Journal of Hand Therapy 33 (2020) 174–179

Contents lists available at ScienceDirect

Journal of Hand Therapy

journal homepage: www.jhandtherapy.org

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3D Printing

Automated 3D-printed finger orthosis versus manual orthosis preparation by occupational therapy students: Preparation time, product weight, and user satisfaction

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ARTICLE INFO

Article history:
Received 11 August 2019
Received in revised form
3 December 2019
Accepted 31 March 2020
Available online 15 May 2020

Keywords:
Swan-neck deformity
3D printing
Occupational therapy

ABSTRACT

Study design: Intra-subject cross-sectional study.
Introduction: Upper limb injuries often require wearing an orthosis. Today, orthoses are custom-made by the clinician or purchased as an off-shelf product. Although 3D printing is a popular solution, the design and adjustment of an orthosis model according to patient-specific anatomy requires technical expertise, often unavailable to the clinicians.
Purpose of the study: (1) To create a software that receives input of anatomic dimensions of the finger and automatically adjusts an orthosis model for patient-specific 3D printing and (2) to compare preparation time, product weight, and user satisfaction of occupational therapy students between the manual method and the automatic 3D printing method.
Methods: A custom code allows the user to measure five anatomic measurements of the finger. The code adjusts a swan-neck orthosis model according to the patient-specific measurements, and a fitted resized 3D-printable file is produced. We recruited 36 occupational therapy students (age 25.4 $\pm$ 1.9 years). They prepared two swan-neck orthoses for a finger of a rubber mannequin: one manually using a thermoplastic material and the other by 3D printing. The preparation time and orthosis weight were measured, and the subjects filled out a user satisfaction questionnaire.
Results: The weight of the 3D-printed orthosis was significantly lower than that of the manual orthosis; however, the preparation time was longer. The subjects were more satisfied with the fit, esthetics, overall process, and product of the 3D-printed orthosis.
Conclusion: The creation of an automated software for the patient-specific adjustment of orthoses for 3D printing can be the missing link for integration of 3D printing in the clinics.

Introduction

The swan-neck deformity is characterized by hyperextension of the proximal interphalangeal joint and flexion at the metacarpophalangeal joint. Orthoses are a frequently used intervention for stabilization and protection of the limb after injuries, such as fractured bones,[1] deformed joints with osteoarthritis,[2] and ruptured ligaments or tendons.[3] Orthoses that restrict hyperextension of the proximal interphalangeal joint are often prescribed to patients with swan-neck deformity. These orthoses were also found to be effective for protecting the proximal interphalangeal joints of volleyball players.[4] The orthoses might be custom-made by the clinician using thermoplastic material or silver or purchased as an off-shelf product.[5]

Three-dimensional (3D) printing has become a widely used method for manufacturing complex items. Specifically, it can be used to produce cost-effective, anatomically accurate, and esthetic orthoses.[6] Other advantages of 3D-printed orthoses are that the virtual model is saved and can be reprinted if the orthosis is to be replaced. Also, a one-piece item with no welded vulnerable end points can be 3D-printed. This is an advantage of 3D-printed items because it avoids areas prone to mechanical failure that exists in the manually manufactured orthosis, that is, where a heat gun was used or where two endings of the material were pressed together before the material cooled. Finally, although the available number of the thermoplastic material of different thicknesses is limited, the

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https://doi.org/10.1016/j.jht.2020.03.022

thickness of the 3D-printed orthosis can be precisely controlled and designed to smoothly vary along the orthosis to induce areas of different stiffnesses, where needed. Unfortunately, although various affordable 3D printers are available, they are rarely used in clinics. One of the most likely reasons for this absence is that manipulating a virtual model of an orthosis to fit the anatomy of the patient requires technological know-how in computer-aided design software.[6,7] For example, a recent study case,[8] a brace for treating swan-neck deformity was manufactured following 3D scanning of the finger, creation of a solid model, manipulation using a 3D modeling application, and conversion to a printable STL file. Because this process requires the usage of 3D modeling applications, most clinicians prefer to use the manual method taught to them during their studies. Until paramedical students are educated in using this new technology, other methods of allowing 3D printing to be accessible to clinicians should be explored. If the process of fitting a 3D-printed orthosis to the patient is simplified, the costs and efforts of training novice clinicians in manufacturing orthoses might be reduced.

For this purpose, we aimed (1) to create a software that receives input of anatomic dimensions of the finger and automatically adjusts an orthosis model for patient-specific 3D printing and (2) to compare the preparation time, product weight, and user satisfaction of occupational therapy (OT) students between the manual preparation method and the automatic 3D printing method.

Methods

Population

We recruited 36 female OT students (mean and SD age of 25.4 ± 1.9 years). All of the participants successfully completed a workshop during the last year, as part of their undergraduate obligations. During the workshop, the students learned to manually manufacture a cock-up wrist brace, resting brace, dynamic brace for flexion and extension, thumb spica brace, ulnar gutter brace, and various finger braces, among which was the swan-neck orthosis. Overall, they received approximately 10 h of training in the preparation of simple and complex orthoses and were also given access to the workshop to practice at their own time before their test. This study was approved by the ethics committee of the university.

Research tools

Kit for manual preparation of the orthosis

The kit included a water bath, set to 70°, thermoplastic material (Orfit 3.2 mm, Orfit Industries NV), and scissors.

Kit for automatic 3D printing preparation of the orthosis

The kit included a digital caliper, a 3D printer (Makerbot replicator 2X, MakerBot Industries) with 1.7 mm ABS filament material, and a novel custom software (see graphic user interface in Fig. 1), coded in LabView (v2017, National Instruments) for automatic fitting of a swan-neck orthosis according to five anatomic measurements (three measurements of the width of the finger: at the midpoints of the proximal and distal phalanges and of the joint itself; two distances from the joint to the midpoints of the distal and proximal phalanges). The finger width measurements may take into account swelling, and the distance measurements may be manipulated to avoid painful areas. The software is free for download and use at https://www.tau.ac.il/~portnoys/Splint.html and can be installed on a computer with a Windows operating

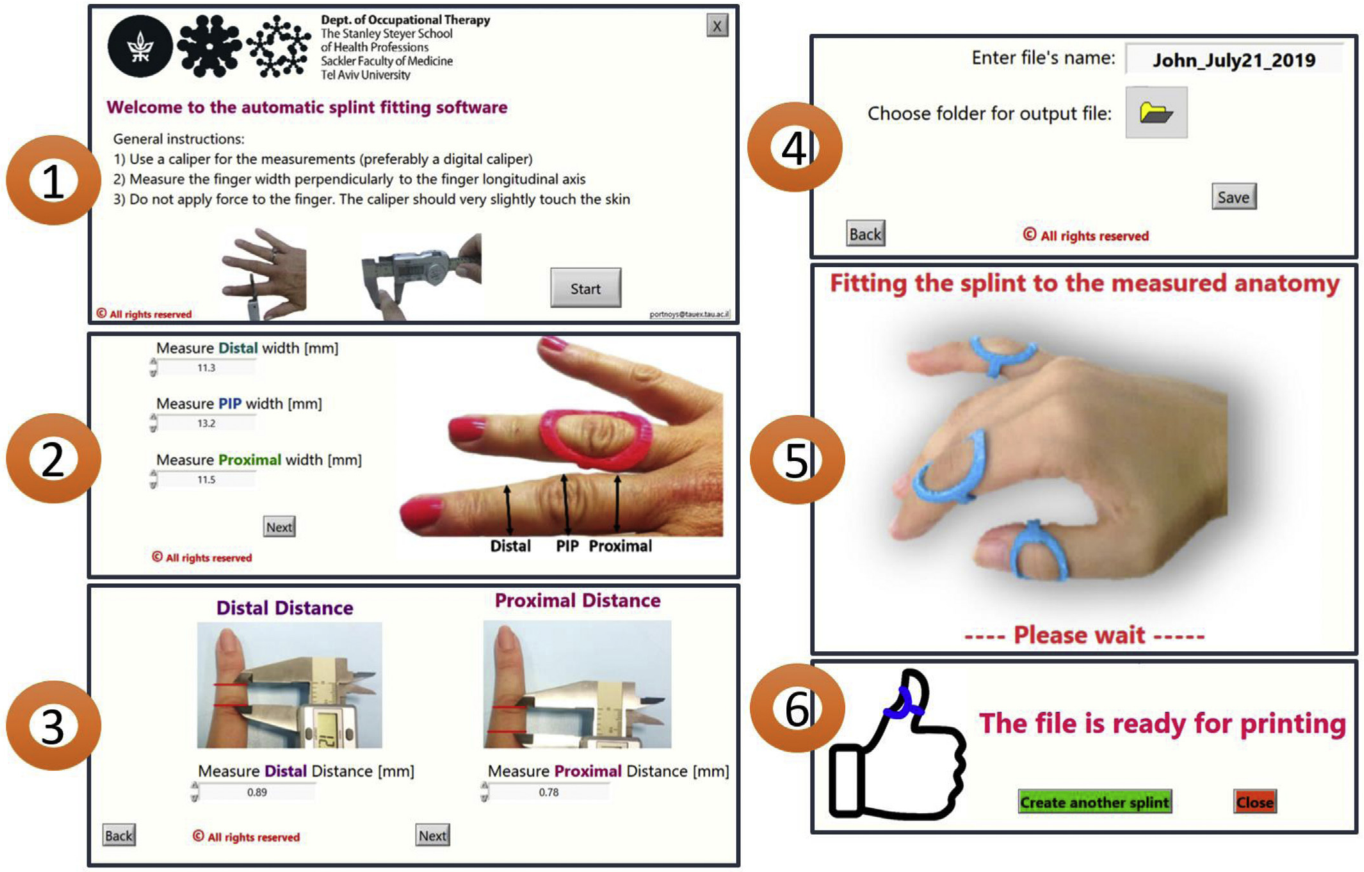

Fig. 1. The graphic user interface of our software comprises of (1) an opening screen with general instructions. In (2) the second screen, the user is asked to input 3 diameters of the fingers and then in screen (3), two lengths of the finger. Then, (4) the target folder and name of the produced file is requested, (5) the file is being produced, and (6) the file is ready for printing. PIP = proximal interphalangeal joint.

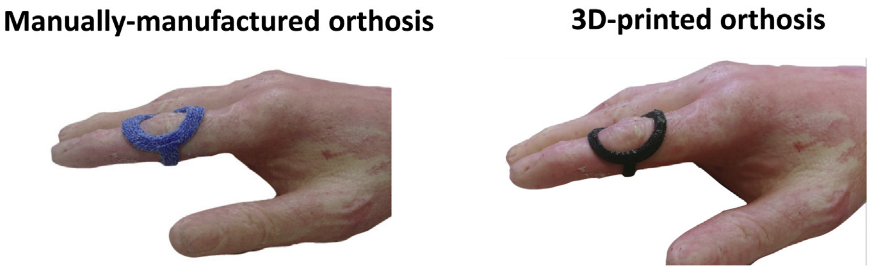

Fig. 2. The subjects prepared two orthoses for a finger of a rubber mannequin with a wooden stick inserted to the second finger, mimicking the bone.

system. The software produces an STL file that can be printed using any 3D printer.

User satisfaction questionnaire

The questionnaire consisted of seven questions. Five questions were scaled from '1' to '5' ('1'-not at all, '2'-mild, '3'-moderate, '4'-high, and '5'-very high), as rated in the Quebec User Evaluation of Satisfaction with assistive Technology 2.0 (QUEST 2.0).[9] The questions concerned the satisfaction level of the subject from the fit and esthetics of the orthosis (as in QUEST 2.0). In addition, the subjects used the QUEST 2.0 scale to rate the difficulty in preparing the orthosis, satisfaction from the overall preparation process, and general satisfaction with the final product. This questionnaire was filled out twice, once after preparing the manual orthosis and once after preparing the 3D-printed orthosis. The subjects were also asked which of the two methods they would have preferred to use in the clinic for the preparation of the swan-neck orthosis and for the preparation of a more complex orthosis. Although our software is currently unable to fit complex orthoses to the anatomy of the patient, the preference of novice OT students of possibly using 3D printing for preparation of complex orthoses might help define future clinical needs and implications of a more advanced software.

Additional tools

We also used a small-scale weighing device (AUY, resolution of 0.1 g), a timer, and a rubber hand lifelike mannequin (Fig. 2), with a wooden stick inserted to the second finger, mimicking the bone.

Research protocol

Each subject read and signed an informed consent form before trial. Then, the subject was asked to prepare a swan-neck orthosis for the same finger of the mannequin, once manually and once using the automatic orthosis fitting software. This order of preparation method was performed in a cross-over design, as 18 subjects prepared the orthosis manually and then prepared the 3D-printed orthosis, and the other 18 subjects prepared the orthoses in a reversed order. Before the subjects started with the preparation of the 3D-printed orthosis, they received a 5 min instruction session of using the caliper and software. After the completion of the preparation of each orthosis, the subjects filled out the satisfaction questionnaire. Only the hands-on time it took to prepare each orthosis was measured. The time receiving the instructions from the researcher and training was not measured. Also, the time of waiting for the water bath to reach 70° and the heating process of the thermoplastic material, as well as the time waiting for the printer to print the orthosis were not included because these times depend on the devices used in the clinic and not the user. Overall, the time for preparing the 3D-printed orthosis included the measurement time and typing the measurements into the software, saving the printable file, opening it in the software of the 3D printer, setting the printing preferences, and sending it to the printer. The time for preparing the manual orthosis included the time needed to create the pattern and mold the orthosis. The weight of each orthosis was measured.

Data analysis

Statistical analyses were performed using SPSS version 25. The Mann–Whitney test was used to find differences in the outcome measures (preparation time, splint weight, and each satisfaction question) between the group who prepared the manual orthosis first and the group who prepared the 3D-printed orthosis first. Normal distribution of the measured parameters was tested using the Shapiro–Wilk test. Because most of the variables were not normally distributed, we conducted nonparametric statistical analyses. The Wilcoxon test was used to compare the outcome measures between the two orthosis preparation methods. For all of the statistical analyses, significance level was set to $P < .05$.

Results

There were no statistically significant differences in all outcome measures between the group who prepared the manual orthosis first ($n = 18$) and the group who prepared the 3D-printed orthosis first ($n = 18$) so that no leaning effect or fatigue were detected. The subjective satisfaction levels of the subjects are presented in Table 1. There were no statistically significant differences in the level of satisfaction concerning the level of difficulty in the preparation method. The subjects reported higher satisfaction from the fit and esthetics of the 3D-printed orthosis compared with the manual preparation method. They were also more satisfied with the overall preparation process and the final product of the 3D printer compared with the manual preparation method.

Table 1
The scores provided by the subjects ($N = 36$) regarding their satisfaction for the fit, esthetics of the orthosis, the difficulty in preparing the orthosis, satisfaction from the overall preparation process, and general satisfaction with the final product

Parameter	Score	1	2	3	4	5	Mean	*P*	Z
Fit	3D-printed	1	0	3	21	11	4.1	**.022**	**−2.299**
	Manual	0	3	10	18	5	3.7		
Esthetics	3D-printed	0	0	4	18	14	4.3	**<.001**	**−4.805**
	Manual	1	10	15	10	0	2.9		
Difficulty	3D-printed	7	20	8	1	0	2.1	.569	−0.570
	Manual	9	12	14	1	0	2.2		
Process	3D-printed	0	0	4	22	10	4.2	**.030**	**−2.174**
	Manual	0	2	15	10	9	3.7		
Product	3D-printed	0	1	5	19	11	4.1	**.011**	**−2.536**
	Manual	0	7	14	8	7	3.4		

The rating score ranged from 1 (not satisfied at all) to 5 (very high satisfaction). The table depicts how many subjects have chosen a specific score for each question regarding each manufacturing method and the mean score. The Wilcoxon test was used to compare the satisfaction levels between the two orthosis preparation methods.

When asked which of the two methods they would have preferred to use in the clinic for the preparation of the swan-neck orthosis, 14 subjects (38.9%) would have preferred the manual preparation method, 16 (44.4%) would have preferred the 3D-printing method, and 6 (16.7%) reported no preference. When asked which of the two methods they would have preferred to use in the clinic for the preparation of a more complex orthosis, 9 subjects (25.0%) would have preferred the manual preparation method, 24 (66.7%) would have preferred the 3D-printing method, and 3 (8.3%) reported no preference.

The weight and preparation time of the orthosis in each of the two methods are presented in Figure 3. The weight of the manual orthosis (median of 1.6 g and interquartile range of 1.3-2.0 g) was significantly higher than that of the 3D-printed orthosis (median of 0.9 g and interquartile range of 0.8-1.0 g). However, its preparation time (median of 95.0 s and interquartile range of 76.3-148.8 s) was significantly shorter compared with the 3D-printed orthosis (median of 279.5 s and interquartile range of 224.3-365.3 s).

Discussion

This is the first study to test the usability of an automated user-friendly software that adjusts an orthosis according to the anatomy of the patient for 3D printing. Our main findings showed that OT students, with minimal experience in splinting and no experience in 3D printing, reported higher satisfaction from the fit and esthetics of the 3D-printed orthosis compared with the manually prepared orthosis and were more satisfied with its overall preparation process and final product compared with the manual preparation method. In spite of these findings, only 44.4% of the subjects reported that they would have preferred to use the 3D printing method in the clinic over the manual method, probably because of the longer time it took them to study the software and perform the anatomic measurements using the digital caliper.

Previous attempts aimed at using virtual models to provide patient-specific fit of an orthosis by using preprepared virtual anatomical models, finite element analysis,[10] or even a program with instructions on how to operate and prepare a 3D orthosis for none-experienced users of computer-aided design software. A previous attempt to simplify the virtual adjustment of an orthosis for 3D printing was recently published by Li and Tanaka.[7,11] The software allowed to adjust a wrist orthosis that had higher complexity of its geometry compared with our chosen swan-neck orthosis. However, their software, tested by 5 participants from a nursing school, required 15 min training, involved manual intervention in the design process, and therefore produced occasional design errors and sometimes crashed because of erroneous generation of the model. We therefore believe that the integration of orthosis adjustment software in clinical use will be faster and easier once the involvement of the clinician is minimized to clinical decisions (eg, which orthosis is needed or how much hyperextension should be applied using a mallet orthosis). For this purpose, the anatomical adjustment of the orthosis should be semiautomatic, by performing some measurements, as herein, or fully automatic, using a 3D scanner.

Interestingly, our results showed that although 38.9% of the subjects would have preferred the manual swan-neck orthosis preparation method, 44.4% would have preferred the 3D-printing method (16% reported no preference). The favorable preference toward 3D printing increased for a more complex orthosis (25.0% would prefer the manual, whereas 66.7% would prefer the 3D printer). We believe that the preference for either methods has several considerations. Specifically, there are two aspects when considering the advantages of 3D printing for orthosis production: the point of view of the therapist and that of the patient. From the point of view of the therapist, using 3D printing for orthosis production might prove more accurate, cheap, and esthetic, but currently involves technology that is not practiced by students, and might therefore be intimidating and inaccessible to them.[12] Once using our simple software, most of the participants felt that they would rather use a software that required simple measurements with a caliper to manual preparation of a complex orthosis. This is an encouraging finding for the future development of 3D printing in orthosis production. Ultimately, clinicians will become familiar and comfortable with using the automated software and it would be a common tool in the clinics. Then, hand therapy experts could envision and create new complex orthosis designs, which would then be easily produced by all clinicians worldwide, without the need for scheduling dedicated workshops or singular expertise.

The present study did not focus on the point of view of the patient regarding the usage of 3D printing of the orthoses.

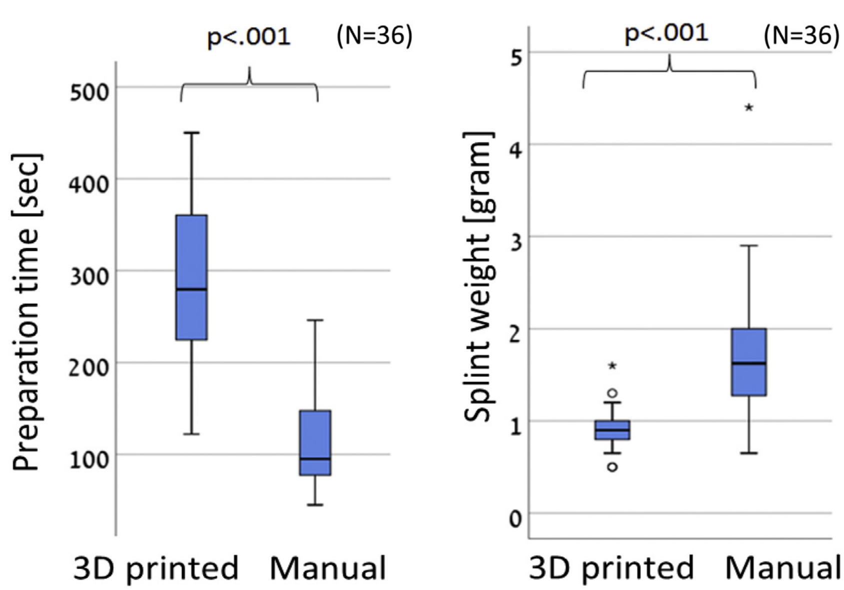

Fig. 3. The preparation time and orthosis weight of the 3D printed and manually prepared orthoses. Outliers are noted by *.

However, several advantageous aspects are noted. First, although the orthosis is being produced by the printer, the therapy session can continue (with exercises, guidance, pain reduction, etc.). Second, assuming that each future household will be equipped with a 3D printer, the adjusted orthosis model can be reprinted by the patient in case the orthosis is lost, damaged, or not supplied in the color preferred by the patient. Third, the esthetics and weight of the orthosis is of great importance.[13] The swan-neck orthosis, for example, is usually prepared for patients with rheumatoid arthritis. They are required to wear the orthosis all day, at work and at home, to prevent the increase of hand stiffness and improve functionality. Consequently, the weight and esthetics of the orthosis are crucial for motivating the patient to use the orthosis throughout the day.[13] The 3D-printed orthosis in our study was indeed significantly lighter and was reported to be more esthetic by the participants, compared with the manually produced orthosis.

Surprisingly, in our study, the preparation time of the manual orthosis was shorter than that of the 3D-printed orthosis. Overall, the difference in the median duration for preparing the manual orthosis and the 3D-printed orthosis was 3 min (Fig. 3). We believe that although the participants were familiar with all of the materials used in the preparation process of the manual orthoses (as they received 10 h of training), they were introduced for the first time not only with the new software but also with the digital caliper and 3D printer, which might have induced some anxiety. In the future, usage of 3D printing may be taught as part of the curriculum so that using a 3D scanner or caliper might not be intimidating to OT students. The integration of knowledge regarding this new technology into health care schools has already been launch successfully, as recently reported by Wagner et al.[14]

The main limitation of this study is that the orthosis was prepared for a finger of a rubber mannequin and not a human finger. This resulted in our inability to question the patient regarding the comfort, fit, and mechanical efficacy of the produced orthosis. However, we chose to use the mannequin so that all of the participants would have identical conditions of the size of the finger and the joint angles of the finger during the fitting of the orthosis and not be distracted by comments or body language from the person being fitted with the orthosis. Also, the study population consisted of OT students, so that the results cannot be generalized to qualified OTs, experienced with splinting techniques. Even among OT students, there is a high variability in orthotic design and fabrication course structure and content in current OT programs,[15] so that our conclusions might not apply to more or less experienced OT students.

In summary, nonexperienced OT students were significantly more satisfied with various aspects of preparing a simple swan-neck orthosis using the automated 3D-printing software provided herein, compared with the manual orthosis preparation process. In the future, health professionals and patients will be exposed to various technologies during their work and daily life, so that simple, automotive, and user-friendly aids might be warranted to ease the transition to futuristic advancements.[16] This might be achieved by future developments of automatic anatomic measurements performed using 3D scanners that would further simplify the fitting process.

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1. The device
  a. facilitates full PIP extension
  b. blocks full PIP extension
  c. maintains the PIP in neutral
  d. has no effect on PIP motion

2. A caliper is used to measure the
  a. thickness of the device
  b. MP to DIP digital length
  c. PIP circumference
  d. finger width

3. The software comprises _____ screens
  a. 4
  b. 5
  c. 6
  d. 7

4. The lowest scores were found to be in
  a. fit
  b. difficulty
  c. esthetics
  d. product

5. There was no significant difference in outcomes comparing the 3D group and the manual group
  a. true
  b. false

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