The Economics of New Technology

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Summary: Emerging technologies have been implicated in the steady rise in healthcare expenditures. Although expensive, new technology has allowed for the treatment of very severe deformities within the field of limb lengthening and reconstruction. Beginning as early as the Ilizarov method of distraction osteogenesis, many of the treatments have resulted in impressive clinical results at the cost of being resource intensive. In addition to the economic cost, the treatments placed a significant burden on the patient who was forced to remain in external fixation for long periods of time. To decrease time in external fixation, lengthening over a nail and lengthening and then nailing were developed. Although certainly an improvement, external fixation was still a major component of treatment, and complications associated with its use remained. The advent of the motorized internal lengthening nail (MLN) has obviated the use of external fixation in a select group of patients and seems to be a step forward for the field. Still, the high upfront costs related to the price of the implant have served to limit its use in resource-poor areas and decrease adoption among cost-conscious surgeons. Although seemingly more expensive, the costs of MLN may be offset by the fact that this treatment requires fewer surgical procedures and may have fewer complications. This article reviews the available evidence with regards to the hospital, surgeon, and total cost when comparing lengthening over a nail versus MLN in the femur and lengthening and then nailing versus MLN in the tibia.

Key Words: motorized lengthening nail—lengthening nail—limb lengthening—Ilizarov—economics—cost-effectiveness—lengthening over a nail—lengthening and then nailing.

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The rising cost of healthcare expenditures has been at the forefront of discussions within the political, economic, and medical spheres. The steady escalation is now estimated to be increasing at a rate of 7% per year with some projections showing the United States' Medicare program set to go bankrupt within 10 years and the overall cost of healthcare to double from US$2.1 trillion to US$4 trillion within that time period.[1] A significant driver of this phenomenon is new medical technology.[2] As such, there has been increased scrutiny given to newly adopted devices that are often more expensive and unproven in terms of their value to the clinician and patient. This is especially prevalent within the field of orthopedic surgery in which many new devices are introduced annually. The difficulties with determining the economic impact of new technology are the multitude of indirect impacts of the device. One common error is confusing the purchase price of a piece of equipment or a drug with the overall cost. The total economic impact of the technology in question is frequently much broader and may or may not include savings or conversely, an induced cost. A new drug or device may be more expensive upfront but less expensive in the long run by either preventing a subsequent condition or obviating a previously necessary and expensive clinical encounter. Because of its ease of use or effectiveness, it may increase utilization of the given therapy thus increasing cost or alternatively make other, more expensive therapies unnecessary. Technology that can prolong life is often costly as it can require extended periods of care that can come at great expense. Because of these factors, research into cost-effectiveness has become ubiquitous within medicine and orthopedic surgery is no exception. Robust studies that delve into the cost of new therapies must measure the direct and indirect costs of the treatments and the outcomes to accurately surmise the cost-effectiveness of a new piece of technology.

DEVELOPMENT OF INTERNAL MOTORIZED LENGTHENING AND PROPOSED ECONOMIC BENEFIT

The prevalence and sophistication of cost-effectiveness studies within orthopedics have increased substantially over the last 10 years.[3,4] Economic evidence is increasingly making an impact on the development of clinical guidelines and practices within orthopedics.[5] In limb lengthening and deformity correction specifically, this research is vital because of the continuous development of new technology that has been vital to the advancement of the field.

From the beginning, the development of the Ilizarov method of distraction osteogenesis represented a major advance in the treatment of limb length discrepancy and deformity correction. Although the original technique has been modified numerous times, the basic tenets remain unchanged: osteotomy, distraction, and subsequent consolidation of bone. Modifications to the technique have been numerous but have primarily sought to shorten the healing time and decrease the burden on the patient. In the treatment of long bone deformity, classic Ilizarov treatment called for osteotomy and subsequent distraction and consolidation utilizing an external fixator. Although achieving impressive results, this method subjected the patient to long periods in a cumbersome external ring fixator. This led to the development of integrated techniques with the chief principle being that the external fixator only needed to remain during the distraction phase and that consolidation could be successfully achieved using solely internal fixation (ie, an intramedullary nail).

For the lower extremity, this resulted in the development of at least 2 methods: lengthening over a nail (LON) and lengthening and then nailing (LATN) (Fig. 1). These approaches offered several theoretical advantages over the traditional technique. First, decreased time in external fixation resulted in decreased health-related complications including pin

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FIGURE 1. Radiographs depicting treatment with lengthening over a nail (LON) and lengthening and then nailing (LATN). A–C, The figures depict LON: lengthening of the femur using an external fixator and intramedullary nail (A). Consolidation of the regenerate after removal of the external fixator (B), and ultimate removal of the intramedullary nail after the union (C). D–F, The figures depict LATN: lengthening of the tibia using an external fixator (D). Consolidation of the regenerate after removal of the external fixator and insertion of an intramedullary nail (E), and ultimate removal of the intramedullary nail after the union (F).

FIGURE 2. Radiographs depicting treatment with magnetic lengthening nail (MLN) of the femur and tibia. A–F, The figures depict MLN: insertion of the MLN (A, D), consolidation of the regenerate after lengthening was completed (B, E), and the final result after removal of the nail (C, F).

tract infections and decreased range of motion of the surrounding joints. Second, there was thought to be an improvement in the patient's satisfaction because of a decreased burden placed on the patient by long periods of external fixation. Lastly, the presence of an internal intramedullary nail was thought to decrease the chance of regenerate fracture as it could be maintained for much longer periods of time compared with a frame.[6–14] LATN and LON, therefore, represented progressions in method but all required the use of an external fixator during the distraction phase, and therefore, the disadvantages of the external fixation frame were decreased but not eliminated.

The next step was the development of a fully implantable lengthening nail to obviate the need for external fixation altogether. Although early designs were plagued with increased complications,[15,16] a newer generation of motorized, remote-controlled, internal lengthening nails were developed and have been shown to be effective and reliable for treating limb length discrepancy.[17–19] Recent comparative studies have noted that internal lengthening through a motorized internal lengthening nail (MLN) may reduce many complications associated with the use of an external fixator, namely pin tract infection, skin traction, knee stiffness, and regenerate fracture (Fig. 2).[14,18–21] In addition, MLN in the femur has been associated with improved patient satisfaction and improved perception of the cosmetic result of the surgery.[14]

Still, concerns exist regarding the high upfront cost of the nail that serves to limit its use in resource-poor areas and decrease adoption among cost-conscious surgeons. Although seemingly more expensive, the costs of MLN may be offset by the fact that this treatment requires fewer surgical procedures and may have fewer complications. This article reviews the available evidence with regards to the hospital, surgeon, and total cost when comparing LON versus MLN in the femur and LATN versus MLN in the tibia.

AVAILABLE EVIDENCE

Unfortunately, there are no published studies that have compare LATN and LON with the traditional Ilizarov method of tibial or femoral lengthening. To date, only 2 studies exist that examine the economic aspects of MLN in detail, with only one being published at this time.

LON Versus MLN for Femoral Distraction Osteogenesis

The first study[22] examined the differences in hospital, surgeon, and total cost between femoral osteogenesis through LON versus MLN. LON was performed with an expectation of 3 procedures: (1) osteotomy+insertion of the intramedullary nail with the application of the external fixator, (2) removal of an external fixator, and (3) removal of the intramedullary nail. By comparison, the expectation for the MLN procedure consisted of (1) osteotomy+insertion of MLN and (2) removal of the intramedullary nail.

In this study, patients' clinical records were retrospectively reviewed and relevant clinical variables including

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length distracted, time to union, and total procedures were recorded. Cost analysis was performed from the payer perspective. Payments to the hospital and the surgeon were calculated separately and then combined to determine total cost. Payments to the hospital were determined by querying the billing department of the institution for payments received for each patient during the appropriate episodes of care. Surgeon payments were determined by obtaining the current procedural terminology codes billed and calculating the expected surgeon fee using the Medicare Physician Fee Schedule. Subsequently, these 2 components were summed to calculate the total cost. All dollar values were corrected for inflation using the Chained Consumer Price Index.

A total of 58 patients were included in the study (19 having undergone LON, whereas 39 had undergone MLN). No notable differences were observed in the demographics between LON and MLN cohorts. In addition, no differences were found in the total length distracted although the time from distraction to completion of the final union was shorter for patients treated with MLN (86 vs. 58 d, $P=0.008$) and patients treated with MLN underwent on average one fewer surgical procedure (3.1 vs. 2.1; $P<0.001$). A summary of the findings can be found in Supplement Table 1 (Supplemental Digital Content 1, http://links.lww.com/TIO/A31).

As shown in Fig. 3, hospital costs were similar in LON and MLN groups (US$45,913 vs. US$41,680, respectively, $P=0.875$). Surgeon payments were higher for patients treated with LON versus MLN (US$4324 vs. US$2769, respectively, $P<0.001$). There was no significant difference in total cost (hospital+surgeon) between LON and MLN (US$50,255 vs. US$44,449, $P=0.482$).

LATN Versus MLN for Tibial Distraction Osteogenesis

The second study is currently unpublished but used nearly identical methodology to compare costs between tibial LATN and the MLN. LATN was performed with an expectation of 3 procedures: (1) osteotomy+application of the external fixator, (2) removal of external fixator and insertion of an intramedullary nail, and (3) removal of the intramedullary nail. By comparison, the expectation for the MLN procedure consisted of: (1) osteotomy+insertion of MLN and (2) removal of the intramedullary nail.

A total of 32 patients were included in the study (17 having undergone LATN, whereas 15 had undergone MLN). No notable differences were observed in the demographics between LATN and MLN cohorts; however, there were significantly more

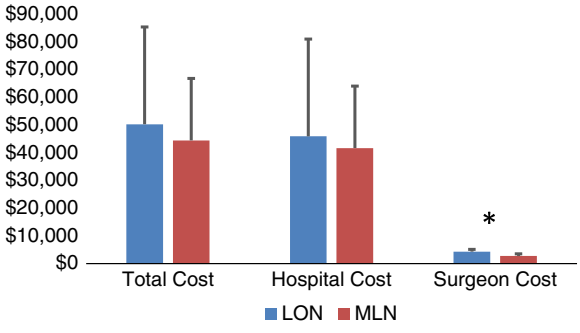

FIGURE 3. Chart showing the comparison of total, hospital, and surgeon costs for the patients treated with LON versus MLN. *$P<0.05$. LON indicates lengthening over a nail; MLN, motorized lengthening nail.

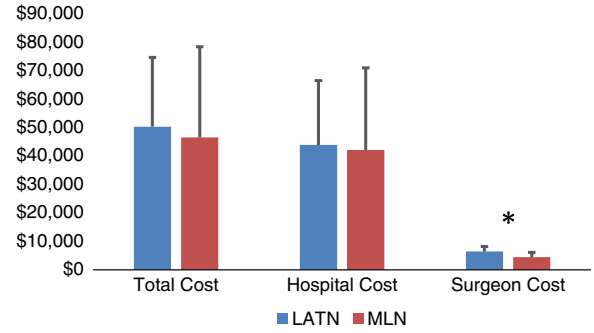

FIGURE 4. Chart showing the comparison of total, hospital, and surgeon costs for the patients treated with LATN versus MLN. *$P<0.05$. LATN indicates lengthening and then nailing; MLN, motorized lengthening nail.

bilateral cases in the LATN group (65% vs. 13%, $P=0.003$). No differences were found in the total length distracted. Patients undergoing MLN underwent ~1 fewer surgical procedure than LATN (3.6 vs. 2.7, $P=0.01$). Unfortunately, data on time to bony union and complications were not recorded for both groups, unlike the previous study. A summary of the findings can be found in Supplement Table 2 (Supplemental Digital Content 2, http://links.lww.com/TIO/A32).

As shown in Fig. 4, hospital costs were similar between LATN and MLN groups (US$43,919 vs. US$42,130, respectively, $P=0.85$). Surgeon payments were higher for patients treated with LATN versus MLN (US$6246 vs. US$4428, respectively, $P<0.001$). There was no significant difference in total cost (hospital+surgeon) between LATN and MLN (US $50,255 vs. US$44,449, $P=0.482$). Costs were adjusted for patients who underwent bilateral procedures to normalize them to the average cost of the procedure on a single limb.

CONCLUSIONS

Only 2 studies exist that directly compare new technologies (MLNs) with previously established therapies (LON and LATN). In both studies, there was no difference found between the LATN/LON versus MLN in terms of total or hospital costs. In the case of LON versus MLN, the latter resulted in a faster time to final bony union with fewer surgical procedures. Thus, the higher cost of implants seen in MLN is likely offset by the decreased number of procedures in this group as compared with LON and LATN. Both studies have limitations. The exact cost of the various components used was not available and the price paid for implants varies from institution to institution so generalizations from these data should be made with caution. Further, both studies were performed in the United States and are thus based on the economics of the US healthcare system. Having said that, the broad principles of early upfront costs versus an increased number of procedures are likely generalizable internationally. In addition, hospital reimbursement, although a better estimation of the cost than billings, is still dependent on the payer mix and therefore subject to selection bias on the basis of the type of patients treated at the institution that performed the study. Next, a direct comparison between internal magnetic nails and ring fixators is difficult as internal magnetic nails have limitations with regard to deformity correction and total distance of lengthening. Thus, although these studies showed no difference in lengthening between LON and LATN versus MLN, a hidden bias could be that the LON/LATN patients had a higher complexity of

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deformity. Lastly, these studies focused on direct costs that were paid by the payer and did not capture indirect or opportunity costs that can be significant.

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