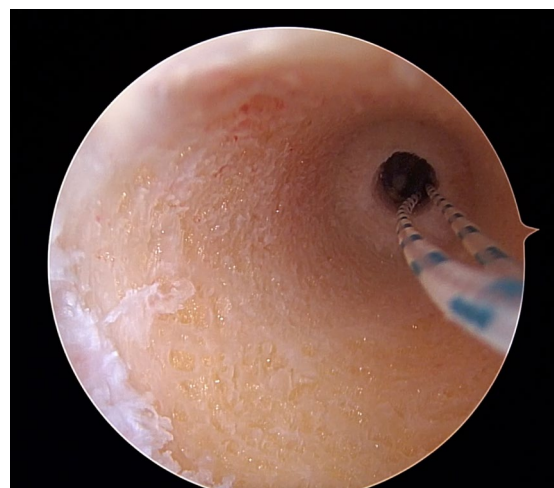


Forward drilling accuracy, retrograde reaming forces and bending stiffness of Stryker's VersiTomic RR as compared to Arthrex FlipCutter II Short

Top level summary

Anterior cruciate ligament (ACL) injury ranks among the top sports medicine injuries, with high rates of associated reconstruction surgeries.¹ Studies have shown that technical errors account for 50% of failed ACL reconstructive surgeries, with tunnel malposition being reported as one of the most common errors.^{1,2} Accurate tunnel placement is critical during reconstruction, as it has been shown that improper tunnel placement can lead to loss of motion and changes in graft length.¹

There is also a need to understand the required axial force to retrograde ream (reverse drill) a tunnel for each product, as too much axial force may result in tooth breakages. An increase in bending stiffness, known as the extent to which the reamer resists deformation in response to a load applied at a given moment arm from chucking position, is expected to positively impact the forward drilling accuracy as well as reduce the required retrograde reaming force. Stryker's VersiTomic Retrograde Reamer (RR) (Retrograde Reamer 4.5 x 10mm) was compared to Arthrex FlipCutter II Short, 10mm in terms of three key measurements: forward tunnel drilling accuracy, force required to retroream a tunnel during all-inside ACL reconstruction, and the quantified bending stiffness.



Methods¹⁻³

Polyurethane foam blocks were used to provide a consistent media for testing. Bone analogues were selected by evaluating clinical literature for ranges of bone densities within the targeted indications for use and matching these to available densities of marketed bone analogues.⁵⁻⁹ 30/12.5 PCF bone analogues were used for testing of the Stryker's VersiTomic RR and Arthrex FlipCutter II reamers.

Forward drilling accuracy:

Tunnels were drilled using a robotic handpiece with Stryker's VersiTomic RR (n = 10) and Arthrex FlipCutter II Short reamers (n = 10) into sawbones samples, placed into vice at a 55° angle. Once drilling was complete, the sawbones sample was readjusted in the vice and drill bits were replaced allowing this to be repeated for a total of 10 times on the same sawbones sample. The sawbones samples were examined under a digital microscope and forward drilling accuracy, as defined as the deviation in X and Y positions between entry and exit points of the tunnel, was determined. The X direction represents drill movement from left to right in the tunnel and the Y direction is indicative of vertical movement.

Reverse drilling (retrograde reaming) force:

Sockets were retroreamed using a robotic handpiece with Stryker's VersiTomic RR (n = 10) and Arthrex FlipCutter II Short reamers (n = 10) into sawbones samples, placed into vice at a 55° angle. A force gauge mounted in line with the drill recorded axial force while retroreaming. Once drilling was complete, the sawbones sample was readjusted in the vice and drill bits were replaced, this step was repeated for a total of 10 times.

Note: 2-sample t-tests ($p < 0.05$) were used to compare the data populations for both the forward drilling accuracy and reverse drilling force tests.

Bending stiffness:

A force of 3.09 lbf was applied 7.77 inches* from chucking position (12mm from the proximal end of the drill) to both VersiTomic RR and FlipCutter II, this was repeated 5 times for each reamer.

Results ^{3,4}

The mean maximum force exerted by Stryker's VersiTomic RR was significantly less than that of the 3.5x10mm Arthrex FlipCutter II Short (Figure 1). The resultant deviation ($p = 0.037$), and the absolute deviation in the Y direction ($p = 0.005$) of VersiTomic RR is significantly less than that of FlipCutter II Short (Figure 2). Although trending, there was no significant difference in the mean absolute deviation ($p = 0.055$) in the X direction. The mean stiffness of VersiTomic RR (6.26 lbf/in) is over twice (2.07x) that of FlipCutter II (3.01 lbf/in).

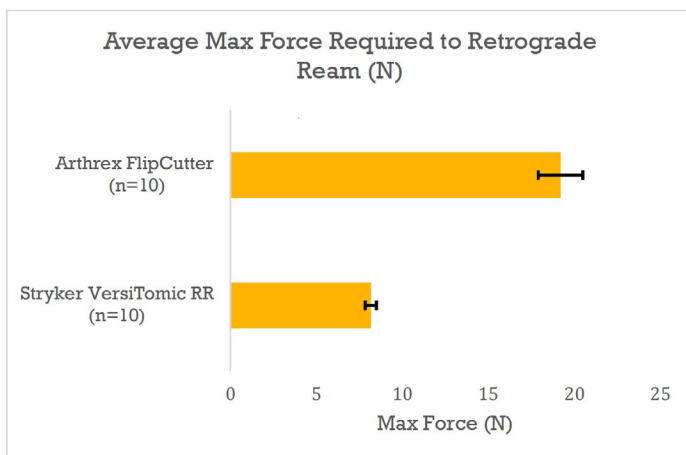


Figure 1. Average max force required to retrograde ream (N)

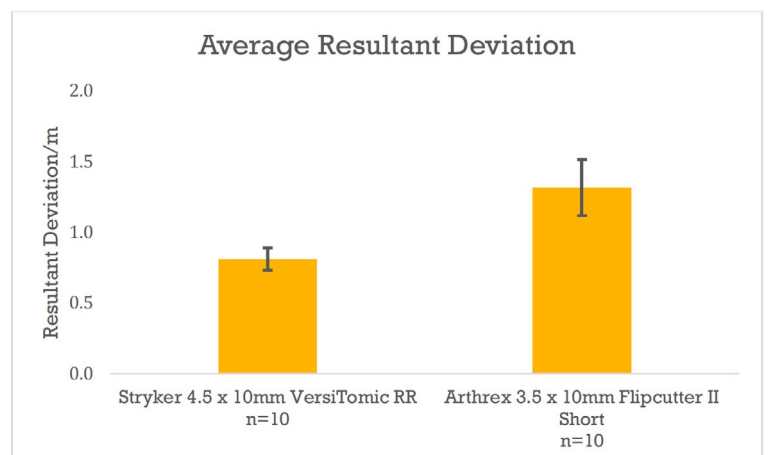


Figure 2. Average resultant deviation (m) for VersiTomic RR and FlipCutter II



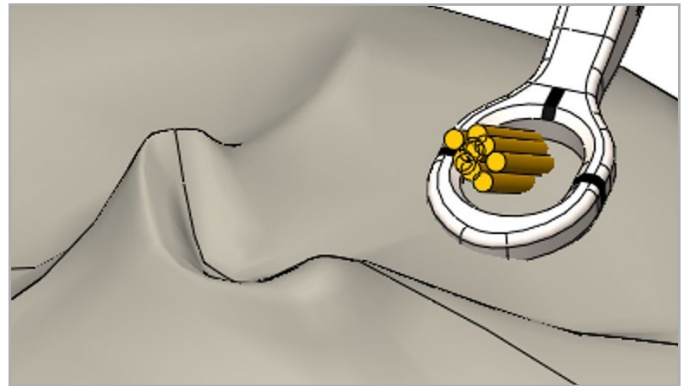
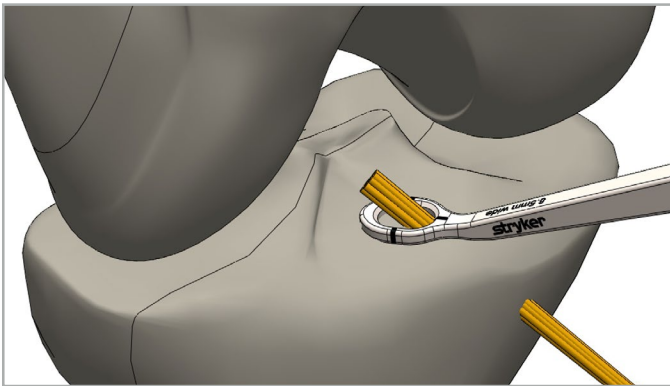
Figure 3. Average stiffness (lbf/in) for VersiTomic RR and FlipCutter II

Clinical relevance

Stryker's VersiTomic RR reamer exhibited less deviation between entry and exit holes compared to the Arthrex FlipCutter II Short in sawbones densities selected for a medium-hard 30 PCF cortical layer and medium 12.5 PCF density cancellous layer. Although there was no significant difference shown in the X direction, the increased skiving of the FlipCutter II resulted in a decrease in accuracy in the Y direction, which contributed to the overall significant difference of 62% in the resultant deviation seen between the two reamers.³ The VersiTomic RR drill required lower axial force to retroream and exhibited less skiving, which may be attributed to the VersiTomic RR having a greater mean stiffness than that of the FlipCutter II Short^{*4}. The lower axial force requirement demonstrates that surgeons may not need to pull the instrument with the same amount of force they may be used to if transitioning from FlipCutter II, Short. It is important to note that this study was performed using sawbones models, further testing is needed to understand the clinical significance of these benchtop findings.

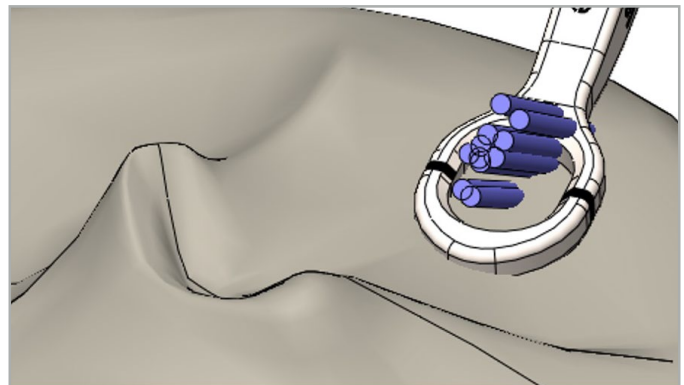
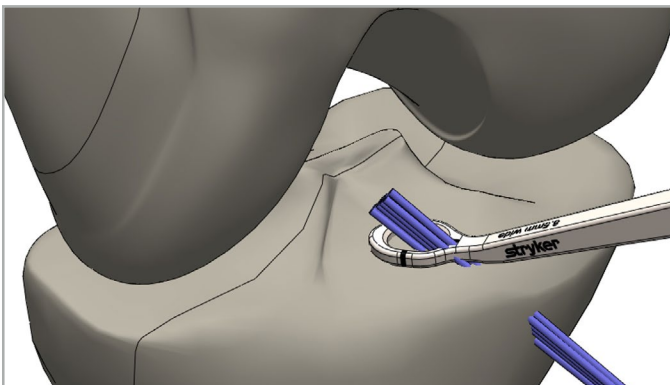
*Bending stiffness calculations were based on validation studies of a predicate device which incorporated Clinical feedback that showed surgeons can leverage up to 24 in-lbf to get the pilot hole.

Stryker's VersiTomic RR



X and Y deviation points shown on a 3D model to demonstrate accuracy and precision of VersiTomic RR versus FlipCutter II Short.

Arthrex FlipCutter II



Stryker's VersiTomic RR resultant deviation ($p=0.037$) demonstrated 62% greater accuracy to Arthrex FlipCutter II Short. Additionally, the absolute deviation in the Y direction ($p=0.005$) was significantly less than that of the FlipCutter II Short

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