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CLINICAL ASPECTS OF LIGMASTER USE AND RESULTS

A key benefit of the LigMaster technology is its capa bility to provide diagnostic information on ligament injury in the form of percentage ligament tear. This information will aid physicians in arriving at the treatment of choice, i.e., surgery vs c onservative treatment. Another benefit of the LigMaster is its use during follow up to monitor recovery, success (or failure) of surgery, return-to-play, etc. The speed and ease of the LigMaster exam mean that it can be used at any appropriate time interval.

Most patients will benefit from at least two LM exams, athletes most likely more. LM procedures are currently billed under CPT code 76006. A fee of $125.00 per 15 minute time period is recommended. A LM ex am performed by an experienced examiner will take between 15 and 30 minutes. Follow-up exams are considered very useful for determining the recovery of ligament function, information that is otherwise unavailable with MRI.

The following outlines the clinical use of LigMaster:

A. The LigMaster is used for the assessment of ligament injury to all of the clinically important ligaments of the ankle, knee, elbow and shoulder. LigMaster determines the percentage of remaining function after the injury and, therefore, the percentage of ligament tear. T he extent of tear determines the treatment of choice, typically the choice between surgery or conservative treatment.

B. Injuries to ligaments are mostly caused by trauma, i.e. a sports injury, car accident, a fall, etc. The first thing a doctor wants to know is the extent of injury, including bone fractures/dislocations, damage to cartilage, joint capsule, ligaments, etc. Therefore, a MRI study is often indicated before anything else is done. If a fracture is identified, then a LigMaster exam cannot be used to assess ligament damage until the fracture has sufficiently healed.

C. MRI can provide information on p ossible ligament damage in most cases. For instanc e, in the knee, the ACL can almost always be imaged, with complete tears seen in about 50% of cases. Intact ACLs are also easily identified, but partial tears, when suspected, cannot be assessed for percentage tear. Typically, tears of 50% or more are treated as if they were 100% tears with surgery, usually an ACL reconstruction using the patients own hamstring or patellar tendon as a graft. Tears smaller than 50%, on the other hand, can be treated successfully with immobilization, braces, etc. It is here that LM can play a crucial role in deciding on the treatment of choice.

D. Aiding in the decision of treatment of choice is one aspect of the LM technology, its role in the 'follow-up' is even more significant. Following the treatment of ligament injury, either surgical or conservative, the surgeon wants to kn ow the progress of his treatment, the recovery or lack thereof, by follow-up exams. Here, LM is ideally suited for t he purpose of m onitoring the recovery of ligament function, whereas MRI is not. LM exams performed at time intervals can provide quantitative information on progress of healing and a time schedule for return-to-play in the case of ath lete patients. LM exams can be performed throughout this process at the discretion of the doctor and billed per procedure.

E. Injuries of the elbow joint and their treatment are similar to ACL injuries, but ankle ligament injuries are different. In ankle trauma, the treatment of fractures takes priority over that of ligaments, but isolated ligament injury, particularly injury to the lateral ligaments that make up about 85% of ankle trauma, is in a class by itself. Ankle ligament injuries are extremely common (23M cases/year in USA) and their outcome depends strongly on the grade of injury. Grade I and II can be treated with Ace wraps, but grades III (rare) and IV (common) need serious attention often including physiotherapy or sur gery. Here again, knowing the grade of injury before you start treatm ent is crucial for final outcome. LM pe rforms this function and provides readouts of progress. Many physicians treat ankle sprains as if they were grade I or II and resort to treatment for grade IV only after the first treatment failed,

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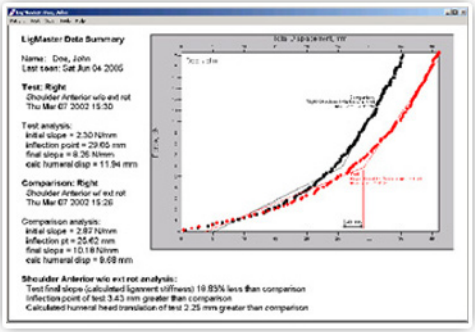

wasting precious time and risking higher failure rates. There is a strong trend going to change this approach in which LM fits nicely.

F. Shoulder ligament injuries are not easily assessed on MRI and are often diagnosed by arthroscopy. This invasive and expensive procedure does not provide information on shoulder stability, the lack of which is often the patient's chief complaint. LM can accurately assess shoulder instability in terms of tear or laxity of the anterior glenohumeral ligaments and measure improvement following treatment by follow-up exams.

G. James R. Andrews MD, Frank C. McCue MD and Arie M. Rijke MD make up the Advisory Board of Board of Ciconia, Inc., the company that holds the patent rights to the LigMaster invention. These physicians have developed the LigMaster system and have extensive clinical experience with it. For references, contact JRA at ljohson@asmi.org. For technical or clinical questions, contact FCM or AMR at amr@virginia.edu or rijke@ligmaster.com.