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3D-Printed Surgical Steel Curettes for the Treatment of Perianal Fistula

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Abstract

Need. The diversity of approaches proposed for the treatment of complex perianal fistulas reflects the fact that no method has yet been shown to be fully satisfactory. We believe the successful treatment of this condition is directly proportional to the amount of fibrous tissue that can be removed. *Technical solution.* We use a kit of small curettes, of different thicknesses and sizes, incorporating spicules that enable the physician to remove fibrous tissue from the fistula tract. The small size and varying thicknesses of the curettes enable them to mould to the curves of the fistula tract and to remove tissue by deroofing from the shallowest to the deepest layers, thus excising the entire fibrous tract. Our hospital has recently incorporated into clinical practice a new model of 3D-printed surgical steel curette, flanked by 2 lateral rings through which the suture is threaded. The central part of the curette contains radially graduated discs, the tips of which perform the debriding action, removing the fibrous tissue from the tract. *Proof of concept.* By using these curettes in conjunction with our standard technique (plugging the tract with platelet-rich fibrin), we have improved the success rate from 67% to 88%. *Next steps.* We have contacted several companies with a view to marketing this product. *Conclusion.* The results obtained are significantly better than those offered by the techniques in current use for the treatment of complex fistulas, without prejudice to outcomes such as anal continence and morbidity and mortality.

Keywords

colorectal surgery, general Surgery, biomedical engineering

Need

Various procedures have been proposed for the treatment of complex perianal fistulas, but none has yet gained broad acceptance.[1]

In recent years, seeking to preserve sphincter function as much as possible when this type of fistula is present, numerous tract-sealing techniques have been considered (such as the use of fibrin glue, stem cells or fistula plugs).[2-4] With these techniques, the results obtained in the treatment of complex fistulas may be directly proportional to the amount of fibrous tissue that can be resected from the tract prior to sealing. Accordingly, the tract should be cleaned as completely as possible.

Technical Solution

With this aim in mind, we have designed a curette[5,6] that is small enough to be drawn along the entire length of the fistula. The curette has a hole at each end through which the sutures passed through the fistula tract can be tied. Thus, by exerting traction on each of the sutures alternately, the curette can be pulled along the entire tract and back again as many times as necessary (Figure 1).

The curette presents various spiculated areas, the passage of which removes all of the fibrous tissue in its path. Moreover, it is available in different sizes, which facilitates resection from the shallowest to the deepest areas of fibrous tissue along the tract. To calculate the size of curette needed to resolve a given situation, the amount of fibrous tissue to be removed must be determined. To do so, we examined 50 pelvic MRI scans of patients with perianal fistula and evaluated the diameter of the fibrous tissue surrounding the tract. In 95% of the cases, this diameter was less than 5 mm. Therefore, we created a graduated set of curettes, the largest of which had a diameter of 5 mm. The successive passage of this range of instruments, from smaller to larger, ensures that in at

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Figure 1. Debriding the anal fistula with cylindrical curettes.

least 95% of cases, all of the fibrous tissue will be removed.

Our initial curette prototype was made of silver and consisted of a central member with peripheral spicules that performed the debriding.

Using a 3D printer and following the same design, we then created a model in plastic, but this material was not strong enough to fully debride the fibrous tissue in the fistula tract.

The final model design (Figure 2) was 3D printed in surgical steel (Figure 3) and was composed of 2 lateral rings, through which the suture can be threaded, and a central structure of discs in a stacked radial arrangement. The tips of this structure are the part of the curette that debrides the fibrous tissue. A more effective resection of the fibrous tissue is achieved by this curette design, thanks to the 360° radial arrangement of the spicules and its sharp cutting edge.

The use of this curette design complements the normal surgical fistula sealing technique by debriding the fistula tract to remove all the granulation tissue in its path,[6] thereby facilitating the presence of healthy tissue and enhancing blood flow, as reported by Buchanan et al, in a study of experimental models in pigs,[7] and by van Koperen et al.[8]

A limitation of the curettes currently used for debriding perianal fistulas is that they are unable to adapt to the

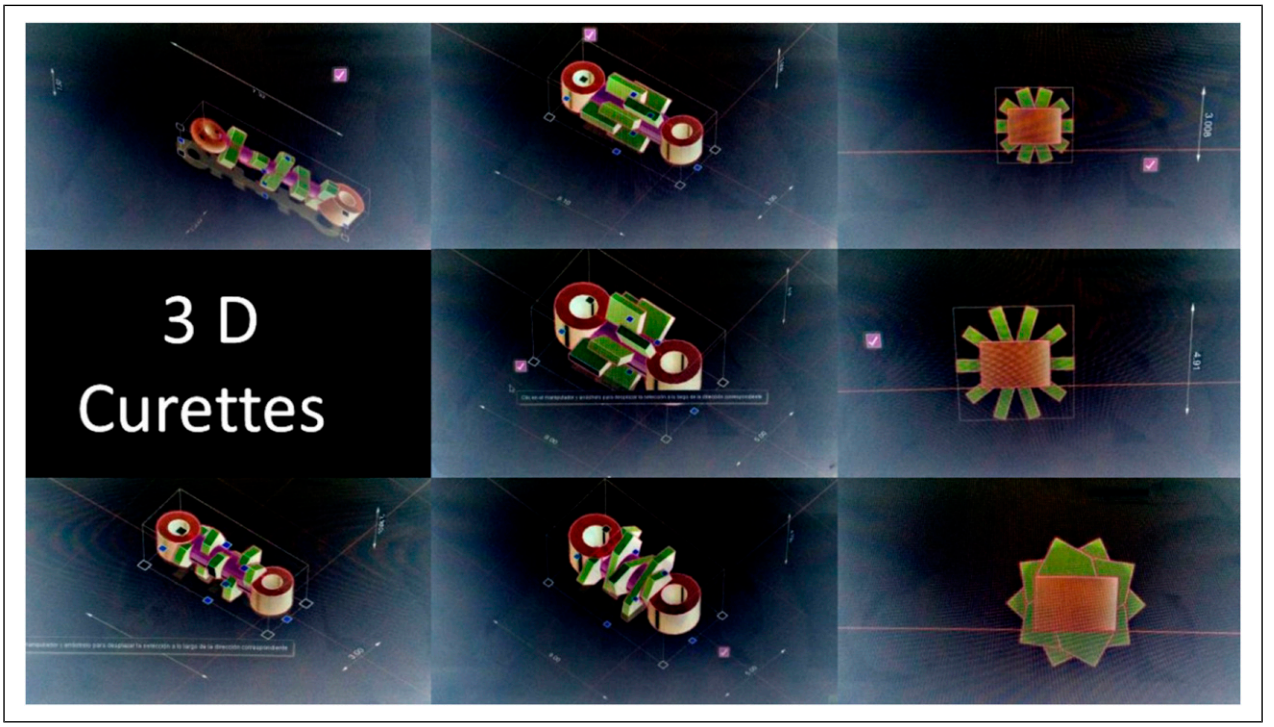

Figure 2. Final computer design of the curettes to be 3D printed from surgical steel.

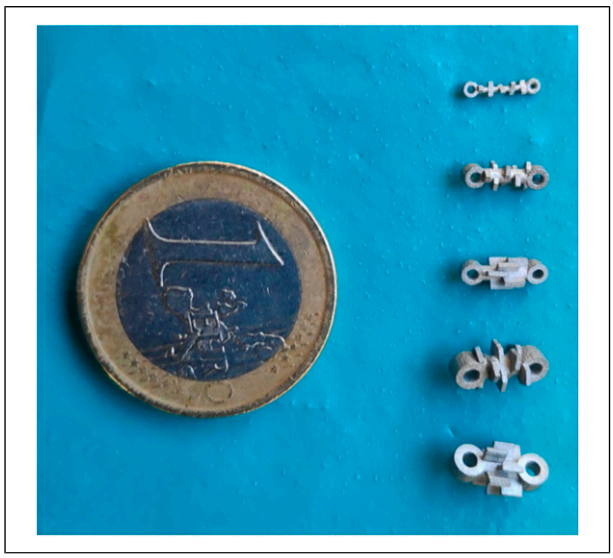

Figure 3. Cylindrical curettes 3D printed from surgical steel.

curvature of the tract. Accordingly, it is impossible to resect the entire path, and these curettes are only used as an auxiliary treatment (the tract is resected to the extent possible with the instrument, after which the appropriate surgical technique is applied). The curette we propose, due to its small size and narrow gauge and its application method based on applying traction, via the suture, to each end of the curette alternately, allows us to pass it along the entire tract as many times as necessary and also to repeat the operation with curettes of different calibres. This approach removes all the fibrous tissue, and so if the internal opening can be closed, then this in itself might provide the definitive treatment of the fistula, with no need for additional treatment.

Proof of Concept

At our hospital, the use of the curettes described has greatly improved the results obtained in fistula sealing treatment, increasing the success rate from 67% to 88%.

Next Steps

On consideration of the results obtained in clinical practice, we have decided to market the product. In this respect, we have contacted several companies and are awaiting their replies.

Conclusion

In summary, the cylindrical curettes described in this article can, in most cases, be used to remove all the fibrous tissue from the fistula tract. The results thus obtained are significantly better than those offered by the techniques in current use for the treatment of complex fistulas without prejudice to outcomes such as anal continence and morbidity and mortality.

Authors Contributions

Study concept and design: Francisco Javier Pérez Lara and Ignacio Diaz de Tuesta Revilla
Acquisition of data: Francisco Javier Pérez Lara and Ignacio Diaz de Tuesta Revilla
Analysis and interpretation: Francisco Javier Pérez Lara and Ignacio Diaz de Tuesta Revilla
Study supervision: Francisco Javier Pérez Lara, Ignacio Diaz de Tuesta Revilla, Francisco Javier Moya Donoso, Jose Manuel Hernández González, and Tatiana Prieto-Puga Arjona

Declaration of Conflicting of Interests

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References

1. Haim N, Neufeld D, Ziv Y, et al. Long-term results of fibrin glue treatment for cryptogenic perianal fistulas: A multicenter study. *Dis Colon Rectum*. 2011;54:1279-1283.
2. Lawes DA, Efron JE, Abbas M, Heppell J, Young-Fadok TM. Early experience with the bioabsorbable anal fistula plug. *World J Surg*. 2008;32:1157-1159.
3. Garcia-Olmo D, Herreros D, Pascual I, et al. Expanded adipose-derived stem cells for the treatment of complex perianal fistula. *Dis Colon Rectum*. 2009;52:79-86.
4. Pascual KJ, Ryoo S-B, Kim JS, et al. Allogeneic adipose-derived stem cells for the treatment of perianal fistula in crohn's disease: A pilot clinical trial. *Colorectal Dis*. 2016; 18(5):468-476.
5. Pérez Lara FJ, Hernández Carmona JM, del Rey Moreno A, Oliva Munoz H. Cylindrical curettes for the treatment of complex perianal fistulas. *Dis Colon Rectum*. 2014;57(9):1140.
6. Perez Lara FJ, Ferrer Berges A, Hernandez Gonzalez JM, Sanchis Cardenas E, del Rey Moreno A, Oliva Munoz H. Method for management of perianal fistula with new device: Progressive curettage of the tract and sealing with platelet-rich fibrin. *Annals of Colorectal Research*. 2016; 4(3):e37452.
7. Buchanan GN, Sibbons P, Osborn M, et al. Pilot study: Fibrin sealant in anal fistula model. *Dis Colon Rectum*. 2005;48: 532-539.
8. Van Koperen PJ, Ten Kate FJW, Bemelman WA, Slors JFM. Histological identification of epithelium in perianal fistulae: A prospective study. *Colorectal Dis*. 2010;12(9):891-895.