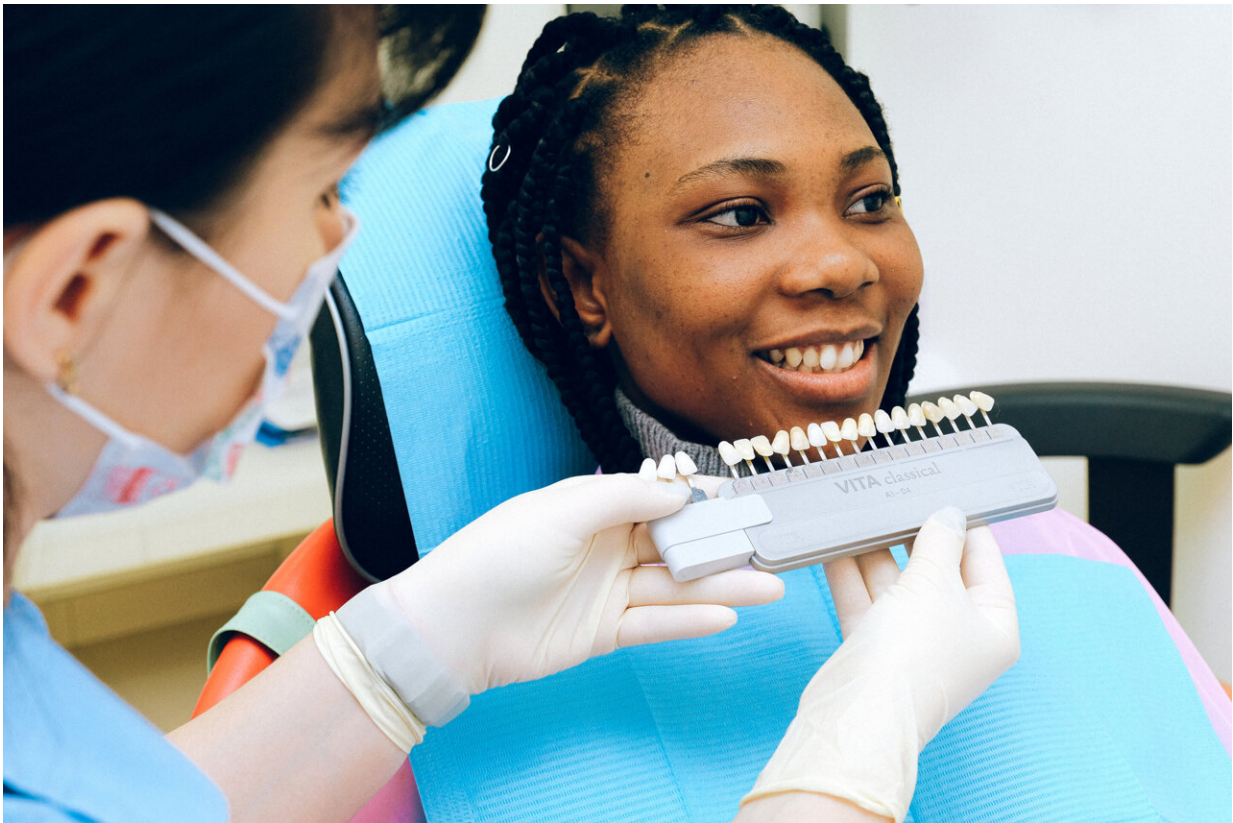


Why women are more likely to have dodgy hip implants or other medical devices

August 12 2019, by Katrina Hutchison



Credit: Anna Shvets from Pexels

The past year has seen [wide concern](#) about the safety of medical implants. Some of the worst scandals have involved devices for women, such as textured [breast implants](#) with links to cancer, and transvaginal

mesh implants, which were the subject of a [senate inquiry](#).

But women are harmed not only by "women's devices" such as breast implants and vaginal mesh. Women are also more likely to be harmed by apparently gender-neutral devices, like [joint replacements](#) and [heart implants](#).

In recently published [research](#), I explored the reasons for this. I found gender biases at all stages of design and use of medical implants.

Proposed changes to how devices are regulated, such as introducing [a national register of all implants](#), will make it quicker to identify dodgy devices. But this will not address gender bias in how devices are designed and used.

Bias starts with design, then lab testing

Biological and social factors [can affect](#) how women present when injured or ill, and how well treatments work. Often, device designers [do not take these differences into account](#).

The lab tests used to make sure implants are safe often ignore the possibility women could have [different reactions to materials](#), or their activities could [place different loads on implants](#).

Bias continues with clinical trials

Some medical device companies [have exploited regulatory loopholes](#) to get devices to market in the UK without clinical trials. Even when trials take place, women [are not always included](#). Or researchers [do not analyse the data for gender differences](#).

Regulators such as the Food and Drug Administration (FDA) in the United States and Australia's Therapeutic Goods Administration (TGA) [often approve devices](#) without data split by gender on how well devices perform or how safe they are.

Then there's the doctor-patient relationship

The gender of the doctor and patient can make a difference to what women learn about their implant. The [very low numbers of women in surgery](#) mean female patients often see male surgeons. And there is [some evidence](#) male doctors tend to treat female patients in a more paternalistic and less patient-centred way.

Then there's the issue of whether surgeons raise important safety issues with their female patients. For example, some surgeons [feel uncomfortable](#) discussing whether it's safe to have sex after a [hip implant](#), especially with female patients. This is important as some sexual positions [are safer](#) than others.

Let's look at one example, a hip implant

The DePuy ASR (articular surface replacement) hip implant caused serious complications for [patients around the world, including Australia](#), such as inflammation, painful growths, dislocations and metal toxicity.

Despite [media coverage](#), few were aware this hip implant was [more than twice as likely](#) to fail in women.

In the case of hip implants, the same models are available for women and men, implying these devices are gender neutral. Most models come in a range of sizes, with some having [better outcomes for women](#). But women are not small men, and there are gender differences in basic

activities involving the hip, [such as walking](#).

When [women stand up from sitting](#) or [have sex](#), the fragile edges of their hip sockets tend to bear greater loads than men's. This "edge loading" increases the risk hip implants will wear down and release dangerous metal particles.

These differences would not matter if lab tests showed equal safety of hip implants for men and women. However, evidence is not collected on this. In fact, international standards for lab tests that measure rates of wear in hip implants ignore gender differences, and only test [normal walking](#) rather than more stressful activities, such as running or having sex.

The FDA, TGA and other regulators often approve new hip implants based on their similarity to already approved models. This [happened](#) with the ASR hip implant. Regulators did not need new data, let alone evidence the hip was equally safe for women and men.

It's a concern internationally

Internationally, there is increasing concern about the regulation and safety of medical implants. An international group of journalists released a [damning report](#) late last year. The [FDA's 510\(k\) process](#), which approves new devices based on their similarity to existing ones, allows approval of some high-risk implants [without additional evidence](#).

The situation is no better [in Europe](#), where commercial agencies do the approvals. This system has been criticised for approving devices [without good data](#) and for [lacking transparency](#) when it comes to [implant](#) recalls.

The FDA has taken some steps to address gender bias, [issuing guidance](#) for companies to provide data on their devices in women and men.

However, this is not binding. A study of devices approved after its introduction found [only 17%](#) included data analysis by sex.

How could we improve things?

In Australia, scandals with implants have led to calls for bans and [registries](#). These are good ideas, but will not prompt new devices to be designed with women in mind, nor improve patient communication.

Surgeons need to raise topics important for their patients to know about surgery, however uncomfortable it makes them feel. Current efforts to improve the [culture of surgery](#), and to attract trainees [who better reflect](#) the communities they serve may help. But there is a long way to go.

Regulators like the TGA and FDA can influence device design by requiring data on the safety and performance of all new (and modified) devices in both [women](#) and men. The FDA experience [shows](#) these requirements must be binding if they are to work.

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