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An Ovine Model for Exclusive Endoscopic Ear Surgery

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IMPORTANCE With the international spread of exclusive transcanal endoscopic ear surgery, the need for a suitable and affordable surgical training model has grown during the past years.

OBJECTIVE To develop and validate an ex vivo animal model for exclusive endoscopic ear surgery.

DESIGN, SETTING, AND ANIMAL MODELS In an experimental study, we compared ovine and human middle ear anatomy in 4 specimens and assessed the lamb as a model for endoscopic ear surgery. After confirming its suitability, we developed a surgical training program for canaloplasty, myringoplasty, and ossiculoplasty. From March 1 to May 31, 2016, the ex vivo model was tested, assessing the time needed for dissection and complications. Each experience was subjectively validated on a scale from 1 (very poor) to 10 (excellent).

MAIN OUTCOMES AND MEASURES Suitability of the lamb model for training in exclusive endoscopic ear surgery.

RESULTS We assessed the suitability of our novel lamb model on 20 ovine middle ears. All interventions could be performed in a satisfactory manner. The mean (SD) time required to perform canaloplasty was 29.7 (13.2) minutes, for middle ear dissection was 7.7 (2.6) minutes, for myringoplasty was 7.7 (4.3) minutes, and for ossiculoplasty was 10.4 (2.7) minutes. The time required for canaloplasty and tympano-meatal flap elevation during dissection decreased from 46.4 minutes in the first 5 cases to 16.2 minutes in the last 5 cases, representing an absolute difference of 30.2 minutes (95% CI, 22.28-38.12). Subjective ratings revealed excellent values for tissue quality (8.9 points of 10), overall satisfaction (8.3 points), and the learning experience (8.8 points).

CONCLUSIONS AND RELEVANCE The ovine model is suitable for endoscopic ear surgery. We describe a novel, exclusively endoscopic approach in an ex vivo animal model for middle ear surgery. The proposed surgical program leads the trainee step by step through the main otologic procedures and is able to enhance his or her surgical skills.

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Video

Supplemental content

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The exclusive transcanal endoscopic approach to surgery of the middle ear was introduced and developed during the past several decades.[1] As for all surgical procedures, adequate training of surgical skills during cadaveric dissection courses is advisable. Such training enhances dexterity and provides experience in performing the procedure, which is required for successful outcomes during future interventions. In fact, surgical simulation has become a valuable and financially attractive part of surgical education, with a beneficial effect on the clinician's competency and the patient's safety.[2] Fresh human cadaveric specimens are the criterion standard of surgical training, although the availability of such specimens is limited owing to high costs and local regulations. The animal model represents a suitable, inexpensive, and reliable alternative to human cadaveric specimens. The safety of the ovine model has recently been described for many procedures in head and neck surgery.[3]

In otologic surgery, the sheep model has been described and validated for the training of stapes surgery,[4,5] for implantable devices,[6] and for the round window insertion of cochlear implants.[7] Comparative anatomy studies allowed for the identification of similarities and differences between the sheep and the human middle ear.[8] The suitability of the sheep model was confirmed by comparative radiologic studies.[9] The ovine model is suitable to train and develop surgical skills in an education program for otologic surgeons.

One main issue in developing an animal model for exclusive endoscopic ear surgery is the incongruence of that model to the human anatomy, particularly the external auditory canal (EAC). In our experience, one of the most difficult steps in

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the exclusive endoscopic approach is to raise the tympanomeatal flap and maneuver the instruments in a possibly bent and narrow EAC. An animal model should meet these difficulties to provide adequate training.

This study compares the human and the ovine endoscopic anatomy and develops a suitable ovine model for exclusive endoscopic ear surgery. In a second phase, we aim to apply and validate the model.

Key Points

Question Is the ex vivo ovine model suitable for training in exclusive endoscopic ear surgery?

Findings In this experimental study using an ex vivo ovine model for middle ear surgery, an endoscopic surgical approach developed to lead trainees step by step through the main otologic procedures was evaluated. Decreased dissection time with ongoing training was observed.

Meaning The ovine model is suitable for training endoscopic ear surgery.

Methods

From March 1 to May 31, 2016, we performed dissection on fresh or previously defrosted (24 hours at ambient air temperature) 6-month-old lamb heads using endoscopes (Karl Storz) with a diameter of 3 mm, length of 15 cm, and angles of 0° and 45°; a 3-charge-coupled device camera system (Karl Storz); and a high-resolution monitor (Karl Storz). The surgical equipment for temporal bone dissection, including a drill, is required. Specimens were obtained at the local butcher from animals intended for the sale of their meat. The University Hospital of Modena Institutional Review Board approved the use of fresh ex vivo ovine heads for this study. Animal welfare was subject to agricultural and veterinary regulations.

Anatomic Studies

Two fresh ovine heads (4 ears) were used for anatomic dissection of the EAC and the middle ear. Moreover, we performed a computed tomographic scan to improve our understanding of the anatomic particularities of this model.

The external ovine ear covers the external meatus and must be partially amputated to access the EAC. The cartilaginous part of the EAC is bent in a posterior direction. When anterior traction is applied to the remnant of the external ear and the cartilaginous EAC, the bony part of the EAC can easily be accessed. A dominant bony prominence in the EAC hinders direct access to the tympanic membrane (TM) (**Figure 1**); after removal of this obstacle, the TM can be assessed. Compared with human anatomy, the very thin membrane presents a large pars flaccida posterior and superior to the malleus, covering the epitympanic space. While raising the tympano-meatal flap (TMF), we were surprised by the lack of an annulus in all specimens.

The ovine middle ear is fairly similar to the human middle ear (eFigure 1 in the Supplement). However, we identified some important differences: The malleus of the ovine ear lies more anteriorly and has a long handle, which is attached to the inferior-anterior floor of the tympanic cavity. The body of the malleus is thin and fragile and presents several ligaments, as well as the insertion of a very large tensor tympani muscle medially. The ovine incus is of similar shape to the human incus, with a short and a long process articulating with the stapes. Unlike Cordero et al,[10] we identified only 1 stapedial tendon. The facial nerve was always dehiscent but in a similar position as in humans. The retrotympanum and hypotympanum containing the round window are hidden behind a bony prominence of the EAC and show almost no pneumatization (Figure 1).

Surgical Model

After thorough anatomic evaluation, we created a step-by-step guide to the exclusive surgical dissection of the ovine ear, performing different routine procedures in otologic surgery.

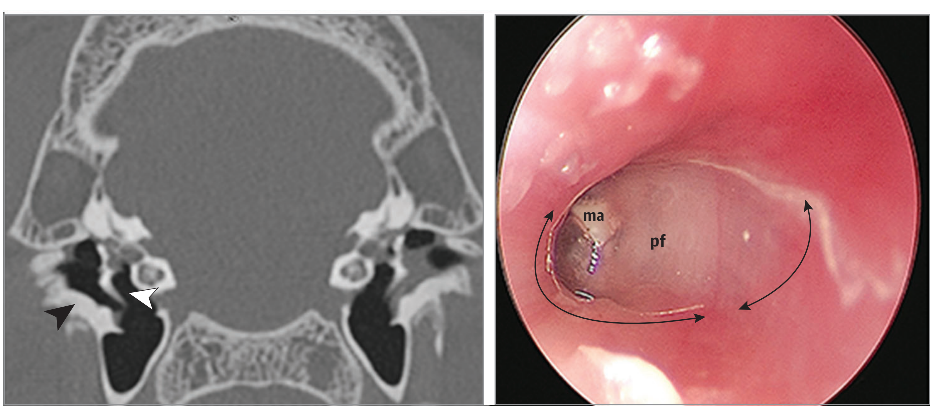
Preparation

The aim of the first preparative step is to permit suitable endoscopic access to the bony part of the EAC. The ovine head is placed on a clean blanket on a table. It is important to orient the nose of the sheep superiorly in the 12-o'clock position to perform the

Figure 1. Endoscopic and Radiologic Evaluation of the Right Ear

A Computed tomographic scan

B Endoscopic view



A, Computed tomographic scan showing the anatomic peculiarities of the ovine model. Black arrowhead, bony prominence of the external auditory canal; white arrowhead, long handle of the malleus. B, Endoscopic view of the same ear. Black arrows indicate direction and extent of the required drilling; ma, malleus; and pf, pars flaccida.

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Figure 2. External Preparation of the Specimen

The ovine head is placed with the nose directed superiorly in the 12-o' clock position and the external right ear is cut about 2 cm from its insertion on the skull. Two tension sutures are placed to enlarge the cartilaginous part of the external auditory canal.

dissection in a surgical position. The external ear is cut at about 2 cm from its insertion on the skull. If there is a large bulging of the tragus, it can be removed. Two tension sutures through the cartilaginous part of the EAC are placed: the first anteriorly and the second inferiorly through the cartilaginous EAC (**Figure 2**). The small hairs in the EAC are then cut. A thorough cleaning of the EAC is performed with the endoscope and suction tube, followed by the inspection of the anatomic landmarks.

Creating the Tympano-Meatal Flap and Consecutive Canaloplasty

The TMF is delineated. Two horizontal incisions in the skin are placed posterio-superiorly at the lateral end of the pars flaccida in the 9-o'clock position and anterio-inferiorly at about the 4-o'clock position. A vertical incision on the EAC laterally on the bulging bony crest completes the skin incision. The flap is created by strictly following the bone using a dissector and cotton swabs. Once the bony bulging is free of skin, it can be removed using a sharp, standard otologic drill. We suggest protecting the flap from the drill with a cotton swab. The most lateral and inferior part of the canal also may be enlarged to allow better maneuvering of the instruments. The more experienced the trainee becomes, the less enlargement of the EAC is necessary.

During this part of the dissection, the handling of the endoscope concomitant with the instrument in the EAC may be difficult for a novice endoscopic ear surgeon but will improve with growing expertise. One principal quality of the otologic surgeon can be trained during this phase: patience.

Access to the tympanic cavity is then created beginning on the lateral end of the pars flaccida. After proper dissection of the pars flaccida, the ossicles are identified and dissected (eFigure 1 in the Supplement). A posterior spine with the emergence of the chorda tympani can be identified (**Figure 3**).

Endoscopic Myringoplasty and Epitympanoplasty

The TM is carefully detached from the posterior part of the malleus and the TMF positioned anteriorly. The dimension of the large attic is assessed using a hook, and an artificial membrane (COOK Medical Biodesign) or a piece of cartilage and perichondrium from the external ear is created. The graft is positioned on the dissected malleus and the flap finally repositioned. Surgeons with more experience may try to perform a myringoplasty for anterior perforations, representing a more challenging dissection (**Figure 4**A and B).

Endoscopic Incus Interposition Ossiculoplasty

First, the incudostapedial joint is identified and disarticulated by a hook, the posterior ligaments of the incus are detached from the epitympanic wall, and the incudomalleolar articulation is mobilized with gentle movements. The incus is then removed from the tympanic cavity, fixed in a small clamp, and tailored by a diamond burr. The removal of the short and long process is required to create a rectangular bony block. A small hole on one side is created to match the head of the stapes. The shaped incus is then repositioned on the stapes (Figure 4C and D).

Validation of the Model

The surgical model was assessed on 20 ears by 2 otologic surgeons with 4 years of experience each (L.A. and M.B.). The time to perform the different steps was assessed, as were possible complications that could occur in real surgery. After each dissection, every surgeon had to provide adequate subjective feedbackin rating the quality of the model and the learning experience on a scale from 1 (very poor) to 10 (excellent) and underwent external evaluation by a senior surgeon.

Statistical analysis was performed using Prism software (GraphPad). A nonparametric Kruskal-Wallis test was used to analyze the improvement of time required to perform the different steps. To this end, we formed chronological groups of 5 dissections, comparing the mean (SD) values using a multiple comparisons model. $P \leq .05$ was considered significant. Results were reported as effect sizes showing the absolute difference between the compared variables and 95% CI around the difference.

Results

All 20 specimens were successfully dissected. The mean (SD) time required to perform canaloplasty and TMF elevation was 29.7 (13.2) minutes, for middle ear dissection was 7.7 (2.6) minutes, for myringoplasty was 7.7 (4.3) minutes, and for ossiculoplasty was 10.4 (2.7) minutes. **Figure 5** summarizes the evolution of the different steps in terms of operating time during the training experience. We observed a statistically significant decrease in time required to perform canaloplasty and TMF elevation when comparing the first group with the last group of 5 interventions. Required dissection time decreased from 46.4 minutes for the first 5 cases to 16.2 minutes for the last 5 cases, representing an

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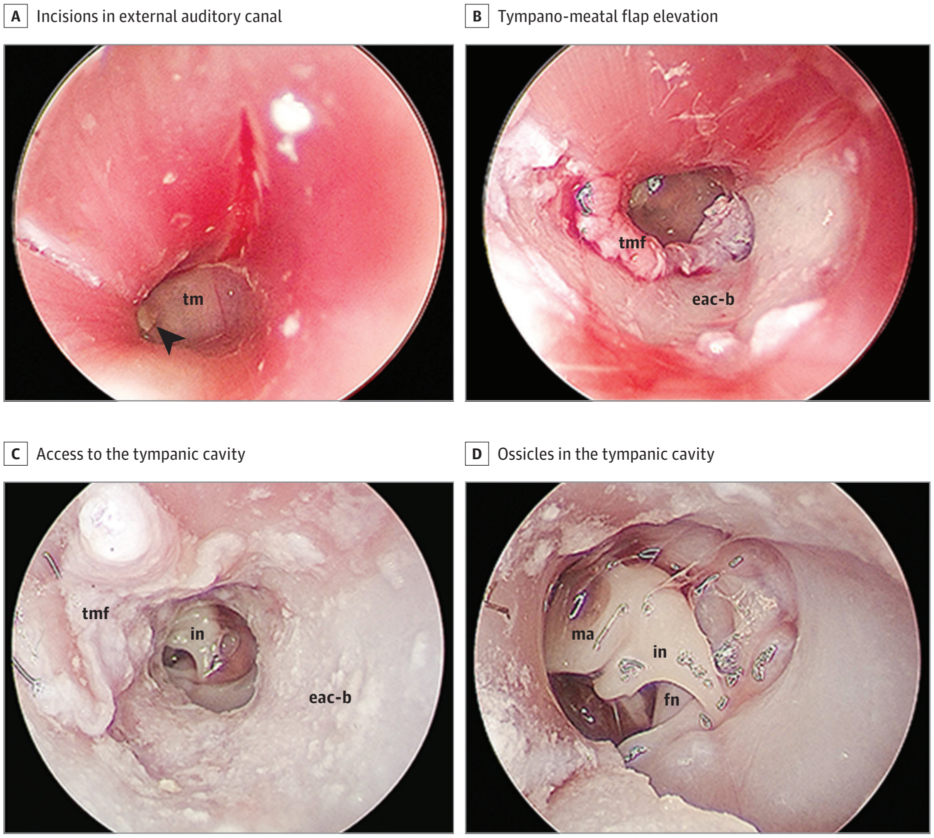
Figure 3. Endoscopic View of Canaloplasty and Tympano-Meatal Flap Elevation of Right Ear



A, Horizontal incisions in the skin of the external auditory canal. Black arrowhead indicates the malleus. B, Tympano-meatal flap elevation. C, Access to the tympanic cavity after dissection of the pars flaccida. D, Ossicles in the tympanic cavity. eac-b indicates bone of the external auditory canal; fn, facial nerve; in, incus; ma, malleus; tm, tympanic membrane; and tmf, tympano-meatal flap.

absolute difference of 30.2 minutes (95% CI, 22.28-38.12), as shown in eFigure 2 in the Supplement. The duration of the other surgical steps (middle ear dissection, myringoplasty, and ossiculoplasty) was almost constant during the whole experience, and differences were not statistically significant.

The observed complications during dissection were 9 perforations of the TM or the TMF, 1 section of chorda tympani, and 3 subluxations of the incudomalleolar joint. The stapes remained intact in all cases.

The model met the expectations of the performing surgeons. The subjective rating revealed excellent values for tissue quality (8.9 points of 10), overall satisfaction (8.3 points), and the learning experience (8.8 points). The different steps were also very positively rated, as summarized in eFigure 3 in the Supplement. The external rating revealed values from 6 to 10, with a mean of 7.4 points of 10.

For teaching purposes, we created a video tutorial containing the endoscopic steps of the ex vivo ovine model for endoscopic ear surgery (**Video**). In this video, canaloplasty, TMF elevation, myringoplasty, and incus interposition ossiculoplasty are demonstrated.

Discussion

The ex vivo ovine model for ear surgery presented in this study is an exclusively endoscopic approach, which has not been described before, to our knowledge. Surgical education requires time and resources to allow the trainee to improve his or her skills under the supervision of an experienced surgeon. It has been shown that the amount of time needed by residents to complete a tympanoplasty type I is 1½ times that needed by attending physicians.[11] This is a logical observation, as every manual task is improved by experience, which may be acquired in the operating room. We must consider that the number of surgical procedures performed by residents is limited owing to work-hour regulations, economic considerations, and the safety of the patient.[12] Therefore, ex vivo training models are widely used in otologic surgical procedures, for example, by means of a temporal bone dissection laboratory.[13] However, the access to human cadaveric specimens may be limited owing to financial or regulatory issues. In this situation, the animal model is a valid alternative.

The ovine model is an inexpensive and reliable model for otologic surgery. The lifelike feeling of fresh specimens provides excellent tissue properties and dissection. Another advantage is the similar size and presentation of the gross anatomic structures of the ovine ear compared with the human ear.[3-5] The learning curve in endoscopic ear surgery may be somewhat different from the learning curve for the microscopic technique for ear surgery[14]; therefore, a proper model for exclusive endoscopic ear surgery is required. The use of an endoscope and, therefore, visualization of the performed dissection on a screen improves the supervision and feedback of

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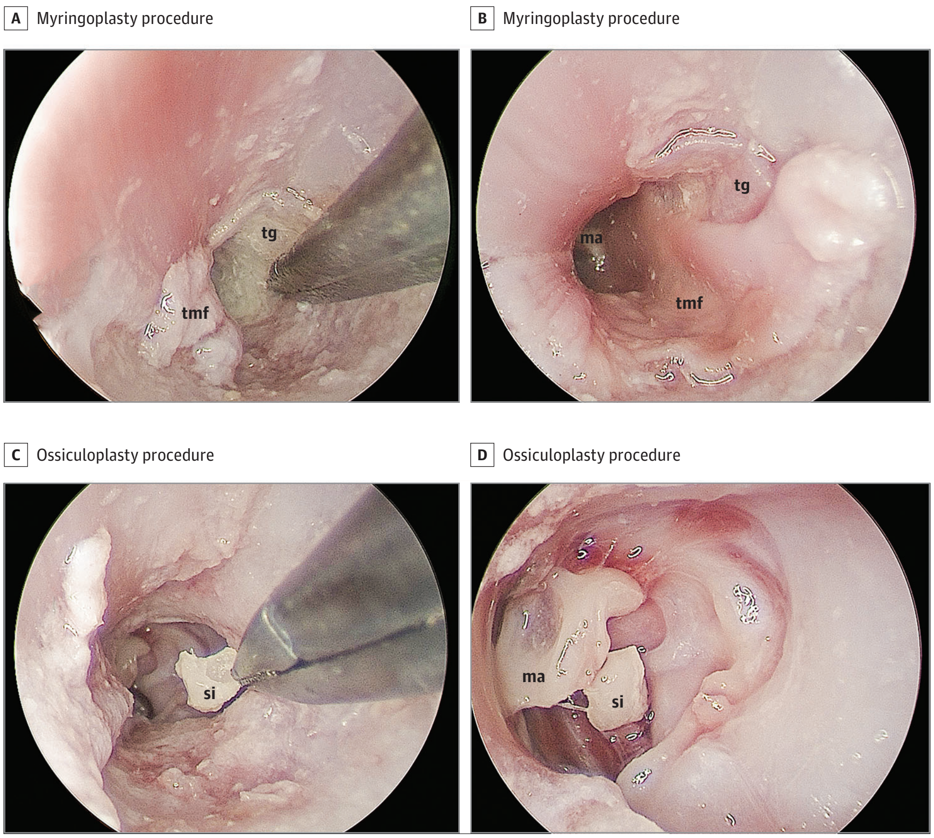
Figure 4. Endoscopic View of Myringoplasty and Ossiculoplasty of Right Ear

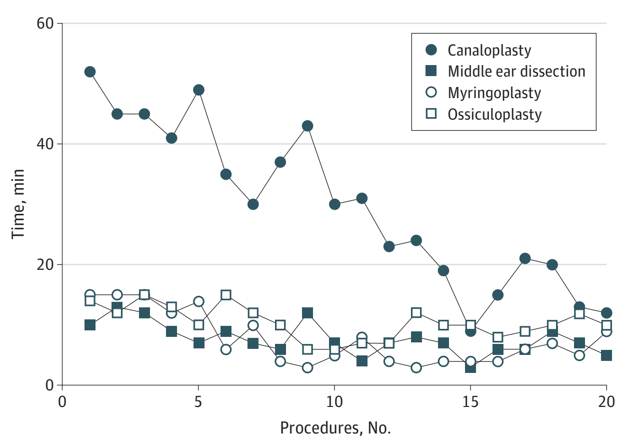


A and B, Myringoplasty procedure. The artificial membrane is positioned on the dissected malleus (ma), and the tympano-meatal flap is then repositioned. C and D, Ossiculoplasty procedure. The shaped incus with a small hole to match the head of the stapes is repositioned between the stapes and the malleus. si indicates shaped incus; tg, tympanic graft; and tmf, tympano-meatal flap.

the supervising faculty member. Both trainee and tutor have the same field of view; therefore, teaching is straightforward, and the suggestions or corrections can be addressed directly.

Cordero at al[10] recently described a model for training endoscopic stapedectomy. In that study, the complete amputation of the cartilaginous part of the EAC and drilling of the bony EAC under microscopic view is suggested. In comparison, our model has the advantage of managing the ovine EAC and the creation of a TMF in a purely endoscopic way. This approach is, in our opinion, an essential difference. Specialized training is needed for the delicate maneuvering of the instruments in the EAC, whose limited space is further compromised by the presence of the endoscope. To this end, we took advantage of the slightly bent ovine ear canal with a bony prominence. The required enlargement of the EAC is performed under endoscopic view, representing excellent training for endoscopic canaloplasty. In our experience during various dissection courses, endoscopic drilling is a challenging task for a novice in endoscopic ear surgery and requires proper training. The correct endoscopic creation of a TMF and enlargement of the EAC is demonstrated by our model of exclusive endoscopic ear surgery.

Figure 5. Assessment of Dissection Times



Chronological surgical times during evaluation of the different steps of the surgical model.

Limitations

The anatomic differences between the ovine and human middle ear represent the main limitation of this model. For instance, the absence of an annulus separating the TM from the mucosa of the ovine middle ear creates some supplementary difficulties to the trainee. The elevation of the TMF is hindered since a main landmark is missing. Another important difference is the absence of bleeding in our ex vivo model. We believe that the training under simplified conditions is suitable, especially for a novice to ear surgery. The experience gained in the concomitant and delicate handling of the endoscope and

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the surgical tools in the EAC and the middle ear are considerable. The overall subjective satisfaction of the performing surgeons rating the proposed surgical program was very high (eFigure 3 in the Supplement). However, this rating has not been evaluated before and therefore represents only the surgeons' experience. The validity of our model is represented by the statistically significant decrease of required dissection time for TMF creation and canaloplasty, indicating its suitability as an animal model for endoscopic ear surgery.

Conclusions

The ovine model is suitable for endoscopic ear surgery. We describe a novel, exclusively endoscopic approach in an ex vivo animal model for middle ear surgery. The proposed surgical program leads the trainee step by step through the main otologic procedures and is able to enhance his or her surgical skills.

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Study concept and design: Anschuetz, Bonali, Ghirelli, Mattioli, Presutti.
Acquisition, analysis, or interpretation of data: Anschuetz, Bonali, Ghirelli, Villari, Caversaccio.
Drafting of the manuscript: Anschuetz.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Anschuetz.
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