



## EDITORIAL

## Cell therapy in sports injuries: Where we are and where we're headed



### Terapia celular en las lesiones deportivas: dónde estamos i a dónde vamos

In 1848, representatives from different English schools met in Cambridge University and created rules for a modern football association to progress from the medieval "folk football" where any method of putting the ball into the opponent's goal was valid, even if that goal were as far away as the neighbouring village. There were no limits as far as field of play or number of team members. Although killing was not permitted, violence was and many would seal their doors and windows to escape damage.

The Cambridge Rules set a code for a game that was to become the most popular sport in the world.

The BOE published RD 477/2014 on the authorisation of "cell therapy" in 2014, with reference to previous European legislation that classifies therapeutic stem cell products as "advanced therapy medicinal products" (annex 1 and 2).

For a product to be termed "medicinal" it must have been manufactured under high pharmaceutical standards, i.e., good manufacturing practices (GMP). The innovative therapy product must have undergone in vitro and large animal model testing, and eventually, audited clinical trials to confirm its viability, particularly its safety, and provide evidence of its efficacy.

The Health Administration has issued a code of rules, therefore, on where and how cell therapy can be practiced, for its ordered and safe use. Nevertheless, a "folk cell therapy" is still being promoted, which, without meeting any of the abovementioned requirements offers "stem cells" that are really a supernatant of centrifuged adipose tissue or bone marrow, the name of a tiny part of the content being applied to a heterogeneous whole. This has created considerable confusion among patients as potential users and even more confusion among doctors as potential prescribers. Fortunately, the Administration has become aware of the enormous risk involved in this situation, to the extent that the federal police in the USA, under the mandate of the FDA, are closing clinics who are behaving fraudulently.

So where are we now with cell therapy?

The use of cultivated chondrocytes to treat focal chondral injuries is considered an established treatment and can be practiced at the request of any surgeon. However, therapies comprising mesenchymal stem cells, for use in joint and tendon disease, can only be used in accredited centres, within the framework of a clinical trial or as occasional treatment, authorised and under the control of the Medicines Agency at all times. This treatment has enabled some elite, retired and amateur athletes to overcome their injuries. The outcomes are currently fulfilling and even exceeding expectations.

In light of the above, we feel our team has just leapt onto a well-indicated pitch, have warmed up well and are expecting good refereeing. However, only the first minute of the first game in a long league season has been played. There are many factors at play. Our level of preparation, technical ability and resilience in the face of difficulties and financial support from sponsors will be decisive in our win over our opponents, i.e., joint and musculotendinous disorders that are refractory to the usual treatments.

We'll take it game by game ... trial by trial ... case by case...

#### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.apunts.2017.11.001>.

Lluís Orozco\*, Robert Soler  
ITRT Centre Mèdic Teknon, Red TerCel, Instituto de Salud  
Carlos III, Spain

\*Corresponding author.

E-mail address: [lluis.orozco@itrt.es](mailto:lluis.orozco@itrt.es) (L. Orozco).