

IMAGING THE FEMALE PELVIC FLOOR FOR TREATING STRESS INCONTINENCE

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ABSTRACT

Images are highly effective tools for medical instructional media, including the user's manual for medical devices. An appropriate image conveys meaning very effectively. However, the image must be carefully planned and patient usability monitored to know if the images are effective or needs adjustment. Patient feedback provides critical information and guidance to know if revisions are necessary to the approval of a final appropriate design. This article examines the protocol used to create and evaluate images for a FDA-cleared medical device to treat female urinary incontinence. Female urinary incontinence is widespread among women, affects their socioeconomic wellbeing and is treatable. Interventions for female urinary incontinence can include non-surgical options such as lifestyle modifications, pelvic floor muscle training and drugs Stress incontinence which is voiding when a woman coughs laughs or sneezes is the most common type of female urinary incontinence. Images in this article are applicable for a medical device which improves pelvic floor muscle tone for use in the home without surgery or narcotics to treat female stress urinary incontinence.

INTRODUCTION

Images can be highly effective tools in helping operators understand the use of a medical device. If a medical device is designed for home healthcare use, it is essential that the

instructions be adequate for comprehension by both health care professionals and lay users. Images should represent simple concepts. Images should be large enough to see and the focal point clear. Color is an effective means to highlight a point in the image(s) but there can be limitations in the user population, including colorblindness. So, images must be carefully planned with the user population in mind. Examining usability of the text and images by patients, working in concert, can indicate if the images are effective and if they need adjustment. This article examines a protocol used to create and evaluate images for a FDA-cleared medical device from home care use to treat female urinary incontinence.

BACKGROUND

Urinary incontinence is the involuntary voiding of urine (Haylen et al., 2010). Incontinence symptoms are highly prevalent and the symptoms have a substantial impact on an individual's overall quality of life (Saarni et al., 2006). The literature suggests a convincing comorbidity between urinary incontinence and sexual dysfunctions, including dyspareunia, vaginismus, diminished sexual desire, and orgasm disorders (Simonelli et al., 2008) and an increased incidence of depression (Avery et al., 2013). Even after adjusting for comorbidities and the physical discomfort often prompts an emotional burden of shame and embarrassment as well as low self-esteem (Newman et al., 2009), there are financial burdens (Ganz et al., 2010). The range of reported prevalence for urinary incontinence of adult women is wide-ranging (40 to 50%) (Manassian 2003), even in same country studies (Bedretdinova et al., 2016), and appears to increase with age. Yet, because urinary incontinence is considered a stigmatizing condition in most cultures, acknowledging the condition is difficult for the individual. A majority of women will not address their urinary incontinence with a licensed healthcare professional (Helfand 2010) even though treating the symptoms instead of the cause can be expensive (Sbak et al., 2008) (Mordor Intelligence 2018) and the taciturnity resulting from the stigma may increase the cumulative cost(s) (Chong et al., 2011). This makes data collection challenging (Bedretdinova et al., 2016). Urinary incontinence symptoms are highly prevalent among women because of their life experiences, musculoskeletal structure and diseases. Women are more likely to discuss their incontinence with a female healthcare professional perhaps because of shared life experiences/expectations (Swenson et al., 2018).

A number of studies show that birthing significantly increase the chances of developing urinary incontinence (Masenga et al., 2019). Additional data suggest obesity is a factor (Greer et al., 2008), but the predispositions can include genetic factors such as issues with the development of the urinary tract (Aoki et al., 2017). Certain life choices such as inactivity, heavy lifting and chronic repetitive motion contribute to the risk for urinary leakage for women of all ages - female college athletes experience a rate of incontinence perhaps as high as 19% (Schettino et al., 2014) as well as active mature adults (Meczekalski et al., 2014) (Bø & Sundgot-Borgen, 2010) as do mothers in their 30's and 40's (Poświata et al., 2014). Other factors associated with urinary incontinence include childhood history, obesity, pelvic surgery, pulmonary disease, diabetes (Brown et al., 1998) and dementia (Sinclair & Ramsay, 2011).

Pelvic floor muscle tone affects continence. The muscles that make up the walls of the bladder are arranged in a very efficient way to hold urine in the bladder and to contract when

needed to empty the bladder. These muscles of the bladder work in concert with the trigonal muscles at the bladder neck and the striated slow-twitch fiber muscles of the urogenital sphincter of the urethra. These muscles respond to intra-abdominal (urinary voiding) cues. When these muscles contract spasmodically, the voiding is called urge incontinence (U.S. National Library of Medicine, 2016).

Also, the pelvic floor muscles play an essential role in the dynamic stability of the musculoskeletal structure and they directly support a woman's organs, including the bladder, uterus, bowel, and intestines. If the pelvic muscles no longer hold the organs in their natural postural position; for example the loss of muscle tone from strain, injury, or non-use, the organs shift, putting pressure on the bladder and this results in *stress urinary incontinence* – voiding when coughing or laughing (U.S. National Library of Medicine, 2016). The symptoms of stress and urge incontinence often coexist, and the combination of these symptoms is termed mixed incontinence. Additional, but less common, subtypes of incontinence in women include postural incontinence (the loss of urine when moving), nocturnal enuresis (the loss of urine during sleep), and coital incontinence (the loss of urine during sexual intercourse). Dyspareunia and related problems are largely due to atrophy of the vulvovaginal epithelium as well as weakening of muscle layers (Sanderson, 2016). 'Functional incontinence' may be used to describe voiding that results from limited mobility (e.g., hip fracture limiting the patient's ability to get to the toilet) or the ability to process information about bladder fullness (e.g., dementia).

The peer-reviewed literature advocates treating stress, mixed and urge female urinary incontinence with pharmaceuticals, surgery, muscle reeducation through exercise or a combination of these strategies. Pelvic floor muscle re-education is the preferred non-narcotic, non-surgical FDA-recognized method. Patient initiated exercise is widely known as "Kegels." Unfortunately, for a significant number of women who try to tone their pelvic floor muscles with patient-initiated Kegel exercises, as many as 60%, find it difficult to determine if their pelvic muscle exercises have been performed correctly, even when guided by a licensed healthcare professional (Bump et al., 1991). As with any exercise, the benefit gained is significantly diminished if the Kegel exercise protocol is poorly executed. To overcome this limitation and significantly increase patient compliance, a medical device can be used to transmit a mild electronic impulse to the muscles. These mild impulses instruct the muscles to work and rest. The electronic muscle instruction technology is termed neuromuscular stimulation. For pelvic floor muscle tone, the technology is sometimes termed AutoKegel[®] (FDA 21 CFR). The work-rest action of the electronic stimulation mimics self-initiated exercise with safe and reliable outcomes that are comfortable as well as clinically proven. Neuromuscular stimulation is not bio-feedback technology. Bio-feedback devices do not instruct the muscles to work and rest. Biofeedback technology only measures the mild neuroelectric signals from self-initiated muscle action (i.e., if the wrong muscles are being used in exercise, biofeedback will still measure muscle action).

Images are an excellent way to explain the "why" and "how" because visual thinking appears to be deeply ingrained in the human brain. Indications suggest people create visual images to accompany their inner speech even when they are prompted to use verbal thinking and when people consciously attempt to think verbally, visual thinking nearly always intrudes (Amit et al., 2017). Perhaps this is why our qualitative data suggests

images are very powerful and particularly useful for explaining the why and how for treating female urinary incontinence. For the population as a whole, stress incontinence is more common than either urgency or mixed incontinence (Cerruto et al., 2013; Senson et al., 2018; Hannestad et al., 2000; Aoki et al., 2017; Irwin et al., 2006). Hence, images in this article focus on female stress urinary incontinence for presentation in the device user's manual and social media.

MEASURES FOR EFFECTIVE IMAGES

Image efficacy can be measured using three criteria. First, tracking direct customer comments by phone, e-mail, and chat. Comments would range from the image being helpful (the most frequent) to calls requesting help with the images (rare). Second, tracking customer service requests and frequently asked questions. Customer-patient's comments guided the User's Manual's evolution, including improvements of the images used in the manual. Third, we scrupulously followed guidance from artists, both technical and classically trained.

A 1,662 data points were tracked over seven months. Many respondents were careful to articulate their subjective viewpoint. The elucidated responses suggest a respondent personality traits of agreeableness (Graziano & Tobin, ²⁰⁰⁹) and conscientiousness (Roberts, et al., 2009). A willingness to be helpful (Habashi, 2016), especially among women in industrialized societies (Thalmayer, 2019) and to be goal directed, to plan, and to be able to delay gratification (Roberts, et al., 2009) are concordant with qualitative data on device use but not in the preview of this article. Data is strictly confidential. As the FDA specification developer manufacture our customer support relays information directly into our quality control program.

A PROTOCOL FOR CREATING EFFECTIVE IMAGES

Research shows that when people scan a page generally their eyes move in a "F" or "Z" pattern. Eye tracking for electronic media is extensive and suggests, that viewers scan to minimize effort in gathering information, not necessarily content in detail (Pernice, 2019). The "F" eye scan appears to be textual based and is a learned scanning technique, because for right-to-left languages such as Arabic, the gaze pattern is reversed (Nielsen, 2006). The "Z" pattern is a scanning technique that is for light textual content and most effective for directing the viewer to action (Cao, 2015). These predominant eye scan patterns suggest the center of the page is the position for critical content, and that this is particularly important if the subject matter is to be viewed in electronic media. So, the location of the priority content is to be at the center of the image.

The type of image is critical in conveying meaning appropriately. There is often an obvious difference between photos and illustrations. The important issue is when to make the choice to best help the viewer fully understand the issue(s). To depict something in a literal way, as such the contents of a kit, photos are often the clear choice. However, a photo can be too literal, and uncomfortable for most – especially regarding a woman's reproductive organs and continence. An illustration is a visual interpretation of an idea, concept or process. Because an illustration can convey meaning, reduce complexity and add interest to any form of communication, it is superior to a photograph. The level of technical expertise can be very high in an illustration. The illustration should be appropriate to

the audience. Color can be used in an illustration to focus attention.

The choice of color scale affects the viewer's visual comparative analysis of the images (Zabala-Travers et al., 2015). Our qualitative data indicates the use of color increased user comprehension appreciably but color in itself is not an educational tool and its over use can be distracting in the instructions for a device (Backinger & Kingsley, 1993). Color, if used carefully, is effective in facilitating understanding in three ways. First, color is a tool to distinguish among items in the image. For example, there are a number of organs supported by the pelvic floor muscles. Selecting a color set for each organ helps the different organs look clearly distinct from each other while also being part of the grouping. No one color should stand out relative to the others unless by design (see point three, highlight). Importantly, the colors should not create the impression of an order, as would be the case with a sequence of same colors that get successively lighter. Such colors would create an apparent order among the items being colored.

Second, colors must appear in some way connected to the viewer's ideas of what is natural; for example, yellow to indicate the bladder or red for muscle tissue. Colors that look unnatural to the viewer do not make a useful scale. Third, color can also be an effective tool to highlight specific information about the issues we wish to convey (e.g., stress incontinence in adult females). An easy way to achieve this emphasis is to color these figure elements (i.e., organs of a woman's pelvic floor) in a color or set of colors that vividly stands out against the rest of the figure. This effect can be achieved with *accent* color scales - both a set of subdued colors and a matching set of stronger, darker, and/or more saturated colors.

Of course, the audience and its knowledge of the subject must be taken into account to relay the stress incontinence story effectively. So, the view of the subject should be from an angle the audience finds natural and not complex. Because the muscles of the pelvic floor and a woman's visceral organs are internal, a perspective (not isometric) view is effective because it can include external reference points to improve a viewer's spatial comprehension. The views must demonstrate the movement of the visceral organs as the pelvic floor muscles lose tone. It is the shift of the visceral organs from their natural position to a new position that puts weight on the bladder and pressure on the sphincter muscles. The loss in muscle tone creates a 'hammock' like effect against which the urethra is compressed during rest and activity. To convey the change, the perspective imagery may be shown in two parts. The organs in their natural position (Figure 1) and after the organs' shift (Figure 2). Perspective imagery in Figures 1 and 2, has added advantages. Since the pelvic floor muscles interact with other muscles in the musculoskeletal structure (i.e., manage shear load of the upper body through the pelvis to the heels – not unlike a Gothic Arch in architecture) (Reider, 2016) an elaborate perspective view can help tell a more broad story about muscle tone. The drawback is that the perspective view story with all its related elements can be too complex. As a rule, a cross section view puts the main subject in the center of the foreground and non-essential elements are selectively removed to focus on the subject.



FIGURE 1
GOOD PELVIC FLOOR MUSCLE TONE WITH
VISCERAL ORGANS IN THEIR NATURAL PROPER POSITION



FIGURE 2
PELVIC FLOOR MUSCLE TONE LOSS WITH
VISCERAL ORGANS IN THEIR DESCENDING HAMMOCK POSITION

Images in Figures 1 and 2 are technically excellent. They are perfect for healthcare professionals and bioengineers, but our qualitative data indicated a less complex, and perhaps a less technical approach is more appropriate for a medical device manual - particularly since the device is for home care use by lay persons (21 CFR 801 Subpart C, K141643). Following our qualitative data we tried a visual approach to communicating pelvic floor muscle tone issues to our audience that was painterly and playful seen in Figure 3.



FIGURE 3
PELVIC FLOOR MUSCLE TONE LOSS WITH
VISCERAL ORGANS IN THEIR DECENDING HAMMOCK POSITION

The illustrator used simple expressive lines and color to render a single image of the pelvic floor in a way that communicates the idea using simple colors in a warm, approachable and clear way. Indications suggest this greatly helped in communicating an understanding of the issues involved in pelvic floor wellness and female urinary stress incontinence – perhaps because the image was abstract and not “clinical.” As one respondent put it, the image did not incite, “a white-coat effect,” a condition idiosyncratic to clinical settings where some patients experience hypertension in the presence of perceived authority (Pickering, et al., 2002).

Because the device instructions will be read in a home setting, a portion of the population has some form of color blindness. Colorblindness is usually a genetic condition (e.g., on the X chromosome) but there are other factors, including disease and trauma. So, colorblindness affects the sexes disproportionately; approximate 0.5% of the female population and 7% of the male population. Monochromacy, where the individual cannot see color at all is rare (approximately 1 in 40,000) (National Eye Institute, 2019). Most people who are color blind are able to adjust and don’t have problems with everyday activities. While the subject of this article is images, not text, it is important to clearly label colored items in black text on a white background when the image is placed in the final product.

CONCLUSION

Our qualitative data indicates images are a highly effective tool because visual thinking is deeply ingrained in the human brain. An appropriate image, whether abstract or highly technical, conveys meaning very effectively and patient knowledge significantly improves outcomes. Plan the image design carefully, but careful field measurement/patient feedback will provide critical information for revisions necessary to the final appropriate design.

It is important for women to know the cause of their urinary incontinence and that this common condition is treatable. Contact a licensed healthcare professional for a complete diagnostic evaluation; including a medical history, physical examination, urinalysis, quality of life assessment and discussion of potential applicable treatment(s) available. Effective non-narcotic and non-surgical options are available for treatment. Some, like pelvic floor exercise and muscle stimulation can take place in the privacy of the woman's home. The images presented in this article are for such purposes.

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