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Development of a new Peyronie's disease self-assessment screening app

Gregory A. Broderick¹, Jesse N. Mills², Lisa Bathish³, Christopher Davis³, Mohit Khera⁴

¹Department of Urology, Mayo Clinic, Jacksonville, FL, USA; ²David Geffen School of Medicine, University of California, Los Angeles, CA, USA; ³Research and Development, Endo USA, Inc., Malvern, PA, USA; ⁴Scott Department of Urology, Baylor College of Medicine Medical Center, Houston, TX, USA

Contributions: (I) Conception and design: L Bathish, C Davis; (II) Administrative support: L Bathish, C Davis; (III) Provision of study materials or patients: L Bathish, C Davis; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Gregory A. Broderick, MD. Department of Urology, Mayo Clinic, Davis Building, 4500 San Pablo Rd S, Jacksonville, FL 32224, USA. Email: Broderick.Gregory@mayo.edu.

Abstract: Peyronie's disease (PD) is an underdiagnosed and undertreated fibroproliferative disorder associated with the formation of plaques that results in penile curvature and discourages some men from seeking medical consultation. The PD self-assessment app, a digital application (app), was developed to increase PD awareness, provide men with a self-screening and educational tool for PD, and help eliminate barriers to seeking consultation with a physician. Prior to deployment, 4 board-certified urologists provided qualitative reviews on the app's usability and utility as a screening tool. The PD self-assessment app features a questionnaire that addresses penile curvature, challenges with penetration, partner distress, and the impact on sexual experiences. The app uses the phone's camera lens to perform a live scan employing a mathematical algorithm to determine the degree of curvature of an erect penis. Results include a three-dimensional (3D) penile simulation and a two-dimensional (2D) penile outline, allowing the user to mark plaque locations and determine the maximum curvature without requiring personal photographs. The user can choose to email their answers to the questionnaire and the representative penile simulation results to their physician. The app also includes external links directing users to an educational website focused on PD and to help with finding a treating physician. The app was designed with privacy and security features including optional password protection, encryption of sensitive data, in-app storage of all screening results, and the erasing of all data when the app is uninstalled. Patients will be empowered to self-assess their PD and locate a PD-experienced physician privately and securely. The app is not designed for diagnosing, treating, curing, or preventing any medical conditions, or diseases, nor does it substitute for a medical consultation. For security, scanning technology, rather than personal photography, is adjunctive to the diagnosis process. The app is designed to be flexible and expandable for future updates. It aims to assist men and their partners in learning about PD, tracking penile deformity, and enabling communication with a health care provider (HCP).

Keywords: Penile curvature; Peyronie's disease (PD); Peyronie's plaque; mobile applications; self-assessment

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Introduction

Peyronie's disease (PD) is a benign, fibroproliferative disorder characterized by acquired formation of scar tissue, or a plaque, in the tunica albuginea of the penis (1,2). Plaques

most likely form in response to injury or microtrauma causing collagen deposition and abnormal wound healing in men genetically predisposed to impaired wound healing (1,3). Scar tissue deposition may result in penile deformities

such as penile bending, indentations, curvature, tapering, shortening, or an hourglass shape (2,3). Men with PD may also have a mass in the penis (nodule), erection and non-erection pain and discomfort, impaired intercourse functionality, and erectile dysfunction (ED), or other sexual function difficulties (1,3).

In addition to physical impacts, PD often causes profound psychological distress. Men with PD tend to have increased anxiety, lower self-esteem, decreased body image, loss of sexual confidence, depression, and difficulty in relationships compared with those without PD (1,4). They express social isolation, shame, and stigmatization related to PD (4). A large, population-based risk estimate study determined that men with PD have increased risks of substance use disorder, anxiety disorder, and self-injurious behaviors (4). The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies (IMPRESS) I and II trials assessed PD's physical and psychological interrelationship utilizing the Peyronie's Disease Questionnaire as a secondary outcome (5). Among the participants in those trials, 84% and 79% had PD-related moderate or severe distress, respectively (6). In addition, 58% of those with a mild/ moderate penile deformity (≤60°) and 72% with severe penile deformity (>60°) were "very" or "extremely" bothered by their PD (7). A 2023 study by Paulis et al. found significant anxiety in 89.1% of 551 patients, severe anxiety in 39.2%, and significant depression in 57.3% (8). When PD patients also had ED, an alarming 91.4% were considered in a depressive state, with depression prevalence and severity correlating with a higher degree of penile curvature (9).

Contributing to the stigmatization and isolation of those with PD, the condition is significantly underdiagnosed and undertreated. A population-based study in the United States estimated the prevalence of definitive PD to be 0.7% (10). However, including those undiagnosed but who probably have PD, estimates substantially increase from 11.8% to 13.0% (10,11). Men can be reluctant to discuss their condition with a health care provider (HCP) and are being diagnosed incidentally while seeking treatment for unrelated conditions such as prostate cancer screening (1,10). Among patients with PD diagnosis or symptoms, only 8% were diagnosed with PD by the first doctor seen for penile symptoms, and 48% were diagnosed with ED (12). HCPs may not regularly assess patients for potential PD, possibly due to the misconception that it is a rare condition not warranting treatment (13). A missed PD diagnosis may contribute to 74% of patients receiving no initial treatments or 15% receiving ED-related treatment instead (12). The mean age of men reporting symptoms or probable PD diagnosis is 49 years, while the mean age of those with a definitive diagnosis is 59 years, indicating delayed diagnosis may be common (13).

Peer-reviewed publications on PD have a consistent call to action to increase awareness and implement screening strategies to help decrease stigmatization and facilitate patient-physician conversations about the disease. There is a critical need for men who are concerned about a curvature of their penis to learn about PD, assess symptoms in the privacy of their home, and have resources to identify treating physicians in their area. Together with the Sexual Medicine Society of North America, we developed a free digital application (app) to increase PD awareness, provide a secure self-screening tool for men concerned about penile curvature, and improve accessibility to HCPs. Herein, we describe the development and features of the app to aid in referring affected patients for earlier PD diagnosis and treatment to lessen physical and psychological effects of this condition.

PD self-assessment app development

Purpose

An English-language Android- and iOS-compatible digital app was developed by Endo Pharmaceuticals Inc. in collaboration with the Sexual Medicine Society of North America as a self-assessment tool for screening and educational purposes. The app was developed so users can conduct a private PD self-assessment to increase their awareness and help alleviate barriers men may have in discussing PD with an HCP. This app may help eliminate delays in seeking a PD diagnosis and treatment, thereby decreasing the psychological distress associated with PD.

The app provides a self-assessment questionnaire, an inapp penile scanning feature, and links to a PD education website and HCP locator. *Figure 1* demonstrates the app user interface and workflow. The app is not intended to diagnose, treat, cure, or prevent any medical condition, disease, or health problem and should not be considered a replacement for consultation with a physician. The app was developed to serve as a conduit to conversations and diagnosis by an HCP. It is available for free on the Apple Store and Google Play under the name "Peyronie's Self-Assessment" or may be scanned from a QR code (*Figure 2*). The app is intended for men 18 years of age and older who may be concerned about a curve in their penis.

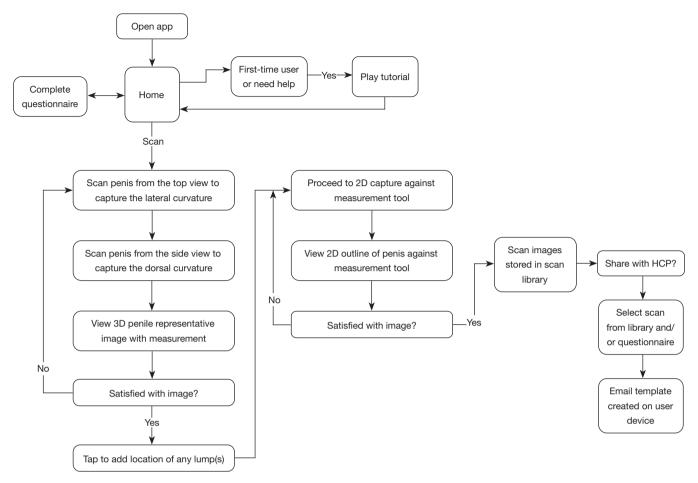


Figure 1 App usage interface and workflow. App, application; 2D, two-dimensional; 3D, three-dimensional; HCP, health care provider.



Figure 2 QR code for downloading the Peyronie's disease self-assessment app.

Privacy

Several features allow users to comfortably explore information and conduct a self-assessment, including a penile scan, in the privacy of their own home. Penile scans are representative images only. No photographs or direct images are created or stored in the app or in the phone's photograph gallery. The user has control over the appgenerated three-dimensional (3D) penile simulations and two-dimensional (2D) line drawings stored within the app. No user account is required, and the app can be locked with a local alphanumeric password or biometric ID using the fingerprint or face unlock features from the user's phone settings. Passwords cannot be reset because no accounts are created. The app uses the local storage space and memory

of the phone, eliminating any third-party, cloud-based security concerns. Images and questionnaire data can only be accessed by the user and are not transferred to any server or database or accessed by the app developers or technical team. No data are shared outside the app unless explicitly initiated by the user from within the app through the email function. All data are erased when uninstalling the app.

HCP and patient qualitative assessments

Before launching the app for public use, 4 board-certified urologists qualitatively assessed the app's utility, features of interest, areas of improvement, and overall impressions. These urologists conveyed enthusiasm for the tool and that users will be empowered by the self-assessment, education, and referral tools. Some urologists noted they may ask new patients to use the app as an initial assessment before their first appointment. All urologists were reassured by the app's security measures but mentioned the challenge of making men aware of the app. A summary of the urologists' qualitative assessment is shown in Figure S1.

The app was also anonymously beta tested by men who responded to an ad on the Sexual Medicine Society of North America for Patients website (2). The men downloaded the app and followed a testing protocol that included taking a scan of their penis. The men noted they were able to successfully capture a scan. One respondent commented, "Seeing the scan of my penis was very cool. I was able to immediately see how this would help the conversation between doctor and patient", and another respondent remarked, "The app is easy to use and impressive technology. It worked better than I expected."

PD self-assessment app features

Scanning procedure and result

Users can document their penile curve by scanning their erect penis with the app, which utilizes the phone's camera with color-based detection or depth sensing capability. Scan results are not direct photographs or images, but rather the scan is converted to 3D and 2D representations (Figure 3A). The app uses a mathematical algorithm to assess the degree of curvature on the 3D image. The app also allows users to mark locations of any lumps or plaques on the 3D image. The 2D image is an outline of the penis captured against a measurement background grid that further aids in documenting curvature. The 3D image,

including curvature degree, and the 2D outline image are stored in a scan library within the app (*Figure 3B*). Users can scan at different time intervals and view them in the app's scan library to estimate any curvature progression or reduction over time. Users have the option to email their 3D and/or 2D penile representations directly from the app to a treating physician via their phone email.

Educational tools

The app provides an instructional tutorial video on how to perform a penile scanning procedure (*Figure 3C*). To get the best scan results, patients are recommended: to complete the 3D scan procedure in a well-lit, clutter-free area with a white or lighter shade background for the image; to hold the phone from the top with no more than a 5-degree tilt and from the side with at least a 70-degree tilt; a mirror or partner may be helpful in lining up the scan, if needed. To complete the 2D outline capture, the user holds the phone at the angle that shows the greatest curvature (i.e., side for dorsal curve, top for lateral curve), placing the greatest curvature in the cross section of the guidelines.

Patients can learn about PD through a link to the Sexual Medicine Society of North America PD educational website (2), https://www.smsna.org/patients/peyronie-s-disease (*Figure 3D*), which provides information on PD, including symptoms, causes, diagnosis, treatments, and related conditions.

Locating HCPs and sending results

Men can use the Sexual Medicine Society of North America online locator to find a provider by name, institution, or geographic area (*Figure 3E*). Listed providers are members of the Sexual Medicine Society of North America who have activated their online profile. If an HCP does not accept patient emails, patients may alternatively bring the app to consultations or email the results to themselves and print or save the images outside of the app.

Self-assessment questionnaire

The questionnaire includes questions on PD signs and symptoms, providing an opportunity for men to contemplate their condition and document information before seeking care. Users may choose to share their questionnaire responses to an HCP through the app. This questionnaire may aid an HCP during an initial



Figure 3 Peyronie's disease self-assessment app features. App features include: (A) penile scanning capability to measure degree of curvature and generate 3D and 2D penile representative images, with the ability to mark the location of any lumps; (B) a library of scans with the option of sending results via email to HCPs; (C) a video tutorial of how to achieve the best scan results; (D) a link to the Sexual Medicine Society of North America educational website for information on Peyronie's disease; (E) a link to locate a Sexual Medicine Society of North America provider by name, organization, city or state; and (F) a self-assessment questionnaire. 2D, two-dimensional; 3D, three-dimensional; HCP, health care provider.

consultation and may assist in shared decision-making. The questions assess penile curvature, penetration difficulty, partner bother, and impact on sexual activity (*Figure 3F*; Table S1).

Relevance of PD self-assessment app

There is a large discrepancy between diagnosed cases of PD and probable but undiagnosed cases (10). Perceived stigmatization, low self-esteem, and profound psychological distress most likely contribute to men's reluctance to discuss PD with their HCP, furthering the underdiagnosed and undertreated cycle. Innovative screening strategies can break down barriers preventing diagnosis and treatment, and subsequently lessen the physical and psychological effects of PD.

This new PD self-assessment app was designed to help facilitate consultation with a physician, document penile deformity, and help improve patient knowledge of the condition. Increasing the awareness of PD symptoms, having conversations about how symptoms affect quality of life, and seeking evaluation by a physician may be difficult for some men due to embarrassment and other psychosocial reasons. The self-screening app allows users to privately self-assess and educate themselves within their homes, alleviating some misconceptions about PD.

The self-scanning feature and self-assessment questionnaire were designed to overcome embarrassment relating to sexual dysfunctions and allow optional sharing of results with a treating professional. Good physician-patient communication may help with emotional aspects of the patient journey with PD, comprehension of medical information, and assessment for potential treatments (14). This improvement in communication can ultimately result in more effective care as patients may be more comfortable sharing sensitive information with their HCPs (15).

Notably, the app is adjunctive to the diagnosis process, not a replacement for it. Only experienced clinicians with appropriate diagnostic tools should evaluate, counsel, and treat a man with PD (16). Clinicians should perform a comprehensive diagnostic evaluation to identify the signs and symptoms of PD that require taking a detailed history to assess factors such as penile deformity, its impact on intercourse, associated pain, and any distress experienced by the patient. Additionally, a physical exam of the genitalia is essential to identify any palpable abnormalities in the penis (16).

The self-assessment app is not a substitute for a

physician or HCP visit. The measurements in the app's supplementary curvature assessment are dependent on several factors, including the degree of erection rigidity at the time of the scan, adequate lighting, and individual mobile phone camera resolutions. However, the curvature assessment can still benefit patients and aid in beginning their PD management journey. One urologist noted that it would be useful for patients to download the app before their first visit. Thus, using the prescreening app may allow for more efficient shared decision-making, which is consistently recommended across clinical guidelines as a vital part of patient counseling (17).

Discussion

Development and use of urology apps have greatly increased in recent years (18). More apps are being designed for patient use with practical tools aimed at self-examinations (18), such as the PD self-assessment app. Urology medical apps generally lack involvement of professional experts, particularly apps targeted for the general population (19). The PD selfassessment app was developed with the participation of a professional expert association and guides patients to reliable and accurate information about PD through the Sexual Medicine Society of North America website (2). The app provides the convenience of at-home measurements, which may be preferred over clinic-based measurements (20,21), and the option to immediately send those results to a treating physician. The 2D and 3D representations (i.e., not photographs) of the penis with curvature analysis provide security and privacy for patients and utility for physician evaluation.

In addition to impacting sexual function, PD greatly affects psychosocial functioning (22). The higher risk of depression, anxiety, substance use disorders, self-injurious behaviors, and other psychiatric outcomes in those with PD makes it vital for patients and providers to recognize physical and psychological symptoms early on (4,23).

Conclusions

The PD self-assessment app gives men a convenient tool to privately assess physical and sexual symptoms, which may ease emotional stress and the consequent delay in seeking diagnosis and treatment. The ability for partners to also interact with the app can further empower couples to work through emotional and physical difficulties and make decisions together that are best for them (2).

The accessibility of this free, user-driven app to the public could help reduce stigma around PD and reduce barriers to diagnosis and treatment, encouraging more men to seek treatment and find a supportive community through the Sexual Medicine Society of North America (2). Partners of men with PD can interact with the app by learning about PD and supporting their partners during assessment and intervention (24). The app's privacy and security empower men with full control over their data. The app features are adaptable and scalable for future releases to further improve patient journeys with PD diagnosis and treatment. For example, the app is now available in Spanish, and future versions of the app are being explored for potential capabilities with a phone's reverse camera and for more easily following treatment outcomes over time. The physical and psychological effects of PD could be lessened by identifying the condition and referring men to appropriate resources through this innovative screening tool. Further research is needed to validate patient instruction compliance, utilization, and follow-through.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-24-273/coif). G.A.B. received consulting fees from Endo, Inc. for his services in the development of the "Peyronie's disease self-assessment" digital app. J.N.M. received fellowship grant support from Endo, Inc., and Boston Scientific, the latter for outside the submitted work. L.B. and C.D. are both full-time employees of Endo, Inc., including during the conduct of the study, and have no other conflicts of interest to declare. M.K. received consulting fees from Endo, Inc., serves as a consultant for Halozyme, Marius Pharmaceuticals, Petros

Pharma, AbbVie, Inc., Tolmar, and Boston Scientific, and holds stocks of Sprout Pharmaceuticals, outside the submitted work. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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