

RESEARCH ARTICLE

Satisfaction Survey - Sexual Satisfaction After Novel Wearable Device Use for Erectile Dysfunction

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Abstract

Background: Erectile dysfunction is the inability to achieve and maintain an erection firm enough for sexual performance. Erectile dysfunction devices such as pumps, constriction devices, and prescription oral phosphodiesterase inhibitors are commonly known treatments for erectile dysfunction.

Aim: Our aim was to evaluate an alternative therapy for erectile dysfunction for the men who currently do not use any form of the aforementioned erectile dysfunction treatment options. This paper discusses a device that allows patients to use a novel wearable device to enhance the normal physiology of an erection to treat erectile dysfunction. Medical comorbidities such as anxiety, attention-deficit/hyperactivity disorder, obesity, hypertension, diabetes & depression, as well as medications such as antidepressants, anti-anxiety medications, opioids and cardiac medications can impact erectile function.

Methods: Our research team surveyed 60 male participants (59 completed the study), 26-81 years of age, about their erectile performance over 12 weeks, during which participants utilized the novel wearable device. Participants completed an intake assessment, submitted them medical history, and reported on their sexual behavior and erectile performance as they used the device over the 12 weeks, during which patients rated their experience with the device, self-esteem, quality of life changes, the impact on their relationships, frequency of erections,

Outcomes: Participants showed improvement in all but one question in the survey over the 12 weeks period, with a particularly higher improvement between weeks 4 and 8, and sustained that improved sexual function and erection quantity and quality through week 12.

Results: Of the participants who concluded the study, 95% reported having overall positive results from using the novel wearable device. With respect to the survey questions, participants showed an average improvement in 96% of all survey questions across the study. Segmenting participants revealed significant improvement among participants within varying

categories.

Clinical Translation: Survey results of patients after use of a wearable device for erectile dysfunction.

Strengths and Limitations: The study is a prospective survey of patients who used the device and helps us better understand patient feedback from this novel treatment plan and in the future a control group who didn't wear the device could be helpful for comparison as well as specific usage parameters.

Conclusions: Attitudes of participants with erectile dysfunction using the device showed significant

improvement in erectile function, quality of life, hopefulness for future sex life and overall self-esteem. Device use over 12 weeks was shown to improve satisfaction among male participants of sexual health and mental health.

Keywords: Erectile Dysfunction; Sexual Health; Male Coaching; Depression.

Introduction

Erectile dysfunction (ED) is defined by the inability to achieve or maintain an erection for sufficient sexual performance.1 There is variation in prevalence by country and by associated comorbidity. Historically, ED is associated with advanced age, heart disease, diabetes, obesity, prescription medication use, alcohol use, and depression [2-7].

The introduction and widespread marketing of oral phosphodiesterase inhibitors (including sildenafil and tadalafil) has increased public awareness of ED and increased treatment for the condition [8]. Unfortunately, fewer than one in three men seek help or treatment for the condition. Oral therapy requires a medical evaluation for a prescription and can be associated with severe side effects, both of which may be barriers to use. Additionally, a significant population of men with ED symptoms do not acknowledge their diagnoses of ED and therefore can be reluctant to take ED medication. There is a role for a non-pharmacologic, non-prescription alternative to help these patients treat their ED.

Alternatives to oral therapies include constriction devices (with or without vacuum pumps), intracavernosal injections, intraurethral suppositories, and surgical implantation of a prosthesis [9-11]. The Eddie (Figure 1) is an FDA-registered Class II medical device that is available without medical evaluation or prescription. It is a wearable device with a unique shape and function that differentiates it from other wearable devices. The horseshoe-shaped device is placed around the base of the penis with the opening inferior. A tension band is applied around the opening to provide compression to the corpora cavernosa. Due to its unique shape, there is minimal pressure to the corpus spongiosum; hence, reduced risk of discomfort with ejaculation or decreased blood flow to the glans penis. There are four sizes, based on penile girth, and two types of constriction bands, so the proper fit and desired amount of constriction can be adjusted. This device can be used as first-line or second-line therapy and can be used in conjunction with oral therapy. There have been no prior published studies on the use of this novel wearable device.

We prospectively studied new users of the device to ascertain the efficacy and satisfaction of this treatment. To avoid any novelty effect of a new device, we followed users longitudinally for 12 weeks. Many medical comorbidities impact erectile function such as diabetes, hypertension, depression, and anxiety. Many of our participants had medical comorbidities (including mental health issues) and took various medications to treat their respective co-morbidities. Our aim was not only to evaluate the results of the group as a whole but also to examine subcategories to determine if there were any identifiable groups for which the device was more or less effective.



Figure 1: Diagram of the Eddie by Giddy Device

Methods

Study Methodology and Demographics

Our study population consisted of 60 men (59 of which completed the study) aged 26-81 (Mean age of 33) in the Austin, TX area who responded to media ads in the local paper and/or on social media. The ad sought qualified candidates to use the wearable ED device at home and visit the study site to provide feedback about their experience. Exclusion criteria included patients with a mental or physical condition that makes erection achievement impossible, participants under age 18, and patients with limited manual dexterity (such as arthritis). Sixty patients were enrolled and 59 completed the study. (The one participant who dropped out reported that he was satisfied with the device but was unable/unwilling to complete the additional surveys). Demographic data is summarized in (Figure 2).

Participants

Average Age: 33

Age Range: 26-81

Demographics

White/Caucasian: 61% Black/African American: 10% Latino/Hispanic: 19% Asian: 5% Pacific Islander: 3.5% Other: 1.5%

Sexual Health Conditions

ED: 68%

Medications

Anti-Depression Medication: 12% Hypertension Medication: 12%

Previous ED Treatments

Prescription: 42% Constriction Device: 41% Supplements: 25.5% Over-the-Counter: 20%

Medical Conditions

Hypertension: 15% Obesity: 8.5%

Mental Health Conditions

Depression: 22% Anxiety: 20% ADD/ADHD: 15%

Figure 2: Participant Overview

The first visit was conducted in person by the research team. Each participant filled out a 65-question survey during each visit on an electronic tablet reviewing their sexual history over the last 3 months, as well as a background section that inquired about other medical conditions, treatments used beforehand, and medication use (Table 1).

The study instrument was developed by the authors to more comprehensively evaluate sexual performance and satisfaction. Participants were given an appropriately sized device and shown the educational video on how to properly use the device. The clinical team was available for clarification and to answer questions about proper usage. Visit 2 was performed 4 weeks after visit 1. Patients were given a series of questions reviewing their experiences with the device over the prior 4 weeks. Visit 3 was conducted 4 weeks later with similar questions. Visit 4, the final encounter, was performed in person 4 weeks later, 12 weeks after the initiation of the study.

The questions from visits 2, 3, and 4 were identical. For each question and participant, we calculated the overall percent improvement-from visit one to visit 4. Further analysis was done by segmenting users into subgroups related to medical conditions, medications, and historical erectile dysfunction treatment(s). For each question, we calculated the overall percent improvement-from visit one to visit 4 (Formula 1)-along with the weighted incremental improvement, which was obtained by multiplying the sum of the incremental improvements by the product of their respective percent change (Formula 2). Both are displayed in (Table 2)

Table 1: Intake Questions

1. First Name:	
2. Last Name:	
3. Please enter your email address:	
4. Please enter your phone number:	
5. What is your age?	
6. Age	
7. What is your height?	
3. What is your weight?	
9. Please select your ethnicity:	
10. Are you a military veteran or active military?	
11. What's your current employment status?	
12. What is your yearly household income?	
13. Medical Conditions	
14. Do you have an active checking account? (For compensation purposes)	
15. Are you experiencing any of the following mental health conditions? Please select all that apply.	
16. Please describe your mental health issues:	
17. Are you experiencing any of the following STIs/STDs? Please select all that apply.	
18. Please describe your other STDs/STIs:	
19. Are you living with any of the following types of cancer? Please select any that apply.	
20. Please describe the type of cancer you're living with:	
21. Do you have any of the following heart health conditions? Please select all that apply.	
22. Please describe the Heart Health issues you're living with:	
23. Do you have any of the following sexual health conditions? Please select all that apply.	
24. Please describe the sexual health condition you're living with:	
25. Do you have any of the following general health conditions? Please select all that apply.	
26. Please describe your General Health issue:	
27. Do you have a penis?	
28. Have you been diagnosed with any mental or physical conditions that make achieving or maintaining an erection difficult or imposs	ible?
29. Please describe:	
30. Have you been diagnosed with arthritis in your hands, or any disabilities or impairments that limit full use of your hands?	
31. Please describe:	
32. What prescription medications are you currently taking? (Select all that apply. Items in parenthesis are only examples, not a comple	te list.)
33. Please describe the prescription medications you're taking:	

34. Are you experiencing any side effects from these medications that contribute to your ED?

35. Please select any recreational drugs you're currently taking. (Select all that apply. Items in parenthesis are examples only, not a complete list.)

36. How many alcoholic beverages do you consume per week?

37. How many cigarettes do you smoke per day?

38. What is your relationship status?

39. How many sexual partners do you currently have?

40. What is your sexual preference?

41. Please select any form of STI/STD protection/contraception you're currently using. (Select all that apply.)

42. Please describe the STI/STD protection/contraception you're using:

43. What ED treatments or ED products have you tried? (Select all that apply. Items in parenthesis are only examples, not a complete list.)

44. Please describe the other types of ED products you have tried:

45. How satisfied are you with the ED treatments or products you have tried?

46. Are you able to achieve an erection?

47. How long do your erections currently last?

48. How long would you like your erections to last?

49. How would you describe your level of interest in sexual activity?

50. In the last 3 months, how often have you felt like you were capable of engaging in sexual activity?

51. In the last 3 months, how often have you experienced difficulty achieving an erection during sexual contact?

52. In the last 3 months, how often have you experienced difficulty maintaining an erection during sexual contact?

53. How long have you had difficulty getting or maintaining an erection?

54. In the last 3 months, how would you describe the frequency of your erections when trying to engage in sexual activity?

55. In the last four weeks, how often did you attempt to masturbate?

56. In the last four weeks, how often were you able to masturbate to the point of orgasm/climax?

57. In the last four weeks, how often did you watch pornography?

58. In the last four weeks, how often did you attempt to engage in (receive) oral sex?

59. When you attempted to receive oral sex, how often were you able to maintain an erection to the point of orgasm/climax?

60. In the last four weeks, how often did you attempt to have sexual intercourse?

61. In the last four weeks, when you attempted sexual intercourse, how often were you able to maintain an erection to the point of orgasm/climax?

62. In the last four weeks, how often have you woken up with an erection?

63. In the last four weeks, how satisfied are you with the quality of your erections?

64. What are your expectations for this study?

65. Will you be able to attend all three in-person visits at the study site in Austin, Texas that will be scheduled between 5/3/21 and 7/30/21?

Table 2: Visit Statistics

	Visit 1 (Average)	Visit 2 (Average)	Visit 3 (Average)	Visit 4 (Average)	Percent Change (V1 to V4)	Total Percent Change
1. How often have you felt sexual desire?	3.80	3.80	3.55	4.07	6%	8%
2. How would you rate your level of sexual desire?	2.27	3.33	3.52	3.86	70%	63%
 How satisfied have you been with your overall sex life? 	1.52	3.20	3.33	3.59	137%	123%
4. How would you rate your confidence that you could achieve an erection?	1.93	3.52	3.61	4.07	110%	98%
5. How would you rate your confidence that you could keep an erection long enough to climax/orgasm?	1.70	3.42	3.68	4.03	137%	119%
6. How would you rate your overall satisfaction level with your erections?	1.70	3.23	3.59	3.97	133%	113%
7. How would you rate the quality of your erections?	1.77	3.32	3.61	3.88	120%	105%
8. How often have you felt the desire to masturbate?	4.00	4.08	4.32	4.42	11%	10%
9. How often have you felt like you were capable of masturbating?	4.22	4.90	5.07	5.17	23%	22%
10. How often did you attempt masturbation?	2.68	3.07	3.31	3.31	23%	22%
11. When you attempted masturbation, how often were you satisfied with your erection?	3.70	4.86	4.95	5.34	44%	41%
12. How much have you enjoyed masturbation?	3.83	4.68	4.82	5.11	33%	31%
13. When you attempted masturbation, how often were you able to achieve an erection?	4.08	5.28	5.30	5.50	35%	33%
14. When you were able to achieve an erection for masturbation, how long were you able to maintain your erection?	2.77	4.16	4.29	3.39	51%	53%
15. When you were able to achieve an erection for masturbation, how often were you able to maintain your erection to completion, i.E. To the point of ejaculation/climax/orgasm?	4.15	5.21	5.20	5.52	33%	31%
16. How often have you felt the desire to receive oral sex?	4.10	4.17	4.29	4.56	11%	11%
17. How often have you felt like you were capable of receiving oral sex?	3.87	4.83	5.02	4.98	29%	28%
18. How often did you attempt to receive oral sex?	1.97	2.27	2.64	2.63	34%	33%
19. When you attempted to receive oral sex, how often were you satisfied with your erection?	3.17	5.12	4.91	5.23	65%	64%
20. How much have you enjoyed receiving oral sex?	3.52	4.86	4.91	5.11	45%	43%
21. When you attempted to receive oral sex, how often were you able to achieve an erection?	3.62	5.21	5.18	5.48	51%	49%

	Visit 1 (Average)	Visit 2 (Average)	Visit 3 (Average)	Visit 4 (Average)	Percent Change (V4 from V1)	Total Percent Change
22. When you were able to achieve an erection to receive oral sex, how long were you able to maintain your erection?	2.45	4.21	4.52	4.10	68%	70%
23. When you were able to achieve an erection to receive oral sex, how often were you able to maintain your erection to completion, i.e. to the point of ejaculation/climax/orgasm?	3.12	4.80	5.09	5.21	67%	62%
24. How much have you felt the desire to have sexual intercourse?	4.35	4.80	4.90	5.15	18%	18%
25. How often have you felt capable of having sexual intercourse?	3.75	4.90	5.00	5.28	41%	38%
26. How often did you attempt sexual intercourse?	2.23	2.73	3.04	2.91	30%	29%
27. When you attempted sexual intercourse, how often were you satisfied with your erection?	3.28	5.02	5.08	5.26	60%	58%
28. How would you rate your enjoyment during sexual intercourse?	3.78	4.94	5.09	5.28	40%	37%
29. When you attempted sexual intercourse, how often were you able to achieve an erection?	3.97	5.15	5.26	5.43	37%	35%
30. When you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?	3.88	5.30	5.43	5.69	47%	44%
 During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner 	3.68	5.19	5.25	5.52	50%	47%
32. When you were able to achieve an erection for sexual intercourse, how long were you able to maintain your erection?	3.00	4.24	4.55	4.15	38%	40%
33. When you were able to achieve an erection for sexual intercourse, how often were you able to maintain your erection to completion, i.e. to the point of ejaculation/climax/orgasm?	3.62	5.13	5.06	5.45	51%	48%
34. How would you rate your confidence in your ability to perform sexually?	1.58	3.50	3.63	3.98	148%	133%
35. How would you rate your confidence that you have pleased your partner sexually?	1.82	3.45	3.69	3.94	117%	104%
36. How would you rate your intimacy levels?	1.68	3.18	3.49	3.59	113%	102%
37. How would you rate the overall quality of your relationship?	2.52	3.71	3.91	3.89	55%	52%
38. How would you rate the communication between you and your partner?	2.55	3.57	3.76	3.81	50%	47%
39. How would you rate your level of output for household chores and/or errands?	2.62	3.40	3.44	3.54	35%	34%

	Visit 1 (Average)	Visit 2 (Average)	Visit 3 (Average)	Visit 4 (Average)	Percent Change (V4 from V1)	Total Percent Change
40. How would you rate the level of closeness of your relationship?	2.35	3.36	3.65	3.65	55%	55%
41. How would you rate your level of self esteem?	2.10	3.37	3.54	3.80	81%	73%
42. How would you rate your overall confidence?	2.17	3.33	3.53	3.78	74%	64%
43. How would you describe your overall mood?	2.43	3.32	3.61	3.76	55%	50%
44. How would you describe your overall quality of life?	2.72	3.53	3.76	3.90	43%	40%
45. How would you describe your level of physical activity?	2.10	3.00	3.20	3.36	60%	55%
46. How would you describe your level of hopefulness for your future sex life?	2.52	3.78	3.81	4.00	59%	56%
47. How would you rate your partners's sexual interest in you?	2.12	3.29	3.43	3.56	68%	63%

 $Overall \, {
m Improvement} = I_{v1
ightarrow v4} = rac{Visit \, 4 \, Score - Visit \, 1 \, Score}{Visit \, 1 \, Score}$

 $Incremental \text{ Improvement} = (I_{v1 \rightarrow v2} + I_{v2 \rightarrow v3} + I_{v3 \rightarrow v4})^* (I_{v1 \rightarrow v2} + I_{v2 \rightarrow v3} + I_{v3 \rightarrow v4})$

Results

During the intake visit, the average length of time of participants noted that they struggled with erections for masturbation was 1-2 years and 40% of participants (24/60) struggled with erections for the purpose of masturbation for over 2 years. These numbers were identical for oral sex. The average length of time they struggled with erections for the purpose of sexual intercourse was 2-3 years and 58% (35/60) struggled with erections for the purpose of sexual intercourse for over 2 years. Patients did report the sizing of their penis with variable sized devices by Giddy (A through D), with A showing smallest girth (5/60), B (14/60), C (20/60) and D the largest girth (19/60).

Overall Attitudes and Behaviors

A summary of the participants' responses in regards to altered status of their ED from using the device is presented in Table 2 along with (Figures 3-5). Responses here were divided into overall improvement during the course of the 12-week monitoring and survey period. The results were shown by averaging the responses on a scale in each category.

CATEGORY (COUNT)	PERCENT
Overall Improvement (59)	95%
ADHD (8)	87%
Antidepressants (7)	100%
Antihypertensives (7)	100%
Anxiety (12)	91%
Depression (13)	84%
High blood pressure (9)	88%
Obesity (5)	100%
Over-the-counter ED Medication (12)	100%
Prescription ED Medication (25)	95%

Percent of individuals who reported an overall improvement for each category

Figure 3: Ongoing improvement in oral sex for users with overall positive results

Participants who noted that they had ED (40/60) showed an improvement in satisfaction with the use of the device, along with those who did not note that they had ED. Many times, ED is only classified by the patient if medically diagnosed by a physician. The sexual dissatisfaction may be contributed to non-ED reasons, and use of the device in non-ED-identifying patients showed improvement as well, reinforcing the underdiagnosis of ED. Participants that had tried other ED solutions trended towards improved satisfaction after just 4 weeks of use.

Participants with prior use of prescription ED medications and prior use of OTC medications showed improvement in satisfaction (Table 3). This is encouraging for those patients who continue to remain unsatisfied with treatments that have been in use prior to using the device. Depression, anxiety, and ADD/ADHD were the mental health categories studied with participants. A large portion of participants in all of these categories showed improved satisfaction over 12 weeks of use (Table 3).

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Ongoing Improvement Oral Sex for Users with Overall Positive Results

- When you were able to achieve an erection to recieve oral sex, how long were you able to maintain your erection?
- When you were able to achieve an erection to recieve oral sex, how often were you able to maintain your erection to completion, i.e. to the point of ejaculation/climax/orgasm?
- When you attempted to recieve oral sex, how often were you able to achieve an erection?
- When you attempted to recieve oral sex, how often were you satisfied with your erection?
- How much have you enjoyed recieving oral sex?

Figure 4: Ongoing improvement in intercourse for users with overall positive results



Ongoing Improvement in Intercourse for Users

 When you were able to achieve an erection for sexual intercourse, how long were you able to maintain your erection?

• When you were able to achieve an erection for sexual intercourse, how often were you able to maintain your erection to completion, i.e. to the point of ejaculation/climax/orgasm?

• During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

When you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?

How would you rate your enjoyment during sexual intercourse?

• When you attempted sexual intercourse, how often were you able to achieve an erection?

How often have you felt capable of having sexual intercourse?

Figure 5: Ongoing improvement in performance and erection quality for users with overall positive results

Participants with prior use of prescription ED medications and prior use of OTC medications showed improvement in satisfaction (Table 3). This is encouraging for those patients who continue to remain unsatisfied with treatments that have been in use prior to using the device. Depression, anxiety, and ADD/ADHD were the mental health categories studied with participants. A large portion of participants in all of these categories showed improved satisfaction over 12 weeks of use (Table 3).

Participants with hypertension and obesity both noted improvement in satisfaction (Table 4). These medical conditions associated with ED are contributing factors to ED from a vasculogenic and endocrine standpoint. A trend was noted after just 4 weeks of use and continued to trend upwards for both categories. Participants using hypertension medications and antidepressants showed a notable increase in satisfaction, particularly with the patients taking antihypertensives studied (Table 3).



Ongoing Improvement in Performance and Erection Quality for Users with Overall Positive Results

How would you rate your confidence that you could keep an erection long enough to climax/orgasm?

How would you rate the quality of your erections?

• How would you rate your overall satisfaction level with your erections?

• How would you rate your confidence that you could achieve an erection?

Table 3: Overall Improvement

Discussion

ED is a common problem for men and there are multiple treatment options. Constriction devices are a commonly used intervention but there is very little published data on them efficacy or user satisfaction. The device is a novel type of wearable device and this is the first study evaluating satisfaction of its users. Participants were followed longitudinally for 12 weeks with serial extensive surveys. There are medical comorbidities (including mental health issues) as well as medication use that can impact ED. Our aim was to evaluate the group as a whole but also to evaluate these subcategories to determine if there were any groups for which the device was more or less effective. Moreover, our goal was to evaluate efficacy of the device in multiple dimensions of sexual health and sexual activity, including overall performance, quality of life, impact on relationships, sex drive, masturbation, oral sex, and penetrative intercourse. When the participants were evaluated as a group, there was overall improvement in sexual activity after commencement of use of the device. Subgroup analysis of participants with (self-identified) diagnoses of ADD/ADHD, anxiety, and depression also showed improvement.

This was true for participants with and without a prior diagnosis of ED. Participants with a history of hypertension and obesity also showed improvement. In terms of medication usage, participants who reported taking antidepressants and antihyperten-

sives reported improvement. Finally, participants who had previously used other modalities of ED treatment including prescription medications, supplements, wearable devices, and over the counter medications all reported improvements.

Multiple dimensions of sexual health and sexual activity were also evaluated. Participants reported improvement in multiple domains of sexual activity including masturbation, oral sex, intercourse, and overall sexual performance. Participants also reported increased sex drive and desire, improved erections, and overall improvement in quality of life. In terms of relationships, participants reported improvement. The 15-question international index of erectile function (IIEF) or the 5-question sexual health inventory for men (SHIM) questionnaires were considered. Both are validated research instruments. A longer survey was chosen to get a more comprehensive evaluation of the participants' function and experience. Limitations of this study include its small size and use of a non-validated questionnaire. Medical conditions and medication use were self-identified.

Conclusions

This is the first published data evaluating the efficacy of a novel wearable device for the treatment of erectile dysfunction (ED). We found that participants had improvement in multiple aspects of sexual performance. This improvement was true across multiple broad categories including medical comorbidities, medication use, and prior treatment. While the mainstay of ED medications remains oral prescription phosphodiesterase inhibitors, there remains a stigma with initial diagnosis of ED by a medical provider, and thus many patients seek out treatment for improvement in sexual experience without medical evaluation. The direct improvement in satisfaction in all categories we found provides evidence that the novel wearable device, can aid in improving sexual performance. The added benefit as a treatment option for patients with comorbidities and other medical conditions, provides non-medicated option that showed improved satisfaction in patients with both psychiatric and vasculo-pathic illness. The treatment algorithm for ED must include these patients that are underdiagnosed, that the novel wearble device is a safer alternative to prescription. ED medication, and the patients surveyed showed there is device that can assist them to improve both sexual health practices and overcoming the stigma of a prescription oral pill being needed to enjoy a more satisfying sexual life.

Author Contributions

Conceptualization, S.P. and C.K.; Data Curation, S.P. and C.K.; Formal Analysis, S.P. and C.K.; Methodology, S.P.; Project administration, S.P.; Resources,12 S.P.; Software, S.P.; Supervision, S.P.; Validation, S.P.; Visualization, S.P. and C.K.; Writing – original draft, S.P. and C.K.; Writing – review and editing, S.P. and C.K.

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