

# Comparison of Graft Preparation and Delivery Performance Between the ViviGen® MIS Graft Delivery System and a Bone Graft Funnel

## ABSTRACT

ViviGen is a cellular bone allograft that uniquely preserves viable lineage-committed bone-forming cells within an osteoconductive corticocancellous bone matrix along with osteoinductive demineralized bone. Since its introduction, ViviGen has quickly become the preferred graft choice for many surgeons across a variety of disciplines, including spine. Recent increases in minimally-invasive surgical (MIS) techniques for spinal fusion led to the development of a new delivery system, ViviGen MIS, for compatibility with these techniques. The goal of this study was to compare the preparation and delivery performance of the ViviGen MIS Graft Delivery System versus a traditional bone graft funnel.

The results of this study indicate that the ViviGen MIS Graft Delivery System offers substantially better graft preparation and delivery performance than a bone graft funnel, resulting in a more than 3× faster total procedure time (defined as graft preparation time + graft delivery time in this study). Further, the ViviGen MIS Graft Delivery System was preferred by the majority of participating surgeons in terms of ergonomics, ease of use, complications with delivery of the graft material, ease of positioning the delivery device, and the exactness of graft delivery to the intended location.

## INTRODUCTION

Spinal fusion surgeries are widely used to treat back pain when conservative treatments have failed.<sup>1,2</sup> Autologous iliac crest bone grafts (ICBG) are the traditional gold standard for such surgeries due to their ability to provide all three necessary components of bone formation: osteoconductivity, osteoinductivity, and osteogenicity.<sup>3</sup> However, the additional surgical procedure needed to procure the ICBG increases operative time and cost, blood loss, and postoperative pain, and the graft quality is potentially limited by patient age, comorbidities, and lifestyle risks.<sup>4</sup>

ViviGen is a cellular bone allograft (CBA), a relatively new class of graft options that contain native viable cells with osteogenic potential within an osteoconductive corticocancellous bone matrix. Demineralized bone is also typically included for osteoinductivity. Thus, CBAs can also provide all three necessary components of bone formation and are theoretically able to provide the benefits of ICBG without associated drawbacks.

While most CBAs rely almost solely on mesenchymal stem cells (MSCs) for their osteogenic potential, ViviGen was uniquely developed to preserve viable lineage-committed bone-forming cells. Preclinical evidence suggests that these types of cells are more ideal than MSCs for bone fusion.<sup>5-8</sup> Since its introduction in 2015, clinical evidence has demonstrated consistently positive outcomes with ViviGen,<sup>9-15</sup> and it has become the preferred graft choice for surgeons across a variety of disciplines, including trauma, foot and ankle, craniomaxillofacial, oral surgery, and spine.

In recent years, there has been increased attention on minimally invasive surgical (MIS) techniques for spinal fusion over traditional open surgeries due to demonstrated reductions in blood loss, complications, and perioperative muscular damage.<sup>16-18</sup> Accordingly, a new delivery system, ViviGen MIS, has been developed for compatibility with these minimally-invasive techniques.

To evaluate the hypothesis that the ViviGen MIS Graft Delivery System provides substantially better graft preparation and delivery performance than a traditional bone funnel, an experiment was conducted in a laboratory setting, in which 8 surgeons prepared and delivered ViviGen to an acrylic spine model using each method. This white paper describes the methods and results of this study.

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## METHODS

### Study Design

The purpose of this study was to compare the graft preparation and delivery performance of the ViviGen MIS Graft Delivery System versus a traditional bone graft funnel.

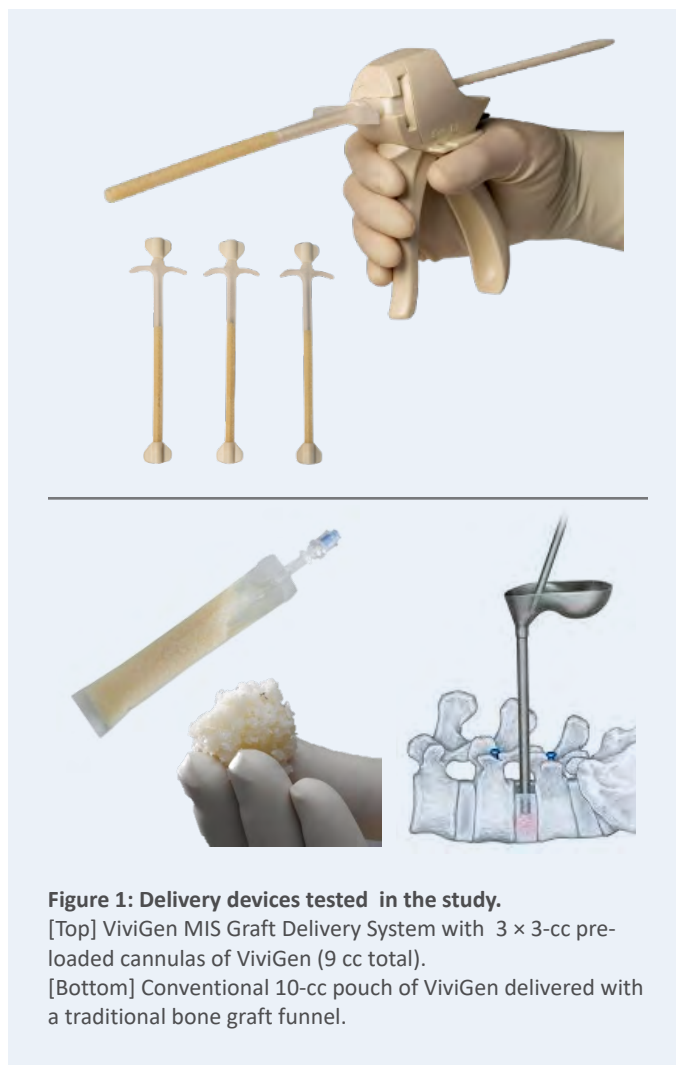
- The primary endpoints were to compare the time to completion (in seconds) for the graft preparation and delivery tasks, and the total procedure time (graft preparation time + graft delivery time) of the ViviGen MIS Graft Delivery System versus a traditional bone graft funnel.
- The secondary endpoints were follow-up qualitative surgeon assessments of their experience with the ViviGen MIS Graft Delivery System versus a traditional bone graft funnel.

Working independently from a tabletop under laboratory conditions, 8 surgeons prepared ViviGen for each device and then delivered the graft to an acrylic spine model. The time required for each task was measured and recorded, and the qualitative surgeon assessments were completed once both devices had been tested.

### Study Procedures

Before testing began, each surgeon's history and experience with grafting and graft delivery devices was recorded. Surgeons were briefed on the use of both devices, and the study procedures, and were permitted time to ask questions.

Each delivery device was pre-assembled and placed ready-to-use on the table with its associated graft material. To minimize bias, surgeons tested each device only once and device order was randomized between surgeons. For the ViviGen MIS Graft Delivery System (Figure 1, top), each surgeon prepared and delivered 3 × 3-cc cannulas pre-loaded with ViviGen (9 cc total), and 1 conventional 10-cc pouch of ViviGen (Figure 1, bottom) was used with the bone graft funnel.



**Figure 1: Delivery devices tested in the study.**  
[Top] ViviGen MIS Graft Delivery System with 3 × 3-cc pre-loaded cannulas of ViviGen (9 cc total).  
[Bottom] Conventional 10-cc pouch of ViviGen delivered with a traditional bone graft funnel.

The preparation and delivery tasks were completed in alternating steps to facilitate proper device loading. For example, the graft was prepared, and an appropriate volume loaded in the first preparation step, then delivered to the model in the first delivery step. The device was then reloaded in the second preparation step, then delivery resumed in the second delivery step, and so on. This cycle continued until the total volume of graft material was used. As such, the ViviGen MIS Graft Delivery System required 3 steps to complete the

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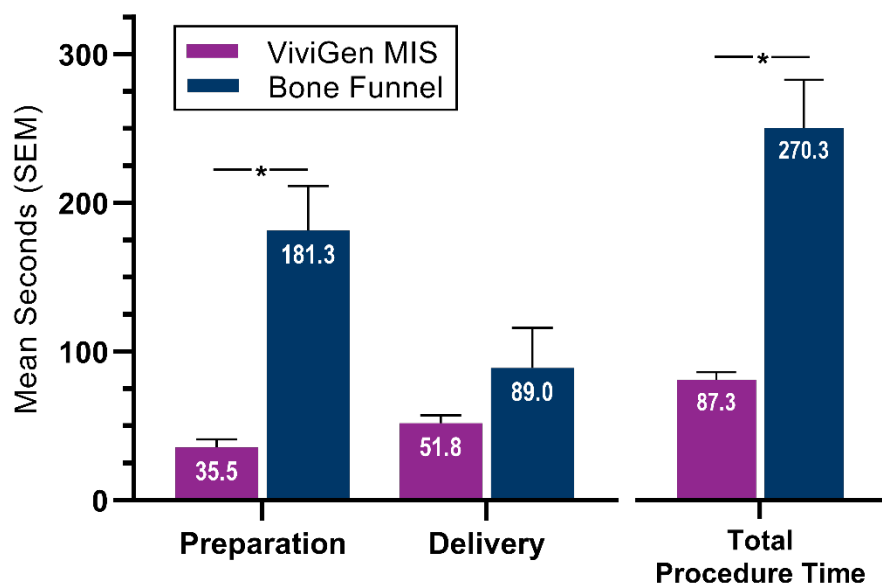


Figure 2: Time to completion of preparation and delivery tasks, and total procedure time (graft preparation time + graft delivery time) for both devices.

Graft preparation and total procedure times were significantly reduced with the ViviGen MIS Graft Delivery System versus the traditional bone graft funnel (\*P<0.01). Although graft delivery times were reduced in all tests, the difference was not statistically significant, likely due to increased variability in graft delivery times with the bone funnel.

preparation and delivery tasks (1 step per cannula). However, the bone graft funnel was loaded with volumes according to each surgeon's preference and the required number of steps for this device varied.

## Data Collection/Analysis

For the time endpoints, a separate calibrated stopwatch was used for each of the preparation and delivery tasks. The respective stopwatch was started when the first item for the next step in that task was picked up from the table by the surgeon, and then paused when the last item was placed back on the table upon step completion. Following completion of all steps, the resulting cumulative times recorded on each stopwatch were reported as the time to completion for that task. Mean differences in time to completion for each task and the mean total procedure time (graft preparation time + graft delivery time) for each device were compared for significance (P<0.05) with 2-sided independent t-tests.

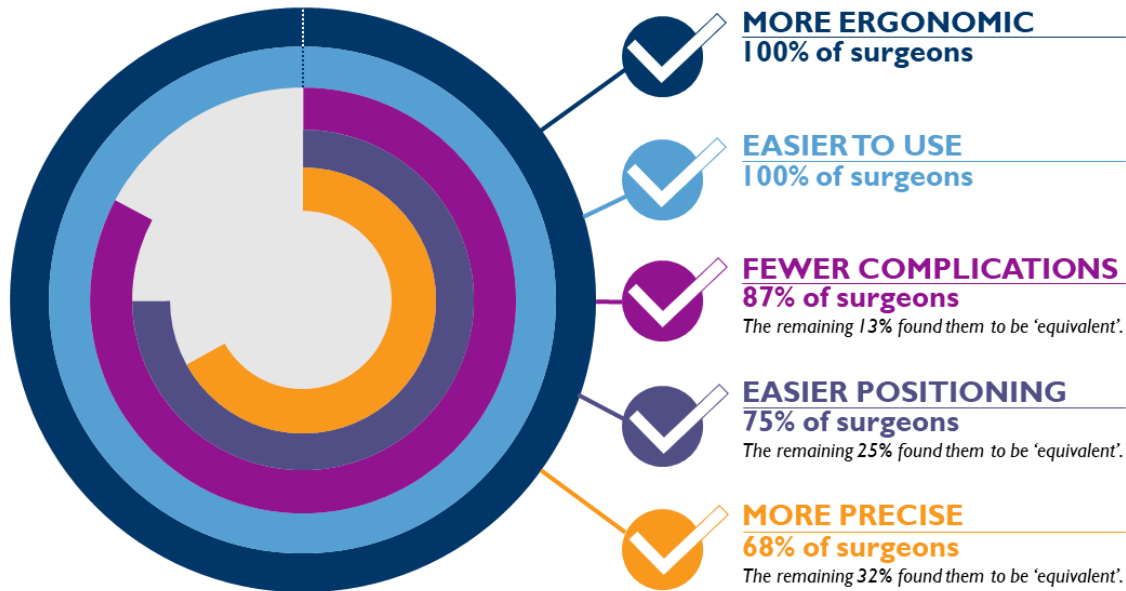
For the follow-up qualitative assessments, surgeons were asked upon study completion to rate their experience with the ViviGen MIS Graft Delivery System as "better/easier", "equivalent/similar", or "worse/more difficult" than the bone graft funnel within 5 categories: ergonomics, ease of use, complications with delivery of the graft material, ease of positioning the delivery device, and the exactness of graft delivery to the intended location. Responses were recorded and reported as the proportion of each within each category.

## RESULTS

### Surgeon Characteristics

The 8 surgeons participating in this study had from 6 to 14 years of experience in orthopedic or neurological surgery with a current rate of 20 to 40 procedures in a typical month. Of these, 50% to 90% of the procedures involved grafting, and the surgeons were experienced with a variety of delivery devices, including bone funnels, syringes, and guns.

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**Figure 3: Follow-up qualitative surgeon assessments.** The ViviGen MIS Graft Delivery System was rated by the majority of surgeons in the study as “better/easier” than the traditional bone funnel in terms of ergonomics, ease of use, complications with delivery of the graft material, ease of positioning the delivery device, and the exactness of graft delivery to the intended location.

## Time to Completion and Total Procedure Time

Time to completion and total procedure time results are presented in Figure 2. The ViviGen MIS Graft Delivery System required less time than the traditional bone graft funnel for preparation and delivery of graft material, and to complete the total procedure.

Mean time to completion (SEM) for the preparation task was 145.8 seconds shorter with the ViviGen MIS Graft Delivery System (35.5 seconds [5.6]) versus the bone graft funnel (181.3 seconds [30.0];  $P < 0.01$ ) and 37.2 seconds shorter for the delivery task (MIS = 51.8 seconds [5.6]; Funnel = 89.0 seconds [27.0]; ns). Mean total procedure time (SEM) was 183.0 seconds shorter with the ViviGen MIS Graft Delivery System (87.3 seconds [5.9]) versus the bone graft funnel (270.3 seconds [34.8];  $P < 0.01$ ).

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## *Follow-up Qualitative Surgeon Assessments*

Results of the follow-up qualitative surgeon assessments are presented in Figure 3. The ViviGen MIS Graft Delivery System was rated by the majority of surgeons in the study as “better/easier” than the bone graft funnel in each of the 5 categories tested.

For ergonomics and ease of use, all 8 surgeons (100%) rated the ViviGen MIS Graft Delivery System as “better/easier” than the bone graft funnel. For complications with delivery of the graft material, 7 surgeons (87%) rated the ViviGen MIS Graft Delivery System as “better/easier” and 1 surgeon (13%) rated the devices as “equivalent”. Six surgeons (75%) rated the ViviGen MIS Graft Delivery System as “better/easier” for ease of positioning and 2 surgeons (25%) rated the devices as “equivalent”. For exactness of graft delivery to the intended location, 5 surgeons (68%) rated the ViviGen MIS Graft Delivery System as “better/easier” and 3 surgeons (32%) rated the devices as “equivalent”. None of the surgeons rated the ViviGen MIS Graft Delivery System as “worse/more difficult” in any of the categories tested.

## DISCUSSION

The purpose of this study was to compare the graft preparation and delivery performance of the ViviGen MIS Graft Delivery System versus a traditional bone graft funnel. Graft preparation and total procedure times were shown to be significantly reduced with the ViviGen MIS Graft Delivery System, resulting in a more than 3× faster total procedure time (graft preparation time + graft delivery time). Although graft delivery times were reduced in all tests, the difference was not statistically significant, likely due to increased variability in delivery times with the bone graft funnel.

Further, the ViviGen MIS Graft Delivery System was preferred by the majority of participating surgeons in terms of ergonomics, ease of use, complications with delivery of the graft material, ease of positioning the delivery device, and the exactness of graft delivery to the intended location. No surgeons rated the ViviGen MIS Graft Delivery System as “worse/more difficult” than the bone graft funnel in any of the 5 categories tested.

## CONCLUSION

The results of this study indicate that the ViviGen MIS Graft Delivery System offers substantially better graft preparation and delivery performance than a bone graft funnel, resulting in a more than 3× faster total procedure time (graft preparation time + graft delivery time).



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