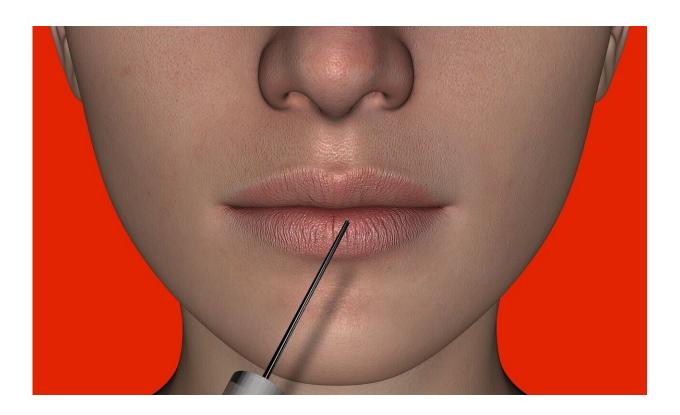


Botox for TMJ disorders may not lead to bone loss in the short term, but more research is needed

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Botox injections to manage jaw and facial pain do not result in clinically significant changes in jaw bone when used short term and in low doses, according to researchers at NYU College of Dentistry. However, they



found evidence of bone loss when higher doses were used.

The researchers, whose findings are published in the *Journal of Oral Health Rehabilitation*, call for further clinical studies to track bone- and muscle-related changes with long-term use of Botox for TMJD, or temporomandibular muscle and joint disorders.

TMJDs are a group of common pain conditions that occur in the jaw joint and surrounding muscles, with the most common type involving the muscles responsible for chewing. While many individuals manage their TMJD symptoms with conservative treatments such as jaw exercises, oral appliances, dietary changes, and pain medication, some do not respond to these treatments.

Botox (or botulinum toxin), an FDA-approved injectable drug known for its wrinkle-reducing capabilities, is approved to treat certain muscle and pain disorders, including migraines. It works in part by temporarily paralyzing or weakening muscles. In the U.S., a Phase 3 clinical trial is currently underway to study the use of Botox to treat TMJD, but in the meantime, it is increasingly being used off-label.

Thus far, small studies using Botox to treat TMJD in humans have had mixed results. In animal studies, Botox injections in jaw muscles have led to major bone loss in the jaw. This is thought to be due to the muscles not being used to exert force needed for bone remodeling, but Botox may also have a direct effect on bone resorption, the process of breaking down bone tissue.

"Given these concerning findings from animal studies, and the limited findings from <u>clinical studies</u>, more research on the safety of Botox for jaw muscles and bones is critically important," said Karen Raphael, professor in the Department of Oral and Maxillofacial Pathology, Radiology and Medicine at NYU College of Dentistry and the study's



lead author.

The NYU study included 79 women with TMJD affecting their facial muscles: 35 of whom received Botox injections (between two and five rounds in the past year) and 44 who were not treated with Botox but may have used other TMJD treatments. Using specialized CT scans, the researchers measured participants' jaw bone density and volume.

The researchers found that jaw bone density and volume were similar between women who had Botox injections to treat their TMJD and those who did not. While most study participants were given relatively low doses of Botox—smaller than in most clinical trials for TMJD—individuals who received higher doses of Botox were more likely to have lower bone density.

Raphael and her colleagues recommend that more human studies be conducted to better understand the impact of the long-term use of Botox on jaw muscles and bones—and whether it just reduces muscle force on bone or also plays a direct role in altering bone resorption.

"Should Botox receive regulatory approval for the treatment of TMJD, we would recommend that a phase IV study be done using low-radiation CT and MRI to track bone- and muscle-related changes with Botox use, examining both dose and long-term use," said Raphael. "Unless specialized imaging of muscle and bone are conducted among patients who receive Botox treatment over long periods, true cumulative effects will remain unknown."

More information: Karen G. Raphael et al, Effect of Multiple Injections of Botulinum Toxin into Painful Masticatory Muscles on Bone Density in the Temporomandibular Complex, *Journal of Oral Rehabilitation* (2020). DOI: 10.1111/joor.13087



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