Editorial

Implant Failure in Orthopaedics: Law Does Not Hold the Surgeon Accountable

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It has been the practice of most patients to hold surgeons responsible for any manufacturing defect in an implant that was carried out and accountable for deficiency of services and sue them for medical negligence.

My implant broke; the surgeons are responsible for this; their service is deficient; this is tantamount to medical negligence—say most patients. This is not true and has no scientific evidence. We come across such instances many times in our practice. According to scientific literature, only 2 to 3% of implant failures are because of compromise and quality.[1] Therefore, before commenting on the poor/low quality of implants used in orthopaedic surgery, we need to understand the complexity involved.

Most implants in orthopaedic surgery and its allied specialties have U.S. Food and Drug Administration (USFDA) approval. The CE European certificate for orthopaedic instruments equally holds good efficacy and performance. In countries where these facilities are unavailable, the local administration has the safety and performance-based check for orthopaedic devices and issues a license for some time. So, instruments of inferior quality cannot be supplied or applied for patient use.

Universally, the raw material and the manufacturing device for orthopaedic implants, such as plates, screws, interlocking nails, rods, arthroscopic screws, spine instruments, and others, remain the same. Therefore, implants that come out of the factory must be in good shape and that will be subjected to a performance test. The implants used for new fracture types, fractures with specific requirements (osteoporosis, metabolic bone disease, metastatic cancers, genetic disorders, etc.), and fractures of unique anatomical locations are tested for more excellent performance and compared with predicate devices. Countries have specifications for testing metallic bone plates, interlocking rods, Kirschner's wires, spinal instruments, arthroscopic screws, and other specialty instruments. The United States evaluates and issues licenses for materials with titanium-6 Aluminium-4 Vanadium, unalloyed titanium, 18 chromium-14 Nickel-2.5 Molybdenum stainless steel bar, wires, and Cobalt-28-Chromium-6 Molybdenum alloys.[2,3] India issues licenses for 316L stainless steel and 316 LVM titanium grade 5 for all orthopaedic surgeries, hand surgeries, spinal surgery, and other subspecialty implants. All these implants do not emit radiation; follow ergonomic principles, construction, and environmental properties; and do not explode during usage. The device and manufacturing process of the implants are designed to eliminate or reduce the risk of infection in the patient. The manufacturers also protect against the mechanical and thermal risks of the implants. Certain standard and accreditation bodies (ISO, ITC, MEDDEV ASTM) regulate the essential safety requirements of the implants.

The USFDA, CE, and other agencies strictly analyze plate and screw characteristics with their engineering drawings, including the safety and performance pathway. There are standard specifications and test methods for metallic bone plates and screws. It follows the worst-case rationale. For each anatomical location, the test is performed on a plate design, interlocking nails, spinal instruments, and other that

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represents the worst case for bending strength, bending structural stiffness performance, rehabilitation activities, and postoperative loading. A similar test is performed for the screws (screw holes that will have the highest and lowest stress under loading).

There are standard bone screws and washer guidance. All mechanical testing is performed on the final and finished versions of the plates, screws, spinal instruments, arthroscopic screws, and interlocking nails/rods. The worst-case bone screw size compatible with the worst-case bone plate for each anatomical location is checked. The torsional strength and driving torque testing of the screw are performed. Interestingly, the FDA does not consider individual screw pullout strength testing because multiple screws are used with the plating, which minimizes en bloc plate pullout.

The USFDA, CE, and other agencies use static four-point bending tests to assess the bone plate's mechanical strength. The criteria are based on aggregated data available from the worst-case plate evaluation. The acceptance criteria include minimum bending strength (N-m) and minimum bending structural stiffness (N-m^2) for all anatomical locations of the bone plate. The humerus has 11.6 and 4.39; elbow (distal humerus and ulna) 6.7 and 0.89; hand, wrist, and forearm 1.6 and 0.18; femur and proximal tibia 26.3 and 8.66; distal tibia 11.9 and 3.49; fibula 2.3 and 0.17; foot 1.2 and 0.13; and clavicle has 11.9 and 1.69. For the test to be successful, the implants must meet the acceptance criteria, or the average of all implants must meet or exceed the above, and the standard deviation should be 10% or less of the calculated averages. Therefore, plate, screw, and orthopaedic implants manufactured from identical raw materials using similar manufacturing processes without any changes in geometry are competent and mechanically strong with good performance.

A hypothetical question arises from the common man: Can the plate break? Yes, the plate can break if we apply a force exceeding the minimum bending strength (N-m) and minimum bending structural stiffness of the implant of specific anatomical areas. This does not mean inferior quality, but it is the inherited and accepted mechanical strength of the plates, screws, and other implants for their application on the bones.

Vital aspects determine a deficiency in the doctor's service and are termed medical negligence. Some of the essential conditions to be fulfilled here is (1) a duty of care, (2) breach of the duty, and (3) consequential damage arising there. It is the duty of an orthopaedic surgeon to use an appropriate implant obtained from a manufacturer during an operative fracture treatment and provide standard medical care. Standard care is the standard of an ordinary skilled man exercising and professing that special skill. A man need not possess the highest expert skills: it is a well-established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art. In the case of a medical professional, negligence means failure to act in accordance with the standards of a reasonably competent medical professional at the time. There may be one or more perfectly proper standards, and if he or she conforms to one of these proper standards, then it is not negligence.[4] Also, an orthopaedic surgeon must follow up with the patient and should not neglect those who underwent an operation. Additionally, the consequent damage from the medical or surgical treatment must be taken care of.

Also, the manufacturer supplies an implant with the required approvals and licenses for use in the patient. The orthopaedic surgeon did not participate in the implant research, designing, collecting raw materials, manufacturing, and the final finished product of the implant. They are at the user's end, like the patient who receives them. Therefore, a treating doctor or orthopaedic surgeon cannot be held medically negligent if an implant breaks or fails. The Tortious liability is to be directly imposed on the product manufacturer. Nevertheless, the implants that fall or break must be sent for metallurgy analysis and another mechanical stress test to prove incompetency or poor quality.

The challenge in fracture fixation surgery is the development of designs and materials that transmit the physiological stress across the implant to the bone interfaces and bone-to-bone fracture interfaces. There are specific characteristics of an ideal fracture fixation. The implant must maintain alignment at the fracture site within variable tolerance and depending on the fracture location. The fracture fixation should allow early mobilization, and the physiological forces must be transmitted across the fracture interfaces within limits. As the manufacturers noted implant failures in the past, there have been various modifications and advancements in the combination of raw materials to foresee the significant breaks in the implants. The failure often occurs at the nail–plate junction, and the break occurs at the nail or plate portion of the implant.[5]

Additionally, the screws fail and cut out of the implant. One known reason for implant failures is the loading forces concentrating over a small area of the implant without being transmitted across the fracture interfaces. Also, cut-out of the implant, especially in an osteoporotic femoral head, is well known. Because of these complications, implant manufacturers have developed various sliding devices. Instead of using more robust materials for the implants, the manufacturers design implants with relatively elastic titanium alloy that addresses implant failure and yields promising results.

The common man's question is why the doctors cannot use a rigid plate and screws or interlocking nails? Researchers have found that fractures occur after removal of rigid plates in osteoporotic long-bone fractures.[5,6] This is because of a mechanically weak bone healing. Therefore, using titanium alloy or graphite-methacrylate composite plates results in less stress shielding and augments efficient bone healing. However, orthopaedic surgeons must balance rigid (stress shielding) and flexible (less stress shielding) implant fixations. The selection purely lies at the surgeon's discretion based on the standard medical care given to the local community, population, or country. Smoking, alcohol abuse, increased body mass index (BMI; > 30 kg/m^2), age, and inadequate or premature weight-bearing ambulation are risk factors for implant break or failure in orthopaedic fracture fixation surgeries.[7,8]

Interestingly, certain countries like India encourage self-dependence and reliance with the motto "Make in India, Made in India" (https://www.makeinindia.com/about). This is a welcome move wherein the country encourages manufacturers to produce orthopaedic implants in their country with research and development analysis, standard raw materials, mechanical testing, and manufacturing devices. Therefore, it is always the country's pride to make orthopaedic implants in the country to serve humanity. But these nationally produced implants are not inferior in quality because they follow all the strict guidelines, protocols, and stringent license regulations and use universal raw materials and manufacturing devices. The make-in-India initiative has transformed India into a global design and manufacturing hub, which is a timely response to meet the critical demand–supply chain. Soon, various sectors opened-up for manufacturing orthopaedic implants, defense equipment, railway equipment, single band retails, etc. This increased the credibility of the country, with visible energy, momentum, and optimism among investors to make the country one of the world's most powerful economies. Therefore, orthopaedic surgeons using nationally produced implants efficiently contribute to the country's prosperity and are not considered to use inferior quality derailing the country's national building initiatives.

It is rational and essential to perform the metallurgy test and biomechanical strength analysis for all broken implants to prove their inferior quality. Without this test, it would be anecdotal to comment on the broken implant quality.

Judicial Pronouncements on Implant Failure in Orthopaedic Surgery

A few observations made by the Hon'ble Supreme Court on a case of implant failure with broken screws in forearm fracture fixations are as follows[9]:

- Doctors have carefully adopted the line of treatment recognized in the medical jurisprudence and are available and admissible to most doctors.
- Earlier, the doctors operated and fitted with a screw and plate, but after some time, they found a delay in the union. Therefore, the doctors advised another operation for grafting thereupon. So, we do not find any negligence or deficiency in duty on the part of the doctors.

Ratio Decidendi

The complainant's allegations appear to be without substance and are not substantiated by any medical evidence or expert. Additionally, the doctor is a well-known orthopaedic surgeon, and the surgery involving internal fixation by plating screws is the standard surgical procedure for a patient with such a fracture. Moreover, it is medically well accepted that even after successful surgery, the union of the bones (3%) may get delayed, as in this case. Still, the respondent/doctor cannot be held responsible because the postoperative X-rays confirmed that the plate and screws were properly fixed.

The State Commission also cited the judgment of the Hon'ble Supreme Court in Jacob Mathew vs. State of Punjab & Anr. (2005) 6 SCC 1, wherein principles of medical negligence have been spelled out, as also in Achutarao Haribhau Khodwa vs. State of Maharashtra (1996) 2 SCC 634, wherein the Hon'ble Apex Court had noted that the skill of medical practitioners differs from doctor to doctor. The very nature of the profession is such that there may be more than one course of treatment that may be advisable for treating a patient, and negligence cannot be attributed to a doctor so long as he or her is performing his or her duty to the best of his or her ability and with due care and caution.

The orthopaedic surgeon had, after due consideration, including proper diagnosis and using his best professional judgment conducted a conservative surgery that involved fitting the screws and plating, which in the majority of cases results in union of the bone joints. Since it did not occur as is known to happen following such surgeries, in this case, another operation for grafting, which is the recommended surgery in cases of nonunion, was recommended. Keeping in view these facts and respectfully following the judgments of the Hon'ble Supreme Court cited to the State Commission, the honorable courts agreed with the State Commission that there was no medical negligence on the part of orthopaedic surgeons in this case.

In the realm of diagnosis and treatment, there is scope for genuine differences of opinion. One professional doctor is clearly not negligent merely because his or her conclusion differs from that of another professional doctor. The true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he or she has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty if acting with ordinary care. There can be a difference in opinion as regards the approach to diagnosis and treatment. But the difference of opinion is not negligence. If two accepted schools of thought exist and a doctor has adopted anyone's method, he or she is not liable.

"The practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence, judged in the light of the particular circumstances of each case, is what the law requires, and a person is not liable in negligence because someone else of greater skill and knowledge would have prescribed different treatment or operated in a different way; nor is he guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art, even though a body of adverse opinion also existed among medical men.

A mere deviation from normal professional practice is not necessarily evidence of negligence. Let it also be noted that a mere accident is not evidence of negligence. So also, an error of judgment on the part of a professional is not negligence per se. Higher the acuteness in emergency and higher the complication, more are the chances of error of judgment. At times, the professional is confronted with making a choice between the devil and the deep sea and he has to choose the

lesser evil. The medical professional is often called upon to adopt a procedure which involves higher element of risk, but which he honestly believes as providing greater chances of success for the patient rather than a procedure involving lesser risk but higher chances of failure. Which course is more appropriate to follow, would depend on the facts and circumstances of a given case. The usual practice prevalent nowadays is to obtain the consent of the patient or of the person in charge of the patient if the patient is not competent to give consent before adopting a given procedure. So long as it can be found that the procedure which was in fact adopted was one which was acceptable to medical science as on that date, the medical practitioner cannot be held negligent merely because he chose to follow one procedure and not another and the result was a failure.

There is a marked tendency to look for a human actor to blame for an untoward event, a tendency which is closely linked with the desire to punish. Things have gone wrong and, therefore, somebody must be found to answer for it. To draw a distinction between the blameworthy and the blameless, the notion of mens rea has to be elaborately understood. An empirical study would reveal that the background to a mishap is frequently far more complex than may generally be assumed. It can be demonstrated that actual blame for the outcome has to be attributed with great caution. For a medical accident or failure, the responsibility may lie with the medical practitioner and equally it may not. The inadequacies of the system, the specific circumstances of the case, the nature of human psychology itself and sheer chance may have combined to produce a result in which the doctor's contribution is either relatively or completely blameless. Human body and its working is nothing less than a highly complex machine. Coupled with the complexities of medical science, the scope for misimpressions, misgivings and misplaced allegations against the operator i.e. the doctor, cannot be ruled out. One may have notions of best or ideal practice which are different from the reality of how medical practice is carried on or how in real life the doctor functions. The factors of pressing need and limited resources cannot be ruled out from consideration. Dealing with a case of medical negligence needs a deeper understanding of the practical side of medicine."[10]

To conclude, orthopaedic surgeons do their best in all their fracture fixations. Care and standard line of management are their golden braces. If consequential damage occurs or known complications arise, surgeons intervene efficiently. Orthopaedic surgeons cannot be held responsible for implant failure or breaking of implants and cannot be held liable for medical negligence.

Conflict of Interest
None declared.

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