腿までのストッキングタイプ

メディカルデニムよりも（ 良い、 悪い、 どちらでもない、 使用したことがない ）

2) 膝までのハイソックスタイプ

メディカルデニムよりも（ 良い、 悪い、 どちらでもない、 使用したことがない ）

Q12) 今後、メディカルデニムの改善すべき点など、お気づきのことがありましたらお聞かせください。(複数回答可)

- 1、色展開をふやしてほしい
- 2、価格を安くしてほしい
- 3、オーダーメイドではなく、サイズを選べるようにしてほしい
- 4、使用推奨期限（現在6カ月）をもっと長くしてほしい
- 5、その他

御協力いただき有難うございました

【担当者が記入する欄】

- ・メディカルデニムを処方（注文）した日 ： 年 月 日
- ・オーダーメイド品をお渡しした日 ： 年 月 日
- ・アンケートを受け取った日 ： 年 月 日
- ・担当者名 ：（ 大澤 晋 ）

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FIGURE 9: Japanese Questionnaire Page 4

Questionnaire translated into English

Medical Denim Survey

First Questionnaire (Medical Denim)

First Medical Denim Wear Experience Questionnaire

Research ID:

Principal Investigator: Susumu Oozawa (Department of Medical Safety Management, Okayama University Hospital)

Research Title: "Evaluation of the Effectiveness of Medical Denim"

This survey aims to analyze the wearing experience and potential future needs of patients who have used the elastic denim "Medical Denim," jointly developed by the Cardiovascular Surgery Research Team of Okayama University Hospital and a jeans manufacturer from the Bingo region. The goal is to enhance treatment and prevention strategies.

No personally identifiable information will be disclosed. Please provide your honest feedback. We appreciate your cooperation in completing this questionnaire (approximate completion time: 10 minutes).

Date of Response: ____ / ____ / ____

Q1) Please provide your gender and age:

Gender: (Male / Female)

Age: (____) years old

Q2) How many times have you ordered Medical Denim?

First time

Second time

FIGURE 10: Questionnaire translated into English Page 1

Third time or more

Q3) Among the many products available for preventing lower limb edema, why did you choose Medical Denim? (Multiple answers allowed)

Recommended by a doctor

Affordable price

Custom-made to fit my needs

Previously used and found beneficial

Appears easier to use than compression stockings

Wanted to try something new

Heard positive reviews

Just a spontaneous decision

Other (Specify: _____)

Q4) How frequently do you wear Medical Denim?

Daily

Every 2-3 days

Less than once a week

Other (Specify: _____)

Q5) How long do you wear Medical Denim per day on average?

Total hours worn: (____) hours

FIGURE 11: Questionnaire translated into English Page 2

Most commonly worn time periods:

Morning: From () to ()

Afternoon: From () to ()

Q6) Please provide your honest evaluation of Medical Denim in the following categories.

Rate each item on a scale of 0-10 (0 = worst, 10 = best).

Fit (Comfort Level)

0 - 10

Compression Sensation

0 - 10

Fashion Compatibility (Fit with Other Clothing)

0 - 10

Leg Lightness After Wearing

0 - 10

Skin Condition (Any Issues?)

0 - 10

Price (Regular price: approx. 35,000 yen; insurance-covered portion: approx. 10,000 yen with 30% copay)

0 - 10

FIGURE 12: Questionnaire translated into English Page 3

Q11) How does Medical Denim compare to other products?

Thigh-high compression stockings

Compared to Medical Denim: (Better / Worse / No difference / Never used)

Knee-high compression socks

Compared to Medical Denim: (Better / Worse / No difference / Never used)

Q12) Do you have any suggestions for improving Medical Denim? (Multiple answers allowed)

More color options

Lower price

Standardized sizes (rather than custom-made)

Longer recommended usage period (currently 6 months)

Other (Specify: _____)

Thank you for your cooperation!

[For Staff Use Only]

Date of Medical Denim Prescription (Order): ____ / ____ / ____

Date of Custom-Made Product Delivery: ____ / ____ / ____

Date of Questionnaire Submission: ____ / ____ / ____

Staff in Charge: (_____)

FIGURE 13: Questionnaire translated into English Page 4

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Acquisition, analysis, or interpretation of data: Daiki Ousaka, Kiyoshi Yamada, Noriko Sakano, Kazumasa Miyake, Takumi Takahashi, Akihiro Matsuoka, Shintaro Yamada, Akira Shinaoka, Susumu Oozawa

Drafting of the manuscript: Daiki Ousaka

Critical review of the manuscript for important intellectual content: Daiki Ousaka, Kiyoshi Yamada, Noriko Sakano, Satoe Kirino, Kazumasa Miyake, Takumi Takahashi, Akihiro Matsuoka, Shintaro Yamada, Akira Shinaoka, Susumu Oozawa

Concept and design: Satoe Kirino, Susumu Oozawa

Disclosures

Human subjects: Consent for treatment and open access publication was obtained or waived by all participants in this study. Okayama University Hospital Ethics Committee issued approval 2106-045. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any

organization for the submitted work. **Financial relationships:** Susumu Oozawa and Satoe Kirino declare(s) non-financial support from Stork Visit Co., Ltd. Stork Visit Co., Ltd. is a university-originated venture from Okayama University, founded by authors Susumu Oozawa and Satoe Kirino. Flow plus Jeans® is a registered trademark of this company. **Intellectual property info:** The authors declare that they have developed the medical device, Flow Plus Jeans®, used in this study. A patent related to the device has been obtained by Susumu Oozawa, and the intellectual property rights are held by Susumu Oozawa or Okayama University. However, the study was conducted independently, and the results presented are not influenced by any financial or commercial interests. **Other relationships:** Takumi Takahashi, Akihiro Matsuoka, Shintaro Yamada are employees of the jeans development company. They were involved in the development of Flow plus Jeans®, including the prototypes used in the preliminary study. Additionally, they contributed to the mannequin-based compression pressure measurement experiments.

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