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輔具與支持

Evaluation on the Mechanical Testing of Mobility Aids

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ABSTRACT

In this study, quality investigation was executed in accordance with CNS 15191 “Wooden walking sticks”, CNS 15192 “Adjustable metal walking sticks”, CNS 15024-4 “Walking aids manipulated by one arm – Part 4：walking sticks with more legs”, and CNS 15037-1 “Walking aids manipulated by both arms – Part 1：Walking frames”. And CNS standards define the sequence of mechanical tests is stability test, static load test and fatigue test.

The results revealed that 4 of 7 adjustable metal walking sticks generate permanent deformation and were out of the acceptance criteria of the CNS standard. Besides, 3 of 5 wheeled walking frames were failed in the fatigue test.

In this study, the recommendations which result from testing reports are made for the requirements of mobility aids on crutch with a single leg, walking sticks with three or more legs and walkers. Those recommendations ensure the safety of users and their usages, and also lead manufacturers on product development.

Key word：Mobility aids, single-foot crutch, walking sticks with three or more legs, walking frame, testing standard

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INTRODUCTION

As medical care and quality of life enhanced, Taiwan becomes an aging population society gradually. When people become geriatric, daily living activities are limited by their physical conditions, diseases or accidents. The mobility aids for home use play important roles in modern society[1,17]. Due to various types of mobility aids and retailing channels, end users have difficulties to purchase the proper mobility aids[11-16,30]. Although the testing procedures of national standards are not exactly matching to usage of users' behaviors, the national standards are set-up to assert the quality of mobility aids. Through the registration and inspection processes from the government bureau, the end users could have better quality of products and more safety assurances[10,35].

Standards Comparison

Common mobility aids for home use are classified as class 1 medical device. These devices fundamentally can be divided into crutch with a single leg or more legs including wooden walking stick and adjustable metal walking stick, and the other is walking frame[18-19]. The worldwide majority standards of mobility aids are ISO[20-29] (International Standard), EN[3] (European Standard), BS[2-3] (British Standard), the CPSA[33] (Japan standard) and CNS[4-9] (Taiwan standard). The corresponding standards for mobility aids are shown in table 1, and the comparisons of relative contents are described as follows：

1. The CNS standards only formulate regulations of wooden walking sticks and adjustable metal walking sticks[8-9], while CPSA standards contain more regulations which are like foldable or assembled sticks[33].
2. For wooden walking sticks, CNS 15191 contains the static loading test and junction strength test[8-9]. BS 5181 only requires static loading test[2] and this standard was replaced by BS EN 1985:1999 on November 29, 2010[3]. CPSA 0073 only requires the strength test[32].
3. For strength test of wooden walking stick, the requirement of domestic standards is to apply 130N force to the position of 300 millimeter from the junction[8], while the strength test of the CPSA 0073 is to apply 150N and 200N force to the center of the stick and the position of 300 millimeter from the handle, respectively[33].
4. For product category, wooden walking sticks are classified as light, medium and heavy type according to the diameter of the rod and the inner diameter of the rubber head in CNS 15191 and BS 5181. In static loading test, the force applied to light, medium and heavy type is 200N, 300N and 400N, respectively [2,8]. However, there is no such classification in the CPSA 0073[33].
5. CPSA 0073 applies to all kinds of walking sticks, such as adjustable, foldable and assembled sticks[33]. However, CNS 15191 and BS 5181 only apply to wooden walking sticks[2,8], and CNS 15192 applies to adjustable metal walking sticks[9], respectively.

Table 1：The corresponding standards for mobility aids

mobility aids	domestic standards	corresponding standards
wooden walking stick	CNS 15191(2010)	BS 5181(1975) CPSA 0073(1996)
adjustable metal walking stick	CNS 15192(2010)	N/A
walking sticks with more legs	CNS 15024-4(2006)	ISO 11334-4(1999)
walking frames	CNS 15037-1 (walking frames) CNS 15037-2 (wheeled walking frames) CNS 15037-3 (additional forearm support walking frames)	ISO 11199-1(1999)

All corresponding performance tests and requirements for domestic standards are shown in table 2. For all mobility aids, the testing items should be raised to the maximum height during tests, but the wooden walking sticks are the exception. Besides, except for the crutch with a single leg[8-9], tests shall be required the mandatory sequence for the walking sticks with three or more legs. The sequence shall be as follows: the stability test, static load test and fatigue test[4]. Based on the standard of walkers, the mandatory sequence of tests shall be as follows: the stability test, static load test and fatigue test[5-6]. For most of standards, testing items can not have cracks, be broken or unsafe occurrences after tests[4-9].

Table 2：Performance tests and requirements for domestic standards

mobility aids	domestic standards	performance tests	requirements
wooden walking stick	CNS 15191(2010)	static loading test	the deformation of testing items should meet the requirement of standard
adjustable metal walking stick	CNS 15192(2010)	static loading test	the deformation of testing items should meet the requirement of standard
walking sticks with more legs	CNS 15024-4	stability test (inward)	Not less than 2°
		stability test (outward)	Not less than 5° for three-leg walking sticks Not less than 7.5° for walking sticks with more legs
		static loading test	the testing items can not show any cracks, broken or unsafe occurrences
		fatigue test	the testing items can not show any cracks, broken or unsafe occurrences
walking frames wheeled walking frames	CNS 15037-1 CNS 15037-2	forward stability test	Not less than 10° (walking frames) Not less than 15° (wheeled walking frames)
		backward stability test	Not less than 7°
		sideways stability test	Not less than 3.5° (walking frames) Not less than 4.5° (wheeled walking frames)
		static loading test	the testing items can not show any cracks, broken or unsafe occurrences
		fatigue test	the testing items can not show any cracks, broken or unsafe occurrences

MATERIALS AND METHODS

I. *Materials*

We purchased 40 samples of mobility aids which are classified as class 1 from general retailing stores. Those samples contained twenty walkers and twenty crutches which are made from different manufacturers. Then the fatigue test, stability test and static loading test are performed to compare the quality[4-9]. The crutches included 17 domestic products and 3 imported products (made from the Chinese mainland). The walkers included 10 domestic products and 10 imported products (made from the Chinese mainland).

II. *Equipments and Performance Tests*

In this study, the necessary equipments including the material testing system (model name：UH8811) and pneumatic cylinder (model name：MCQA-11 100-300M) were provided by the Foot & Recreation Technology Research Institute (FRT). All performance tests are in compliance with the requirements of the CNS standards[4-9], and the test criteria are as follows:

1. wooden walking stick：Static loading test is according to section 8.2 of CNS 15191.
2. Adjustable metal walking sticks：Static loading test is according to section 9.1 of CNS 15192.
3. walking sticks with three or more legs：Inwards stability test, outwards stability test, static loading test and fatigue test are according to section 4.3, 4.4, 4.6 and 4.7 of CNS 15024-4, respectively.

4. walking frames：Fatigue test, static loading test, forward stability test, backward stability test and sideways stability test are according to section 4.3, 4.4, 4.6, 4.7 and 4.8 of CNS 15037-1, respectively.
5. wheeled walking frames：Forward stability test, backward stability test, sideways stability test, static loading test and fatigue test are according to section 4.4, 4.5, 4.6, 4.10 and 4.11 of CNS 15037-2, respectively.

III. *Testing Procedures*

Stability test and fatigue test are common items in each national standard[30-31], and static loading test is associated with the safety of the product[11-12]. These tests are chose to evaluate the mechanical property of mobility aids. According to mobility aids category, the difference of test methods were described as follows：

1. *Crutches with Single Leg:*

   Static loading test was executed as follows：

   The static forces applied at the midpoint of handgrip of stick are 200N、300N、400N respectively. The applied force should last five minutes and measure the deformation of stick, and finally measure its permanent deformation after ten minutes. (The static loading test of adjustable metal walking stick should be only applied 400N.)

2. *Walking Sticks with More Legs*

   There are three types of walking sticks with more legs defined in the domestic standard CNS 15024-4[4]: three-leg walking sticks, four-leg walking sticks and five-leg walking sticks. The sequences of performance tests shall be as follows: stability test, static loading test and fatigue test.

   a. Stability test was executed as follows：

Stability tests include inward stability test and outward stability test. The inward stability test places the walking sticks on the same raised direction of testing plane, with the tips of the two legs closed to the user when the walking stick is in normal use. The 250N static force is applied at the center of handgrips, then the testing plane is raised gradually and the tilting angle of stick is measured. The outward stability test for other legs is similar to inward stability test.

b. Static loading test was executed as follows：

Tilt the test plane at 3°, and apply 1000N gradually over a minimum period of 5 sec at the midpoint of the front handgrips vertically, and then the force last for 10 seconds. While the sample specified maximum user's weight is 100 kilograms, the applied force shall be 1000N. If the specified maximum user's weight is not 100 kilograms, the applied force shall increase or decrease 10N per kilogram.

c. Fatigue test was executed as follows：

Adjust 450N cyclic force to perform the fatigue test. Then set 200000 cycles and 0.5 sec loading time. If the sample specified maximum user's weight is not 100 kilograms, the applied force shall increase or decreases 4.5N per kilogram.

3. *Walkers:*

For the static loading and fatigue tests of walkers, testing items are placed on a horizontal testing plane other than 3 °testing plane used in walking sticks. The sequences of performance tests shall be as follows: stability test, static loading test and fatigue test.

a. Forward stability test was executed as follows：

Two front legs of walkers are placed in the same raised direction of the testing plane. The 250N force shall be applied at the midpoint of the virtual line of two front handgrips and shall remain vertically, and then raise the adjustable plane gradually until the sample is tilted. Then, the backward and sideways stability tests follow the same procedures with different orientations.

b. Static loading test was executed as follows：

Apply 1500N force gradually over a minimum period of 2 sec, and then the force lasts for 5 seconds. If the specified maximum user's weight is not 100 kilograms, the applied force shall increase or decrease 15N per kilogram.

c. Fatigue test was executed as follows：

After setting 200000 cycles and 0.5 sec loading time, adjust 800N cyclic force to perform the fatigue test. If the sample specified maximum user's weight is not 100 kilograms, the applied force shall increase or decreases 8N per kilogram.

IV. *Testing Criterion*

The requirement of the static loading tests are that the testing items can not show any cracks, broken or unsafe occurrences, and the deformation from any parts needs to meet the limited range. Besides, when items are dropped, tilting angle need to achieve the standard requirements in the stability tests[4-9].

RESULTS

Twenty walkers and twenty crutches were purchased from general retailing stores, and the fatigue test, static loading test and stability test were performed. The crutches included 4 wooden walking stick, 7 adjustable metal walking stick and 9 walking sticks with more legs. The walkers included 10 walking frames and 10 wheeled walking frames. The statistical charts of test results for crutches and walkers are shown in Table 3 and table 4, respectively.

Table 3：Test results of crutches

category	wooden walking stick	adjustable metal walking stick	walking sticks with more legs
Stability test pass (%)	x	7 (100%)	9(100%)
Static loading test pass (%)	4 (100%)	3 (43%)	9(100%)
Fatigue test pass (%)	x	7 (100%)	7(78%)

Table 4：Test results of walkers

category	walking frames	wheeled walking frames
Stability test pass (%)	15 (100%)	5 (100%)
Static loading test pass (%)	15 (100%)	5 (100%)
Fatigue test pass (%)	15 (100%)	2 (40%)

The testing procedures and methods are simulated to users' behaviors. The testing results can be helpful and applied for the quality and safety of the products. The summary conclusions of testing results as follows:

1. For stability test, all crutches and walkers fulfilled the requirements of national standards, regardless whether they are made in Taiwan or made in China.

2. For static loading test, all of the testing samples including wooden sticks, crutches and walkers pass the requirements of domestic standards. However, there are four samples of adjustable metal walking sticks deformed permanently. But these permanent deformations are smaller than 1 millimeter.
3. For fatigue test, two crutches of K type handgrips failed in the test, other types of handgrips of crutches all passed in the fatigue test. Therefore, the types of handgrips might be a critical factor for crutches. Besides, for walking frames without wheels, all testing items pass the requirements of standards. But there are three wheeled walking frame samples are failed in the fatigue test. Fatigue test is a very important indication for users and manufacturers. It serves as a key index for the walking frames.

DISCUSSION

In Taiwan, registrations for class 1 medical devices only require document review. We still cannot neglect the importance of the post-market product validation. Through these testing and inspection standards, end users may be able to purchase safer products, and manufacturers may ensure quality of medical devices. It might also serves as a good marketing strategy for the homemade products to enter the global market. Therefore, the followings are the suggestions how the products can meet the end users' needs.

1. For wooden walking sticks and adjustable metal walking sticks, we suggest that static loading test in CNS 15191[8] and CNS 15192[9] could be added on the regulation requirements. According to these standards, the deformation

from any parts of sample can not fail the requirements after static loading test.

2. For walking sticks with more legs, we suggest that stability test, static load test and fatigue test in CNS 15024-4[4] could be added on the regulation requirements. According to the standard, the tilting angle of inward stability test should not be less than 2 degrees. For three-leg walking sticks, the tilting angle of outwards stability test should not be less than 5 degrees. For four- or more legs walking sticks, the tilting angle of outward stability test should not be less than 7.5 degrees. After static loading test and fatigue test, samples shall not show any cracks, broken or unsafe occurrences.
3. For walkers, we suggest that stability test, static loading test and fatigue test in CNS 15037-1[5] could be added to the regulation requirements. According to these standards, the tilting angle of forward stability test should not be less than 10 degrees, and the tilting angle of backward stability test should not be less than 7.5 degrees. In sideways stability test, the tilting angle should not be less than 3.5 degrees. After static loading test and fatigue test, samples shall not show any cracks, broken or unsafe occurrences.

REFERENCES

1. Andrich, R., Ferrario, M., Moi, M. 1998. A model of cost-outcome analysis for assistive technology. Disabil Rehabil. 20(1): 1-24.
2. British Standards Institute. 1975. Specification for wooden walking sticks. BS 5181.
3. British Standards Institute. 1999. Walking aids. General requirements and test methods. BS EN 1985:1999
4. Bureau of Standard, Metrology & inspection, M.O.E.A, ROC. 2006. Walking aids manipulated by one arm - Requirements and test methods - Part 4: Walking sticks with three or more legs. CNS 15024-4:1-16.
5. Bureau of Standard, Metrology & inspection, M.O.E.A. R.O.C. 2006. Walking aids manipulated by both arms - Requirements and test methods - Part 1: Walking frames. CNS 15037-1:1-16.
6. Bureau of Standard, Metrology & inspection, M.O.E.A, ROC. 2006. Walking aids manipulated by both arms - Requirements and test methods - Part 2: Rollators. CNS 15037-2:1-21.
7. Bureau of Standard, Metrology & inspection, M.O.E.A, ROC. 2006. Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables. CNS 15037-3:1-21.
8. Bureau of Standard, Metrology & inspection, M.O.E.A, ROC.2010. Wooden walking sticks. CNS 15191:1-6.
9. Bureau of Standard, Metrology & inspection, M.O.E.A, ROC. 2010. Adjustable metal walking sticks. CNS 15192:1-7.
10. Church, G., Glennen, S. 1992. The handbook of assistive technology. San Diego, CA: Singular Publishing Group.
11. Cook, A. M., Hussey, S. M. 2002. Assistive technologies: principles and practice. (2nd ed.). St. Louis Mosby.
12. Day, H., Jutai, J. 1996. Measuring the psychosocial impact of assistive devices: the PIADS. Can J. Psychol. 9 : 159-168.
13. Demers, L., Monette, M., Lapierre, Y., Arnold, D. L., Wolfson, C. 2002. Reliability, validity, and applicability of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) for adults with multiple sclerosis. Disabil Rehabil. 24: 21-30.
14. DeRuyter, F. 1995. Evaluating outcomes in assistive technology: do we understand the commitment? Assist Technol. 7: 3-8; 9-16.
15. Dijcks, B. P., Wessels, R. D., de Vlieger, S. L., Post, M. W. 2006. KWAZO, a new instrument to assess the quality of service delivery in assistive technology

provision. Disabil Rehabil. 28: 909-914.
16. Evans, S., Frank, A. O., Neophytou, C., de Souza, L. 2007. Older adults' use of, and satisfaction with, electric powered indoor/outdoor wheelchairs. Age Ageing. 36: 431-435.
17. Fuhrer, M. J. 2001. Assistive technology outcomes research: challenges met and yet unmet. Am. J. Phys. Med. Rehabil. 80: 528-535.
18. Fuhrer, M. J., Jutai, J. W., Scherer, M. J., DeRuyter, F. 2003. A framework for the conceptual modelling of assistive technology device outcomes. Disabil Rehabil. 25: 1243-1251.
19. Hammel, J., Angelo, J. 1996. Technology competencies for occupational therapy practitioners. Assist Technol. 8: 34-42.
20. International Organization for Standardization.1999. Walking aids manipulated by both arms - Requirements and test methods - Part 1: Walking frames. ISO 11199-1.
21. International Organization for Standardization. 2005. Walking aids manipulated by both arms - Requirements and test methods - Part 2: Rollators. ISO 11199-2.
22. International Organization for Standardization. 2005. Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables. ISO 11199-2.
23. International Organization for Standardization. 2008. Wheelchairs - Part 4 : Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range. ISO 7176-4.
24. International Organization for Standardization. 2008. Wheelchairs - Part 10: Determination of obstacle-climbing ability of electric wheelchairs. ISO 7176-10.
25. International Organization for Standardization. 2008. Wheelchairs - Part 14: Power and control systems for electric wheelchairs - Requirements and test methods. ISO 7176-14.
26. International Organization for Standardization. 2009. Wheelchairs - Part 9: Climatic tests for electric wheelchairs. ISO 7176-9.
27. International Organization for Standardization. 2009. Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters. ISO 7176-21.
28. International Organization for Standardization. 2008. Wheelchairs - Part 5： Determination of dimensions, Mass and maneuvering Space. ISO 7176-5.
29. International Organization for Standardization. 1999. Walking aids manipulated by one arm - Requirements and test methods - Part 4: Walking sticks with three or more legs. ISO 11334-4.
30. King, T. W. 1999. Assistive technology: Essential human factors. Needham

Height, MA: Allyn & Bacon.
31. Kohn, J. G., Mortola, P., LeBlanc, M. 1991. Clinical trials and quality control: checkpoints in the provision of assistive technology. Assist Technol. 3: 67-74.
32. Lacoste, M., Weiss-Lambrou, R., Allard, M., Dansereau, J. 2003. Powered tilt/recline systems: why and how are they used? Assist Technol. 15 : 58-68.
33. Ministry of International Trade and Industry. 1986. Approval Standard and Standard Confirmation Method for Walking Sticks. CPSA 0073：1-21.
34. Nosek, M. A., & Krouskop, T. A. 1995. Demonstrating a model approach to independent living center-based assistive technology services. Assist Technol, 7: 48-54.
35. SHHD 1970. The future of the artificial lim of State for Scotland. Scottish Home and Health Department, Edinburgh.
36. Wessels, R. D., De Witte, L. P. 2003. Reliability and validity of the Dutch version of QUEST 2.0 with users of various types of assistive devices. Disabil Rehabil. 25: 267-272.

行動輔具之力學性質檢測評估

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摘要

本研究依據中華民國國家標準 CNS 15191「木手杖」、CNS 15192「可調式金屬手杖」、CNS 15024-4「三腳或多腳步行手杖」及 CNS 15037-1「助行器」之規定進行靜態負載試驗、穩定性試驗及疲勞試驗品質調查。測試結果發現，在靜態負載測試中，有 7 個可調式金屬手杖中有 4 個發生永久變形，以致於為不符合產品，在疲勞測試中，5 台助行車中就有 3 台在疲勞測試中為不符合產品。

因此，本研究依據檢測過程及測試數據，對單腳枴杖、三腳或多腳枴杖和助行器行動輔具相關國內標準提出建議，除了保障使用者使用安全外，更讓製造商在產品上有所依循。

關鍵詞：行動輔具、單腳枴杖、三腳或多腳枴杖、助行器