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Letter to the Editor concerning “Charité total disc replacement: clinical and radiographical results after an average follow-up of 17 years” (M. Putzier et al.)

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I read with interest the paper by Putzier et al. [13] describing long-term clinical and radiographic results in the earliest patients implanted with the CHARITÉ Artificial Disc. As one of the two inventors of the device; the surgeon of record for all of the first 50 operated patients over several years in conjunction with my doctoral thesis [2]; and having knowledge of the other 21 patients including their clinical outcomes; I believe it is necessary to put the results described in the paper into the proper context.

First, it should be noted that the number of patients and the number of implanted model SB I disc prostheses is incorrect. There were 13 patients implanted with the SB I prosthesis, not 15. These 13 patients (5 males, 8 females) received 14 prostheses (not 16). The wrong number of cases is reflected in all relevant tables and is a basis for incorrect statistical calculations. Therefore all statistical conclusions made by the authors are flawed.

The authors used data from this study to come to the conclusion, “Proof that long-term results of TDR implantation in (patients with) DDD are at least as good as fusion results is still missing.”

The authors used the specific wording “at least as good as”. These words are normally reserved to describe the statistical results of a prospective, randomized, non-inferiority study, such as the U.S. FDA IDE study of the CHARITÉ Artificial Disc reported by Blumenthal et al. [1]. Instead, the study presented is Level IV data, a case series describing results with three different devices, which in no way resembles a prospective, randomized, non-inferiority design. Further, the authors attempt to demonstrate significance (or non-significance) with respect to various clinical and radiological results achieved with each of the three devices. However, with a lost to follow-up rate of 25.4%, incorrect patient/prosthesis numbers and extremely small sample sizes in each group, the power of their statistical analysis is highly problematic. The

statement, "...there was no significant difference in the clinical or radiographic long-term outcome between these three different TDR types" is built upon a faulty statistical analysis. In addition, they attempt to correlate clinical and radiological results and compare TDR to fusion when patients in the fusion groups previously had a TDR procedure. Therefore, "proof" one way or the other certainly cannot be ascertained using these data. On the whole the comparison between the outcome after prosthetic implantation and fusion as stated in this publication therefore cannot stand.

The authors described the three different versions of the CHARITÉ Artificial Disc (SB CHARITÉ I, SB CHARITÉ II, and SB CHARITÉ III). It is not correct that model SB I had 5 and later 11 teeth. The authors noted that only the third-generation of the device was made commercially available beginning in 1987. This is an important distinction. Though, the design principles for each of the three devices are essentially the same, a mobile sliding UHMWPE core between two metal endplates, the authors seem to trivialize the change from pressed stainless steel plates to compact Cobalt Chromium alloy plates.

The same applies to the sizes of the prosthesis SB CHARITÉ III, which in the 1980s was only available in three sizes, with an increased surgical risk of implantation at the time with the dissection required in cases with the larger prosthetic plates. The SB I and SB II devices consequently provided insufficient endplate coverage with the limited selection of sizes. In the group of all patients with SB II devices 21 of the 88 SB II endplates (44 SB II prostheses) showed material damages beginning between 3 and 12 months after implantation. Now there are seven footprint sizes of the CHARITÉ Artificial Disc available, allowing for more complete coverage of the vertebral endplate to the cortical rim, which should reduce the incidence of subsidence. At the time these early cases were performed, only 0° and 5° lordotic endplates were available. Since then, 7.5° and 10° endplates have been added, allowing for a more customized lordosis to be built into the disc space representing the patient's adapted anatomy. The instrumentation used to implant the prosthesis in the 1980s has been updated significantly, easing the technical difficulty of the procedure. In 1998, titanium calcium phosphate porous coating was added to aid in fixation of the prosthesis endplates to the vertebral endplates. Perhaps more importantly the indications and contraindications for TDR have been narrowed considerably since the device was first designed. Today for instance, diagnosing lumbar DDD is more effective by using MRI which was unavailable at the time the CHARITÉ Artificial Disc was implanted in the first patients. All of these changes combined yield an entirely different approach to TDR procedures compared to the very first cases performed with this device [3].

At that time the prosthesis was invented, the approach was to learn by doing rather than learning from the experience of others. The knowledge now available regarding the loading and biomechanics of the lumbar spine with and without disc implantations was not available to the inventors or even known 20 years ago. Clearly, one cannot draw modern clinical conclusions based on the results from those very early designs. Just 30% (16 patients) of the total reported study population of Putzier et al. were implanted with a commercially available device, and their data show no cases of subsidence or implant fracture in patients receiving the third-generation device.

Unfortunately, the reported data does not describe the positioning of the implanted prostheses within the intervertebral space, although the authors generally point out the high importance of the optimal implantation of the prosthesis. It is also unfortunate that the authors did not have personal experience implanting the CHARITÉ Artificial Disc. In the group of the first 50 patients with a CHARITÉ prosthesis, in whom 60 prostheses were implanted, a central position of the prosthesis in AP view was achieved in only 27 segments and a dorsal position of the disc in lateral view in only 12 segments. The figures of the SB III device in the paper published by Putzier et al. clearly show a positioning of the prostheses which are too anterior. McAfee et al. [11] demonstrated a statistical correlation between prosthesis positioning and clinical outcomes at 2 years. Patients with poor implant placement had statistically worse clinical outcomes than patients with optimal placement. Therefore the conclusion made by the authors: "...these patients (patients with functional implants) were significantly less satisfied with long-term outcome of the surgery than patients with spontaneously ankylosed motion segments or fusion after implant failure" must be doubted. Also of note, the authors did not write anything about the early outcomes or baseline clinical data, nor if the original indications match the indications of today.

The paper was accepted for publication on August 8, 2005. Unfortunately, the authors did not have the opportunity to review the paper by Lemaire et al. [10] published that same month which describes clinical and radiographic outcomes in 100 patients implanted with the third-generation device and a minimum follow-up of 10 years. In 1989, the two inventors visited Dr. Lemaire to show him the CHARITÉ Artificial Disc and to discuss the clinical and biomechanical principles of the prosthesis. At that time, the 5-year learning curve for the development and application of the first Total Disc Replacement worldwide had already been realized, and there were no further changes to the basic design of the implant. Shortly thereafter, Dr. Lemaire, with surgical assistance from the inventors, implanted his first CHARITÉ Artificial Disc. His series had a lost to follow-up

rate of 6.5%, a return to work rate of 91.6%, and 90% with an excellent or good clinical outcome. Lemaire reported in his paper five (5%) cases of secondary arthrodesis and only two (2%) cases of ossification affecting device mobility. With a mean ROM in extension/flexion of 10.3° at 10 years it is highly unlikely Lemaire's patients will show a much higher rate of spontaneous ossification at 15+ years.

Lumbar TDR, no matter the device used, has been maligned in the literature [7, 8, 12, 15, 16]. The majority of opponents of TDR make the erroneous assumption that a lumbar fusion procedure is a winning procedure for the patient each and every time, despite ample evidence to the contrary, most recently described by Geisler et al. [9]. Bringing forth the results in the earliest patients, as Putzier et al. have done, with the procedures performed prior to all of the changes described above combined with the collective knowledge gained over two decades; and pronouncing that the long-term results are not at least as good as fusion, demonstrates a misunderstanding of how to interpret clinical literature.

Using the logic of Putzier et al., total hip and knee replacement would not be the standard of care in elderly patients with degenerative arthritis. Organ transplantation would not be an option. Cardiac bypass surgery would not be performed. Laparoscopic and other minimally invasive surgical approaches would not be used. Pacemakers would not have been developed and implanted. The list of

devices and surgical approaches that would not be in use today if results in the earliest of patients were used as reasoning for not performing the procedure, is endless. Advancements in Medicine would be stagnant.

The development of the CHARITÉ Artificial Disc was, and continues to be an important scientific advancement in the treatment of lumbar DDD in properly indicated patients. With this implant and the experiences gained through developing it, a new worldwide strategy for the treatment of spinal disorders has begun. Many implants for the functional maintenance of the lumbar and cervical spine were created with new treatment concepts born from the first experience with lumbar TDR. Thousands of patients have been helped by the CHARITÉ Artificial Disc worldwide. It is too easy to cast stones using incomplete, and from the onset dubious results from the earliest available experience, and argue for maintaining the imperfect status quo for decades into the future, while at the same time ignoring evidence of good long-term outcomes such as the paper by Lemaire and presentations made at medical society meetings [4–6, 14]. However, those who invent or pioneer a procedure and know they are correct and those who come after them and see the future now, will remain undaunted.

It is my strong belief that lumbar arthroplasty is not going to go away, and it will stand the test of time with additional new developments.

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