

# Role of Permacol Injection in the Treatment of Patients With Fecal Incontinence

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Fecal incontinence (FI) is defined as the uncontrolled passage of feces or gas over at least 1-month duration in an individual of at least 4 years of age who had previously achieved control [1-4]. Incontinence has a negative impact on self-esteem and quality of life (QoL) and may result in significant secondary morbidity, disability, and cost [1]. Prevalence rates vary widely depending on the method used for fecal incontinence examination and the target population examined, but, in general, they range between 1.4% and 18%. In institutionalized patients, however, incontinence may affect up to 50%, which is a frequent reason for transfer to nursing homes [2-6]. The Mature Woman's Health Study, which used Neilson data to survey women aged  $\geq 45$  years, indicated that nearly 20% of women have FI at least once per year and that 9.5% have at least 1 episode per month [7].

According to the recommended standard for the treatment of patients with FI specified by the American Society of Colon and Rectal Surgeons Clinical Practice Guideline, medical management is 1C, sphincter repair for external anal sphincter defects is 1B, biofeedback is 1B, and sacral neuromodulation is 1B as well. The recommended standard for injection of bulking agents is 2B, which is lower than other treatment methods [1]. Injection of bulking agents was first used on patients suffering from urinary incontinence, and the first report of such a method being used for anal incontinence was presented in 1993 when Shafik [8] injected polytetrafluoroethylene paste (Teflon, Dupont, Wilmington, DE, USA) into the anus to treat a patient with FI. An ideal bulking agent should be nonirritable, biocompatible, nonimmunogenic

and durable. Other elements that must be considered when selecting a bulking agent are ease of implant, migration, inflammation reaction, and more [9].

Of the numerous bulking agents used, the main ones include bovine glutaraldehyde cross-linked collagen (Contigen, Bard Urological, Convington, GA, USA), autologous fat, and carbon-coated zirconium-oxide beads in water-based gel (Durasphere, Boston Scientific Corp., Boston, MA, USA) while dextranomer microspheres in nonanimal stabilized hyaluronic acid gel (Solesta, Oceana Therapeutics Inc., Edison, NJ, USA), porcine dermal collagen (Permacol, Covidien, Gosport, UK), polytetrafluoroethylene paste (Teflon, Dupont, Wilmington, DE, USA), polydimethylsiloxane elastomer in hydrogel carrier (PTQ, Uroplasty BU, Geleen, The Netherlands), synthetic calciumhydroxylapatite ceramic microspheres in an aqueous-based gel carrier (Coaptite, Bioform Medical Inc., San Mateo, CA, USA), and ethylene vinyl alcohol dissolved in dimethyl sulphoxide are also widely used. Newly created or enhanced bulking agents continue to be released into the market [9].

Permacol is cross-linked porcine dermal collagen. It has been designed to resist breakdown by collagenase in the body and maintain a long-standing increase in bulk. The product is biocompatible and once injected is incorporated into host tissue, with associated cellular and microvascular in growth. No evidence has been found for its being associated with irritancy or allergenicity [10, 11]. Although the characteristics of Permacol are known, previous research about Permacol injection has shown that the number of patients with recurring symptoms of anal incontinence increases in as little as 6 weeks, which leads one to question the durability of Permacol [12]. In other words, the conditions just after an injection are not maintained, but rather the bulking agent is absorbed by surrounding tissues, often leading to the need for another injection.

This research lacks objective data on, for example, anal pressure as it merely assessed patients' conditions centered on an evaluation of QoL. Also, the number of target patients is small while that of tracked and observed patients is even smaller. Six of the 9 research papers on anal manometry presented in this systematic journal review failed to show meaningful changes in the mean

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resting pressure [13]. Similarly, this research does not show a significant difference from previous research results [14]. Despite the relatively short period of tracking and observation, the QoL showed a meaningful change, which is a result similar to those of other studies done in the past.

With the injection of bulking agents, the treatment method normally used in urology clinics has been applied to patients with anal incontinence. The action mechanisms are similar; however, a greater amount of inflating agent is used, and the procedure is less likely to be effective.

### CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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